ENFORCEMENT AND COMPOUNDING COMMITTEE REPORT

Amy Gutierrez, PharmD, Chair, Professional Member
Allen Schaad, RPh, Professional Member
Rosalyn Hackworth, Public Member
Greg Murphy, Public Member
Greg Lippe, Public Member

Report of the Enforcement and Compounding Committee Meeting held on September 16, 2014.

IV. ENFORCEMENT AND COMPOUNDING COMMITTEE

Part 1: Enforcement Matters
a. FOR DISCUSSION AND POSSIBLE ACTION: Proposed Changes to 16 CCR section 1744 Regarding Required Warning Labels on Prescription Container Labels

Attachment 1

Background
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.

Assembly Bill 1136 (Levine), signed by the Governor on September 9, 2013, 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. 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 1.

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.
During this meeting, the committee reviewed the comments provided by pharmacy schools and it was recommended to keep the language as broad as possible and not individual drugs as the drugs will change over time. 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.

Comments from the public noted that in the definitions of the Business and Professions Code it stated that Schedule II, III, IV and V drugs refer to any drug listed in the Health and Safety Code and recommended that the language be more specific so as not to mislead the pharmacist or pharmacy student and that the statute would be tougher to enforce with the statute being more general.

**Attachment 1** includes a copy of Business and Professions Code section 4074.

---

**MOTION:** Enforcement and Compounding Committee: The committee recommended that the board adopt the revisions to section 1744 of the Title 16 California Code of Regulations, as follows:

**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. Monoamine oxidase inhibitors.

3. Nitrates.


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

b. FOR DISCUSSION AND POSSIBLE ACTION: Seek Repeal of Health and Safety Code Section 11164.5(a), Approval to Receive Electronic Prescriptions for Controlled Substance Prescriptions

Attachment 2

Background

Health and Safety Code section 11164.5(a) requires the approval of the Board of Pharmacy and the CA Department of Justice (DOJ) before a hospital or pharmacy may receive electronic data transmission prescriptions or computer entry prescriptions or orders. This provision was enacted before the Drug Enforcement Administration (DEA) promulgated their e-prescribing requirements several years ago.

Kaiser Permanente recently requested the board’s position on whether this provision is operative and how is the board complying with it.
Board staff do not believe that there is any need to retain this provision since the DEA has promulgated the required regulations to permit e-prescribing, and the staff recommend amending subdivision (a) out of 11164.5. There will likely need to be additional conforming changes to 11164.5 if subdivision (a) is removed. This should be part of the committee’s discussion.

Attachment 2 contains a copy of Kaiser’s inquiry and Health and Safety Code sections 11164 and 11164.5(a).

During the meeting, the committee heard from representatives of Kaiser who requested approval to allow Kaiser to electronically prescribe controlled substances once approved by the DEA, provide Kaiser with an exemption, or provide additional guidance so that Kaiser could proceed in a lawful manner.

Dr. Gutierrez sought legal clarification from DAG Kellogg on whether the board needed its own provisions or if the board could just comply with the federal regulations and was advised that the board no longer needed this provision.

MOTION: Enforcement and Compounding Committee: The committee recommended that section 11164.5(a) of the Health and Safety Code be eliminated and to include in the language that the board does not need to enforce this section while the legislation is pending.

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

Attachment 3

At the March 2014 Enforcement and Compounding Committee, 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 has 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

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

* In transit losses

### DEA 106 Reports by License Category

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

<table>
<thead>
<tr>
<th>No. of Reports</th>
<th>Dosage Units Lost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chain Store:</td>
<td>652</td>
</tr>
<tr>
<td>Community:</td>
<td>291</td>
</tr>
<tr>
<td>Hospital:</td>
<td>230</td>
</tr>
<tr>
<td></td>
<td>564,061</td>
</tr>
<tr>
<td></td>
<td>533,045</td>
</tr>
<tr>
<td></td>
<td>28,073</td>
</tr>
</tbody>
</table>

2014 Losses (6 months only)

<table>
<thead>
<tr>
<th>No. of Reports</th>
<th>Dosage Units Lost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chain Store:</td>
<td>443</td>
</tr>
<tr>
<td>Community:</td>
<td>108</td>
</tr>
<tr>
<td>Hospital:</td>
<td>97</td>
</tr>
<tr>
<td></td>
<td>226,866</td>
</tr>
<tr>
<td></td>
<td>289,751</td>
</tr>
<tr>
<td></td>
<td>990</td>
</tr>
</tbody>
</table>

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.

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.

At the April 2014 Board Meeting when this topic was discussed, the board asked the committee to draft regulation language to require monthly counts of a pharmacy’s fastest controlled substances as a form of inventory control.

**Attachment 3** includes a copy of recent articles on drug diversion from pharmacies.

At this meeting, 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. It was also suggested to gain input from clinics at a future committee meeting.
MOTION: Enforcement and Compounding Committee: The committee recommended the board 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 30th, 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.
(e) 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.

d. FOR DISCUSSION: Discussion Regarding the Future Demonstration of the Use of Automated Technology in Hospitals and Skilled Nursing Facilities and the Tools for Identification of Medication Diversion from These Units

Background
Chairperson Gutierrez is considering a future meeting agenda item where the committee can learn about drug storage security features to deter diversion that are built into
automated dispensing and storage devices used in hospitals and skilled nursing facilities. Time will be devoted at this meeting for a discussion of this topic, but a more in-depth review will be scheduled for a future meeting where the committee will be able to view some of the anti-diversion technology or features in use in California.

During the meeting, the committee heard comments from the public and recommended that as an agenda item for a future committee meeting, the committee would invite some of the larger automated vendors to provide background on how their technology could identify and address drug diversion in a hospital setting. It was suggested that the board start with some of the vendors that the board has had to report to the Attorney General’s Office.

e. FOR DISCUSSION: Discussion Regarding the Drug Enforcement Administration’s Regulations for the Take Back of Prescription Medication

Attachment 4

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

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

Attachment 4 contains a Wall Street Journal article about the regulations and the DEA’s requirements for drug take back (pages 151-200) along with their comments to written comments received in response to the prior proposed regulation.

During the meeting, the committee reviewed the attachment where it was noted that the Wall Street Journal article was found interesting because it talked about how this requirement is going to be positive on the one side but on the other side its introducing a whole new stream of drugs coming back into the pharmacy which the DEA is calling waste. Ms. Herold stated that the board needed to have some kind of regulations in place for this program.

Ms. Herold further stated that the committee will have a draft of proposed language at a future committee meeting.
f. **FOR DISCUSSION: Discussion of the Federal Rescheduling of Hydrocodone to Schedule II**

**Attachment 5**

**Background**

Hydrocodone combination products are pharmaceuticals containing specified doses of hydrocodone in combination with other drugs in specified amounts. These products are approved for the marketing for the treatment of pain and for cough suppression.

The Drug Enforcement Administration (DEA) has secured the “up scheduling” of hydrocodone combination products from Schedule III to Schedule II of the federal Controlled Substances Act. At the April 2014 board meeting, the board directed that the board submit a letter of support to the DEA, along with a request for a transition period to fully implement this change.

**Attachment 5** includes a copy of the board’s letter of support.

Below is a copy of a subscriber alert the board will release after the discussion at this meeting.

1. Starting October 6, 2014, all HCPs will be reclassified at the federal level as Schedule II controlled substances, does this mean California law has also reclassified all hydrocodone combination products as Schedule II controlled substances?
   **A:** Technically, no; there has been no equivalent change to California law, or to the controlled substance schedules in California. But for many intents and purposes, the practical effect will be the same: that all prescribers and practitioners in California will be required to treat HCPs as Schedule II controlled substances.

2. Prescriptions written for HCPs before October 6, 2014 that are presented to the pharmacy for dispensing on or after October 6, 2014: are these to be dispensed as a Schedule II or Schedule III controlled substance?
   **A:** On and after October 6, 2014, under federal law, all HCPs must be prescribed according to federal Schedule II requirements. This means no HCP prescription issued on or after this date may authorize any refills. Also, for example, as of October 6, 2014, oral, telephone or fax-transmitted prescriptions for HCPs are no longer possible. The DEA has stated, however, that it will allow refills on HCPs written and initially filled before October 6 (under Schedule III requirements and limitations), to be dispensed up to six months from October 6, 2014 (until April 8, 2015). This extends the Schedule III treatment of prescriptions for HCPs written and initially dispensed prior to October 6, 2014 to the maximum allowable period for Schedule III refills.

The DEA has stated, however, that it will allow refills on HCPs written before
October 6 (under Schedule III requirements and limitations), to be dispensed up to six months from October 6, 2014 (before April 8, 2015). This extends the Schedule III treatment of prescriptions for HCPs written before October 6, even if provided to the pharmacy on or after October 6 to the maximum allowable period for Schedule III refills (before April 8, 2015).

3. Prescriptions written for hydrocodone combination products dispensed before October 6, 2014 as a Schedule III, but with refills remaining, can the remaining refills be dispensed?
   A: According to guidance from the DEA, yes.

4. If a patient presents a prescription for a hydrocodone combination product on or after October 6, 2014 that was written before October 6, 2014 with refills, can the refills be honored?
   A: Yes, up to April 8, 2015, so long as the original date on the prescription does not exceed 180 days, or the maximum allowable period for Schedule III refills.

5. When transmitting to CURES, should I change my computer software to report all HCPs dispensed as Schedule II controlled substances or keep HCPs as Schedule III controlled substances until California law (also) reschedules all HCPs to a Schedule II controlled substance?
   A: Health and Safety Code section 11165, subdivision (d) references and incorporates the federal controlled substance schedules for the purpose of defining the reporting requirements under CURES. As a result, dispensers in California are responsible for reporting to CURES controlled substances dispensed according to the federal schedules. Thus, a software change will be required.

6. Like some states, is California precluding pharmacies from refilling HCPs prescriptions written prior to October 6, 2014?
   A: No, the federal allows such refills to be filled pursuant to limitation in existing law for refilling Schedule III drugs.

From the federal announcement:
On Friday, August 22, 2014, the DEA published in the Federal Register the final rule to transfer HCPs from federal Schedule III to federal Schedule II. HCPs have been controlled in schedule III since enactment of the Controlled Substances Act (CSA) in 1971. HCPs are the most frequently prescribed opioid in the United States: nearly 137 million prescriptions for HCPs were dispensed in 2013.

- Effective October 6, 2014, HCPs will be controlled as Schedule II substances under the Controlled Substances Act (CSA).
- DEA is also permitting legitimate HCP prescriptions issued before October 6, 2014 to be refilled until April 8, 2015, if the prescription authorizes refills.
The Notice of Proposed Rulemaking (NPRM), Final Rule, and its supporting documents (i.e., medical and scientific evaluations, and economic impact analysis) may be viewed online at www.regulations.gov, Docket No. DEA-389.

Alternatively, the documents can be obtained on the DEA website at www.deadiversion.usdoj.gov.

Questions and Answers;

1. Starting October 6, 2014, all HCPs will be reclassified at the federal level as Schedule II controlled substances, does this mean California law has also reclassified all hydrocodone combination products as Schedule II controlled substances?

   A: Technically, no; there has been no equivalent change to California law, or to the controlled substance schedules in California. But for many intents and purposes, the practical effect will be the same: that all prescribers and practitioners in California will be required to treat HCPs as Schedule II controlled substances.

2. Prescriptions written for HCPs before October 6, 2014 that are presented to the pharmacy for dispensing on October 6, 2014: are these dispensed as a Schedule II or Schedule III controlled substance?

   A: On and after October 6, 2014, under federal law, all HCPs must be prescribed according to federal Schedule II requirements. This means no HCP prescription issued on or after this date may authorize any refills. Also, for example, as of October 6, 2014, oral, telephone or fax-transmitted prescriptions for HCPs are no longer possible. The DEA has stated, however, that it will allow refills on HCPs written and initially filled before October 6 (under Schedule III requirements and limitations), to be dispensed up to six months from October 6, 2014 (until April 8, 2015). This extends the Schedule III treatment of prescriptions for HCPs written and initially dispensed prior to October 6, 2014 to the maximum allowable period for Schedule III refills.

3. Prescriptions written for hydrocodone combination products dispensed before October 6, 2014 as a Schedule III, but with refills remaining, can the remaining refills be dispensed?

   A: According to guidance from the DEA, yes.

4. If a patient presents a prescription for a hydrocodone combination product on or after October 6, 2014 that is written on October 6, 2014 with refills, can the refills be honored?

   A: No, the DEA stated the prescription needed to be presented before October 6 to use the refills.
5. When transmitting to CURES, should I change my computer software to report all HCPs dispensed as Schedule II controlled substances or keep HCPs as Schedule III controlled substances until California law (also) reschedules all HCPs to a Schedule II controlled substance?

A: Health and Safety Code section 11165, subdivision (d) references and incorporates the federal controlled substance schedules for the purpose of defining the reporting requirements under CURES. As a result, dispensers in California are responsible for reporting to CURES controlled substances dispensed according to the federal schedules. Thus, a software change will be required.

During the meeting, Dr. Gutierrez highlighted the reclassification of hydrocodone containing products to Schedule II and advised the audience that a subscriber alert would be sent out after the meeting regarding the change.

Ms. Herold also stated that that she would share the Q&A list with the Medical Board and Dental Board. Dr. Gutierrez requested board staff to work with the Medical Board to get the word out.

Comments from the public included encouraging the board to work with the pharmacies and pharmacists to let prescribers know how the board intends to implement the transition period so that there is not an impact on the patient and prescribers.

**g. FOR DISCUSSION: Discussion of the Federal Rescheduling of Tramadol to Schedule IV**

**Attachment 6**

**Background**

Tramadol is a centrally acting opioid analgesic that has been on the market since the mid-1990s. Subsequently, the FDA approved for marketing generic, combination, and extended release tramadol products as dangerous drugs but not as controlled substances. However, over the years, the board and other entities have identified instances where tramadol was misused in part because as a dangerous drug, it was more readily available than a controlled substance would be.

In mid-August, the DEA secured the scheduling of tramadol into Schedule IV of the controlled substances schedule.

**Attachment 6** includes a copy the board’s subscriber alert and the article from the Federal Register / Vol. 79, No. 127 / Wednesday, July 2, 2014 / Final Rule.

During the meeting, the committee reviewed the subscriber alert and article from the Federal Register.
h. **FOR INFORMATION: Update on the Alternative Process for Pharmacists to Become Registered to Access CURES**

**Background**

Last year, SB 809 (DeSaulnier) was enacted to enhance the CURES prescription drug monitoring program.

Part of the discussion associated with the bill’s progression through the Legislature was the growing concern about the need for pharmacists and prescribers to access CURES before dispensing or prescribing controlled drugs. To access CURES to see the history of controlled drugs dispensed to a single patient over the last year, a prescriber or pharmacist must have been preapproved by the CA Department of Justice. However, an abysmally low number of prescribers and dispensers have applied for and been granted access to CURES.

Provisions enacted in SB 809 require all prescribers and pharmacists to be registered with the DOJ to access CURES by January 1, 2016. However, the new computer system and funding for staffing for the DOJ to operate the CURES system will not be available until perhaps July 2015. Meanwhile, the Department of Consumer Affairs’ agencies are transferring to a new computer system of their own that will create new systems for license issuance and renewal. Only the first one-third of DCA’s boards have converted to the new BreEZe system. It may be late 2014 before phase II converts (this board is part of this group).

As such, it appears likely that few, if any, DCA boards will be able to comply with the January 1, 2016 CURES registration deadline for licensees.

The current process for CURES registration is frustrating and laborious. Individuals must start an email contact with the DOJ, then fill out an application they download, and then copy various documents (driver’s license, professional license) and have the whole package notarized and then mailed to the DOJ. Lacking staff, the DOJ is taking months to process this material.

Board staff has implemented a process whereby the board can authenticate the identity of a pharmacist and aid the DOJ in getting this individual registered. The board began accepting applications in July 2014 and has to date received approximately 150 applications.

Currently there are 9,268 pharmacists registered with CURES, about 25 percent of all pharmacists.

During the meeting, Dr. Gutierrez provided an update on how many pharmacists have registered for CURES access. Ms. Herold indicated the board would come prepared to accept CURES registration applications at the California Society Health System Pharmacists (CSHP) booth at the end of October 2014.
i. FOR INFORMATION: Summary of Presentation by Rita Shane, PharmD, FASHP, FCSHP on Medication Reconciliation in Health Care Facilities

Medication reconciliation is intended to ensure the accuracy of a medication list of drugs taken by a patient. It involves the review, update, and reconciliation of medications at each encounter.

Rita Shane, PharmD, has advised that given the errors in medication lists that occur when patients are admitted to the hospital, evidence supports that pharmacy staff need to ensure these lists are updated and corrected in order to prevent hospital medication errors, reduce readmissions and prevent medication errors when the patients go home.

A physician colleague of Dr. Shane recently completed a randomized controlled trial showing there were seven errors per medication list for patients admitted to the hospital. The same trial also showed the impact of pharmacy staff on reducing these errors.

Presentation at the Committee Meeting
During the meeting, Dr. Shane provided a PowerPoint presentation regarding medication reconciliation in health care facilities. The PowerPoint presentation can be found at the back of the meeting minutes.

The committee suggested sharing the data with the California Hospital Association (CHA) Medication Safety Committee, as a first step and obtain some recommendations by that committee. Ms. Herold also indicated that she’d like to see this as a collaboration across professions.

Attachment 7 includes a related article on this topic.

j. FOR DISCUSSION: New Committee Issues Scheduled for Board Discussion at This Meeting (Not Discussed at the September 2014 Meeting)

1. DEA Release of Drug Take Back Regulations
   The board will need to promulgate regulations on this in the future. The board needs to discuss how this will proceed.

2. FDA Guidance on Drug Supply Chain Security Act
   Earlier this month, the FDA issued a guidance document regarding its future plans for implementation of the federal Drug Quality and Security Act. This law was enacted on November 27, 2013, and instituted new product tracing requirements for prescription drugs, preempted any then existing state requirements for tracing prescription drugs (including California’s e-pedigree requirements), established
minimum licensure requirements for wholesalers and required separate licensure of third-party logistics providers if states regulated them as wholesalers. These comments and questions and answers are provided in Attachment 8.

Regarding product tracing, the FDA reiterated that no state may establish, continue in effect, or apply any requirement that is inconsistent with, more stringent that product tracing requirements of section 582, section 503(e) or under subchapter H.

Regarding wholesale drug distributor standards and licensing, the FDA reiterated that no state may establish, or continue any standards, requirements or regulations that are inconsistent with, less stringent than, directly related to or covered by the standards or requirements of 503(e). Thus, states many not impose standards, requirements or regulations to wholesaler drug distributors that fall below these minimum standards. In the coming months, the FDA may issue new wholesale drug distributor regulations under section 583 that will take effect two years after they are finalized by the FDA. At that times, states should have reanalyzed their licensing laws to determine if they fall below the federal standards.

Regarding third-party logistics providers, the FDA reiterated that on November 27, 2013, federal law prohibited states from regulating third-party logistics providers (3PLs) as drug wholesalers. Since California required 3PLs to be licensed as wholesalers, these provisions were preempted, and in 2014, the board secured enactment of new requirements for 3PLs (AB 2605, Bonilla). The federal guidance specifies that states can do such licensure. In the future, once federal regulations are in place, the state will have two years to review and modify its regulations to ensure California’s requirements are not inconsistent with, less stringent than, directly related to or covered by the federal regulations.

3. Publication of a Board Appeal Decision Involving License Revocation Involving Fraud

A request was submitted and approved to the Court of Appeals to publish the Court’s opinion in the case of: Tu Ngoc Hoang v. California State Board of Pharmacy, California Court of Appeal, Fourth Appellate District Division Three, Case No. G0419275.

The court’s opinion rejected Plaintiff’s argument that revocation is only reserved for dangerous conduct. This was a case involving fraud where there was no patient harm, but there was unscrupulous conduct. The court reiterated the Board's authority to suspend or revoke for unprofessional conduct without requiring patient harm.

The court’s opinion refers to the Board’s disciplinary guidelines and referred to language in the guidelines that stated that there are no required factors for minimum or maximum penalty. This emphasizes the fact that penalty determination...
is a matter of the Board’s discretion and is not simply a ministerial act contingent on the number of factors met.

The court’s opinion involves legal issues of continuing public interest, applies an existing rule of law to a set of facts significantly different from those stated in published opinions and clarifies an existing statute.

Attachment 9 includes a copy of the letter to the Court of Appeal and the Court’s opinion.


The National Transportation Safety Board (NTSB) recently analyzed toxicology tests from 6,677 pilots who died in a total of 6,597 aviation accidents between 1990 and 2012. The results demonstrate a significant increase in the use of a variety of potentially impairing drugs. The study found significantly increasing trends in pilots’ use of all drugs, potentially impairing drugs (those with a US Food and Drug Administration warning about sedation or behavior changes in routine use), controlled substances, and illicit drugs (those defined as Schedule I by the US Drug Enforcement Administration).

In the study, the pilot was considered to be positive for a drug if it could be qualitatively or quantitatively identified in blood or tissue; drugs identified only in urine or used as part of resuscitative efforts were excluded.

Overall, 98% of the study pilots were male and 96% were flying privately rather than for commercial purposes. The average age of study pilots increased from 46 to 57 years over the study period.

The large increase in the proportion of fatally injured pilots with evidence of potentially impairing drugs suggests an increasing risk of impairment in general aviation. Aviation is the only transportation mode in which a fatally injured operator (pilot) routinely undergoes extensive toxicology testing; no similar testing is routinely performed for fatally injured operators of boats, trains, trucks, or cars. Given the general increase in drug use in the population, it is likely that there has been a similar trend in drug use among operators across all modes of transportation.

The NTSB issued two recommendations to California healing arts boards, specifically the Medical Board, Nursing Board, Pharmacy Board and Osteopathic Medical Board. The safety recommendations include the following:

(I-14-1) Include in all state guidelines regarding prescribing controlled substances for pain a recommendation that health care providers discuss with patients the effects
their medical condition and medication use may have on their ability to safely operate a vehicle in any mode of transportation.

And;

(I-14-2) Use existing newsletters or other routine forms of communication with licensed health care providers and pharmacists to highlight the importance of routinely discussing with patients the effect their diagnosed medical conditions or recommended drugs may have on their ability to safely operate a vehicle in any mode of transportation.

The NTSB is interested in these recommendations because they are designed to prevent accidents and save lives.

Attachment 10 includes a copy of the NTSB letter.

k. FOR INFORMATION: Enforcement Statistics, 1st Quarter 2014-15

Attachment 11 includes the first quarterly report of the committee’s goals, enforcement workload statistics, and SB 1441 Program Statistics for the fiscal year.

Regrettably the board is not meeting its success indicators for its enforcement related activities. This is in part because of a number of vacancies within the office as well as the training of new inspector staff that has occurred over the past two years, when the board received a significant number of new staff as well as conducting sterile compounding inspections. As we continue to focus our efforts on completing the oldest cases as well as fill vacant positions, we anticipate gradual improvement in all areas.

Part 2: Compounding Matters

a. FOR DISCUSSION: Discussion Regarding FDA’s Expectations for Human Drug Compilers

Attachment 12

The Food and Drug Administration (FDA) 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 (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 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 FDA’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).

Attachment 12 includes a copy of the FDA Press Release and the article from the Federal Register / Vol. 79, No. 127 / Wednesday, July 2, 2014 / Proposed Rule.

At this meeting, the committee reviewed the press release and article from the Federal Register.

*The next two items (b & c) were discussed as one item.*

b. **FOR INFORMATION: Results of the Board’s Implementation and Inspections of California Sterile Compounding Facilities**

Attachment 13

Presentation at the Committee Meeting
During the meeting, Dr. Ratcliff highlighted the top ten violations found during compounding inspections which included lack of compounding self-assessment, quality assurance issues, facility issues, adequate compounding attire, general compounding quality assurance issues, process validations issues, insufficient or nonexistent policies and procedures, substandard equipment used, and lack of training.

Attachment 13 includes the data found as a result of compounding inspections in California and Out-of-State Facilities.

c. **FOR INFORMATION: Data on Violations Found During Out-of-State Compounding Inspections**

d. **FOR INFORMATION: Recalls of Compounded Drugs Throughout the United States**

Attachment 14

Between November 8, 2013 and September 11, 2014, the board posted seven subscriber alerts related to compounding drug recalls.

Attachment 14 includes copies of the subscriber alerts.

During the meeting, the committee reviewed the attachments and Dr. Gutierrez noted that there was still quite a bit of recalls going on.
e. **FOR DISCUSSION: Future Meeting Dates**

The committee will select meeting dates for 2015. Once established, these dates will be posted on the board’s website under the Board Meetings tab.

The minutes from the September 16, 2014 committee meeting are provided in Attachment 15.
Attachment 1
B&PC 4074
(a) A pharmacist shall inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription if both of the following apply:

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

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

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

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

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

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

(Amended by Stats. 2013, Ch. 304, Sec. 1. Effective January 1, 2014.)
Attachment 2
June 5th, 2014

California State Board of Pharmacy
Attn: Virginia Herold, Executive Officer

1625 N. Market Blvd., N-219
Sacramento, CA 95834

RE: Request to add agenda item for upcoming Licensing or Enforcement & Compounding Subcommittee Meeting

TOPIC: Health and Safety Code (H&S) 11164.5(a) requirement to receive approval from the Board of Pharmacy and Department of Justice before a hospital or pharmacy may receive electronic data transmission prescriptions

We are writing to request that the above topic be added as an agenda item for discussion at either the next Licensing or Enforcement & Compounding Subcommittee meeting scheduled.

As the law currently reads, H&S 11164.5 requires that pharmacies obtain approval from the California Board of Pharmacy and the Department of Justice prior to a pharmacy being able to receive electronic prescriptions for controlled substance prescriptions

H&S 11164.5(a) also states that the “California State Board of Pharmacy shall maintain a list of all requests and approvals granted pursuant to this subdivision.” It seems that approval can be implied as the Board inspectors have already inspected pharmacies without commenting on not having received approval from the Board or the Department of Justice. We have inquired on how pharmacies may take steps to receive such approval and were informed that there is no such approved list, as the Board’s policy is to accept any pharmacy’s system that meets the DEA requirements.

In the alternative to placing this on the agenda of one of the committee meetings, if a process has already been adopted for approval or if approval is not necessary, please consider this a request for approval or exemption and respond affirmatively so that we have documentation for future reference. Our system will comply with the DEA’s regulatory compliance certification mandate for controlled substances prescribing.

Sincerely,

Kaiser Permanente Pharmacy Administration
HEALTH AND SAFETY CODE - HSC

DIVISION 10. UNIFORM CONTROLLED SUBSTANCES ACT [11000 - 11651] (Division 10 repealed and added by Stats. 1972, Ch. 1407.)

CHAPTER 4. Prescriptions [11150 - 11209] (Chapter 4 added by Stats. 1972, Ch. 1407.)

ARTICLE 1. Requirements of Prescriptions [11150 - 11180] (Article 1 added by Stats. 1972, Ch. 1407.)

Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber’s address and telephone number; the name of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(b) (1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.

(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.

(c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.
(e) This section shall become operative on January 1, 2005.

(Amended by Stats. 2006, Ch. 286, Sec. 2. Effective January 1, 2007.)
ARTICLE 1. Requirements of Prescriptions [11150 - 11180]  

(a) Notwithstanding Section 11164, with the approval of the California State Board of Pharmacy and the Department of Justice, a pharmacy or hospital may receive electronic data transmission prescriptions or computer entry prescriptions or orders as specified in Section 4071.1 of the Business and Professions Code, for controlled substances in Schedule II, III, IV, or V if authorized by federal law and in accordance with regulations promulgated by the Drug Enforcement Administration. The California State Board of Pharmacy shall maintain a list of all requests and approvals granted pursuant to this subdivision.

(b) Notwithstanding Section 11164, if approved pursuant to subdivision (a), a pharmacy or hospital receiving an electronic transmission prescription or a computer entry prescription or order for a controlled substance classified in Schedule II, III, IV, or V shall not be required to reduce that prescription or order to writing or to hard copy form, if for three years from the last day of dispensing that prescription, the pharmacy or hospital is able, upon request of the board or the Department of Justice, to immediately produce a hard copy report that includes for each date of dispensing of a controlled substance in Schedules II, III, IV, and V pursuant to the prescription all of the information described in subparagraphs (A) to (E), inclusive, of paragraph (1) of subdivision (a) of Section 4040 of the Business and Professions Code and the name or identifier of the pharmacist who dispensed the controlled substance.

(c) Notwithstanding Section 11164, if only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy’s or hospital’s computer system shall not permit the received information or the controlled substance dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law, once the information has been received by the pharmacy or the hospital and once the controlled substance has been dispensed, respectively. Once the controlled substance has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.

(d) Nothing in this section shall be construed to exempt any pharmacy or hospital dispensing Schedule II controlled substances pursuant to electronic transmission prescriptions from existing reporting requirements.

(Added by Stats. 2000, Ch. 293, Sec. 4. Effective January 1, 2001.)
Attachment 3
The opioid abuse and misuse epidemic: Implications for pharmacists in hospitals and health systems

Daniel J. Cobaugh, Carl Gainor, Cynthia L. Gaston, Tai C. Kwong, BarbaraJean Magnani, Mary Lynn McPherson, Jacob T. Painter, and Edward P. Krenzelok

Misuse and abuse of prescription opioids in the United States constitute a public health crisis that has grown to epidemic proportions over the last decade. The Centers for Disease Control and Prevention (CDC) has identified prescription drug abuse and overdose as one of the top five health threats for 2014. It is imperative that pharmacists across the health system have a complete understanding of this epidemic. This article reviews the role of opioids in pain management, the epidemiology of opioid misuse and abuse, the clinical toxicology of these medications, and the role of laboratory analyses in monitoring opioid therapy; knowledge of opioid metabolic pathways and assay limitations is essential for appropriate use and interpretation of screening and confirmatory tests. In recent years, there has been an increase in federal enforcement actions against pharmacies and prescription drug wholesalers involved in improper opioid distribution, as well as increased reliance on state-level prescription drug monitoring programs to track patterns of opioid use and improper sales. Pharmacies are urged to implement or promote appropriate guidelines on opioid therapy, including the use of pain management agreement plans; policies to ensure adequate oversight of opioid prescribing, dispensing, and waste disposal; and educational initiatives targeting patients as well as hospital and pharmacy staff.

Conclusion. Pharmacists in hospitals and health systems can play a key role in recognizing the various forms of opioid toxicity and in preventing inappropriate prescribing and diversion of opioids.

Am J Health-Syst Pharm. 2014; 71:1539-54
Opioid abuse and misuse

Sertürner isolated morphine from opium; beginning in the 1850s, injectable morphine was used to treat both acute and chronic pain.

Opioids provide their pharmacologic effects by binding to opioid receptors located both within and outside of the central nervous system. Depending on which receptors they bind to and their level of intrinsic activity, opioids are classified as full or partial agonists, mixed agonist–antagonists, or opioid antagonists. The primary opioid receptor is the μ receptor. The μ receptor is responsible for supraspinal analgesia, respiratory depression, euphoria, sedation, decreased gastrointestinal motility, pruritus, anorexia, sedation, and physical dependence. The κ receptor, another opioid receptor, is responsible for spinal analgesia, dyspnea, opioid dependence, sedation, respiratory depression, and dysphoria. The σ receptor is responsible for dysphoria, psychotomimetic effects, and stress-induced depression. The role of the δ-opioid receptor has not been well studied.

Opioids are used routinely to treat both acute and chronic cancer pain and noncancer pain. Numerous clinical guidelines have been published over the past 20 years to guide practitioners in the appropriate use of opioids to treat moderate-to-severe pain. The management of acute and chronic pain is generally best accomplished through a multimodal approach that includes nonpharmacologic interventions, as well as nonopioid analgesics (e.g., acetaminophen, nonsteroidal antiinflammatory drugs [NSAIDs]), opioids, and coanalgesics (e.g., anticonvulsants, antidepressants, skeletal muscle relaxants, topical or oral anesthetics). Appendix A lists the American Pain Society recommendations for considerations when selecting analgesics to treat acute or chronic pain.

Opioid therapy for acute pain

One potential strategy to reduce postoperative pain is the use of preemptive analgesics. However, there is limited evidence that demonstrates major clinical benefits (e.g., consistent immediate postoperative pain relief, reduced need for supplemental analgesia) after the use of preemptive analgesics. Despite these findings, it is clear that optimal postoperative pain management begins preoperatively, continues through the perioperative period, and is sustained through the postoperative period as indicated clinically. One useful strategy is the use of a multimodal approach.

Opioids are used to treat acute pain when the pain cannot be managed with nonopioid therapy alone. For example, the acute pain after a dental procedure may be primarily controlled with the use of nonopioids such as an NSAID, possibly supplemented with an oral opioid as needed. Alternatively, a patient who has had major surgery will likely require parenteral opioid therapy for several days, potentially supplemented with nonopioid analgesics or coanalgesics. While morphine, hydromorphone, and fentanyl are the most frequently used parenteral opioids for acute pain, the selection of a specific opioid for a given patient must be individualized. It is imperative that the clinician obtain a pain medication history that captures previous opioid therapy and adverse reactions. For example, a patient may report that morphine causes significant itching whereas hydromorphone does not. Genetic polymorphisms may explain the interpatient variability often seen with opioid dosing. In 2013 the Food and Drug Administration (FDA) added a boxed warning to the drug label of codeine-containing products regarding overdose deaths experienced by children after tonsillectomy or adenoidectomy. Children from certain ethnic groups are ultrarapid metabolizers of codeine, which can lead to higher-than-expected serum concentrations of morphine and a risk of death.

When opioids are part of the acute pain management regimen, they may be administered by the oral, parenteral, and neuraxial routes. Research dating back almost 50 years demonstrated that small i.v. doses of morphine administered on an as-needed basis for acute pain are superior to scheduled dosing. The use of patient-controlled analgesia is a standard intervention used in contemporary pain management for the treatment of acute pain. Increasingly, neuraxial opioid administration is part of an effective multimodal acute pain management plan.

When determining the dose of an opioid for acute pain, it is critically important for clinicians to take into account whether the patient is opioid naive or opioid tolerant. Opioid-tolerant patients are those who have been taking regularly scheduled prescribed opioids or have a history of substance abuse related to illicit use of prescription opioids, illicit drug use, or participation in an opioid maintenance program. To avoid underdosing the patient with acute pain and possibly precipitating opioid withdrawal, this opioid tolerance must be taken into consideration. One possible strategy is to continue a previously used opioid while treating the acute pain separately; another involves calculating a larger opioid dose to treat the acute pain that incorporates an equianalgesic dose of the previous opioid.

Another important skill for practitioners is the ability to safely and accurately calculate equianalgesic opioid doses when converting a patient from one opioid to another or from one route of administration or dosage formulation to another. A commonly seen error occurs when postoperative patients are switched from an effective dosage of parenteral hydromorphone (e.g., 1 mg i.v. every four hours) to a nonequivalent and ineffective oral opioid (e.g., oral oxycodone 5 mg every four hours). This could result in pain relief failure...
as well as a loss of trust in the health care team by the patient and assumptions by providers that the patient is exhibiting drug-seeking behavior when the patient is actually demonstrating appropriate pain relief-seeking behavior.

**Opioids to treat chronic pain**

Chronic pain management strategies are often viewed differently by practitioners depending on whether it is chronic cancer pain or noncancer pain, although the same analgesics are used to treat both. Both nonpharmacologic and pharmacologic strategies are used to treat chronic cancer pain and noncancer pain in a multimodal strategy. The prevalence of pain in cancer patients and persistent pain in cancer survivors is high, and opioids are frequently part of the treatment strategy. Researchers who conducted a recent systematic review of observational studies on the effectiveness of opioid therapy for cancer pain assigned a strong recommendation to the use of these agents to treat chronic cancer pain.26,27 The prevalence of pain in cancer patients and persistent pain in cancer survivors is high, and opioids are frequently part of the treatment strategy. Researchers who conducted a recent systematic review of observational studies on the effectiveness of opioid therapy for cancer pain assigned a strong recommendation to the use of these agents to treat chronic cancer pain.23

The use of opioids in the management of acute pain and chronic cancer pain is more widely accepted than their use in treating chronic noncancer pain. There are many reasons to explain this finding. The available evidence that opioids conclusively reduce pain severity and increase function (e.g., activities of daily living) in patients with chronic noncancer pain is not convincing. A review by Trescot and colleagues24 concluded that there was weak evidence of the long-term (i.e., six months or longer) effectiveness of morphine and transdermal fentanyl in reducing pain and improving function. This review found no evidence of effectiveness of other opioids. Long-term opioid therapy may be associated with tolerance, opioid-induced hyperalgesia, physical and psychological dependence, persistent adverse effects, a lower quality of life, higher rates of depression, and increased healthcare utilization.25

**Role of the urine drug test**

Published practice guidelines for opioid therapy for noncancer pain from governmental agencies and professional organizations (Appendix B) recommend using urine drug testing as part of the initial patient evaluation, the treatment plan agreement, and monitoring and assessment of therapy.26,27 The urine drug test supplements tools such as patient self-reporting and behavioral monitoring, identifies noncompliance with the prescribed medications, and detects the use of alcohol, undisclosed medications, and illicit drugs.

The advantage of urine drug tests is that there are well-established analytical methods and extensive experience in result interpretation; the disadvantages include specimen collection and the potential for tampering and adulteration. Oral fluid testing, or saliva testing, is gaining in popularity and has an advantage over urinalysis in that it entails a simple and noninvasive specimen collection process. Oral fluid testing, however, faces technical challenges with regard to both screening and confirmation methodologies.28

The urine drug test menu, whether performed inhouse or by a reference laboratory, should test for commonly prescribed opioids and the typical illicit drug groups (Table 1). The urine drug test is performed in most clinical settings by immunoassays, which, if positive, may lead to confirmation testing.

Proper utilization of immunoassay-based urine drug testing and correct interpretation of results must take into consideration the limitations of immunoassays.29

Most immunoassays, such as those for the amphetamines, benzodiazepines, and opioids, are class assays; they detect not one target drug but a family of related compounds.28,29 For example, the opiates immunoassays detect morphine (the target analyte) and codeine and also the related opioids with a phenanthrene ring, such as hydromorphone, hydrocodone, dihydrocodeine, and oxycodone, with varying sensitivities; these opioids, when present singly or in combination, can also produce a positive immunoassay result. Thus, an immunoassay cannot be used to monitor a patient using a prescribed opioid for possible abuse of another (i.e., nonprescribed) opioid.

**Immunoreactivity assays for a drug**

Immunoreactivity assays for a drug determine the assay sensitivity for that drug.28 For example, the opiates assay is less reactive to hydromorphone than to morphine and thus requires that a comparatively higher hydromorphone concentration be present for a positive result. Therefore, a patient may test negative for the prescribed opioid due to lower assay sensitivity, especially if the drug is taken in low doses, which can result in urine drug concentrations that fall below the assay cutoff; this is a “clinical” false-negative result and does not necessarily indicate nonadherence.30,31 In this case, an alternative (and more sensitive and specific) assay should be able to detect the specific opioid. For example, oxycodone is poorly detected by the opiates assay, and the nonopiate opioids buprenorphine, fentanyl, and methadone are not detected by the opiates assay at all. Detection of these drugs requires analyte-specific (i.e., drug-specific) immunoassays.

Most clinical laboratories perform confirmation testing using mass spectrometry (MS) assays such as liquid chromatography–mass spectrometry (LC/MS). The MS assays offer specific identification of drugs and metabolites and quantitative measurement at low concentrations, thus allowing interpretation of cases involving the presence of minor opioid metabolites or pharmaceutical impurities.30 MS, however, is costly and technologically challenging, and its deployment is limited to large laboratories.

Correct interpretation of urine drug test results requires knowledge of the limitations of the assay meth-
odology. Moreover, there should not be unrealistic expectations of what information can be obtained from the urine drug test. For example, the urine drug concentration cannot be extrapolated reliably to gauge the serum drug concentration, nor can it be used to infer patient adherence with the prescribed dosage regimen.

When interpreting an unexpected negative urine drug test, nonadherence may not be the only explanation. Besides the reasons mentioned previously, other possible explanations include dilution or substitution of the urine sample; genetic polymorphism in enzymes and transporters involved in opioid metabolism and transport (e.g., cytochrome P-450 enzymes, uridyl glucuronide transferase, P-glycoprotein), which can result in lower drug concentrations; and altered pharmacokinetics due to disorders involving reduced gastrointestinal absorption (e.g., diarrhea, short-gut syndrome), concurrent medications, or diet.32

An unexpected positive result suggests the patient may have taken undisclosed medications or illicit drugs. Other explanations, however, must also be considered. For example, the unexpected opioid may be present as a minor metabolite of the prescribed opioid and not as a result of abuse of the unexpected (nonprescribed) opioid. For example, hydromorphone is a prescription opioid but also a minor

<table>
<thead>
<tr>
<th>Drug/Classa</th>
<th>Target Analyte(s)b</th>
<th>Cutoff Values (ng/mL)b</th>
<th>Typical Confirmation Assay Targetsb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamines</td>
<td>d-Methamphetamine</td>
<td>500, 1000</td>
<td>Amphetamines, Methamphetamine, M ethylendioxyamphetamine (MDMA), M ethylendioxyamphetamine (MDA)</td>
</tr>
<tr>
<td>Barbiturates</td>
<td>Secobarbital</td>
<td>200, 300</td>
<td>Amobarbital, Butalbital, Pentobarbital, Phenobarbital, Secobarbital</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>Nordiazepam</td>
<td>200, 300</td>
<td>Diazepam, Nordiazepam, Oxazepam, Temazepam, Clonazepam, 7-aminoclonazepam, Alprazolam, α-hydroxyalprazolam, Flunitrazepam, 7-aminoflunitrazepam, Lorazepam</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>Buprenorphine, Norbuprenorphine</td>
<td>5</td>
<td>Buprenorphine, norbuprenorphine</td>
</tr>
<tr>
<td>Cocaine</td>
<td>Benzoylecgonine</td>
<td>150, 300</td>
<td>Benzoylecgonine, cocaine, cocaethylene</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>Fentanyl</td>
<td>2</td>
<td>Fentanyl, norfentanyl</td>
</tr>
<tr>
<td>Marijuana</td>
<td>Δ9-Tetrahydrocannabinolcarboxylic acid</td>
<td>20, 50</td>
<td>Δ9-Tetrahydrocannabinolcarboxylic acid</td>
</tr>
<tr>
<td>Methadone</td>
<td>Methadone</td>
<td>300</td>
<td>Methadone, methadone metabolitea</td>
</tr>
<tr>
<td></td>
<td>Methadone metabolitea</td>
<td>300</td>
<td>Methadone, methadone metabolitea</td>
</tr>
<tr>
<td>Opiates</td>
<td>Morphine</td>
<td>300, 2000</td>
<td>Morphine, Codeine, Oxycodone, Oxymorphone, Hydrocodone, Hydromorphone</td>
</tr>
<tr>
<td></td>
<td>Oxycodone</td>
<td>100</td>
<td>Oxycodone, noroxycodone, oxymorphone</td>
</tr>
</tbody>
</table>

*Reproduced, with permission, from reference 31.  
*Consult laboratory for specifics of assays in use.  
*a-2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP).
metabolite of morphine (Figure 1). Knowing the metabolic pathway and the relative concentrations of both morphine and hydromorphone may help to distinguish between the two scenarios.

An alternative explanation for an unexpected positive urine test result is that high-sensitivity MS assays can detect opioids at very low concentrations, and some opioids are impurities created during pharmaceutical manufacturing processes; specifically, hydrocodone and codeine are impurities in pharmaceutical preparations of oxycodone and morphine, respectively. A very low ratio (<1%) of the unexpected opioid (e.g., hydrocodone) to the prescribed opioid (e.g., oxycodone) suggests that the unexpected opioid is present as a manufacturing impurity.

The urine drug test is a useful laboratory test for the management of patients on chronic opioid therapy. Consultation with a clinical laboratory professional can help to maximize the clinical efficacy of the urine drug test.

**Epidemiology of opioid misuse and abuse**

Reports from CDC, the Drug Abuse Warning Network (DAWN), and the National Poison Data System have demonstrated an alarming increase in opioid misuse and abuse over the last two decades. Poisoning deaths in the United States nearly doubled from 1999 to 2006, from 20,000 to 37,000. This was due largely to deaths from prescription opioid analgesics, with methadone, oxycodone, and hydrocodone most frequently implicated. This increase in deaths coincided with a nearly fourfold increase in the use of prescription opioids nationally. A review of data on individuals with adverse drug events who were treated in emergency departments from January 1, 2004, through December 31, 2005, found that central nervous system agents constituted the most frequently implicated therapeutic category (21.4% of cases); within that category, opioid-containing analgesics were the most frequently implicated medication class, accounting for an estimated 1,167 (24.8%) of the evaluated cases. Sales of prescription opioids in 2010 were four times those in 1999. Overdose deaths involving opioid medications now exceed deaths involving heroin and cocaine combined. In 2010 alone, 16,500 people died from analgesic-related overdoses, the majority of which involved opioids. Deaths from opioid analgesics have been reported across the United States, in all age groups, and specific opioids such as hydrocodone, methadone, morphine, and oxycodone have been implicated. In 2008, overdose death rates ranged from 5.5 per 100,000 population in Nebraska to 27.0 per 100,000 in New Mexico. The prevalence of nonmedical use of opioids in 2008–09 ranged from 3.6% in Nebraska to 8.1% in Oklahoma. Rates of prescription opioid sales in 2008 ranged from 3.7 kg per 10,000 population in Illinois to 12.6 kg per 10,000 in Florida, with the highest sales rates reported in the Southeast and the Northwest.

In a review of 295 unintentional pharmaceutical overdose deaths in West Virginia, opioids were implicated in 93% of cases. However, 44% of the decedents had not been prescribed an opioid. Ninety percent of the decedents were men ranging in age from 18 to 70 years, with a mean age of 39 years. Sixty-three percent of the deaths were associated with pharmaceutical diversion, and 21% involved evidence of doctor shopping. The 35- to 44-years age range was associated with a notably higher rate of doctor shopping. Substance abuse indicators were identified in 95% of the decedents, and having prescriptions for five or more controlled substances was more common in women (30.9%) than in men (16.7%).

DAWN also collects important data that provide insights into recent national trends in drug-related mor-
SPECIAL FEATURE Opioid abuse and misuse

7.3 to 13.4 per 100,000 people.41 The number of visits related to opioid analogues increased by 111% (from 144,600 to 305,900 visits) in the same time period. Visit rates increased across the five years for fentanyl, hydrocodone, hydromorphone, methadone, morphine, and oxycodone; for oxycodone, estimated annual emergency department visits increased from 41,700 to 105,200.38

In Florida, from 2003 through 2009, the death rate due to prescription drugs increased by 84.2%, from 7.3 to 13.4 per 100,000 people.41 The greatest increases in rates were observed with oxycodone (264.6%), alprazolam (233.8%), and methadone (79.2%). Figure 2 compares Florida overdose trends for opioids as a group and for hydrocodone, methadone, morphine, and oxycodone specifically.

Clinical toxicology

While all opioids have some degree of affinity for the µ-, δ-, and κ-opioid receptors, the µ-opioid receptor is responsible for the majority of the adverse effects associated with opioid misuse, abuse, and overdose.43 The classical elements of the opioid toxidrome include altered mental status, hypoventilation, decreased bowel motility, and miosis. Contrary to conventional wisdom, miosis is not a universal finding in opioid-toxic patients and neither its presence nor absence is pathognomonic of opioid toxicity or the lack thereof. For example, hypoxic patients and those who coingest anticholinergic agents may exhibit mydriasis. Other findings may include peripheral vasodilation, pulmonary edema, hypertension, bradycardia, chest wall rigidity, and myoclonus (with fentanyl) and seizures (with meperidine).42-44 Opioids induce a delay in gastric emptying and may increase the risk of vomiting and pulmonary aspiration that can complicate respiratory depression.45 Respiratory depression, modulated by the effects of opioids on medullary chemoreceptors’ ability to detect hypercapnia, and the consequent reduced respiratory rate are diagnostic of opioid toxicity; a respiratory rate of less than 12 breaths per minute is characteristic.46 Each opioid has unique pharmacokinetic and pharmacodynamic properties that determine the extent and duration of toxicity and affect treatment decisions, and these differences must be considered when evaluating the patient with opioid toxicity. While not yet applicable clinically, human genomics is linked to the magnitude of toxicity for some drugs, and, as mentioned previously, at least one opioid receptor polymorphism has been identified and may have diagnostic and treatment implications in the future.37

Characteristics of selected opioids

Buprenorphine. Buprenorphine is a potent semisynthetic opioid with partial agonist activity at the µ receptor. Its primary indication is treatment of opioid addiction since it has an extraordinarily high affinity for the µ receptor and the ability to prevent binding of other opioids. Buprenorphine formulations for opioid maintenance therapy are sublingual tablets and a sublingual film that are coformulated with naloxone, which serves as a deterrent to the i.v. abuse of buprenorphine. Unlike methadone, whose use requires the individual to obtain a daily dose at a methadone clinic, buprenorphine is dispensed through licensed office-based practices, and multiple doses can be dispensed.48,49 Consequently, unintentional exposures to buprenorphine are now commonplace in the pediatric population and may be associated with significant morbidity.48,51 Due to the long half-life of buprenorphine, children who may have been exposed to a single dose should be hospitalized for 24 hours and even longer if the use of naloxone was necessary to reverse the associated central nervous system and respiratory depression.50 The high affinity of buprenorphine for the µ receptor may necessitate doses of naloxone that exceed customary doses in both children and adults or the use of a naloxone infusion.52 Buprenorphine has minimal bioavailability, and since most pediatric exposures involve the sublingual route, the use of activated charcoal is unnecessary unless there are coingestants that dictate its use.

Fentanyl. Fentanyl is a pure synthetic opioid agonist of high potency (80–100 times that of morphine) with a short duration of action.53 It is a µ-opioid receptor agonist indicated for the treatment of chronic pain, with delivery achieved via transdermal patches, nasal spray, and transmucosal products. Intravenous fentanyl is used in the perioperative setting, postoperatively for pain management, and as a sedative in the emergency department and critical care settings, and it is associated with notable morbidity and mortality when abused or when prescribed inappropriately to opioid-naïve individuals. Fentanyl patch ingestion for abuse purposes is common; unused or spent patches contain fentanyl in a matrix or reservoir that becomes bioavailable when ingested.54-58 Additionally, the inappropriate use of fentanyl patches on compromised skin (e.g., sunburned skin) or with external heat sources such as heating pads and blankets, saunas, and hot tubs increases transdermal absorption and may result in fentanyl toxicity.59 Fentanyl toxicity is characterized by the classical opioid toxidrome along with sustained central nervous system and respiratory depression. Unlike the parenteral therapeutic use of fentanyl, the ingestion of patches is associated with an extremely long duration of action that may necessitate the prolonged use of naloxone.

Hydrocodone. The fixed combination of hydrocodone and acet-
aminophen is the most commonly prescribed generic medication in the United States.60 Given the prominent presence of hydrocodone-containing products in U.S. homes, children are at a pronounced risk of being exposed to hydrocodone. Hydrocodone has considerable abuse potential and is associated with substantial morbidity and mortality.61 As with other opioids, hydrocodone has considerable affinity for μ receptors and its toxic effects are consistent with the classical opioid toxidrome. Hydrocodone has been approved for manufacture in a single-entity extended-release form as a Schedule II product, but currently it is always combined with acetaminophen as an oral analgesic product.62 Therefore, overdoses of hydrocodone-containing analgesics are also complicated by the presence of acetaminophen and are one of the leading causes of acetaminophen-related fatalities due to hepatic necrosis.63,64 Consequently, when an exposure to a hydrocodone-containing product is suspected, serum acetaminophen and salicylate concentrations should be obtained. Hydrocodone is also available with ibuprofen as a combination product. The treatment of an overdose may include the use of activated charcoal to prevent drug absorption, naloxone to reverse the effects of hydrocodone, and acetylcysteine to treat acetaminophen toxicity. If the patient develops salicylate toxicity from a combination hydrocodone–aspirin product, appropriate supportive care (e.g., airway protection and ventilatory support, sodium bicarbonate to reverse acidemia, sedatives, anticonvulsants) and interventions (e.g., hemodialysis) must be initiated to prevent possibly life-threatening salicylate toxicity.

**Methadone.** The use of methadone, a synthetic μ agonist, has evolved beyond its traditional role in helping to prevent opioid withdrawal in patients enrolled in methadone maintenance programs. Methadone is now also used in the management of severe pain in patients with cancer or non-cancer-related chronic pain. Methadone’s long half-life of approximately 24 hours (range, 8–59 hours) makes it suitable for once-daily dosing and ideal for the prevention of opioid withdrawal; that characteristic is also one of its major toxicological drawbacks, since methadone toxicity, especially a decreased level of consciousness and respiratory depression, may be prolonged considerably. Therefore, a naloxone infusion is often necessary to prevent the recurrence of respiratory depression.66 Opioid-addicted individuals who rely on or abuse methadone often use multiple pharmaceuticals that produce synergistic toxicity and increased morbidity and mortality.67-69 This is especially true when methadone users take benzodiazepines concurrently.68-70 Methadone, like all opioids, may cause airway musculature relaxation and resultant airway obstruction and sleep apnea. Benzodiazepines contribute to death by exacerbating the adverse effects of methadone. Researchers who evaluated 1193 opioid overdoses that occurred in one Australian state over a 10-year period reported that nearly

![Figure 2. Opioid overdose deaths in Florida in 2003–09, with death rates shown for opioids as a class and for specific opioid medications.41](image-url)
63.7% of methadone-related fatalities \((n = 193)\) were complicated by the concurrent presence (and likely the abuse) of benzodiazepines.\(^6\) Another often overlooked adverse event that is associated with both methadone maintenance use and overdose is Q-T interval prolongation, which increases the risk of developing ventricular dysrhythmias, including torsades de pointes.\(^7\)\(^-\)\(^9\)

**Oxycodone.** Oxycodone is a potent semisynthetic opioid and, like other potent opioids, has a high affinity for the \(\mu\) receptors. It has been used commonly in combination with both aspirin and acetaminophen. However, when oxycodone was introduced in 1995 as a single-entity sustained-release preparation, its use became widespread and its abuse became epidemic.\(^7\) Abusers ingested, injected, and nasally insufflated the product, since crushing and snorting the drug resulted in its rapid release and high blood concentrations. The sustained-release product has been reformulated to reduce the abuse potential.\(^7\) Similar to methadone, oxycodone is often abused concurrently with benzodiazepines such as alprazolam and other psychoactive drugs that enhance toxicity.\(^7\)\(^-\)\(^9\) Especially in overdose, oxycodone is associated with an increased risk of Q-T interval prolongation.\(^7\)\(^-\)\(^9\)

**Diagnosis and treatment**

Respiratory depression is the result of opioid toxicity, and supportive care to restore ventilation and oxygenation is the cornerstone of patient management. The conventional management of respiratory depression in most poisoned patients is to perform endotracheal intubation and provide ventilatory support. In contrast, respiratory depression in the patient with opioid toxicity can be treated with the competitive \(\mu\)-opioid receptor antagonist naloxone.\(^4\) Unless the patient has a traumatic brain injury, has prolonged hypoxia, or has used an additional substance or substances that produce central nervous system or respiratory depression, naloxone will reverse the adverse effects of opioids. Therefore, intubation is unnecessary in most patients experiencing opioid intoxication. Naloxone is generally administered intravenously. Opioid-dependent individuals who abuse substances intravenously may have inadequate vascular access; naloxone is effective via any parenteral route (intramuscular, subcutaneous, or sublingual), through an endotracheal tube, intranasally, or by nebulization.\(^4\)\(^,\)\(^2\)\(^-\)\(^8\)\(^,\)\(^4\)\(^-\)\(^4\)

While naloxone can rapidly reverse the symptoms of opioid toxicity, its administration can precipitate acute opioid withdrawal. Opioid withdrawal is unlikely to be life-threatening. However, it is extremely uncomfortable for the patient, who may become agitated and combative. In the emergency department setting, naloxone should be administered intravenously at the smallest effective dose and then adjusted accordingly to reverse respiratory depression. The initial adult i.v. dose is 0.04 mg and can be followed (if necessary) by progressively larger doses every 2–3 minutes until opioid toxicity is reversed\(^4\)\(^,\)\(^8\)\(^-\)\(^5\); some clinicians advocate adjusting the dose by 0.04-mg increments to prevent withdrawal.\(^8\) The half-life of naloxone is approximately 30 minutes, whereas the half-life of most opioids exceeds that notably, necessitating the continued administration of naloxone to prevent recurrent respiratory depression; this is often accomplished through the use of a naloxone infusion. Patients who receive naloxone must not be discharged until several hours have passed since the last naloxone dose in order to ensure that opioid toxicity is no longer a risk. In the prehospital setting, it may be difficult for emergency medical providers and companions of opioid users to administer naloxone parenterally. The administration of intranasal naloxone has been determined to be as effective as parenteral administration, and this intervention has been implemented in many cities worldwide.\(^4\)\(^,\)\(^3\)\(^-\)\(^4\) Additionally, in early 2014 FDA approved a naloxone delivery system that enables subcutaneous or intramuscular naloxone administration by individuals who are not health professionals.\(^8\) The apparatus is technically similar to the automatic defibrillators that are located in public venues. When activated, it provides the person who is administering the naloxone with verbal instructions on the use of the drug. The device delivers 0.4 mg of naloxone per dose.

Opioids may be taken by any route (e.g., orally, intravenously, via nasal insufflation); therefore, gastrointestinal decontamination may not be indicated or effective. If the opioid was ingested, the only gastrointestinal decontamination that may be effective is the administration of an aqueous slurry of activated charcoal within two hours of the ingestion\(^8\); gastric lavage, emesis, and cathartics have no role in these cases. The clinician must recognize that coingestants (e.g., acetaminophen) or illicit drugs (e.g., cocaine) may have been used and that the patient may require additional treatment to prevent or reverse the effects of these agents.

With some overdoses, such as those involving acetaminophen, laboratory testing is diagnostic and determines the appropriate therapeutic interventions (e.g., acetylcysteine administration). However, laboratory testing has limited value in the treatment of the patient with opioid toxicity.\(^8\) Most initial laboratory toxicology screens focus on analyzing a urine specimen, which provides only qualitative evidence of exposure to opioids with a phenanthrene ring (e.g., morphine). The semisynthetic (e.g., hydrocodone) and synthetic (e.g., fentanyl) opioids may be detected only at higher concentrations (as with hydrocodone) or not at all (as with fentanyl) with the conventional assays that are utilized by most hospitals.\(^8\) In a patient with...
respiratory depression, waiting for the results of a laboratory test delays the use of appropriate therapy. The patient history and the clinical presentation are the best indicators that the patient is experiencing opioid toxicity and requires treatment.

**Legal implications**

As a result of the increases in opioid-related deaths, over the last two years the Drug Enforcement Administration (DEA) has become much more aggressive in its enforcement of the Controlled Substances Act (CSA) with respect to prescription drug wholesalers, physicians, pharmacists, and pharmacies that distribute, prescribe, and dispense controlled substances. Historically, DEA focused its enforcement actions on independent community pharmacies more than retail chain or hospital pharmacies, but in 2012 that focus expanded to include legal actions against large chain pharmacies, long-term care pharmacies, and prescription drug wholesalers.

A brief review of some of the prosecutions undertaken by DEA and a state government in 2012 and 2013, as well as the resulting court actions (summarized in news releases available from the U.S. Department of Justice website [www.justice.gov/dea/pr/news.shtml]), is illustrative of the current practice environment:

1. **DEA issued an immediate suspension order on a wholesaler’s distribution facility.** DEA alleged that the wholesaler endangered the public health by selling excessive quantities of oxycodone to certain pharmacies in Florida. This was one of the first times DEA argued that a drug wholesaler had a responsibility for the actions of its customers. This action was settled with the wholesaler agreeing to not sell any controlled substances from its Florida facility until May 2014, establish a customer monitoring program, and report suspicious orders to DEA.

2. **DEA suspended the controlled substance registrations of two retail chain pharmacies in central Florida, alleging that the pharmacies had improperly sold massive quantities of oxycodone.** Although the parent corporation argued that the pharmacies had adopted new policies to verify the legitimacy of prescriptions for such drugs, DEA revoked the registrations in October 2012.

3. **A national long-term care pharmacy agreed to pay $50 million to resolve claims that its facilities dispensed controlled substances improperly.** Two of the allegations against the long-term care pharmacy were that some prescriptions did not contain all the items required by CSA regulations (21 C.F.R. 1306.14 and 1306.24) and that the pharmacy had not properly documented partially filled prescriptions. The DEA administrator was quoted as saying, “This case highlights the responsibilities of pharmacists, doctors and others when prescribing and dispensing controlled substances.”

4. **The attorney general of West Virginia filed legal actions against over a dozen drug wholesalers, alleging that the distributors failed to properly assure that orders for controlled substances were for legitimate quantities, thereby contributing to the drug abuse problems in West Virginia.**

5. **DEA took separate actions against at least six Florida chain pharmacies and issued an immediate suspension of registration against the chain’s wholesale distribution center.** The agency alleged that the pharmacies did not keep adequate records and filled prescriptions that were not issued for a legitimate medical use. These cases and others pending in additional states were resolved when the pharmacy chain agreed to pay $80 million—the largest settlement in DEA history—and to the suspension of dispensing privileges in some stores until 2015.

Health-system pharmacists are subject to the same level of DEA scrutiny as retail pharmacists and have similar responsibilities in relation to controlled substances.

Numerous health systems operate outpatient and retail pharmacies, and hospitals have risks associated with employee theft, loss or destruction of controlled substances, record-keeping issues, and documentation of a legitimate medical need for the use of opioids.

The diversion of opioids and other controlled substances from hospital pharmacies may result from improper actions by employees. Hospitals, like many other employers, are subject to the risk that some employees will steal merchandise. In addition, hospital pharmacies are at risk for diversion related to the use of prefilled syringes or single-use vials of controlled substances when the prescriber orders a dose that is less than the total contents of the syringe or vial. If the syringe or vial contains 100 mg of an opioid but the prescribed dose is 75 mg, the disposal of the remaining 25 mg can become a diversion risk. As an example, a nurse could carry an empty sterile vial in a pocket and, instead of destroying the excess drug, inject it into the vial; this pattern could be repeated several times throughout the shift, and by the time the nurse left the hospital at the end of the day, he could have diverted a substantial quantity of a controlled substance that was extremely difficult to trace. In this case, the hospital could not identify or demonstrate a shortage from the patient records. A director of pharmacy must be vigilant to these risks and establish and consistently apply policies and procedures that will minimize the risk of employee theft or diversion of controlled substances.

