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

ENFORCEMENT AND COMPOUNDING COMMITTEE
MEETING MATERIALS
JUNE 24, 2015

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

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

II. ENFORCEMENT MATTERS

a. PRESENTATION: Drug Enforcement Administration on its Requirements for the Take Back of Prescription Medications

Attachment 1

Ruth Carter and Mimi Paredes from the Drug Enforcement Administration will provide a presentation regarding the DEA's regulations for the take back of prescription medications.

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

The final rule authorizes certain DEA registrants (manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies, and hospitals/clinics with an on-site pharmacy) to modify their registrations with the DEA to become authorized collectors.

All collectors may operate a collection receptacle at their registered location, and collectors with an on-site means of destruction may operate a mail-back program.

Retail pharmacies and hospitals/clinics with an on-site pharmacy may operate collection receptacles at long-term care facilities.

A copy of the final rule is provided in **Attachment 1.**

b. DISCUSSION: Development of Board Regulations for Pharmacies and Reverse Distributors That Take Back Prescription Medication from Patients, Referencing the Drug Enforcement Administration's Regulations for the Take Back of Prescription Medication

Attachment 2

At the December 2014 committee meeting, Ms. Herold provided an overview of the DEA's new drug take-back regulations. This presentation is provided in **Attachment 2**. Committee discussion included how an average person would know which drugs are acceptable for disposal. The committee heard comments from the public in which the board was asked not to place the collection burden on pharmacists.

At the March 2015 committee meeting, Ms. Herold provided a brief overview of the first draft of the proposed language that would provide guidance to pharmacies assisting patients in destroying unwanted prescription medication. The language would also ultimately provide guidance to reverse distributors and pharmacies that choose to establish a mail back service or provide a collection receptacle. At that meeting, the committee reviewed the proposed language and heard public comment.

At this meeting, the committee will resume work on the proposed regulation, following information provided by the DEA during its presentation earlier in the meeting. The plan is to draft the components of the proposed regulation and to bring for discussion at the July Board Meeting. The board needs to complete work on this draft in the near future as many communities are establishing requirements for collection of unwanted pharmaceuticals.

One major component of the DEA regulations deals with the liners that will fit inside collection receptacles. Once full, this liner will be removed, sealed and provided to a DEA-registered reverse distributor for destruction.

Board staff believes a representative from a take-back company with incineration facilities will appear before the committee to demonstrate the strength and durability of its take back receptacle liners.

Since there are no guarantees of what medications and other items may be placed in the collection receptacles, the board needs to consider several items:

1. Strength and tear resistance of the liners as sharps and other items may be placed in these collection receptacles, even if the public is advised not to make such deposits. Bags that can be punctured, torn or possibly leak will create a serious health risk to those who come in contact with the liners or near receptacles.
2. Possible placement of hazardous drugs in receptacles could require special consideration: are specialty liners needed for all receptacles that can handle antineoplastic drugs (to prevent exposure to hazardous drugs).

   For example,

   > "The adverse health effects associated with antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs) in cancer patients and some non-cancer patients treated with

these drugs are well documented. The very nature of antineoplastic agents make them harmful to healthy cells and tissues as well as the cancerous cells. For cancer patients with a life-threatening disease, there is certainly a great benefit to treatment with these agents. However, for the health care workers who are exposed to antineoplastic agents as part of their work practice, precautions should be taken to eliminate or reduce exposure as much as possible." Source: "Occupational Exposure to Antineoplastic Agents and other Hazardous Drugs" see: http://www.cdc.gov/niosh/topics/antineoplastic/

A list of NIOSH antineoplastic agents is provided in the link below and in **Attachment 2.**
http://www.cdc.gov/niosh/docket/review/docket233/pdf/FRN_HD_LIST_2014.pdf

c. PRESENTATION: Healthcare Distribution Management Association on Deadlines and Distributor and Pharmacy Readiness to Meet Requirements for Exchange of Transaction Information, Transaction Histories and Transaction Statements as Required by the Federal Drug Supply Chain Security Act of 2013

Attachment 3

Scott Moody, from the Healthcare Distribution Management Association, will make a presentation on the requirements and ramifications of the Drug Quality and Security Act (DQSA).