The final area for legal consideration is the actual use of controlled substances in the health-system environment for inpatients and outpatients. Health-system pharmacists must be familiar with DEA regulations controlling the use of opioids in the inpatient setting. Hospitals have the same legal duty as retail pharmacies to ensure that controlled substances are ordered for
a legitimate medical purpose. The definition of legitimacy is subject to change, however, as evidenced by the September 2013 change in the FDA labeling standards for long-acting and extended-release opioid analgesics. The new labeling indicates that these drugs should only be used for pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative options are inadequate.

This issue of appropriate opioid therapy may appear to be less of a problem in the hospital environment than in the retail sector, but health-system pharmacists must remain vigilant for questionable orders or prescriptions. As individuals who abuse drugs find it more difficult to obtain opioids from retail pharmacies, they may turn to emergency departments and outpatient pharmacies to obtain these medications. Further, health-system pharmacists must also remember that all orders, prescriptions, and prescription labels must be complete and accurate, as mandated by DEA regulations. Policies should be in place to ensure that these record-keeping requirements are met.

In addition to ensuring that opioids are being ordered for a legitimate medical purpose and that proper record-keeping and labeling procedures are followed, health-system pharmacists must understand the restrictions on using opioids for maintenance or detoxification of patients who are drug addicted. The basic rule is that only an opioid treatment program registered with DEA is permitted to use an opioid drug to maintain or detoxify an opioid-addicted individual; the one exception is if a buprenorphine product is ordered by a specially certified prescriber. However, there is a critical exception in the DEA regulations pertaining to hospitalized patients: Provisions of 21 C.F.R., section 1306.07(c), stipulate that the hospital staff is permitted to provide opioid maintenance or detoxification therapy to a patient as an incidental adjunct to medical or surgical treatment of conditions other than addiction, thereby allowing a hospitalized addicted person to avoid the risk of withdrawal while being treated for some other condition. It is even possible to withdraw the patient from the opioid addiction if the withdrawal is accomplished during legitimate treatment for some other medical or surgical condition. The other important exception found in section 1306.07(c) is that hospital staff may administer or dispense opioids to an addicted patient with intractable pain for whom no relief or cure is possible or none has been found after reasonable efforts. As an example, this provision protects health-system pharmacists treating a patient with cancer (as either an inpatient or an outpatient) who has become addicted to opioids.

**Prescription drug monitoring programs**

Prescription drug monitoring programs (PDMPs) are electronic databases created and overseen at the state level to collect data on opioids and other controlled substances as well as noncontrolled drugs with potential for abuse. PDMPs are currently active in 47 states. New Hampshire and Maryland are in the process of implementing systems, and the District of Columbia has pending legislation. Missouri is the only state without a PDMP and no pending legislation. Missouri is the only state without a PDMP and the District of Columbia has pending legislation. Missouri is the only state without a PDMP and no pending legislation. The goals of individual PDMPs vary from state to state, but in general these programs are designed to (1) monitor prescribing and dispensing to individual patients, thereby providing treatment history information to the health professionals responsible for a patient’s care, (2) provide information to parties, including law enforcement, for the identification and deterrence of prescription drug abuse and diversion, (3) provide information to practitioners and third parties for the identification of individuals at risk for addiction to a controlled substance, and (4) provide information to researchers and public health officials for identification of drug-use trends and public health needs.

Because PDMP laws flow from state legislatures and the rules and regulations are determined by the executive body identified in each state’s statutes, each state has determined its own laws, regulations, rules for implementation, and program structure. There is state-to-state variation in terms of which agency houses the program (e.g., department of public health, office of attorney general, board of pharmacy), which controlled substances are monitored (e.g., Schedule II only, Schedules II–V, other drugs), how often pharmacy reporting is required (e.g., weekly, biweekly, monthly), and who can query the database (e.g., prescribers, pharmacists, law enforcement). Another key factor differing among states is whether the system is proactive or reactive. In proactive systems, information is delivered to prescribers or dispensers when certain prescribing or dispensing thresholds are met by a patient under their care. Reactive systems query available information, but the system is utilized only at the discretion of the prescriber or dispenser. Finally, states differ in requirements for prescribers or pharmacists to utilize the PDMP. Currently, 16 states require mandatory PDMP use when various conditions are met before certain controlled substances can be prescribed.

The effectiveness of PDMPs in accomplishing the goals listed above has not been investigated thoroughly. Research that has been conducted in this field has generally examined either the effect programs have on opioid-related outcomes (e.g., hospital admissions, mortality) or the ability of the program to influence behaviors associated with abuse and misuse of opioids.

There are conflicting findings regarding the ability of PDMPs to
reduce mortality related to opioid abuse. A 2011 study of opioid overdose deaths in 19 states found that PDMP status was not associated with decreased drug overdose or opioid-related mortality.94 However, new data from the RADARS (Researched Abuse, Diversion and Addiction-Related Surveillance) System’s Poison Center Program and Opioid Treatment Program surveillance databases show an association between the presence of a PDMP and a decrease in the number of poison center interventions as well as a decrease in admissions for opioid overdose.95 One weakness in this area of research thus far has been the treatment of PDMP presence as a dichotomous variable. Because of the varying structures of these programs, their effectiveness is likely to vary from state to state; this is especially true when comparing reactive and proactive programs.

While the effectiveness of PDMPs at reducing poor outcomes associated with opioids has not been shown definitively, the ability of these programs to influence the behavior of prescribers, pharmacists, and patients is well established. Studies using survey methods have shown that providers who utilize PDMP reports are likely to change their prescribing practices in response to the new information. These studies have taken place in a variety of settings (e.g., primary care,96 emergency department,97 substance abuse treatment programs98) and in several distinct geographic locations.99-101 While studies of pharmacists are more limited, pharmacists’ attitudes toward PDMPs have been positive, with their primary use of the programs being to help reduce doctor shopping.102 One of the most straightforward uses of PDMPs is altering this aberrant patient behavior by providing a coordinated and convenient source of controlled substance use information to prescribers, pharmacists, and law enforcement. One study showed that PDMP implementation reduced the time necessary to conduct investigations into possible doctor shopping from 156 to 16 days.101

CDC and the Office of National Drug Control Policy have identified PDMPs as important strategies in the response to the opioid abuse and misuse epidemic.103 The continued expansion of PDMPs to cover all 50 states and the District of Columbia is a good first step in implementing this strategy; however, looking beyond this, the National Alliance for Model State Drug Laws and the National Safety Council have recommended PDMP best practices for states to consider.104 Interstate data sharing, the expansion of authorized users (including allowing delegate access), and the determination of compulsory-use requirements by professional licensing boards are key components of these recommendations.104 As the expansion of PDMPs across the nation continues, utilization of the growing body of evidence relating to these programs to identify and implement program improvements will be important. Implementing evidence-based policy changes to increase PDMP effectiveness at achieving the various program goals described above will ensure greater utility for all stakeholders in the future.

Implications for medication-use policy in health systems

Opioids are included on the Institute for Safe Medication Practices list of high-alert medications (i.e., agents associated with a high risk of patient harm when used inappropriately) and require heightened oversight in hospitals and health systems.105 Institutional policies, beyond federal and state legal requirements, further dictate appropriate use and monitoring of opioids and promote standardized practices to prevent and identify diversion. Clinical policies can address appropriate treatment of severe pain with opioid medications, which requires ongoing assessment and reassessment of analgesia, activities of daily living, adverse effects, and aberrant behavior along with appropriate documentation. Operational policies outline procedures to ensure proper control and accountability and prevent diversion.

Consistent practice for appropriate screening, assessment, and prescribing for pain can be directed through computerized prescriber order entry (CPOE), clinical decision support (CDS), pharmacy and therapeutics committee–approved guidelines, and formulary restrictions. Printed or computerized order sets should include best practices and standardized prescribing of appropriate doses, patient-controlled analgesia, epidural opioid infusions, procedure-specific dosing protocols, and monitoring. Discharge and ambulatory care order sets or protocols can be utilized to ensure consistent discharge analgesia regimens and minimize the amount of opioid dispensed after routine outpatient procedures or minor surgeries. If the prescriber concludes that opioids are required, a standard minimal number of doses for each procedure can be designated (e.g., 5–10 doses) instead of an ample supply to cover any and all pain. By minimizing the amounts of opioids that are prescribed routinely but are not used by patients, the amounts of opioids available in the community for misuse and abuse can be reduced.

Prescribers can receive additional direction through best-practice alerts or red flags built into CPOE and CDS systems regarding dose limits and the risks of respiratory depression or misuse. Safe prescribing through formulary restrictions and guidelines further minimizes risk and liability from high-harm opioids such as meperidine and codeine. Due to the risk of neurotoxicity, meperidine is not recommended for pain treatment and should be removed from the formulary or restricted to treatment of rigors.106,107 Codeine use should also be limited due to the drug’s unpredictable analgesia arising from a genetic polymorphism and a recent FDA boxed warning on its use.
in children after tonsillectomy or adenoidectomy.\textsuperscript{108,109}

Some emergency departments restrict the prescribing of opioids by limiting quantities to a small amount for the short-term treatment of acute pain and restricting treatment of patients with chronic pain.\textsuperscript{10,111} In some emergency departments, patients with chronic pain are treated with nonopioid analgesics and then referred for follow-up care. In conjunction with these policies, emergency physicians do not replace lost or stolen opioids, and signage in the emergency department delineates the policy clearly. These policies and practices are most effective if coordinated within a geographic area.

Management of opioid-dependent chronic pain can be challenging due to common comorbidities of depression, anxiety, and addiction.\textsuperscript{112,113} Development of institutional guidelines or protocols can provide a consistent and safe method of initiating and monitoring therapy for these patients.\textsuperscript{114,115} Along with a thorough history and physical examination, chronic pain management plans should include universal screening for illicit drug use and addictive disorders prior to initiation of treatment. One exception is the patient with limited life expectancy. Screening may include the urine drug screen, review of public records for prior convictions, and evaluation of state PDMPs. Similarly, as discussed in Appendix B, a pain management agreement plan (PMAP), or “opioid contract,” should be constructed for most patients. The intent of the PMAP is to provide full disclosure of the risks and benefits of opioid therapy and institutional policies with regard to ongoing regular pain assessment, random urine drug screening, and the use of a single opioid prescriber group and pharmacy. In addition, the PMAP addresses consequences of missed appointments, aberrancies in urine drug tests, and illegal actions related to substance abuse. Violation of a PMAP may require the placement of limits on a patient’s opioid supply, more frequent clinic appointments and urine drug screening, selection of therapy with a lower street value, or referral to a substance abuse specialist. In addition to these measures, some facilities require more frequent monitoring and documentation of therapeutic benefit for patients receiving opioid doses over a target threshold (e.g., greater than 120 mg of oral morphine equivalents per day) to identify potentially inappropriate use and minimize harmful consequences associated with high opioid doses.\textsuperscript{116}

The pharmacist’s role in opioid therapy and developing guidelines, policies, and patient education to promote safe practices is paramount in both the inpatient and ambulatory care settings.\textsuperscript{117} In addition to their important legal responsibilities to ensure appropriate prescribing and dispensing, ambulatory care pharmacists should further define organizational practices for consistent dispensing of opioids. For example, pharmacies could require a check of the state PDMP prior to the dispensing of opioids to new or unfamiliar patients, especially those residing a long distance from the pharmacy, along with a government-issued identification for picking up opioid prescriptions. Other standards might include criteria for contacting prescribers and law enforcement officials regarding potentially forged or altered prescriptions, frequent requests for early prescription refills, and unusual patient behavior. A standard documentation process for the steps required for prescription validation should be implemented as well. Despite their best efforts to identify inappropriate prescriptions, pharmacists may face the challenge of opioid prescriptions written by valid prescribers for large quantities of opioids with questionable indications (sometimes referred to as “pill-mill” operations) but with insufficient information to validate a patient–prescriber relationship. One pharmacy chain limited the dispensing of inappropriate prescriptions by identifying prescribers writing for larger quantities of high-risk medications more frequently than others within the same specialty and geographic area.\textsuperscript{118} Pharmacist from these facilities stopped filling prescriptions if the prescribers were unable or unwilling to justify their practice of prescribing high volumes of high-risk medications. As discussed above, the absence of these types of measures can place health-care systems, pharmacies, and pharmacists in legal jeopardy.

Education of healthcare staff, as well as patients, on appropriate treatment of pain, including nonopioid and nonopioid therapy, and the risk of opioid diversion is recommend ed to minimize opioid abuse.\textsuperscript{116,117} Pharmacists can be instrumental in developing educational content for their institution, patients, and the public. Medication counseling during dispensing provides the perfect opportunity to counsel patients to lock up opioids, never share medications with others, and appropriately dispose of unused medications.

Prevention of opioid diversion within the healthcare system occurs through implementation of comprehensive policies accounting for opioids from the point of ordering to administration to the patient.\textsuperscript{119}

The numbers of personnel responsible for ordering, receiving, and taking inventory of controlled substances should be limited, and those responsibilities should be rotated. Preemployment criminal background checks and urine drug screening should be considered for employees with these direct responsibilities. Technology and automated dispensing devices further facilitate tracking and documentation of opioids and generate utilization reports. One vulnerable step in the process is opioid waste disposal.\textsuperscript{120} A “second-witness” policy (i.e., a requirement that not just one but two coworkers be present during the disposal of drug waste), with appropriate documentation,
Opioid abuse and misuse

leadership role in preventing diversion. Health systems must play a key role in preventing diversion of anesthesia agents. Routine surveillance along with timely and thorough investigation of diversion reports is also required. Random audits by independent personnel not responsible for opioid tracking or documenting opioid use should be conducted to help ensure appropriate ordering, stock­
ing, dispensing, disposal, and returns of controlled substances. All staff can conduct informal surveillance if educated on the risk of diversion and provided a means of anonymous reporting. Any report on questionable behavior or discrepancies must be investigated fully. Some institutions utilize a formal controlled substance diversion team consisting of experts from multiple disciplines to further investigate aberrances.

Despite the web of policy for pre­
scribing, dispensing, and tracking opioids throughout a facility, addicts and those diverting opioids for financial profit are innovative and willing to take risks. Policies, procedures, and guidelines require ongoing review and updating. Healthcare practitioners must be vigilant and collaborate to ensure appropriate treatment of pain while minimizing misuse and abuse.

Opioid misuse and abuse have reached epidemic proportions in the United States, and there has been an increase in associated morbidity and mortality. Pharmacists in hospitals and health systems must play a key leadership role in preventing diversion and inappropriate prescribing and dispensing of opioids. In order to most effectively develop health system–based medication-use poli­

cies that aim at reducing the misuse and abuse of opioids, it is imperative that health-system pharmacists understand the appropriate role of opioids in the treatment of pain, the epidemiology of the opioid abuse epidemic and the clinical toxicology of these agents, legal implications for individual pharmacists and depart­
ments of pharmacy, and state-level monitoring programs that can be incorporated into prescribing, dispensing, and monitoring processes.

Conclusion
Pharmacists in hospitals and health systems can play a key role in recognizing the various forms of opioid toxicity and in preventing inap­
propriate prescribing and diversion of opioids.

References


63. Cicero TJ, Inciardi JA, Munoz A. Trends in abuse of Oxycotin and other opioid
SPECIAL FEATURE  Opioid abuse and misuse


Opioid abuse and misuse

Chronic opioid therapy should be started only when the perceived benefit outweighs any real or potential risk.

Informed consent and opioid management plans. When starting opioid therapy, the risks and benefits of therapy should be explicitly discussed with the patient. The patient needs to have a clear understanding of the goals of therapy, probable outcomes, and alternatives to chronic opioid therapy. For many if not most chronic noncancer pain conditions, nonpharmacologic therapies (e.g., physical, cognitive behavioral) and nonopioid therapies (e.g., adjuvant analgesics) are critically important to the overall success of the therapeutic plan, and patients must be willing to attempt a trial of these interventions in addition to opioid therapy.

Initiation and titration of chronic opioid therapy. The initiation of opioid therapy should be considered a short-term therapeutic trial, with frequent assessment of whether or not the goal is achieved. It is critically important that practitioners set realistic therapeutic goals in the treatment of chronic noncancer pain, which include not only a reduction in pain severity but demonstrated improvement in functioning. Selection of a specific opioid to treat chronic noncancer pain is also a patient-specific decision based on patient- and drug-related variables. Patient-related variables include considerations such as renal and hepatic functions, body habitus (for transdermal opioids), ability to swallow tablets or capsules, history of responsiveness to opioids in the past (positive and negative), and history of opioid allergy or intolerance, among others. The six opioids recommended for the management of chronic severe pain in the elderly by an international expert panel are buprenorphine, fentanyl, hydromorphone, methadone, morphine, and oxycodone.

Methadone. Methadone is an opioid with complicated and variable pharmacokinetic and pharmacodynamic parameters. Clinicians who choose to use methadone for chronic opioid therapy must become expert in the use of this agent. This includes a keen understanding of whether or not a patient is an appropriate candidate for methadone after performing a careful risk assessment, including a cardiac assessment; dosing strategies for both opioid-naive and opioid-tolerant patients; and how to monitor a patient receiving methadone. Methadone has a very long and variable half-life; therefore, starting doses should be conservative, patients should be monitored closely, and doses should not be adjusted before four to seven days.

Monitoring. Patients receiving chronic opioid therapy must be regularly monitored to ensure progress is being made toward achieving therapeutic goals, adherence to the prescribed therapy, and avoidance of adverse effects. Efforts (e.g., urine drug screening) to ensure the prescribed opioid is not being abused or diverted may be part of the monitoring plan.

High-risk patients. Patients with a concurrent history of drug abuse, psychiatric issues, or aberrant drug-related behaviors should only receive chronic opioid therapy if the clinician is able to implement more stringent and frequent monitoring. In difficult cases, patients may benefit from referral to an appropriate healthcare provider.

Dose escalations, high-dose opioid therapy, opioid rotation, and indications for discontinuation of therapy. When repeated dosage escalations have occurred or the patient experiences adverse effects from opioid therapy, the clinician should reevaluate the benefits and burdens of therapy. Patients may require tapering and discontinuation of opioid therapy or conversion to a different opioid.

Opioid-related adverse effects. Practitioners should be knowledgeable of opioid-related adverse effects and prevent, identify, and manage such adverse effects as they occur.

Use of psychotherapeutic cointerventions. Psychotherapeutic interventions, functional restoration, interdisciplinary therapy, and nonopioid therapies should routinely be integrated into the patient’s plan of care.

Driving and work safety. Patients should be counseled about the risks of driving and work safety while taking opioids and counseled about avoiding unsafe behaviors.

Identifying a medical home and when to obtain consultation. If the patient’s primary care provider is not prescribing the chronic opioid therapy, there should be close communication between this provider and other prescribers. Patients with chronic pain often benefit from interdisciplinary pain management.

Breakthrough pain. Patients with persistent pain that requires around-the-clock opioid therapy should be evaluated for a trial of “as-needed” opioid therapy after considering the risks and benefits of such an intervention.

Opioids in pregnancy. Women of childbearing age should be counseled about the risks and benefits of chronic opioid therapy during pregnancy and after delivery. The use of opioids during pregnancy is not encouraged, and risks to the patient and newborn must be considered and dealt with.

Opioid policies. Practitioners need to be aware of state and federal laws and guidelines as they pertain to chronic opioid therapy. Opioids are an effective tool in the management of acute and chronic pain, but as with all pharmacotherapeutic interventions, risks and benefits must be assessed before and during therapy to ensure safe and effective outcomes for patients.
Four Case Studies on Diversion Prevention

Jerry Siegel, PharmD, FASHP, Ryan A Forrey, PharmD, MS

Effectively addressing drug diversion is a challenging pursuit for hospitals throughout the United States, but failure to do so can easily jeopardize patient safety. Although it is common to believe that one’s own hospital is an exception—since diversion could never happen here—this is certainly a misconception. The exact prevalence of drug diversion is unknown, because the deceptive and secretive nature of the problem, as well as health care institutions’ reluctance to acknowledge lapses in medication security, makes quantifying its pervasiveness difficult. However, recognizing that drug diversion is occurring at your hospital is the first step toward preventing it.

To develop an effective diversion-prevention program, one must gain an understanding of who diverts, what drugs are the most common targets, which areas of the hospital are most likely to be targeted, and when and why diverters misdirect drugs. A program that addresses all of these points is most likely to be successful. At the Ohio State University (OSU) Wexner Medical Center, our diversion-prevention program—named Code N (for narcotics)—emphasizes the urgency of combating diversion. The key functions of the Code N program are enabled via a team of practitioners that quickly convene if evidence indicates a diversion scenario is in progress. The team comprises the director of pharmacy, the director of nursing, and representatives from risk management (the department responsible for calling the code), human resources, hospital security, hospital administration, as well as the manager of the discipline or patient care area under review. This team will meet within 24-48 hours of the discovery of potential diversion to review evidence and determine if a course of intervention is necessary. The success of this program is highly dependent on the multidisciplinary nature of our team and the rapid rate of response.

Who May Become a Diverter?
Anyone with access to desirable drugs—controlled substances, high-cost medications, and other drugs deemed valuable—may become a diverter. In any case of diversion, patients, their families, physicians, pharmacists, nurses, technical staff, and others are put at risk. In health care settings that comply with secure medication storage requirements, diversion detection and prevention efforts focus primarily on staff with access to that storage.

CASE REPORT: The Unexplained Empty Vial
While cleaning under the bed of a discharged patient in the medical/surgical unit, housekeeping found an empty sufentanil vial. The director of pharmacy was perplexed as to why this medication was found in this location, as it is never stocked or dispensed outside of the pharmacy and was not administered to the discharged patient. Suspecting diversion, she began an internal investigation and found no anomalies, despite careful review of administration records for the patient’s medical/surgical unit nurses, the anesthesiologist, and the operating room and post-anesthesia care unit nurses.

Three weeks later, hospital security requested a review and identification of medications found in the belongings of Jane Doe, an employee being terminated for performance issues. The director of pharmacy identified several tablets and nearly empty vials of controlled substances in her possession. Jane Doe also tested positive for several controlled substances in a urine toxicology screen.
Five years prior, Jane Doe was hired as a third-shift pharmacy technician. After exemplary performance in that role, she obtained a nursing position in the medical/surgical department. However, after changing positions, her pharmacy access was not revoked, an oversight that Jane Doe eventually discovered. She began entering the satellite pharmacies after hours to remove used controlled substance vials from hazardous waste receptacles and obtained sufficient medication to inject herself by pooling multiple vials. Jane Doe was working in the unit the night before the empty sufentanil vial was discovered. Had Jane Doe’s diversion been discovered prior to (or in absence of) her termination proceedings pursuant to her performance, she would have been offered treatment through the hospital. In this case, her diversion was reported to the police as well as the state board of nursing. Jane Doe was subjected to criminal charges and her license was suspended pending successful completion of a rehab treatment program.

**Access to Medications**

A comprehensive diversion-prevention program should focus on nurses, pharmacists, anesthesiologists, and pharmacy technicians—practitioners who regularly access medications as a function of their job duties. Many hospitals design their diversion-prevention programs to address the nursing staff first because of the sheer size of this workforce. Nurses who administer drugs daily, and may perceive drug availability due to poor or nonexistent workplace controls, have twice the normal rates of drug misuse. Knowledge of drugs has not been shown to prevent addiction among nurses, but rather to promote self-medication. Nurses who are abusing drugs often cite the nature of their work as a component driving their addiction. Contributing factors include:

- Stress
- Access to controlled substances
- Belief that medications are safe, efficacious, and helpful
- Caregiver burnout
- Belief that their training and knowledge of controlled substances can protect them from addiction

Some hospitals and risk managers are wary of sharing cases of confirmed diversion, as they can create a negative perception of the hospital. Regardless, it is essential that drug abuse education be emphasized in the training of all health care practitioners and that all employees be made fully aware that a stringent diversion program is in place at the institution and that it will be strictly enforced. Knowledge about addiction does not prevent the pharmacologic action of the agents. Thus, from a management standpoint, we have to temper staff from working excessive overtime and beware of proffering rewards and accolades for doing so. Working long hours may be a root cause of diversion as long hours ensure continuous access to drugs.

**Controlling Access**

When medication access is no longer appropriate for a given employee, for whatever reason, procedures must be in place to remove that person’s access to the electronic medical record, ADCs, and any form of electronic security (such as badge readers) that grant physical access to a restricted space. To enable this, establish a process whereby departments notify the information technology (IT) data security group (or its equivalent) of upcoming employment transfers or terminations daily or whenever they occur; immediate or urgent terminations should be communicated rapidly as well. Moreover, the IT department must notify the department requesting an access change after the user’s access has been revoked. Implementing enhanced technology to coordinate and synchronize these notifications with minimal human intervention is key. Integrating ADC systems into the institution’s

user database can increase control and decrease the risk of invalid users retaining access to controlled substances. However, even advanced systems cannot prevent all instances of unauthorized access, so continuous vigilance is required.

When an employee transfers from one position to another within the hospital, medication access must be re-evaluated prior to the move. Because the human resources department often manages transfers, rather than IT data security staff, coordination and early warning can be challenging. Our hospital requires a background check for all employees before initial hire and at the time of each transfer. Coupling an access review with a background check is an effective method to formalize a systematic procedure for medication security.

The pharmacy department also must conduct a regular audit of all pharmacy users’ access to secured medication storage areas. Ensure that support and ancillary employees (such as office assistants or clerks) whose job descriptions do not include medication handling do not have access to medication storage areas.

**What Drugs are Targeted for Diversion?**

Opioids are the most commonly diverted medications in the health care setting by far, but narcotics are not the only drugs at risk of diversion. The choice to divert one drug over another is contingent on the goal of the diverter, as well as whether the drug is stolen for personal use or to sell to others.

**Diversion for Personal Use**

Diverters who redirect products for personal use tend to begin with less potent oral agents, such as acetaminophen with codeine or acetaminophen with hydrocodone, as access and inventory of these DEA Schedule III drugs is often less restricted compared with Schedule II drugs. As the diverter’s tolerance to the narcotic grows, the diversion pattern is likely to intensify. Schedule II and injectable opioids may become the next target.

In an anonymous study of drug misuse among nurses, 20% of those surveyed admitted to misusing one or more prescription substances. Easy access was highly correlated with drug misuse. Among these practitioners:

- 60% used an opioid
- 45% used a tranquilizer
- 11% used sedatives
- 3.5% used amphetamines
- 1.9% used inhalants

**Diversion for Sale**

An individual who is diverting opioids for sale typically focuses on oral, brand name medications with the highest street value, such as OxyContin and Percocet, or their generic equivalents. Controlled non-opioid medications that may be diverted for sale include the sedatives ketamine and midazolam (see **SIDEBAR**).

**CASE REPORT: No Perceived Problem**

An inpatient charge nurse called the pharmacy ADC manager to report that furosemide 20 mg tablets were out of stock twice in one week. ADC records indicated that an inventory of 15 tablets should have been in the machine, but the pocket was empty. The ADC manager refilled the pocket and
reviewed the usage reports, finding that the furosemide pocket had been refilled six times in the last three months. One particular nurse had been working every day that the furosemide stock had been refilled. Upon questioning, the nurse admitted that she had an eating disorder and had been taking the furosemide to assist with weight loss. She did not think that taking the diuretic would be a problem because, in her words, it was just furosemide, not a narcotic. In this institution, all diversion was treated equally, regardless of the substance being diverted. The hospital reported the nurse to the police for theft, as well as the state board of nursing. She had to appear before the board and ultimately had action against her license, which remained a permanent part of her professional record.

Where Does Diversion Occur?
Diversion can occur in numerous areas of the hospital; consequently, more than one approach is required for prevention. Quite often, diversion occurs at the patient’s bedside.

- **Substitution:** A common method of drug substitution is to replace a patient’s prescribed opioid with another agent, such as saline or sterile water. An injection of sterile water will provide a sting (a feeling similar to an injection of the medication), but no therapeutic effects, so the diverter may sedate the patient with diphenhydramine or lorazepam to mask the lack of analgesia. Sometimes the diverter will not remove all of the opioid but dilute it so the patient receives partial pain relief. In one instance, the antipsychotic medication haloperidol was substituted for a diverted opioid.

- **Improper Charting:** Diverters will often put forth considerable effort to identify patients who can be used to cover for their diversion. Non-verbal patients, or those whose reports are considered unreliable, may have difficulty reporting inadequately controlled pain. For patients who are able to respond to a simple pain scale, improper charting may be used to obfuscate the reason for a dosage increase. The diverter will then administer the original dose to the patient, while keeping the remainder for personal use (see TABLE 1).
CASE REPORT: Too Much Information

The pharmacy department set up a phone hotline to enable anonymous reporting of suspicious behavior. The call is recorded and will trigger a page to the narcotics manager. The manager can then alert the pharmacy manager on-call for review and potential action. The intent of the hotline is for immediate reporting of a caregiver impaired while on duty or in the act of diversion.

The hotline received a tip that a nursing unit manager had improperly removed a controlled medication from an ADC that was intended for a patient who had been discharged that day. The ADC had been set to automatically remove patients from the profile eight hours after discharge. When questioned, the manager stated that the patient was coming back to the hospital to pick up the medication. An inventory of the ADC revealed that the manager removed numerous 4 mg syringes of hydromorphone, which is not a medication that would be given to a discharged patient. A search of her office and locker found no evidence of the diverted medication. Further investigation revealed that she had been injecting diverted opioids into grapes and eating them in plain sight of her staff.

The manager had received diversion prevention training, and therefore knew how to run reports and determine if certain activities would be detected. As a manager, she had access to four ADC units. She deduced that if she removed opioids from more than one unit, the standard deviation (SD) report would not compile all of her activity, but instead compare activity on each unit separately. By keeping her activity on each unit less than 2 standard deviations (SD), she could stay below the 4+ SD that would have triggered an investigation. This incident drove home the fact that no one is above suspicion and that caution must be applied in how we train and how much we train. The facility
should be cognizant of not providing the means by which to divert.

Be aware that while training personnel in how to identify diversion, you could be inadvertently providing information that teaches methods for successful diversion. Interestingly, in this instance, the pharmacy department’s training program provided the nurse manager with the information that allowed her to divert, while the hospital’s anonymous diversion hotline assisted in uncovering her diversion. Nevertheless, educating staff to be observant and vigilant will improve diversion detection and prevention.

**Why Do Medical Professionals Divert?**

It can be difficult to understand why medical professionals would risk their years of training, professional reputations, and personal livelihoods to engage in drug diversion. However, addiction knows no bounds, and anyone can develop a substance use disorder. Among all drug users, most are functioning in the community and nearly 66% are employed. Furthermore, an estimated 10% to 20% of nurses have substance abuse problems, and they tend to abuse prescription drugs instead of street drugs.

**CASE REPORT: The Supernurse**

Monthly reports from the controlled substances vault showed that a registered nurse on one of our patient care units had a 3+ SD use of controlled substances compared with fellow nurses in the same time frame. Further investigation revealed that this nurse was the only one who gave several patients acetaminophen with oxycodone after charting their pain scales. Review of the charts showed that the highest doses were always removed, and no doses were wasted. The unit’s head nurse vouched for the nurse in question, saying he was one of the most well-respected and reputable nurses in the department. She insisted that this nurse was beyond reproach—never taking vacation, always volunteering to work overtime, and available whenever someone called in sick.

Because never wanting to be away from work—where there is access to narcotics—is a potential red flag for diversion (see TABLE 2), the decision was made to interview this nurse and ask for an explanation for why his utilization patterns were notably different than his peers. For confidentiality, we interviewed him in a conference room outside his own unit. The nurse denied any wrongdoing and was insulted that we were questioning him. (That reaction was not surprising, as denial is common in substance use interventions.) After he regained his composure, we again asked him to explain the high volume of use and the unusual usage pattern. He emphasized how concerned he was for his patients and that he did not want to see them suffer, unlike some of his colleagues who encouraged patients not to use narcotic pain medication.

When the head nurse questioned his judgment in always offering patients the highest dose, the nurse said that he always removed the highest dose, and if all tablets were not used he would save them for later. We then inquired why he did not follow policy and waste the medication per protocol, and the nurse replied that he did not want to waste other nurses’ time and throw away viable medication. The next question was whether or not he sometimes forgot he had the drugs and accidentally took them home after his shift, which he strongly denied. As he became increasingly upset, he was asked how long had he been taking medications from the unit and why he was taking them. At this time, the nurse finally confessed to diverting the drugs. He said he had received prescription pain medications several years ago for a work-related back injury, but that his doctor had refused to prescribe additional narcotics when he would not take time off from work for physical therapy. One day a patient only
wanted one of the two tablets offered, so he took the other tablet. Because no one seemed to notice, this became his method for diversion. He apologized profusely, but explained that using the pain medication was the only way he could get through a shift. As his addiction increased, he volunteered to work more often. He rationalized that his ability to keep working was in the best interest of the hospital. This nurse was placed in a rehabilitation program.

**Technology to Monitor for Diversion**

In our experience, automated surveillance programs detect about one-half of diversions that are discovered; the other 50% are revealed through direct observation and tips reported to the pharmacy. Although not a substitute for human instinct and evaluation, technology is a vital component of any diversion-prevention program.

**Automated Dispensing Cabinets (ADCs):** To prevent diversion in the operating suite, accountability requires accurate record keeping for dispensing and waste. The use of ADCs may assist with dispensing accountability, but reconciliation of the inventory is essential.

**Spectrophotometry:** Some institutions use spectrophotometers to perform a qualitative assay of returned narcotics, as these devices can detect a wrong drug, diluted drug, or missing drug. It is important to be aware of the limitations of these devices, as they cannot detect all types of drugs. When staff is aware that a spectrophotometer is being used, this may deter diversion, but spectrophotometry is only one tool in a comprehensive diversion-prevention program. Keep in mind that a diverter may research which narcotics the spectrophotometer cannot detect. To increase the odds of detection, run random, unpredictable sample assays, and also assay all suspicious returns, whether late, left behind, or returned with missing information.

High-performance liquid chromatography (HPLC) is required to do a quantitative analysis of returned narcotics, but HPLC is beyond the scope of many pharmacies. Waste samples for HPLC must be sent to a toxicology laboratory for evaluation, a process that can be time-consuming and costly.

**Diversion Monitoring Software:** Diversion-monitoring systems can be useful to screen for variations in utilization. However, for this software to be effective, the pharmacist or technician must be trained to accurately interpret the results. For example, screens set to detect all users at 1+ SD of variance from the mean will return hundreds of false-positive reports, making follow-up impossible. We have found the monthly reports of all users with a threshold of 3+ SD narrows the reports to a more manageable sample group. Each user with 3+ SDs then must be investigated to determine if a reasonable explanation exists for the higher utilization. Although this report works for unit-based users, float nurses may avoid accurate screening unless they themselves are compared as a user group.

**Conclusion**

Potential diversion opportunities in a health care setting are too numerous for any one individual or technology to monitor effectively. Successful prevention and detection must rely on multiple strategies, and the following have demonstrated effectiveness:

- Incorporate dispensing by users within the pharmacy department in routine diversion-monitoring programs
- Connect time-keeping (clocking-in) devices with ADCs so that access to dispensing systems outside of an employee’s work hours can be prevented or more easily detected
- Link pain scale charting to dispensing devices to better correlate higher doses of medication with the patient condition and nursing documentation
• Use bedside bar coding and bar code dispensing to facilitate tracking and detection of discrepancies
• Retrieve data from the EHR on uncharted doses dispensed and review these unreconciled medication reports for trends
• Work with IT data security to program financial/billing systems to identify cases of dispensed but uncharted controlled substances or other medications targeted for diversion

Utilizing multiple diversion-prevention strategies will best ensure diversion is effectively detected, addressed, and prevented at your hospital. While a percentage of hospital staff will always seek to divert drugs, developing and implementing a comprehensive, robust diversion-prevention program is the most effective tool to combat this ongoing challenge.

References


Tips for Nurse Training in Diversion Prevention

Fostering a sense of responsibility for controlled substances and other medication products that are commonly diverted should be essential to any nurse training program. Emphasizing accountability and clearly demonstrating the hospital's commitment to diversion prevention and policy enforcement will serve as a powerful measure in creating a safe and responsible work environment. The following are just a sample of actions aimed at this goal:

- Only remove medications for your assigned patients
- Only remove current dose of medication for your patient
- Properly document medication administration and pain scores
- All wastes of medications must have a documented witness
- Do not be a virtual witness to medication wasting
- Do not loan your ID badge or pass-codes to anyone
- Return unused medications according to procedure
- Report medication discrepancies promptly to pharmacy (on-line reporting available)
- Report attempted, inappropriate access to medications to pharmacy
- Report witnessed or suspected medication diversion to pharmacy (hotline number)

Click here to view a larger version of these Tips

Jerry Siegel, PharmD, FASHP, is the former senior director for pharmaceutical services at The Ohio State University Medical Center, where he worked for over 35 years. He graduated from
The Ohio State University College of Pharmacy with both his BS and PharmD. Jerry also served as assistant dean of medical center affairs at The Ohio State University College of Pharmacy. He remains a clinical associate professor there. Prior to focusing on administration, Jerry worked as a clinical microbiologist and as a clinical pharmacist in transplantation and hematology/oncology. He has lectured extensively on immunology, infectious disease, and pharmacoconomics, and is a Fellow of ASHP.

Ryan A. Forrey, PharmD, MS, is an associate director in the department of pharmacy at The Ohio State University (OSU) Wexner Medical Center, and a clinical assistant professor at the OSU College of Pharmacy, Columbus, Ohio. In his position at OSU, Ryan is responsible for the pharmacy operations of the inpatient cancer hospital and five hospital-based ambulatory chemotherapy infusion clinics. He also teaches graduate-level lectures on pharmacy management at the OSU College of Pharmacy and serves as a preceptor for the Health-System Pharmacy Administration Residency Program at the OSU Wexner Medical Center. Ryan has presented on controlled substance diversion detection and prevention at numerous national and international meetings.

SIDEBAR

**Diversion for Sale**

*Diversion of controlled substances for sale occurs in hospital settings*, but is less common than diversion for personal use. Dealing in narcotics often requires large quantities of controlled substances to meet customers’ demands. In a patient care area, high-volume diversion should trigger even a basic surveillance system early on.

Larger-scale diversion is more likely to occur in a hospital when the same person orders and receives the inventory. Other diversion-for-sale schemes involve robbery rather than passive diversion. Robberies have increased at outpatient and retail pharmacies as access to prescriptions for controlled substances has become more restricted. Therefore, outpatient pharmacies should be aware of this potential threat.

A proactive diversion program should not focus exclusively on controlled substances, because non-controlled medications of high value also may be diverted. Diversion may occur during shortages (eg, ciprofloxacin tablets during the anthrax scare of 2001) or where health care workers’ access make certain agents tempting (eg, fluconazole tablets or diuretics).
Attachment 4
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.
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.

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
DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR PARTS 1300, 1301, 1304, 1305, 1307, and 1317

[Docket No. DEA-316]

RIN 1117-AB18

Disposal of Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

SUMMARY: This rule governs the secure disposal of controlled substances by registrants and ultimate users. These regulations will implement the Secure and Responsible Drug Disposal Act of 2010 by expanding the options available to collect controlled substances from ultimate users for the purpose of disposal, including: take-back events, mail-back programs, and collection receptacle locations. These regulations contain specific language allowing law enforcement to voluntarily continue to conduct take-back events, administer mail-back programs, and maintain collection receptacles. These regulations will allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs (NTPs), hospitals/clinics with an on-site pharmacy, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles. In addition, this rule expands the authority of authorized hospitals/clinics and retail pharmacies to voluntarily maintain collection receptacles at long-term care facilities. This rule also reorganizes and consolidates previously existing regulations on disposal, including the role of reverse distributors.
DATES: Effective date: This rule is effective [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

Compliance date: All Memoranda of Agreement (MOAs) and Memoranda of Understanding (MOUs) issued pursuant to current 21 CFR 1307.21 will not be effective after [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Registrants may consult § 1317.05(a)(5) for information on requesting new MOAs and MOUs for disposal of controlled substances.

FOR FURTHER INFORMATION, CONTACT: Imelda L. Paredes, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Outline

I. Executive Summary
   A. Purpose of the Regulatory Action
   B. Summary of the Major Provisions of the Regulatory Action
   C. Summary of Changes in the Final Rule

II. Background and Legal Authority

III. Discussion of Comments
   A. Support for the Proposed Rule (1 issue)
   B. Definitions and Terms (12 issues)
   C. Types of Entities That May Operate a Collection Program (9 issues)
   D. Locations Where Authorized Collectors May Maintain Collection Receptacles or
Host Take-Back Events (1 issue)

E. Registration Requirements for Authorized Collectors (5 issues)

F. Law Enforcement (7 issues)

G. Collection Receptacle Design, Inner Liners, Placement, and Security (24 issues)

H. Mail-Back Programs (11 issues)

I. Take-Back Events (6 issues)

J. Prohibition on Handling, Sorting, and Inventoring Inner Liner Contents and Mail-Back Package Contents (8 issues)

K. Long-Term Care Facilities (LTCFs) (21 issues)

L. Disposing on Behalf of Ultimate Users (Other than Residents of LTCFs) (3 issues)

M. Registrant Return, Recall, and Transfer (3 issues)

N. Destruction (19 issues)

O. Economic Concerns (18 issues)

P. Recordkeeping and Reporting (8 issues)

Q. Hazardous Materials Transportation and Hazardous Waste Destruction (3 issues)

R. Transporting Collected Substances (3 issues)

S. Miscellaneous Comments (2 issues)

IV. Regulatory Analyses

I. Executive Summary

A. Purpose of the Regulatory Action

who wanted to dispose of unused, unwanted, or expired pharmaceutical controlled substances had limited disposal options. The Controlled Substances Act (CSA) only permitted ultimate users to destroy those substances themselves (e.g., by flushing or discarding), surrender them to law enforcement, or seek assistance from the United States Drug Enforcement Administration (DEA). These restrictions resulted in the accumulation of pharmaceutical controlled substances in household medicine cabinets that were available for abuse, misuse, diversion, and accidental ingestion.

The Disposal Act amended the CSA to authorize ultimate users to deliver their pharmaceutical controlled substances to another person for the purpose of disposal in accordance with regulations promulgated by the Attorney General. 21 U.S.C. 822(g), 828(b)(3). This final rule implements regulations that expand the entities to which ultimate users may transfer unused, unwanted, or expired pharmaceutical controlled substances for the purpose of disposal, as well as the methods by which such pharmaceutical controlled substances may be collected. Specified entities may voluntarily administer any of the authorized collection methods in accordance with these regulations.

B. Summary of the Major Provisions of the Regulatory Action

The DEA is implementing new regulations for the disposal of pharmaceutical controlled substances by ultimate users in accordance with the Disposal Act. In drafting the implementing regulations, the DEA considered the public health and safety, ease and cost of program implementation, and participation by various communities. To this end, the DEA found that in order to properly address the disposal of controlled substances by ultimate users, it was necessary to conduct a comprehensive review of DEA policies and regulations related to each element of the disposal process, including the transfer, delivery, collection, destruction, return,
and recall of controlled substances, by both registrants and non-registrants (i.e., ultimate users). The reverse distributor registration category, which is pertinent to the process of registrant disposal, was included in this comprehensive review. These regulations are incorporated into a new part 1317 on disposal. Definitions relating to the disposal of controlled substances are added to § 1300.05(b), including definitions for “employee,” “law enforcement officer,” “non-retrievable,” and “on-site” and definitions relating to controlled substances generally are revised or added to § 1300.01.

The goal of this new part on disposal, consistent with Congress’s goal in the Disposal Act, is to set parameters for controlled substance diversion prevention that will encourage public and private entities to develop a variety of methods for collecting and destroying pharmaceutical controlled substances in a secure, convenient, and responsible manner. Also, consistent with the Disposal Act’s goal to decrease the amount of pharmaceutical controlled substances introduced into the environment, particularly into the water, these regulations provide individuals with various additional options to dispose of their unwanted or unused pharmaceutical controlled substances beyond discarding or flushing the substances. As a result of these regulations, the DEA hopes that the supply of unused pharmaceutical controlled substances in the home will decrease, thereby reducing the risk of diversion or harm.

**Ultimate User Disposal**

An ultimate user is defined by the CSA as a “person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.” 21 U.S.C. 802(27). This rule provides three voluntary options for ultimate user disposal: (1) take-back events, (2) mail-back programs, and (3) collection receptacles. Individuals lawfully entitled to dispose of an ultimate
user decedent’s property are authorized to dispose of the ultimate user’s pharmaceutical controlled substances by utilizing any of the three disposal options. All of the collection methods are voluntary and no person is required to establish or operate a disposal program. The rule also does not require ultimate users to utilize any of these three methods for disposal of controlled substances. Although the three methods of disposal allowed by this rule seek to help protect the environment and prevent controlled substances from being diverted to illicit uses, this rule does not prohibit ultimate users from using existing lawful methods.

The DEA regulations provide specific language that will continue to allow Federal, State, tribal, and local law enforcement to maintain collection receptacles at the law enforcement’s physical location; and either independently or in partnership with private entities or community groups, to voluntarily hold take-back events and administer mail-back programs. 21 CFR 1317.35. Thus, ultimate users will continue to be able to surrender their unwanted pharmaceutical controlled substances to law enforcement.

The DEA is also authorizing certain registrants (manufacturers, distributors, reverse distributors, narcotic treatment programs (NTPs), hospitals/clinics with an on-site pharmacy, and retail pharmacies) to be “collectors,” with authorization to conduct mail-back programs. 21 CFR 1317.40 and 1317.70. All registrants that choose to establish mail-back programs must provide specific mail-back packages to the public, either at no cost or for a fee, 21 CFR 1317.70. Collectors that conduct mail-back programs must have and utilize an on-site method of destruction to destroy returned packages, 21 CFR 1317.05.

These DEA regulations authorize collectors to maintain collection receptacles at their registered location. 21 CFR 1317.40. Thus, ultimate users will be able to carry their unwanted pharmaceutical controlled substances to an authorized retail pharmacy or other authorized
collector location and deposit those controlled substances in a secure container for disposal. Hospitals/clinics and retail pharmacies that are authorized to be collectors may also maintain collection receptacles at long-term care facilities (LTCFs). 21 CFR 1317.40. LTCFs may dispose of pharmaceutical controlled substances on behalf of an ultimate user who resides, or has resided, at that LTCF, 21 CFR 1317.80, through a collection receptacle that is maintained by an authorized hospital/clinic or retail pharmacy at that LTCF. 21 CFR 1317.40 and 1317.80.

With this rule, the DEA allows all pharmaceutical controlled substances collected through take-back events, mail-back programs, and collection receptacles to be comingled with non-controlled substances, although such comingling is not required. 21 CFR 1317.65, 1317.70, and 1317.75. Pharmaceutical controlled substances collected by collectors may not be individually counted or inventoried. 21 CFR 1317.75. This rule also imposes various registration, security, and recordkeeping requirements.

The DEA appreciates there is a cost to entities that choose voluntarily to provide these methods of collection and destruction. The DEA acknowledges that some State and local pharmaceutical disposal programs receive funding and other support from numerous sources, including conservation groups, local governments, State grants, and public and private donations. These expanded methods of disposal are expected to benefit the public by decreasing the supply of pharmaceutical controlled substances available for misuse, abuse, diversion, and accidental ingestion, and protect the environment from potentially harmful contaminants by providing alternate means of disposal for ultimate users. However, other advantages may accrue directly to those entities that opt to maintain a disposal program. For example, those authorized registrants that choose to maintain collection receptacles may be enhanced by the increased consumer presence at their registered locations and the goodwill that develops from providing a valuable
community service. In addition, mail-back program collectors may partner with third parties to make mail-back packages available to the public. Those authorized registrants that choose to administer mail-back programs may gain from the opportunity to distribute to consumers promotional, educational, or other informational materials with the mail-back packages.

**DEA Registrant Disposal**

The DEA has deleted the existing rule related to registrant disposal, 21 CFR 1307.21, and incorporated similar requirements on proper disposal procedure and security in a new part 1317 on disposal. These changes provide consistent disposal procedures for each registrant category, regardless of geographic location. In addition, the DEA has modified DEA Form 41 and is explicitly requiring that form to be used to record the destruction of controlled substances that remain in the closed system of distribution and also to account for registrant destruction of pharmaceutical controlled substances collected from ultimate users and other non-registrants pursuant to the Disposal Act. As stated in the NPRM, a controlled substance dispensed for immediate administration pursuant to an order for medication in an institutional setting remains under the custody and control of that registered institution even if the substance is not fully exhausted (e.g., some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized, commonly referred to as “drug wastage” and “pharmaceutical wastage”). Such remaining substance must be properly recorded, stored, and destroyed in accordance with DEA regulations (e.g., § 1304.22(c)), and all applicable Federal, State, tribal, and local laws and regulations, although the destruction need not be recorded on a DEA Form 41.

**Reverse Distributors**

The DEA is providing regulations for entities that reverse distribute that are clear and
consistent. Entities that reverse distribute are often the last registrant to possess controlled substances prior to destruction; however, the recordkeeping safeguards that exist when controlled substances are distributed between registrants are not present when these registrants destroy controlled substances. Because reverse distributors routinely acquire controlled substances for destruction from other registrants and may also be authorized as collectors, reverse distributors accumulate greater amounts of controlled substances that are destined for destruction in comparison to other registrants. The DEA is defining “reverse distribute;” revising the definition of “reverse distributor;” (21 CFR part 1300) outlining security (21 CFR part 1301), inventory, recordkeeping requirements, and other procedures that reverse distributors must follow to acquire controlled substances from registrants and to destroy such acquired substances. 21 CFR part 1304. The DEA also is clarifying that these security, inventory, and recordkeeping requirements apply to certain specified entities that reverse distribute but are not registered as reverse distributors. See, e.g., 21 CFR 1304.11(e)(3) (“each person registered or authorized to reverse distribute”). The DEA believes that these regulations will help all registrants that reverse distribute comply with the CSA in a manner that decreases the risk of the diversion of controlled substances during the disposal process.

Return and Recall

This rule removes the existing regulation on return and recall, 21 CFR 1307.12, and incorporates separate return and recall requirements for registrants and non-registrants into new §§ 1317.10 and 1317.85. This rule also imposes various recordkeeping requirements pertaining to controlled substances acquired for the purpose of return or recall in §§ 1304.22 and 1305.03. The DEA has simplified the requirements of § 1317.10(a) to more clearly describe the records that registrants must keep.
Methods of Destruction

Existing DEA regulations do not specify a standard to which controlled substances must be destroyed. With this final rule, the DEA is implementing a standard of destruction—non-retrievable—for registrants that destroy controlled substances, and procedures for the destruction of controlled substances. 21 CFR 1300.05 (“non-retrievable”), 1317.90, and 1317.95. The DEA is not requiring a particular method of destruction, so long as the desired result is achieved. This standard is intended to allow public and private entities to develop a variety of destruction methods that are secure, convenient, and responsible, consistent with preventing the diversion of such substances. Destruction of controlled substances must also meet all other applicable Federal, State, tribal, and local laws and regulations. Once a controlled substance is rendered “non-retrievable,” it is no longer subject to the requirements of the DEA regulations.

As explained above under “Compliance Date,” this final rule supersedes all existing MOAs and MOUs that registrants may have pursuant to § 1307.21, including MOAs and MOUs pertinent to storage of controlled substances. The DEA retains in the new part 1317 the ability for practitioners to request assistance from the local Special Agent in Charge (SAC) regarding the disposal of controlled substances. 21 CFR 1317.05. Practitioners may request a new MOA or MOU pursuant to the new § 1317.05(a)(5).

C. Summary of the Changes in the Final Rule


---

1 All of the comments submitted, except two comments, are available for public inspection online at www.regulations.gov. Two comments are not posted (at the commenters’ request) in order to protect confidential business information.
The DEA is making a number of significant changes after thorough consideration of the issues raised by the comments and the potential diversion risks associated with these changes.

In response to concerns regarding ultimate users’ ability to have convenient disposal options, the DEA is vastly expanding those entities that may be authorized as collectors, expanding the authority of those collectors to maintain collection receptacles at LCTFs, and relaxing some of the proposed security requirements related to storage and destruction of controlled substances.

**Authorized Collectors**

In addition to manufacturers, distributors, reverse distributors, and retail pharmacies, the final rule also authorizes registered NTPs, as well as hospitals/clinics with an on-site pharmacy, to operate disposal programs. 21 CFR 1317.40. By permitting these additional registrant categories to be collectors, the DEA anticipates that ultimate users will now have even more locations where they can securely, safely, responsibly, and conveniently dispose of their unwanted pharmaceutical controlled substances.

In this final rule, the DEA is permitting those entities registered as NTPs to become authorized collectors to manage collection receptacles at their registered locations. As stated in the Disposal Act, “the nonmedical use of prescription drugs is a growing problem in the United States.” Multiple commenters, including a national organization that represents NTPs, recommended that the DEA include NTPs as authorized collectors. The DEA recognizes the valuable role that NTPs have in helping those seeking substance abuse treatment. After considering the importance of providing secure, convenient, and responsible disposal options for those ultimate users currently receiving treatment for narcotic substance abuse or entering a narcotic treatment program, and the benefits of allowing NTPs to provide the opportunity to
patients to dispose of unused controlled substances, the DEA is permitting NTPs to be collectors with certain enhanced security controls. 21 CFR 1317.75.

Due to the nature of the healthcare provided, NTPs face unique security challenges and heightened diversion risks and, as such, the final rule requires NTPs to securely place and maintain collection receptacles in a room that does not contain any other controlled substances and is securely locked with controlled access. 21 CFR 1317.75. The DEA understands that this security measure will require employees of the NTP to accompany the patient to the collection receptacle to facilitate the patient’s disposal. See 21 CFR 1317.75. Additionally, as the Disposal Act and these regulations are intended to address the prescription drug abuse problem, NTPs and other collectors are not authorized to collect schedule I controlled substances. E.g., 21 CFR 1317.75. Collectors must be vigilant in ensuring that such illicit substances are not collected intentionally or inadvertently. E.g., 21 CFR 1317.70 and 1317.75.

After extensive review and careful deliberation, in this final rule, the DEA is also permitting registered hospitals/clinics with an on-site pharmacy to become authorized collectors to maintain collection receptacles inside their registered locations or at LTCFs, and to conduct mail-back programs. 21 CFR 1317.30, 1317.40, 1317.70, and 1317.80. In response to the NPRM, many commenters stated that collection receptacles located inside of hospitals would provide ultimate users with an opportunity to dispose of medication that may no longer be needed or may be expired. In determining whether to allow hospitals/clinics to become authorized collectors, the DEA carefully weighed the diversion risks with the convenience of authorizing such entities to be collectors. The DEA determined that the diversion risks require the DEA to limit those registered hospitals/clinics that may become collectors to those with on-site pharmacies, and also impose separate security conditions on the monitoring and location of
collection receptacles inside hospitals/clinics that become authorized collectors. 21 CFR
1317.75.

The DEA is requiring these additional security measures in order to help protect against the diversion of collected controlled substances because hospitals/clinics are generally much larger and are open to a much larger general population than the other registrants authorized to be collectors; and, as discussed in the NPRM, hospitals/clinics do not operate under the same business model or with similar theft and loss prevention procedures as the other registrants authorized to become collectors. For example, the general public typically enters retail pharmacies for short durations in order to conduct retail business and retail pharmacies generally have open, clearly observable common areas with little opportunity to conceal an unlawful purpose. It would be unusual and suspicious for a person to spend an extended amount of time in a retail pharmacy without a known, specific purpose, triggering routine theft and loss prevention measures.

In contrast, hospitals are generally open 24-hours per day and allow for unsupervised public access for extended periods of time; they are much larger than retail pharmacies and many interactions occur behind closed doors without routine theft and loss prevention measures; and foot traffic generally is not routinely monitored for unlawful purposes. The DEA believes that limiting authorized collection activities to hospitals/clinics with an on-site pharmacy is necessary to help protect against diversion because these hospitals/clinics routinely handle a large volume of controlled substances that are dispensed to in-patients as well as to the public, and these entities are more experienced with security, theft and loss prevention procedures, and inventory, recordkeeping and reporting requirements than those hospitals/clinics without an on-site pharmacy.
For reasons discussed in the NPRM, this final rule generally requires that, when authorized collectors choose to install collection receptacles, those collection receptacles must be placed inside their registered locations in the immediate proximity of a designated area where controlled substances are stored and at which an employee is present. 21 CFR 1317.75; see also 1317.05. The DEA recognizes that hospitals/clinics with an on-site pharmacy can be unique in their design and it may be more effective to install collection receptacles at various locations within the hospital/clinic, depending on factors such as security, convenience, and accessibility. As such, it would be challenging for authorized hospitals/clinics to adhere to the general rule to place collection receptacles in the immediate proximity of where controlled substances are stored and at which an employee is present. Accordingly, the DEA is requiring hospitals/clinics that are collectors to place collection receptacles in locations that are regularly monitored by employees. 21 CFR 1317.75. In addition, the DEA is prohibiting such collectors from placing collection receptacles in the proximity of any area where emergency or urgent care is provided. In the DEA’s experience, the risk of diversion is particularly high in areas where emergency or urgent care is provided because of the often chaotic environment and the extended amounts of time persons spend in such areas.

This rule also makes clear that DEA registrants cannot use the collection receptacles to dispose of unused controlled substances in their inventory or stock. 21 CFR 1317.05 and 1317.75. Pharmaceutical controlled substances remain under the custody and control of the DEA registrant if they are dispensed by a practitioner for immediate administration at the practitioner’s registered location (such as a hospital) pursuant to an order for medication. If that 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), then the DEA registrant is
obligated to destroy the remaining, unusable controlled substances, and record the destruction in accordance with § 1304.22(c). The DEA registrant shall not place such remaining, unusable controlled substance in a collection receptacle as a means of disposal. Hospital/clinic staff must also not dispose of any controlled substances in inventory or stock in a collection receptacle.

The security requirements described above are the minimum required in order to detect and prevent diversion in the unique circumstances of NTPs and hospitals/clinics. These registrants should be vigilant in the execution of their responsibilities as registrants to ensure that collected controlled substances are not diverted to illicit use, and that they do not collect illicit substances. Finally, all registrants are reminded of the responsibility to report theft and significant loss of controlled substances within one business day of discovery.

**Long-Term Care Facilities (LTCFs)**

Significant changes are made in this final rule to help ensure that LTCFs have adequate disposal options. In addition to allowing retail pharmacies to manage and maintain collection receptacles at LTCFs, the DEA is also allowing hospitals/clinics with an on-site pharmacy to manage and maintain collection receptacles at LTCFs. The DEA hopes that expanding those authorized to collect at LTCFs will maximize disposal opportunities for LTCF residents.

In addition, the DEA is alleviating two security requirements proposed to apply to collection receptacles located at LTCFs. First, the DEA is permitting authorized hospitals/clinics and retail pharmacies to store inner liners that have been sealed upon removal from a collection receptacle at LTCFs in a securely locked, substantially constructed cabinet or a securely locked room with controlled access for up to three business days until the liners can be transferred for destruction. The DEA encourages collectors to schedule inner liner removals and installations to coincide with existing LTCF visits when possible, for example, arranging a routine system in
which medication deliveries coincide with the removal and transfer of sealed inner liners for appropriate destruction, thereby making storage of sealed inner liners unnecessary. Collectors may not transfer sealed inner liners from LTCFs to their primary registered location (i.e., the hospital/clinic or retail pharmacy location). As echoed in the comments, the DEA remains concerned about the security risks of hospital/clinic and retail pharmacy employees transporting large quantities of collected substances, making them potential targets for drug seekers. Instead, collectors should deliver sealed inner liners to a reverse distributor or distributor’s registered location by common or contract carrier pick-up or by reverse distributor or distributor pick-up at the LTCF, pursuant to § 1317.05(c)(2)(iv).

Second, the DEA relaxed the two-employee integrity requirement for inner liner installation, removal, storage, and transfer at LTCFs. Collectors will retain the option to authorize two of their own employees to install, remove, store, and transfer inner liners; however, the DEA is permitting collectors the option to designate a supervisor-level employee of the LTCF (e.g., a charge nurse, supervisor, or similar employee) to install, remove, store, or transfer inner liners with only one employee of the collector.

The DEA modified the above security requirements (storage and two-person integrity) to provide flexibility sufficient to encourage authorized hospitals/clinics and retail pharmacies to collect at LTCFs, while ensuring the minimum protections required to prevent diversion at LTCFs. The DEA hopes that the inclusion of certain hospitals/clinics as authorized to maintain collection receptacles at LTCFs, and the modifications described above will result in expanded safe and secure disposal options for LTCF residents. The DEA emphasizes that if LTCFs dispose of LTCF residents’ controlled substances in collection receptacles, such activity must be in accordance with this regulation and all other applicable Federal, State, tribal and local laws.
and regulations, including environmental laws and regulations.

The DEA acknowledges that there may be some LTCFs that will not have a collection receptacle, and there will be instances where LTCF residents are incapable of disposing of their own unused or unwanted medication. As ultimate users, LTCF residents may use any of the disposal options afforded other ultimate users in this final rule (e.g., mail-back programs), in addition to the disposal options currently available to ultimate users (e.g., flushing or otherwise discarding) that will remain options even after this final rule is implemented. For example, an LTCF resident may request that LTCF personnel place the resident’s unwanted medication in a mail-back package, seal the mail-back package, and deposit that package into the facility’s outgoing mail system. 21 CFR 1317.70. LTCFs should be mindful however that the touchstone for this disposal method is the individual nature of the disposal activity; institutional facilities such as LTCFs should ensure that the individual patient is the disposer, and should be wary of establishing any protocols whereby the facility itself is engaging in collection activities. Simply providing the method of disposal (e.g., mail-back packages) does not implicate that concern.

Destruction

After careful and thorough consideration of comments received regarding the burdens associated with the proposed 14-day destruction requirement, the DEA is extending the time those registrants that reverse distribute have to destroy controlled substances to 30 days. 21 CFR 1317.15(d). The DEA anticipates that this extension will allow reverse distributors and distributors adequate time to collect and destroy controlled substances in a safe, convenient, and secure manner, while also preventing diversion and diversion opportunities.

Practitioner Physical Security

In this final rule, the DEA is not amending § 1301.75(b) pertaining to practitioner
physical security and is instead adding a new paragraph (c) to clarify that practitioners shall only store sealed mail-back packages and inner liners containing collected substances at their registered location in a securely locked, substantially constructed cabinet or a securely locked room with controlled access. The DEA has made corresponding changes to §§ 1317.05(c)(1)(ii) and (c)(2)(ii). Part of this requirement was included in the proposed rule; however, after careful consideration of a number of comments, the DEA believes that the proposed requirement did not provide sufficient controls to protect against diversion and was impracticable. Pharmacies and institutional practitioners cannot store sealed inner liners or returned mail-back packages by dispersing them throughout the stock of noncontrolled substances. 21 CFR 1301.75(b) and (c).

Other Changes to the final rule

In addition to the changes described above, the DEA determined that the rule, as proposed, required other modifications, as generally described below. The DEA is also implementing additional technical modifications that will not have a substantive effect on this rule (e.g., relocating some sections in proposed part 1317 to other sections within title 21 of the CFR, re-phrasing some sections from the proposed rule to be simpler, clearer and easier to understand, and eliminating redundancy).

In the general definitions section of the DEA regulations, the DEA is amending § 1300.01(b) to be clear that the definitions that generally apply to most other parts of chapter II of title 21 of the CFR also apply to part 1317. In response to a number of comments, in § 1300.01(b) the DEA is amending the definition of “reverse distributor” to clarify that a reverse distributor is a person registered with the DEA as a reverse distributor.

Definitions were moved from § 1317.02 to § 1300.05 to provide consistency within the CFR pertaining to definitions. The DEA adds § 1300.05 “Definitions relating to the disposal of
controlled substances,” moves the terms “authorized employee,” “law enforcement officer,” and “non-retrievable” from part 1317 to § 1300.05(b), adds a definition of “on-site” to § 1300.05(b), and deletes the definitions of “for cause” and “inner liner” that were in proposed part 1317. The DEA also moves the definition of “collection” to § 1300.01(b). These changes are in response to comments or related to the movement of several other requirements from part 1317 to other parts, as discussed below.

In addition to moving them to § 1300.05(b), the DEA amends the definitions of “authorized employee” and “law enforcement officer.” The DEA is omitting the word “authorized” from the definition of “authorized employee,” and codifying the definition of “employee” in harmony with the general common law of agency. The DEA is modifying the definition of “law enforcement officer” in part 1317 to specifically include officers from law enforcement components of Federal agencies, and authorized police officers of the Veterans Health Administration and the Department of Defense. In addition, this rule clarifies who may qualify as a “law enforcement officer” for the purpose of disposal. The DEA is changing references to “law enforcement agencies” to “law enforcement” in order to include law enforcement components of Federal agencies.

Although the DEA defined “inner liner” in the NPRM, the final rule does not amend the CFR to add a definition for inner liner. As described below, inner liners used in the collection of controlled substances must meet the specifications outlined in § 1317.60. The DEA also is not amending the CFR to add a definition of “for cause,” and instead is providing an explanation of “for cause” as it relates to the sections to which it applies.

The DEA added a definition of “on-site” to § 1300.05(b) to clarify that “on-site” means “located on or at the physical premises of the registrant’s registered location” for purposes of
destruction and registration as a collector. Specifically, a controlled substance is destroyed “on-
site” when destruction occurs on the physical premises of the destroying registrant’s registered
location, and a hospital/clinic has an “on-site” pharmacy when it has a pharmacy located on the
physical premises of the registrant’s registered location.

Text was added to the registration table in § 1301.13 to reflect that distributors, as a
coincident activity to distribution, may acquire controlled substances from collectors for the
purpose of destruction. The registration table was updated so that it would be consistent with the
regulations in the final rule, which authorize distributors to destroy controlled substances
acquired from collectors.

The DEA received a number of comments indicating confusion regarding the procedures
a registrant must follow to modify their DEA registration to become a collector. In order to
clarify such requirements, the DEA is further revising § 1301.51. The additional revisions
clarify the requirements by listing them independently of other types of registration
modifications (e.g., change of name or address) and clearly indicating that any modifications
may be made in writing by mail or online. 21 CFR part 1301. Also, the submission method has
been modified from “letter” to “written request” to accurately encompass the various ways the
modification request may be submitted (e.g., online), and the phrase “to be paid” was deleted
from § 1301.51(c) for stylistic reasons. Similarly, the DEA is further revising § 1301.52 to
clarify that any registrant who has been authorized as a collector and who desires to discontinue
their collection of pharmaceutical controlled substances from ultimate users must notify the
DEA.

The DEA is also streamlining certain registration and security procedures by moving
certain requirements from part 1317, as proposed in the NPRM, to part 1301. Reverse distributor
employee security requirements in proposed § 1317.20 were moved to § 1301.74(m) for ease of reference and consistency. Collector security requirements in proposed § 1317.45 were moved to § 1301.71(f) for clarity and consistency.

The DEA determined that inclusion of recordkeeping and reporting requirements in part 1317 may lead to confusion among registrants. As such, the DEA is moving all recordkeeping and reporting requirements from part 1317, as proposed in the NPRM, to part 1304—Records and Reports of DEA Registrants—in order to maintain consistency and consolidate all recordkeeping and reporting requirements into one part. In § 1304.03, “each” was changed to “every,” and “who” was changed to “that” for stylistic reasons. In § 1304.11(e)(2), the first sentence, pertaining to an exception for reverse distributors, was removed and incorporated into § 1304.11(e)(3) of the final rule to accurately reflect the type of registrants to which the section applies.

The DEA is expanding the locations where a collector may maintain records in § 1304.04(a)(3). The text in § 1304.21(a) was updated to specifically include inner liners and mail-back packages, which were inadvertently overlooked in the NPRM. 21 CFR § 1304.21(c) was updated to include the general recordkeeping requirements for collection activities as outlined in the final rule. The recordkeeping requirements for disposal of controlled substances in 21 CFR § 1307.21 were moved to § 1304.21(e) and amended to include recordkeeping procedures for destruction. The title and introductory text in § 1304.22 were updated to accurately reflect their contents. Additionally, § 1304.22 was modified to include recordkeeping requirements for collected controlled substances. The second sentence in both § 1304.25(a)(9) and § 1304.25(b)(9), which required compliance with part 1317 when destroying narcotic controlled substances, were removed as superfluous. All disposal and destruction activities are
clearly delineated in part 1317. Also, various Automation of Reports and Consolidated Ordering System (ARCOS) requirements are removed from part 1317, as proposed in the NPRM, and are consolidated and moved to § 1304.33. In addition, the title of § 1304.33 has been changed to add clarity, and the acronym “ARCOS” is clearly spelled out. The formatting for § 1304.33(f) was modified for ease of understanding, and “who” was changed to “that” in two locations for consistency.

The DEA is also amending § 1305.03 to add a new paragraph (f) to clarify that collectors are exempt from order form requirements for pharmaceutical controlled substances collected through mail-back programs and collection receptacles for the purpose of disposal. The title of § 1307.11 no longer references reverse distributors and has been changed to “Distribution by dispenser to another practitioner” because reverse distributor activities were moved to part 1317.

As discussed in the preamble to the NPRM and as mentioned in proposed § 1317.100, the DEA clarifies in § 1304.21 of this final rule that, in addition to any other recordkeeping requirements, all registrants that destroy or cause the destruction of a controlled substance must maintain a record of that destruction on a DEA Form 41. This requirement had been discussed in the preamble to the proposed rule, and in proposed § 1317.100 the DEA stated “any registered person that destroys or causes the destruction of a controlled substance shall maintain a record of destruction on a form issued by DEA….” The DEA has determined that this requirement to keep such records on DEA Form 41 should be explicitly stated in the regulatory text, and not just the preamble, for registrants to clearly understand the requirements to which they are bound. As stated above, this requirement to record destruction activities on the DEA Form 41 does not apply to drug wastage or pharmaceutical wastage which must be properly recorded, stored, and destroyed in accordance with DEA regulations, and all applicable Federal, State, tribal, and local
laws and regulations. 21 CFR part 1304.

The DEA is modifying proposed § 1317.70 to address the procedures that a collector must follow when ceasing operation of a mail-back program. This modification requires such collector to make reasonable efforts to notify the public of their intent to cease mail-back collection activities. 21 CFR 1317.70. Such collector must also establish an agreement with another collector authorized to conduct a mail-back program to receive all remaining packages and arrange for the forwarding of such packages to the second collector’s registered location. These procedures will ensure that another authorized entity will be responsible for receiving and destroying any mail-back packages that were disseminated but not received back by the collector prior to the time that they ceased operation of their mail-back program.

Finally, the DEA is modifying proposed § 1317.75 for two purposes. The first modification clarifies that collected controlled and non-controlled substances can be comingled, but are not required to be comingled. 21 CFR 1317.75. As previously discussed, the second modification to this section allows certain LTCF employees, as designated by the collector authorized to maintain a collection receptacle at that LTCF, to install, seal, remove, store, and transfer for destruction the inner liners of the collection receptacle along with an employee of the collector. 21 CFR 1317.80. This modification allows greater flexibility for collectors authorized to maintain collection receptacles at LTCFs.

II. Background and Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, but are collectively referred to as the “Controlled Substances Act” or the “CSA” for
the purpose of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for a sufficient supply of controlled substances and listed chemicals for legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety. To this end, controlled substances are classified into one of five schedules based upon: the potential for abuse, currently accepted medical use, and the degree of dependence if abused. 21 U.S.C. 812. Listed chemicals are separately classified as list I or list II chemicals based on their use and importance to the manufacture of controlled substances. 21 U.S.C. 802(33)–(35).

The CSA establishes a closed system of distribution that requires the DEA to monitor and control the manufacture, distribution, dispensing, import, and export of controlled substances and listed chemicals until they reach their final lawful destination. The secure destruction of unused, recalled, tainted, expired, or otherwise unwanted pharmaceutical controlled substances is essential to preventing the diversion of these substances into the illicit market.

In order to maintain this closed system of distribution, persons who handle (manufacture, distribute, dispense, import, export, engage in research, or conduct instructional activities), or propose to handle, controlled substances and listed chemicals are required to register with the DEA at each principal place of business or professional practice. Persons registered with the DEA are permitted to possess controlled substances and listed chemicals as authorized by their registration and must comply with the applicable requirements associated with their registration. 21 U.S.C. 822.
Not all persons who possess controlled substances are required to register with the DEA. For example, a patient who receives a pharmaceutical controlled substance pursuant to a lawful prescription, i.e., an ultimate user, is not required to register with the DEA in order to receive and possess that substance. 21 U.S.C. 822(c)(3); see also 21 U.S.C. 957(b)(1)(C). The CSA defines an “ultimate user” as “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.” 21 U.S.C. 802(27).

While Congress envisioned a closed system of distribution that would control a substance from its manufacture or import through the traditional chain of distribution moving from registrant to registrant until it reached its final lawful use (e.g., dispensed to the ultimate user, etc.), it did not account for circumstances in which pharmaceutical controlled substances were lawfully dispensed to, and possessed by, an ultimate user but not fully used. Although ultimate users are exempt from CSA registration requirements for the possession of pharmaceutical controlled substances, if they distribute (e.g., deliver or transfer) such substances without the appropriate registration, they are in violation of the CSA. Such unlawful distribution includes the transfer of pharmaceutical controlled substances for the purpose of disposal.

---

2 21 U.S.C. 822(c)(3) and 957(b)(1)(C) except “ultimate users” who possess substances for purposes referenced in 21 U.S.C. 802(25); however, “ultimate user” is defined in 21 U.S.C. 802(27).

3 It is unlawful to knowingly or intentionally manufacture, distribute, dispense, or possess with the intent to manufacture, distribute, or dispense, a controlled substance without the appropriate registration. 21 U.S.C. 841(a).

4 The terms “disposal,” “dispose,” or “disposition” appear several times in the CSA and its implementing regulations, but are not defined. For example, in the CSA, see 21 U.S.C. 822(g); 824(f)–(g); 826(c), (e)–(f); 827(a)(3), (d)(1); 842(a)(7); 853(n); 880(a)(2); 881(c)(1); 958(d)(6); and in the CFR, see 21 CFR 1307.21(b) and 1304.22(a)(2)(ix). The term “net disposal,” however, is defined at 21 CFR 1300.01(b). As used, the terms refer to a variety of activities that ultimately result in eliminating the availability of controlled substances for use. For example, within the meaning of the CSA, a controlled substance can be “disposed of” by destruction, return, recall, sale, or through the manufacturing process. The Disposal Act allows an ultimate user to deliver a lawfully obtained controlled substance to another person “for the purpose of disposal.” The DEA believes that the ultimate user disposal authorized by the Disposal Act includes the transfer or delivery of controlled substances for purposes of destruction, return, and recall. Such ultimate user activities are consistent with the intent to remove unused, unwanted, tainted, and expired substances from households and out of the reach of children and teenagers thereby
The Disposal Act, enacted on October 12, 2010, amended the CSA to allow an ultimate user to “deliver” a pharmaceutical controlled substance “to another person for the purpose of disposal” if the person receiving the substance is authorized to receive it and the disposal takes place in accordance with regulations issued by the Attorney General to prevent the diversion of controlled substances. 21 U.S.C. 822(g)(1). The Attorney General delegated responsibility for promulgating the Disposal Act implementing regulations to the DEA.5

In addition to authorizing ultimate users to deliver their pharmaceutical controlled substances to another person for the purpose of disposal, the Disposal Act also authorizes any person lawfully entitled to dispose of an ultimate user decedent’s property to deliver the ultimate user’s pharmaceutical controlled substances to another person for the purpose of disposal if the ultimate user dies while in lawful possession of the substances. The Disposal Act also gives the DEA the ability, by regulation, to authorize LTCFs to dispose of pharmaceutical controlled substances on behalf of ultimate users who reside, or have resided, at the LTCF. Congress directed the DEA, in promulgating the Disposal Act implementing regulations, to consider the public health and safety, ease and cost of program implementation, and participation by various communities. The implementing regulations may not require any person to establish or operate a delivery or disposal program.

III. Discussion of Comments

The DEA had received 192 comments on the NPRM when the comment period closed on February 19, 2013. These comments are summarized below, along with the DEA’s responses.

reducing the risk of diversion and protecting the public health and safety. As used in this Final Rule, the DEA uses the terms “disposal” and “dispose” to generally refer to the wide range of activities that result in controlled substances being unavailable for further use. When necessary to specify a particular activity within the disposal process, the particular activity is identified (e.g., transfer, deliver, collect/collection, return, recall, and destroy/destuction).

5 The Attorney General’s delegation of authority to the DEA may be found at 28 CFR 0.100.
A.  **Support for the Proposed Rule (1 issue)**

[1] **Issue:** The DEA received 192 comments for this rulemaking during the 60-day comment period. The vast majority of the comments were overwhelmingly positive with the commenters agreeing that there should be more options for secure, convenient, and responsible disposal of controlled substances. Nineteen commenters supported the rule as written in the NPRM. Almost every other commenter supported the rule to some degree, although many commenters had concerns with the implementation of the specific disposal procedures described in the NPRM.

**Response:** The DEA appreciates the support for this rulemaking and is privileged to implement regulations to allow for the collection and disposal of controlled substances in a secure, convenient, and responsible manner. The DEA considered all of the comments and ramifications of implementing proposed changes to the rule. In finalizing this rule, the DEA considered public health and safety, ease and cost of program implementation, and participation by various communities.

B.  **Definitions and Terms** (12 issues)

[1] **Issue:** Five commenters asked the DEA to define “ultimate user.”

**Response:** An ultimate user is defined by the CSA as “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.” This definition, codified at 21 U.S.C. 802(27), was not amended or otherwise modified by the Disposal Act.

[2] **Issue:** Ten commenters asked the DEA to clarify the term “retail pharmacy” and to specify whether “closed-door pharmacies,” such as those that service LTCFs, “Federal pharmacies,” and

---

6 Definitions and terms specific to particular comment categories, such as “Law Enforcement” and “Long-Term Care Facilities (LTCFs),” are located in those specific sections.
other pharmacies that only provide services to a distinct population are considered retail pharmacies.

**Response:** The intended meaning of “retail pharmacy” with regard to collectors was discussed in the NPRM but was not defined in the proposed rule itself. The DEA intends “retail pharmacy” to include any entity registered with the DEA as a retail pharmacy as opposed to those entities registered as a hospital/clinic. Depending on a variety of factors, including State authority and authorized business practices, some entities that dispense controlled substances may be registered with the DEA as either a retail pharmacy or a hospital/clinic. 21 CFR part 1301. In other words, pharmacies are not registered with the DEA as “Federal pharmacies,” “LTCF pharmacies,” or even “closed-door pharmacies.” All of these pharmacies may be registered as retail pharmacies provided they meet the requirements of 21 U.S.C. 822 and 823, and they may be authorized as collectors upon proper application. As previously discussed, the DEA is also allowing entities registered as hospitals/clinics with an on-site pharmacy to be collectors. 21 CFR 1317.40. Therefore, patients of pharmacies that dispense controlled substances pursuant to a hospital/clinic registration may benefit if the hospital/clinic opts to modify its registration to become a collector.

[3] **Issue:** Approximately 10 commenters asked the DEA to expand the definition of “authorized employee.” These commenters expressed concern that the definition of “authorized employee” in the NPRM was too limited in scope, and would result in a burden on smaller-staffed pharmacies, as well as pharmacies that employ contract pharmacists and part-time employees. One commenter asked whether or not physician-owners will be considered authorized employees.
Response: The DEA carefully considered the commenters’ concerns and is modifying the proposed definition of “authorized employee.” 21 CFR § 1300.05(b). In this rule, the DEA is omitting the word “authorized” from the definition of “authorized employee” because the rule already specifies what conditions qualify employees to conduct certain disposal activities (i.e., authorized collectors may not employ, as an agent or employee who has access to or influence over collected substances, any person who has been convicted of a felony offense related to controlled substances or who has, at any time, had an application for registration with DEA denied, had a DEA registration revoked or suspended, or surrendered a DEA registration for cause). Also, the DEA is modifying the definition of “employee” by adopting the general common law of agency’s definition of the term and moving the definition from proposed part 1317 to part 1300. As a result of these changes, part-time personnel and physician-owners may be considered “employees” for the purpose of disposal if they meet the relevant criteria.

Where Congress does not define “employee,” the DEA utilizes the common law to determine who is an “employee.” Under U.S. Supreme Court precedent, the factors relevant to determining whether a person is an “employee” under the common law include, but are not limited to: 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.
See Nationwide Mut. Ins. Co. v. Darden, 503 U.S. 318, 323–24 (1992). Other applicable factors may be considered and no one factor is dispositive. See id. at 324.

After evaluating the relevant factors in the context of controlled substance security and diversion prevention, in the context of disposal, the following criteria will determine whether a person is an “employee” regardless of the number of hours per week the person works: persons who are directly paid by the registrant; who are subject to direct oversight by the registrant; who are required, as a condition of employment, to follow the registrant’s procedures and guidelines pertaining to the handling of controlled substances; who receive a performance rating or performance evaluation on a regular/routine basis from the registrant; who are subject to disciplinary action by the registrant; and who render services at the registrant’s registered location. This definition is incorporated in the new § 1300.05, titled “Definitions Relating to the Disposal of Controlled Substances.” These criteria focus on the degree of management and control that a registrant has over the person, and thus, adherence to these criteria will directly impact the security of controlled substances within the registrant’s custody and control. The DEA believes that these criteria are the minimum required to ensure controlled substances are accounted for and not diverted to illicit purposes. Under the definition, contract personnel who do not meet these criteria are not “employees” for the purposes of disposal.

[4] Issue: One commenter stated that the proposed definition of “authorized employee” was too expansive, and that controlled substances should be handled only by individuals who hold a professional license.

Response: The DEA carefully considered the diversion risks associated with allowing various types of persons to handle collected substances. The definition of “employee,” as stated in this final rule, will help reduce diversion risks while ensuring that authorized collectors have
sufficient ability to safely and securely manage the collection of controlled substances. 21 CFR part 1300. Individuals who do not hold a professional license are considered “employees” if they meet the criteria as explained above.

[5] **Issue:** Five commenters asked the DEA to define the term “common or contract carrier.”

**Response:** The DEA declines to define this term for the purpose of this rule. The DEA’s primary concern regarding common or contract carriers is not about how these terms are defined, but whether there is adequate security to prevent diversion when controlled substances are being transported. As explained in § 1301.74(e), when shipping controlled substances, non-practitioner registrants are responsible for selecting common or contract carriers that provide adequate security to guard against in-transit losses. In addition, non-practitioner registrants are responsible for employing precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against in-transit losses. Although these specific requirements apply to non-practitioners, all registrants (practitioners and non-practitioners) shall provide effective controls and procedures to guard against theft and diversion of controlled substances. 21 CFR part 1301.

[6] **Issue:** One commenter suggested that the DEA modify the definition of “non-retrievable” to read: “means to permanently alter any controlled substance’s physical and/or chemical state through essentially irreversible means in order to render that controlled substance unavailable and unusable for all practical purposes. This definition is not intended to require destruction beyond the state at which a controlled substance becomes unavailable, unusable, and, subsequently, no longer available for diversion.”

**Response:** The DEA declines to modify the definition as suggested. Such a change would significantly weaken the non-retrievable standard to a state where controlled substances could
easily be diverted. The permanent and irreversible alteration of controlled substances is the cornerstone of the non-retrievable standard.

[7] **Issue:** Some commenters asked the DEA to clarify the meaning of the terms “regularly” and “practitioner” used in the proposed § 1317.05(a)(4).

**Response:** “Practitioner” is defined in the CSA at 21 U.S.C. 802(21) as “a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.” The term “regularly” has its ordinary meaning, with no specific or technical implications. The DEA understands the ordinary meaning of “regularly” to generally be considered as being on a routine basis or at routine intervals.

[8] **Issue:** One commenter suggested that the DEA distinguish reverse distributors who only collect controlled substances for the purpose of disposal from reverse distributors who also handle non-controlled substances and other waste products. This commenter suggested that the DEA lessen the requirements for those reverse distributors that only collect controlled substances for disposal.

**Response:** The DEA does not distinguish between different “types” of reverse distributors. All reverse distributors receive controlled substances for the purpose of disposal—either through return to the manufacturer who accepts returns, or through destruction. 21 CFR part 1300. The regulations impose the minimum requirements for reverse distributors when handling controlled substances regardless of whether they also handle other substances. Therefore, there is no basis
to relax the requirements for reverse distributors whose activities are limited solely to the collection of pharmaceutical controlled substances for the purpose of disposal.

[9] **Issue:** One commenter asked the DEA to clarify the difference between “transfer” and “transport” as used in proposed § 1317.95.

**Response:** These terms have their ordinary meaning. Generally, the DEA uses the term “transport” to refer to the physical movement of an item from one location to another while “transfer” is used to refer to conveying possession or control (actual or constructive) from one entity to another.

[10] **Issue:** One commenter asked the DEA to clarify the phrase “causes the destruction” as it could be interpreted to mean any person involved in the process.

**Response:** As previously discussed, proposed § 1317.100 is relocated in this final rule to § 1304.21(e). The DEA included the term “causes the destruction” to encompass such circumstances where a registrant does not itself destroy the controlled substance but is still responsible for the destruction; for example, when a registrant or a registrant’s employee initiates the destruction process by engaging a third-party destruction facility that will perform the actual destruction pursuant to § 1317.95(c). This final rule clarifies this distinction in §§ 1317.95(c) and 1304.21(e).

[11] **Issue:** One commenter stated that the rule should be clarified in use of the word “may” with regard to individual counting and inventorying of collected substances. The commenter indicated that the word seems open for interpretation.

**Response:** The commenter is specifically referring to the NPRM statement “[c]ontrolled substances collected by collectors may not be individually counted or inventoried.” The DEA understands that this phrase may be misinterpreted to mean that authorized collectors are not
required to count or inventory collected substances. To clarify, the DEA is modifying §§ 1317.60 and 1317.70 to clearly indicate that sealed inner liners and returned mail-back packages “shall not be opened, x-rayed, analyzed, or otherwise penetrated.” The DEA also modifies § 1317.75(c) to specify that this prohibition includes counting or inventorying collected substances prior to sealing and removing an inner liner that contains collected substances, as well as after the inner liner is sealed. The DEA discusses below the different requirements applying to law enforcement.

[12] Issue: One commenter noted that the DEA used inconsistent time requirements throughout the proposed rule, such as “timely,” “prompt,” and “as soon as practicable, but no later than 14 days.” Additionally, several commenters requested clarification regarding the definition of the word “prompt” in the proposed rule, and commenters asked for clarification regarding how the DEA would determine whether an action is “prompt.” Commenters asked for guidance as to what time range the DEA would find reasonably acceptable.

Response: The DEA’s use of different time standards throughout the proposed rule was intentional as the different circumstances of each requirement warrant different standards. The various timing requirements are intended to be flexible enough to account for individual circumstances while also ensuring sufficient and adequate controls to prevent diversion and opportunities for diversion. The DEA considered imposing specific timelines (e.g., three days, five days); however, the wide variety of business models and activities made it impossible in most circumstances to set a specific deadline that would prevent diversion and diversion opportunities. Additionally, violations of specific timelines would be per se violations of the regulations, whereas violations of the flexible “prompt” and “as soon as practicable” standards would be considered under each registrant’s individual circumstances. The DEA’s determination
will be guided by whether the registrant has fulfilled its responsibility to provide effective controls and procedures to guard against theft and diversion. All controlled substances destined for destruction must be rendered non-retrievable in order to be destroyed in a manner consistent with this rule. As such, a controlled substance will have been promptly destroyed if it is promptly rendered non-retrievable. 21 CFR 1317.95. “Timely” refers to actions that have a specific time period for compliance, e.g., 30 days. Therefore, in each instance in which the rule uses the word “timely” to refer to destruction requirements for reverse distributors, it refers to the specific time period (14 days in the proposed rule, 30 days in the final rule) in which reverse distributors are required to destroy controlled substances. 21 CFR 1317.15.

C. Types of Entities That May Operate a Collection Program (9 issues)

[1] Issue: Several commenters asked the DEA to retain the provision in the proposed rule to permit retail pharmacies to maintain collection receptacles. These commenters stated that retail pharmacies will provide a convenient option for ultimate users who desire to safely and securely dispose of their unused or unneeded controlled substances. Commenters also asked the DEA to retain the provision to permit retail pharmacies to manage collection receptacles at LTCFs.

Response: The DEA appreciates the support for the provisions in the rule that permit retail pharmacies to manage collection receptacles at not only the primary registered location of the retail pharmacy, but also LTCFs. 21 CFR 1317.40 and 1317.80. The DEA believes that these two provisions will provide ultimate users and others with convenient options to safely and securely dispose of unused controlled substances. The DEA retained these provisions in the final rule.

[2] Issue: Eighteen commenters asked the DEA to permit hospitals to become authorized collectors so that they may maintain collection receptacles. An additional two commenters asked
the DEA to allow specialized hospitals and clinics to maintain collection receptacles. These commenters stated that collection receptacles located inside of hospitals would provide ultimate users with an opportunity to dispose of medication that may no longer be needed or may be expired.

**Response:** The DEA selected methods for disposal that provide opportunities for ultimate users to securely, conveniently, and responsibly dispose of their unused, unwanted, and expired pharmaceutical controlled substances while also preventing diversion. As previously discussed, after extensive review and careful deliberation, the DEA is permitting certain registered hospitals/clinics to become authorized collectors. 21 CFR 1317.40. In order to counterbalance the diversion risks of allowing collection receptacles to be located inside hospitals/clinics, the DEA is only allowing those hospitals/clinics with on-site pharmacies to become collectors. The DEA is requiring these collectors to place collection receptacles in locations that are regularly monitored by employees, and is prohibiting these collectors from placing collection receptacles in the proximity of any area where emergency or urgent care is provided. 21 CFR 1317.75.

[3] **Issue:** One commenter suggested that hospitals of a certain size be required to become authorized collectors.

**Response:** The DEA is not requiring, nor is the DEA authorized to require, any entity to implement a collection program or maintain a collection receptacle. The Disposal Act explicitly states that the “regulations may not require any entity to establish or operate a delivery or disposal program.” 21 U.S.C. 822(g)(2).

[4] **Issue:** It was requested that the DEA allow military treatment facility pharmacies (registered with the DEA as a hospital/clinic), and the Indian Health Service (IHS), including IHS pharmacies (IHS, Tribal, and Urban programs) to become authorized collectors. One commenter
also suggested that the DEA permit collection receptacles in select areas of military installations, such as ambulatory care clinics and service member barracks.

**Response:** As previously discussed, any registered hospital/clinic with an on-site pharmacy and any retail pharmacy may be authorized to be a collector. 21 CFR 1317.40. Ambulatory care clinics and service member barracks are generally not registrants. As discussed in the NPRM, the Disposal Act did not give the DEA authority to create new classes of registration solely for the purpose of conducting ultimate user disposal activities. The DEA is allowing hospitals/clinics with an on-site pharmacy and retail pharmacies to be responsible for and manage collection receptacles in non-registrant LTCFs because the Disposal Act acknowledged that LTCFs “face a distinct set of obstacles to the safe disposal of controlled substances due to the increased volume of controlled substances they handle.” 21 CFR 1317.80. LTCF residents generally have limited mobility; accordingly, this final rule authorizes LTCFs to dispose of controlled substances on behalf of ultimate users who reside or have resided at the LTCF. 21 CFR 1317.30. Furthermore, un-registered ambulatory care clinics and service member barracks generally lack adequate safeguards to ensure the security of collected pharmaceutical controlled substances; thus, allowing collection receptacles at such locations poses an unacceptable risk of diversion and threatens the public health and safety.

[5] **Issue:** Eight commenters asked the DEA to permit non-registrants to collect non-controlled substances for the purpose of disposal.

**Response:** The DEA’s authority regarding drug disposal is specific to pharmaceutical controlled substances. Non-registrants may collect non-controlled substances pursuant to all applicable Federal, State, tribal, and local laws and regulations; however, all regulations and laws relevant to controlled substances will apply if controlled substances are collected, even inadvertently.
[6] **Issue:** One commenter asked the DEA to permit LTCFs to become authorized collectors.

**Response:** The DEA is without authority to permit LTCFs to become authorized collectors. As discussed in the NPRM, authorized collectors must first be registrants in order for the DEA to impose and enforce these regulations upon them. A majority of LTCFs do not have State authority with respect to controlled substances—a fundamental prerequisite to obtaining a DEA registration. The Disposal Act authorized the development of regulations to permit LTCFs to dispose of controlled substances on behalf of ultimate users who reside or have resided in their facilities. The DEA is permitting hospitals/clinics with an on-site pharmacy and retail pharmacies to become authorized collectors with authority to install and maintain collection receptacles at LTCFs, and declines to extend this authority to the LTCFs themselves. 21 CFR 1317.40.

[7] **Issue:** Several commenters urged the DEA to create a new status that permits non-registrant organizations to become authorized collectors for the sole purpose of collecting controlled substances from ultimate users and others authorized to dispose of controlled substances on behalf of ultimate users. One commenter asked that the DEA allow non-profit, non-registrant organizations to register as authorized collectors with a reduced fee.

**Response:** The DEA is not developing a new category of registrant specifically for collecting pharmaceutical controlled substances from ultimate users. Any entity that wishes to collect controlled substances from ultimate users must do so in accordance with this rule, which includes provisions for specified existing registrant categories to modify their registration to become authorized as collectors. Any person not already registered with the DEA, wishing to become authorized as a collector must first satisfy all of the requirements for registration
identified in the CSA and its implementing regulations. Non-registrant organizations may
partner with law enforcement and with registrants that are collectors. 21 CFR 1317.65.

[8] Issue: One commenter asked the DEA to clarify how a local government may register with
the DEA to become an authorized collector.

Response: As discussed above, the DEA is not creating a new registration category for the
exclusive purpose of collecting controlled substances from ultimate users. Persons registered
with the DEA as manufacturers, distributors, reverse distributors, NTPs, hospitals/clinics with an
on-site pharmacy, or retail pharmacies may apply to modify their registration to become an
authorized collector in the manner proscribed by this final rule. 21 CFR part 1301. Any person
not already registered with the DEA, wishing to become authorized as a collector must first
satisfy all of the requirements for registration identified in the CSA and its implementing
regulations. These requirements include being authorized to handle controlled substances by the
State in which the applicant is located unless exempt by statute or regulation. The DEA
encourages entities that are not registrants to partner with authorized collectors or law
enforcement. 21 CFR 1317.65. For example, local governments may partner with authorized
mail-back collectors to provide mail-back packages to the public.

[9] Issue: One commenter asked the DEA to clarify that no Federal or State government entity
may require registrants to amend their DEA registration to become authorized collectors.

Response: The Disposal Act specifically prohibits the DEA from requiring any entity to
establish or operate a delivery or disposal program. 21 U.S.C. 822(g)(2). The prohibition does
not extend to every Federal and State agency and the DEA does not have the authority to
institute such a prohibition.
D. *Locations Where Authorized Collectors May Maintain Collection Receptacles or Host Take-Back Events (1 issue)*

[1] **Issue:** Six commenters asked the DEA to permit retail pharmacies to manage collection receptacles at establishments other than the retail pharmacy’s registered location, such as community centers. Commenters stated other locations may be more convenient for ultimate users and would thus maximize participation. Two commenters asked the DEA to allow collection receptacles at unregistered locations such as permanent household hazardous waste collection sites.

**Response:** The DEA acknowledges that in some locations, and under certain circumstances, alternative settings may be more convenient for ultimate users, but that is not the only consideration. The DEA believes that in order to adequately ensure the safety and welfare of the public, collection receptacles must be located inside the DEA-registered location of authorized collectors. 21 CFR part 1317.75. Authorized collectors, as registrants, are readily familiar with the security procedures and other requirements to handle controlled substances. Most publicly-accessible locations where controlled substances are not typically handled, such as community centers and hazardous waste collection sites, are not targets for theft in the same manner as those locations where pharmaceutical controlled substances are regularly handled. Thus, those locations are unlikely to be familiar with, or to have in place, the security controls necessary to ensure the security of collected substances and prevent diversion of controlled substances. However, law enforcement may continue to conduct take-back events, and other persons may partner with law enforcement to conduct such take-back events at various locations. 21 CFR 1317.65.
E. Registration Requirements for Authorized Collectors (5 issues)

[1] **Issue:** Several commenters asked the DEA to clarify whether or not registration modifications for authorized collectors may be conducted online.

**Response:** Registration modifications may be conducted online. For the final rule, the DEA is modifying the text of § 1301.51 to clarify that online modifications are indeed permitted. Registrants may go to www.DEAdversion.usdoj.gov to modify their registration when they start or stop collection activities.

[2] **Issue:** Three commenters stated that it is overly burdensome to require authorized collectors to modify their registration each time they start or stop collection activities. These commenters asked that the DEA provide additional details regarding the registration modification process.

**Response:** The DEA carefully reviewed the registration requirements and did not find indications to suggest that registration modifications will be overly burdensome. The rule requires that a registrant must apply to modify their DEA registration prior to initiating any collection activities. 21 CFR part 1301. Authorization as a collector is subject to renewal in the same manner as registration. The DEA will consider an authorized collector to be conducting collection activities until the registration is modified, revoked, surrendered, suspended, or otherwise terminated. If an authorized collector stops collection activities, he/she must modify his/her registration to indicate such. The requirement to modify a registration requires a simple written notification to the DEA. This written notification can be easily and quickly conducted online in a few minutes. 21 CFR part 1301. The registrant may go online and select the option to indicate that the registrant has ceased collecting. Registrants without ready access to the online notification method can easily and quickly communicate such information to the DEA in writing via the mail, which the DEA will process promptly upon receipt.
[3] **Issue:** One commenter suggested that the DEA relax requirements for registration modifications regarding LTCF collection receptacles. This commenter was concerned that registration modifications may outpace the DEA’s resources.

**Response:** The DEA evaluated this request and determined that the registration requirements regarding LTCF collection receptacle management are necessary to ensure accountability and prevent diversion; the related procedures are the minimum necessary to ensure that authorized collectors maintain the receptacles in a manner that is consistent with the applicable regulations. 21 CFR part 1301.

[4] **Issue:** One commenter asked the DEA to clarify whether or not an entity may apply for registration as a reverse distributor with the sole intent of providing destruction services for collected substances.

**Response:** Any entity may apply for registration as a reverse distributor pursuant to and in accordance with 21 U.S.C. 822–823, and 21 CFR part 1301. Reverse distributors are not required to conduct all activities that they are authorized to perform.

[5] **Issue:** Two commenters asked the DEA to clarify whether a destruction facility must be registered with the DEA.

**Response:** Pursuant to this rule, a destruction facility is not required to register with the DEA simply because a registrant utilizes that facility to destroy controlled substances in a manner consistent with this rule and all other applicable Federal, State, tribal, and local laws and regulations. At this time, the DEA does not believe it is appropriate to require these entities to be registered because the destroying registrant maintains possession and control of the substances (and therefore retains responsibility and accountability) until the substances are rendered non-retrievable. 21 CFR part 1301. All handling, monitoring, reporting, recordkeeping, and
witnessing with regard to the destruction of pharmaceutical controlled substances must be performed by registrants or their employees. The DEA has omitted the language that was proposed for § 1317.15(c)(4) in order to prevent confusion.

F. Law Enforcement (7 issues)

[1] Issue: Several commenters asked the DEA to expand the definition of “law enforcement officer” to include law enforcement components of Federal agencies and civilian law enforcement officers.

Response: The final rule definition is expanded from the proposed rule to specifically include officers of the law enforcement components of Federal agencies, and police officers of the Veterans Health Administration and the Department of Defense. The NPRM proposed a definition of “law enforcement officer” to include persons who are employees of a “law enforcement agency.” The DEA is modifying this definition in the final rule to specifically include employees of law enforcement components of Federal agencies. Any person who meets the criteria for “employee” and “law enforcement officer” outlined in the final rule will be a qualified officer for the purposes of disposal of pharmaceutical controlled substances, regardless of whether the person is considered a “civilian” law enforcement officer. 21 CFR part 1300.

[2] Issue: Four commenters stated it would be overly burdensome to require law enforcement to have a collection receptacle that fits the specifications in the NPRM. These commenters stated that the collection receptacle would pose logistical issues, and that the volume of drugs collected would likely exceed the volume that the receptacle could contain. Commenters also noted that it is unnecessary to mandate that law enforcement utilize collection receptacles at take-back events.

Response: Law enforcement are not required to have a collection receptacle that meets all of the specifications in the rule, and the text of the rule is amended to clarify that the specifications
apply to authorized collectors and not law enforcement. The only suggested requirements for the physical construction of collection receptacles maintained by law enforcement are that they be securely placed and maintained at the law enforcement’s physical location. 21 CFR 1317.35. Also, law enforcement are not required to utilize collection receptacles at take-back events. The text of the final rule states, “[e]ach take-back event should have at least one receptacle for the collection of permitted substances...” 21 CFR 1317.65. Thus, law enforcement should have some sort receptacle at take-back events.

[3] Issue: Commenters expressed concern that law enforcement may not have the facilities to store the collected substances until they are shipped to a destruction facility.

Response: The rule suggests that law enforcement store collected substances in a manner that is consistent with its standard procedures for storing illicit controlled substances. The language used in the text of the rule, “should,” is suggestive. Law enforcement are encouraged to follow the guidance in 21 CFR 1317.35; however, they are not required to do so. It should be noted that the requirements in 21 CFR 1317.65 pertaining to law enforcement presence at take-back events are mandated; however, the DEA only suggests procedures for the storage and transportation of pharmaceutical controlled substances collected at take-back events.

[4] Issue: One commenter asked the DEA to permit entities other than law enforcement to conduct take-back events.

Response: If an authorized collector or other entity wishes to conduct a take-back event, the event must be held in partnership with law enforcement, as provided in the rule. 21 CFR 1317.65. Take-back events are intended to be limited-duration events that may take place at an unregistered location that is easily accessible to the public, such as a community center or town center. Given the likelihood of publicity and low physical security at such locations, the DEA
believes that it is imperative to ensure active law enforcement participation for the safety of the event participants and the community, as well as to help deter theft and diversion of pharmaceutical controlled substances.

[5] **Issue:** Commenters urged the DEA to relax the “authorized employee” requirement for civilian law enforcement officers. These commenters stated that the DEA should treat civilian law enforcement officers as “authorized employees” for the purposes of this rule. They stated that these officers and employees currently assist with take-back events, and if they were no longer permitted to, there would be a staffing shortage to assist with take-back events. Additionally, several commenters encouraged the DEA to allow civilian law enforcement employees to handle collected substances if they meet the same requirements as an employee or handle the substances in a manner consistent with law enforcement protocols.

**Response:** In the NPRM, “authorized employee” referred to those registrant personnel who would be permitted to directly participate in the disposal process. “Authorized employee” did not pertain to law enforcement officers or to take-back events. In the final rule the definition is modified, but it still only pertains to those persons who may be permitted to directly participate in the disposal process. 21 CFR part 1300. With respect to law enforcement and take-back events, as discussed above, any person who meets the criteria for “employee” and “law enforcement officer” outlined in the final rule will be a qualified officer for the purposes of disposal of pharmaceutical controlled substances, regardless of whether the person is considered a “civilian” law enforcement officer. The DEA declines to expand the law enforcement authority to specifically include civilian law enforcement employees. Only employed law enforcement officers, as defined by this final rule, may handle pharmaceutical controlled substances at take-back events. As discussed in the NPRM and previous responses to this issue,
the DEA believes that this level of security is necessary to prevent theft and diversion and to ensure the safety of the public due to the highly publicized nature of take-back events and the fact that such events are likely to occur at locations with minimal security. The DEA does not believe that this requirement will hinder the success of take-back events. As previously discussed, only one law enforcement officer must oversee the take-back event, and at the discretion of the law enforcement agency or law enforcement component of a Federal agency, this officer may also be the law enforcement officer who maintains control and custody of the collected substances. 21 CFR 1317.65. There are no prohibitions against other persons assisting law enforcement officers conduct the take-back event.

[6] **Issue:** One commenter asked the DEA to address what rights Military Provost Marshal Officers have with respect to collecting controlled substances from ultimate users.

**Response:** Under § 1317.35 of the new regulation, Federal law enforcement may continue to conduct take-back events and mail-back programs, and operate collection receptacles as further detailed in the regulation. If the Office of the Provost Marshal is considered “Federal law enforcement,” it would be eligible to conduct such collection activities. Federal law enforcement can, and in some cases must, appoint a law enforcement officer to oversee those activities. The appointed officer would then have the authority granted by his/her agency.

[7] **Issue:** One commenter asked the DEA to clarify how law enforcement may transport and deliver collected substances to a destruction facility (i.e., whether they may ship such substances using a common carrier) and how law enforcement can comply with Department of Transportation (DOT) requirements when transporting substances that may contain hazardous materials.
Response: The DEA has no expertise or authority to interpret or apply the DOT laws, regulations, or guidelines regarding transportation of pharmaceutical controlled substances that may constitute hazardous materials. As such, interested persons are encouraged to contact the DOT directly with their specific circumstances, and such persons can obtain more information at www.phmsa.dot.gov/hazmat. However, the DEA understands that the DOT’s Hazardous Materials Regulations apply to entities that place hazardous materials in commercial transportation, and not government vehicles operated by government personnel solely for non-commercial purposes. If more detailed guidance is necessary, the DEA encourages law enforcement and other entities to consult the DOT for guidance on transporting collected substances that may contain hazardous materials. For additional commentary on hazardous material disposal please see comment section “Q.” entitled “Hazardous Materials Transportation and Hazardous Waste Destruction.”

G. Collection Receptacle Design, Inner Liners, Placement, and Security (24 issues)

Clarification of Terms

[1] Issue: One commenter noted that the DEA interchangeably used the terms “container” and “shell” when referring to the outer collection receptacle.

Response: The DEA is modifying the final rule to consistently use the term “container” when referring to the outer portion of collection receptacles. This change is purely for stylistic consistency and makes no substantive change to the rule.

Collection Receptacle Design

[2] Issue: The DEA specifically requested comments regarding the value of the use of a uniform symbol to be placed on collection receptacles. The DEA received 22 comments regarding the use of a uniform symbol. Five commenters supported the use of a uniform symbol, and 17
commenters opposed the use of a uniform symbol. One commenter suggested that the symbol be yellow. Four commenters noted that the use of such a symbol is unnecessary given the requirement to clearly mark and label the receptacles. Three commenters expressed concern that the use of such symbols would result in the receptacles becoming targets for diversion. One commenter was not opposed to the use of a uniform symbol but does not believe it is essential. One commenter indicated that the use of a uniform symbol should be contingent upon the location and security of the collection receptacle.

Response: The DEA appreciates all of the comments submitted in response to this request. After careful consideration, the DEA declines to include a uniform symbol requirement in this final rule. However, the DEA may consider requiring a uniform symbol on collection receptacles after a sufficient time to observe the effects of the existing requirement to clearly mark and label collection receptacles.

[3] Issue: Eleven commenters stated that any signage indicating what ultimate users may deposit into the collection receptacle should be in plain language. These commenters noted that most ultimate users cannot distinguish between controlled substances and non-controlled substances. Other commenters stated that no sign should be required at all, and others suggested the use of pictograms instead of words. Others raised concerns that signage will draw attention to the receptacles, thus increasing risk for theft and diversion.

Response: The final rule does not require any specific language, design, or color choice for the display on the collection receptacle as long as the sign indicates that only schedules II–V controlled substances and non-controlled substances are acceptable. 21 CFR 1317.75. As explained above, comingling is permitted but not required. 21 CFR 1317.75. Plain language, pictograms, or a combination of the two, may be used, as long as it is clear that schedule I...
controlled substances, controlled substances not lawfully possessed by the ultimate user, and illicit or dangerous substances are not permitted to be placed in the container. The DEA believes that some notice regarding what substances may be disposed in collection receptacles is necessary in order to provide guidance to the public and to discourage the use of receptacles for disposing trash or other items. While the diversion risks presented by the requirement for signage is mitigated by physical security requirements (e.g., that the receptacle be securely fastened to a permanent structure), authorized collectors should be mindful that the selected signage not transform the receptacle into a target for theft or diversion.

[4] Issue: Four commenters suggested that the collection receptacle sign encourage ultimate users to remove medication from its container before placing the medication in the collection receptacle. Several of the commenters who had participated in authorized pharmaceutical controlled substance take-back programs noted that the packaging for medication is voluminous, and that including such packaging will be burdensome since it will necessitate changing inner liners more frequently.

Response: The DEA appreciates these commenters’ concerns. Although collectors may encourage ultimate users to remove substances from their containers before depositing them into a collection receptacle or mail-back package, the DEA declines to require it. The DEA has declined to mandate whether substances must be disposed of, with or without packaging, because such requirements would not necessarily affect security or increase the risks of diversion, and as such, should be left to the individual collectors and other relevant authorities who best know the needs and requirements of their programs and locations.

[5] Issue: Other commenters indicated that some hazardous waste disposal regulations require the disposal of medication containers, which may not fit into the receptacles.
Response: As discussed in the immediately preceding comment, the DEA is neither requiring nor prohibiting medication containers to be disposed of with pharmaceutical controlled substances. Moreover, there is no indication that the vast majority of medications will not fit into the “small opening” that the collection receptacles specifications require. For additional commentary on hazardous waste disposal please see comment section “Q.”, entitled “Hazardous Materials Transportation and Hazardous Waste Destruction.”

[6] Issue: The DEA received comments that the inner liner should be a large plastic tub or bucket within a receptacle that can be easily removed and the collected items either dumped into smaller containers or sorted before being secured into storage for disposal or prior to destruction.

Response: The DEA carefully considered the specifications of both the inner liner and the outer container of the collection receptacle. To prevent diversion and protect the public health and safety, the DEA drafted this rule with the precisely considered objective of limiting the number of people who handle the collected substances. The DEA’s extensive experiences in regulating and enforcing the closed system of distribution established by the CSA have demonstrated that a key factor in reducing diversion risk is limiting the handling of controlled substances. In the context of disposal, this means prohibiting the sorting of collected substances once they are deposited into a collection receptacle.

[7] Issue: One commenter stated that the collection receptacle design specifications will require current collection programs for non-controlled substances to install new collection receptacles if those programs wish to additionally collect pharmaceutical controlled substances. This commenter stated that such installations will be burdensome and will discourage participation for these programs.
Response: The DEA deeply appreciates the concern and activism of local communities and other groups currently conducting non-controlled substance drug take-back programs and their wish to expand collection activities to pharmaceutical controlled substances. Programs such as these are an important and vital component of the communities they serve. The DEA understands that publication of this final rule may necessitate the need for some programs to implement new procedures and install new equipment in order to additionally collect pharmaceutical controlled substances. The DEA has not established the new requirements lightly or without considerable deliberation as to its impacts on existing programs. However, the risk of diversion for non-controlled substances is relatively low compared to the much higher risk of diversion, and the corresponding and associated risks to public health and safety, for pharmaceutical controlled substances. The DEA has been charged by Congress with the enforcement of the controlled substance laws of the United States, and must ensure that pharmaceutical controlled substances are properly secured and not easily susceptible to theft or diversion. Accordingly, the collection receptacle design specifications outlined in § 1317.75 will be implemented as proposed.

[8] Issue: A commenter asked the DEA to permit the use of similar receptacles that may already exist and were designed for the deposit and storage of medical waste.

Response: The DEA is not prohibiting the use of collection receptacles that currently exist on the market as long as such receptacles meet all of the design specifications outlined in § 1317.75 of this rule.

[9] Issue: Five commenters stated that the requirement for a collection receptacle to be fastened to a permanent structure is burdensome. Several commenters pointed out that many pharmacies do not own the property that is their DEA-registered location, and such fixtures and installments
are prohibited. One commenter pointed out that this requirement would be particularly burdensome for small, rural pharmacies. Another commenter asked if the requirement applies if the collection receptacle is located in a locked room, inaccessible to the public.

Response: The DEA appreciates the willingness of pharmacies to aid in the societal goal of helping to combat unauthorized access to and abuse of pharmaceutical controlled substances. The DEA understands that there may be logistical concerns for some retail pharmacies that wish to maintain a collection receptacle at their registered location. However, the DEA believes that permanently-secured, fixed containers are the minimum required to prevent diversion and theft of collected substances. The requirement that collection receptacles be securely fastened to a permanent structure applies to all authorized collectors’ collection receptacles, no matter the location of the registrant. 21 CFR 1317.75. Although the final rule does not expressly prohibit collection receptacles from being placed in a locked room that is inaccessible to the public, the final rule does mandate that collection receptacles at authorized collectors’ registered locations must be accessible to ultimate users, and others authorized to dispose of controlled substances on behalf of ultimate users, as they are the only people who may deposit pharmaceutical controlled substances into a collection receptacle (e.g., ultimate users cannot transfer pharmaceutical controlled substances to pharmacy staff). 21 CFR 1317.30. The DEA encourages retail pharmacies leasing their commercial space to work with their landlords to allow for the installation of collection receptacles under the conditions established by this rule.

[10] Issue: Nine commenters stated that requiring an outer container with an inner liner is unnecessary and burdensome. These commenters proposed that the collection receptacle be designed in such a way that it can be returned to the reverse distributor as a complete unit.
**Response:** The DEA appreciates the value in utilizing temporarily secured containers that can be sealed and shipped for destruction; however, the DEA believes that such systems present an unreasonable risk of diversion because, even when secured, such containers can be relatively easily removed when compared to a securely fastened and locked outer container. Relatedly, the DEA is requiring that collection receptacles be “substantially constructed,” which is intended to ensure that the construction is such that unauthorized access to the contents of the receptacle is not easily obtained. 21 CFR 1317.75. Accordingly, the DEA is requiring that collection receptacles have a substantially-constructed outer container and removable inner liners. 21 CFR 1317.60 and 1317.75.

[11] **Issue:** Three commenters stated that the collection receptacle should not be required to have a traditional lock, but that its opening be designed so that the contents cannot be removed.

**Response:** In implementing the Disposal Act to provide secure and responsible disposal methods for pharmaceutical controlled substances by ultimate users, the DEA must ensure that collected substances are properly secured and not easily susceptible to theft or diversion. The requirements pertaining to collection receptacles were carefully considered and designed to limit the handling of the controlled substances, from ultimate user to destruction. These considerations dictated the size of the opening. However, the NPRM and the final rule allow for flexibility regarding a traditional lock, and require that “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).” 21 CFR 1317.75(f).
[12] **Issue:** One commenter suggested that the DEA conduct a national pilot program prior to implementation of the final rule to ensure that collection receptacle requirements are feasible and effective.

**Response:** The DEA believes that the need to implement this rule in order to allow secure convenient options for disposal outweighs the delay and limited benefit that may be obtained by implementing any pilot programs or other testing or research. Through various outreach efforts, including the public meeting the DEA held in January 2011, comments from industry, and information obtained from pilot programs, the DEA believes that it has effectively researched and analyzed the various aspects of this rule. Also, the DEA believes that implementation of this rule is important to helping reduce the amount of unwanted pharmaceutical controlled substances available for theft, diversion, and accidental ingestion.

[13] **Issue:** One commenter asked the DEA to allow a Special Agent in Charge (SAC) to approve container and inner liner designs.

**Response:** As discussed in the NPRM, the DEA determined that the elimination of individual SAC approval for various aspects of disposal or destruction is necessary in order to ensure clear and consistent requirements throughout the United States, thus reducing the potential for confusion regarding requirements for ultimate users and authorized collectors. Specific approval of individual collection receptacles and inner liner designs is not required. All collection receptacles and inner liner designs must meet the specifications outlined in this final rule. 21 CFR 1317.60 and 1317.75.

[14] **Issue:** One commenter suggested that national pharmacy organizations educate the public on proper disposal methods and various disposal options. This commenter suggested that such organizations post information online and disseminate leaflets at retail establishments.
**Response:** With regard to patient information regarding disposal, the DEA is not requiring any entity to educate the public on proper disposal methods and their various disposal options. However, the DEA anticipates that many entities will voluntarily choose to do so. The DEA applauds and encourages voluntary, educational outreach to the public on issues related to the abuse potential and proper disposal of pharmaceutical controlled substances, whether it be through law enforcement, community groups, or professional organizations.

*Collection Receptacle Inner Liners*

[15] **Issue:** Several commenters asked for clarification regarding inner liner tracking requirements. Specifically, commenters asked how unique identification numbers should be assigned, how tracking systems are to be implemented, and what entity will be responsible for placing identification numbers on inner liners. One commenter suggested that the DEA regulate the manufacture of inner liners or require that inner liners be sequentially numbered.

**Response:** The rule outlines the design requirements and the recordkeeping requirements for inner liners. The purpose of a unique identification number is to provide for complete and accurate records that can be inventoried to ensure that each liner is accounted for from receipt, to installation, removal, storage, transfer, and destruction. 21 CFR part 1304. The unique identification numbers therefore must be unique to the individual collector. 21 CFR 1317.60. The DEA does not intend to require any particular method for assigning such numbers and is modifying the text of proposed § 1317.60(e) by indicating that only inner liners must bear a permanent, unique identification number. The company manufacturing the inner liners may assign the numbers. The DEA does not have authority to directly regulate the manufacturers of the inner liners.
[16] **Issue:** One commenter suggested that the inner liner be clear so that it can be visually inspected for non-compliant items.

**Response:** Due to associated increased risks for diversion, the DEA determined that the contents of the inner liners must not be viewable once the inner liner is sealed. 21 CFR 1317.60. The DEA appreciates the concerns regarding certain non-compliant items being placed in collection receptacles; however, for reasons discussed in previous comments, no one is permitted to handle the contents of inner liners. 21 CFR 1317.75. The DEA would like to point out that the text of the rule does not prohibit items from being observed *prior* to being placed in the collection receptacle, which could be an effective way to ensure that such non-compliant items are not placed in the collection receptacle.

[17] **Issue:** Several commenters indicated that the requirement to store sealed inner liners in the same manner as schedule II controlled substances will be overly burdensome and will reduce the amount of space available for storing schedule II inventory at retail pharmacies. These commenters suggested that the DEA allow the authorized collector to transfer collected substances in inner liners to a secure warehouse facility for storage until they can be picked up or shipped.

**Response:** The DEA appreciates these concerns but declines to permit authorized collectors to transfer collected substances to warehouse facilities for storage. Filled inner liners must be stored only at primary registered locations (and at LTCFs in accordance with § 1317.80(c)) and may not be transported to off-site warehouses. The basis for this requirement is that the risk of diversion increases each time inner liners change hands or are transported. However, as previously discussed, this final rule expands the NPRM requirement and authorizes practitioners
to store collected substances at their registered location in either a securely locked, substantially constructed cabinet or a securely locked room with controlled access. 21 CFR 1317.05.

[18] Issue: Four commenters stated that the DEA should permit schedule I controlled substances to be disposed of via collection receptacles, mail-back packages, or take-back events.

Response: The Disposal Act addresses the issue of unused prescription drugs, and it allows the DEA to provide ultimate users with a secure and responsible method to dispose of pharmaceutical controlled substances. This rule does not address the disposal of illicit controlled substances, e.g., those substances controlled in schedule I of the CSA. Schedule I controlled substances, by definition, have no accepted medical use in treatment in the United States, and may not be lawfully prescribed or otherwise distributed to any person. In fact, any transfer of a schedule I controlled substance by an ultimate user is a violation of the CSA, unless the ultimate user is participating in an investigational use of drugs pursuant to 21 U.S.C. 355(i) and 360b(j), and the delivery is conducted in accordance with 21 CFR 1317.85.

Collection Receptacle Placement and Safety

[19] Issue: Ten commenters expressed concern regarding security in retail pharmacies with collection receptacles. Several commenters asked the DEA to provide guidance for proper security measures. One commenter asked for clarification on an authorized collector’s liability should a receptacle become subject to diversion or if improper substances are deposited.

Response: The DEA appreciates the concerns of the commenters and has carefully considered the risks and benefits associated with collection receptacles located in authorized retail pharmacies. The DEA’s rationale for allowing collection at authorized retail pharmacies was described in the NPRM. As previously noted, the DEA is not requiring any pharmacy to provide a collection receptacle. Each registrant is free to weigh the risks and benefits in determining
whether or not to seek status as an authorized collector. The DEA proposed the rule with the security requirement for permanently-secured, fixed containers based on a determination that this was the minimum required to help reduce the risk of diversion and theft of pharmaceutical controlled substances. 21 CFR 1317.75. At retail pharmacies, the location of collection receptacles within the immediate proximity of a designated area where controlled substances are stored and at which an employee is present is anticipated to provide an additional layer of security due to the increased visibility of the receptacles. 21 CFR 1317.75. While potential violations of the CSA and its implementing regulations are investigated and assessed independently, this final rule imposes the minimum required procedures to prevent and detect diversion. Even so, each authorized collector’s circumstances are unique. All registrants should be mindful of their responsibility to provide effective controls and procedures to guard against theft and diversion under 21 CFR 1301.71(a), and their duty to report thefts and significant losses of controlled substances under 21 CFR 1301.74 and 1301.76.

[20] Issue: One commenter suggested that the inner liners be nondescript and free of any markings that would indicate their contents. This commenter was concerned that any markings on the inner liners would increase diversion risks and make them potential targets for drug seekers.

Response: The DEA appreciates the commenter’s concern for potential diversion risks that inner liners might pose, and made the determination to require them only after careful consideration of the associated risks and benefits of their use, and alternatives to their use. The DEA is requiring the size of the inner liner to be clearly marked on the outside of the liner, and for the inner liner to bear a unique identification number in order to help ensure accountability, and to identify and prevent diversion. 21 CFR 1317.60. Given the totality of information
reviewed, the DEA concluded that a requirement for the contents to be non-viewable once the inner liner is sealed will help reduce diversion risks and deter drug seekers.

[21] **Issue:** One commenter stated that requiring contents of the inner liner to be non-viewable could lead to diversion as staff could record controlled substances as being disposed of without actually placing them into the receptacle.

**Response:** The rule prohibits authorized collectors’ staff from handling collected substances, even for the purpose of depositing them into the collection receptacle. Ultimate users, and those who are authorized to handle controlled substances on behalf of ultimate users for the purpose of disposal, are the only persons who may deposit pharmaceutical controlled substances into a collection receptacle. 21 CFR 1317.30. Therefore, the DEA does not envision a circumstance where pharmaceutical controlled substances might be recorded as having been disposed of, but were in actuality diverted as a result of pharmacy staff never having placed the substances into the collection receptacle.

[22] **Issue:** One commenter indicated that the use of an inner liner that is removable and sealable immediately upon removal without emptying or touching the contents is impractical because the contents may spill or fall out and then must be handled.

**Response:** The DEA carefully considered the design and security requirements for inner liners and determined that the collection receptacle option will help to minimize the risk of diversion while ensuring safety and convenience for ultimate users and collectors. As discussed in the NPRM, inner liners that allow opportunities for collectors to sort or otherwise handle the collected substances would decrease security and increase the risk of diversion. The DEA does not believe that overfill or spillage from the inner liners will be a concern as the requirement that inner liners fit within the outer container of the collection receptacle is designed to prevent such
occurrences. However, security requirements, such as the presence of two employees to remove or supervise the removal of an inner liner, help reduce the risk of theft and diversion if such instances do occur. 21 CFR 1304.22, 1317.60, and 1317.75. If spillage occurs, a registrant’s responsibility to provide effective controls and procedures to guard against theft and diversion of controlled substances would require the registrant to take corrective action to prevent spillage from recurring.

[23] **Issue:** Several commenters asked the DEA to identify the maximum allowable capacity for a receptacle and the maximum duration that controlled substances may be stored in the receptacle.

**Response:** There is no maximum or minimum capacity for collection receptacles at this time. Although there is no maximum duration that the collected substances may remain in the collection receptacle at this time, authorized collectors are reminded of their responsibility to provide effective controls and procedures to guard against theft and diversion, 21 CFR 1301.71(a), and their duty to report thefts and significant losses of controlled substances under 21 CFR 1301.74 and 1301.76.

[24] **Issue:** Several commenters asked the DEA to allow “disposal companies,” distributors, and reverse distributors to manage and maintain collection receptacles at the registered locations of authorized collector retail pharmacies and at LTCFs on behalf of the authorized collector retail pharmacies. These commenters also asked if such entities may establish a fee system for such services.