The DQSA preempted California's e-pedigree law, and instead established national requirements for tracking drugs through the supply chain. The first round of tracking requirements became effective January 1 with requirements for drug wholesalers. The second part of the requirements for pharmacies are set to take effect July 1. A copy of the federal law and a brief article on upcoming deadlines can be found in **Attachment 3.**

This will be the first opportunity for the committee to discuss these new requirements. Over the next few months, board inspectors will be working with the board's administrators to establish educational materials for licensees. Updates will be provided at future committee meetings.

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

Attachment 4

Background

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

As background: the board's staff compiled statistics regarding the most dispensed medications in California, the top ten drug losses reported to the board throughout 2014, as well as the number of loss reports by license type. **Attachment 4** includes tables displaying these statistics.

In 2014, the top 10 controlled substances reported lost or stolen amount to nearly 1.9 million dosage units. These numbers are only estimates since they are provided by the entity when it first realizes there has been a loss. As such, the reported numbers are most likely significantly less than actual losses.

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

At the January 2015 Board Meeting, the board reviewed proposed language from the committee. The proposed language was rejected by the board and Chair Gutierrez and Ms. Herold reported that the committee would continue to revise the language.

Prior to the March 2015 committee meeting, after hearing comments from the board and the public at the January Board Meeting, board staff revised the proposed language to include a reconciliation process for the 10 highest volume controlled substances.

At the March 2015 committee meeting, the committee reviewed the new proposed language and decided to further revise the language to require a perpetual inventory for only schedule II controlled substances.

At the April 2015 board meeting, the board discussed perhaps requiring an inventory for the top-10 diverted drugs, but also asked the enforcement committee to continue working on the language.

Chair Gutierrez has encouraged the development of requirements for a reconciliation and periodic physical counts of controlled medications. The proposed draft below is intended to be a discussion document for the committee at this meeting.

1715.55 Reconciliation and Inventory Report of Controlled Substances

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances.
(b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain

secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section.

(c) Perform a Periodic Inventory: A pharmacy or clinic shall perform an inventory of controlled substances every six months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of controlled substances in the pharmacy or clinic on the date of the inventory. The Inventory Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.
    (1) The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be readily retrievable for three years.
    (2) The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided:
        a. A physical count of all controlled substances is performed, not an estimated count of how much medication is in a container.
        b. The federal Drug Enforcement Administration biennial inventory was taken at least 5 months or not more than 7 months from the last inventory required by this section.

(d) Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.
    (1) Losses shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration.
    (2) Likely causes of overages shall be identified in writing and retained.
    (3) Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1.

(e) Adjustments to the Inventory Report shall be made following reconciliation, only after the reporting and documenting of any losses or accounting made for overages.
    (1) Each adjustment to the Inventory Report made to correct the stock on hand count shall be annotated to show any adjustment in the number of controlled substances on hand in the pharmacy or clinic, and who made the annotation, and the date.

(2) The pharmacist-in-charge or consultant pharmacist shall countersign the adjusted Inventory Report.

(3) The original Inventory Report and amended Inventory Report following reconciliation shall be readily retrievable in the pharmacy or clinic for three years.

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

(g) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses, including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing.

For possible reference, prior proposed language from the September 2014, December 2014, and March 2015 Enforcement and Compounding Committee meetings as well as the April 2015 Board Meeting is included in **Attachment 4**.

e. DISCUSSION: <u>Data Reporting Rates of E-Prescribing in the U.S. and California</u>

Attachment 5

Surescripts issued its 2014 National Progress Report which indicated a 19% growth in overall e-prescriptions. Additionally, although e-prescriptions for controlled substances increased 400 percent to 1.67 million, only 1.4 percent of providers were enabled to participate. This report is provided in **Attachment 5** and is for information. The report contains a number of statistics about e-prescribing.

Amazingly, California is the second largest state for the e-prescribing of controlled substances, with 4.26 percent of all controlled substances e-prescribed. Within the state, 71 percent of California's pharmacies and only 8.58 percent of California's prescribers have systems in place to enable e-prescribing. California's percentage is greater than New York where there is a requirement that all prescriptions be e-prescribed by March 2016 (which was postponed from March 2015 this year).

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

Attachment 6

Background

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

At the March 2015 committee meeting, to ensure that third-party logistics providers adhere to board regulations for all drug distributors, the committee reviewed and discussed proposed regulation requirements for third-party logistics providers that originate from drug wholesalers. The committee also reviewed and discussed a proposed self-assessment form that a board inspector could use when inspecting a facility.