**Response:** Distributors and reverse distributors will not be permitted to manage or maintain collection receptacles at retail pharmacies or LTCFs. 21 CFR 1317.40 and 1317.80. The DEA determined that no entities other than retail pharmacies and hospitals/clinics with an on-site
pharmacy will be permitted to manage collection receptacles at LTCFs. 21 CFR 1317.40 and 1317.80. As discussed in the NPRM, this rule establishes a checked system of transfers where each registrant who handles collected substances serves as a source of verification for the other registrants that handle the same substances, thus ensuring that the collected substances reach their intended destination with accountability and a reduced risk of diversion. In order to maintain this system, all collected substances must be handled in the manner described in this rule, including the requirement that the handling of a collection receptacle inner liner be restricted to employees of the authorized collector as provided, with the limited exception for LTCFs. 21 CFR 1317.80. Such requirements ensure that persons handling collected substances during the disposal process are accountable to their employer, and the number of entities handling the collected substances is reduced while also providing a secure system of checks that increases the level of accountability.

H. Mail-Back Programs (11 issues)

[1] Issue: Thirteen commenters stated that the on-site destruction requirement for mail-back programs is severely limiting due to the limited number of commercial incinerators. These commenters urged the DEA to allow collectors to receive mail-back packages whether or not they have a means of on-site destruction. Several commenters also asked the DEA to allow collectors to use a third party to destroy mail-back packages.

Response: As discussed in the NPRM, an on-site method of destruction for mail-back packages is the minimum necessary to prevent diversion of controlled substances destined for destruction. 21 CFR 1317.05. Importantly, an on-site method of destruction reduces the accumulation of controlled substances in a single location, and minimizes the transfer of controlled substances between various locations. This is intended to help minimize the risk of diversion. For each of
the three methods of ultimate user disposal included in this rule, the DEA has attempted to minimize the number of entities that handle the collected substances in order to minimize the risk of diversion, which increases each time a controlled substance is transferred to a new person. It is emphasized that authorized collectors may partner with reverse distributors and other authorized registrants with on-site methods of destruction to promote mail-back programs, e.g., empty mail-back packages may be disseminated at hospitals/clinics and retail pharmacies and mailed back to a reverse distributor with an on-site method of destruction.

[2] Issue: One commenter strongly supports the requirement that authorized collectors who conduct a mail-back program use an on-site method of destruction; however, other commenters expressed concern that the requirement would discourage authorized collectors from conducting mail-back programs. Several commenters noted that very few destruction facilities currently exist and there was concern that such facilities do not have proper security to handle controlled substances.

Response: As indicated in the previous response, mail-back programs have the potential to provide a secure and responsible means of disposal without geographical restriction within the United States. As such, the existence of a small number of appropriate destruction sites should not impact ultimate users’ ability to participate or the potential for mail-back programs to develop. In other words, a single destruction site can support many different mail-back programs and an unlimited number of mail-back packages may be provided to ultimate users at various locations throughout the United States to be mailed back to a single destruction site. Also, as discussed in the NPRM, the DEA hopes that the rule will encourage innovation and expansion of destruction methods beyond incineration so that additional entities may provide destruction services for mail-back programs in the future.
[3] **Issue:** A few commenters expressed concern that no entities will undertake the implementation of a mail-back program because of the related expense, noting that the requirement that mail-back packages be pre-addressed with pre-paid postage will be very costly. A commenter also asked the DEA to clarify whether unregistered retail pharmacies working with a registered authorized collector would be permitted to make mail-back packages available to patients.

**Response:** As discussed in the NPRM, authorized collectors who conduct mail-back programs are encouraged to collaborate to operate mail-back programs by partnering with other entities to assist with the dissemination of mail-back packages to ultimate users, in order to minimize costs. Additionally, pre-paid postage will ensure that the package is not returned to sender, which will help reduce its handling and therefore, the diversion risks. Pre-addressed envelopes will help ensure that the package is delivered to the authorized location.

[4] **Issue:** One commenter asked the DEA to clarify whether there are specific testing requirements in regard to the packaging standards (e.g., water/spill proof, tear resistant, sealable, etc.). One commenter asked the DEA to clarify the distinction between packages damaged as part of normal transport and packages damaged by other means, such as tampering.

**Response:** The DEA is not requiring specific testing requirements to ensure packages meet the standards provided in § 1317.70 (e.g., water/spill proof, tear resistant, sealable, etc.). However, the packages must be consistent with these standards. Collectors authorized to receive mail-back packages must make a determination based on the facts and circumstances as to whether or not an apparently damaged package became so through normal transportation or through tampering or other intentional means.
[5] **Issue:** Commenters expressed concern that the requirement for mail-back collectors to issue mail-back packages with unique identification numbers is burdensome and does not seem to provide any useful information since ultimate users are not required to notify collectors that they have mailed a package, and it is likely that many packages will not be used. Five commenters asked the DEA to explicitly state that authorized collectors who conduct mail-back programs will not be responsible for reconciling mail-back packages that were never returned.

**Response:** The DEA believes that recording the unique identification numbers of mail-back packages in accordance with § 1317.70 is a reasonable recordkeeping requirement designed to help identify and prevent diversion; this information can aid investigations and is useful for that purpose alone. The DEA recognizes that disseminated packages may go unused, and this alone should not form the basis for unreasonable scrutiny of authorized collectors. Additionally, at this time, authorized collectors are not responsible for tracking mail-back packages that were disseminated but never returned.

[6] **Issue:** One commenter disagreed with the DEA’s assessment that mail-back programs are more susceptible to diversion and therefore require stricter controls.

**Response:** The DEA carefully considered the diversion risks in mail-back programs. Based on the DEA’s experience, the DEA believes that the risks of diversion associated with mail-back programs are great because of necessary actions including the handling of the packages, mail sorting, and mail delivery by non-registrants. The DEA believes that the security measures established by this rule are the minimum required to reduce the risk of diversion inherent to mail-back programs.

[7] **Issue:** One commenter expressed concern that mail-back packages would be subject to greater risks of diversion in rural areas.
Response: The DEA appreciates the commenter’s concern. The DEA has considered the diversion risks for mail-back programs, including packages originating in rural areas. It may be true that mail-back packages originating in some rural areas may be subject to an increased risk of diversion due to fewer people being able to readily witness theft from a mailbox. However, it may also be true that risks of diversion from mail-back programs might be lower in rural areas due to less traffic (pedestrian, vehicular, or equine), resulting in fewer opportunities for tampering with or theft of mail-back packages. Regardless, the DEA believes that the relative risks of diversion of mail-back packages in rural areas are mitigated by the required security procedures and are outweighed by the benefits of providing ultimate users a means to dispose of unused, unwanted, or expired pharmaceutical controlled substances.

[8] Issue: The United States Postal Service (USPS) has raised a number of issues relating specifically to the mail-back program, and also to the disposal regulations in general. The USPS asked the DEA to make several changes to the terminology used in the proposed rule, so that the DEA regulations will be consistent with standard USPS products and services. The USPS also requested that the DEA clarify that all registrants must comply with USPS laws and regulations, including applicable USPS requirements for packaging and mailing pharmaceuticals.

The USPS asked the DEA to consistently refer to “mail-back packages” as “mailing packages” rather than “mailers” as the USPS refers to “mailers” as persons or entities entering a mailing. The USPS also asked the DEA to remove any references to “business reply mail” that are inconsistent with the USPS’s use of the term. The USPS asked that proposed § 1317.85 specify that ultimate users may return recalled controlled substances to the manufacturer or other authorized registrant by U.S. Mail. The USPS also asked the DEA to clarify that inner liners are requirements for collection receptacles—not mail-back packages.
The USPS also requested that the DEA state that collectors operating a mail-back program must exclusively use the United States Postal Service. The USPS also asked the DEA to make all references to “mail system” in the preamble refer exclusively to the United States Postal Service. The USPS asked that they not be prohibited from transporting controlled substances to a reverse distributor on behalf of law enforcement, especially in light of the fact that law enforcement may operate mail-back programs.

Response: The DEA appreciates the time taken by the USPS to review the proposed rule and submit thoughtful comments with their concerns and suggestions. In addition, the DEA acknowledges that the USPS understands these regulations and has experience responsibly handling controlled substances. The DEA is modifying some of the terminology that was used in the NPRM, per the USPS’s concerns and suggestions. Rather than use the term “mailing packages,” all references to “mailers” are changed to “mail-back packages.” The DEA believes this will better avoid the confusion regarding “mailers” being defined as persons or entities that enter a “mailing.” The reference to “business reply mail” is also removed. The DEA declines to specify that “mail” or “mail system” refers exclusively to the USPS; however, the USPS is a shipping option.

Additionally, in § 1317.85, ultimate users still have the options to return a recalled controlled substance as is currently allowed under § 1307.12 of the existing regulations. The text of the rule clearly states that all persons and entities must comply with applicable Federal laws and regulations, which includes USPS laws and regulations. Also, inner liners are requirements for collection receptacles—not mail-back packages. The mail-back package specifications are outlined in § 1317.70.
While the USPS asked that the text of the regulation specifically state that mail-back packages may be sent via the U.S. Postal Service as well as by common or contract carrier, the DEA declines to make this change. The DEA considers the USPS to be a common or contract carrier for purposes of the CSA.

[9] **Issue:** One commenter asked the DEA to clarify whether the regulation that requires mail-back programs to include only mail-back packages mailed from within the United States will preclude USPS-serviced mail-back programs in any of the areas in which it operates (e.g., the Caribbean District, other territories such as Guam, and United States military installations).

**Response:** The term “import” means “any bringing in or introduction of” a controlled substance into any area. Pursuant to 21 U.S.C. 952, it is unlawful to import controlled substances into the customs territory of the United States (the 50 States, the District of Columbia, and Puerto Rico), except under specific circumstances not relevant to ultimate user disposal. Thus, an ultimate user located outside of the customs territory of the United States is not permitted to send a mail-back package into the customs territory of the United States.

[10] **Issue:** One commenter asked the DEA to clarify whether authorized collectors operating mail-back programs may use carrier services that allow packages to be held at a carrier facility until the packages can be picked up.

**Response:** Although some changes to business operations may need to occur in order for an authorized collector to effectively establish and maintain a mail-back program, the requirements established by this rule are the minimum required to detect and prevent diversion. As described in this rule, mail-back packages must be pre-addressed to the authorized mail-back location with the on-site destruction method, and thus, the packages must be delivered to the authorized mail-back location rather than picked up by the collector. 21 CFR 1317.70. The pre-addressed
delivery location must be capable of receiving such deliveries on a regular basis without interruption. Otherwise, the opportunities for diversion increase as the packages are delayed or stored during transit.

[11] **Issue:** One commenter suggested that the DEA establish a national mail-back program.

**Response:** This rule authorizes certain collectors to conduct mail-back programs. 21 CFR 1317.40 and 1317.70. There is no limitation regarding the geographic coverage of mail-back programs within the United States if the programs comply with all applicable Federal, State, tribal, and local laws and regulations. At this time, the DEA does not have the resources to operate a national mail-back program.

I. **Take-Back Events (6 issues)**

[1] **Issue:** One commenter indicated it would be difficult for ultimate users to participate in take-back events, particularly in rural areas.

**Response:** The DEA has attempted to expand the variety of disposal options while also ensuring secure and responsible drug disposal, and the DEA anticipates that the expansion to include certain hospitals/clinics to become authorized as collectors will provide more disposal options for ultimate users, including those in rural areas. Additionally, the DEA encourages those persons living in rural areas who are unable to utilize a collection receptacle or attend a take-back event to dispose of unwanted pharmaceutical controlled substances in the same manner in which the pharmaceutical controlled substances were received, i.e., if the substances were delivered by a mail-order pharmacy, the DEA encourages the pharmacy to include a mail-back package for safe disposal; or, if the substances were dispensed at a pharmacy, the DEA encourages pharmacies to have a collection receptacle available for safe disposal. Nonetheless, the DEA recognizes that some ultimate users may not have convenient access to any of the
disposal options available in this rule. Until the availability of these disposal options increases, ultimate users who wish to dispose of unwanted pharmaceutical controlled substances may continue to dispose of them in manners consistent with all applicable Federal, State, tribal, and local laws and regulations. The DEA’s Office of Diversion Control website provides information regarding safe disposal of pharmaceutical controlled substances, including guidance from the FDA and the EPA. Ultimate users can find this information at www.DEAdiversion.usdoj.gov.

[2] **Issue:** Several people asked the DEA to clarify the role of law enforcement at take-back events. One commenter asked the DEA to relax the two-employee requirement for law enforcement officers handling collected substances. Another commenter stated that law enforcement officer supervision, rather than direct participation, should suffice.

**Response:** Law enforcement must appoint at least one law enforcement officer employed by the agency to oversee collection at the take-back event. 21 CFR 1317.65. “Oversee” has its common, everyday meaning: to supervise, manage, watch over, and direct in an official capacity. The direct participation this rule mandates is that a law enforcement officer must maintain custody and control of the collected substances from the time they are collected to the point in time that they are securely transferred, stored, or destroyed. 21 CFR 1317.65. This rule does not require two law enforcement officers to be present at take-back events; however, law enforcement may determine that two or more law enforcement officers are necessary at a particular take-back event due to safety and security concerns. In the alternative, law enforcement may determine that the same law enforcement officer may oversee the take back event and also maintain custody and control 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 has occurred, as outlined in § 1317.65(b). Although the participation of law enforcement is required at take-back events, the DEA is not requiring law enforcement to hold or participate in take-back events. As discussed in the NPRM, law enforcement must determine how often available resources allow them to hold take-back events.

[3] Issue: A few commenters requested that the DEA allow other authorized collectors, such as retail pharmacies and reverse distributors, to become authorized to hold take-back events. One commenter stated that law enforcement officers’ presence should be optional if there is a collection receptacle at the event that meets the specifications in the rule.

Response: If an authorized collector or other entity wishes to conduct a take-back event, the event must be held in partnership with law enforcement. 21 CFR 1317.65. Take-back events are intended to be limited-duration events that may take place at an unsecure location that is easily accessible to the public, such as a community center or town center. Given the likelihood of publicity and limited physical security at such locations, the DEA believes that it is important to ensure active law enforcement participation for the safety of the event participants and the community. The DEA believes that active law enforcement participation will help deter theft and reduce diversion risks. The presence of a collection receptacle at a take-back event does not preclude the need for law enforcement presence at the collection site because the publicity for the event increases the receptacle’s visibility for drug seekers, thus increasing diversion risks.

[4] Issue: A number of entities expressed concern that the implementation of this rule will result in the cessation of DEA-sponsored national take-back events. These commenters felt that take-back events will be too costly for communities and law enforcement, and commenters suggested that the DEA continue take-back events and provide a transition plan from the national take-back
events until implementation of the rule.

**Response:** The DEA-sponsored national take-back events were initiated as a means of providing safe and convenient disposal of pharmaceutical controlled substances by ultimate users until alternative options could be implemented. The DEA is committed to continuing national take-back events until the effective date of this final rule. The DEA believes that implementation of disposal methods is best tailored to local communities by local communities. The DEA encourages public and private partnerships to optimize the expanded disposal options in a cost-efficient manner.

[5] **Issue:** One commenter expressed concern that existing take-back events would likely be unable to continue under this rule. This commenter was concerned that the prohibition of sorting would cause a burden since non-controlled substances and packaging could not be sorted from controlled substances. This commenter stated that it will be overly burdensome for programs to handle all collected substances as schedule II controlled substances.

**Response:** The DEA does not intend for this rule to require changes to existing non-controlled substance take-back programs. The security measures required by this rule are the minimum necessary to ensure a safe and secure means of disposal of pharmaceutical controlled substances. It should be noted however, that law enforcement are not required to follow the physical security requirements for handling, sorting, or storing collected controlled substances. 21 CFR 1317.35. The physical security requirements applicable to law enforcement in the final rule at §§ 1317.35 and 1317.65 state that law enforcement “should” take certain measures; and that law enforcement “shall” appoint a law enforcement officer to oversee a take-back event and law enforcement officers “shall” maintain custody and control of the collected substances. Additionally, this rule provides a number of previously unavailable means of ultimate user
disposal that are likely to decrease the frequency of and need for community take-back events. The DEA would like to clarify that comingling of controlled and non-controlled substances is permitted, but not required, and co-sponsors of take-back events may specify that only controlled substances will be accepted. Another method to alleviate the burdens would be to provide a separate receptacle for non-controlled substances at the take-back event. Additionally, as discussed in response to previous comments, this rule does not require that collected substances be in their original packaging, and law enforcement may discourage or prohibit ultimate users from disposing of original packaging into the collection receptacle for controlled substances at take-back events.

[6] Issue: One commenter indicated that municipalities and other organizations should be permitted to “take the lead” in organizing and conducting take-back events in conjunction with, and in the presence of, law enforcement. Other commenters raised concerns that such events conducted in partnership with local government and community groups would no longer be allowed, and that the requirements would prevent controlled substance take-back events from being held concurrently with other take-back events, such as for the disposal of hazardous waste and non-controlled substances.

Response: The rule permits any entity to partner with law enforcement to hold a pharmaceutical controlled substances take-back event. 21 CFR 1317.65(a). Municipalities or other organizations may partner with law enforcement as long as such events are conducted in accordance with all applicable laws and regulations pertaining to the disposal of pharmaceutical controlled substances. The DEA emphasizes that take-back events are intended to be one-time or periodic events held in a community center or other convenient and accessible location, and that there is no prohibition against holding such events in conjunction with events for the
disposal of other substances, such as hazardous waste or non-controlled pharmaceuticals.

J. **Prohibition on Handling, Sorting, and Inventoring Inner Liner Contents and Mail-Back Package Contents (8 issues)**

[1] **Issue:** One commenter adamantly stated that collected substances should not be sorted under any circumstances. This commenter expressed concerns about diversion risks and the brokering of unused controlled substances.

**Response:** The DEA agrees that the diversion risks of handling, sorting, or inventoring collected substances outweigh any perceived benefits. The DEA has carefully considered all of the various commenters’ concerns on the prohibition of handling, sorting, and inventoring inner liner contents and mail-back package contents, and will retain these prohibitions. As provided in §§ 1317.60(c) and 1317.70(f), inner liners shall be sealed *immediately* upon removal from the permanent outer container; sealed inner liners and returned mail-back packages shall not be opened, x-rayed, analyzed, or otherwise penetrated. Accordingly, their contents shall not be sorted or inventoried subsequent to being placed into a collection receptacle or mail-back package. To clarify this, § 1317.75(c) was modified to add the prohibition against individually handling substances after they have been deposited into a collection receptacle. These specific security measures are designed to help prevent and reduce the opportunities for diversion (including the re-introduction of tainted pharmaceutical controlled substances into the stream of commerce).

[2] **Issue:** Twenty-four commenters stated that pharmacists and other volunteers should be permitted to sort collected substances, particularly in the presence of law enforcement officers at take-back events. One commenter stated that the DEA should recognize the accountability,
expertise, and experience of healthcare professionals, and the DEA should utilize these experts in an effort to broaden medication disposal efforts.

**Response:** The DEA appreciates the valuable expertise and experience of healthcare professionals, including pharmacists. The DEA has carefully considered the comments in response to the NPRM, and the remarks at the January 2011 public meeting. The DEA believes that the disposal methods outlined in this rule will provide ultimate users and their authorized representatives with expanded options to safely and securely dispose of unwanted, unused, and expired pharmaceutical controlled substances. Pursuant to § 1317.65, law enforcement may continue to conduct take-back events when a law enforcement officer maintains control and custody of collected substances at take-back events and only the ultimate user transfers controlled substances to law enforcement control and custody. However, non-law enforcement personnel may assist the law enforcement officer, and the final rule does not prohibit healthcare professionals from voluntarily polling ultimate users about the substances they are discarding or from assisting ultimate users to separate pharmaceutical controlled substances from non-controlled substances during the disposal process, and inventorying the non-controlled substances.

Furthermore, nothing in this rule prohibits law enforcement from partnering with authorized collectors or other entities to inventory or sort substances that have been collected by law enforcement provided that the collected substances remain under the control and custody of law enforcement. This final rule in § 1317.65(b) requires that law enforcement maintain control and custody of the collected substances from the time the substances are collected until secure transfer, storage, and destruction has occurred. Therefore, if law enforcement opts to inventory or sort collected substances within their possession, law enforcement should provide adequate
security to prevent diversion or theft of controlled substances within their possession and control as a result of, or during, inventorying or sorting.

[3] **Issue:** Thirty-eight commenters stated that the DEA should permit collectors or certain non-registered persons to handle, sort, and inventory collected substances for data collection and research purposes. Many of these commenters urged the DEA to provide an exception to allow pharmacists and volunteers to inventory and sort controlled substances under the supervision of law enforcement officers. Numerous commenters stated that inventorying collected substances is crucial to determining a root cause analysis of medication waste. Others stated that such information could help guide prescribing practices and be used in educational settings. Several commenters stated that inventorying collected substances is necessary to determine outcome measures for grants for disposal programs. Also, several commenters stated that the DEA should provide an exception for Institutional Review Board-approved research projects.

**Response:** The DEA understands and appreciates these comments. As discussed in the preceding response, law enforcement has the discretion to partner with other entities to conduct a take-back event pursuant to § 1317.65(a). There are no restrictions on how law enforcement handles the collected substances so long as they maintain control and custody of the substance. Accordingly, law enforcement may inventory and sort substances that law enforcement collects. The diversion-related concerns present when authorized registrants collect controlled substances from ultimate users is not present when law enforcement collects substances from ultimate users. Taking into account the totality of the various risks and benefits, the DEA believes that this final rule imposes the minimum necessary controls to allow a secure and responsible means by which ultimate users can dispose of pharmaceutical controlled substances. Relying on its experience, and as discussed in the NPRM, the DEA finds that any potential benefits of allowing authorized
collectors or unregistered persons to independently inventory or sort controlled substances after receipt from the ultimate user do not outweigh the risks of diversion, except when the controlled substances remain in the control and custody of law enforcement, as mentioned in the previous response.

Data collection is not impossible under the rule even though collected substances cannot be sorted or inventoried after they have been deposited into a collection receptacle or received by a collector through a mail-back package (unless the collection is conducted by law enforcement and the substances are within the custody and control of law enforcement). For example, authorized collectors may seek information voluntarily from ultimate users regarding the substances the ultimate user is disposing. And, data such as the weight of the inner liners, the number of ultimate users attending a take-back event, and the number of mail-back packages received in relation to the number of packages disseminated, can be useful measures. The rule only prohibits authorized collectors from physically handling the substances, such as taking the substances from the ultimate user, or sorting substances after the ultimate user has deposited them into a receptacle or mail-back package. 21 CFR 1317.70 and 1317.75.

[4] **Issue:** Twenty-two commenters stated that contents should be sorted to ensure adequate storage space. Several commenters stated that packaging and pill bottles should be sorted since they are voluminous. Other commenters stated that non-controlled substances should be sorted from controlled substances.

**Response:** Pursuant to §§ 1317.70(b) and 1317.75(b), comingling of controlled and non-controlled substances is permitted, but it is not required. In addition, this rule does not require pharmaceutical controlled substances collected from ultimate users to be collected and stored in the original packaging, and collectors may institute procedures to prevent inadvertently
collecting packaging. Authorized collectors may address adequacy of space issues by choosing not to collect comingled pharmaceutical controlled substances and non-controlled substances, refusing to accept the original controlled substance packaging, or by increasing destruction frequencies. In addition, the DEA has expanded the available storage options for practitioners in this final rule by allowing practitioners to store sealed inner liners and returned mail-back packages in a securely locked room with controlled access. 21 CFR 1317.05.

[5] Issue: A commenter noted that authorized collectors should have direct supervision over the substances that are placed into collection receptacles to prevent undesirable materials from being deposited into collection receptacles.

Response: Each potential authorized collector must weigh all of the potential risks and benefits in deciding whether to implement and manage any ultimate user disposal program, including any necessary steps to prevent the unwanted collection of regulated hazardous waste or otherwise undesirable materials, in a manner consistent with this rule and all other applicable Federal, State, tribal, and local laws and regulations. Authorized collectors may view what ultimate users deposit into collection receptacles, and they may ask what substances are being deposited.

Although the actual disposal of a pharmaceutical controlled substance into a collection receptacle must be performed by an ultimate user in accordance with § 1317.30, the authorized collector maintains ultimate control over that receptacle and should institute necessary measures to protect against the collection of unwanted substances so long as such measures are consistent with this rule and all other applicable Federal, State, tribal, and local laws and regulations.

[6] Issue: Several commenters asked that the DEA permit pharmacy staff to deposit collected substances into collection receptacles. These commenters asked the DEA to consider situations where the pharmacy is completely blocked from the public (such as with a bullet-proof barrier).
Response: For the reasons discussed in the NPRM and in previous comment responses, the DEA declines to allow pharmacy staff to handle pharmaceutical controlled substances collected from ultimate users. The registered location of any retail pharmacy that wishes to become an authorized collector must satisfy the specifications for collection receptacles and inner liners. 21 CFR 1317.60 and 1317.75. If a retail pharmacy desires to be an authorized collector, that pharmacy shall only allow ultimate users (and others authorized to dispose of controlled substances on behalf of ultimate users) to deposit the pharmaceutical controlled substances directly into the collection receptacles in accordance with § 1317.30. The requirements of the collection receptacles were carefully considered and designed to limit the number of hands that handled the pharmaceutical controlled substances in order to prevent diversion and diversion opportunities, as well as to prevent the re-introduction of tainted pharmaceutical controlled substances into the closed system of distribution.

[7] Issue: Twenty commenters suggested that the DEA permit some sort of inspection for inner liner and mail-back package contents to ensure that unacceptable contents are removed, such as x-raying and scanning. These commenters were particularly concerned about mercury-containing thermometers, iodine-containing medications, medical sharps, compressed cylinders, and other hazardous waste. Other commenters expressed concern that by allowing comingling of substances in collection receptacles, employees may be subjected to hazardous conditions if unsafe or hazardous materials are deposited.

Response: The DEA understands and appreciates these concerns of the commenters; however, the DEA has concluded that allowing inspection of inner liners and mail-back packages presents an unacceptable risk of diversion. These issues were closely reviewed prior to the NPRM and re-reviewed in association with these comments. Whether an authorized collector comingles
ultimate users’ pharmaceutical controlled substances with non-controlled substances is within the
discretion of that authorized collector. This rule does not mandate comingling. 21 CFR
1317.75. Each potential authorized collector must weigh all of the potential risks and benefits in
deciding whether to implement and manage any ultimate user disposal program, including any
necessary steps to prevent the unwanted collection of regulated hazardous waste or otherwise
undesirable materials, in a manner consistent with this rule and all other applicable Federal,
State, tribal, and local laws and regulations. As discussed in response to previous comments,
collectors may control the substances collected, and they may view substances before they are
deposited into collection receptacles. For additional commentary on hazardous waste disposal,
please see comment section “Q.”, entitled “Hazardous Materials Transportation and Hazardous
Waste Destruction.”

[8] Issue: Some commenters urged the DEA to require authorized collectors to provide clear
instructions on what may and may not be placed in mail-back packages in order to reduce
instances in which hazardous materials/waste may be inadvertently destroyed in a manner that is
not consistent with environmental or other applicable laws or regulations due to the prohibition
against opening or inspecting the contents of mail-back packages.

Response: The rule includes a requirement for the collector to provide packages with
instructions indicating what substances are permitted to be included in the package. 21 CFR
1317.70. The rule does not require specific language for such instructions, which must
ultimately be determined by the collector in a manner consistent with the rule.

K. Long-Term Care Facilities (LTCFs) (21 issues)

Definitions and Terms Specific to LTCFs
[1] **Issue:** Commenters asked the DEA to clarify the meaning of “LTCF” with regard to assisted living facilities, hospice facilities, and residential care in private homes, as the meaning of LTCF often varies by State.

**Response:** LTCF is defined at § 1300.01(b) and “means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.”

[2] **Issue:** Commenters asked the DEA to clarify the meaning of “have resided” with regard to a LTCF’s ability to dispose of controlled substances on behalf of residents.

**Response:** The phrase “have resided,” is utilized in the Disposal Act, but was not defined by Congress. The DEA has not determined a need to apply a technical definition for this phrase apart from its ordinary meaning. The DEA understands the ordinary meaning of “have resided” to be typically understood as persons who have died or otherwise recently departed a location without manifesting intent to return. Thus, for example, as discussed in response to issue [7] below, when a LTCF resident is transferred to another facility, the resident “has resided” at the LTCF, and the LTCF may dispose of the former resident’s pharmaceutical controlled substances in an authorized collection receptacle. 21 CFR 1317.30.

*Registration of Collection Receptacles at LTCFs*

[3] **Issue:** Commenters asked the DEA to clarify whether an authorized LTCF location where an authorized collector maintains a collection receptacle would be considered a “registered location” of the retail pharmacy.

**Response:** The location of the collection receptacle is both a registered location and a controlled premise. It is a registered location of the authorized hospital/clinic or retail pharmacy because the authorized collector may only install and manage a collection receptacle at a LTCF pursuant to the authority granted by the DEA, and they are limited at that location to conducting only
those activities that are specifically authorized and required under this rule as necessary to the installation and maintenance of that authorized collection receptacle. LTCFs with authorized collection receptacles are “controlled premises” pursuant to 21 U.S.C. 880(a) and 21 CFR 1316.02(c); accordingly, the DEA may enter LTCFs and conduct administrative inspections in furtherance of, and in carrying out, the responsibilities charged to the DEA by the CSA pursuant to 21 U.S.C. 880(b) and 21 CFR 1316.03.

Disposal Methods and Procedures at LTCFs

[4] **Issue:** A commenter asked the DEA if LTCFs may use an on-site method of destruction. Three commenters specifically asked if LTCFs may continue their current drug disposal method of “sewering.” Other commenters asked the DEA to clarify how existing methods of disposal utilized by LTCFs will be impacted by this rule and to provide for an interim method of disposal for LTCFs.

**Response:** Although the DEA appreciates the commenters’ concerns, the DEA cannot comment on each potential method of disposal occurring at LTCFs prior to these regulations. The implementation of authorized disposal methods for ultimate users is strictly voluntary and, with the exception of law enforcement-sponsored programs, generally such programs have no lawful means of existence prior to the effective date of this rule. It is important to note that this rule provides additional options for disposal and does not prohibit any methods currently used by LTCFs that are consistent with Federal, State, tribal, and local laws and regulations. For example, LTCFs are not prohibited by this final rule from destroying patients’ unwanted pharmaceutical controlled substances at the LTCF, on behalf of the resident patients, in accordance with applicable Federal, State, tribal, and local laws and regulations, including environmental laws and regulations. However, as explained further below, the DEA has
considered the diversion risks and determined that the installation and maintenance of collection receptacles by authorized hospitals/clinics and retail pharmacies is the most secure and responsible means by which registrants may collect and dispose of LTCF residents’ pharmaceutical controlled substances.

As stated in § 1317.90(a), the requirement to render controlled substances “non-retrievable” applies only to DEA registrants that destroy controlled substances. The “non-retrievable” language does not apply to ultimate users. As discussed in the NPRM, the DEA does not believe that “sewering” would render a pharmaceutical controlled substance “non-retrievable.” However, such a requirement would not apply to a LTCF unless the LTCF is itself a registrant and destroying its own pharmaceutical controlled substance stock pursuant to § 1317.05(a).

[5] Issue: Many commenters indicated that the DEA should provide LTCFs with additional options for disposal of controlled substances on behalf of residents. Approximately fifteen commenters asked the DEA to expand which registrants are permitted to manage collection receptacles at LTCFs. Seven commenters asked the DEA to permit LTCFs to use mail-back packages. Several commenters stated that LTCFs should be allowed to use the same disposal options that this rule affords ultimate users.

Response: As previously discussed, this rule in § 1317.40 expands the types of registrants that may be authorized as collectors, and permitted to manage and maintain collection receptacles at LTCFs. In addition to retail pharmacies (including “closed-door pharmacies” that service LTCFs), hospitals/clinics with an on-site pharmacy may maintain collection receptacles at LTCFs. Furthermore, the options available to all ultimate users to dispose of their pharmaceutical controlled substances are also available to LTCF residents. As ultimate users
(defined in 21 U.S.C. 802(27) as persons who have lawfully obtained, and who possess, a
controlled substance for their own use or for the use of a member of their household), LTCF
residents may avail themselves of all disposal methods made available by this rule to ultimate
users, including participation in authorized mail-back programs. For example, on behalf of an
LTCF resident, an LTCF employee may place the resident’s unwanted pharmaceutical controlled
substances in a mail-back package, seal it, and deposit it into the facility’s outgoing mail system.
Care should be taken to ensure that LTCF residents’ use of mail-back programs does not result in
the accumulation of pharmaceutical controlled substances in a single location susceptible to
internal or external diversion threats.

The DEA has carefully considered the risks and benefits of collection activities at LTCFs.
Among the DEA’s specific considerations were that LTCFs typically have large volumes of
controlled substances on-site and that they are typically not registered with the DEA. The DEA
also specifically considered the risks and benefits associated with LTCF personnel disposing of
pharmaceutical controlled substances on behalf of persons who reside or have resided at that
LTCF. The DEA determined that in order to adequately protect the public health and safety, and
to prevent diversion, the collection of such substances must be limited to certain registrants that
are well-equipped to handle the unique circumstances surrounding the disposal of controlled
substances at LTCFs. After careful deliberation, the DEA determined such registrants should be
limited to retail pharmacies and hospitals/clinics with an on-site pharmacy. 21 CFR 1317.40. In
making its determination, the DEA took consideration of the fact that hospitals/clinics with on-
site pharmacies, and retail pharmacies, routinely dispense large volumes of controlled substances
in a public setting. Additionally, many hospitals/clinics with on-site pharmacies and retail
pharmacies have experience working closely with LTCFs or have well-established, on-going
relationships with LTCFs. For example, many retail pharmacies and hospitals/clinics directly deliver pharmaceutical controlled substances to LTCF residents, some retail pharmacies have developed expertise in dispensing substances at LTCFs via an automated dispensing system (ADS) (i.e., mechanical systems that perform operations or activities relative to the dispensing of medications), and some LTCFs share common management or ownership with hospitals/clinics.

The DEA recognizes that other types of registrants also have relationships with LTCFs, and considered authorizing other types of registrants to install and manage collection receptacles at LTCFs. However, after careful consideration, the DEA determined that the presence of certain factors that increase opportunities for diversion in the specified circumstances weigh against further expanding the types of registrants that may collect at LTCFs.

Specifically, the DEA declines to allow reverse distributors to install and maintain collection receptacles at LTCFs because reverse distributors are at the end of the supply chain. It would be contrary to the public health and safety and pose an increased risk of diversion to authorize a reverse distributor to independently install and maintain a collection receptacle at an LTCF, remove the inner liner, transport collected substances to the final destruction location, and ensure they are destroyed. One of the principal factors considered by the DEA in coming to this conclusion is the fact that in such a situation, the reverse distributor would be the sole registrant to maintain the only records of installation, removal, and destruction. Such an authorization would be contrary to the closed system of distribution where each registrant who handles controlled substances serves as a source of verification for the other registrants that handle the same substances, thus ensuring that controlled substances reach their intended destination with accountability and a reduced risk of diversion. The regulations implemented by this final rule specifically utilize this system of checks for collection activities at LTCFs. Retail pharmacies
and hospitals/clinics with an on-site pharmacy are registrants. As established in this final rule, when retail pharmacies and hospitals/clinics maintain collection receptacles at an LTCF, they may not transport sealed inner liners. Rather, they are expected to transfer sealed inner liners to another registrant for destruction pursuant to § 1317.05(c)(2)(iv). Two-registrant integrity allows the DEA to verify and cross-check each registrants’ records. Conversely, LTCFs and destruction facilities are generally not registrants. Therefore, if a reverse distributor were authorized to install and maintain collection receptacles at LTCFs, and also pick-up, transport, and destroy sealed inner liners from LTCFs, the DEA would be unable to verify the reverse distributor’s removal or destruction records with another registrant’s records. Allowing this would not meet the two-registrant integrity requirement that is the minimum required to ensure accountability, particularly when collected substances are destined for destruction.

As discussed in responses to other comments, because LTCFs are generally not registrants, the DEA is unable to allow such facilities to be authorized collectors for the purpose of disposing ultimate user-collected substances, or handle disposed substances on behalf of another registrant. We note that although LTCFs may not use mail-back packages or administer a mail-back program, ultimate users who reside in LTCFs may use mail-back packages under this rule. 21 CFR 1317.30 and 1317.70.

[6] **Issue:** One commenter asked the DEA to allow a LTCF resident, or the resident’s legal representative, to dispose of controlled substances through all available means, whether the resident is alive or deceased.

**Response:** All means of disposing of pharmaceutical controlled substances are available to ultimate users and persons lawfully entitled to dispose of an ultimate user decedent’s property, including those ultimate users who reside, or have resided, in a LTCF. 21 CFR 1317.30.
[7] **Issue:** Commenters also asked the DEA to address how LTCFs should handle situations in which a resident is transferred to a hospital and the resident leaves unwanted medication at the LTCF.

**Response:** Pursuant to the Disposal Act, Congress provided the DEA authority to authorize LTCFs only to “dispose of controlled substances on behalf of ultimate users who reside, or have resided,” at the LTCF. 21 CFR 1317.30. When a LTCF resident is transferred to a hospital or other facility, the resident “has resided” at the LTCF, and if the medication is intentionally left at the LTCF, it is “unwanted,” and the resident has discontinued use. Accordingly, the LTCF may dispose of the former resident’s pharmaceutical controlled substances by depositing the substances into an authorized collection receptacle immediately, but no longer than three business days after discontinuation of use. 21 CFR 1317.80.

[8] **Issue:** Several commenters indicated that the three-day disposal provision for LTCFs is overly restrictive and potentially costly for residents. These commenters stated that three days is too short a time span and will result in residents being forced to purchase additional medications when there is a short break in use as a result of illness, hospitalization, or a trial dosage reduction. One commenter stated that three days is not a long enough time period to determine if the patient may need the medication again in the future.

**Response:** The DEA declines to extend the timeframe for LTCFs to dispose of pharmaceutical controlled substances on behalf of LTCF residents. As previously discussed, LTCFs are required to dispose of pharmaceutical controlled substances “immediately, but no longer than three business days after the discontinuation of use” in § 1317.80(a). With respect to “discontinuation of use,” the final rule modifies § 1317.80(a) to include a permanent discontinuation as directed by the prescriber, as a result of the resident’s transfer from the LTCF, or as a result of death. The
DEA cannot readily foresee a circumstance where a short break in use as a result of illness, short-term hospitalization, or a trial dosage reduction would be considered a discontinuation of use. Also, if the prescriber has not yet determined whether or not a medication is needed in the future, then it is likely that there has not yet been a “discontinuation of use.”

*Collection Receptacle Maintenance at LTCFs*

[9] **Issue:** Fifteen commenters indicated that the requirement to have two employees of the authorized collector retail pharmacy remove and install inner liners is burdensome, and it will discourage retail pharmacies from installing and maintaining collection receptacles at LTCFs. The commenters suggested that the DEA allow LTCF personnel to remove, store, and replace the inner liners. A commenter suggested that LTCF personnel be permitted to sort out non-controlled substances to reduce the amount of material collected in the receptacles.

**Response:** As explained above, the DEA is amending the final rule to allow flexibility in the requirement that two employees of the authorized collector be present for the installation and removal of inner liners at LTCF collection receptacles. As amended, the final rule in §1317.80(c) provides that installation, storage, and removal may also be performed by one employee of the authorized collector and one supervisor-level employee of the LTCF (e.g., a charge nurse, supervisor, or similar employee) designated by the hospital/clinic or retail pharmacy authorized to collect at that location. Hospitals/clinics and retail pharmacies that choose the flexibility allowed by using a supervisor-level employee from the LTCF are reminded that they are still ultimately responsible for the security of the collected substances, as well as keeping complete and accurate records and fulfilling reporting requirements. The contents of the inner liners may not be sorted once deposited into a receptacle, pursuant to §1317.75(c), but, as previously stated, §1317.75(b) states that comingling of controlled and non-controlled
substances is permitted but not required. Therefore, the authorized collector or the LTCF may choose to limit the collected substances to pharmaceutical controlled substances to maximize available space in the collection receptacle. This can be easily accomplished at LTCFs because trained medical personnel will be depositing substances into collection receptacles and should be well-equipped to sort controlled substances from non-controlled substances before depositing the substances into a collection receptacle. Also, as previously discussed, inner liners may be stored at LTCFs in accordance with § 1317.80(d). Another available option to manage volume and the prohibition of on-site storage is for an authorized collector to maintain more than one collection receptacle at an LTCF.

[10] Issue: Commenters asked the DEA to clarify whether reverse distributors are permitted to pick up collection receptacle inner liners from an authorized LTCF location.

Response: In accordance with § 1317.05(c)(2)(iv), reverse distributors may pick up inner liners from collection receptacles located at authorized LTCFs, and reverse distributors may receive the inner liners that are sent to the reverse distributor’s registered location from the LTCF by common or contract carrier. However, the inner liner must be removed from the collection receptacle under the supervision of either two employees from the hospital/clinic or retail pharmacy that is managing the receptacle, or one employee from the managing hospital/clinic or retail pharmacy and one supervisor-level employee of the LTCF (e.g., a charge nurse, supervisor, or similar employee) designated by the authorized collector, pursuant to § 1317.80(c).

[11] Issue: Several commenters expressed concern regarding the transportation and storage of substances collected from LTCFs, specifically with regard to the safety of employees who transport collected substances from LTCFs and logistical difficulties (e.g., storage space) that
may result in fewer retail pharmacies willing to install and maintain collection receptacles at LTCFs.

**Response:** As previously discussed, hospitals/clinics and retail pharmacies may store sealed inner liners at the LTCF in a securely locked, substantially constructed cabinet, or a securely locked room with controlled access for up to three business days pursuant to § 1317.80(d). However, the DEA encourages LTCFs and authorized collectors managing collection receptacles at LTCFs to exhaust other, more secure, alternatives, including: arranging regularly scheduled pick-ups by reverse distributors or common or contract carriers to coincide with removal of the inner liner or delivery of controlled substances to the LTCF; operating multiple collection receptacles at a LTCF to help minimize overflow; and pursuing ultimate user disposal options through members of the patients household or other persons lawfully entitled to dispose of a LTCF patient’s property. The DEA believes these alternatives are better options than storage at LTCFs. LTCFs are generally unregistered locations with large quantities of highly pilferable controlled substances in high doses. The DEA carefully weighed the benefits with the risks of allowing storage at LTCFs, including the potential for creating a new avenue of diversion at a location over which the DEA has limited regulatory oversight. However, in consideration of the circumstances unique to LTCFs, and to ease the burden on LTCFs and authorized collectors, the DEA is permitting in this final rule sealed inner liners to be stored at LTCFs in accordance with § 1317.80(d).

The DEA has also relaxed the rule, in § 1317.80(c), to allow flexibility in the two-person integrity requirement with respect to collection at LTCFs by allowing authorized hospitals/clinics and retail pharmacies to designate a supervisory-level employee of the LTCF as one of the authorized persons to conduct or oversee the installation, removal, storage and transfer
inner liners. However, the authorized collector may opt to have two or more of its own employees perform or oversee these activities. In addition, authorized collectors that are practitioners may not themselves transport collected substances to a destruction location. 21 CFR 1317.05. Rather, the practitioner may destroy the collected substances by delivering the sealed inner liners to a reverse distributor or distributor’s registered location by common or contract carrier, or a reverse distributor or distributor may pick-up sealed inner liners at the LTCF. 21 CFR 1317.05.

[12] **Issue:** Commenters indicated that the installation and maintenance of collection receptacles by retail pharmacies at LTCFs will likely result in considerable costs, burdens, and other liabilities, and, as such, few retail pharmacies will be willing to install and maintain collection receptacles at LTCFs, and few LTCFs will want to bear the costs.

**Response:** The DEA carefully considered the costs associated with all aspects of disposal, along with all other considerations such as convenience, safety, and the risk of diversion, including the security and design of collection receptacles. As discussed in the preamble to this rule, participation in any disposal program for ultimate users is voluntary and the DEA is not authorized to impose the burden of costs upon any specific entity. As such, each registrant that may become authorized as a collector must individually weigh the associated benefits and burdens in determining whether to do so. In order to accommodate LTCF residents, the DEA has expanded the authorized collectors that may maintain collection receptacles at LTCFs to include certain hospitals/clinics and retail pharmacies. 21 CFR 1317.40. The DEA has also relaxed the two-person integrity requirements with respect to LTCFs, and is allowing for storage of sealed inner liners at the LTCF in order to reduce the burdens on hospitals/clinics and retail
pharmacies. 21 CFR 1317.80. These are the minimum requirements to ensure that safety and security of LTCF residents, and to deter and detect diversion.

[13] **Issue:** Several commenters expressed concerns over liability when a collection receptacle is installed at a LTCF because the collector pharmacy is fully responsible for the receptacle but does not have constant, direct supervision over it. The commenters did not specify what type of liability (e.g., criminal, civil, administrative, etc.) was concerning, however, the commenters suggested that the DEA provide the authorized collector retail pharmacies a release from responsibility when installing and maintaining a collection receptacle at a LTCF.

**Response:** It would be contrary to the public health and safety to authorize an entity to collect pharmaceutical controlled substances from ultimate users, and also absolve that entity from any responsibility for such collection. In any event, the DEA does not have authority to provide a general release from liability to all hospitals/clinics and retail pharmacies that apply for, and are authorized to, install and maintain a collection receptacle at a LTCF as part of their registered activities. Part of the purpose in authorizing only certain hospitals/clinics and retail pharmacies to install and maintain collection receptacles at LTCFs is to ensure that a responsible registrant under the regulatory authority of the DEA is charged with ensuring the secure and responsible collection of pharmaceutical controlled substances at LTCFs. As such, with regard to authorized collection receptacles at LTCFs, all responsibility for such receptacles, including compliance with the CSA and DEA regulations, rests with the hospital/clinic or retail pharmacy authorized to install and maintain the collection receptacle. The DEA designed the physical security controls and other accountability measures (e.g., recordkeeping, two-person integrity, regular monitoring by LTCF personnel) for collection receptacles at LTCFs in an effort to minimize the risk of diversion in circumstances where constant, direct supervision by the hospital/clinic or retail
pharmacy is not feasible. In the event an authorized collector knows or has reason to know diversion from collection receptacles is occurring, the authorized collector must take steps to prevent the diversion, including reporting to the appropriate authorities pursuant to §§ 1301.74 and 1301.76. Such action stems from the responsibility to provide effective controls and procedures to guard against theft and diversion as required by § 1301.71(a).

Security at LTCFs

[14] Issue: One commenter asked the DEA to clarify the required security measures for collection receptacles at LTCFs. Two commenters asked the DEA to outline what LTCF staff must do to monitor the collection receptacle.

Response: The required security measures outlined in §§ 1317.60 and 1317.75 that apply to all collection receptacles also apply to those located at LTCFs unless stated otherwise in the rule. The rule provides that a collection receptacle must be located in an area that is regularly monitored by LTCF personnel. 21 CFR 1317.75(d)(2)(iii). “Regularly monitored” has its ordinary meaning. The goal of this requirement is to prevent diversion; accordingly, specific examples would depend on individual circumstances. However, a sub-basement or other seldom-used storage area would not be considered to be regularly monitored by LTCF personnel because those areas are not routinely accessed by LTCF personnel in the course of conducting the everyday the business of the LTCF. The requirement that the receptacle be “regularly monitored” is designed to prevent diversion opportunities, and to ensure that diversion would be detected as soon as possible. Only authorized collectors may install, manage, and maintain collection receptacles at LTCFs, therefore, only the authorized collectors may remove, seal, transfer, and store or supervise the removal, sealing, transfer, and storage of sealed liners. 21 CFR § 1317.80(b). The authorized collector is responsible for ensuring the regular monitoring of
LTCF personnel and ensuring the appropriate security procedures are in place at LTCFs in the event of suspected tampering or diversion. If tampering or diversion is suspected, LTCF personnel should notify law enforcement authorities and the authorized collector, as the circumstances warrant.

[15] **Issue:** Eight commenters expressed concern for the safety of residents of LTCFs. These commenters are concerned that collection receptacles in LTCFs may affect resident safety due to these locations becoming a potential target for drug seekers. Five commenters suggested that the DEA increase penalties for offenses related to collected substances at LTCFs. One commenter encouraged the DEA not to authorize the installation of collection receptacles at LTCFs because their presence may compromise the safety of staff and residents.

**Response:** Congress authorized the DEA to implement regulations authorizing LTCFs to dispose of controlled substances on behalf of ultimate users who reside, or have resided, at such LTCFs. The DEA has considered the risks associated with authorizing the installation and maintenance of collection receptacles at LTCFs, as discussed in the NPRM, and determined that the security measures described in this rule, in § 1317.75, are the minimum required to ensure the safe and secure disposal of pharmaceutical controlled substances at LTCFs. If authorized collectors or LTCFs believe the presence of a collection receptacle endangers the safety or security of the LTCF residents under particular circumstances, they should take additional measures as appropriate to ensure the safety of the residents and staff, and to ensure the security of the collected substances. And, if those other alternatives have failed to abate the observed dangers, the authorized collector can choose to discontinue placing a collection receptacle at a particular LTCF.
The CSA already provides for administrative, civil, and criminal sanctions for individuals and registrants that violate the CSA. The DEA is without authority to mandate enhanced penalties for violations of the CSA that involve LTCFs.

[16] **Issue:** Two commenters expressed concern about security issues due to potential stockpiling of unwanted controlled substances at LTCFs. These commenters listed the following reasons as the bases for their concerns: the three business day disposal requirement, the lack of guidance on the frequency at which inner liners must be removed, the two employee requirement for installing and removing inner liners, and lack of a realistic alternative for disposal if no retail pharmacy manages a collection receptacle at the facility. These commenters stated that stockpiling would increase diversion risks and would be a liability for the LTCF.

**Response:** As discussed in the NPRM and in response to comments in this final rule, these new regulations expand the options available to ultimate users (including LTCF residents) to dispose of excess pharmaceutical controlled substances. A resident, a member of the resident’s household, and an individual lawfully entitled to dispose of the decedent resident’s property all may dispose of a resident’s pharmaceutical controlled substances using any of the several methods of disposal mentioned here. 21 CFR 1317.30.

If there is a collection receptacle at the LTCF, the collected substances should not accumulate under the procedures outlined in this rule. One of the primary goals of the procedures outlined in these new regulations is to prevent the accumulation of collected substances while awaiting destruction. For example, LTCFs are required to deposit pharmaceutical controlled substances into collection receptacles “immediately, but no longer than three business days after the discontinuation of use,” pursuant to § 1317.80(a). Although the DEA has not specifically proposed regulations regarding the frequency at which the inner...
liners of collection receptacles must be replaced, an authorized collector that maintains a
collection receptacle at a LTCF should coordinate with that LTCF in order to ensure that the
inner liners are replaced at a frequency suitable to ensure continuous safe and secure disposal by
the LTCF. This type of coordination is part of an authorized collector’s responsibility to provide
effective controls and procedures to guard against theft and diversion as required by §
1301.71(a). Controls against diversion are ineffective when stockpiling of unused
pharmaceutical controlled substances at a LTCF is the result of an authorized collector’s failure
to adequately maintain a collection receptacle. It is emphasized that there is no limit on the
number of collection receptacles that an authorized collector may install and maintain at a LTCF.
Accordingly, the number of receptacles may be increased to account for volume and/or pick-up
schedules.

As previously discussed, this rule allows but does not require authorized collectors to
store sealed inner liners at a LTCF for up to three business days in a securely locked,
substantially constructed cabinet or a securely locked room with controlled access, pursuant to
§ 1317.80(d). However, the DEA encourages collectors to schedule inner liner removals and
installations to coincide with existing LTCF visits when possible, for example, arranging a
routine system in which medication deliveries coincide with the removal and transfer of sealed
inner liners for appropriate destruction, thereby making sealed inner liner storage unnecessary.

Other Concerns Regarding LTCF Drug Disposal

[17] Issue: One commenter expressed concern that the DEA’s assumption that controlled
substances in LTCFs have been dispensed to, and are thus the property of, a resident may result
in the reluctance of LTCFs to use automated dispensing systems to dispense to an ultimate user
as needed.
Response: Congress has defined “dispense” to mean the delivery of a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner. 21 U.S.C. 802(10). The DEA is bound to this definition. Accordingly, once a pharmaceutical controlled substance has been dispensed to a patient, including a resident of a LTCF, the substance is the property of the patient or ultimate user. The use of an automated dispensing system (ADS) does not change the analysis. An ADS is conceptually similar to a vending machine. A pharmacy stores bulk drugs in the machine in separate bins or containers and programs and controls the ADS remotely. Only authorized staff at the LTCF would have access to its contents, which are dispensed on a single-dose basis at the time of administration pursuant to a prescription. The ADS electronically records each dispensing, thus maintaining dispensing records for the pharmacy. Because the controlled substances are not considered dispensed until the system provides them, substances in the ADS are counted as pharmacy stock. Even though ADSs in LTCFs are used to dispense medications for administration on an as-needed basis (i.e., one dose at a time) in accordance with a practitioner’s prescription, the substance is the property of the LTCF resident once dispensed. Even though a pharmaceutical controlled substance is the property of the ultimate user once dispensed from the ADS, the LTCF may dispose of the medication on behalf of an ultimate user who resides, or has resided at an LTCF by depositing the medication into an authorized collection receptacle located in the LTCF. 21 CFR § 1317.80. Controlled substances held within the ADS that have not been dispensed to a patient are considered inventory or stock of the registrant and therefore must be disposed of by the registrant in accordance with 21 CFR § 1317.05.

[18] Issue: Commenters indicated that LTCFs may be serviced by multiple pharmacies which could result in controlled substances from multiple servicing pharmacies being disposed of in a
single receptacle installed by one such pharmacy and asked the DEA to clarify how to manage such situations (e.g., how other pharmacies would contribute to the efforts of collection; whether drugs dispensed by other pharmacies can be disposed of in the receptacle). Commenters also asked the DEA to clarify the process and requirements for the collection receptacle when the LTCF changes ownership or pharmacy service.

**Response:** This rule allows certain hospitals/clinics and retail pharmacies to become collectors at LTCFs pursuant to § 1317.40, after properly modifying their registrations, in accordance with part 1301. This rule does not require authorized collectors to have any pre-existing or other relationships with the LTCF. Depending on the circumstances, there may be more than one authorized collection receptacle at a single LTCF. Other than the regulations specific to the installation and maintenance of collection receptacles and all related laws and regulations, the DEA is not, at this time, regulating the relationship between the authorized collector and the LTCF, or between multiple authorized collectors that have relationships with the LTCF, and the DEA is not prohibiting collectors from refusing to collect any certain specified pharmaceutical controlled substances. However, conduct that implements exclusionary or anti-competitive actions at an LTCF that adversely affects competing registrants will be referred to the appropriate authorities for action. It is important to remind authorized collectors with collection receptacles at LTCFs that they are solely responsible for the security, integrity, and maintenance of their own collection receptacles and they must be vigilant and ensure complete accountability for any pharmaceutical controlled substances they collect at LTCFs. If a LTCF changes ownership and changes its name, the authorized collector must modify its registration in accordance with § 1301.51(b)(2) to reflect the new name of the LTCF.
[19] Issue:  One commenter specifically suggested that the DEA restrict collection receptacles at LTCFs to the collection of controlled substances and to require signage indicating such in order to ensure compliance with State Medicaid program directives requiring the recovering of non-controlled drugs for potential credit or restocking.

Response:  The DEA is modifying the final rule in §§ 1317.70(b) and 1317.75(b) to clearly indicate that comingling of controlled and non-controlled substances is permitted but not required. The DEA’s authority is limited to controlled substances. As such, the DEA cannot promulgate regulations requiring signage pertaining to compliance with State Medicaid programs or any other programs outside the DEA’s scope of authority, but collectors are free to post signage pertaining to non-controlled substances. Moreover, collectors may post any information they deem appropriate for the safe and secure disposal of controlled substances. All collections that may include pharmaceutical controlled substances, whether comingled or not, must be consistent with this rule, and all other applicable Federal, State, tribal, and local laws and regulations.

[20] Issue:  Two commenters referenced prescription labeling requirements that prohibit the transfer of controlled substances to a person other than to whom it was prescribed. The commenters asked for clarification regarding such transfers and transfers to a person lawfully entitled to dispose of an ultimate user decedent’s property. The commenters indicated that such transfers could be considered dispensing and therefore outside of the authority of the LTCF employee. Additional concerns included State laws that prohibit LTCFs from giving back unused controlled substances to the resident or another person and those that require such substances to be destroyed at the facility.

Response:  Pursuant to 21 U.S.C. 825(c), FDA regulations require that when a schedule II, III,
or IV controlled substance is dispensed to or for a patient, the label include a warning that Federal law “prohibits the transfer of the drug to any person other than the patient for whom it was prescribed.” 21 CFR 290.5. This is not a regulation within the DEA’s authority; however, the regulation does not appear to be inconsistent with the Disposal Act. As described in detail in the NPRM, the CSA expressly provides that it is unlawful to distribute a controlled substance except as provided. The CSA permits an ultimate user who has lawfully obtained a pharmaceutical controlled substance to deliver the controlled substance to another person for the purpose of disposal only if that person is authorized to receive such substance and in accordance with the implementing regulations. The CSA further provides that if a person dies while lawfully in possession of a pharmaceutical controlled substance, any person lawfully entitled to dispose of the decedent’s property may deliver the substance to another person for the purpose of disposal under the same conditions described above. Pursuant to the Disposal Act, a LTCF may dispose of a resident’s pharmaceutical controlled substances in accordance with these regulations. When a LTCF deposits a pharmaceutical controlled substance into a collection receptacle in accordance with these regulations, it is not “dispensing.” As discussed, “dispense” means the delivery of a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner. 21 U.S.C. 802(10).

With regard to State laws, the DEA cannot comment on the laws of each individual State because these laws are outside of the DEA’s purview. The DEA is tasked by Congress with implementing Federal laws related to controlled substances. However, nothing contained within the DEA regulations should be construed as authorizing or permitting any person to do any act he/she is not authorized or permitted to do under other Federal laws or under the law of the State in which he/she desires to perform such act, nor shall compliance with the DEA’s regulations be
construed as compliance with other Federal or State laws. 21 CFR 1307.02.

[21] **Issue:** One commenter asked the DEA to discuss whether the HHS reviewed the rule with regard to their “anti-kickback” statute. This commenter expressed concern over whether or not the HHS would permit a retail pharmacy that dispenses to a particular LTCF to provide collection services to the same LTCF free of charge.

**Response:** All collection and disposal of controlled substances must be conducted in accordance with all applicable laws and regulations, including HHS regulations. This rule neither imposes requirements or regulations for the funding of disposal programs, nor imposes requirements or regulations regarding fees that registrants may charge to operate disposal programs.

L.  *Disposing on Behalf of Ultimate Users (Other than Residents of LTCFs) (3 issues)*

[1] **Issue:** Commenters asked the DEA to clarify how hospitals, schools, summer camps, or other entities may dispose of controlled substances that unintentionally end up in their possession (e.g., when persons abandon controlled substances and return is not possible). Also, several commenters asked the DEA to explain how controlled substances may be disposed of when the ultimate user or other authorized person is unable to dispose of them due to death or incapacitation.

**Response:** The DEA has limited authority regarding who may deliver pharmaceutical controlled substances for the purpose of disposal. Pursuant to the Disposal Act, Congress granted the DEA authority to authorize three groups of people to deliver controlled substances for the purpose of disposal. First, an “ultimate user” who has lawfully obtained a pharmaceutical controlled substance may deliver the substance to another person who is authorized to accept it for the purpose of disposal. The CSA defines “ultimate user” as “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his
household or for an animal owned by him or by a member of his household.” 21 U.S.C. 802(27). Second, if a person dies while lawfully in possession of a pharmaceutical controlled substance, any person lawfully entitled to dispose of the decedent’s property may deliver the substance to another person for the purpose of disposal. 21 CFR 1317.30. Third, LTCFs may dispose of pharmaceutical controlled substances on behalf of ultimate users who reside or have resided at such facilities. 21 U.S.C. 822(g). The DEA has no authority to expand the types of individuals and entities lawfully permitted to deliver pharmaceutical controlled substances for the purpose of disposal. The DEA has carefully considered its statutory authority, diversion risks, public safety, convenience for ultimate users, and the interests of the public. The DEA believes that this rule provides safe and convenient disposal options for ultimate users and other authorized persons. The DEA understands that there may be circumstances where there is no authorized person to dispose of the controlled substances, such as when controlled substances are abandoned at a school or summer camp, and return to the ultimate user is not feasible. In such instances, the affected entities should contact local law enforcement or their local DEA office for guidance on proper disposal procedures.

[2] Issue: The DEA received a number of comments regarding the lack of provisions for hospice and other homecare programs to dispose of controlled substances on behalf of patients. According to the commenters, many hospices have written policies and procedures in place for the management and disposal of controlled substances in the patient’s home. Given the available options for ultimate user disposal, commenters expressed concern that hospices may no longer be able to assist families in disposing of a deceased patient’s drugs. Commenters suggested that the DEA allow hospice staff to dispose of a decedent’s controlled substances by sewering or landfill disposal.
Response: The DEA appreciates the difficulties facing home hospice staff with regard to the disposal of pharmaceutical controlled substances. The Disposal Act provides that “if a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent’s property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided” for ultimate users. 21 U.S.C. 822(g)(4). Otherwise, home hospice and homecare personnel are not authorized to receive pharmaceutical controlled substances from ultimate users for the purpose of disposal. In addition, an ultimate user includes “a person who has lawfully obtained, and possesses, a controlled substance for his own use or for the use of a member of his household.” 21 U.S.C. 802(27). Accordingly, a member of the hospice patient’s household may dispose of the patient’s pharmaceutical controlled substances, but the home hospice or homecare provider cannot do so unless otherwise authorized by law (for example, under state law) to dispose of the decedent’s personal property.

This rule provides a number of options for ultimate users and persons lawfully entitled to dispose of a deceased ultimate user’s property to safely and securely dispose of pharmaceutical controlled substances, yet the DEA does not require ultimate users to utilize these options. However, it is unlawful for ultimate users to transfer pharmaceutical controlled substances to unauthorized persons, and it is unlawful for unauthorized persons to receive such substances. It is also unlawful for any person to possess a controlled substance unless authorized to do so under the CSA (i.e., an ultimate user, an entity registered with the DEA, or an entity exempt from registration with the DEA). 21 U.S.C. 844(a). Home hospice and other homecare providers are encouraged to assist their patients, and their patients’ families, in disposing of pharmaceutical controlled substances in accordance with the CSA and its implementing regulations. While
education is paramount, home healthcare agencies are also encouraged to partner with authorized collectors to promote or jointly conduct mail-back programs.

[3] **Issue:** One commenter asked the DEA to clarify the authority for a hospice employee to utilize a LTCF’s collection receptacle for the disposal of controlled substances of a LTCF resident who is also a patient of the hospice.

**Response:** This rule does not specifically address hospice care or hospice employees, who are typically not registrants. As discussed, it is unlawful to possess a controlled substance unless authorized to do so under the CSA. 21 U.S.C. 844(a). The DEA has, however, provided options for the disposal of pharmaceutical controlled substances by a LTCF on behalf of a person who resides, or has resided, at the LTCF, regardless of whether or not that person is also receiving hospice care. The Disposal Act authorized the Attorney General to allow LTCFs to dispose of controlled substances on behalf of ultimate users who reside, or have resided, at the LTCF, in a manner determined by the Attorney General. 21 U.S.C. 822(g)(3). LTCF is defined as “a nursing home, retirement care, mental care, or other facility or institution which provides extended health care to resident patients.” 21 CFR part 1300. Congress specifically allowed the Attorney General to consider permitting LTCFs to dispose of pharmaceutical controlled substances on behalf of LTCF residents. This allowance did not extend to other persons who are simply attending to a person who is resident of the LTCF. As such, a hospice employee is not authorized to dispose of pharmaceutical controlled substances on behalf of a person who resides or has resided at a LTCF.

M. **Registrant Return, Recall, and Transfer (3 issues)**

[1] **Issue:** One commenter urged the DEA to retain the existing regulations in part 1307. This commenter stated that part 1307 adequately addresses registrant return, recall, and transfer. The
commenter stated that part 1307 functions properly; thus, there is no need to change it, and
the commenter expressed concern that the new regulations will disrupt existing business practices.
The commenter was particularly concerned that most controlled substances returned to
distributors are re-salable and “not intended for disposal.” Other commenters indicated
confusion with regard to registrants seeking assistance from a SAC when disposing of controlled
substances.

**Response:** The DEA first notes that the terms “disposal” and “destruction” are not
interchangeable in the context of the rule. As described in the NPRM at footnote 4 and in this
final rule at footnote 4, the terms “disposal,” “dispose,” and “disposition” appear several times in
the CSA but are not defined. In the NPRM and this final rule, the DEA uses the terms “disposal”
and “dispose” to refer generally to the wide range of activities that result in controlled substances
being unavailable for further use or one entity ridding themselves of such substances (e.g.,
returns). Within the CSA, a controlled substance can be “disposed of” by destruction, return,
recall, sale, or through the manufacturing process. As such, the modified regulations regarding
registrant disposal codify existing practice, expand available options, and implement consistent
procedures among registrants in accordance with their authorized business activities. This
required deleting the existing regulations at § 1307.21 which authorized the SACs to individually
authorize disposal. The new rule eliminates the authority of the SACs to individually authorize
disposal methods for non-practitioners, and retains this option for practitioners. 21 CFR 1317.05.
Otherwise, the new regulations maintain existing disposal practices for registrant inventory and
authorize: prompt on-site destruction; prompt delivery of controlled substances to a reverse
distributor; and prompt delivery (for the purposes of return and recall) to the person from whom
the controlled substance was obtained, the manufacturer, or a registrant authorized to accept
returns on the manufacturer’s behalf. Additionally, non-practitioners may promptly transport the controlled substances to a reverse distributor, a destruction location, or the location of any person authorized to receive the controlled substances for the purpose of return or recall. 21 CFR 1317.05. The DEA appreciates that by eliminating the option for a SAC to authorize specific disposal procedures on a case-by-case basis for non-practitioners, some reverse distributors may need to alter their disposal practices. Although this change may impact current business practices, as discussed in the NPRM, nationwide consistency is necessary in the disposal pharmaceutical controlled substances.

[2] **Issue:** One commenter asked the DEA to clarify what method of return is permitted other than via a freight forwarding facility pursuant to § 1317.10.

**Response:** With regard to the use of freight forwarding facilities pursuant to 21 CFR 1317.10(c), use of the word “may” indicates that the use of freight forwarding facilities is permitted but not required. Other authorized methods of transferring pharmaceutical controlled substances for the purpose of return or recall are outlined in § 1317.05(a)(3) and (4) for practitioners, and in 21 CFR 1317.05(b)(3) and (4) for non-practitioners.

[3] **Issue:** One commenter stated that it will be difficult for reverse distributors to adjust current business operations to meet the 14-day destruction requirement for recalled controlled substances, because product returns may be received from thousands of customers across the country. Additionally, this requirement may not be consistent with other agencies’ regulations and policies governing manufacturers’ voluntary recalls and other product recalls.

**Response:** As explained further below, the 14-day destruction requirement (which this final rule extends to 30 days) does not apply to recalled pharmaceutical controlled substances. 21 CFR 1317.15.
N.  

_Destruction (19 issues)_

Non-Retrievable Destruction Standard

[1] **Issue:** Forty commenters asked the DEA to outline performance standards and parameters for the “non-retrievable” destruction standard. Although many commenters applauded the DEA for proposing a standard that will permit future innovation, many commenters felt that innovation may be hindered by the uncertain terms. Commenters asked the DEA to list currently-approved methods, and to outline how the DEA will evaluate new technology intended to render controlled substances “non-retrievable.”

**Response:** In the NPRM, the DEA indicated that incineration and chemical digestion are some examples of current technology that may be utilized to achieve the non-retrievable standard. The preamble of the NPRM states that sewering (disposal by flushing down a toilet or sink) and landfill disposal (mixing controlled substances with undesirable items such as kitty litter or coffee grounds and depositing in a garbage collection) are examples of current methods of disposal that do not meet the non-retrievable standard. The term non-retrievable is defined in the rule and is results-oriented because the DEA’s concern is that the substance be permanently rendered to an unusable state. The performance standard is that the method renders the substance so that it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. 21 CFR part 1300. The DEA will not be routinely engaged in evaluating new technologies intended to render controlled substances “non-retrievable.” Much like the DEA does not evaluate, review, or approve the specific processes or methods utilized to produce, synthesize or propagate a controlled substance, the DEA will not evaluate, review, or approve the processes or methods utilized to render a controlled substance non-retrievable, as long as the desired result is achieved.
[2] **Issue:** Twenty commenters asked the DEA to include the language regarding sewering and landfill disposal in the text of the regulation. These commenters applauded the DEA for stating that sewering and landfill disposal do not meet the “non-retrievable” standard; however, these commenters asked the DEA to include this same language in the text of the regulation.

**Response:** The DEA has determined that the most effective way of ensuring that the non-retrievable standard of destruction remains current with continuously changing technology is to provide a required end result rather than specify what means achieve or fail to achieve that result. A substance is rendered non-retrievable when its physical or chemical state is permanently and irreversibly altered and it may be unique to a substance’s chemical or physical properties; the same means of destruction may not render every controlled substance non-retrievable. 21 CFR part 1300. Thus, the DEA declines to amend the text of the regulation to include such a broad prohibition. In consideration of the Disposal Act’s goal to decrease the amount of pharmaceutical controlled substances introduced into the environment, the DEA emphasizes that sewering and landfill alone do not meet the non-retrievable standard. Once a controlled substance is rendered non-retrievable, it is no longer subject to the requirements of the DEA regulations.

[3] **Issue:** Several commenters requested that the DEA review and approve new destruction methods prior to allowing their use.

**Response:** As discussed in the immediately preceding responses, the DEA will not be engaged in reviewing or approving new destruction methods prior to allowing their use.

[4] **Issue:** One commenter suggested that the DEA provide a transition period to allow for additional research into the means by which a non-retrievable state may be achieved. This commenter proposed a timeframe, such as five years, to allow appropriate technology to develop.
This commenter also suggested that the DEA permit sewering and landfill disposal in the interim.

Response: The DEA believes that technology by which pharmaceutical controlled substances may be rendered non-retrievable currently exists, thus providing existing opportunities for compliance with this rule and negating the need for a transition period beyond the effective date of this rule.

[5] Issue: Several commenters suggested that the DEA collaborate with the United States Environmental Protection Agency (EPA) to develop best practices for achieving a non-retrievable state using environmentally responsible methods.

Response: The DEA appreciates the environmental concerns surrounding the destruction of pharmaceutical controlled substances. The DEA has worked with, and is continuing to work with, the EPA regarding secure and responsible drug disposal, particularly for pharmaceutical controlled substances that may also be considered hazardous wastes. Additionally, the DEA has clearly stated in the rule that all methods of destruction must comply with all applicable Federal, State, tribal, and local laws and regulations, including EPA regulations.

[6] Issue: A commenter asked the DEA to clarify whether or not the non-retrievable standard of destruction applies to substances disposed from households, and this commenter stated that the DEA should develop and endorse a practical solution for in-home disposal.

Response: Ultimate users may continue to dispose of their own pharmaceutical controlled substances in the manner recommended by other Federal and State agencies, such as the FDA, Office of National Drug Control Policy (ONDCP), and EPA. The non-retrievable standard is only applicable to inventoried controlled substances (i.e., a registrant’s stock) and collected controlled substances (i.e., substances collected from ultimate users by authorized collectors) to
be disposed of by registrants, pursuant to § 1317.90. The non-retrievable standard does not apply to non-registrants.

[7] Issue: Several commenters asked the DEA to clarify whether or not controlled substances that were rendered “non-retrievable” will be regulated by the DEA.

Response: As provided in the definition, 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. 21 CFR part 1300. Once a substance is rendered non-retrievable, it is no longer subject to the requirements of the DEA regulations. The DEA believes that further regulations regarding substances that have been rendered non-retrievable are currently unnecessary because a non-retrievable substance cannot be abused and diversion to illicit use is futile.

*Incineration and Chemical Digestion Destruction Methods*

[8] Issue: Several commenters asked the DEA to specifically recommend incineration as the preferred method to achieve a non-retrievable state.

Response: The DEA believes that any actual or perceived endorsement or recommendation of a specific destruction method, beyond the provision of examples of current methods in the preamble, could suppress exploration and implementation of new technologies as people may assume that the endorsed or recommended methods are required at the exclusion of other methods. As such, the DEA is specifying a required result—non-retrievable—rather than a required method for achieving that result. 21 CFR 1317.90.

*On-Site Destruction Methods*

[9] Issue: Several commenters asked the DEA to clarify what “on-site destruction” means.
Response: As provided in § 1300.05(b) of the final rule, on-site destruction means that the controlled substances are destroyed on the physical premises of the destroying registrant’s registered location. Collectors that are authorized to conduct mail-back programs must have and utilize an on-site method of destruction, pursuant to 21 CFR 1317.05(c)(1). The requirement for an on-site method of destruction does not apply to non-registrants.

[10] Issue: Commenters also expressed concern that distributors are unlikely to have an existing on-site method of destruction because they are not typically licensed as waste handlers and suggested that the DEA provide alternatives to on-site destruction for hospitals and other medical facilities.

Response: This rule does not require any distributor or other registrant to utilize an on-site method of destruction except under certain circumstances in order to conduct a voluntary activity (e.g., receipt of mail-back packages as an authorized collector in accordance with § 1317.05(c)(1)).

[11] Issue: One commenter asked the DEA to consider the use of collection receptacles with deactivation technology.

Response: This rule does not prohibit on-site destruction of pharmaceutical controlled substances by authorized collectors with “deactivation” capability so long as such destruction is consistent with the standards set forth in the rule and the destruction results in a non-retrievable state. 21 CFR 1317.90.

Other Destruction-Related Concerns

[12] Issue: Approximately 20 commenters stated that the 14-day destruction requirement is impractical. These commenters suggested that the DEA allow more time since there are a limited number of commercial incinerators in the United States. Several commenters stated that
reverse distributors must accumulate large amounts of controlled substances in order to obtain favorable pricing. Other commenters stated that the requirement will make it difficult for reverse distributors to properly process and record all transactions, and it will impose substantial financial and operational restrictions on reverse distributors as most reverse distributors do not have on-site destruction and may need to travel long distances to reach an appropriate destruction facility.

**Response:** The DEA has carefully and thoroughly considered these concerns, and the final rule in § 1317.15(d) extends the destruction requirement timeframe from 14 calendar days to 30 calendar days and eliminates the “as soon as practicable” standard with respect to this destruction requirement. The DEA remains concerned about increased diversion risks due to pharmaceutical controlled substances remaining at a single location for extended periods of time. As discussed in detail in the NPRM, prescription drug abuse is an American epidemic, and it is America’s fastest growing drug problem. When large volumes of pharmaceutical controlled substances accumulate, they become an attractive target for drug seekers and drug abusers. Accordingly, regardless of the applicable timeframe to destroy controlled substances, reverse distributors are reminded that they must be vigilant and adhere to the requirements in the CSA and the implementing regulations. Finally, these registrants are reminded of their responsibility to provide effective controls and procedures to guard against theft and diversion, and their responsibility to notify the DEA of any theft or significant loss of any controlled substances within one business day of discovery. 21 CFR part 1301. The DEA continuously monitors compliance with the CSA and applicable regulations to ensure that controlled substances are not diverted to illicit purposes. If necessary, the DEA may consider revising the requirements applicable to reverse distributors’ destruction activities, or imposing additional security
requirements.

[13] **Issue:** Several commenters asked the DEA to clarify the day the clock starts for the 14-day destruction requirement.

**Response:** As discussed above, the final rule extends the timeframe from 14 days to 30 days. Day 1 is the day the substances are physically acquired through pick-up or delivery. 21 CFR 1317.15.

[14] **Issue:** One commenter asked the DEA to clarify whether or not the 14-day destruction requirement applies to law enforcement.

**Response:** This destruction requirement does not apply to law enforcement. Law enforcement guidelines are outlined in § 1317.35.

[15] **Issue:** One commenter suggested that the DEA apply the 14-day destruction requirement to all authorized collectors that destroy or cause the destruction of controlled substances, not just reverse distributors.

**Response:** As previously discussed, the final rule extends the destruction requirement timeframe from 14 days to 30 days. 21 CFR 1317.15. This requirement applies to reverse distributors destroying any controlled substance, as well as distributors when destroying sealed inner liners acquired from authorized collectors for destruction. Pursuant to § 1317.05(c), authorized collectors that maintain mail-back programs or collection receptacles must promptly destroy mail-back packages and inner liners, without adhering to a certain number of days in order to provide them some flexibility depending upon their particular circumstances.

[16] **Issue:** Two commenters stated that all management and disposal of controlled substances should be restricted to DEA-registered hazardous waste disposal companies.
Response: The DEA believes that restricting the management and disposal of controlled substances as suggested would severely burden registrants without adding benefit. Pursuant to this rule, a destruction facility is not required to register with the DEA simply because a registrant utilizes that facility to destroy pharmaceutical controlled substances in a manner consistent with this rule and all other applicable Federal, State, tribal, and local laws and regulations. The DEA does not find it necessary to register these entities because the destroying registrant maintains possession and control of the substances (and therefore retains responsibility and accountability) until the substances are rendered non-retrievable. This is because all handling, monitoring, security, recordkeeping, and witnessing with regard to the pharmaceutical controlled substances is performed or supervised by registrants.

[17] Issue: One commenter indicated that the DEA should provide for broader Federal approval for methods of destruction rather than allowing for regionally-based guidance through the relevant SAC.

Response: As discussed, this rule expands the options available to registrants for proper disposal, but does not require any particular method of destruction, so long as the substances are rendered non-retrievable. This rule does not authorize SACs to specifically authorize any particular method of destruction, but it does allow a practitioner to seek guidance from the relevant SAC regarding the disposal of controlled substances. 21 CFR 1317.05.

[18] Issue: Several commenters asked for clarification regarding the means by which an authorized collector may promptly destroy collected substances, and whether chemical treatment of controlled substances until such time as controlled substances can be retrieved for destruction would be considered prompt destruction.

Response: As discussed, the DEA is not requiring any particular method or means of
destruction. All controlled substances destined for destruction must be rendered non-retrievable in order to be destroyed in a manner consistent with this rule. 21 CFR 1317.90. If chemical treatment renders a substance non-retrievable, it has been properly destroyed and is no longer subject to the DEA’s regulations.

[19] Issue: One commenter suggested that the DEA require controlled substances to be partially destroyed prior to disposal in collection receptacles, such as by grinding them up and mixing them with kitty litter.

Response: With regard to mixing pharmaceutical controlled substances with other substances prior to depositing them in a collection receptacle, this rule neither prohibits nor requires such activity. Some authorized collectors may find it desirable to direct ultimate users to mix pharmaceutical controlled substances with non-hazardous items, such as kitty litter, prior to depositing in receptacles; however, the DEA declines to mandate such a requirement for all authorized collectors. The security controls required by this rule are the minimum required to ensure the safe and secure disposal of pharmaceutical controlled substances.

O. Economic Concerns (18 issues)

Continuation of Existing Programs

[1] Issue: Eighteen commenters with experience operating a disposal program stated that following the new regulations will be prohibitively costly, and their current program will be forced to stop collection activities. These commenters stated that they sort controlled substances from non-controlled substances and packaging. According to these commenters, controlled substances represent a small fraction of their total volume of collected substances, and the sorting prohibition will substantially increase costs.

Response: As explained above, comingling of controlled and non-controlled substances is
permitted by the rule in § 1317.75, but it is not required, and this rule does not require
pharmaceutical controlled substances collected from ultimate users to be collected and stored in
the original packaging. Authorized collectors may choose to address adequacy of space issues
by choosing not to collect comingled controlled substances and non-controlled substances and by
excluding packaging materials from being deposited into the collection receptacle. Also, law
enforcement continues to have autonomy regarding their collection activities, and this rule does
not prohibit law enforcement from handling collected substances. Prior to the effective date of
this rule, it is unlawful for ultimate users to transfer controlled substances to any entity
(excluding law enforcement), except in the limited circumstances allowed under 21 CFR
1307.21(a)(2).

[2] Issue: Several commenters stated that they would have to hire additional help for their
program to continue, and that they would no longer be able to rely on volunteers or other
personnel that did not meet the NPRM’s “authorized employee” definition.

Response: As discussed, in § 1300.05(b) the final rule modifies the proposed definition of
“authorized employee” to omit the word “authorized.” In this final rule, the DEA is adopting the
general common law of agency’s definition of the term “employee.” Any person who meets
certain criteria may have access to or influence over collected substances on behalf of an
authorized collector. Also, under this rule, volunteers may assist with disposal programs or take-
back events as long as they do not have access to or influence over the collected controlled
substances.

Two Employee Requirement

[3] Issue: Approximately 30 commenters felt that it would be infeasible for two employees to
oversee disposal procedures due to limited personnel. Commenters suggested allowing an
“authorized employee” of another registrant, such as a reverse distributor, to satisfy the second “authorized employee” requirement. One commenter stated that the DEA should clarify that under proposed § 1317.75(g), installation and removal of inner liners may be performed by a law enforcement officer instead of two employees.

**Response:** The DEA believes that the two-employee integrity requirement is a necessary security measure to effectively guard against diversion and to ensure that the controlled substances are handled, transferred, and recorded in a manner that is consistent with all applicable laws and regulations. The DEA carefully considered the various concerns and took steps to alleviate some of these concerns. First, as just discussed, the final rule modifies the proposed definition of “authorized employee” to instead adopt the common law of agency’s definition of the term “employee,” thus including employees that were excluded by the definition proposed in the NPRM (e.g., part-time employees and off-duty law enforcement officers). 21 CFR part 1300. Second, as previously discussed, the final rule relaxes the two employee requirement for collection receptacles located at LTCFs in § 1317.80(c). The DEA is making this exception because of the unique circumstances faced by LTCFs, as recognized by the Disposal Act, and in keeping with the DEA’s historically accommodating regulations with respect to LTCFs (e.g., §§ 1306.11(f) and 1306.13(b) regarding faxing schedule II prescriptions and dispensing partial prescriptions). The DEA believes that the above changes will alleviate some of the concerns expressed by the commenters while maintaining the necessary security to reduce diversion risks.

[4] **Issue:** Twenty-seven commenters stated that the requirement to have two employees from the pharmacy present to remove and install a collection receptacle’s inner liner is excessive and too costly. Several commenters noted that this requirement alone will dissuade retail pharmacies
from managing collection receptacles. Several commenters stated that small pharmacies may not have two employees working during the same shift, or even have two people employed full-time by the pharmacy. Two commenters suggested requiring a dual-lock system on collection receptacles, where the collector registrant retains one key and a reverse distributor retains the other.

**Response:** The DEA carefully considered the commenters’ concerns, and amended the text of the rule to address this issue. In the context of this issue, the two-employee requirement only applies to installation and removal of the inner liners which does not need to be accomplished by two employees on the same shift. Also, dual-locks on collection receptacles at retail pharmacies are not a reasonable alternative because collectors are authorized only at their own registered location or controlled premise. If a retail pharmacy employee retained one key in a dual-lock system, and a reverse distributor retained the other key, then the reverse distributor would be handling collected substances at the retail pharmacy’s registered location or controlled premise, an activity that is not permitted. Reasonable alternatives include installing and removing an inner liner during a shift change, or other times when there is more than one employee present. The final rule also modifies the proposed definition of “authorized employee,” by adopting the common law of agency’s definition of “employee” and correspondingly eliminating the requirement that employees authorized to conduct disposal activities be employed full-time by the authorized collector. 21 CFR part 1300. The DEA believes that the two-employee integrity requirement is a necessary security measure to effectively guard against diversion and to ensure that the controlled substances are handled, transferred, and recorded in a manner that is consistent with all applicable laws and regulations.
Several commenters stated that the requirement that two employees from a retail pharmacy be present to install and remove inner liners at LTCFs is prohibitively burdensome. Several commenters stated that most retail pharmacies do not have a vehicle for this purpose, and it is a liability to have pharmacy employees traveling to LTCFs to change inner liners. Two commenters suggested that the requirement should be one employee from the pharmacy and one employee from the LTCF.

Response: The DEA carefully considered alternatives that will provide convenient options for the unique population of LTCF residents, but will also provide safe and secure disposal. As amended, the final rule in § 1317.80(c) provides that inner liner installations, storage, removals, and transfers at LTCFs may be performed either by two employees of the authorized collector, or by one employee of the authorized collector and a supervisor-level employee of the LTCF designated by the authorized collector. The DEA believes that this modification is important to encourage hospitals/clinics and retail pharmacies to maintain collection receptacles for LTCF residents, by easing the burdens on authorized collectors who maintain collection receptacles at LTCFs--the only collectors who maintain collection receptacles at locations away from their primary registered locations. Additionally, the DEA recognizes that some authorized collectors do not have a vehicle specifically for the purpose of travelling to LTCFs, or currently allow employees to travel. The DEA notes that no particular vehicle is required to transport employees of the authorized collector to the LTCF, and, as discussed above, the DEA encourages authorized collectors managing a collection receptacle at a LTCF to coordinate removal of inner liners with the delivery of controlled substances dispensed to LTCF residents.

Fifteen commenters stated that it will be economically burdensome to have two employees of the reverse distributor accompany the collected substances to the point of

[6] Issue: Fifteen commenters stated that it will be economically burdensome to have two employees of the reverse distributor accompany the collected substances to the point of
destruction to witness the destruction. These commenters noted that waste management companies often travel hundreds of miles to reach a destruction facility. The commenters stated that it is unreasonable to have two employees of the reverse distributor accompany the collected substances and witness the destruction, and some commenters suggested that the DEA permit other security mechanisms, such as GPS devices and security cameras, to serve in lieu of the second employee.

Response: The DEA believes that the two-employee integrity requirement is a necessary security measure to effectively guard against diversion and to ensure that the collected substances are handled, transferred, and recorded in a manner that is consistent with all applicable laws and regulations. 21 CFR 1317.95. The DEA notes that the DEA registrants who expressed concern regarding this requirement already adhere to it in their current business practices. However, the DEA has thoroughly and carefully considered the commenters’ concerns and considered the following alternatives to the two-person integrity requirement: (1) requiring destruction facilities to register with the DEA; (2) requiring the transferring registrant (e.g., retail pharmacies, hospitals/clinics, etc.) to accompany the controlled substances to the point of destruction; (3) requiring on-site destruction; (4) requiring additional recordkeeping and witnessing at the point of destruction by the non-registrant destruction facility; and (5) requiring GPS devices or security cameras to serve in lieu of the second employee. The DEA did not elect these alternatives because the DEA is without sufficient authority to impose them, or the alternatives were impractical, excessive, did not provide adequate security, would result in voluminous, difficult to maintain and verify records, and/or would reduce the disposal options available to ultimate users.
The two-person integrity requirement is of paramount importance when transporting controlled substances to the point of destruction because these persons are uniquely entrusted with ensuring the substances are destroyed and not diverted to illicit purposes. Registrants that destroy on-site also face diversion risks and security concerns and must adhere to the two-person integrity requirement when destroying controlled substances. These diversion risks and security concerns increase substantially in the case of reverse distributors because they routinely acquire from other registrants large volumes of controlled substances destined for destruction, and they routinely transport those substances to a remote, un-registered location for destruction, yet there is no independent mechanism to ensure or verify that the substances within their possession are actually destroyed and not diverted.

Furthermore, as explained previously, in every other transfer of controlled substances in the closed system of distribution, there are two registrants on each side of the transfer to ensure accountability and identify and prevent diversion. When controlled substances are transferred for destruction, there may not be a registrant verifying the destruction of the controlled substances. Adherence to the two-employee integrity requirement will provide accountability for the controlled substances during the destruction process, preventing possible loss, possible theft, and diversion of the controlled substances.

Similarly, the DEA declines to allow GPS devices or security cameras to serve in lieu of a second employee. These types of security measures can be compromised, and do not provide the same level of deterrence or risk mitigation as the presence of a second person because they are strictly after-the-fact methods of diversion control as opposed to providing security throughout the transportation and destruction process. GPS devices cannot provide information as to whether or not controlled substances were removed from the transporting vehicle, and
cameras cannot observe transportation and destruction from all angles. For example, a single driver being monitored by GPS and video could drive to the destruction facility on the approved route, remove the controlled substances from the vehicle, move with the controlled substances out of the view of the camera, and place the controlled substances into a separate vehicle or hidden spot off camera rather than destroying them. In such a scenario, neither the GPS, nor the camera would indicate any sort of diversion, whereas a second person would be present throughout transportation and destruction to serve as a deterrent and ensure that the controlled substances were actually destroyed.

For these reasons, the DEA believes that the two-person integrity requirement is the most reasonable, secure, and economic substitute for another registrant serving as an independent verification method at the end of the closed system of distribution.

*Implementation Costs*

[7] **Issue:** One commenter indicated that the enhanced security procedures proposed for the disposal process will be overly burdensome and costly. This commenter recommended that the DEA meet with industry stakeholders to identify options that will allow innovation while maintaining security.

**Response:** The security requirements in this rule are the minimum needed to protect the public health and safety, to ensure accountability, and to reduce the risk of diversion during the disposal process. In addition, there were multiple opportunities for industry stakeholders (and any other interested persons) to participate in the rulemaking process for this rule through participation in the public meeting held in January 2011, and the submission of written comments during the open comment period. The DEA carefully considered discussion from the meeting, as well as the written comments submitted in response to the NPRM.
[8] **Issue:** Eleven commenters stated that the regulations proposed in the NPRM are too costly, and the costs will discourage potential collectors from participating. Several commenters expressed concern about the costs associated with retail pharmacies managing collection receptacles, particularly at LTCFs.

**Response:** As provided in the Disposal Act and discussed in the NPRM, the DEA cannot require any entity to establish or maintain a disposal program. Based on information received from the public and industry during the public meeting in 2011, as well as information received in response to the NPRM, the DEA believes that many entities are eager to voluntarily establish disposal programs. Entities may choose to establish disposal programs for various reasons, including for profit, to build goodwill in the community, to attract customers, to advertise businesses, and to preserve the environment.

[9] **Issue:** Several commenters provided feedback regarding costs related to voluntary implementation and maintenance of disposal programs, although none provided any actual data that could be applied to the cost analysis except for a suggestion that the DEA review information from a report on waste collection, and one commenter that provided an estimate without any supporting data. Generally, commenters indicated that the proposed methods of collection would have associated costs incurred through recordkeeping, purchase of inner liners, changes in procedures, increases in destruction costs, and development of mail-back packages and collection receptacles. Commenters encouraged the DEA to further explore the potential costs of the proposed options as well as additional alternatives.

**Response:** The DEA appreciates the commenters’ concerns regarding potential costs associated with the implementation and maintenance of disposal programs. The DEA has updated its economic analysis to address, directly, the costs of this rule with respect to those registrants that
do choose to establish a collection program. Such implementation, however, is strictly voluntary; thus, any entity that does not wish to incur the related costs may choose not to participate. Additionally, as described in the NPRM, the DEA anticipates that a variety of interest groups, corporations, community groups, and other entities will work together to provide secure and responsible disposal options pursuant to this rule.

[10] **Issue:** One commenter suggested that the DEA provide an exception for analytical labs from the requirements of proposed § 1317.95(c) (§ 1317.95(d) in the final rule), which requires that two employees handle the destruction of controlled substances, in instances where the testing renders a substance non-retrievable.

**Response:** The DEA declines to provide a blanket exception for analytical laboratories for the described situation. The DEA believes that such instances as described by the commenter will be incidental to testing. If the testing is specifically designed to develop new methods of destruction or destruction is otherwise not incidental to testing, all destruction must be in accordance with the provisions in subpart C of this rule.

[11] **Issue:** One commenter expressed concern that this rule will impose obligations on authorized collectors that are inconsistent with obligations imposed by other agencies, particularly the FDA, EPA, and DOT. The commenter stated that the potential liability stemming from such conflicts will discourage participation.

**Response:** The DEA has worked directly with other Federal agencies regarding the implementation of this rule, including the EPA and DOT. The DEA believes that authorized collectors may comply with this rule and other agency regulations. Authorized collectors should contact applicable agencies for further guidance if they believe that their specific circumstances may lead to conflicts.
**Funding and Incentives**

[12] **Issue:** One commenter asked the DEA to allow private/public partnerships for collection receptacles, mail-back programs, and take-back events.

**Response:** This rule does not dictate what funding sources are permitted or prohibited. Entity partnerships are not prohibited as long as the authorized collector follows all procedures outlined in this rule.

[13] **Issue:** Ten commenters expressed concern that there is no mandate, funding, or incentive for collectors to participate. Two commenters suggested that the DEA establish incentives to encourage participation, or require all pharmacies to install and maintain collection receptacles. Several commenters indicated that without a clear source of funding, cost mitigation, or participation incentive, it is unlikely that registrants will voluntarily accept the financial burdens associated with the provision of collection opportunities.

**Response:** The DEA appreciates the suggestions and concerns of the commenters regarding funding for voluntary controlled substances collection programs. The DEA points out that the Disposal Act did not authorize the DEA to assign responsibility of funding to any entity, and the Disposal Act specifically required the DEA to promulgate the implementing regulations in such a way that participation would not be mandatory. The DEA’s intent in soliciting comments regarding this rule’s potential economic impact was to gain knowledge regarding potential costs—not which entities should fund disposal programs. The DEA has attempted to provide regulations that minimize the financial burden while retaining a level of security to ensure public safety and reduce diversion risks. This rule does not address the responsibility of costs associated with any collection program. The DEA recognizes that collection programs will have associated costs and each entity that chooses to establish and maintain such a program must
determine how to manage such costs.

*Other Economic Concerns*

[14] **Issue:** A number of commenters urged the DEA not to impose additional fees on registrants that choose to become authorized collectors. These commenters asked the DEA to clarify whether or not there will be any cost to modify a registration to become an authorized collector. One commenter suggested that the DEA offer a reduced fee for non-profit organizations to become registered as reverse distributors.

**Response:** Section 1301.51(c) states that no fee will be required to modify a registration to become authorized as a collector. Pursuant to 21 U.S.C. 886a, fees charged by the DEA under its diversion control program must be set at a level that ensures the recovery of the full costs of operating the various aspects of the program. The DEA last modified the registration fees on April 16, 2012. 77 FR 15234. If the DEA determines in the future that such fees should be modified in order to ensure the recovery of the full costs of the diversion control program, including those contained in this rule, the DEA will propose a modified fee schedule pursuant to the notice-and-comment rulemaking process. The DEA currently provides limited exceptions and exemptions from registration fees to very specific groups and entities as identified in part 1301. At this time, the DEA does not anticipate expanding such exceptions and exemptions as a result of or in conjunction with the implementation of this rule.

[15] **Issue:** A few commenters noted that DEA’s Economic Impact Analysis estimated the universe of potential respondents to include distributors, reverse distributors, manufacturers, and retail pharmacies, without considering hospitals, surgery centers, dental clinics, veterinary practices, or physicians’ offices.

**Response:** The DEA’s analysis included a universe of potential respondents comprised of only
those entities that may be affected by the rule—those registrants that are eligible to become
authorized collectors (i.e., distributors, reverse distributors, manufacturers, NTPs, and
hospitals/clinics with an on-site pharmacy, and retail pharmacies).

[16] **Issue:** Two commenters stated that the DEA did not appropriately calculate the costs
associated with the proposed rule. One commenter stated that the DEA should acknowledge the
costs associated with recordkeeping requirements, purchasing inner liners, purchasing mail-back
packages, procedural changes, and increased destruction costs.

**Response:** As discussed previously, the economic analysis of the final rule takes into account
costs associated with voluntary performance of collection activities even though the provisions
that facilitate non-registrant disposal are completely voluntary, not mandated. Any collector,
reverse distributor, distributor, or law enforcement that chooses to engage in the voluntary
activities described in this section, does so based on its own evaluation of costs and benefits
(tangible and intangible).

[17] **Issue:** One commenter stated that the economic impact analysis is inadequate because it
does not acknowledge that parts of this rule are an “indirect” mandate for LTCFs. This
commenter referred to incidents where LTCFs will have no other options for controlled
substance disposal if patients are unable to dispose of the medication and there is no other person
authorized to dispose of the controlled substances.

**Response:** In response to this comment, the final rule modifies the language of § 1317.80(a), as
proposed, which appeared to prohibit LTCFs from using any disposal method other than a
collection receptacle. Under the final rule, LTCFs may dispose of controlled substances on
behalf of an ultimate user who resides, or has resided, at such LTCF. 21 CFR 1317.30 and
1317.80. The DEA notes that the decision to implement and manage a collection program for
ultimate user disposal is voluntary. It should be noted that LTCF residents are ultimate users themselves and they, members of their households, and persons lawfully entitled to dispose of a decedent’s personal property, may avail themselves of all disposal methods made available by this rule. 21 CFR 1317.30.

[18] Issue: One commenter stated that the DEA did not consider veterinary practices, prisons, or clinics when calculating the economic impact analysis.

Response: In the proposed rule, the DEA considered veterinary practices, prisons, and clinics in the accompanying calculations concerning economic impact to the extent that these entities would be registered as practitioners or non-practitioners. For the final rule, the DEA calculated the economic impact on these entities to the extent that they could become collectors. Not all registrants are eligible to become authorized collectors. Of this specified list of entities inquired about by the commenter, only a small subsection, specifically hospitals/clinics with on-site pharmacies, may become authorized as collectors in accordance with this final rule. 21 CFR 1317.40 and 1317.70.

P. Recordkeeping and Reporting (8 issues)

[1] Issue: One commenter asked the DEA to clarify whether or not the recordkeeping requirements in the rule apply to all registrants or only authorized collectors.

Response: The new recordkeeping requirements contained in this rule are applicable to all registrants, including authorized collectors. To clarify this important distinction, the DEA moved the recordkeeping provisions in proposed part 1317 to part 1304.

[2] Issue: Several commenters urged the DEA to remove the inventory and recordkeeping requirements for mail-back packages and inner liners. The commenters believe that such recordkeeping will be challenging and provide limited benefits. One commenter suggested that
the DEA instead adopt tracking procedures currently used in some non-controlled substance collection programs.

**Response:** As described in the NPRM, inventory and recordkeeping requirements for collected substances are necessary for a number of reasons, including accountability of collected substances within the possession and control of authorized collectors. The inventory and recordkeeping requirements included in this rule are generally consistent with those otherwise required of registrants, thus minimizing burden. The DEA believes that these inventory and recordkeeping requirements are necessary to help minimize the risk of diversion and to identify diversion of controlled substances destined for destruction.

[3] **Issue:** One commenter suggested that the DEA eliminate ARCOS reporting requirements for reverse distributors regarding collected substances from ultimate users. Another commenter asked the DEA to clarify what information is required for ARCOS reporting.

**Response:** In this final rule, § 1304.33(g) (relocated from proposed § 1317.50) exempts reverse distributors and distributors that acquire controlled substances from collectors or law enforcement from reporting to ARCOS with respect to pharmaceutical controlled substances collected through mail-back programs and collection receptacles.

[4] **Issue:** One commenter asked the DEA to clarify what records reverse distributors must keep when receiving collected substances from law enforcement.

**Response:** The recordkeeping requirements in §1304.22(e)(4) that apply to controlled substances acquired by registrants that reverse distribute from collectors also apply to those acquired from law enforcement. The final rule also adds a new paragraph in § 1304.11(e)(3)(iii) specifying the information relating to controlled substances acquired from collectors and law enforcement that a registrant that reverse distributes must maintain in its inventories. Under the
revised § 1304.03(a), these provisions relating to reverse distributors apply to any entity that reverse distributes, as defined in § 1300.01(b), whether or not it is registered with the DEA as a reverse distributor. Finally, the requirement in § 1304.21(e) to maintain a DEA Form 41 applies to the destruction of a sealed inner liner or mail-back package by a registrant that reverse distributes.

[5] **Issue:** Commenters asked the DEA to clarify who is responsible for tracking the mail-back packages, and how mail-back packages that were disseminated but not returned to the authorized collector will be reconciled with the inventory.

**Response:** There is currently no requirement for the authorized collector to reconcile the inventory in order to determine which packages were not returned. As discussed in the NPRM, the DEA does not believe that requiring authorized collectors to institute a tracking or notification system for ultimate users is necessary at this time, although such systems are not prohibited so long as the collector does not require the ultimate user to provide personally identifiable information, as specified in § 1317.70(d).

[6] **Issue:** Commenters asked the DEA to eliminate the following recordkeeping requirements for inner liners: tracking unused inner liners on hand, recording the acquisition date, recording the installation date, and the requirement that two employees witness the removal and installation of inner liners.

**Response:** As previously discussed, the DEA believes that all of the inventory and recordkeeping requirements in part 1304 are the minimum necessary to ensure accountability and identify diversion.

[7] **Issue:** Two commenters asked the DEA if reporting to the FDA is sufficient to satisfy the DEA’s reporting requirements for cases of controlled substance recalls.
Response: No. Regardless of any other Federal, State, tribal, or local agency requirements, each registrant must maintain records and make reports to the DEA in a manner consistent with the requirements of chapter II of title 21 of the CFR.

[8] Issue: One commenter asked the DEA to clarify the recordkeeping requirements of § 1317.50(b)(2)(iii)—specifically, the requirement to record the registration number of the collection location when the collection occurs at a LTCF, which typically does not have a registration number.

Response: The final rule moves the referenced requirements to new § 1304.22(f). The record should include the approved collection location address of the LTCF and the authorized collector’s registration number.

Q. Hazardous Materials Transportation and Hazardous Waste Destruction (3 issues)

[1] Issue: Approximately 20 commenters expressed concern that the requirements outlined in this rule for the transportation of collected substances conflict with current regulations under the DOT’s Pipeline and Hazardous Materials Safety Administration (PHMSA). One concern involved the comingling of collected substances that the DOT considers “hazardous materials” with nonhazardous materials or hazardous materials of a different class. Other concerns included how inner liners from collection receptacles that contain hazardous materials should be labeled and packaged for transport, and other notice requirements for hazardous waste under the DOT’s PHMSA.

Response: All drug disposal activities must be conducted in a manner consistent with this rule and all other applicable Federal, State, tribal, and local laws and regulations. Compliance with the destruction requirements outlined in subpart C of this rule does not exempt any entity from complying with other Federal, State, tribal, or local laws or regulations. It is not within DEA’s
expertise or authority to opine what pharmaceutical controlled substances could be hazardous materials subject to DOT regulations. However, the DEA consulted with the DOT during various stages of this rulemaking. The DEA has been informed that if collected substances include hazardous materials, the transportation of those materials is subject to all applicable DOT regulations, including the “Hazardous Materials Regulations” (HMR). The DEA encourages entities to consult www.phmsa.dot.gov/hazmat for information regarding the HMR. In particular, the DEA encourages entities to contact the DOT’s PHMSA regarding its “Approvals and Permits Program.” PHMSA issues approvals and special permits to entities that apply for authorization to use agency approved alternatives to the HMR. Interested entities may consult www.phmsa.dot.gov/hazmat/regs/sp-a. for more information. The DEA has worked with the DOT to facilitate this process in an effort to ensure maximum participation in the collection of controlled substances for secure and responsible disposal, and the DEA will continue to work with the DOT to facilitate registrant compliance with all applicable laws and regulations. For these purposes, it should be noted that sealed collection receptacle inner liners may be transported inside of a shipping container that is labeled and packaged for transport with the necessary notice requirements applicable to hazardous waste under the DOT’s PHMSA.

[2] **Issue:** One commenter asked whether or not law enforcement must comply with the DOT’s PHMSA requirements for transporting collected substances that may contain hazardous materials.

**Response:** It is not within the DEA’s expertise or authority to opine on the applicability of DOT regulations. However, the DEA believes that the DOT’s Hazardous Materials Regulations apply to entities that place hazardous materials in commercial transportation, and not government vehicles operated by government personnel solely for non-commercial purposes. However, State
and local governments may have different regulations that do apply to government entities or law enforcement. The DEA encourages these entities to consult the DOT as well as their State and local governments for specific guidance on transporting collected substances that may contain hazardous materials.

[3] **Issue:** Commenters asked the DEA whether or not collected substances must be destroyed as hazardous waste under the EPA’s Resource Conversation and Recovery Act (RCRA).

**Response:** It is not within the DEA’s expertise or authority to opine what pharmaceutical controlled substances could be hazardous waste subject to EPA regulations. The DEA does not have the authority to regulate hazardous waste and thus cannot advise on whether or not collected substances must be destroyed as hazardous waste pursuant to RCRA. However, the DEA has worked with the EPA at various stages of this rulemaking, and the DEA continues to work with the EPA to ensure the secure and responsible disposal of controlled substances, including those that may be considered hazardous waste. The DEA believes that there is a small portion of pharmaceuticals that are regulated as hazardous waste, and an even smaller portion of pharmaceuticals that are regulated as both controlled substances and hazardous waste. However, pharmaceutical controlled substances that are collected directly from ultimate users via mail-back programs or collection receptacles may fall under RCRA’s Household Hazardous Waste Exemption; if so, EPA RCRA regulations would not apply in those instances. The DEA acknowledges that some state and local regulations may be more stringent.

The DEA is working with the EPA to ensure that this final rule will enable LTCF residents to responsibly, securely, and safely dispose of controlled substances that may also be considered hazardous waste. Collected substances from LTCFs may pose a unique challenge since the EPA currently uses a bifurcated system to determine whether pharmaceutical waste
from LTCFs must be treated as hazardous waste under the RCRA. If the waste is generated by the resident, it does not have to be treated as hazardous waste and is exempt under the Household Hazardous Waste Exemption. If the waste is generated by the LTCF, it must be treated as hazardous waste unless it is otherwise exempt. Hazardous waste generated by LTCFs may be exempt if the LTCF is a “conditionally-exempt small quantity generator.” To qualify under such exemption, the LTCF must generate less than or equal to 100 kilograms of non-acute hazardous waste, and less than or equal to one kilogram of acute hazardous waste on a monthly basis. The DEA believes that most LTCFs may qualify under this conditional exemption. Also, the DEA acknowledges that many pharmaceuticals that are recognized as acute hazardous waste (e.g., blood thinners) are non-controlled substances. The DEA hopes that authorized collectors and LTCFs will collaborate to minimize the impact that disposing of such pharmaceuticals may have on collection efforts by separating these non-controlled substances from controlled substances to be deposited into collection receptacles.

The EPA is aware of the concerns regarding collected substances at LTCFs, and according to the Fall 2013 Regulatory Agenda, the EPA is currently drafting regulations to address hazardous waste pharmaceuticals, including the small group of pharmaceutical controlled substances that the EPA classifies as hazardous waste under the RCRA, when discarded. According to the Regulatory Agenda, the EPA’s proposal, “Management Standards for Hazardous Waste Pharmaceuticals,” may propose to “revise the regulations to improve management and disposal of hazardous waste pharmaceuticals,” and clarify regulation of reverse distribution. The abstract for the proposal may be viewed at www.reginfo.gov. Interested persons are encouraged to follow the progress of this pending regulatory action.
The DEA encourages authorized collectors and others to seek guidance directly from the EPA, and the DEA encourages such persons to consult www.epa.gov for more information. All drug disposal and destruction must be conducted in a manner consistent with this rule and all other applicable Federal, State, tribal, and local laws and regulations.

R. **Transporting Collected Substances (3 issues)**

[1] **Issue:** One commenter indicated that transporting collected substances directly to the destruction location will be virtually impossible because drivers must stop for rest breaks.

**Response:** The DEA recognizes that transportation to destruction facilities may occur over long distances. The requirement to transport collected substances directly to the destruction facility means that the collected substances should be constantly moving towards their final destruction destination and unnecessary or unrelated stops, and stops of an extended duration should not occur. The final rule in §§ 1317.05(b)(4) and 1317.95(c)(1) is modified to specify this requirement, which is designed to reduce the opportunities for diversion.

[2] **Issue:** Several commenters were concerned that this rule will change their existing transport procedures that were already approved by their local SAC.

**Response:** In promulgating this rule, the DEA carefully considered the impact of these changes to existing procedures and is requiring the minimum procedures necessary to ensure safe and secure means of transporting controlled substances. The rule provides a nationwide standard, and allows non-practitioners the flexibility to determine the best method of transportation considering their own individual circumstances while also ensuring accountability and reducing theft and diversion risks. Any previous waivers, Memorandums of Understanding, or Memorandums of Agreement issued in accordance with § 1307.21 shall be superseded by this final rule once it becomes effective. However, practitioners may seek assistance from their local
SAC pursuant to § 1317.05(a)(4).

[3] **Issue:** Other commenters sought guidance on whether or not the DEA will limit the quantity of controlled substances that may be transported, and whether or not there will be additional requirements for interstate transport of collected substances.

**Response:** This final rule does not impose any transportation quantity limits or any requirements specific to interstate transport of controlled substances.

S. **Miscellaneous Comments (2 issues)**

[1] **Issue:** Approximately eight commenters asked the DEA to expand the rule to include procedures for controlled substances that have been “partially administered” or “partially dispensed.” These commenters referred to institutional settings where transdermal patches are used, as these used patches may contain residual amounts of controlled substances.

**Response:** As previously discussed, destruction of the residual amounts of controlled substances administered by a practitioner to a patient that remain in the delivery apparatus (in this instance, the transdermal patch) must continue to be recorded in accordance with existing § 1304.22(c). In accordance with the revised § 1304.21, these destructions are not required to be recorded on DEA Form 41. All disposals of inventory must be accomplished in accordance with § 1317.05(a), and all other applicable recordkeeping and inventory requirements.

[2] **Issue:** One commenter indicated that §§ 1317.15 and 1317.95 may conflict in that § 1317.15 allows for storage by a reverse distributor while § 1317.95 does not.

**Response:** The DEA has reviewed the relevant portions of this rule and determined that §§ 1317.15 and 1317.95 do not conflict. Section 1317.15 encompasses the wider topic of reverse distributor activities, including the acquisition and storage of controlled substances from other registrants, whereas § 1317.95 deals exclusively with the actual destruction process and the
procedures that are required for destruction once substances are in the possession and control of the reverse distributor (including securely stored substances).

IV. Regulatory Analyses

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act of 1980 (RFA) (5 U.S.C. 601-612), has reviewed this rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. In developing this rule, the DEA considered numerous alternatives for each requirement and method of collection and evaluated the impact of this rule on small entities. The DEA has concluded that the rule will not have a significant economic impact on a substantial number of small entities. The DEA updated the economic impact analysis after considering comments made by the public in response to the NPRM. The updated economic impact analysis of the final rule may be viewed in the rulemaking docket at www.regulations.gov.

In developing this rule, the DEA considered several options for both registrant and non-registrant disposal and reverse distributor destruction requirements. The DEA analyzed alternative methodology approaches keeping in mind its obligations under the CSA. The DEA considered three options for non-registrant disposal: (1) “Single Collection,” which would permit non-registrants to utilize only one method of collection to dispose of their lawfully possessed controlled substances; (2) “Open Collection,” which would authorize any person to collect controlled substances from ultimate users for disposal, regardless of their status as a registrant; and (3) “Multiple Collection,” which would authorize non-registrants to utilize more than one method of collection to transfer controlled substances for the purpose of disposal to law enforcement and certain registrants. In addition, the DEA considered two options for registrant
disposal: (1) “Retain Existing Regulations,” which would make no changes to the existing registrant disposal regulations (§§ 1307.12 and 1307.21); and (2) “Establish Consistent National Standards,” which would eliminate existing regulations on the disposal of controlled substances (§§ 1307.12 and 1307.21) and promulgate a new part that would comprehensively outline the process and procedure for the disposal of controlled substances by registrants and non-registrants.

Finally, the DEA considered four options for reverse distributors: (1) “On-site Requirement,” which would require reverse distributors to have and utilize an on-site method of destruction; (2) “Prompt Requirement,” which would require reverse distributors, like all other registrants, to promptly destroy controlled substances; (3) “No Requirement,” which would retain the current destruction standard and would not put a deadline on when reverse distributors must destroy controlled substances acquired for destruction; and (4) “No Later Than 30 Calendar Day Requirement,” which would require reverse distributors to destroy controlled substances received for the purpose of destruction no later than 30 calendar days from receipt. The DEA performed a qualitative analysis of each of these alternatives and selected the “Multiple Collection” option for non-registrant disposal, the “Establish Consistent National Standards” option for registrant disposal, and the “No Later than 30 Calendar Day Requirement” option for reverse distributors.

In accordance with the RFA, the DEA evaluated the impact of this rule on small entities. While all 1.5 million DEA registrants must comply with the rule as it relates to the disposal of pharmaceutical controlled substances, only a small subset of the registrants are associated with activities where the rule imposes new mandatory requirements or provides options for voluntary activities. Therefore, the DEA examined the impact of two mandatory provisions in the rule: the
30-day destruction requirement for reverse distributors and the two employee transportation requirement for manufacturers, distributors, and reverse distributors. Additionally, the DEA estimated the level of voluntary participation in collection activities in accordance with the rule and the resulting cost impact.

The mandatory provisions and voluntary participation activities are estimated to affect 53,533 entities (439 manufacturers, 585 distributors, 55 reverse distributors, 656 narcotic treatment programs (NTPs), 3,068 hospitals/clinics, 29,582 pharmacies, and 19,148 long term care facilities (LTCFs). Of the 53,533 affected entities, 50,714 (423 manufacturers, 555 distributors, 38 reverse distributors, 610 NTPs, 1,346 hospitals/clinics, 29,328 pharmacies, and 18,414 long term care facilities), or 94.7% are estimated to be small entities.

Both the 30-day destruction and the two employee transportation requirements associated with the mandatory portions of the rule will apply to the 55 reverse distributors that receive controlled substances from other registrants for disposal, of which 38 were estimated to be small entities. The potential increase in destruction, transport, travel, and labor cost associated with these two requirements was analyzed for each of the 38 small entities. Additionally, reverse distributors with on-site destruction facilities may receive authorization to voluntarily operate a mail-back program. The DEA estimates that the three small reverse distributors with on-site destruction facilities will each operate a mail-back program. The DEA does not estimate that any reverse distributors will operate collection receptacles at their registered locations because of the small numbers of employees that work at those locations. However, reverse distributors will be impacted by the destruction of controlled substances from collection receptacles that are transferred to them for destruction. The total estimated cost of the mandatory portions and voluntary participation aspects of the rule was compared to the estimated annual revenue for
each of the small reverse distributors. The economic impact of the mandatory portion and voluntary participation aspects of this rule is estimated to be significant, greater than one percent of annual revenue, for two (5%) of 38 affected small businesses.

The two-person transportation requirement associated with the mandatory portions of the rule also affects 423 small manufacturers and 555 small distributors that transport to reverse distributors or to an unregistered, off-site location for destruction. The potential increase in labor cost associated with the two-person requirement was analyzed for manufacturers and distributors. Additionally, a small number of manufacturers and distributors are estimated to volunteer to operate collection receptacles at their registered locations primarily for use by their employees. However, the DEA believes that manufacturers and distributors will not operate collection receptacles at their registered locations unless they believe there will be a benefit to them for the service. The economic impact of the mandatory portion and voluntary participation aspects of this rule is estimated to be significant for none (0.0%) of the 423 small manufacturers and none (0.0%) of the 555 small distributors.

The rule also permits certain other registrant categories to voluntarily conduct collection activities. The DEA estimates some retail pharmacies, hospitals/clinics with on-site pharmacies, and NTPs will voluntarily participate as collectors by operating collection receptacles at their locations. Some retail pharmacies and hospitals/clinics with an on-site pharmacy are also estimated to operate collection receptacles at LTCFs. The level of participation and operating costs were estimated to determine the number of small entities with impact greater than 1% of revenue.

In summary, the DEA estimates that zero (0.0%) of the 423 small manufacturers, zero (0.0%) of the 555 small distributors, two (5.0%) of 38 small reverse distributors, 62 (10.2%) of
the small NTPs, zero (0.0%) of the 1,349 small hospitals/clinics, 810 (2.8%) of the 29,328 small pharmacies, and zero (0.0%) of the 18,414 small long term care facilities may be significantly impacted by this rule (that is, where the annual cost is estimated to be greater than 1% of annual revenue). But DEA emphasizes that these estimates are entirely dependent on the level of voluntary participation by these entities. All of the provisions relating to collection activities by manufacturers, distributors, NTPs, hospitals/clinics, pharmacies, and LTCFs are completely voluntary and these entities would be free to choose whether or not to participate based on their own review of the cost to them and the anticipated benefits in providing collection receptacles.

In total, the DEA estimates that 874 (1.7%) of the 50,714 affected small entities may be significantly affected by this rule. The DEA’s assessment of economic impact by size category indicates that the rule will not have a significant effect on a substantial number of these small business entities.

In accordance with the RFA (5 U.S.C. 605(b)), the Administrator hereby certifies that this rulemaking has been drafted consistent with the RFA, that a regulatory analysis on the effects or impacts of this rulemaking on small entities has been done, and that the rule will not have a significant economic impact on a substantial number of small entities.

Executive Orders 12866 and 13563

This rule was developed in accordance with the principles of Executive Orders 12866 and 13563. Based on the completed economic analysis, the DEA does not anticipate that this rulemaking will have an annual effect on the economy of $100 million or more or adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. An economic analysis of the final rule can be found in the rulemaking docket at
Public comment was received in public meetings held on January 19–20, 2011, and through a solicitation for comment in the NPRM to help inform and develop these rules. Although not an economically significant rule, this rule on the disposal of controlled substances has been reviewed by the Office of Management and Budget (OMB).

The DEA has determined that reverse distributors currently destroy controlled substances within the “No Later than 30 Calendar Day” requirement the majority of the time. However, it is recognized that there may be instances when reverse distributors do not currently meet this requirement. Additionally, many manufacturers, distributors, and reverse distributors currently employ two persons to transport controlled substances for destruction. However, it is recognized that there may be instances when manufacturers, distributors, and reverse distributors do not currently meet this requirement. For these instances, the DEA estimated the cost to accommodate the requirements and has determined the cost is not a significant economic impact.

Moreover, the DEA estimated a range of costs of voluntary participation for manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies that may participate to collect ultimate user pharmaceutical controlled substances.

In summary, the DEA estimates that the annual total cost to the economy as a result of the rule is $2,719,319 for the mandatory provisions of this rule and the total annualized cost of the mandatory provisions and the voluntary participation aspects of the rule ranges from $44,896,787 to $73,222,427. The DEA estimates the highest cost in any given year occurs in the first year, ranging from $45,282,242 to $99,075,339. Accordingly, the DEA does not anticipate that this rulemaking will have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity,
competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

Since the aspects of the rule that facilitate non-registrant disposal are completely voluntary (not mandated), manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies may become collectors if they choose to engage in the voluntary activities based on its own evaluation of costs and benefits (tangible and intangible). For the purposes of this analysis, the DEA assumes that an entity will volunteer to perform the activities to facilitate non-registrant disposal only if there is a net zero or positive benefit to the entity. For example, a pharmacy may derive tangible benefits, such as additional revenue from increased retail traffic to the pharmacy. Collectors may also derive tangible benefits such as public safety and good will from their collection activities. Any collector that chooses to engage in these voluntary activities can decide to cease these activities at any time. Therefore, for the purposes of this analysis, the DEA estimates that the cost of the voluntary participation aspects of this rule are offset by the benefits of the voluntary participation aspects of this rule and have a net zero economic impact. The total cost of the mandatory provisions and voluntary participation aspects of the rule ($73,222,427 at the highest voluntary participation rate) is compared to the benefit of this rule. In evaluating the costs and benefits of the rule, the annual cost of the rule is compared with the anticipated reduction in the growth rate of costs associated with diversion of controlled substances into the illicit market. The cost-benefit analysis uses the costs associated with the nonmedical use of prescription opioids, $8.6 billion in 2001 and $53.4 billion in 2006. These are conservative estimates of the rapidly growing total cost associated with diversion of controlled substances into the illicit

---

market. Although there is a lack of evidence to quantify the cost savings or public health impacts of the rule, the DEA believes that this rule reduces the growth in the cost of the diversion of controlled substances into the illicit market by at least $44.9 to $73.2 million annually and, therefore, this rule will have positive net economic benefits, including benefits related to the health and safety of the citizens and residents of the United States.

_Paperwork Reduction Act_

Pursuant to § 3507(d) of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 _et seq._), the DEA has identified the following collections of information related to this rule and has submitted these collection requests to the OMB for review and approval. This rule implements the Disposal Act, in addition to reorganizing and consolidating existing regulations on disposal into a comprehensive regulatory framework for the destruction of controlled substances. In accordance with the CSA, which establishes a closed system of distribution for all controlled substances, registrants are required to make a biennial inventory and maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of. 21 U.S.C. 827(a) and 958. These records must be in accordance with and contain such relevant information as may be required by regulations promulgated by the DEA. 21 U.S.C. 827(b)(1).

In this rule, the DEA revises existing, and adds a minimum amount of new, registrant recordkeeping requirements. These requirements are consistent with requirements already required by statute and regulation.

_Title: Implementation of Registrant Recordkeeping Requirements Pursuant to the CSA, 21 U.S.C. 827_

The records that registrants are required to maintain pursuant to law are a vital
component of the DEA’s enforcement and control responsibilities—such records alert the DEA to problems of diversion and ensure that the system of controlled substances distribution is open only to legitimate handlers of such substances.

The DEA is revising the information that reverse distributors are currently required to record for clarity and consistency, and adding a minimum amount of new requirements. For all controlled substance records, reverse distributors will be required to maintain their existing business records so that the record of receipt is maintained with the corresponding record of return or destruction. By maintaining all relevant business records together, the DEA will be able to trace each substance received by a reverse distributor from its acquisition to its disposition, whether by destruction or return to the manufacturer.

The DEA estimates that there will be 60 respondents to this information collection and that their estimated frequency of response will vary because, in accordance with 21 U.S.C. 827 and 958, registrants make an initial and biennial inventory and maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of. Under existing law, reverse distributors are required to maintain, for at least two years, inventory records and records of controlled substances received, delivered, destroyed, or returned to the manufacturer. The annual hour burden for recordkeeping for reverse distributors is estimated to increase by 34 hours due to the requirements in this final rule, and the annualized cost to respondents is estimated to be $719. The DEA is also modifying information that registrants are required to record in the return and recall process. The DEA is eliminating the previous rule on return and recall, § 1307.12, and implementing separate rules on the return and recall of controlled substances for registrants and non-registrants in part 1317. The return and recall recordkeeping requirements reflect these changes.
The DEA estimates that the universe of potential respondents to this information collection will be 1,511,389 respondents (all registrants may transfer controlled substances for return or recall). The DEA estimates that the frequency of response will vary, because, in accordance with 21 U.S.C. 827(a), registrants must make an initial and biennial inventory and maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of. Because registrants are already required to maintain records in accordance with 21 U.S.C. 827(a)–(b), the DEA anticipates that the annual hour burden will not be increased by this rule.

The DEA is implementing new recordkeeping requirements for registrants that collect controlled substances from ultimate users and other non-registrants in accordance with the new authority provided in the Disposal Act. The implementation of the Disposal Act regulations will provide ultimate users, LTCDs, and other non-registrants safe and convenient options to transfer controlled substances for the purpose of disposal: take-back events, mail-back programs, and collection receptacles. Registered manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies may obtain authorization from the DEA to be a collector pursuant to § 1317.40. A collector is a registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy that is authorized under this rule to receive a pharmaceutical controlled substance from an ultimate user for the purpose of destruction, as defined in part 1300. The DEA is requiring information that collectors must record based on the particular ultimate user collection method implemented (i.e., mail-back program or collection receptacle).

The DEA estimates that the universe of potential participants to this information
collection will be 87,736 respondents (Manufacturers—536, Distributors—829, Reverse Distributors—60, Narcotic Treatment Programs—1,332, Hospitals/Clinics—15,953, Retail Pharmacies—69,026). However, the DEA estimates that the participants to this information collection will be 54,457 respondents (Manufacturers—107, Distributors—166, Reverse Distributors—10, Narcotic Treatment Programs—999, Hospitals/Clinics—2862, Retail Pharmacies—34,513, and an additional 15,800 hospitals/clinics and retail pharmacies operating collection receptacles at LTCFs). The DEA estimates that the frequency of response will vary, because, in accordance with 21 U.S.C. 827(a), registrants must make an initial and biennial inventory and maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of. The DEA notes, however, that the option to become a collector is voluntary and no entity is required to establish or operate a disposal program as a collector. While the authorization to collect is a new activity, the DEA has estimated the level of participation. The estimated 54,457 respondents are estimated to have an annualized hour burden of 89,406 with an estimated annualized cost of $1,670,064. The DEA will continue to monitor and analyze the potential burden of the new requirements imposed by this rule.

The DEA is authorizing reverse distributors to acquire controlled substances from law enforcement and authorized collectors that have acquired controlled substances from ultimate users and other non-registrants. The DEA is also authorizing distributors to acquire controlled substances from authorized collectors that collect controlled substances from ultimate users. The DEA is requiring these reverse distributors and distributors to maintain complete and accurate records, in accordance with part 1304, of controlled substances received, delivered, or otherwise

9 The universe of potential participants includes all registrants that could potentially become collectors. It is likely that this estimate will be adjusted downward once the DEA obtains more information.
transferred for the purpose of destruction.