At the April 2015 board meeting, Ms. Herold stated that the proposed language is still a draft and that the board is still in the process of setting up the program.

At this meeting, the board will review and discuss the proposed language.

Attachment 6 contains a copy of the proposed regulation and self-assessment for third-party logistics providers.

g. DISCUSSION: Update on CURES 2.0

Ms. Herold will provide an update on the latest iteration of the Controlled Substance Utilization Review and Evaluation System.

III. COMPOUNDING MATTERS

a. DISCUSSION: Critical IQ's Article on "Quarterly Standards for Large Scale Sterile Compounding Facilities"

Attachment 7

Federal legislation has established a new regulatory category for pharmaceutical compounders that supply healthcare providers with prepared, non-patient specific medicines for use in hospitals, offices and clinics. These "outsourcing facilities" will be subject to more rigorous quality and safety standards modeled after the Current Good Manufacturing Practices (CGMPs) that apply to pharmaceutical manufacturers.

In light of the new law, the paper in **Attachment 7** reviews the differences between traditional and outsourced compounding and describes the key CGMP provisions that are critical to ensuring drug quality and patient safety when compounding occurs at a larger scale.

b. DISCUSSION: Update of SB 619 (Morrell) – Licensure of Outsourcing Facilities

Attachment 8

As stated in agenda item a (above), federal law has created a new licensing category relating to prescription drugs known as outsourcing facilities. Outsourcing facilities are sterile facilities that typically compound non-patient specific prescription drugs in large quantities. These facilities are currently licensed by the board as sterile compounding pharmacies.

Senate Bill 619 (Morrell) would require the board to license an outsourcing facility if it compounds non-patient specific medication for patients or practitioners inside or outside of California. Other provisions of the bill would:

- Specify the activities an outsourcing facility can and cannot perform
- Apply the licensing requirement to out-of-state outsourcing facilities that ship compounded prescription drugs into the state
- Require the board to report to the Legislature by January 1, 2018 on its licensing and regulatory efforts
- Authorize the board to issue a cease and desist order to an outsourcing facility if the board determines that there is an immediate threat to public health
- Specify the fees for issuance or renewal of a license for an outsourcing facility, including a requirement that an out-of-state outsourcing facility must also provide reasonable funding to cover the costs for out-of-state inspections

At this meeting, the Ms. Herold will provide an update on the status of the bill.

A copy of Senate Bill 619 is provided in **Attachment 8**.

c. DISCUSSION: U.S. Food and Drug Administration's Draft Guidance Document on Guidance for Industry; Compounding Animal Drugs from Bulk Drug Substances

Attachment 9

The draft guidance in **Attachment 9** sets forth the Food and Drug Administration's (FDA) current thinking regarding compounding animal drugs from bulk drug substances by state-licensed pharmacies, licensed veterinarians, and facilities that register with the FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act**.**

The committee may recommend to the board that the document be reviewed and comments be provided consistent with board policy and California law in the area. Comments are due in August.

d. REVIEW: Sterile Compounding Licensure Statistics

The number of licensed sterile compounding facilities has increased to over 1,000, a 183 percent increase between July 1, 2013 and June 1, 2015. Below are statistics on the number of licensed sterile compounding facilities.

July 1, 2013:	**California Sterile Compounding Facilities**	**244**
361	**California Exempt Sterile Compounding Facilities**	**24**
	Non-Resident Sterile Compounding Facilities	**93**
July 1, 2014	**California Sterile Compounding Facilities**	**786**
989	**California Exempt Sterile Compounding Facilities**	**115**
	Non-Resident Sterile Compounding Facilities	**88**
June 1, 2015	**California Sterile Compounding Facilities**	**812**
1024	**California Exempt Sterile Compounding Facilities**	**122**
	Non-Resident Sterile Compounding Facilities	**90**

At the meeting, staff will provide statistics on the number of violations and disciplinary actions taken by the board.

IV. REMAINING MEETING DATES FOR 2015

- September 2, 2015
- December to be determined

Attachment 1

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Part II

Department of Justice

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, et al.

Disposal of Controlled Substances; Final Rule

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 October 9, 2014.