The DEA estimates that the universe of potential respondents to this information collection will be 889 respondents (Distributors—829, Reverse Distributors—60). The DEA estimates that the frequency of response will vary, because, in accordance with 21 U.S.C. 827(a), registrants must make an initial and biennial inventory and maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of. The authorization for reverse distributors to acquire controlled substances collected by law enforcement and collectors, and the authorization for distributors to acquire controlled substances from collectors, is new. Although the DEA has estimated the level of participation, the DEA is unable to estimate the number of information collection events because destruction of multiple acquisitions of controlled substances can be on a single form. The DEA’s initial estimate for the annual hour burden is 472 hours (32 minutes per event), with an estimated annualized cost of $10,037. The DEA will continue to analyze the potential burden of the new requirements imposed by this rule.

Title: Registrant Record of Controlled Substances Destroyed—DEA Form 41

OMB Control Number: 1117-0007

Form Number: DEA Form 41

The records that registrants are required to maintain pursuant to law are a vital component of the DEA’s enforcement and control responsibilities—such records alert the DEA to diversion and ensure that the system of controlled substances distribution is open only to legitimate handlers of such substances. The DEA is requiring registrants involved in the destruction of controlled substances to record certain information. The record of destruction must include the signature of the two employees of the registrant that witnessed the destruction,
in addition to other information about the controlled substance disposed of and the method of destruction utilized. The DEA is modifying existing DEA Form 41 to record the destruction of controlled substances that remain in the closed system of distribution and to account for registrant destruction of controlled substances collected from ultimate users and other non-registrants outside the closed system pursuant to the Disposal Act. DEA Form 41 has previously been approved by the OMB and assigned OMB control number 1117-0007. In accordance with the CSA, registrants that destroy controlled substances and utilize DEA Form 41 will be required to keep and make available the information in the specified format, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General. 21 U.S.C. 827(b).

The DEA estimates that there will be 87,736 respondents (Manufacturers—536, Distributors—829, Reverse Distributors—60, Narcotic Treatment Programs—1,332, Hospitals/Clinics—15,953, Retail Pharmacies—69,026) to this information collection. The number of respondents (87,736) represents the total number of registrants in business activities that are most likely to destroy controlled substances. The DEA estimates that the frequency of response will vary, because in accordance with 21 U.S.C. 827(a), registrants must maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of, and, as a result, will make a record of destruction each time they destroy a controlled substance. The DEA estimates that the average time per response will be 30 minutes and that the total annual burden will be 43,868 hours, with an estimated total annual cost burden of $928,247.

*Executive Order 12988*
This rule meets the applicable standards set forth in §§ 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law, impose enforcement responsibilities on any State or diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

National Environmental Policy Act (NEPA)

This rule provides options for the collection of controlled substances by registrants and non-registrants consistent with DEA regulations and Federal, State, tribal, and local laws and regulations. Provision of these options is intended to result in increased collection and destruction of unused controlled substances and thereby prevent diversion of such unused substances to illicit uses and result in collection and destruction of larger quantities in economical and environmentally sound manners. This rule establishes legal requirements for the handling of controlled substances. Destruction of controlled substances must be consistent with Federal, State, tribal and local laws and regulations.

The DEA and registrants have disposed of controlled substances since passage of the CSA. By regulation, the U.S. Department of Justice categorically excluded the DEA from further NEPA analysis with respect to regulations relating to the storage and destruction of controlled substances. This rule does not authorize any new methods of storage, transportation, or destruction of controlled substances, but is limited to the procedures and records pertaining to the collection of controlled substances for destruction. Accordingly, this proposed rule does not
significantly affect the quality of the human environment. The DEA has, therefore, determined that this rule does not have significant individual or cumulative effects on the human environment and is excluded from detailed analysis pursuant to 28 CFR part 61, Appendix B.

*Unfunded Mandates Reform Act*

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.*), on the basis of information contained in the “Regulatory Flexibility Act” section above, the DEA has determined and certifies pursuant to the UMRA that this action would not result in 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 for inflation) in any one year…” Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA of 1995.

*Executive Order 13175*

This rule does not have tribal implications warranting the application of Executive Order 13175. The rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

*Congressional Review Act*

This rule is not a major rule as defined by the Congressional Review Act (5 U.S.C. 804). This rule will not result in an annual effect on the economy of $100,000,000 or more, a major increase in costs or prices, or have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign based companies in domestic and export markets.
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:


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)

<table>
<thead>
<tr>
<th>Business Activity</th>
<th>Controlled Substances</th>
<th>DEA Application Forms</th>
<th>Application Fee ($)</th>
<th>Registration Period (years)</th>
<th>Coincident Activities Allowed</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) Manufacturing</td>
<td>Schedules I–V</td>
<td>New–225 Renewal–225a</td>
<td>3,047</td>
<td>1</td>
<td>Schedules I–V: May distribute that substance or class for which registration</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>(ii) Distributing</th>
<th>Schedules I–V</th>
<th>New–225</th>
<th>1,523</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Renewal–225a</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

May acquire Schedules II–V controlled substances from collectors for the purposes of destruction.

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

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

* * * * *

(i) Controlled substances acquired and possessed in accordance with this section shall be
distributed only to persons under the general supervision of the medical officer employed by the owner or operator of the vessel, aircraft, or other entity, except in accordance with part 1317 of this chapter.

8. Revise § 1301.51 to read as follows:

§ 1301.51 Modification in registration.

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

(1) The request shall contain:

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

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

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

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

(b) Any manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy registered pursuant to this part, may
apply to modify its registration to become authorized as a collector by submitting a written request to the Registration Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. Additionally, such request may be submitted on-line at www.DEAdversion.usdoj.gov.

(1) The request shall contain:

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

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

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

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

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

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

§ 1301.52 Termination of registration; transfer of registration; distribution upon
discontinuance of business.

* * * * *

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

* * * * *

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

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

§ 1301.71 Security requirements generally.

* * * * *

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

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

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

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

   * * * * *

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

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

   * * * * *

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

13. In § 1301.75, redesignate paragraphs (c) and (d) as paragraphs (d) and (e) and add a new
paragraph (c) to read as follows:

§ 1301.75 Physical security controls for practitioners.

* * * * *  

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

* * * * *

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

§ 1301.76 Other security controls for practitioners.

* * * * *  

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

* * * * *

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

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

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

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

§ 1304.03 Persons required to keep records and file reports.

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

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

§ 1304.04 Maintenance of records and inventories.

(a) * * *

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

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

§ 1304.11 Inventory requirements.

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

* * * * *

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

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

(i) The name of the substance, and

(ii) The total quantity of the substance:

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

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

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

(iii) For controlled substances acquired from collectors and law enforcement: the
number and size (e.g., five 10-gallon liners, etc.) of sealed inner liners on hand, or

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

* * * * *

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

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

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

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

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

(A) The date of the inventory;

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

(C) The unique identification number of each package on hand, whether unused or awaiting destruction.
(ii) For registrants authorized to collect through a collection receptacle, the record shall include the following information about each unused inner liner on hand and each sealed inner liner on hand awaiting destruction:

(A) The date of the inventory;

(B) The number and size of inner liners (e.g., five 10-gallon liners, etc.);

(C) The unique identification number of each inner liner.

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

§ 1304.21 General requirements for continuing records.

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

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

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

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

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

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

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

* * * * *

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

(1) For controlled substances acquired for the purpose of return or recall to the manufacturer or another registrant authorized by the manufacturer to accept returns on the
manufacturer’s behalf pursuant to part 1317 of this chapter:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Mail-Back Packages:

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

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

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

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

(2) Collection receptacle inner liners:

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

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

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

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

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

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

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

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

* * * * *

(a) * * * *

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

(b) * * *

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

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

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

* * * * *

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

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

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

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

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.
§ 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–
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).
§ 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 5
April 28, 2014

Drug Enforcement Administration
Attn: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

RE: COMMENTS OF THE CALIFORNIA STATE BOARD OF PHARMACY
Docket No. DEA-389
Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II

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. DEA-389, titled “Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II.” We will be brief. We strongly support and encourage this timely action, as we believe Schedule II is more appropriate for hydrocodone combination products (HCPs). As we will explain below, however, we do urge you to keep in mind, as you schedule the timing of this transition, the innumerable patients (and their practitioners) who rely on HCPs for legitimate treatment, and respectfully suggest that the Drug Enforcement Administration (DEA) provide sufficient notice and a period of transition to enable those patients and practitioners to adjust their prescribing regimens to the additional requirements that must now be met.

Our experience in California with HCPs illustrates the need for their rescheduling. Our state leads the nation in utilization of HCPs, with over 1.4 billion dosage units dispensed from April 2012 to April 2013.\(^1\) And that figure obviously does not capture usage not pursuant to a prescription. We have seen firsthand the strong potential for abuse of these drugs, which have now significantly surpassed other opioid analgesics, including Schedule II drugs of abuse such as oxycodone and morphine, in their legitimate and illegitimate utilization in California. We are also experiencing consistent and increasing trends in diversion and self-use of these drugs.

It seems obvious that HCPs belong in Schedule II. We support their rescheduling.

\(^1\) Data from the Controlled Substance Utilization Review and Evaluation System (CURES), California’s prescription drug monitoring program (PDMP) to which Schedule II-IV controlled substance prescriptions are reported.
Our only caution would be that you not make this decision suddenly and without some period of time for adjustment and transition. This may occur naturally as a consequence of the rulemaking process, but in the event the rulemaking proceeds relatively quickly, we would ask that you consider building in an adjustment period to allow those patients and practitioners (in long-term care settings, especially) making legitimate use of HCPs for pain management to make changes in their prescribing protocols that will be necessitated by this reclassification, and/or to consider a switch in their treatment plan to another medication or methodology of pain treatment.

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@dea.ca.gov.

Sincerely,

STANLEY C. WEISSER, R.Ph.
President, California State Board of Pharmacy
Attachment 6
Please be aware that effective August 18, Tramadol will move to Schedule IV in the Federal Controlled Substances Schedule. A link to the DEA's website where this action is formally listed is http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0702.htm

This classification also makes Tramadol a Schedule IV medication in California.

In California, the prescribing of C-IV drugs is governed by the Health & Safety Code, including section 111164. This means a California security prescription form will now be required to prescribe Tramadol in writing, just like any other Schedule IV medication. Additionally, oral orders for Tramadol, as a Schedule IV medication, are permitted.

California law provides that Schedule IV medications can be refilled according to the parameters specified in Health & Safety Code section 11200.

Also on August 18, the dispensing of Tramadol is required to be reported in CURES.

Patients with a new prescription for Tramadol written on or after August 18 need to be written on security paper or turned into an oral prescription by the pharmacy, which will require a confirming call to the prescriber's office.

An existing prescription for Tramadol with refills on file in a pharmacy can be refilled for up to six months from August 18, unless the refills indicated on the prescription run out sooner, or reach the quantity limits specified in Health & Safety Code section 11200.

To unsubscribe from this email list please click on the link below and follow the instructions on the web page.

https://www.dca.ca.gov/webapps/pharmacy/subscribe.php
SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, but they are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purposes of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, every controlled substance is classified in one of five schedules based upon its potential for abuse, currently accepted medical use, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR part 1308. Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, “add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by [21 U.S.C. 812(b)] for the schedule in which such drug is to be placed * * * *” The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA, 28 CFR 0.100, who in turn has redelegated that authority to the Deputy Administrator of the DEA, 28 CFR part 0, appendix to subpart R.

The CSA provides that scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary of the Department of Health and Human Services (HHS), or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action was initiated by four petitions to schedule tramadol under the CSA, and is supported by, inter alia, a recommendation from the Assistant Secretary of the HHS and an evaluation of all relevant data by the DEA. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule IV controlled substances on persons who handle or propose to handle tramadol.

Background

Tramadol is a centrally acting opioid analgesic that produces its primary opioid-like action through an active metabolite, referred to as the “M1” metabolite (O-desmethyltramadol). It was first approved for use in the United States by the U.S. Food and Drug Administration (FDA) in 1995 under the trade name ULTRAM®. Subsequently, the FDA approved for marketing generic, combination, and extended release tramadol products. Because of its chemical structure, 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol can exist as different isomeric forms. Thus, various prefixes can be associated with the name. Some examples of these prefixes include dextro, levo, d, l, R, S, cis, trans, erythro, threo, (+), (−), racemic, and may include combinations of these prefixes sometimes with numerical designations. Any such isomer is, in fact, 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol. Tramadol is typically formulated as a racemic mixture identified as (2)-cis-2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol hydrochloride.

HHS and DEA Eight-Factor Analyses

On September 16, 2010, the Assistant Secretary of the HHS provided to the DEA a scientific and medical evaluation and scheduling recommendation entitled “Basis for the Recommendation to Schedule Tramadol in Schedule IV of the Controlled Substances Act.” After considering the eight factors in 21

© 2014-2023, U.S. Government
U.S.C. 811(c), as well as the substance’s abuse potential, legitimate medical use, and dependence liability, the Assistant Secretary of the HHS recommended that tramadol be controlled in schedule IV of the CSA under 21 U.S.C. 812(b). The DEA conducted its own eight-factor analysis of tramadol pursuant to 21 U.S.C. 811(c). Both the DEA and HHS analyses are available in their entirety in the public docket for this rule (Docket No. DEA–351) at http://www.regulations.gov under “Supporting and Related Material.”

**Determination To Schedule Tramadol**

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from the HHS, the Deputy Administrator of the DEA published in the Federal Register a notice of proposed rulemaking (NPRM) entitled “Schedules of Controlled Substances: Placement of Tramadol Into Schedule IV” which proposed to place tramadol in schedule IV of the CSA. 78 FR 65923, Nov. 4, 2013. The proposed rule provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations by December 4, 2013. No requests for such a hearing were received by the DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposed rule on or before January 3, 2014.

**Comments Received**

The DEA received 27 comments on the proposed rule to schedule tramadol. Sixteen commenters expressed support for controlling tramadol as a schedule IV controlled substance, nine commenters were opposed to tramadol being placed into schedule IV of the CSA, and two commenters did not take a position.

**Support of the Proposed Rule**

Sixteen commenters supported controlling tramadol as a schedule IV controlled substance. Among those 16 commenters expressing support were two State Boards of Pharmacy. One veterinary distributor’s association stated that it supports the DEA designating tramadol as a schedule IV controlled substance because it will enable distributors to operate with efficiency and consistency across the United States along with requiring an increased level of due diligence and monitoring. A national veterinary medical association, a national healthcare association, and a national pharmacy association were also among those who expressed support for the rule.

Several commenters supporting the rule expressed their concern regarding the abuse potential and resulting threat to public health posed by tramadol. Writing in support of scheduling tramadol, a local multi-agency prescription drug abuse task force described tramadol as a “‘loop hole’ drug which is addictive, abused, and diverted,” but which is not yet realized as such by many patients and prescribers due to its current non-controlled status. One commenter stated that given the abuse potential of tramadol (which according to the commenter is often abused in combination with other controlled substances), scheduling this drug will ensure that it is subject to the same controls as other similarly addictive controlled substances. Yet another commenter noted that although analgesics are addictive to a very small percentage of people that use them, scheduling this drug would reduce the number of emergency room visits and number of overdose deaths.

A certified pharmacy technician described her experiences of witnessing the abuse of tramadol by patients on a daily basis. She stated the stricter controlled substance laws of the State of Mississippi have seemed to lessen the abuse. A group of pharmacy students noted that tramadol, marketed as ULTRAM®, is currently the only uncontrolled opioid on the market. Another commenter who supported the rule stated: “In the field of pharmacy, some patients have expressed concern about the reclassification of tramadol, believing that new regulations could complicate or impede new and chronic patients from receiving their prescriptions.” This commenter noted that this is a common misconception since schedule IV controlled medications are in fact readily available for those with a valid prescription and the appropriate medical condition. In addition, the commenter noted that these types of prescriptions also have the added convenience of being easily transferrable between pharmacies, phoned-in by prescribers, and refilled five times over a six month period.

**DEA Response:** The DEA appreciates the support for the rule.

**Opposition to the Proposed Rule**

1. Access to Pain Medication by the Elderly

An association for consulting pharmacists stated that controlling tramadol would limit access to needed pain medications for elderly patients and opposed the proposed scheduling until a workable solution to ensure timely access for patients in long-term care facilities (LTCFs) can be reached. Specifically, the commenter expressed concern that, should tramadol become a controlled substance, LTCF nurses would no longer be able to call-in or fax a chart order directly to the pharmacy. According to the commenter, in LTCFs, prescribers must call, hand deliver, or fax controlled substance prescriptions to pharmacies, and this in turn involves LTCF employees having to track down the (often non-employee) prescriber. This practice, according to the commenter, can severely impede delivery of prescription medications to LTCF patients.

**DEA Response:** The processes and procedures associated with dispensing a controlled substance are not relevant factors to the determination whether a substance should be controlled or under what schedule a substance should be placed if it is controlled. See 21 U.S.C. 811 and 812. Nonetheless, controlling tramadol as a schedule IV controlled substance should not hinder legitimate access to the medicine, whether within the LTCF setting or elsewhere. As summarized by a State Board of Pharmacy who wrote in support of controlling tramadol: “Scheduling a medication does not make it impossible to prescribe, dispense and administer the medication. However, it does alert practitioners, dispensers and perhaps even some patients that the medication has some potential dangers for addiction and misuse, and frequent monitoring and evaluation by practitioners and dispensers of such drugs is necessary for appropriate patient care.”

Currently, tramadol is a non-controlled medication that the FDA has approved only for prescription use. Tramadol, as a schedule IV controlled substance, will continue to require a prescription, either orally or in writing. 21 U.S.C. 829(b). The CSA allows for the legitimate prescribing and use of controlled substances; therefore, the control of tramadol should not hinder patient access to the medication. The prescription for tramadol, as a controlled substance, may only be issued by an individual practitioner who is either registered with the DEA or exempt from registration. 21 CFR 1306.03. A prescription for a controlled substance must also be issued for a legitimate medical purpose by an individual practitioner acting in the course of his professional practice. 21 CFR 1306.04(a). Upon the effective date of this rule, tramadol prescriptions may be filled up to six months after the date prescribed, and may be refilled up to
five times within six months after the date on which such prescription was issued. 21 U.S.C. 829(b); 21 CFR 1306.22 (a) and (e); see also 21 CFR 1306.23 (b) and (c). In addition, there are no dosage unit limitations for prescriptions for schedule III, IV, or V controlled substances unless the controlled substance is prescribed for administration to an ultimate user who is institutionalized. 21 CFR 1306.24(c).

The substantive requirement that a practitioner acting in the usual course of professional practice determine that tramadol is medically necessary to treat the patient does not hinder legitimate access; the procedural requirements relating to transmission of a legitimate prescription do not hinder legitimate access either. Once an individual practitioner makes a medical determination to prescribe a schedule III through V controlled substance, a prescriber’s agent may call-in or fax a prescription for it. See 21 CFR 1306.03(b), 1306.21(a). The DEA recognizes the unique challenges pertaining to handling and using controlled substances at LTCFs and has previously addressed related concerns. A DEA registered practitioner may not delegate to a nurse, a pharmacist, or anyone else his or her authority to make a medical determination whether to prescribe a particular controlled substance. However, oral prescriptions for controlled substances in schedules III-V may be communicated to a pharmacy by an employee or agent of the prescribing practitioner, 21 CFR 1306.03(b). Note that the prescribing practitioner remains responsible for ensuring that the prescription conforms “in all essential respects to the law and regulations,” 21 CFR 1306.05(f). 75 FR 61613, 61614, Oct. 6, 2010. This requires the practitioner alone to determine—on a prescription by prescription basis—whether the prescription is supported by a legitimate medical purpose and that all the essential elements of the prescription are met.

2. Fear of Criminal Action

Some commenters expressed concern that scheduling tramadol would deter prescribers from properly treating pain for fear of facing criminal action.

DEA Response: One of the most important principles underlying the CSA is that every prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. 21 CFR 1306.04(a); U.S. v. Moore, 423 U.S. 122 (1975) (holding registered physicians may be prosecuted for violation of the CSA when their activities fall outside the usual course of professional practice). The DEA Policy Statement entitled “Dispensing Controlled Substances for the Treatment of Pain,” 71 FR 52715 (Sept. 6, 2006), makes clear that this longstanding requirement should in no way interfere with the legitimate practice of medicine or cause any practitioner to be reluctant to provide legitimate pain treatment. Providers (as well as ultimate users) become subject to administrative, civil, and/or criminal proceedings when their activity involving controlled substances is not authorized by, or in violation of, the CSA.

3. Shift to the Black-Market

Several commenters stated that scheduling tramadol would limit their access to tramadol, causing them to have to buy tramadol on the street.

DEA Response: As discussed above, schedule IV controlled medications are readily available for legitimate medical use.

4. Scientific Data Not Sufficient

One commenter reviewed selected published literature and submitted a short review document with a conclusion that “the current available scientific evidence supports the continuation of a non-controlled classification” of tramadol.

DEA Response: The CSA mandates that both the HHS and DEA conduct a review of the drug or other substance as related to the eight factors enumerated in 21 U.S.C. 811(c): (1) Its actual or relative potential for abuse; (2) scientific evidence of its pharmacological effect, if known; (3) the state of current scientific knowledge regarding the drug or other substance; (4) its history and current pattern of abuse; (5) the scope, duration, and significant of abuse; (6) what, if any, risk there is to the public health; (7) its psychic or physiological dependence liability; and (8) whether the substance is an immediate precursor of a substance already controlled. The Assistant Secretary of the HHS provided a scientific and medical evaluation and a scheduling recommendation to control tramadol as a schedule IV controlled substance. In accordance with 21 U.S.C. 811(c), the DEA conducted its own analysis of the eight factors determinative of control. Besides published literature, various other data as detailed in the supporting documents were considered in making the scheduling determination for tramadol. Thus, the scheduling determination is based on a comprehensive evaluation of all available data as related to the above mentioned eight factors. The summary of each factor as analyzed by the HHS and the DEA, and as considered by the DEA in this scheduling action, was provided in the proposed rule. Both the DEA and the HHS analyses have been made available in their entirety under “Supporting and Related Material” of the public docket for this rule at http://www.regulations.gov under Docket No. DEA-351.

As discussed in detail in the DEA’s eight-factor analysis, collectively, the available information regarding tramadol supports an abuse potential that is less than that of schedule III and similar to that for schedule IV. Preclinical self-administration studies show that tramadol produces limited reinforcing effects, consistent with schedule IV. At supra-therapeutic doses, tramadol can produce subjective reinforcing effects similar to that of morphine (C–II) and approaching that of oxycodone (C–II). At high doses (but not therapeutic doses), tramadol can produce subjective reinforcing effects similar to propoxyphene (C–IV). For both tramadol and propoxyphene, the doses required to produce significant subjective reinforcing effects are in a range causing sufficient adverse effects. These observations indicate that the subjective reinforcing effects, a reflection of abuse potential, of tramadol are less than that of morphine or oxycodone, but similar to that of propoxyphene.

Based on the review of the HHS evaluation and scheduling recommendation and all other relevant data, the DEA has found that tramadol has an abuse potential and meets the requirements for schedule IV controls under the CSA.

5. Disagreement With Tramadol Classification as an Opioid

One commenter who supported the rule stated that tramadol should not be compared to hydrocodone because hydrocodone is an opioid and tramadol is psychotropic in nature and very similar to, if not the same as, a serotonin-norepinephrine reuptake inhibitor (SNRI).

DEA Response: In the NPRM and supporting documents, the DEA compared tramadol mainly to propoxyphene (narcotic schedule IV). Based on both the HHS and the DEA analyses, there is strong scientific evidence that tramadol and propoxyphene are similar regarding

---

4 E.g., “Preventing the Accumulation of Surplus Controlled Substances at Long Term Care Facilities,” 66 FR 20833, Apr. 25, 2001; “Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies,” 75 FR 61613, Oct. 6, 2010.
their behavioral pharmacology and
abuse potential pattern, thus suggesting
that it is appropriate to control tramadol
as a schedule IV controlled substance.

In addition, as stated in the
supporting scientific documents, both
the HHS and the DEA deem tramadol
to be an opioid because tramadol shares
similar pharmacological activities with
opioids that are controlled under the
CSA (schedules II–IV). (The labeling for
FDA approved tramadol products states
that tramadol is a centrally acting opioid
analgesic.) An examination of the
general pharmacology (including
behavioral pharmacology) of tramadol
reveals that tramadol produces many
pharmacological effects similar to those
of other opioids. These pharmacological
effects include, but are not limited to,
algesia, respiratory depression,
miosis, cough suppression, and
inhibition of bowel mobility, and as
such, tramadol is considered an opioid.
The opioid pharmacology of tramadol
primarily resides with its metabolite,
O-desmethyltramadol, designated “M1,”
and to a much lesser extent with
tramadol, the parent drug. In addition,
tramadol resembles some opioids
insofar as it has the additional
pharmacological effects of blocking the
reuptake of norepinephrine and
serotonin.

The CSA defines an “opiate” as “any
drug or other substance having an
addiction-forming or addiction-
sustaining liability similar to
morphine or being capable of conversion into
a drug having such addiction-forming or
addiction-sustaining liability.” 21 U.S.C.
802(18). Opium, opiates, derivatives of opium and opiates,
including their isomers, whether
produced directly or indirectly by
extraction from substances of vegetable
origin, or independently by means of
chemical synthesis, are “narcotic drugs”
as defined by the CSA. 21 U.S.C.
802(17). As discussed in the supporting
eight-factor documentation, preclinical
studies demonstrate that tramadol, as
other opioids in schedules I through IV,
exhibits complete generalization to
morphine and is able to produce some
reinforcing effects. Repeated
administration of tramadol in animals
caused dependence development,
evidenced by a withdrawal syndrome
similar in intensity to pentazocine
(schedule IV) or propoxyphene (narcotic
schedule IV).

Although, generally, the controls
imposed by the CSA on drugs and other
substances depend on the schedule into
which they are placed, there are certain
additional requirements and restrictions
for narcotic drugs. For example, narcotic
drugs in schedule III, IV, or V may not
be imported into the United States
unless it is found that such importation
is needed to provide for the legitimate
medical, scientific, or other legitimate
purposes under the specified, limited
circumstances described in 21 U.S.C.
952(a). Narcotic controlled substances
may not be exported unless the
conditions imposed by 21 U.S.C. 953(a)
are satisfied.

6. Never-Ending Practice of Drug
Scheduling

Two commenters raised concerns
that, despite the scheduling of drugs
such as tramadol, individuals will
always find substances to abuse, thus
creating “a never ending story of
scheduling drugs.”

DEA Response: Pursuant to 21 U.S.C.
811(a), the CSA authorizes the DEA,
under authority delegated by the
Attorney General, to add to such a
schedule any drug or other substance if
it is found that the drug or other
substance has a potential for abuse, and
makes with respect to such drug or
other substance the findings prescribed
by 21 U.S.C. 812(b). As such, the
scheduling authority established by
Congress specifically allows new
substances to be added to the list of
controlled substances without regard to
the number of substances already
controlled. See also 21 U.S.C. 812(a)
(“Such schedules shall initially consist of
**&*” (emphasis added)).

Requests for Staggered Implementation of Various Portions of the Rule

A national association that represents
primary healthcare distributors
commented that although they
recognized the underlying reasons for
scheduling tramadol and agreed with
the reasoning and basis for controlling
tramadol, the DEA should provide an
extended time period before
implementation to allow registrants to
become compliant with portions of the
rule regarding security, labeling and
packaging, and reporting. The
association requested that the
requirements for conducting inventory of
tramadol products within wholesale
distribution centers take place as of the
effective date of the final scheduling
decision. The association’s concerns (as
well as the DEA’s responses) are
outlined and discussed below.

1. Request for Staggered Effective Dates,
   Generally

   The association requested that the
   DEA implement handling requirements
   for tramadol in stages. For example,
   they requested that the requirement for
   conducting inventory of tramadol
   products within wholesale distribution
centers take place as of the effective date
   of the final scheduling decision but
delaying the requirements for
   compliance with the security
   provisions of 21 CFR 1301.71–1301.93.

   DEA Response: Generally, scheduling
   actions for drugs and other substances
   currently marketed in the United States
   are effective 30 days from the date of
   publication of the final rule in the
   Federal Register. In order to ensure the
   continued availability of tramadol for
   legitimate medical use, while also
   ensuring it is not subject to misuse,
   abuse, and diversion, the DEA is
   establishing an effective date of this
   final rule for all handling requirements
   45 days from the date of publication.
   This 45-day period will provide a
   reasonable time for registrants to
   comply with the handling requirements
   for a schedule IV controlled substance
   and was established upon a full
   consideration of the totality of
   circumstances specific to tramadol.

   Although the DEA has in the past, for
   some scheduling actions, allowed for
   additional time for compliance with
   certain handling requirements beyond
   the general effective date, the DEA has
   specifically chosen to forgo staggered
   implementation dates of handling
   requirements as different
   implementation dates lead to confusion
   and inconsistent application of the law.

2. Security

   The association recommended a
   minimum of 120 days from the date of
   the final rule to allow for compliance in
   order to provide storage, revise
   operating procedures, train staff, and
   amend monitoring systems.

   DEA Response: In order to ensure the
   continued availability of tramadol for
   legitimate medical use, while also
   ensuring it is not subject to misuse,
   abuse, and diversion, the DEA is
   establishing an effective date of this
   final rule, including security
   requirements, 45 days from the date of
   publication. Upon promulgation,
   registrants must comply with the
   applicable security provisions of 21 CFR
   1301.71–1301.93. This 45-day period
   will provide a reasonable time for
   registrants to comply with the security

---

3 Including their isomers, esters, ethers, salts, and
   salts of isomers, whenever the existence of such
   isomers, esters, ethers, and salts is possible within
   the specific chemical designation; however, does
   not include the isoquinoline alkaloids of opium.

4 Pursuant to 5 U.S.C. 553(d) and in accordance
   with 21 CFR 1308.45, a final rule scheduling a
   substance shall not be effective less than 30 days
   from the date of its publication in the Federal
   Register unless the Administrator finds that
   conditions of public health or safety necessitate an
   earlier effective date.
requirements for a schedule IV controlled substance. As noted by the 
association, it is believed that 
distributors of tramadol already have 
adequate space within their warehouse 
cages to store the anticipated volume of 
tramadol and “thus construction or 
expansion of cage space is unlikely to 
result.” Accordingly, it is 
reasonably likely that handlers and 
proposed handlers of tramadol have 
already instituted or made plans to 
institute the necessary modifications 
regarding security, including 
amendments to their suspicious orders 
monitoring systems to include tramadol 
orders. In order to provide handlers of 
tramadol a reasonable time period to 
comply with schedule IV handling 
requirements, including those for 
security, the DEA is allowing an 
additional 15 days, as compared to the 
generally allotted 30 days, from 
publication in the Federal Register 
before this rule becomes effective. After 
45 days from the date of the final rule, 
tramadol will be subject to schedule III– 
V security requirements.

The DEA has carefully considered the 
security requirements for compliance 
with this rule. As confirmed by the 
association, current distributors of 
tramadol are DEA registrants with 
existing controlled substance storage 
that complies with DEA regulations. 
The DEA understands that handlers of 
tramadol may need to make 
modifications to their current security 
procedures for compliance. These 
modifications necessary for security 
compliance will be a one-time 
modification to provide for the 
appropriate storage, revision of 
operating procedures, training of staff, 
and amendments to suspicious order 
monitoring systems to include customer 
verifications. The DEA believes that a 
45-day period will provide handlers of 
tramadol adequate time to implement 
these one-time modifications in 
compliance with the DEA security 
regulations. Registrants are familiar with 
the applicable security regulations, and 
already have systems in place with 
respect to other controlled substances. 
Accordingly, revising operating 
procedures, amending monitoring 
systems, and training staff with respect 
to tramadol should be easily 
accomplished within the 45-day 
compliance timeframe. The DEA 
strongly advises current registrants (and 
those entities that may seek registration 
as a result of this action) to work closely 
with their local DEA office regarding the 
applicable security requirements and 
any necessary modifications due to 
compliance with this rule. 21 CFR 
1301.71(d).

3. Distribution of Products With the Pre-
Control Label

The association stated that in 
accordance with 21 CFR 1302.05, the 
DEA has the authority to set a date on 
which labeling and packaging 
requirements will become effective, and 
requested clarification of when the 
distribution of products with the pre-
scheduling label should cease. The 
association also requested clarification 
as to whether the cessation of the 
manufacturer of products for commercial 
containers with the pre-scheduling 
labeling will also mean that 
manufacturers would be required to 
rename distribution to wholesale 
distributors of products they might have 
in stock bearing the pre-scheduling 
label. The association stated that the 
ambiguity of the compliance period 
poses a dilemma for those in the 
tramadol supply chain, and requested 
the DEA to act to meet healthcare needs 
and avoid waste by allowing products 
bearing the pre-scheduling label to 
move through the supply chain until the 
inventory is depleted. Alternatively, 
the association suggested that the DEA 
allow distributors to continue to sell 
pre-scheduling labeled product for at 
least 180 days after the effective date of 
the final rule.

**DEA Response: As of the effective** 
date of the final rule, pursuant to 21 
U.S.C. 821, 823, and 958(e) and in 
accordance with 21 CFR 1302.03, 
manufacturers are required to print 
upon the labeling of each commercial 
container of tramadol they distribute the 
designation of tramadol as “C–IV.” It 
shall be unlawful for commercial 
containers of tramadol to be distributed 
without bearing the label properly 
identifying it as a schedule IV 
controlled substance in accordance with 
21 CFR part 1302. As clearly stated in 
21 CFR 1302.05, “[a]ll labels on 
commercial containers of, and all 
labeling of, a controlled substance 
which either is transferred to another 
schedule or is added to any schedule 
shall comply with the requirements of 
§1302.03, on or before the effective date 
established in the final order for the 
transfer or addition.” Accordingly, the 
DEA is requiring that commercial 
containers of tramadol distributed on 
or after 45 days from the date of 
publishation of the final rule be labeled 
as “C–IV” and be packaged in 
accordance with 21 CFR part 1302.

From the 2007 Economic Census, the 
DEA estimates that the inventory 
turnover ratio for the industry 7 is 
approximately 11.3.⁸ The inventory 
turnover ratio represents the number of 
times the inventory sells (turns) in a 
year. The 11.3 inventory turnover ratio 
equates to an average of 32 days to sell 
inventory. The 11.3 turnover ratio is 
consistent with that of large distributors 
where financial information was 
publicly available and reviewed. 
Publicly reviewed data reports that 
about 85% of all revenues (an indirect 
indicator of dosage units moved) from 
drug distribution in the United States 
come from three public wholesalers, 
each with annual revenue in the 
billions. The DEA additionally notes 
that many regional and specialist 
pharmaceutical wholesalers have been 
acquired by the largest three 
distribution companies. The inventory 
turnover ratio is a reasonable estimate 
for the entire industry and all products 
under the circumstances. Because the 32 
days to sell inventory is an average 
based on industry-wide census data, it 
is possible for an individual company 
and/or product line to have shorter or 
longer time to sell.

Since tramadol is a widely prescribed 
drug, with nearly 40 million 
prescriptions written in 2012,⁹ the DEA 
expects distributors to receive and 
distribute tramadol at high volume and 
with regularity; thus, anticipating 
shorter than average days to sell 
tramadol than overall industry average 
inventory. However, to accommodate 
those distributors that have lower than 
average industry turnover ratio, the DEA 
is establishing an effective date of this 
final rule, including labeling and 
packaging requirements, 45 days from 
the date of publication. The DEA 
believes this will provide a reasonable 
time for distributors to sell existing 
stock with pre-control labeling and 
packaging and to stock inventory with 
post-control labeling and packaging.

Additionally, the DEA believes that 
any distributor that requires more than 
45 days to sell tramadol inventory under 
normal circumstances can make minor 
modifications to ordering and stocking 
procedure for a transitional period to 
meet the established effective date at 
minimal cost. Distributors also have the 
option of returning excess stock of 
tramadol product without the “C–IV”

---

⁷ NAICS 424210—Drugs and druggists’ sundries merchant wholesalers; Merchant wholesalers, 
except manufacturers’ sales branches and offices. 

⁸ The inventory turnover ratio is calculated by dividing the 2007 “cost of goods sold” for the industry of $280,481,051,000 by the 
average end-of-year 2006 total inventories of $24,782,835,000. 

⁹ IMS Health, National Sales Perspective™ (NSP).
label to the manufacturer, as authorized by 21 CFR 1307.12.

The DEA takes this opportunity to clarify that the regulation pertaining to labeling of commercial containers applies only to distributions by manufacturers and distributors. The DEA does not regulate the labeling and packing of commercial containers of controlled substances downstream of distributors.

As summarized in the NPRM, and discussed in detail in the supporting eight factor analyses, tramadol meets the statutory requirements for control and for placement in schedule IV. Based upon the reasons discussed above, the DEA believes that 45 days is a reasonable amount of time for registrants to modify their operations so that the necessary safeguards are in place to prevent the abuse and diversion of tramadol.

4. Automation of Reports and Consolidated Orders System (“ARCOS”) Reporting

The association stated that only schedule I and II (and some schedule III) products are subject to reporting under the DEA’s Automation of Reports and Consolidated Orders System (“ARCOS”), so it would be an error to require distributors to report tramadol (a schedule IV narcotic) to ARCOS.

DEA Response: DEA regulations do not require distributors to file ARCOS reports for schedule IV narcotics.

Scheduling Conclusion

Based on consideration of all comments, the scientific and medical evaluation and accompanying recommendation of the HHS, and based on the DEA’s consideration of its own eight-factor analysis, the DEA finds that these facts and all other relevant data constitute substantial evidence of potential for abuse of tramadol. As such, the DEA is scheduling tramadol as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA outlines the findings required for placing a drug or other substance in any particular schedule. 21 U.S.C. 812(b).

After consideration of the analysis and recommendation of the Assistant Secretary for Health of the HHS and review of all relevant and available data, the Deputy Administrator of the DEA, pursuant to 21 U.S.C. 812(b)(4), finds that:

1. Tramadol has a low potential for abuse relative to the drugs or substances in schedule III. The abuse potential of tramadol is comparable to the schedule IV controlled substance propoxyphene;

2. Tramadol has a currently accepted medical use in treatment in the United States. Tramadol and other tramadol-containing products are approved for marketing by the FDA to manage moderate to moderately severe pain; and

3. Abuse of tramadol may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

Based on these findings, the Deputy Administrator of the DEA concludes that tramadol, including its salts, isomers, and salts of isomers, warrants control in schedule IV of the CSA. 21 U.S.C. 812(b)(4).

Requirements for Handling Tramadol

Upon the effective date of this final rule, any person who handles tramadol is subject to the CSA’s schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, engagement in research, and conduct of instructional activities, of schedule IV controlled substances including the following:

Registration. Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities with) tramadol, or who desires to handle tramadol, must be registered with the DEA to conduct such activities, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312 as of August 18, 2014. Any person who currently handles tramadol and is not registered with the DEA must submit an application for registration and may not continue to handle tramadol as of August 18, 2014 unless the DEA has approved that application, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

Disposal of stocks. Any person who does not desire or is not able to obtain a schedule IV registration must surrender all quantities of currently held tramadol in accordance with the procedures outlined in 21 CFR 1307.21 on or before August 18, 2014, or may transfer all quantities of currently held tramadol to a person registered with the DEA on or before August 18, 2014.

Security. Tramadol is subject to schedule III–V security requirements and must be handled and stored pursuant to 21 U.S.C. 821 and 823, and in accordance with 21 CFR 1301.71–1301.93 as of August 18, 2014.

Labeling and Packaging. All labels and labeling for commercial containers of tramadol must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302 as of August 18, 2014.

Inventory. Every DEA registrant who possesses any quantity of tramadol on the effective date of this final rule must take an inventory of all stocks of tramadol on hand as of August 18, 2014, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11 (a) and (d).

Any person who becomes registered with the DEA after August 18, 2014 must take an initial inventory of all stocks of controlled substances (including tramadol) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including tramadol) on hand every two years, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Records and Reports. All DEA registrants must maintain records with respect to tramadol pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR parts 1304 and 1312 as of August 18, 2014.

Prescriptions. All prescriptions for tramadol or products containing tramadol must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of August 18, 2014.

Importation and Exportation. All importation and exportation of tramadol must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and be in accordance with 21 CFR part 1312 as of August 18, 2014.

Liability. Any activity involving tramadol not authorized by, or in violation of, the CSA, occurring as of August 18, 2014 is unlawful, and may subject the person to administrative, civil, and/or criminal action.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget
In accordance with the RFA, the DEA evaluated the impact of this rule on small entities. Specifically, the DEA examined the registration, storage, inventory and recordkeeping, and disposal requirements for the 367,046 small entities estimated to be affected by the rule: 55 manufacturers; 1,418 distributors/importers/exporters; 50,032 pharmacies; and 315,541 entities employing or holding registrations as individual practitioners/mid-level practitioners/hospitals/clinics. Ten States currently control tramadol as a schedule IV controlled substance under State law, with requirements that meet or exceed the DEA’s requirements for schedule IV controlled substances discussed in the NPRM. Entities in these States are not economically impacted by this rule.

Based on the DEA’s understanding of its registrants’ operations and facilities, the DEA estimates a non-recurring expense for system modification and initial inventory cost of $245,01 for all entities and an additional $10,000 for secure storage for 50% of distributors, importers, and exporters. As discussed in the EIA prepared in association with the development of this final rule, manufacturers, pharmacies, physician offices/hospitals/clinics/other health care facilities, and 50% of distributors, importers, and exporters are assumed to meet the requirement of the rule without the need to expand secure storage area. The DEA estimates these costs, on an annualized basis, will have significant economic impact (cost greater than 1% of annual revenue) on 0 of 55 (0%) of small manufacturers; 50 of 1,418 (3.5%) of small distributors; 107 of 50,032 (0.2%) small business pharmacies; and 661 of 315,541 (0.2%) of individual practitioners/mid-level practitioners/hospitals/clinics, totaling 818 of 367,046 (0.2%) of all small entities. The percentage of small entities with significant economic impact is not substantial, and therefore, this rule will not result in significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 et seq.), the DEA has determined and certifies pursuant to UMRA that this action would not result in 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 million or more (adjusted for inflation) in any one year * * * *". Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets. However, pursuant to the CRA, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

2. Amend § 1308.14 by adding a new paragraph (b)(3) to read as follows:

§ 1308.14 Schedule IV.

(3) 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers and salts of these isomers (including tramadol)—

9752
DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9674]

RIN 1545–BM07

Guidelines for the Streamlined Process of Applying for Recognition of Section 501(c)(3) Status

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations that provide guidance to eligible organizations seeking recognition of tax-exempt status under section 501(c)(3) of the Internal Revenue Code. These regulations also amend the requirements of section 508. The final and temporary regulations amend current regulations to provide a streamlined application process that eligible organizations may use to apply for recognition of tax-exempt status under section 501(c)(3). The text of the temporary regulations also serves as the text of the proposed regulations (REG–110948–14) set forth in the notice of proposed rulemaking published in the Federal Register, to meet the notice requirement of the Internal Revenue Code.

DATES: Effective date: These regulations are effective July 1, 2014.

Applicability date: For dates of applicability, see §§1.501(a)–1T(f)(1), 1.501(c)(3)–1T(h)(1), 1.508–1T(c)(1).

FOR FURTHER INFORMATION CONTACT: James R. Martin or Robin Ehrenberg at (202) 371–5800 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 508 requires an organization seeking tax-exempt status under section 501(c)(3), as a condition of its exemption, to notify the Secretary of the Treasury (or his delegate) that it is applying for recognition of exempt status in the manner prescribed in the Treasury Regulations, unless it is specifically excepted from the requirement. Section 1.508–1(a) describes the process for giving notice, and requires that an organization “submit[] a properly completed and executed Form 1023, exemption application.” Section 1.501(c)(3)–1(b)(1)(v) states that an organization must, to establish its exemption, submit a detailed statement of its proposed activities with and as a part of its application for exemption. Similarly, §1.501(a)–1(b)(1)(iii) provides that an organization described in section 501(c)(3) shall submit with, and as part of, an application, a detailed statement of its proposed activities. Section 1.501(a)–1(b)(2) states that the Commissioner may require any additional information deemed necessary for a proper determination of whether a particular organization is exempt, and when deemed advisable in the interest of an efficient administration of the internal revenue laws, the Commissioner may, in the cases of particular types of organizations, prescribe the form in which the proof of exemption shall be furnished.


Explanation of Provisions

The Treasury Department and the IRS have considered how the process of meeting the notice requirement of section 508 can be made more efficient for certain smaller organizations. The IRS is developing a streamlined form and process for these organizations. Accordingly, this Treasury decision amends §§1.501(a)–1, 1.501(c)(3)–1, and 1.508–1 to permit eligible organizations to use a streamlined process, described in guidance published in the Internal Revenue Bulletin, to meet the notice requirements of section 508.

Specifically, this Treasury decision amends §§1.501(a)–1 and 1.501(c)(3)–1 to authorize the Treasury Department and the IRS to prescribe, in applicable regulations or other guidance published in the Internal Revenue Bulletin, an exception to the requirement that an organization applying for tax-exempt status provide a detailed statement of its proposed activities. This document also amends the §1.501(a)–1 provisions relating to the Commissioner’s ability to retroactively revoke a determination because of a change in the law or regulations, or for other good cause, to reference the Commissioner’s authority to retroactively revoke a determination under section 7805(b). No substantive change is intended by this amendment.

This Treasury decision also amends the requirement in §1.501(a)–1(b)(3) that an organization claiming to be exempted from filing annual returns file a statement supporting its claim with and as a part of its application. This amendment would provide flexibility for the Treasury Department and the IRS to prescribe in published guidance other methods of notifying the IRS that the organization is claiming an annual filing exemption.

In addition, this document amends §1.508–1 to provide that eligible organizations may use Form 1023–EZ, “Streamlined Application for Recognition of Exemption Under Section 501(c)(3) of the Internal Revenue Code,” to notify the Commissioner of their applications for tax-exempt status under section 501(c)(3). This Treasury decision also amends §§1.501(a)–1 and 1.508–1 to state that the office to which applications should be submitted will be published in the Internal Revenue Bulletin or instructions to the Form 1023 or Form 1023–EZ.

Finally, this Treasury decision makes certain technical revisions to the regulations. In §1.501(a)–1, the reference to “internal revenue district” is removed because such reference has been made obsolete by the enactment of the Internal Revenue Service Restructuring and Reform Act of 1998, Public Law 105–206, 112 Stat. 685. References to a district director in §§1.501(a)–1, 1.501(c)(3)–1, and 1.508–1 are also modified, as those positions no longer exist within the IRS. Proposed regulations in the Rules and Regulations section of this issue of the Federal Register use the text of these temporary regulations as the text of the proposed regulations. Treasury and the IRS seek comments on all aspects of the proposed rules, including whether additional technical revisions are necessary. Simultaneously with the publication of this Treasury decision, the Treasury Department and the IRS will release for publication a Revenue Procedure that provides procedures for applying for recognition of exemption using Form 1023–EZ.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. For the applicability of the
Attachment 7
Patients interact with a healthcare system in various inpatient and outpatient settings, creating a constantly evolving medication list and opportunities for medication errors. Medication reconciliation is an iterative process in which the patient’s best possible medication list is documented, verified, and compared to the current list of prescribed medications with the intent of optimizing pharmaceutical care and reducing medication errors. The effect of this dynamic process on patient safety outcomes has been extensively evaluated, but the magnitude of benefit is variable. Inconsistent, incomplete, or inaccurate medication histories are well described in the literature, with clinically important error rates ranging from 11% to 59%. Without an accurate and complete medication history, it is impossible to conduct a clinically effective medication reconciliation. According to the Joint Commission’s National Patient Safety Goals (NPSGs), the foundation of meaningful medication reconciliation is the acquisition of a complete and accurate home medication history, documenting what a patient actually takes, within 24 hours of the first encounter for all admissions and at outpatient visits. The process to acquire the best possible medication history necessitates a structured patient interview and the use of additional sources for data verification. Clinicians face many challenges when trying to obtain a complete medication history, including a patient’s health literacy and knowledge of medications, as well as time limitations.

**Purpose.** The implementation and outcomes of a pharmacy technician medication history program are described.

**Summary.** An interprofessional medication reconciliation team, led by a clinical pharmacist and a clinical nurse specialist, was charged with implementing a new electronic medication reconciliation system to improve compliance with medication reconciliation at discharge and capture compliance-linked reimbursement. The team recommended that the pharmacy department be allocated new pharmacy technician full-time-equivalent positions to assume ownership of the medication history process. Concurrent with the implementation of this program, a medication history standard was developed to define rules for documentation of what a patient reports he or she is actually taking. The standard requires a structured interview with the patient or caregiver and validation with outside sources as indicated to determine which medications to document in the medication history. The standard is based on four medication administration category rules: scheduled, as-needed, short-term, and discontinued medications. The medication history standard forms the core of the medication history technician training and accountability program. Pharmacy technicians are supervised by pharmacists, using a defined accountability plan based on a set of medical staff approved rules for what medications comprise a best possible medication history. Medication history accuracy and completeness rates have been consistently over 90% and rates of provider compliance with medication reconciliation rose from under 20% to 100% since program implementation.

**Conclusion.** A defined medication history based on a medication history standard served as an effective foundation for a pharmacy technician medication history program, which helped improve provider compliance with discharge medication reconciliation.

*Am J Health-Syst Pharm.* 2014; 71:1567-74

**NOTE**

**Experience with a pharmacy technician medication history program**

**JULIE B. COOPER, MICHELLE LILLISTON, DEANNE BROOKS, AND BRUCE SWORDS**

Julie B. Cooper, Pharm.D., BCPS, is Clinical Pharmacist; Michelle Lilliston, Pharm.D., BCPS, is Clinical Pharmacist; and Deanne Brooks, Pharm.D., is Director of Pharmacy, Moses H. Cone Memorial Hospital, Cone Health, Greensboro, NC. Bruce Swords, M.D., Ph.D., is Chief Medical Information Officer, Cone Health.

Address correspondence to Dr. Cooper (julie.cooper@conehealth.com).

The authors have declared no potential conflicts of interest.

Copyright © 2014, American Society of Health-System Pharmacists, Inc. All rights reserved. 1079-2082/14/0902-1567. DOI 10.2146/ajhp130590
providers’ perceptions, interviewing patients is a reliable method of acquiring the best possible medication history.7-9 Medication lists documented in electronic medical records (EMRs), in claims databases, and by patients on standardized forms have not been shown to be reliable without additional patient interview.10-13 However, many health systems remain reluctant to invest resources in this patient safety initiative, and less-rigorous alternatives continue to be evaluated to fulfill minimum requirements for medication reconciliation.14,15

Obtaining an accurate medication history, which is the foundation for effective medication reconciliation, is a resource-intensive process, and the literature available on this topic provides little guidance on best practices for obtaining a complete medication history.1,15-19 As a result, the pharmacist often has to use his or her clinical judgment to determine the best method for collecting the most-relevant information.20

Identifying one person to own the role of documenting the best possible medication history has been proposed as a means of optimizing resource utilization by eliminating redundant efforts of multiple clinicians.21 Pharmacist involvement with medication reconciliation has been demonstrated to be cost-effective, but pharmacist resources are limited and expensive.3,20,22 With training, pharmacy technicians have been shown to effectively document the best possible medication history.23-25 Pharmacy technician training is challenging, and supervision in this decentralized role has not been well described. Pharmacy technician programs have used structured patient interviews, standardized forms, and pharmacist verification to ensure accuracy.23,26 Regardless of who documents the patients’ medication history, standardization and accountability of what medications to document in a best possible medication history are necessary to ensure a consistent, complete, and accurate medication history as a foundation for effective medication reconciliation.

This article describes the implementation of and experience with a pharmacy medication history program in which pharmacy technicians collect the best possible medication history for new admissions, surgical preadmissions, and emergency department (ED) visits for a five-hospital, 1035-bed community health system. This program is based on a structured interview process using a medication history standard that defines specific rules for which medications to document in the best possible medication history and is coupled with a defined process for pharmacy technician training and accountability.

Needs assessment

In 2005, an interprofessional medication reconciliation team consisting of nurses, pharmacists, hospital administrators, and a physician champion was charged with implementing a program to comply with the Joint Commission’s NPSG for medication reconciliation.5 At our institution, physicians are responsible for conducting medication reconciliation, but not all of them performed this task. A provider survey revealed that the primary reason physicians did not perform medication reconciliation was their perception of the poor quality of the medication history documented by nurses. To address this issue, the medication reconciliation team evaluated three models for obtaining the most complete patient medication history: nursing-only documentation, pharmacy technician documentation, and a blended model in which nurses documented the medication history and consulted a pharmacist to review the history in specific high-risk patients (patients taking more than 10 medications or taking antiretrovirals, anticoagulants, or antiseizure medications).

The team also created a medication reconciliation order form for physicians to use when conducting medication reconciliation on admission and at discharge.

In 2006, the blended model was selected as the preferred model for obtaining medication histories because it offered an incremental improvement in the quality of information gathered. The blended model was problematic, however, due to limited accountability and a lack of guidance provided to nurses about how to document a medication history. Wide variances in the quality of the medication histories remained despite pharmacist intervention in 10% of medication histories across the health system. Overall rates of medication reconciliation remained low with wide variability, from 80% for surgeons admitting patients for planned procedures to less than 20% for specialists caring for patients admitted via the ED. However, the health system maintained the blended model for medication history documentation due to the human resource cost associated with alternatives.

In 2008, an interprofessional heart failure core measures team consisting of physicians, nurses, pharmacists, and hospital administrators was created to develop an action plan for addressing major barriers to compliance with the Joint Commission’s heart failure core measures. Since 2006, the health system had developed reimbursement contracts linked to full compliance with specific Joint Commission core measures. In 2008, the system was failing to meet these standards due to the inability to comply with the medication reconciliation requirements for this patient population.27 Key barriers identified were the multiple medication history lists in patients’ charts and a lack of physician compliance with medication reconciliation at discharge. The heart failure core measures team reported to hospital administration
that without significant changes in the system’s medication reconciliation process, potential reimbursement would be lost.

As a result, in 2008, the interprofessional medication reconciliation team was reconvened, led by a clinical pharmacist and a clinical nurse specialist, with new administrative and physician champions. The team was charged with implementing a new electronic medication reconciliation system to improve compliance with medication reconciliation at discharge and capture compliance-linked reimbursement. In light of the challenges associated with the blended model for obtaining medication histories, the medication reconciliation team recommended that the pharmacy department be allocated new pharmacy technician full-time-equivalent (FTE) positions to assume ownership of the medication history process. The team believed that the use of pharmacy technicians would be a cost-effective strategy for improving the quality of medication histories. To ensure quality and accountability, the team developed specific standards for completing patient medication histories, which were approved by the medical staff.

**Resources obtained**

In 2008, the pharmacy department’s request for additional staff to conduct medication histories for the health system was based on the average time it took to complete a best possible medication history. Based on internal studies, it was determined that a single technician completing medication histories for admitted patients on multiple nursing units could complete, on average, 16 medication histories per shift. Thus, dividing the average admissions per day by 16 was the foundation of pharmacy technician FTE estimates. It was also determined that program implementation, training, and supervision of a systemwide pharmacy medication history program would require a minimum of one pharmacist FTE. In January 2009, the pharmacy department’s request for additional staff (total of four pharmacy technician FTEs) was approved. The technicians were responsible for completing admission medication histories for all nonsurgical admissions to Moses H. Cone Memorial Hospital, a 517-bed community teaching hospital and the flagship hospital for Cone Health.

After success with the initial implementation, the program was expanded with incremental FTE increases by campus. In 2010, 5 additional FTEs were allocated for completing telephone medication histories for presurgical patients. Rates of medication histories per shift were measured in a pilot study at an average of 20 medication histories per eight-hour shift; efficiency was limited by a nearly 50% rate of being unable to reach the patient on the first attempted telephone call. By the end of 2011, a total of 10.5 FTEs had been allocated for admission medication histories on all Cone Health campuses systemwide. In 2012, 17 additional FTEs were allocated for program expansion to all ED visits systemwide (four EDs) during hours when ED arrivals per hour were greater than four based on an average productivity of 25 medication histories per eight-hour shift. Efficiency was improved in this environment due to a lower average number of medications per patient and the close geographic proximity of patients.

Pharmacy now completes medication histories for all admitted inpatients, all surgical preadmissions, and a large proportion of ED visits within our five-hospital, 1035-bed community health system.

**Establishing standards**

Over the course of multiple inquiries into the quality of medication histories documented by nurses in our health system, the key quality barrier identified was the lack of a standard set of expectations regarding what should be documented on a patient’s home medication list on admission. As a result, we established a set of standards for documenting medication histories, which were compiled into a document called the medication history standard. Our goals were to establish accountability for completing a high-quality best possible medication history and improve patient safety.

It is not always feasible to obtain a complete list of a patient’s prescribed medications, especially when he or she arrives at the hospital during hours when physicians’ offices are closed. Documenting such a list is further complicated by the fact that most patients have multiple physicians and thus multiple lists of prescribed medications. Ultimately, most patients have two lists of medications—a prescribed list and a list of what the patient is actually taking. Focusing on what the patient actually takes protects the patient from adverse events resulting from admission orders for medications they are not taking and gives providers information on compliance on which to base management decisions on admission and education at discharge.

The interprofessional medication reconciliation team, in collaboration with community physicians, wrote the medication history standard that was subsequently approved by the pharmacy and therapeutics committee and the medical executive committee of Cone Health. The medication history standard requires a structured interview with the patient or caregiver and any necessary follow-up with other sources to determine which medications to document in the best possible medication history. Documented medications are defined under the following four categories: scheduled, as-needed, short-term, and discontinued medications.

Scheduled medications are medications the patient takes on a regular
NOTE  Medication history program

basis and are included on the list if the patient has taken a dose in the past 30 days. If a patient takes a medication with a frequency greater than monthly (e.g., medroxyprogesterone injections administered every three months), the medication will be included as a scheduled medication if a dose was taken within the period of that frequency.

As-needed medications taken within 30 days of hospitalization are also included in the medication history along with information about specific symptoms and frequency. A subcategory of as-needed medications called “emergency medications” was added shortly after program implementation, allowing for the documentation of specific emergency medications even if the patient had never used the medication. Examples of emergency medications used on an as-needed basis include sublingual or spray nitroglycerin, injectable epinephrine, and albuterol inhaler.

Short-term medications are taken on a regular basis for a brief duration (e.g., an antibiotic). If a patient has taken a dose of a short-term medication in the seven-day period before admission, it will be included in the best possible medication history with details about the start and planned stop dates.

Discontinued medications are medications recently taken in any of the three preceding categories, mentioned by a patient or still in his or her possession, that have been discontinued by a prescribing physician or intentionally by the patient for a specific reason (e.g., an intolerable adverse effect). If a patient indicates that a prescribing physician stopped a medication, the drug will not be included in the best possible medication history. If a patient indicates that he or she intentionally stopped a medication for a specific reason other than inability to acquire the medication, the medication will not be included in the best possible medication history.

Training and evaluation

The medication history standard forms the basis by which medication histories are measured for quality, as well as the foundation for training pharmacy technicians to obtain medication histories. Additional elements of the training program include detailed guidance on documentation, workflow, and performance expectations. The technicians begin their training with a half-day shadowing program in which they observe an experienced pharmacy technician obtaining patient medication histories. The program also includes a three-hour interactive lecture highlighting the medication history standard and key elements of a complete medication history. Initial skills demonstration is accomplished through a half day of simulated medication histories via role-playing with a pharmacist using standardized patient scripts. Each technician then performs a minimum of 10 directly observed medication histories. This phase of the training can be accomplished in less than a week. In the next phase of training, a pharmacist completes indirect observation for 100% of the technician’s medication histories and provides timely feedback until the measured rates of both accuracy and completeness exceed 90%.

An evaluation form was developed to assist the pharmacists with both direct and indirect observations of the technician’s performance (Figure 1). During direct observation, a pharmacist enters a patient’s room with a technician and observes the technician taking the best possible medication history. For indirect observation, a pharmacist reviews the medication history documented in the EMR after it has been completed. Accuracy is defined as the number of correctly documented medications divided by the total number of medications. Completeness is defined as the number of completed elements of a structured medication history interview divided by the total number of required elements.

Management of pharmacy technicians

In 2009, the first four pharmacy technicians volunteered to learn to take medication histories. Since program inception, the staff of medication history–trained technicians has grown through the hiring of new staff members and by training existing pharmacy technicians. The culture of integrated staffing in the department of pharmacy led to a natural rotation between dispensing and medication history roles. Integrated staffing maintains a sense of the pharmacy team and limits burnout. Key qualifications sought for new technician hires include strong communication skills, time management, work ethic, and computer skills. North Carolina does not require pharmacy technician certification, but Cone Health requires certification within one year of hire. In 2011, medication history taking was established as a new major work activity for pharmacy technicians, emphasizing the importance of the investment to train and supervise technicians in this function.

After the initial training period, all pharmacy technicians receive ongoing supervision of their performance in taking medication histories. For each technician, minimums of 10 directly observed histories and 20 indirectly observed histories are reviewed annually. The three objective measures for the evaluation of this activity are individual rates for accuracy, completeness, and volume of medication histories per shift. Direct and indirect observations are used to follow up on skill development. Technicians are given face-to-face feedback for directly and indirectly observed histories as well as quarterly reports detailing their performance measures. A team of clinical pharmacists, staffing an eight-hour medication history shift five days per week, supervises the technicians.
Figure 1. Evaluation form used by pharmacists to assist with both direct and indirect observations of pharmacy technician's performance when completing a medication history.