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 October 9, 2014. 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:

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- C. Summary of Changes in the Final Rule

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IV. Regulatory Analyses

I. Executive Summary

A. Purpose of the Regulatory Action

On October 12, 2010, the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act) was enacted (Pub. L. 111–273, 124 Stat. 2858). Before the Disposal Act, ultimate users 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. 21CFR 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

The DEA carefully considered the 192 individually-submitted comments received in response to the Notice of Proposed Rulemaking (NPRM) on the Disposal of Controlled Substances.[1] 77 FR 75784, Dec. 21, 2012. The comment period closed on February 19, 2013. 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/

[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.

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).[2] 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.[3] Such unlawful distribution includes the transfer of pharmaceutical controlled substances for the purpose of disposal.[4]

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.

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

[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(e)(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 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/destruction).

[5] The Attorney General's delegation of authority to the DEA may be found at 28 CFR 0.100.

considered public health and safety, ease and cost of program implementation, and participation by various communities.

B. Definitions and Terms[6] *(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 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

[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.

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.DEAdiversion.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 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 Web site 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 Inventorying 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 inventorying collected substances outweigh any perceived benefits. The DEA has carefully considered all of the various commenters' concerns on the prohibition of handling, sorting, and inventorying 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.

[5] Issue: 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.

[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 *www.regulations.gov*. 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 [7] and $53.4 billion in 2006.[8] 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

[7] Clin. J. Pain (The Clinical Journal of Pain), Volume 22, Number 8, October 2006.

[8] Clin. J. Pain (The Clinical Journal of Pain), Volume 27, Number 3, March/April 2011.

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, LTCFs, 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).[9] 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 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

[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.

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:

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

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

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

* * * * *

(e) * * *

(1)

Business activity	Controlled substances	DEA application forms	Application fee ($)	Registration period (years)	Coincident activities allowed
(i) Manufacturing	Schedules I–V	New—225 Renewal—225a.	3,047	1	Schedules I–V: May distribute that substance or class for which registration 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.
(ii) Distributing	Schedules I–V	New—225 Renewal—225a.	1,523	1	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.DEAdiversion.usdoj.gov*.

(1) The request shall contain:

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

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

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

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

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

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

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

* * * * *

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

* * * * *

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

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

§ 1301.71 Security requirements generally.

* * * * *

(f) A collector shall not employ, as an agent or employee who has access to or influence over controlled substances acquired by collection, any person who has been convicted of any felony offense relating to controlled substances or who, at any time, had an application for registration with DEA denied, had a DEA registration revoked or suspended,

or has surrendered a DEA registration for cause. For purposes of this subsection, ''for cause'' means in lieu of, or as a consequence of, any Federal or State administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

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

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

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

* * * * *

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

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

* * * * *

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

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

§ 1301.75 Physical security controls for practitioners.

* * * * *

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

* * * * *

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

§ 1301.76 Other security controls for practitioners.

* * * * *

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

* * * * *

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

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

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

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

§ 1304.03 Persons required to keep records and file reports.

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

* * * * *

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

§ 1304.04 Maintenance of records and inventories.

(a) * * *

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

* * * * *

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

§ 1304.11 Inventory requirements.

* * * * *

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

* * * * *

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

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

(i) The name of the substance, and

(ii) The total quantity of the substance:

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

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

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

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

(iv) For controlled substances acquired from law enforcement: the

number of sealed mail-back packages on hand.

* * * * *

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

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

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

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

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

(A) The date of the inventory;

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

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

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

(A) The date of the inventory;

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

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

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

§ 1304.21 General requirements for continuing records.

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

* * * * *

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

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

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

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

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

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

* * * * *

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

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

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

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

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

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

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

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

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

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

(iii) For controlled substances in a commercial container, carton, crate, drum, or other receptacle that has been opened: If the substance is listed in

Schedule I or II make an exact count or measure of the contents; or if the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents shall be made.

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

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

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

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

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

(1) Mail-Back Packages:

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

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

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

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

(2) Collection receptacle inner liners:

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

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

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

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

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

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

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

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

* * * * *

(a) * * *

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

(b) * * *

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

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

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

* * * * *

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

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

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

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

* * * * *

PART 1305—ORDERS FOR SCHEDULE I AND II CONTROLLED SUBSTANCES

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

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

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

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

* * * * *

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

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

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

PART 1307—MISCELLANEOUS

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

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

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

The revision reads as follows:

§ 1307.11 Distribution by dispenser to another practitioner.