### Evaluation of Medication History

<table>
<thead>
<tr>
<th>Direct Observation Only</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Gel in/wash out (and observed other contact precautions as required)?</td>
<td></td>
</tr>
<tr>
<td>2. Acknowledged the patient and used 2 patient identifiers upon room entry?</td>
<td></td>
</tr>
<tr>
<td>3. Introduced himself/herself to patient and/or family/caregiver?</td>
<td></td>
</tr>
<tr>
<td>4. Explained intent, described duration based on number of meds and asked the patient if it would be OK to discuss home medications with others room?</td>
<td></td>
</tr>
<tr>
<td>5. Home medication entered into computer while in room with patient?</td>
<td></td>
</tr>
<tr>
<td>6. Used interpreter as necessary? Correctly determined need to use outside resources?</td>
<td></td>
</tr>
<tr>
<td>7. Asked if patient takes any other OTCs and/or herbal medications? Specifically asked about patches, creams, injectables, eye drops &amp; inhalers?</td>
<td></td>
</tr>
<tr>
<td>8. Asked open-ended questions? Asked adequate follow-up questions?</td>
<td></td>
</tr>
<tr>
<td>9. Observed MED RULE for SAD medications?</td>
<td></td>
</tr>
<tr>
<td>10. Thanked the patient and asked if he/she had questions before exiting room?</td>
<td></td>
</tr>
<tr>
<td>11. Used references for drug knowledge (e.g., had to look up a dose form, etc., via Micromedex, Epocrates, etc.)?</td>
<td></td>
</tr>
<tr>
<td>12. Correctly categorized medications for inclusion on medication history: Scheduled, PRN, Stepped &amp; Short Term.</td>
<td></td>
</tr>
<tr>
<td>13. Correctly identified and documented stopped medications.</td>
<td></td>
</tr>
<tr>
<td>14. Took history efficiently (average should be 5 meds in 7 minutes)?</td>
<td></td>
</tr>
</tbody>
</table>

### Direct or Indirect Observation: Completeness Rate: 10 = # of yes (15-24) / 10, or DO = # of yes (1-24) / 24

15. Documented allergies AND reactions? | | [yes] [no] |
16. Documented primary pharmacy & info source for each medication? | | [yes] [no] |
17. Documented last dose for each medication (and time for beta-blockers)? | | [yes] [no] |
18. Selected correct medication for each entry? Duplicate medications? | | [yes] [no] |
19. Documented indications and time-based frequency for each PRN medication? | | [yes] or N/A [no] |
20. "Additional instruction" comments adequate and appropriate? | | [yes] [no] |
21. All medications include doses, strengths, and frequencies? Corrected outpatient medication entered incorrectly? | | [yes] [no] |
22. Changed medication history status to "in progress" and marked as reviewed upon completion? | | [yes] [no] |
23. Follow up plan adequately documented? | | [yes] or N/A [no] |
25. Number of medications correct total number of medications (Accuracy Rate) | | | | |

Addtional Comments: | | [yes] [no] |

9/21/13 Cone Health
Technicians needing improvement are given an action plan along with individualized coaching by a pharmacist. Currently, over 80 technicians have successfully completed the medication history training program systemwide, and over 90% of the existing technician staff has been successfully trained to complete medication histories.

Based on structured evaluation, including both direct and indirect observations of technicians’ medication histories, the accuracy and completeness rates have remained consistently over 90%. In our largest facility (517 beds), medication histories are provided 24 hours per day for an average of 79 admissions, 60 surgical preadmissions, and over 200 ED visits daily. As of 2012, technicians completed an average of 21 medication histories per shift at an accuracy rate of 92.59% and a completeness rate of 92.18%.

In 2012, a new EMR was implemented, requiring complete staff reeducation on workflow and the syntax of medication history documentation. The rules for the standard remained unchanged. Accuracy and completeness rates fell below 80% during the first quarter of implementation but have since risen and remain above 90%. The maintenance of medication history quality through a medical record transition demonstrated the value of a medication history standard as the foundation for accountability and training.

**Challenges to establishing workflow**

In 2009, Cone Health had three distinct EMRs for the ED, inpatient setting, and ambulatory care clinics. None of these records allowed for easy identification of patients being admitted. Medication history staffing began with a single pharmacy technician completing best possible medication histories in the ED for patients who were to be admitted. Due to patient identification challenges, histories were primarily completed on the floor after admission. Admitted patients were identified by an e-mail that was automatically sent by the hospital registration system to a designated medication history inbox. As the program expanded and staff grew to more than one medication history technician per shift, designated work areas were established based on geographic location to optimize timely completion of best possible medication histories. The e-mail system was utilized as a communication tool for necessary follow-up (e.g., calling a patient’s pharmacy after it opened). Despite the challenging system limitations, the rate of patients whose best possible medication histories were not completed by pharmacy within 24 hours of admission was less than 1% in 2012.

Patient identification—a key limitation to program efficiency—was dramatically improved with the implementation of a single EMR. The status of the medication history was integrated into a universally accessible list of all inpatients, the ED track board, and the operating room schedule. Universal availability of the status of the medication history allows a team of medication history technicians working in remote geographic areas of the hospital to collaborate and complete best possible medication histories in a timely manner. Follow-up information is now documented directly on the medication history screen, making it easily accessible to all clinicians. Workflow challenges are now primarily linked to integrating an expanded staff of medication history technicians into an evolving workflow in a recently renovated and expanded ED and on multiple campuses.

**Program impact on medication reconciliation**

The metrics evaluated during initial implementation of the medication history program were rate of provider compliance with discharge medication reconciliation, provider time spent completing discharge medication reconciliation, and rate of compliance with heart failure core measures. Rates of provider compliance with medication reconciliation at discharge rose from 25% in 2006 to 89% in December 2010 and to over 90% in October 2011, despite the absence of an administrative utilization mandate for community physicians. When transitioning to the new EMR, the use of computerized prescriber order entry was mandated for all community physicians. Since the implementation of a new fully integrated EMR, health system rates of compliance with medication reconciliation have been 100%. In 2009, a single cardiology nurse practitioner recorded times for completion of discharge medication reconciliation for 20 patients before and after implementation, demonstrating a significant reduction in the total time for a complicated medical discharge (from 30 to 23 minutes [\( p = 0.007, \) Student’s \( t \) test]). Full compliance with the heart failure core measures rose from 84% in the quarter before implementation to 95% in the quarter after implementation and has since remained above 95% for the health system.

**Discussion**

After determining that the poor quality of the gathered medication histories was the key barrier to provider compliance with medication reconciliation, a pharmacy technician-driven medication history program was implemented. The program was built upon a compliance-based medication history standard written by an interprofessional group of pharmacists, physicians, and nurses.

After the implementation of a fully integrated EMR in 2012, the medication history standard required adaptation to accommodate the specific documentation syntax of the new system. Full pharmacy department ownership of medication history entry for the majority of ED visits
before EMR implementation facilitated the transition to computerized prescriber order entry by reducing the number of hard stops physicians encountered when entering admission orders. Standardization has also reduced the time pharmacists spend in order verification.

However, the lack of an established and nationally standardized definition of a best possible medication history has presented challenges with the new EMR. Specifically, the EMR does not allow for robust documentation of medications the patient is not taking or taking differently than prescribed. As a result, to protect patient safety in the inpatient setting, prescribed medications that the patient is either not taking or taking differently than prescribed must be reentered into the EMR. This workflow removes important audit information from easily accessible lists in the EMR (e.g., original prescription date, refills), increasing the time required for the ambulatory care clinician attempting to perform detailed medication reconciliation. Postimplementation optimization of the new EMR is ongoing to maximize patient outcomes across the continuum of care.

Establishing a highly accountable pharmacy medication history program was a complex, multifaceted process with many challenges and setbacks. It took four years to convince our health system of the value of a high-quality best possible medication history as the cornerstone of patient safety. Physician leadership systemwide has been essential for program implementation and expansion. Provider utilization of electronic tools was key to the ultimate clinical utility of a best possible medication history documented by pharmacy. The lack of resources allocated for provider training slowed implementation. The success of the pharmacy medication history program at this health system lies not only in standardization but also in accountability. The exceptional pharmacy technician staff of our health system have stepped up and grown dramatically since program inception. Pharmacists’ ownership of best possible medication history accountability and ongoing role in medication reconciliation have also been critical to maintaining quality. The best possible medication history is at the heart of medication safety; taking the time to recruit, train, and retain the right technicians has been a sound investment.

In the rapidly evolving healthcare marketplace, the importance of patient safety and optimizing pharmaceutical care cannot be overemphasized, as the rate of errors is high without a system in place for prevention, especially in the ED.1,17-19 Without standardization of the documented best possible medication history, it may be difficult to demonstrate the clinical utility and cost-effectiveness of medication reconciliation.2,22 Our health system is currently evaluating the cost benefit of our standardized best possible medication history service for all ED arrivals. Regardless of the outcome of this analysis, the Joint Commission requires that a medication history be documented for all patients on arrival at the health system.3 Medication histories that are inconsistently and incorrectly documented may result in risk adverse events, especially in fully integrated EMRs.15,16,20 A standardized best possible medication history documented once in a timely manner for each patient reduces redundancy and patient confusion and gives accurate information to the ED provider, an important decision-maker regarding the use of healthcare resources. Utilizing pharmacy technicians to staff this program significantly reduces the cost per medication history.20,28 The investment in pharmacy technician FTEs to ensure a standardized best possible medication history for all patients has dramatically improved provider compliance with medication reconciliation.

Conclusion
A defined medication history based on a medication history standard served as an effective foundation for a pharmacy technician medication history program, which helped improve provider compliance with discharge medication reconciliation.

References
Attachment 8
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

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

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

For questions regarding this draft document contact CDER Office of Compliance at 301-796-3100 or drugtrackandtrace@fda.hhs.gov.

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

October 2014
Procedural
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

Additional copies are available from:
Office of Communications
Division of Drug Information, WO51, Room 2201
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Silver Spring, MD 20993
Phone: 301-796-3400; Fax: 301-847-8714
druginfo@fda.hhs.gov

and/or
Office of Communication, Outreach and Development, WO71, Room 3128
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Silver Spring, MD 20993
Phone: 800-835-4709 or 240-402-7800
ocod@fda.hhs.gov

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

October 2014
Procedural
TABLE OF CONTENTS

I. INTRODUCTION ............................................................................................................. 1
II. BACKGROUND ............................................................................................................... 2
III. QUESTIONS AND ANSWERS ....................................................................................... 3
    A. Product Tracing ............................................................................................................... 3
    B. Wholesale Drug Distributor Standards and Licensing .................................................. 4
    C. Third-Party Logistics Provider Standards and Licensing .............................................. 5
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

This draft guidance, when finalized, will represent the Food and Drug Administration’s (FDA’s) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

The Food and Drug Administration (FDA) is issuing these questions and answers to assist industry and State and local governments in understanding the effects of section 585 (Uniform National Policy) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) added by Title II of the Drug Quality and Security Act (DQSA), which was enacted on November 27, 2013. Title II, which is also referred to as the Drug Supply Chain Security Act (DSCSA), establishes a Federal system for tracing prescription drug products through the pharmaceutical distribution supply chain and requires trading partners to pass, receive, and maintain certain product and distribution information. The DSCSA also requires FDA to establish Federal standards for licensing of wholesale drug distributors and third party logistics providers; the Agency is currently drafting these regulations. Section 585 sets forth a uniform national policy preempting States from establishing or continuing in effect certain standards and requirements.

FDA is issuing this guidance to (1) help industry and States understand the immediate effects of the law and (2) clarify section 585’s effect on State product tracing and standards and requirements for wholesale distributor and third-party logistics provider (3PL) licensing.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should

1 This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

2 For brevity, in this guidance, references to section 585 of the FD&C Act are cited as section 585.

3 Section 585 uses the phrase “State and political subdivision of a State.” For purposes of this document, the word States will mean States and political subdivisions of States.
be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

On November 27, 2013, the DSCSA (Title II of Public Law 113-54) was signed into law. The DSCSA outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. The DSCSA adds sections 581 through 585 as Subchapter H of the FD&C Act. These sections establish definitions (section 581), requirements for supply chain participants (section 582), standards for and licensing of wholesale drug distributors (section 583) and third-party logistics providers (section 584), and a Uniform National Policy (section 585).

Section 585, as added by section 205 of the DQSA, states:

(a) PRODUCT TRACING AND OTHER REQUIREMENTS.—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable under section 503(e) (as amended by such Act) or this subchapter (or regulations issued thereunder), or which are inconsistent with—

(1) any waiver, exception, or exemption pursuant to section 581 or 582; or

(2) any restrictions specified in section 582.

(b) Wholesale Distributor and Third-Party Logistics Provider Standards—

(1) IN GENERAL.—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under section 503(e) (as amended by such Act), in the case of a wholesale distributor, or section 584, in the case of a third-party logistics provider.

(2) State Regulation of Third-Party Logistics Providers.—No State shall regulate third-party logistics providers as wholesale distributors.
III. QUESTIONS AND ANSWERS

A. Product Tracing

1. How does section 585(a) affect State tracing requirements?

Beginning on November 27, 2013, the date of enactment of the DSCSA, States were preempted from establishing or continuing in effect any requirements for tracing prescription drugs through the pharmaceutical distribution supply chain that are inconsistent with, more stringent than, or in addition to any requirements applicable under section 503(e) of the FD&C Act (21 U.S.C. 353(e) (as amended by the DSCSA)) or Subchapter H (added by the DSCSA) or regulations issued thereunder.

Section 585 enumerates the types of requirements that States are preempted from establishing or continuing in effect in any manner that is inconsistent with, more stringent than, or in addition to Federal law, including: statements of distribution history, transaction history, transaction information, or transaction statement of a product as the product changes ownership in the supply chain, verification, investigation, disposition, notification, or recordkeeping relating to the distribution systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system.

In addition, no State may establish, continue in effect, or apply any requirement that is inconsistent with any waiver, exception, or exemption granted by FDA pursuant to sections 581 or 582 of the FD&C Act or any restrictions specified in section 582.

2. What product tracing requirements apply before January 1, 2015?

Prior to January 1, 2015, the Federal pedigree requirements of section 503(e)(1) of the FD&C Act, remain in effect. Therefore, until January 1, 2015, States may not regulate tracing in any way that is inconsistent with, more stringent than, or in addition to the requirements of section 503(e)(1) of the FD&C Act.

3. What product tracing requirements apply on or after January 1, 2015?

Beginning January 1, 2015, the Federal tracing requirements of section 582 of the FD&C Act established under the DSCSA, go into effect. After that date, States may not regulate tracing in any way that is inconsistent with, more stringent than, or in addition to those requirements.

4. Which State requirements are preempted?

Any requirements for tracing drugs through the pharmaceutical distribution supply chain that are inconsistent with, more stringent than, or in addition to any requirements applicable under section 503(e) of the FD&C Act, as amended by the DSCSA, or under subchapter H (or regulations issued thereunder) are preempted.
B. Wholesale Drug Distributor Standards and Licensing

1. How does section 585(b) affect State wholesale drug distributor standards and licensing?

Beginning on November 27, 2013, States were preempted from establishing or continuing any standards, requirements, or regulations with respect to wholesale distributor licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards or requirements applicable under section 503(e) of the FD&C Act (as amended by the DSCSA). Thus, States may not impose standards, requirements, or regulations with respect to wholesale drug distributors that fall below the minimum standards established by Federal law.

2. Will States need to change their wholesale drug distributor licensing laws before the new Federal wholesale drug distributor regulations take effect?

Each State will have to analyze its own laws to determine the impact of section 585; however, FDA understands that, in general, the current Federal standards, requirements, and regulations have been the basis for most current State laws. Therefore it is likely those State laws would not fall below the minimum standards established by federal law and would not need to be changed.

The new wholesale drug distributor regulations issued under section 583 will take effect two years after they are finalized by FDA. By that time, States should have reanalyzed their licensing laws in order to determine if those laws fall below the minimum standards established by federal law.

3. Can States continue to license wholesale drug distributors before the new Federal regulations for wholesale drug distributor standards and licensing go into effect?

Yes. States can continue to license wholesale drug distributors before the regulations issued according to section 583 (as added by 204 of the DSCSA) become effective, as long as the State regulations are not inconsistent with, less stringent than, directly related to, or covered by Federal law. The DSCSA contemplates that states will continue to license wholesale drug distributors before the new regulations go into effect. For example, section 503(e)(1)(A) (as amended) requires a wholesale drug distributor to 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. In addition, the distributor must be licensed by the State into which the drug is distributed (if required by that State).

4. What wholesale drug distributor standards and licensing requirements apply after the new Federal regulations go into effect?

When the new Federal licensure regulations of the FD&C Act become effective (see section 583(a), (e)), States will be preempted from continuing or establishing licensure in any way that

---

4 Please refer to section 583(b) of the FD&C Act for additional information on content requirements for wholesale drug distributor licensing standards.
C. Third-Party Logistics (3PL) Provider Standards and Licensing

1. How does section 585(b) affect 3PL standards and licensing?

Beginning on November 27, 2013, States are preempted from establishing or continuing any standards, requirements, or regulations with respect to 3PLs that are inconsistent with, less stringent than, directly related to, or covered by the standards or requirements applicable under section 584 of the FD&C Act. Thus, States may not impose standards, requirements, or regulations with respect to 3PLs that fall below the minimum standards established by Federal law.

2. Can States license 3PLs before the new Federal regulations for 3PL standards and licensing go into effect?

Yes. States can license 3PLs before the new Federal regulations issued according to section 584 become effective. The DSCSA contemplates that States can license 3PLs before the new Federal regulations become effective. For example, section 584(b) of the FD&C Act requires 3PLs to report “the State by which the facility is licensed” beginning 1 year after the date of enactment of the DSCSA.

3. What 3PL standards and licensing requirements apply after Federal regulations go into effect?

Once the new Federal licensing regulations for 3PLs become effective (see section 584(d)), States will be preempted from continuing or establishing licensure in any way that falls below the minimum standards established by those regulations. When the final regulations are published, States will know whether they need to change any standards, requirements, or regulations that they may have established that are inconsistent with, less stringent than, directly related to, or covered by those Federal regulations.

5 The licensing regulations for wholesale drug distributors are to be issued not later than 2 years after the date of enactment of the Drug Supply Chain Security Act (section 583(a)); the final regulation will take effect “2 years after the date that such final regulation is published” (section 583(e)(3)).

6 Please refer to section 584(d)(2)(C) – (H) of the FD&C Act for additional information on content requirements for third-party logistics provider licensing standards.

7 The licensing regulations for 3PLs are to be issued not later than 2 years after the date of enactment of the Drug Supply Chain Security Act (section 584(d)(1)); the final regulation will take effect “1 year after the date that such final regulation is issued” (section 584(d)(3)(C)).
4. Can States license 3PLs using their licensing program for wholesale drug distributors?

Section 585(b)(2) does not permit states to license 3PLs as wholesale drug distributors. States would need to establish separate licensing programs for wholesale drug distributors and 3PLs.
Attachment 9
October 1, 2014

Hon. William F. Rylaarsdam, Acting Presiding Justice
Hon. William W. Bedsworth, Associate Justice
Hon. Richard D. Fybel, Associate Justice
Court of Appeal of the State of California
Fourth Appellate District, Division Three
601 West Santa Ana Blvd.
Santa Ana, CA 92701

RE: Request for Publication

Tue Ngoc Hoang v. California State Board of Pharmacy
California Court of Appeal, Fourth Appellate District Division Three, Case No. G049275

Honorable Justices:

Pursuant to California Rules of Court, rule 8.1120, Respondent California Board of Pharmacy, Department of Consumer Affairs (“Board”), respectfully requests publication of the Court’s opinion in this case, filed September 12, 2014. The Board’s request meets the standards for certification of Court of Appeal opinions set forth in rule 8.1105, subdivisions (c)(2), (c)(4) and (c)(6) because the Court’s opinion involves legal issues of continuing public interest, applies an existing rule of law to a set of facts significantly different from those stated in published opinions and clarifies an existing statute. A copy of the Court’s opinion is attached to this request.

The Board of Pharmacy is responsible for enforcing statutes and regulations concerning pharmacy practice and the effective delivery of dangerous drugs and controlled substances to the general public. While the Board of Pharmacy serves an important public function, there are very few published opinions involving the enforcement of pharmacy law in disciplinary proceedings against pharmacists. Over the past 70 years, there are less than a dozen such opinions and there were only two such published cases in the last 20 years (Smith v. State Bd. of Pharmacy (1995) 37 Cal.App.4th 229 and Angelier v. State Board of Pharmacy (1997) 58 Cal.App.4th 592).
I. THE COURT’S OPINION INVOLVES LEGAL ISSUES OF CONTINUING PUBLIC INTEREST

The Court’s opinion should be published because it involves legal issues of continuing public interest pursuant to California Rules of Court, rule 8.1105(c)(6). It is often argued in disciplinary cases that since there was no harm to the public, revocation is too severe a penalty. A similar argument was raised by the plaintiff in this case, who argued that revocation is “reserved only for dangerous conduct that threatens the safety of the public.” Whether the maximum penalty of revocation requires a showing that the conduct threaten public safety and what conduct is considered a threat to public safety are questions that are of continuing public interest. The Court’s decision is the first time these questions were directly answered in a Board of Pharmacy case.

The Court’s opinion rejected the plaintiff’s argument that revocation is only reserved for dangerous conduct that threatens the safety of the public and affirmed the Board’s authority to suspend or revoke a license for professional dishonesty without the qualification that revocation requires the existence of physical harm, or even an identifiable injured victim. The proposition that the existence of a victim is not required was espoused in Hughes v. Board of Architectural Examiners (1998) 68 Cal.App.4th 685, but has not been addressed in a Board of Pharmacy case.

To dispel the possible argument that disciplinary matters against health care professionals may not fall within the purview of Hughes, the Court’s opinion extends the Hughes holding that the existence of a victim is not required for license revocation to a health care professional.

In addition, the Court’s opinion noted that the Board’s Disciplinary Guidelines did not require the existence of specific factors or combination of factors for imposition of the minimum or maximum penalty. As such, the Court’s opinion emphasizes the Board’s discretion in setting the penalty for the unprofessional conduct of its licensees, including revocation of licensure.

II. THE COURT’S OPINION APPLIES AN EXISTING RULE OF LAW TO A SET OF FACTS SIGNIFICANTLY DIFFERENT FROM THOSE STATED IN PUBLISHED DECISIONS

Another reason for the Court’s opinion to be published is that the opinion applies an existing rule of law to a set of facts significantly different from those stated in published decisions, pursuant to California Rules of Court, rule 8.1105(c)(2).

The Court’s opinion applies the existing rule of law that authorizes the Board to discipline its licensees for unprofessional conduct to the unique facts of this case, that is, fraudulent conduct alone. Disciplinary proceedings before the Board typically involve violations for errors in filling prescriptions or the mishandling of drugs, which could adversely affect a patient’s health and safety. Yet, the charges in this case are based on fraud (dishonesty) alone.
Smith v. State Bd. of Pharmacy (1995) 37 Cal.App.4th 229 is the only published case involving a disciplinary matter before the Board that alleged dishonesty as a cause for discipline. However, the allegations against the pharmacist also included excessive furnishing of controlled substances and the death of a patient from an overdose, in addition to the dishonesty charged for removing pharmacy records from the pharmacy without the owner’s knowledge in order to conceal evidence of a patient's death. The primary issue in the case was whether the dispensing pharmacist could be disciplined for ordinary negligence; the dishonesty charged was not the crux of the case.

As such, if published, the Court’s opinion will be the only published Board of Pharmacy case that involves discipline for fraud, independent of any findings of direct patient harm or discrepancies in filling prescriptions.

III. THE COURT’S OPINION ADVANCES A NEW INTERPRETATION, CLARIFICATION, CRITICISM OR CONSTRUCTION OF A PROVISION OF A CONSTITUTION, STATUTE, ORDINANCE OF COURT RULE

Finally, the Court’s opinion should be published because it clarifies the provisions of Government Code section 11517(c)(2)(E)(ii), pursuant to California Rules of Court, rule 8.1105(c)(4). The plaintiff in the instant case argued that due process required another hearing after the Board rejected the administrative law judge’s proposed decision and before the Board’s issuance of its final decision and order. The Court’s opinion confirms that due process does not require another hearing and that the provisions of Government Code section 11517(c)(2)(E)(ii) are not unconstitutional.
For the foregoing reasons, the California Board of Pharmacy requests publication of the Court’s opinion in this case.

Sincerely,

JAMES M. LEDAKIS
Supervising Deputy Attorney General

MARICHELLE S. TAHIMIC
Deputy Attorney General

For KAMALA D. HARRIS
Attorney General

MST:
SD2013706304/70956189.doc

cc: Ismail Amin, Esq.
IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA
FOURTH APPELLATE DISTRICT
DIVISION THREE

TUE NGOC HOANG,

Plaintiff and Appellant,

v.

CALIFORNIA STATE BOARD OF PHARMACY,

Defendant and Respondent.

Appeal from a judgment of the Superior Court of Orange County, Kirk H. Nakamura, Judge. Affirmed.

The Amin Law Group, Ismail Amin, Saehwa Kang, and Katherine J. Vescera for Plaintiff and Appellant.

Kamala D. Harris, Attorney General, Alfredo Terrazas, Assistant Attorney General, Linda K. Schneider and Marichelle S. Tahimic, Deputy Attorneys General, for Defendant and Respondent.
PlaintiffTueNgocHoang,apharmacistdoingbusinessasOrangePharmacy(Orange),appealsfromajudgmentdenyinghispetitionforawritofmandate. ThepetitionsoughttooverturnadecisionbydefendantCaliforniaStateBoardofPharmacyrevokingplaintiff’spharmacylicenseandOrange’spermittooperateapharmacy.Plaintiffarguesdefendant’sdecisionwasundulyharsh,notsupportedbythefindings,anddeniedhimdueprocess.Wedisagreeandaffirmthejudgment.

FACTS AND PROCEDURAL BACKGROUND

Plaintiff heldapharmacylicenseissuedbydefendantandwastodoing businessasOrangeunderapermitdefendantissuedtoit. AsOrange’spharmacist-in­charge,plaintiffwasresponsiblefortheopharmacy’scompliancewiththelawsand regulationsconcernedwiththeoperationofthebusiness. (Bus. & Prof. Code, § 4113, subd. (c).)


A fifth count alleged plaintiff had engaged in dishonest, fraudulent or deceitful conduct. The Accusation alleged that during 2005 and 2006, Orange was not authorized to receive payments from CalOptima, an entity administering Medi-Cal benefits in Orange County, for filling qualified patients’ drug prescriptions. Orange nonethelessunlawfullyreceivednearly$150,000inCalOptimapaymentsthroughacovertarrangementwithanotherpharmacynamedPacificPharmacy(Pacific).

Anadministrativelawjudg(eALJ)conductedathreedayhearingonthe Accusation. Plaintiff appeared throughcounsel, butdidnotpersonallyattendthehearing. TheALJissuedaproposeddecisionfindingtheunlawfuldrugtransferand
documentation allegations unsupported by the evidence, but that Orange engaged in “dishonest conduct” concerning CalOptima payments for which plaintiff was “personally responsible.”

The ALJ’s decision cited the following evidence in support of the finding of dishonesty and fraud. Prior to 2005, plaintiff had a contract with the pharmacy benefits manager (PBM) that processed prescription drug claims for patients covered by CalOptima. That year CalOptima imposed a new condition, which required each pharmacy contracting with its PBM to permit on-site reviews of its operations as part of a fraud prevention program.

Pacific agreed to the new on-site review condition, but plaintiff objected to it and refused to renew his contract with CalOptima’s PBM. In April, CalOptima notified plaintiff that it had terminated Orange’s authorization to seek payment for filling its patients’ drug prescriptions.

To retain the patronage of Orange’s Medi-Cal patients, plaintiff entered into a surreptitious arrangement with Que Buu, Pacific’s pharmacist in charge, whereby Orange used Pacific’s billing authority to obtain payment for filling the drug prescriptions of persons covered by CalOptima. Under the arrangement, Orange created a set of labels containing its name, address, and phone number for each CalOptima-qualified patient for whom it filled a prescription. Orange sent Pacific a record of having filled the prescription and Pacific then created a duplicate set of prescription labels for the same patients. Using its label, Pacific applied to CalOptima’s PBM for payment, thereby representing to the PBM that it had filled the prescription. Upon receiving payment from CalOptima for the drug prescriptions actually filled by Orange, Pacific then funneled the money to Orange. Both pharmacies maintained records of the prescriptions Orange sent to Pacific for collection, the reimbursements Pacific received from the PBM, and the payments Pacific made to Orange. To foster an appearance of legitimacy for this
arrangement, Orange and Pacific also created documents such as refill pharmacy contracts, purchased and borrowed logs, returned to stock memoranda, and labels that incorrectly stated that prescriptions had been transferred.

At the hearing, defendant presented evidence that, between July and December 2005, payments from CalOptima’s PBM to Pacific increased from approximately $43,000 to over $73,000. One of defendant’s inspectors estimated 38 percent of Pacific’s reimbursements from CalOptima between August 2005 and November 2006 were for Orange-filled prescriptions. He prepared a tabulation of invoices Orange had provided to Pacific for billing CalOptima that totaled over $149,000.

During a September 2006 inspection of Pacific, one of defendant’s inspectors discovered a log for Orange’s prescriptions. Buu acknowledged the existence and purpose of the arrangement between Orange and Pacific. Subsequently, defendant’s inspectors visited Orange and spoke with Paul Hoang, plaintiff’s son and the pharmacy’s business manager.

Hoang testified at the hearing, claiming Orange and Pacific “[w]ere acting as refill pharmacies” for each other, “including . . . CalOptima patients.” He stated, “We never believed that what we did was wrong or dishonest.” But Buu contradicted Hoang, admitting Pacific billed CalOptima for drug prescriptions filled by Orange and denied Orange acted as a refill pharmacy for Pacific in 2005 and 2006.

In his proposed decision, the ALJ recommended plaintiff’s pharmacy license and Orange’s permit be revoked, but the revocations be stayed for five years with both placed on probation with certain conditions. Defendant timely issued an order of nonadoption of the ALJ’s proposed decision and stated it would decide the matter based on the record produced during the administrative hearing along with written argument from the parties.

After receiving briefs from both parties, defendant issued its decision revoking plaintiff’s license and Orange’s permit. Defendant’s factual findings largely
repeated the ALJ’s findings. Citing its disciplinary guidelines, defendant found plaintiff’s conduct constituted a Category III violation, which includes “fraudulent acts committed in connections with the licensee’s practice.” The minimum level of discipline for a Category III violation is revocation, stayed, three to five years probation, and 90 days of actual suspension. The maximum discipline is license revocation. Similar levels of discipline apply to a pharmacy permit.

Defendant gave the following explanation for revoking the license and permit: “In order to determine the appropriate measure of discipline, it is necessary to weigh and balance [plaintiff’s] violations of law as well as factors in justification, aggravation, or mitigation. Protection of the public is the Board’s highest priority. . . . [¶] [Plaintiff], as the owner and pharmacist-in-charge of Orange Pharmacy, is responsible for the dishonest and fraudulent acts attributable to both licenses. The cause for discipline proven is serious and demonstrates [plaintiff’s] willingness to commit dishonest acts for his own financial gain. In aggravation, these acts were also not isolated incidents, but rather occurred several times over many months and involved deliberate acts to deceive a public benefits program. These acts also demonstrate that [plaintiff] refused to abide by standards set by a county-organized integrated health care system in deliberate disregard of the public policy set by an agency acting on behalf of the public. Although [plaintiff and Orange] have, so far, had an unblemished history with the Board, these violations call into question [plaintiff’s] judgment and trustworthiness. His failure to acknowledge the violations and submit evidence that he accepts responsibility is troubling. The Board is also concerned about the lack of any evidence of remorse or the submission of any evidence that [plaintiff] had undergone any sort of rehabilitation with respect to his conduct. Without such evidence, the Board cannot offer assurances that such conduct might not repeat and that [plaintiff and Orange] are safe to practice with or without restriction.”
Plaintiff filed a petition for a writ of administrative mandamus in the superior court and obtained a temporary stay of the license and permit revocations. After a hearing, the trial court, exercising its independent judgment, denied the petition, terminated the stay imposed on defendant’s license and permit revocation order, and denied plaintiff’s request for a further stay pending this appeal. Plaintiff sought to extend the stay by filing a petition for a writ of supersedeas in this court, but we denied relief.

DISCUSSION

Plaintiff notes defendant’s disciplinary guidelines contain a list of 15 factors it must consider in determining the level of discipline to impose. He claims a review of these factors “shows that revocation . . . was a grossly disproportionate penalty under the circumstances” and thus defendant’s “decision was not supported by its findings.” Alternatively, he contends defendant’s decision to reject the ALJ’s proposed decision and issue its own ruling resulted in a denial of constitutional due process because he and Orange “were not afforded a final hearing before their license and permit were subsequently revoked . . . .” Plaintiff’s arguments lack merit.

This appeal involves a writ seeking relief from an adverse administrative proceeding under Code of Civil Procedure section 1094.5. That statute provides, “The inquiry in such a case shall extend to the questions whether the respondent has proceeded without, or in excess of, jurisdiction; whether there was a fair trial; and whether there was any prejudicial abuse of discretion. Abuse of discretion is established if the respondent has not proceeded in the manner required by law, the order or decision is not supported by the findings, or the findings are not supported by the evidence.” (Code Civ. Proc., § 1094.5, subd. (b).) “Where it is claimed that the findings are not supported by the evidence, in cases in which the court is authorized by law to exercise its independent
judgment on the evidence, abuse of discretion is established if the court determines that the findings are not supported by the weight of the evidence.” (Code Civ. Proc., § 1094.5, subd. (c).)

Defendant is authorized to bring formal disciplinary proceedings against anyone holding a pharmacy license. (Bus. & Prof. Code, § 4300, subds. (b), (e); Gov. Code, §§ 11500 et seq.) Thus, it had the jurisdiction to consider whether plaintiff’s actions warranted revocation of his pharmacy license. (Bus. & Prof. Code, § 4300, subds. (a) [“Every license issued may be suspended or revoked”], (b) [“The board shall discipline the holder of any license . . . whose case has been heard by the board and found guilty”].)

Also, the procedure employed in this case was the manner provided by law for conducting a disciplinary action. Business and Professions Code section 4300, subdivision (e) declares disciplinary proceedings shall be conducted under the Administrative Procedures Act (Gov. Code, § 11500 et seq.). Government Code section 11517, subdivision (c)(1) authorizes “a contested case” to be “originally heard by an administrative law judge.” After the ALJ issues his or her proposed decision, “[t]he agency may” take one of five courses of action. One alternative is “Reject the proposed decision, and decide the case upon the record, including the transcript . . . with or without taking additional evidence.” (Gov. Code, § 11517, subd. (c)(2)(E); see Kifle-Thompson v. State Bd. of Chiropractic Examiners (2012) 208 Cal.App.4th 518, 531 [“the Board was well within its jurisdiction to reject the ALJ’s proposed decision, and render its own decision based ‘upon the record, including the transcript . . . with or without taking additional evidence[]’” and “[o]nce the Board determined not to adopt the proposed decision, that decision served no ‘identifiable function in the administrative adjudication process or, for that matter, in connection with the judicial review’ of that process”].)

Plaintiff’s claim the foregoing procedure violated his and Orange’s right to due process of law and denied them a fair trial is incorrect. In Gore v. Board of Medical
Quality Assurance (1980) 110 Cal.App.3d 184, a physician, was charged with having engaged in gross negligence, but after a hearing, an ALJ exonerated him. The defendant board rejected this proposed decision, made a finding of gross negligence, and suspended the plaintiff’s license. On appeal, the plaintiff asserted the very same argument made in this case. The appellate court rejected it. “There is no merit in petitioner’s claim that the administrative procedure prescribed by section 11517, subdivision (c) of the Government Code is unconstitutional because it authorizes respondent board to decide the case for itself if the proposed decision by the administrative judge is not adopted. [¶] The requirements of due process of law are fully met where, as here, the licensee was accorded judicial review of the administrative decision in which the court weighed the evidence and rendered its independent judgment on the merits. [Citations.]” (Id. at p. 190.)

In this case, the ALJ conducted a three-day evidentiary hearing and then issued a proposed decision that defendant chose not to adopt. Government Code section 11517, subdivision (c)(2)(E)(ii) allowed defendant to receive additional briefing from the parties and redecide the matter and reach a different conclusion even though its decision is based on the evidence previously introduced during the administrative hearing. Finally, defendant’s ruling was subject to independent review by the superior court under Code of Civil Procedure section 1094.5. Plaintiff and Orange were accorded due process and a fair trial in this case.

Plaintiff argues his right to maintain his existing pharmacy license and Orange’s right to retain its permit to operate a pharmacy constitute fundamental rights. We agree. (San Benito Foods v. Veneman (1996) 50 Cal.App.4th 1889, 1896-1897 [food processor’s license a fundamental right; “While the administrative agency’s decision had a purely economic effect on plaintiff . . ., the nature of the right itself was crucial to plaintiff’s economic viability”].) In this circumstance, “the superior court exercises its
independent judgment upon the evidence disclosed in a limited trial de novo in which the court must examine the administrative record for errors of law and exercise its independent judgment upon the evidence.” (JKH Enterprises, Inc. v. Department of Industrial Relations (2006) 142 Cal.App.4th 1046, 1057.) But in doing so, “a trial court must afford a strong presumption of correctness concerning the administrative findings, and the party challenging the administrative decision bears the burden of convincing the court that the administrative findings are contrary to the weight of the evidence.” (Fukuda v. City of Angels (1999) 20 Cal.4th 805, 817.)

The trial court expressly stated in its statement of decision that it exercised its independent judgment in ruling on the petition and found defendant’s decision was supported by “the weight of the evidence.” On appeal, “[e]ven when . . . the trial court is required to review an administrative decision under the independent judgment standard of review, the standard of review on appeal of the trial court’s determination is the substantial evidence test. [Citations.]” (Fukuda v. City of Angels, supra, 20 Cal.4th at p. 824.)

The balance of plaintiff’s argument concerns the propriety of defendant’s decision to revoke his license and Orange’s permit. Although plaintiff repeatedly asserts he does not believe he did anything wrong, his appellate briefs do not even provide a summary of the evidence, much less explain why it fails to support defendant’s findings.

As noted, defendant is authorized by statute to determine whether to suspend or revoke a pharmacist’s license where it finds the licensee has engaged in unprofessional conduct. (Bus. & Prof. Code, §§ 4300, subd. (a).) Unprofessional conduct includes “any act involving moral turpitude, dishonesty, fraud, deceit, or corruption.” (Bus. & Prof. Code, § 4301, subd. (f).) We review a claim an administrative agency imposed excessive discipline for abuse of discretion. “‘In reviewing the severity of the discipline imposed, we look to the correctness of the
agency’s decision rather than that of the trial court.’ [Citation.] ‘“The penalty imposed by an administrative body will not be disturbed in mandamus proceedings unless an abuse of discretion is demonstrated. [Citations.] Neither an appellate court nor a trial court is free to substitute its discretion for that of the administrative agency concerning the degree of punishment imposed. [Citation.]” [Citation.] [¶] “In reviewing the exercise of this discretion we bear in mind the principle ‘courts should let administrative boards and officers work out their problems with as little judicial interference as possible . . . . Such boards are vested with a high discretion and its abuse must appear very clearly before the courts will interfere.’”’ [Citation.] ‘The policy consideration underlying such allocation of authority is the expertise of the administrative agency in determining penalty questions.’ [Citation.]” (Cassidy v. California Bd. of Accountancy (2013) 220 Cal.App.4th 620, 633.)

There was no abuse of discretion here. The guidelines state “[n]o single one or combination of the . . . factors is required to justify the minimum and/or maximum penalty in a given case,” and that the recommended discipline for the categories of violations “assume a single violation of each listed statute or regulation.” Thus where, as here, there are “multiple violations, the appropriate penalty shall increase accordingly.” With the assistance of another pharmacy, plaintiff, as Orange’s pharmacist-in-charge, intentionally created an elaborate scheme that allowed Orange to repeatedly skirt CalOptima’s requirement that it participate in the agency’s fraud prevention program in order to be authorized to seek payment for filling the drug prescriptions of qualified patients. The evidence supports a finding that not only did Pacific use its prescription labels to obtain payment for prescriptions filled by Orange, the two pharmacies also created false documents to assist in covering up their scheme.

Plaintiff argues he did not financially benefit from the scheme. We disagree. The fraudulent use of Pacific’s billing authority to receive payments from
CalOptima allowed plaintiff and Orange to retain the patronage of Medi-Cal patients who otherwise would have likely filled prescriptions through another pharmacy.

He also claims license revocation “is reserved only for dangerous conduct that threatens the safety of the public.” But plaintiff cites no authority for this proposition and, in fact, the law is to the contrary. In upholding a board’s decision to revoke an architect’s license for fraud, deceit, and willful misconduct, *Hughes v. Board of Architectural Examiners* (1998) 68 Cal.App.4th 685 declared: “We are unwilling to hold, as plaintiff’s arguments would require, that the Board is precluded from revoking a person’s license . . . absent a showing of actual harm to a client,” in part because it “would be contrary to the commonsense notion that one with a demonstrated history of professional dishonesty in the past may well act in accordance with that history in his professional dealings in the future. There is nothing in the law or in logic that requires the existence of a victim . . . before the Board may order a license revoked as part of its effort to protect the people of California from unscrupulous conduct” (*id.* at p. 693).

In addition, plaintiff never presented any evidence reflecting he was remorseful for his behavior or that he had made efforts to obtain counseling. In fact, he continues to insist, contrary to the findings of both the ALJ and defendant, the scheme of falsely representing to CalOptima’s PBM that Pacific had filled prescriptions actually filled by Orange, was not wrong. Defendant found plaintiff’s “failure to acknowledge the violations and submit evidence that he accepts responsibility [to be] troubling,” and expressed “concern[] about the lack of any evidence of remorse or the submission of any evidence that [plaintiff] had undergone any sort of rehabilitation with respect to his conduct.” Contrary to plaintiff’s argument, the consideration of his lack of remorse or proof of rehabilitation was appropriate. (*Hanna v. Dental Bd. of California* (2012) 212 Cal.App.4th 759, 767 [no abuse of discretion where board revoked license in part finding licensee’s “unwillingness to admit any wrongful acts, and her failure to establish that she
had undergone any rehabilitation demonstrated that the public could not be adequately protected unless appellant’s license was revoked”).

   Given these factors, we conclude defendant properly exercised its discretion in revoking plaintiff’s pharmacy license and Orange’s permit.

   DISPOSITION

   The judgment is affirmed. Respondent shall recover its costs on appeal.

   RYLAARSDAM, ACTING P. J.

   WE CONCUR:

   BEDSWORTH, J.

   FYBEL, J.
Attachment 10
The National Transportation Safety Board (NTSB) is an independent federal agency charged by Congress with investigating every civil aviation accident in the United States and significant accidents in other modes of transportation—railroad, highway, marine, and pipeline. We determine the probable cause of the accidents and issue safety recommendations aimed at preventing future accidents. In addition, we carry out special studies concerning transportation safety and coordinate the resources of the federal government and other organizations to provide assistance to victims and their family members affected by major transportation disasters. We are providing the following information to urge the state of California to take action on the safety recommendations being issued in this letter.

On September 9, 2014, we adopted our safety study, *Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment*. Additional information about this topic and the resulting recommendations may be found in the study, which can be accessed at our website, [http://www.ntsb.gov](http://www.ntsb.gov), under report number SS-14/01.

As a result of this safety study, we issued six new recommendations, including four recommendations to the Federal Aviation Administration and the following two recommendations to the 50 states (including the state of California), the District of Columbia, and the Commonwealth of Puerto Rico:

**I-14-1**

Include in all state guidelines regarding prescribing controlled substances for pain a recommendation that health care providers discuss with patients the effect their

---

medical condition and medication use may have on their ability to safely operate a vehicle in any mode of transportation.

I-14-2

Use existing newsletters or other routine forms of communication with licensed health care providers and pharmacists to highlight the importance of routinely discussing with patients the effect their diagnosed medical conditions or recommended drugs may have on their ability to safely operate a vehicle in any mode of transportation.

An informational article that could be distributed to fulfill Safety Recommendation I-14-2 is enclosed for your consideration.

Acting Chairman HART, and Members SUMWALT, ROSEKIND, and WEENER concurred in these recommendations.

The NTSB is vitally interested in these recommendations because they are designed to prevent accidents and save lives. We would appreciate receiving a response from you within 90 days detailing the actions you have taken or intend to take to implement them. When replying, please refer to the safety recommendations by number. We encourage you to submit your response electronically to correspondence@ntsb.gov. If it exceeds 10 megabytes, including attachments, please e-mail us at the same address for instructions. Please do not submit both an electronic copy and a hard copy of the same response.

By:

Enclosure

cc: Ms. Kimberly Kirchmeyer
    Executive Director
    Medical Board of California

    Louise Bailey, MEd, RN
    Executive Officer
    California Board of Registered Nursing

    Ms. Virginia Herold
    Executive Officer
    California Board of Pharmacy

    Ms. Angelina M. Burton
    Executive Director
    Osteopathic Medical Board of California
Evidence That Pilots Are Increasingly Using Over-the-Counter, Prescription, and Illicit Drugs

The National Transportation Safety Board (NTSB) recently analyzed toxicology tests from 6,677 pilots who died in a total of 6,597 aviation accidents between 1990 and 2012. The results demonstrate a significant increase in the use of a variety of potentially impairing drugs.

The study found significantly increasing trends in pilots’ use of all drugs, potentially impairing drugs (those with a US Food and Drug Administration warning about sedation or behavior changes in routine use), controlled substances, and illicit drugs (those defined as Schedule I by the US Drug Enforcement Administration). The final report, Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment, is available on the NTSB’s Safety Studies web page under report number SS-14/01.

In this study, the pilot was considered to be positive for a drug if it could be qualitatively or quantitatively identified in blood or tissue; drugs identified only in urine or used as part of resuscitative efforts were excluded.

Overall, 98% of the study pilots were male and 96% were flying privately rather than for commercial purposes. The average age of study pilots increased from 46 to 57 years over the study period.

Over the course of the study, for fatally injured pilots, the following was found:

- The proportion of pilots testing positive for at least one drug increased from 10% to 40%.

- More than 20% of all pilots from 2008-2012 were positive for a potentially impairing drug, and 6% of all pilots were positive for more than one potentially impairing drug.

- Overall, the most common potentially impairing drug pilots had used was diphenhydramine, a sedating antihistamine (the active ingredient in many Benadryl and Unisom products).

- During the most recent 5 years studied, 8% of all pilots tested positive for controlled substances; hydrocodone and diazepam each accounted for 20% of the positive findings.

- The percentage of pilots testing positive for marijuana use increased to about 3% during the study period, mostly in the last 10 years.

The large increase in the proportion of fatally injured pilots with evidence of potentially impairing drugs suggests an increasing risk of impairment in general aviation. Aviation is the only transportation mode in which a fatally injured operator (pilot) routinely undergoes extensive toxicology testing; no similar testing is routinely performed for fatally injured operators of boats, trains, trucks, or cars. Given the general increase in drug use in the population, it is likely that there has been a similar trend in drug use among operators across all modes of transportation.
These results highlight the importance of routine discussions between health care providers and pharmacists and their patients about the potential risks that drugs and medical conditions can create when patients are operating a vehicle in any mode of transportation.
Attachment 11
## Strategic Planning: Enforcement

<table>
<thead>
<tr>
<th>Success Indicators</th>
<th>Related Performance Measures</th>
<th>Acceptance Percentage</th>
<th>Actual Percentage Green Light Status</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A Complete all desk investigations within 120 days.</td>
<td>[CP, CC, EF, QE, RC]</td>
<td>〇 93%</td>
<td>▼ 74% 〇 75% ▼ 71%</td>
<td>This goal decreased 6% over last quarter due to a 73% increase in caseload.</td>
</tr>
<tr>
<td>1B Open all complaints within 10 days.</td>
<td>[CP, CC, EF, QE, RC]</td>
<td>〇 90%</td>
<td>▼ 76% 〇 75% 〇 99%</td>
<td></td>
</tr>
<tr>
<td>1C Review all investigations within 30 days.</td>
<td>[CP, CC, EF, QE, RC]</td>
<td>〇 97%</td>
<td>n/a</td>
<td>Under Development</td>
</tr>
<tr>
<td>1D Complete all field investigations within 120 days.</td>
<td>[CP, CC, EF, QE, RC]</td>
<td>〇 94%</td>
<td>▼ 74% 〇 75% ▼ 47%</td>
<td>Due to the high volume of sterile compounding inspections this quarter this goal was not met.</td>
</tr>
<tr>
<td>1E Close all Board investigations and mediations within 180 days.</td>
<td>[CP, CC, EF, QE, RC]</td>
<td>〇 97%</td>
<td>▼ 94% 〇 93% ▼ 52%</td>
<td>This goal showed a 1% improvement over last quarter. Due to the high volume of sterile compounding inspections this quarter this goal was not met.</td>
</tr>
<tr>
<td>1F Issue citations and fines within 30 days.</td>
<td>[CP, CC, EF, QE, RC]</td>
<td>〇 96%</td>
<td>▼ 92% 〇 91% ▼ 55%</td>
<td>Due to the number of cases to be split and issued there was a delay in issuing citations.</td>
</tr>
</tbody>
</table>
## Strategic Planning: Enforcement

<table>
<thead>
<tr>
<th></th>
<th>Objective</th>
<th>Responsible Parties</th>
<th>Status</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1G</td>
<td>Issue letters of admonishment within 30 days.</td>
<td>CP, CC, EF, QE, RC</td>
<td>98%</td>
<td>61%</td>
</tr>
<tr>
<td>1H</td>
<td>Complete all field investigations for cases involving drug abuse within 60 days.</td>
<td>CP, HE, QE, RC</td>
<td>98%</td>
<td>%</td>
</tr>
<tr>
<td>1I</td>
<td>Refer all cases to the AG’s office within 10 days.</td>
<td>CP, QE, RC</td>
<td>97%</td>
<td>93%</td>
</tr>
<tr>
<td>1J</td>
<td>Secure pleadings from AG’s office within 90 days after referral.</td>
<td>CP, QE, RC</td>
<td>96%</td>
<td>27%</td>
</tr>
<tr>
<td>1K</td>
<td>Inspect 100 percent of all licensed facilities once every three years by June 30, 2015.</td>
<td>CP, QE, RC</td>
<td>90%</td>
<td>n/a</td>
</tr>
<tr>
<td>1L</td>
<td>Review draft pleadings within 30 days.</td>
<td>CP, QE, RC</td>
<td>90%</td>
<td>7%</td>
</tr>
<tr>
<td>1M</td>
<td>Perform quarterly status reports for all referral cases pending.</td>
<td>CP, QE, RC</td>
<td>90%</td>
<td>20%</td>
</tr>
<tr>
<td>1N</td>
<td>Secure mail votes on all decisions within 30 days of receipt.</td>
<td>[CP, QE, RC]</td>
<td>97%</td>
<td>91%</td>
</tr>
<tr>
<td>1O</td>
<td>Complete petitions to revoke probation cases within 30 days.</td>
<td>[CP, QE, RC]</td>
<td>98%</td>
<td>95%</td>
</tr>
<tr>
<td>1P</td>
<td>Quarterly evaluate 5% of the Pharmacist Recovery Program (PRP) participants to ensure the PRP Contractor is in compliance with the contract.</td>
<td>[CP, QE, RC]</td>
<td>98%</td>
<td>95%</td>
</tr>
<tr>
<td>1Q</td>
<td>Pursue disciplinary action, within 10 days, on a licensee closed a public risk from the Pharmacists Recovery Program.</td>
<td>[CP, QE, RC]</td>
<td>98%</td>
<td>95%</td>
</tr>
</tbody>
</table>
1A. Complete all desk investigations within 120 days.
(Recorded as number of cases submitted)

![Bar chart showing the number of completed desk investigations by quarter and fiscal year.]

1B. Open all consumer complaints within 10 days.
(Recorded as number of cases opened)

![Bar chart showing the number of opened consumer complaints by quarter and fiscal year.]

1C. Review all investigations within 30 days.
(Recorded as number of cases reviewed)

1D. Complete all field investigations within 120 days.
(Recorded as number of cases submitted)
1E. Close all Board investigations and mediations within 180 days.  
(Recorded as number of cases closed)

1F. Issue citations and fines within 30 days.  
(Recorded as number of citations issued)
1G. Issue letters of admonishment within 30 days.  
(Recorded as number of letters of admonishment issued)

1H. Complete all field investigations for cases involving drug abuse within 60 days.
11. Refer all cases to the AG’s Office within 10 days.
(Recorded as number of cases referred)

1J. Secure pleadings from AG’s Office within 90 days after referral.
(Recorded as number of pleadings received)
1K. Inspect 100 percent of all licensed facilities once every three years by June 30, 2015.

1L. Review draft pleadings within 30 days.
   (Recorded as number of pleadings filed)
1M. Perform quarterly status reports for all referral cases pending.
(Recorded as number of cases pending over 90 days.

1N. Secure mail votes on all decisions within 30 days of receipt.
(Recorded as number of decisions received for mail vote)
10. Complete petitions to revoke probation within 30 days.
(Recorded as number of cases submitted)

1P. Quarterly evaluate 5% of the Pharmacist Recovery Program (PRP) participants to ensure the PRP Contractor is in compliance with the contract.
(Recorded as number of participants in the PRP.)
1Q. Pursue disciplinary action, within 10 days, on a licensee closed a public risk from the Pharmacists Recovery Program. (Recorded as number of participants closed a public risk)
<table>
<thead>
<tr>
<th>Workload Statistics</th>
<th>July-Sept</th>
<th>Oct-Dec</th>
<th>Jan-Mar</th>
<th>Apr-June</th>
<th>Total 14/15</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Complaints/Investigations</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Received</td>
<td>636</td>
<td></td>
<td></td>
<td></td>
<td>636</td>
</tr>
<tr>
<td>Closed</td>
<td>855</td>
<td></td>
<td></td>
<td></td>
<td>855</td>
</tr>
<tr>
<td>4301 letters</td>
<td>19</td>
<td></td>
<td></td>
<td></td>
<td>19</td>
</tr>
<tr>
<td>Pending (at the end of quarter)</td>
<td>1604</td>
<td></td>
<td></td>
<td></td>
<td>1604</td>
</tr>
<tr>
<td><strong>Cases Assigned &amp; Pending (by Team) at end of quarter</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compliance / Routine Team</td>
<td>748</td>
<td></td>
<td></td>
<td></td>
<td>748</td>
</tr>
<tr>
<td>Drug Diversion/Fraud</td>
<td>340</td>
<td></td>
<td></td>
<td></td>
<td>340</td>
</tr>
<tr>
<td>Probation/PRP</td>
<td>65</td>
<td></td>
<td></td>
<td></td>
<td>65</td>
</tr>
<tr>
<td>Mediation/Enforcement **</td>
<td>113</td>
<td></td>
<td></td>
<td></td>
<td>113</td>
</tr>
<tr>
<td>Criminal Conviction</td>
<td>335</td>
<td></td>
<td></td>
<td></td>
<td>335</td>
</tr>
<tr>
<td><strong>Application Investigations</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Received</td>
<td>210</td>
<td></td>
<td></td>
<td></td>
<td>210</td>
</tr>
<tr>
<td>Closed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Approved</td>
<td>93</td>
<td></td>
<td></td>
<td></td>
<td>93</td>
</tr>
<tr>
<td>Denied</td>
<td>16</td>
<td></td>
<td></td>
<td></td>
<td>16</td>
</tr>
<tr>
<td>Total ***</td>
<td>145</td>
<td></td>
<td></td>
<td></td>
<td>145</td>
</tr>
<tr>
<td>Pending (at the end of quarter)</td>
<td>181</td>
<td></td>
<td></td>
<td></td>
<td>181</td>
</tr>
<tr>
<td><strong>Letter of Admonishment (LOA) / Citation &amp; Fine</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOAs Issued</td>
<td>43</td>
<td></td>
<td></td>
<td></td>
<td>43</td>
</tr>
<tr>
<td>Citations Issued</td>
<td>320</td>
<td></td>
<td></td>
<td></td>
<td>320</td>
</tr>
<tr>
<td>Total Fines Collected ****</td>
<td>$464,781.92</td>
<td></td>
<td></td>
<td></td>
<td>$464,781.92</td>
</tr>
</tbody>
</table>

* This figure includes reports submitted to the supervisor and cases with SI awaiting assignment.
** This figure include reports submitted to the citation and fine unit, AG referral, as well as cases assigned to enf. Staff
*** This figure includes withdrawn applications.
****Fines collected (through 9/30/2014 and reports in previous fiscal year.)
## Board of Pharmacy Enforcement Statistics
### Fiscal Year 2014/2015

<table>
<thead>
<tr>
<th>Administrative Cases (by effective date of decision)</th>
<th>July-Sept</th>
<th>Oct-Dec</th>
<th>Jan-Mar</th>
<th>Apr-June</th>
<th>Total 14/15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referred to AG's Office*</td>
<td>91</td>
<td></td>
<td></td>
<td></td>
<td>91</td>
</tr>
<tr>
<td>Accusations Filed</td>
<td>87</td>
<td></td>
<td></td>
<td></td>
<td>87</td>
</tr>
<tr>
<td>Statement of Issues Filed</td>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td>9</td>
</tr>
<tr>
<td>Petitions to Revoke Filed</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Pending</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-accusation</td>
<td>246</td>
<td></td>
<td></td>
<td></td>
<td>246</td>
</tr>
<tr>
<td>Post Accusation</td>
<td>341</td>
<td></td>
<td></td>
<td></td>
<td>341</td>
</tr>
<tr>
<td>Total*</td>
<td>613</td>
<td></td>
<td></td>
<td></td>
<td>613</td>
</tr>
<tr>
<td>Closed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revocation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Intern Pharmacist</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Pharmacy Technician</td>
<td>49</td>
<td></td>
<td></td>
<td></td>
<td>49</td>
</tr>
<tr>
<td>Designated Representative</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Wholesaler</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Sterile Compounding</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Revocation, stayed; suspension/probation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Intern Pharmacist</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Pharmacy Technician</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Designated Representative</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Wholesaler</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Sterile Compounding</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Revocation, stayed; probation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td>8</td>
</tr>
<tr>
<td>Intern Pharmacist</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Pharmacy Technician</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Designated Representative</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Wholesaler</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Sterile Compounding</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Surrender/Voluntary Surrender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Intern Pharmacist</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Pharmacy Technician</td>
<td>11</td>
<td></td>
<td></td>
<td></td>
<td>11</td>
</tr>
<tr>
<td>Designated Representative</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Wholesaler</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Sterile Compounding</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>
## Board of Pharmacy Enforcement Statistics
### Fiscal Year 2014/2015

### Workload Statistics

<table>
<thead>
<tr>
<th>Public Reproval/Reprimand</th>
<th>July-Sept</th>
<th>Oct-Dec</th>
<th>Jan-Mar</th>
<th>Apr-June</th>
<th>Total 14/15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacist</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Intern Pharmacist</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Pharmacy Technician</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Designated Representative</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Wholesaler</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Sterile Compounding</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Licenses Granted</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacist</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Intern Pharmacist</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Pharmacy Technician</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Designated Representative</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Wholesaler</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Sterile Compounding</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Licenses Denied</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacist</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Intern Pharmacist</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Pharmacy Technician</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Designated Representative</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Wholesaler</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Sterile Compounding</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

| Cost Recovery Requested** | $230,373.00 | $230,373.00 |
| Cost Recovery Collected** | $76,974.01  | $76,974.01  |

* This figure includes Citation Appeals

** This figure includes administrative penalties

### Immediate Public Protection Sanctions

<table>
<thead>
<tr>
<th>Sanctions</th>
<th>July-Sept</th>
<th>Oct-Dec</th>
<th>Jan-Mar</th>
<th>Apr-June</th>
<th>Total 14/15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Suspension Order</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Automatic Suspension / Based on Conviction</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Penal Code 23 Restriction</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Cease &amp; Desist - Sterile Compounding</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>
As of September 30, 2014.

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.
Licensees with substance abuse problems who are either on board probation and/or participating in the Pharmacist Recovery Program (PRP)

<table>
<thead>
<tr>
<th>Board of Pharmacy</th>
<th>July - Sep</th>
<th>Oct - Dec</th>
<th>Jan - Mar</th>
<th>Apr - Jun</th>
<th>Total 14/15</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRP Intakes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRP Self-Referrals</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRP Board Referrals</td>
<td>3</td>
<td></td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRP Under Investigation</td>
<td>2</td>
<td></td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>PRP In Lieu Of</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Number of PRP Intakes</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>New Probationers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacists</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Interns</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technicians</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total New Probationers</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>PRP Participants and Contracts</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total PRP Participants</td>
<td>63</td>
<td>63</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contracts Reviewed</td>
<td>58</td>
<td></td>
<td></td>
<td></td>
<td>58</td>
</tr>
<tr>
<td>Probationers and Inspections</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Probationers</td>
<td>90</td>
<td>90</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inspections Completed</td>
<td>60</td>
<td></td>
<td></td>
<td></td>
<td>60</td>
</tr>
<tr>
<td>PRP Referrals to Treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Referrals to Treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug Tests</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug Test Ordered</td>
<td>991</td>
<td></td>
<td>991</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug Tests Conducted</td>
<td>910</td>
<td></td>
<td></td>
<td>910</td>
<td></td>
</tr>
<tr>
<td>Relapse</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relapsed</td>
<td>3</td>
<td></td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major Violation Actions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cease Practice/Suspension</td>
<td>4</td>
<td></td>
<td></td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Termination - PRP</td>
<td>3</td>
<td></td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Referral for Discipline</td>
<td>2</td>
<td></td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Exit from PRP or Probation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Successful Completion</td>
<td>3</td>
<td>3</td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Termination - Probation</td>
<td>3</td>
<td></td>
<td></td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Voluntary Surrender</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Surrender as a result of PTR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public Risk</td>
<td>2</td>
<td></td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Non-compliance</td>
<td>18</td>
<td></td>
<td></td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Patients Harmed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Patients Harmed</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>
### SB 1441 – Program Statistics

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

<table>
<thead>
<tr>
<th>Board of Pharmacy</th>
<th>July-Sep</th>
<th>Oct-Dec</th>
<th>Jan-Mar</th>
<th>Apr-Jun</th>
<th>Total 14/15</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug of Choice at PRP Intake or Probation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacists</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td>3</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ambien</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opiates</td>
<td>2</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>2</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxycodeone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Morphine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>1</td>
<td></td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Barbiturates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marijuana</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heroin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cocaine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methamphetamine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical Amphetamine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phentermine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methadone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zolpidem Tartrate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydromorphone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Promethazine w/Codeine</td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Intern Pharmacists</td>
<td>July-Sep</td>
<td>Oct-Dec</td>
<td>Jan-Mar</td>
<td>Apr-Jun</td>
<td>Total 14/15</td>
</tr>
<tr>
<td>Alcohol</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opiates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrocodone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxycodeone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barbiturates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marijuana</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heroin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cocaine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methamphetamine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical Amphetamine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phentermine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methadone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zolpidem Tartrate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydromorphone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Promethazine w/Codeine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy Technicians</td>
<td>July-Sep</td>
<td>Oct-Dec</td>
<td>Jan-Mar</td>
<td>Apr-Jun</td>
<td>Total 14/15</td>
</tr>
<tr>
<td>Alcohol</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opiates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrocodone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxycodeone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barbiturates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marijuana</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heroin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cocaine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methamphetamine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical Amphetamine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phentermine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methadone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zolpidem Tartrate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydromorphone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Promethazine w/Codeine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist Recovery Program</td>
<td>July-Sep</td>
<td>Oct-Dec</td>
<td>Jan-Mar</td>
<td>Apr-Jun</td>
<td>Total 14/15</td>
</tr>
<tr>
<td>Alcohol</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opiates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrocodone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxycodeone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barbiturates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marijuana</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heroin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cocaine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methamphetamine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical Amphetamine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phentermine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methadone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zolpidem Tartrate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydromorphone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Promethazine w/Codeine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Licensees with substance abuse problems who are either on board probation and/or participating in the Pharmacist Recovery Program (PRP)

<table>
<thead>
<tr>
<th>Board of Pharmacy</th>
<th>July - Sep</th>
<th>Oct – Dec</th>
<th>Jan-Mar</th>
<th>Apr-Jun</th>
<th>Total 14/15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant Files Audited</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>
Drug Of Choice - Data entered from July 2014 to June 2015

Pharmacist

Intern

Technician

1 Alcohol
2 Opiates
3 Hydrocodone
4 Oxycodone
5 Benzodiazepines
6 Barbiturates
7 Marijuana
8 Heroin
9 Cocaine
10 Methamphetamine
11 Pharmaceutical Amphetamine

Printed on 10/13/2014
Attachment 12
FDA News Release

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–1305, 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.

(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 impermissibly 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 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. 360ee(e); 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 503B(a)(4), 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 such drugs or 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/GuidanceComplianceRegulatoryInformation/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 (cispamide, 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, cispamide, 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/GuidanceComplianceRegulatoryInformation/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)(6) 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 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.

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, 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 501(a)(2)(B), 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.

**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 most frequently 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. Armeanph, 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 PROPELISD 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, once the product available only through an investigational limited access program
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),1 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),2 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 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),3 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 <i>Staphylococci</i> during treatment and a potential for drug interactions. On June

---

1 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.

2 This citizen petition was originally assigned docket number 2006P–0081. 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.
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.

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.4 In a letter to FDA dated

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 (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-recent 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 1329) 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 (alatrofloxacin mesylate) Injection and TROVAN (trovafloxacin mesylate) tablets, 100 mg and 200 mg, to in-patient 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.)

IV. Environmental Impact

FDA has determined under 21 CFR 25.30(b) 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 therefore, the Agency proposes to certify that this proposed rule will not have a significant economic impact on a substantial number of small entities.
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(b)(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 oral 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.)


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:


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.

Astenizole: All drug products containing astenizole.

Azaribine: All drug products containing azaribine.

Benoxaprofen: All drug products containing benoxaprofen.

Bithionol: All drug products containing bithionol.

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

Butamaben: All parenteral drug products containing butamaben.

Camphorated oil: All drug products containing camphorated oil.
Dibromsalan: All drug products containing dibromsalan.

Diamthazole dihydrochloride: All drug products containing diamthazole dihydrochloride.

Dexfenfluramine hydrochloride: All drug products containing dexfenfluramine hydrochloride.

Dihydrostreptomycin sulfate: All drug products containing dihydrostreptomycin sulfate.

Dipyrone: All drug products containing dipyrone.

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.

Etrezinate: All drug products containing etretinate.

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 metabolbromsalan.

Methamphetamine hydrochloride: All parenteral drug products containing methamphetamine hydrochloride.

Metapyrilene: All drug products containing metapyrilene.

Methoprolol: All drug products containing metoprolol.

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, 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 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.

Tegaserod maleate: All drug products containing temafloxacin.

Tetrahydrofuran: All drug products containing tetrahydrofuran.

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

Tetrycycline: All drug products containing tetrycycline in a concentration greater than 25 milligrams/milliliter.

Ticrynafen: All drug products containing ticrynafen.

Trichromosal: All drug products containing trichromosal.

Trichloroethene: All aerosol drug products intended for inhalation containing trichloroethene.

Troglitazone: All drug products containing troglitazone.

Truprofloxacin 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 13
Inspection Findings
(6/26/14 – 9/5/14)

140 Sterile Compounding Inspections

66 Hospital/LSC

63 Annual/new inspections of current licensed sterile compounders

11 Non-resident Inspections

137 violations were found in 58 of these pharmacies
Inspection Outcomes
(6/27/14 – 9/5/14)

137 non-compliance issues were recorded in 57 pharmacies

<table>
<thead>
<tr>
<th>Category</th>
<th>Violations</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital/LSC (28)</td>
<td>55</td>
<td>40.1%</td>
</tr>
<tr>
<td>PHY/LSC (21)</td>
<td>48</td>
<td>35.0%</td>
</tr>
<tr>
<td>NRP/NSC (8)</td>
<td>34</td>
<td>24.8%</td>
</tr>
</tbody>
</table>
Top Violations in HSP/LSC (N=55)
(6/26/14 – 9/5/14)

• Compounding records incomplete  13  23.6%
• Ceiling, walls, surfaces not disinfected weekly  11  20.0%
• Compounding self-assessment not completed  4  7.3%
Top Violations in PHY/LSC (N=48)
(6/26/14 – 9/5/14)

- Master formula incomplete  4  33.3%
- Ceiling, walls, surfaces not disinfected weekly  3  25.0%
- Compounding self-assessment not completed  3  25.0%
Top Violations in NRP/NSC (N=34)  
(6/26/14 – 9/5/14)

• Compounding self-assessment not completed  6  17.6%
• Ceiling, walls, surfaces not disinfected weekly  3  8.8%
• P&P’s not reviewed annually by PIC  3  8.8%
Inspections to be Completed
(9/1/14 – 12/31/14)

In CA

9/1/14 expiration = 46 (completed)
10/1/14 expiration = 43
11/1/14 expiration = 273
12/1/14 expiration = 49

Non-resident

9/1/14 expiration = 11 (completed)
10/1/14 expiration = 7 (scheduled)
11/1/14 expiration = 10
12/1/14 expiration = 7
Attachment 14
Cappello, Susan@DCA

From: Pharmacy_Subscriberlist@DCA
Sent: Thursday, December 19, 2013 2:08 PM
To: PHARM-GENERAL@LISTSERV.DCA.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Recall notice - Abrams Royal Pharmacy

Abrams Royal Pharmacy is recalling all unexpired lots of sterile products dispensed nationwide due to concerns of lack of sterility assurance. Sterile products are injectable medications, IVs, eye drops, pellet implants, nasal sprays, inhalation solutions, and eye ointments.

All recalled products have a label that includes Abrams Royal Pharmacy’s name and phone as well as a lot number. While not every label contains an expiration date, consumers can call the pharmacy with the lot number and learn the expiration date.

The recall was issued after a single, isolated report of an adverse event involving a patient in California who received a compounded medication from the pharmacy. Out of an abundance of caution, Abrams Royal is recalling all sterile products within expiry. If there is microbial contamination in products intended to be sterile, patients are at risk for serious, potentially life-threatening infections.

The recalled products were distributed to health care facilities, physicians, and patients from June 17, 2013 through December 17, 2013.

To return product or request assistance related to this recall, users should contact Abrams Royal at 214-349-8000, Monday through Friday, between 9:00 a.m. and 7:00 p.m. CST, and on Saturday between 9:00 a.m. and 3:00 p.m. CST.

Customers that have product which is being recalled should stop using it and contact the pharmacy to arrange for return of unused product. Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using these products. Adverse reactions may be reported to the FDA’s MedWatch program via:

Online: www.fda.gov/medwatch/report.htm
Mail: use postage-paid, pre-addressed Form FDA 3500 found at www.fda.gov/MedWatch/getforms.htm.
Fax: 1-800-FDA-0178
Abrams Royal Pharmacy shall immediately **CEASE AND DESIST** from compounding sterile injectable products for shipment into California. This cease and desist order shall remain in effect for 30 days or until the date of a hearing seeking an interim suspension order, whichever is earlier. Pursuant to Business and Professions Code section 4127.3, subdivision (c), within 15 days of the receipt of this notice you may request a hearing before the president of the board to contest the cease and desist order.

Additionally Abrams Royal Pharmacy shall contact **EACH PRESCRIBER AND PATIENT** in California for whom Abrams Royal Pharmacy has prepared sterile injectable medications to determine if the patient or prescriber has any such preparation in his/her possession. Any such preparation in the possession of prescribers/patients shall be recalled. The product is to be returned to Abrams Royal Pharmacy.

To view the Order to Cease and Desist go to: [http://www.pharmacy.ca.gov/enforcement/fy1213/abrams.pdf](http://www.pharmacy.ca.gov/enforcement/fy1213/abrams.pdf)
AUDIENCE: Risk Manager, Biomedical Engineer

ISSUE: The Nephros non-medical water filtration SafeSpout and SafeShower products may pose risks to health potentially resulting in adverse health events or death. Exposure to harmful bacteria may occur when the fiber filter or the sealing compound, holding the fiber in place, breaks apart. If the filter breaks, patients could be exposed to bacteria or viruses, which could result in infection or death. To date, reports of one death and one infection are associated with this recall.

This recall involves all production lots of the following point-of-use (POU) filters, manufactured between July 2011 and September 2013 and distributed between October 2011 and October 2013:

SafeSpout 70-0233, 70-0238
SafeShower HH (Hand Held) 70-0237
SafeShower FH (Fixed Head) 70-0236

BACKGROUND: The Nephros SafeSpout and SafeShower are intended to filter water for washing and drinking. They are intended to be installed at the end of a standard sink faucet or shower head.

RECOMMENDATION: If you are in possession of any of the filters identified above, please remove them from use immediately. See the Recall Notice for additional information.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178
L-citrulline by Medisca: Alert - Potentially Subpotent Product

AUDIENCE: Medical Geneticist, Pediatrics, Pharmacy

ISSUE: FDA is notifying health care professionals, patients, and caregivers of adverse events reported in patients who were administered L-citrulline repackaged and distributed by Medisca Inc. L-citrulline is used to treat certain urea cycle disorders, rare genetic disorders primarily diagnosed in children. FDA has received adverse event reports associated with potentially subpotent L-citrulline. Subpotent L-citrulline in patients with certain urea cycle defects can lead to high ammonia levels, which is serious and potentially life-threatening.

In addition to the identified lot number 96453, FDA is investigating reports that may include additional lot numbers.

BACKGROUND: Medisca supplies pharmacies nationwide with L-citrulline. The product is sold to pharmacies and clinics in containers filled with powdered L-citrulline, and it may be compounded into tablets, capsules, or liquids by pharmacies, or remain a powder.

RECOMMENDATION: FDA recommends health care professionals quarantine lots of L-citrulline from Medisca and not administer to patients until FDA provides additional information.

Patients should contact their physician or health care provider if they have concerns about the use of L-citrulline.

FDA asks health care professionals, patients, and caregivers to report adverse reactions or quality problems experienced with the use of L-citrulline packed by any companies, including Medisca, to the FDA’s MedWatch Adverse Event Reporting program:

• Complete and submit the report online at http://www.fda.gov/medwatch/report.htm
• Download and complete the reporting form, then submit it via fax at 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the FDA Statement, at:

To unsubscribe from this email list please click on the link below and follow the instructions on the web page.

https://www.dca.ca.gov/webapps/pharmacy/subscribe.php
FDA has tested samples from recalled lots of Medisca's L-citrulline product, and were analyzed by several laboratory methods to identify the ingredient that was repackaged by Medisca and labeled as L-citrulline. FDA has found that the samples contain N-acetyl-leucine, which is used to treat a certain type of dizziness (acute vestibular vertigo). No L-citrulline was found in the samples FDA tested.

FDA alerts health care professionals and patients that Medisca is voluntarily recalling certain lots of its L-citrulline product after testing indicated that it does not contain any L-citrulline.

- Medisca is voluntarily recalling all L-citrulline product with the above lot numbers.
- Health care professionals should discontinue dispensing from these lots, contact patients, and return all unused product to Medisca Inc.
- Patients and caregivers should stop using any product with these lot numbers.
- FDA has received several adverse event reports associated with Medisca's L-citrulline product. FDA is investigating reports that may include additional lot numbers, continues to investigate the full scope of this issue and will continue to provide additional information as it becomes available.

[Posted 02/14/2014]

AUDIENCE: Medical Geneticist, Pediatrics, Pharmacy

ISSUE: FDA is notifying health care professionals, patients, and caregivers of adverse events reported in patients who were administered L-citrulline repackaged and distributed by Medisca Inc. L-citrulline is used to treat certain urea cycle disorders, rare genetic disorders primarily diagnosed in children. FDA has received adverse event reports associated with potentially subpotent L-citrulline. Subpotent L-citrulline in patients with certain urea cycle defects can lead to high ammonia levels, which is serious and potentially life-threatening.

In addition to the identified lot number 96453, FDA is investigating reports that may include additional lot numbers.

BACKGROUND: Medisca supplies pharmacies nationwide with L-citrulline. The product is sold to pharmacies and clinics in containers filled with powdered L-citrulline, and it may be compounded into tablets, capsules, or liquids by pharmacies, or remain a powder.

RECOMMENDATION: FDA recommends health care professionals quarantine lots of L-citrulline from Medisca and not administer to patients until FDA provides additional information.

Patients should contact their physician or health care provider if they have concerns about the use of L-citrulline.
FDA asks health care professionals, patients, and caregivers to report adverse reactions or quality problems experienced with the use of L-citrulline packed by any companies, including Medisca, to the FDA’s MedWatch Adverse Event Reporting program:

- Complete and submit the report online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Download and complete the reporting form, then submit it via fax at 1-800-FDA-0178

[02/14/2014 - Statement - FDA]
The Board of Pharmacy has issued an Order to Cease and Desist effective July 21, 2014 to Unique Pharmaceuticals LTD., located at 5920 S. General Bruce Dr., Temple, TX 97502.

Unique Pharmaceuticals LTD shall immediately Cease and Desist from compounding sterile injectable products for shipment into California.
During the semi-annual testing of sterile cleanrooms and anteroom, the air samples from the anteroom tested positive for microorganisms. Surface and air samples taken from the biosafety cabinets used in sterile compounding showed no bacterial or fungal contamination. Although these results may have been due to the testing procedures themselves, as a precaution Advance Outcome Management Pharmacy Services, are recalling ALL Sterile Compounded Products.

Please immediately check inventory, quarantine, and discontinue distribution of the affected product and contact your wholesaler for directions.

To unsubscribe from this email list please click on the link below and follow the instructions on the web page.

https://www.dca.ca.gov/webapps/pharmacy/subscribe.php
Call to Order

Dr. Gutierrez, chair of the committee, called the meeting to order at 10:18 a.m.

Dr. Gutierrez welcomed those in attendance. Roll call of the board members present was taken and a quorum of the committee was established.

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

No public comments were received.
II. ENFORCEMENT MATTERS

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

Background
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.

Assembly Bill 1136 (Levine), signed by the Governor on September 9, 2013, 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. The required label may be printed on an auxiliary label that is affixed to the prescription container.

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

A number of California’s schools of pharmacy offered to assist, but not all schools have yet provided comments.

All proposed changes submitted were aggregated onto 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)

One commenter stated;

I recommend since specific labeling is required on containers by AB 1136, pharmacy software programs need a list of specific drugs to link to the warnings so they can be indexed to the drug by the software.

However another stated the current list primarily contains drug classes rather than individual drugs. That approach should be maintained since listing individual drugs will quickly become outdated as new drugs are marketed, and again the pharmacist can exercise judgment regarding which individual drugs within a class are of concern.

The committee reviewed and developed new text for section 1744.

Discussion

Dr. Gutierrez recommended that the committee keep the proposed language as broad as possible and not list individual drugs as the drugs will change over time. This also would allow the pharmacist to use his or her professional judgment.

Dr. Gray recommended including a portion of the statute’s lead in paragraphs in the proposed revised regulation as the pharmacist tends to go right to the regulation without referring to the statute. Dr. Gray also noted that in the definitions of the Business and Professions Code it stated that Schedule II, III, IV and V drugs refer to any drug listed in the California Health and Safety Code.

Dr. Gutierrez suggested including a portion of the language in Business and Professions Code section 4074(2) (b) as part of the introduction to 1744, specifically, “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.” In addition to this language indicate that the list is not all inclusive and a pharmacist is still required to use his or her professional judgment.

Committee Recommendation:

Motion: Recommend that the board adopt the revisions to section 1744 of the Title 16 California Code of Regulations, as follows:

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) Monoamine oxidase inhibitors.

(3) Nitrates.

(4) Cycloserine.

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

M/S: Hackworth/Schaad
Support: 4 Oppose: 0 Abstain: 0

b. FOR DISCUSSION AND POSSIBLE ACTION: Remaining Need for Health and Safety Code Section 11164.5(a), Approval to Receive Electronic Prescriptions for Controlled Substance Prescriptions

Background
Health and Safety Code section 11164.5(a) requires the approval of the Board of Pharmacy and the CA Department of Justice (DOJ) before a hospital or pharmacy may receive electronic data transmission prescriptions or computer entry prescriptions or orders. This provision was enacted before the Drug Enforcement Administration (DEA) promulgated their e-prescribing requirements several years ago.

Kaiser Permanente recently requested the board’s position on whether this provision is operative and how is the board complying with it.

Board staff do not believe that there is any need to retain this provision since the DEA has promulgated the required regulations to permit e-prescribing, and the staff recommend amending subdivision (a) out of 11164.5. There will likely need to be additional conforming changes to 11164.5 if subdivision (a) is removed. This should be part of the committee’s discussion.
Discussion
Dr. Gray provided background on the history of this provision indicating that in 2000, the DEA wanted to move to electronic prescribing but it hadn’t come up with a system yet to do so. California changed its law in order to be ready for electronic prescribing, however the DOJ Bureau of Narcotic Enforcement was dissolved and this requirement was never enacted.

Grace Toy of Kaiser’s National Compliance Office requested approval from the committee to allow Kaiser to electronically prescribe controlled substances once approved by the DEA, provide Kaiser with an exemption, or provide additional guidance so that Kaiser could proceed in a lawful manner.

Dr. Gutierrez asked DAG Kellogg whether the board needed its own provisions or if the board could just comply with the federal regulations. DAG Kellogg advised that the board no longer needed this provision.

Committee Recommendation

Motion: Recommended that Section 11164.5(a) of the Health and Safety Code be eliminated.

Comments

Dr. Gray agreed that the board no longer needs to approve systems approved by the DEA and that the committee should recommend elimination of section 11164.5(a) to the full board.

Ms. Herold cautioned that striking Health and Safety Code section 11164.5(a) may have consequences to other subdivisions of section 11164.5 and that the board would have to ensure it does not somehow alter other components of 11164.5(b) – (d). Eliminating this section would also require the board to sponsor legislation to amend the Health and Safety Code.

Ms. Herold stated that staff would work with legal counsel to review the other sections and bring it forward to the board with the rest of what may need to be done to the section.

Dr. Gray further requested that the board pursue emergency legislation so that the change could go into effect as soon as it was signed by the governor because the legislative process could be drawn out. An alternative suggestion was made that perhaps it could be written into the language that the board would not enforce this section while legislation is pending.

Amended Motion: Recommend that section 11164.5(a) of the Health and Safety Code be eliminated and to include in the language that the board does not need to enforce this section while the legislation is pending.
c. FOR DISCUSSION AND POSSIBLE ACTION: Proposed Regulation for Pharmacies Aimed at Reducing Losses of Controlled Substances

At the March 2014 Enforcement and Compounding Committee, 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 has 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](image-url)
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.

At the last meeting, it was noted that 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

Enforcement and Compounding Committee Meeting Minutes – September 16, 2014
Page 9 of 28
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 April 2014 Board Meeting when this topic was discussed, the board asked the committee to draft regulation language to require monthly counts of a pharmacy’s fastest controlled substances as a form of inventory control.

Staff’s Proposed Language: Add as section 1715.65 to 16 California Code of Regulations:

1715.65 Monthly Inventory Counts of Fastest Moving Controlled Substances
(a) Every June 30th, each pharmacy and clinic licensed by the board shall identify its top 10 controlled substances dispensed by the licensee as measured in dosage units in the prior 12 months (July 1 – June 30).
(b) Effective July 1 and each month thereafter until the next June 30 (for a total of 12 months), the pharmacy or clinic shall count and reconcile the inventory of the top 10 controlled substances identified pursuant to subdivision (a). This reconciliation shall include for each of the controlled substances:
(1) The inventory recorded on the first of the preceding month
(2) The additions to inventory made in the preceding month (e.g., purchases, transfers in, will-call items that were never handed out that were counted as dispositions the prior month)
(3) The dispositions (e.g., dispensing, saleable returns to a wholesaler, drugs provided to a reverse distributor for destruction) from inventory made in the preceding month
(4) The drugs in quarantine waiting for the reverse distributor,
(5) The final inventory count on the first of the month
(6) The pharmacy shall attempt to reconcile overages or shortages. Shortages must be reported to the board.
(7) The name of the individual conducting the inventory and date the inventory required by this subdivision was performed
(c) Losses of controlled substances identified from the monthly audit shall be reported to the board as required by section 1716.5 and Business and Professions Code section 4104.
(d) The pharmacist-in-charge or consultant pharmacist for the clinic shall sign each monthly inventory performed under this section indicating he or she has reviewed the inventory taken.
(e) The pharmacist-in-charge or consultant pharmacist shall perform a quality assurance review of the monthly and annual inventories to establish secure methods to prevent losses of all dangerous drugs.

Discussion and Comment
Dr. Gutierrez highlighted the need for pharmacies to perform monthly counts of a pharmacy’s fastest moving controlled substances as a form of inventory control.
Performing these counts would allow the pharmacy to find a potential diversion problem early on.

Mr. Lippe sought clarification on what was classified as the loss type of “other” as noted the drug loss report. Ms. Herold indicated that these losses are unaccounted for and the pharmacy does not know why the losses occurred.

Dr. Gutierrez sought clarification on what was classified as the loss type of “customer theft.” Ms. Herold provided scenarios wherein a customer would reach over the counter and grab the bag or a spouse of one of the pharmacy staff would take the controlled drug from a pharmacy.

Ms. Herold commented that the losses at the community pharmacies are similar to those losses at chain stores. Dr. Gutierrez was surprised at the high number of losses at a retail pharmacy compared to a hospital pharmacy.

Dr. Gutierrez recommended that the medical director sign for the inventory in a clinic as the consultant pharmacist only performs quarterly reviews. Dr. Gutierrez recommended changing the language in item (e) as the pharmacy should already have measures in place.

The board heard many comments regarding whether to include hospital pharmacies and clinics in this proposed regulation. It was noted that clinics do not have a pharmacist in charge but a consultant pharmacist that performs quarterly reviews and that the doctors are responsible for the daily operation of the clinic. It was also noted that hospitals routinely perform regular counts of controlled substances and perhaps this regulation was not needed for hospital pharmacies. It was also suggested to include exempt hospitals (known as drug rooms). Some felt the medical director should also be held accountable.

Dr. Gutierrez commented that the language be amended to require consultant pharmacist and medical director sign for the inventory. Ms. Herold inquired if the board should include pharmacies that are licensed under Business and Professions Code section 4057 and require the medical director to perform the monthly inventory.

Dr. Gray recommended, for clarity purposes, that where the proposed language states “clinic” that it is clear that a “clinic” is a clinic licensed by the board, same as for a hospital. It was further noted that clinics do not have a sophisticated computer system and monthly counts would be very difficult to perform because it is only noted in a patient’s medical record with handwritten notes of what was administered. Significant modifications would have to take place for a clinic to adhere to this proposed regulation.

Dr. Gutierrez inquired if the proposed language was intended to affect the clinic at the administration level. Ms. Herold stated that this language is intended to account for what comes in, what goes out, what’s quarantined, what’s in pending, and then what’s the
difference between stock on hand and what records indicates should be in stock. Dr. Gray
feels there needs to be some clarification as to who needs to then perform these counts.

Ms. Sodergren suggested that the committee inquire as to how a clinic complies with the
records requirement in Business and Professions Code section 4081.

Dr. Gutierrez asked if there was anyone from a clinic in the audience.

Dr. Gutierrez suggested the committee focus on community pharmacies and add hospitals
and clinics to the regulation at a later date. Dr. Gutierrez also suggested getting input from
clinics at the next committee meeting.

**Committee Recommendation**

**Motion:** Recommend the board 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 30th, 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.
(e) 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.

**M/S: Lippe/Hackworth**

Support: 4  
Oppose: 0  
Abstain: 0

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

Chairperson Gutierrez is considering a future meeting agenda item where the committee can learn about drug storage security features to deter diversion that are built into automated dispensing and storage devices used in hospitals and skilled nursing facilities. Time will be devoted at this meeting for a discussion of this topic, but a more in-depth review will be scheduled for a future meeting where the committee will be able to view some of the anti-diversion technology or features in use in California.

**Discussion and Comments**

Dr. Gutierrez indicated that a hospital has a different set of circumstances than a retail pharmacy. Dr. Gutierrez further stated that it would be a good idea to see what the technology provides to prevent drug diversion. She recommended that for future agenda items, the committee invite some of the larger automated vendors to provide background on how their technology can identify and address drug diversion in a hospital setting.

Mr. Lippe concurred with Dr. Gutierrez that it would be a good idea to see these demonstrations.

A representative from DYNA Labs volunteered the co-founder of DYNA Labs to speak at a future meeting on this topic.

Ms. Herold stated that the committee is looking for presentations on this topic and the kinds of reports are available from these types of devices. Ms. Herold further stated that the board has recently sent some California hospital pharmacies to the Attorney General’s Office because the pyxis machine had been raided by staff and an access report was never pulled or reviewed. Ms. Herold suggested that if a pharmacy has an access report to a dispensing unit, to start looking at it. Dr. Gutierrez stated that there needs to be some kind of reconciliation. Ms. Herold further stated that the reports are reviewed, they offer really good protection.

Ms. Herold asked the committee if they wanted her to start contacting entities that the board knows use these devices to provide demonstrations. It was noted that Omnicell, Pyxis, and Talyst were three entities that sell this type of machine.
Lynn Paulsen, UCSF, asked about having the software companies provide a presentation. These companies would focus on auditing rather than on how cool the machine is. Dr. Gutierrez noted that software packages were add-ons and marketed themselves. Dr. Gutierrez stated that auditing is only a portion of what the board is looking at and there are a lot of security issues. Dr. Paulsen indicated that the manufacturers may not tell you their weakest points. Dr. Paulsen also commented that most machines throughout the United States have the same keys that open the back of the machines.

Dr. Gray noted that there will be vendors at the CSHP annual seminar meeting in San Francisco at the end of October 2014 that they will have these machines on display. The board could ask CSHP for the list of which companies will be attending. In addition, ASHP will also have vendors at its annual clinical meeting in Anaheim in December 2014.

Dr. Gutierrez suggested that the board start with some of the vendors that the board has had to report to the Attorney General’s Office.

No further comment was provided from the committee or public.

e. **FOR DISCUSSION: The Drug Enforcement Administration’s Regulations for the Take Back of Prescription Medication**

On Tuesday, September 9, 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.

*Attachment 4* contains the DEA’s requirements for drug take back (pages 151-200) along with their comments to written comments received in response to the prior proposed regulation.

The committee will have the opportunity to discuss the DEA’s requirements and options for future action, if any, by the board in this area. *Attachment 4* also contains a *Wall Street Journal* article about the regulations.

**Discussion and Comment**
Dr. Gutierrez stated that she found the *NY Times* article interesting because it talked about how it’s going to be positive on the one side but on the other side it’s introducing a whole new stream of drugs coming back into the pharmacy.

Ms. Herold stated that the DEA is calling the drugs waste and trying to keep them separate which is why the board needs to have some regulations in place in this area.

The DEA developed some requirements that offer opportunities for the board to move in the right direction. The board recommended dual key lock boxes in a pharmacy but DEA wanted one key with two people auditing the contents. The board has already been contacted by Senator Jackson’s office asking when the board’s regulations will be ready. The regulations also need to include some inventory requirements.

Ms. Herold will have staff draft proposed language. Ms. Herold feels that the board will need a series of public meetings before the board moves forward with a regulation package.

Dr. Gutierrez asked the audience if there were any facilities interested in participating. No volunteers came forward.

Dr. Gray stated that pharmacies are being pressured politically locally for healthcare organizations to get involved. He further indicated that healthcare organizations would be forced by local ordinances to get involved. Dr. Gray felt that the local city or county would pass laws that mandate pharmacies get a DEA permit and then establish these programs.

Dr. Gray was also unclear if the pharmacy was expected to inventory or separate the drugs as it was his impression that the board did not want these drugs inventoried as it would make it easier for diversion, safety and contamination. Lastly he questioned who the inventory requirement fell on, the pharmacy or the reverse distributor.

Ms. Herold further stated that the DEA and the board want these programs to be voluntary.

Ms. Herold advised Dr. Gutierrez that the board will have something for the committee to review at a future meeting.

f. FOR DISCUSSION: Rescheduling of Hydrocodone to Schedule II

**Background**

Hydrocodone combination products (HCP) are pharmaceuticals containing specified doses of hydrocodone in combination with other drugs in specified amounts. These products are approved for the marketing for the treatment of pain and for cough suppression.

The Drug Enforcement Administration (DEA) has secured the “up scheduling” of hydrocodone combination products from Schedule III to Schedule II of the federal Controlled Substances Act. At the April 2014 board meeting, the board directed that the
board submit a letter of support to the DEA, along with a request for a transition period to fully implement this change.

**Attachment 5** includes a copy of the board’s letter of support.

Below is a copy of a subscriber alert the board will release after the discussion at this meeting.

1. Starting October 6, 2014, all HCPs will be reclassified at the federal level as Schedule II controlled substances, does this mean California law has also reclassified all hydrocodone combination products as Schedule II controlled substances?
   **A:** Technically, no; there has been no equivalent change to California law, or to the controlled substance schedules in California. But for many intents and purposes, the practical effect will be the same: that all prescribers and practitioners in California will be required to treat HCPs as Schedule II controlled substances.

2. Prescriptions written for HCPs before October 6, 2014 that are presented to the pharmacy for dispensing on or after October 6, 2014: are these to be dispensed as a Schedule II or Schedule III controlled substance?
   **A:** On and after October 6, 2014, under federal law, all HCPs must be prescribed according to federal Schedule II requirements. This means no HCP prescription issued on or after this date may authorize any refills. Also, for example, as of October 6, 2014, oral, telephone or fax-transmitted prescriptions for HCPs are no longer possible. The DEA has stated, however, that it will allow refills on HCPs written and initially filled before October 6 (under Schedule III requirements and limitations), to be dispensed up to six months from October 6, 2014 (until April 8, 2015). This extends the Schedule III treatment of prescriptions for HCPs written and initially dispensed prior to October 6, 2014 to the maximum allowable period for Schedule III refills.

   The DEA has stated, however, that it will allow refills on HCPs written before October 6 (under Schedule III requirements and limitations), to be dispensed up to six months from October 6, 2014 (before April 8, 2015). This extends the Schedule III treatment of prescriptions for HCPs written before October 6, even if provided to the pharmacy on or after October 6 to the maximum allowable period for Schedule III refills (before April 8, 2015).

3. Prescriptions written for hydrocodone combination products dispensed before October 6, 2014 as a Schedule III, but with refills remaining, can the remaining refills be dispensed?
   **A:** According to guidance from the DEA, yes.

4. If a patient presents a prescription for a hydrocodone combination product on or after October 6, 2014 that was written before October 6, 2014 with refills, can the
refills be honored?
A: Yes, up to April 8, 2015, so long as the original date on the prescription does not exceed 180 days, or the maximum allowable period for Schedule III refills.

5. When transmitting to CURES, should I change my computer software to report all HCPs dispensed as Schedule II controlled substances or keep HCPs as Schedule III controlled substances until California law (also) reschedules all HCPs to a Schedule II controlled substance?
A: Health and Safety Code section 11165, subdivision (d) references and incorporates the federal controlled substance schedules for the purpose of defining the reporting requirements under CURES. As a result, dispensers in California are responsible for reporting to CURES controlled substances dispensed according to the federal schedules. Thus, a software change will be required.

6. Like some states, is California precluding pharmacies from refilling HCPs prescriptions written prior to October 6, 2014?
A: No, the federal allows such refills to be filled pursuant to limitation in existing law for refilling Schedule III drugs.

From the federal announcement:
On Friday, August 22, 2014, the DEA published in the Federal Register the final rule to transfer HCPs from federal Schedule III to federal Schedule II. HCPs have been controlled in schedule III since enactment of the Controlled Substances Act (CSA) in 1971. HCPs are the most frequently prescribed opioid in the United States: nearly 137 million prescriptions for HCPs were dispensed in 2013.

- Effective October 6, 2014, HCPs will be controlled as Schedule II substances under the Controlled Substances Act (CSA).
- DEA is also permitting legitimate HCP prescriptions issued before October 6, 2014 to be refilled until April 8, 2015, if the prescription authorizes refills.
- The Notice of Proposed Rulemaking (NPRM), Final Rule, and its supporting documents (i.e., medical and scientific evaluations, and economic impact analysis) may be viewed online at www.regulations.gov, Docket No. DEA-389.
- Alternatively, the documents can be obtained on the DEA website at www.deadiversion.usdoj.gov.

Questions and Answers;
a. Starting October 6, 2014, all HCPs will be reclassified at the federal level as Schedule II controlled substances, does this mean California law has also reclassified all hydrocodone combination products as Schedule II controlled substances?
A: Technically, no; there has been no equivalent change to California law, or to the controlled substance schedules in California. But for many intents and purposes,
the practical effect will be the same: that all prescribers and practitioners in California will be required to treat HCPs as Schedule II controlled substances.

2. Prescriptions written for HCPs before October 6, 2014 that are presented to the pharmacy for dispensing on October 6, 2014: are these dispensed as a Schedule II or Schedule III controlled substance?
A: On and after October 6, 2014, under federal law, all HCPs must be prescribed according to federal Schedule II requirements. This means no HCP prescription issued on or after this date may authorize any refills. Also, for example, as of October 6, 2014, oral, telephone or fax-transmitted prescriptions for HCPs are no longer possible. The DEA has stated, however, that it will allow refills on HCPs written and initially filled before October 6 (under Schedule III requirements and limitations), to be dispensed up to six months from October 6, 2014 (until April 8, 2015). This extends the Schedule III treatment of prescriptions for HCPs written and initially dispensed prior to October 6, 2014 to the maximum allowable period for Schedule III refills.

3. Prescriptions written for hydrocodone combination products dispensed before October 6, 2014 as a Schedule III, but with refills remaining, can the remaining refills be dispensed?
A: According to guidance from the DEA, yes.

4. If a patient presents a prescription for a hydrocodone combination product on or after October 6, 2014 that is written on October 6, 2014 with refills, can the refills be honored?
A: No, the DEA stated the prescription needed to be presented before October 6 to use the refills.

5. When transmitting to CURES, should I change my computer software to report all HCPs dispensed as Schedule II controlled substances or keep HCPs as Schedule III controlled substances until California law (also) reschedules all HCPs to a Schedule II controlled substance?
A: Health and Safety Code section 11165, subdivision (d) references and incorporates the federal controlled substance schedules for the purpose of defining the reporting requirements under CURES. As a result, dispensers in California are responsible for reporting to CURES controlled substances dispensed according to the federal schedules. Thus, a software change will be required.

Discussion and Comments
Dr. Gutierrez asked how this change would work for CURES and was advised that it was a software problem and the pharmacy will need to secure the necessary software changes. Ms. Herold stated this was a transition period and the pharmacy will have to figure out how to manage it. Mr. Lippe asked if the pharmacy would get in trouble if they chose not to refill a prescription if they didn’t want to or could accommodate refills of a Schedule II drug.
during the DEA’s six-month transition. He was advised that the pharmacy would not be disciplined for this.

Jeff Nehira representing Dignity Health asked if the board could comment on what if the prescription was transferred after October 6. The committee questioned if a prescription for HCPs transferred could be filled as a refill prescription because it would be hard to validate when that prescription was filled and refilled.

Dr. Gray representing Kaiser Permanente, stated that the ability to refill is permissive, not required. There isn’t one system that allows you to change from Schedule III to II. The board should be prepared to receive some complaints from patients who are unable to get their prescription refilled. Dr. Gray suggested that since the state is looking ahead with electronic prescribing, the statute should be changed, as these prescriptions will be received electronically through a very secured DEA system and that a pharmacy should be able to fill an out of state prescription.

Scott Clark representing the California Medical Association encouraged the board to work with the pharmacies and the pharmacists to let prescribers know how the board intends to implement the transition period so that there is not an impact on the patient and prescribers.

Ms. Herold advised the audience that the Medical Board and the Dental Board are aware of the change. Ms. Herold further stated that she had shared the Q&A list with those boards. Dr. Gutierrez requested board staff to work with the Medical Board to get the word out.

Dr. Paulson feels that even though the DEA said there could be refills it should be communicated as no refills. She stated the systems are just not going to allow it and it should be communicated as no refills.

Dr. Acosta commented that maybe the software could re-write the prescription or if the pharmacy could find a way for the pharmacy to identify if there were refills remaining. Dr. Ratcliff stated if you could access the original prescription and track on this document how many refills were remaining during this transition period.

g. **FOR DISCUSSION: Rescheduling of Tramadol to Schedule IV**

**Background**

Tramadol is a centrally acting opioid analgesic that has been on the market since the mid-1990s. Subsequently, the FDA approved for marketing generic, combination, and extended release tramadol products as dangerous drugs but not as controlled substances. However, over the years, the board and other entities have identified instances where tramadol was misused in part because as a dangerous drug, it was more readily available than a controlled substance would be.
In mid-August, the DEA secured the scheduling of tramadol into Schedule IV of the controlled substances schedule.

**Attachment 6** includes a copy the board’s subscriber alert and the article from the Federal Register / Vol. 79, No. 127 / Wednesday, July 2, 2014 / Final Rule

At this meeting, the committee reviewed the subscriber alert and article from the Federal Register. There was no committee or public comment.

**h. FOR INFORMATION: Update on the Alternative Process for Pharmacists to Become Registered to Access CURES**

Last year, SB 809 (DeSaulnier) was enacted to enhance and rev up the CURES prescription drug monitoring program.

Part of the discussion associated with the bill’s progression through the Legislature was the growing concern about the need for pharmacists and prescribers to more frequently access CURES before dispensing or prescribing controlled drugs. To access CURES to see the history of controlled drugs dispensed to a single patient over the last year, a prescriber or pharmacist must have been preapproved by the CA Department of Justice. However, a low number of prescribers and dispensers have applied for and been granted access to CURES.

Provisions enacted in SB 809 require all prescribers and pharmacists to be registered with the DOJ to access CURES by January 1, 2016. However, the new computer system and funding for staffing for the DOJ to operate the system will not be available until perhaps July 2015. Meanwhile, the Department of Consumer Affairs’ agencies are transferring to a new computer system of their own that will create new systems for license issuance and renewal. Only the first one-third of DCA’s boards have converted to the new BreEZe system at this time.

As such, it looks likely that few if any DCA boards will be able to comply with the January 1, 2016 CURES registration deadline for licensees at the current rates of registration.

The current process for CURES registration is frustrating and laborious. Individuals must start an email contact with the DOJ, then fill out an application they download, and then copy various documents (driver’s license, professional license) and have the whole package notarized and then mailed to the DOJ. The DOJ is currently taking about one month to process this material.

Board staff has implemented a process whereby the board can authenticate the identity of a pharmacist and aid the DOJ in getting this individual registered. The board began accepting applications in July 2014 and has to date received approximately 150 applications.
Currently there are 9,268 pharmacists registered with CURES, about 25 percent of all pharmacists.

Ms. Herold indicated the board would come prepared to accept CURES registration applications at the California Society Health System Pharmacists (CSHP) booth at the end of October 2014.

Public Comment
Holly Strom indicated that a DEA number was not required for CURES registrations and urged all pharmacists to register.

Satinder Sandhu, representing Walgreens, inquired as to the length of time it was taking to process CURES applications and was advised that the application process was taking approximately three weeks. Ms. Herold also stated that if you don’t access CURES at least once every six weeks, you’ll be bounced off. It was recommended that pharmacists sign-in at the beginning of every month so that they don’t get placed in the inactive status and have to go through the revalidation process.

Jill Hacker, CSHP, inquired if all licensed pharmacists were required to register even if they weren’t currently dispensing or if they were living out of state. Ms. Hacker was advised that the law states that all licensed pharmacists must register for CURES. Ms. Hacker indicated that CSHP may consider legislation to amend the law for exemptions in the future.

No additional committee or public comment was provided.

i. FOR DISCUSSION: Presentation by Rita Shane, PharmD, FASHP, FCSHP on Medication Reconciliation in Health Care Facilities

Medication reconciliation is intended to ensure the accuracy of a medication list of drugs taken by a patient. It involves the review, update, and reconciliation of medications at each encounter.

Rita Shane, PharmD, has advised that given the errors in medication lists that occur when patients are admitted to the hospital, evidence supports that pharmacy staff need to ensure these lists are updated and corrected in order to prevent hospital medication errors, reduce readmissions and prevent medication errors when the patients go home.

A physician colleague of Dr. Shane recently completed a randomized controlled trial showing there were seven errors per medication list for patients admitted to the hospital. The same trial also showed the impact of pharmacy staff on reducing these errors.

A PowerPoint presentation was provided by Dr. Shane regarding medication reconciliation in health care facilities.
A related article on this topic is provided in Attachment 7.

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

Dr. Gutierrez sought clarification on whether the study was based on the patient being a good historian of all medications he or she takes or the “gold standard” pharmacist. Dr. Shane indicated that the study was based on the gold standard pharmacist as well as consulting with the primary care and/or prescribing physician.

Mr. Lippe asked Dr. Shane to explain what SureScript’s function was. Dr. Shane explained that SureScript’s is a hub for prescription data that is e-prescribed to which all the different prescription benefit management (PBM) companies upload information.

Dr. Gutierrez asked Dr. Shane what she was proposing. Dr. Shane stated she would like the committee to consider regulations that require hospitals to create better and more accurate medication lists.

Ms. Herold asked if this process was being implemented at Cedar’s Sinai and as advised that Cedar’s Sinai started doing medication reconciliation with high risk patients and emergency admissions in 2011.

It was asked if pharmacy technicians could perform this task. It is unclear if these tasks are viewed as discretionary or nondiscretionary. It was recommended that a specially trained pharmacy technician perform this duty.

Dr. Shane further stated that California pharmacies should take a leadership role in owning the medication lists.

Dr. Gutierrez suggested sharing this data with California Hospital Association (CHA) Medication Safety Committee, as a first step and get some recommendations by the committee. Ms. Herold commented that she’d like to see this as a collaboration across professions.

Public comment supported the idea of medication reconciliation lists and to continue discussions with all groups. It was also noted that there is a regular nationally published newsletter on medication reconciliation findings. Outpatient pharmacy technicians were found to be better suited for cataloging medications.

No additional committee or public comment was provided.

Dr. Gutierrez recessed for a 30-minute lunch break at 12:30 p.m.

The meeting reconvened at 1:04 p.m.
III. COMPOUNDING MATTERS

a. FOR DISCUSSION: FDA’s Expectations for Human Drug Compounders

The Food and Drug Administration (FDA) 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 (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 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 FDA’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).

Attachment 8 includes a copy of the FDA Press Release and the article from the Federal Register / Vol. 79, No. 127 / Wednesday, July 2, 2014 / Proposed Rule

This information was provided to the committee for information.

At this meeting, the committee reviewed the press release and article from the Federal Register. There was no committee or public comment.

b. FOR DISCUSSION: Request by Kaiser Permanente for Clarification Regarding End-Product Testing as Required by 16 CCR section 1751.7

Attachment 9

Background
Kaiser Permanente has requested an opportunity to discuss enforcement of Title 16 California Code of Regulations section 1751.7. This section specifies the requirements of a Quality Assurance Program for sterile compounding pharmacies. Specifically, the law provides that:

1751.7. Sterile Injectable Compounding Quality Assurance and Process Validation.
(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:
(1) Cleaning and sanitization of the parenteral medication preparation area.
(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.
(3) Actions to be taken in the event of a drug recall.
(4) Written justification of the chosen expiration dates for compounded sterile injectable products.

(b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

Kaiser Permanente indicates that various inspectors are interpreting section 1751.7(a) differently. They have asked for the board to clarify. A copy of the request is provided in Attachment 9.

At this meeting, Steve Gray and Doug O’Brien of Kaiser Permanente, sought clarification regarding the need for end product testing as they are concerned with interpretation and misunderstanding by board inspectors related to testing.

Kaiser indicates that over the past 18 months, especially during sterile compounding pharmacy inspections, they have encountered substantial variation in interpretation of the regulations among Board inspectors. These variations range from no findings, to consultative recommendations, to orders of correction despite Kaiser’s consistent policies, procedures and practices.
The committee was advised by Dr. Gray that Kaiser is referring to sterile to sterile and general non-sterile compounding.

Dr. Gray indicated that there have been inconsistencies with the interpretation of 16 CCR 1735 and 16 CCR 1751 by inspectors during non-sterile and sterile compounding inspections over the past year and a historical context for misinterpretation going back to before 2006 and these are not the principles that was agreed upon.

Ms. Herold cautioned all those in attendance that most of what was presented is part of a pending regulation where there is an open 45-day comment period and any discussion would complicate the rulemaking and that the committee cannot provide any comment on the pending regulation.

Ms. Herold further stated that there is a process set up to review a final outcome of an investigation where some sort of action was taken and that is an office conference where additional information can be presented to resolve discrepancies. Additionally, the board provides training sessions with board inspectors where supervisors work to build a single set of standards. The board has spent considerable time to ensure that staff has been trained.

Ms. Herold indicated that testing for potency should be completed to validate what the prescription states.

Dr. Gray indicated that testing is not always possible or necessary such as in a topical cream however the process could be validated.

Dr. Gutierrez asked if staff could come up with a letter of expectations from a testing perspective that is consistent with the law so that everyone is on the same page what the requirements are.

Dr. Ratcliff asked Dr. Gray his interpretation of Section 16 CCR 1735.8 (c) and the meaning of “...include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products...” and what his definition of analysis was. Dr. Gray advised that nowhere in that section does it refer to “testing.”

Dr. Gray further stated that if he developed a quality assurance plan that has standards of qualitative and quantitative integrity, potency, quality and that plan is followed then he is satisfied that product meets label strength requirements. Dr. Gray states that process validation is not the same as potency testing. Ms. Herold disagreed and that the board has always expected some kind of testing to be performed on routinely compounded products. Dr. Gray suggested that the board have a discussion with staff and the board on how to test a product where there is no testing available on a periodic basis.
Dr. Ratcliff referenced 16 CCR 1751.7(a) and asked how Kaiser performs a periodic sampling to assure that a product meets required specifications. Dr. Ratcliff was advised that the pharmacist validates that the pharmacy technician has good technique; the room is good, the hood is good, and the technician is periodically watched compounding things and as a result the product is fully tested because of all the processes that were followed. Dr. Ratcliff indicted that Kaiser doesn’t seem to be complying with 1751.7(a).

Public comment included that testing for potency is problematic because there are no tests for a lot of medications. It was also noted that the package inserts are relied upon that the end product will meet the criteria. Costs would be ridiculously high to obtain a potency test and be cost prohibitive. There should be some consideration when following the manufacturer’s instructions that no analysis be required.

No additional comments from the committee or public were received.

c. FOR INFORMATION: Results of the Board’s Implementation and Inspections of California Sterile Compounding Facilities

At this meeting
Supervising Inspector Robert Ratcliff, PharmD, provided an update regarding the board’s implementation and inspections of California sterile compounding pharmacies.

Attachment 10 includes the data found as a result of sterile compounding inspections in California.

Dr. Gutierrez recessed for a 10-minute break at 2:19 p.m.

The meeting reconvened at 2:30 p.m.

d. FOR INFORMATION: Data on Violations Found During Out-of-State Compounding Inspections

Supervising Inspector Robert Ratcliff, PharmD, provided an update regarding the board’s inspections of out of state sterile compounding pharmacies.

Attachment 10 also includes the data describing results from sterile compounding inspections of out-of-state sterile compounding pharmacies.

Dr. Ratcliff introduced new compounding Supervising Inspector Christine Acosta.

Dr. Ratcliff stated that there were 140 sterile compounding inspections conducted and 137 violations were found during June 26, 2014 to September 5, 2014. The top violations found were incomplete compounding records; ceiling, walls and surfaces were not cleaned
weekly; incomplete compounding self-assessments; incomplete master formulas; and policy and procedures were not reviewed annually.

Dr. Ratcliff indicated that board inspectors have been instructed to check the FDA website for warning letters and FDA’s 483 inspection reports prior to inspecting the larger pharmacies and out-of-state pharmacies.

Dr. Gutierrez inquired whether the out-of-state pharmacies were 503(b)s and was advised that about half of the out of state inspections were of 503(b)s. Dr. Gutierrez inquired whether the out-of-state pharmacies are performing testing and was advised they were.

Public Comment
Marie Cottman representing Pacific Compounding Pharmacy indicated that they have been asked to provide a lot compounded products to doctors’ offices. Ms. Cottman asked where the board stood since these compounded medications were not patient specific as required by the FDA. It was suggested that they review Business and Professions Code section 4052.

e. FOR INFORMATION: Recalls of Compounded Drugs Throughout the United States

Between November 8, 2013 and September 11, 2014, the board posted seven subscriber alerts related to compounding drug recalls.

Attachment 11 includes copies of the subscriber alerts.

The committee reviewed the attachments. Dr. Gutierrez noted that there are still quite a bit of recalls occurring. There was no committee or public comments.

IV. MEETING DATES FOR 2014

Dr. Gutierrez reminded the audience that the next enforcement and compounding committee meeting was scheduled for December 17, 2014.

In addition, Dr. Gutierrez informed the audience that the sterile compounding public hearing was scheduled for November 4, 2014 in Sacramento. She also indicated that if anyone was interested in submitting written comments on the proposed language that there was a specific format requested and that format could be found on the board’s website.

Ms. Herold informed the audience that at this hearing, there would be time allowed for oral comments to be provided on to the proposed changes, but the commenter would be not be receiving comments in response.
V. **FUTURE MEETING DATES**

The committee will select meeting dates for 2015. Once established, these dates will be posted on the board’s website under the Board Meetings tab.

Dr. Gutierrez adjourned the meeting at 2:50 p.m.
**Recommendations to Improve Medication Safety: Risks Associated with Medication Reconciliation and Transitions of Care**

Rita Shane, Pharm.D., FASHP, FCSHP  
Chief Pharmacy Officer  
Cedars Sinai Medical Center, Los Angeles  
Assistant Dean, Clinical Pharmacy  
UCSF School of Pharmacy

---

**Background**

- Medication reconciliation (med rec) is required by The Joint Commission and the Center for Medicare/Medicaid Services as part of Meaningful Use
- The process is intended to ensure the accuracy of the medication list at each patient encounter
- Medication lists are entered into electronic health records (EHR) by a variety of individuals (both licensed and unlicensed) across different healthcare settings
- The medications entered are not always accurate
- These lists are used to create hospital medication orders resulting in continuation of inaccurate and/or incorrect medications

---

**Ensuring the Accuracy of the Medication List**

---

**Evidence**

- 54-86% of patients have discrepancies in medications upon admission to the hospital with an estimated 3.3 discrepancies or errors/patient
- Reported rates of inpatient medication errors range from 45% to 76% due to inaccuracies in medication histories and reconciliation with most errors occurring on admission
- 14-80% of patients experienced at least 1 medication discrepancy or error post-discharge
- 19% of patients experienced an adverse event within 3 weeks of hospital discharge, 67% were attributed to medications and 12% of the adverse drug events were preventable

---

**Sources of Medication Lists**

Errors introduced in any of these settings can become “hardwired” into the pt record

- Home setting
  - Family members
  - Caregivers
  - Home health nurses
- Settings
  - Certified medical assistants
  - Physicians
  - Community pharmacies
  - Patients
- Nursing facility
  - Nurses
  - Physicians
  - Pharmacists
  - Pharmacy technicians
  - Pharmacy residents, students
**CMS 2012-Meaningful Use**

- Any licensed healthcare professional and **credentialed medical assistants**, can enter orders into the medical record
- Credentialed medical assistants are:
  - Certified medical assistants-graduates of an accredited medical assisting program
  - Training requirements: 2-6 units of pharmacology training (based on evaluation of 4 California programs)
  - Medical assistants (who are not certified) who have completed a required order entry course


---

**Medical Assistants Requirements for Order Entry into Electronic Health Records**

- 2 yr recent experience in a health care facility under the supervision of a licensed health care provider (LHP)
- Application signed by supervising LHP attesting proficiency in areas including pharmacology
- Completion of Assessment-Based Recognition in Order Entry (ABR-DE) training-S courses (1 hr each)
  - Clinical Laboratory Testing
  - Lost in Translation: Eliminate Medical Errors
  - Medical Records: A Vital Wave
  - Disease Screening
  - Legal Aspects of Patient Care Documentation

---

**Prior to Admission Medication History Drug-Related Problems in High Risk Patients (Errors or Discrepancies)**

<table>
<thead>
<tr>
<th>November 2011—March 2013</th>
<th>Drug-Related Problems (DRPs) Resolved: 6,184 (803 patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Average: 7.7/patient</td>
</tr>
<tr>
<td></td>
<td>• 54% of resolved DRPs were classified as life-threatening or serious</td>
</tr>
<tr>
<td></td>
<td>• 35% of inpatient orders needed to be corrected</td>
</tr>
<tr>
<td></td>
<td>• Based on risk stratification algorithm only 25% of patients had both high medication adherence and literacy</td>
</tr>
</tbody>
</table>

---

**Prior to Admission (PTA) Drug-Related Problems (DRPs) Examples**

<table>
<thead>
<tr>
<th>Medication on PTA List</th>
<th>Drug-Related Problem</th>
<th>DRP Type</th>
<th>Capacity for Harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flecainide</td>
<td>PTA List: Med not listed on PTA med list</td>
<td>Omission of Medication</td>
<td>Life-Threatening</td>
</tr>
<tr>
<td></td>
<td>Finding: Pt reports taking flecainide 50 mg BID</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>PTA List: Med not listed on PTA med list</td>
<td>Omission of Medication</td>
<td>Serious</td>
</tr>
<tr>
<td></td>
<td>Finding: Pt reports taking Plavix 75 mg daily</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methotrexate</td>
<td>PTA list: methotrexate 10mg daily</td>
<td>Wrong Frequency</td>
<td>Life-Threatening</td>
</tr>
<tr>
<td></td>
<td>Finding: Pt reports taking 10mg every Sunday</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mycophenolate</td>
<td>PTA List: Mycophenolate 360 mg BID</td>
<td>Wrong Dose</td>
<td>Serious</td>
</tr>
<tr>
<td></td>
<td>Finding: Pt reports taking 720 mg BID</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**Resolution of Post-Discharge Drug-Related Problems (DRPs)**

<table>
<thead>
<tr>
<th>Post discharge Medication Reconciliation</th>
<th>January 2013—June 2013</th>
<th>DRPs Resolved: 601 (207 patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Average: 2.9 DRPs/patient</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 58% of patients had discrepancies between their discharge medication list and what they were taking</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 33% of patients were taking more medications than were prescribed*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Estimated 16% of patients would have been readmitted based on physician evaluation**</td>
<td></td>
</tr>
</tbody>
</table>

*Excludes vitamins, herbs, OTC supplements
**Validated by hospitalist physicians

---

**Pharmacist's Role in Evaluating Medications (Focus on Hospitals)**

- High risk patients or therapies such as
  - Chemotherapy
  - Blood thinners
  - Antibiotics
- Drugs with narrow therapeutic index
- ICU
Pharmacist’s Impact on Readmissions

**Examples of Pharmacist Post Discharge Follow up**

<table>
<thead>
<tr>
<th>Reason for Admission</th>
<th>Drug Related Problems Identified</th>
<th>Intervention</th>
<th>Adverse Outcome Prevented</th>
</tr>
</thead>
<tbody>
<tr>
<td>54 y/o w/ HTN &amp; DVT admitted for sickle cell crisis &amp; left parietal stroke</td>
<td>Discontinued warfarin, metoprolol, and carvedilol</td>
<td>Intervened: Pharmacist contacted MD and confirmed that warfarin and anti-hypertensives should be restarted. Pharmacist educated pt on medications and instructed pt to not adjust any med w/o speaking to MD.</td>
<td>Avoided potential thromboembolism, readmission, and/or death.</td>
</tr>
<tr>
<td>92 y/o w/ altered mental status found to have a UTI &amp; toxic blood pressure and low blood pressure</td>
<td>Continued taking medications that had been stopped, including digoxin, metoprolol, and zolpidem</td>
<td>Intervened: Instructed patient to discontinue warfarin, amlodipine, thrombolytics, digoxin, and zolpidem.</td>
<td>Avoided potential drug toxicity, life-threatening arrhythmias, recurrence of confusion, readmission, and/or death.</td>
</tr>
</tbody>
</table>

**Examples of Pharmacist Post-Discharge Follow-Up Skilled Nursing Facility Patients**

<table>
<thead>
<tr>
<th>Reason for Hospital Admission</th>
<th>Drug Related Problems Identified Post Discharge and Pharmacist Intervention</th>
<th>Adverse Outcome Prevented</th>
</tr>
</thead>
<tbody>
<tr>
<td>98 y/o M from home w/ hip fracture and multiple medical issues</td>
<td>Issue discovered: Pt had self-discontinued warfarin, ambulipine, and carvedilol</td>
<td>Intervened: Called SNF to d/c fentanyl 25mcg patch as an inpatient. Dose was increased to 50mcg 1 hour prior to discharge.</td>
</tr>
<tr>
<td>79 y/o M w/ ESRD - HD on TURF  with catheter-related S. aureus bacteremia.</td>
<td>Issue discovered: Per ID, vancomycin after dialysis to be continued after d/c and was on discharge medication list. There was an order at the SNF for vancomycin but not at the dialysis center. Pt dialyzed on Sat after d/c but did not receive vancomycin.</td>
<td>Intervened: Ensured vancomycin administration occurred.</td>
</tr>
</tbody>
</table>

**Prospective Study of 30 Day Readmission Rates for High Risk Patients Who Received Post Discharge Follow-Up**

- **Relative Risk Reduction:** 45%
- **Did NOT receive intervention:** 23%
- **Received intervention:** 13%

**Pharmacist’s Impact on Readmissions**

- **Source:** ASHP-APhA Medication Management in Care Transitions Best Practices. 2013

**Minimizing Errors in Medication Histories Obtained at Hospital Admission**

- **Randomized Controlled Trial**
  - High Risk Patients* admitted via Emergency Dept
  - 300 pt enrolled; 283 in final analysis
  - Median age: ~76 (range: 50-83)
  - Median # of meds* 14 (range: 10-19)

*High risk: ≥ 10 chronic meds, Acute MI, CHF, admitted from SNF, on anticoagulants, insulin, narrow therapeutic index drugs, history of transplant
Minimizing Errors in Medication Histories Obtained at Hospital Admission

Randomized Controlled Trial

- Pt histories independently evaluated within 24 hr by gold standard pharmacist (proven study methodology)
- Gold standard pharmacist took patient history, compared with history taken, determined # errors and severity of errors:
  - Low capacity for harm: vitamin, laxative
  - Serious: beta blocker for hypertension
  - Life Threatening: transplant drug

Results: Number of Errors

- Adding a Pharmacist or Pharmacy Technician to Usual Care Reduced Medication History Errors per patient (81%), p < 0.0001

<table>
<thead>
<tr>
<th></th>
<th>Usual care</th>
<th>Usual Care + Pharmacist</th>
<th>Usual Care + Pharmacy Technician</th>
</tr>
</thead>
<tbody>
<tr>
<td>Errors Per Patient</td>
<td>7.4</td>
<td>1.4</td>
<td>1.5</td>
</tr>
</tbody>
</table>

Results: Severity of Errors

- Adding a Pharmacist or Pharmacy Technician to Usual Care Reduced Weighted Medication Errors by >17/ patient (82%), p < 0.0001
- 2 Life Threatening Errors or
- 4 Serious Errors or
- 17 Low-Capacity for Harm Errors

Recommendations to Ensure Patient Safety

Patient Safety Imperatives
- Medication lists are frequently inaccurate and can lead to harm
- Ensuring the accuracy of the medication list at each transition of care is essential, especially when patients are admitted to and discharged from the hospital setting

Recommendations to Ensure Patient Safety
- Hospital pharmacies should be responsible for ensuring the medication list is accurate upon admission
- Evidence supports that trained technicians can gather prescription information for the medication list for the pharmacist’s review
- For high risk pts, pharmacists should conduct post-discharge follow up to prevent adverse drug events and admissions

Appendix

References

**MedAL Score**

**Medication Adherence and Literacy Score**

<table>
<thead>
<tr>
<th>Medication Literacy (Scale 0-4)</th>
<th>High Literacy (4 points)</th>
<th>Intermediate (2-3 points)</th>
<th>Low Literacy (0-1 point)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Adherence (4 points)</td>
<td>No Post DC Follow-up</td>
<td>No Post DC Follow-up</td>
<td>Perform Post DC Follow-up</td>
</tr>
<tr>
<td>Intermediate (2-3 points)</td>
<td>No Post DC Follow-up</td>
<td>Score 6: No Post DC Follow-up</td>
<td>Perform Post DC Follow-up</td>
</tr>
<tr>
<td>Low Adherence (0-1 point)</td>
<td>Perform Post DC Follow-up</td>
<td>Perform Post DC Follow-up</td>
<td>Perform Post DC Follow-up</td>
</tr>
</tbody>
</table>

**Use of the Medication Adherence and Literacy Algorithm to Identify Pts At Risk for 30 Day Readmission**

**Value as Predictive Indicator**

The odds of readmission for the group identified as needing post-discharge follow-up was 2.8 times greater than for the group identified as not needed post-discharge follow-up (95% CI 0.172 - 0.710, p=0.0045)

**Conclusion:** The MedAL algorithm can serve as a tool to identify patients that are at risk for readmission within 30 days. Post-discharge follow-up of patients identified by the MedAL algorithm may reduce 30-day admission rates.