* * * * *

§ 1307.12 [Removed]

■ 27. Remove § 1307.12.

■ 28. Revise § 1307.13 to read as follows:

§ 1307.13 Incidental manufacture of controlled substances.

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

§ 1307.21 [Removed]

■ 29. Remove § 1307.21.

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

§ 1307.22 Delivery of surrendered and forfeited controlled substances.

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

* * * * *

■ 31. Add part 1317 to read as follows:

PART 1317—DISPOSAL

Sec.
1317.01 Scope.

Subpart A—Disposal of Controlled Substances by Registrants

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

Subpart B—Disposal of Controlled Substances Collected From Ultimate Users and Other Non-Registrants

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

Subpart C—Destruction of Controlled Substances

1317.90 Methods of destruction.
1317.95 Destruction procedures.

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

§ 1317.01 Scope.

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

Subpart A—Disposal of Controlled Substances by Registrants

§ 1317.05 Registrant disposal.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(v) *Non-practitioner methods of destruction.* Collectors that are non-practitioners (i.e., manufacturers, distributors, narcotic treatment programs, and reverse distributors) shall dispose of sealed inner liners and their contents by utilizing any method in paragraph (b)(1), (b)(2), or (b)(4) of this section, or by delivering sealed inner liners and their contents to a distributor's registered location by common or contract carrier or by distributor pick-up at the collector's authorized collection location for destruction. Freight forwarding facilities may not be utilized to transfer sealed inner liners and their contents.

§ 1317.10 Registrant return or recall.

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

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

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

§ 1317.15 Reverse distributor registration requirements and authorized activities.

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

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

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

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

(i) Delivery to the reverse distributor by an authorized registrant directly or by common or contract carrier may only be made to the reverse distributor at the reverse distributor's registered location. Once en route, such deliveries may not be re-routed to any other location or person, regardless of registration status.

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

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

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

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

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

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

Subpart B—Disposal of Controlled Substances Collected From Ultimate Users and Other Non-Registrants

§ 1317.30 Authorization to collect from non-registrants.

(a) The following persons are authorized to collect controlled substances from ultimate users and other non-registrants for destruction in compliance with this chapter:

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

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

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

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

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

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

§ 1317.35 Collection by law enforcement.

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

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

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

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

(b) Law enforcement that conducts a take-back event or a mail-back program or maintains a collection receptacle should maintain any records of removal, storage, or destruction of the controlled substances collected in a manner that is consistent with that agency's recordkeeping requirements for illicit controlled substances evidence.

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

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

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

§ 1317.40 Registrants authorized to collect and authorized collection activities.

(a) Manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies that desire to be collectors shall modify their registration to obtain authorization to be a collector in accordance with § 1301.51 of this chapter. Authorization to be a collector is subject to renewal. If a registrant that is authorized to collect ceases activities as a collector, such registrant shall notify the Administration in accordance with § 1301.52(f) of this chapter.

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

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

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

(c) Collectors may conduct the following activities:

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

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

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

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

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

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

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

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

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

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

§ 1317.60 Inner liner requirements.

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

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

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

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

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

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

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

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

§ 1317.65 Take-back events.

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

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

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

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

(e) Only ultimate users and persons entitled to dispose of an ultimate user decedent's property in lawful possession of a controlled substance in Schedule II, III, IV, or V may transfer such substances to law enforcement during the take-back event. No other person may handle the controlled substances at any time.

§ 1317.70 Mail-back programs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 1317.75 Collection receptacles.

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

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

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

sorted, inventoried, or otherwise individually handled.

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

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

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

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

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

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

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

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

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

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

(4) The outer container shall prominently display a sign indicating that only Schedule II–V controlled and non-controlled substances, if a collector chooses to comingle substances, are acceptable substances (Schedule I controlled substances, controlled substances that are not lawfully possessed by the ultimate user, and other illicit or dangerous substances are not permitted); and

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

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

§ 1317.80 Collection receptacles at long-term care facilities.

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

(b) Only authorized retail pharmacies and hospitals/clinics with an on-site pharmacy may install, manage, and maintain collection receptacles at long-term care facilities and remove, seal, transfer, and store, or supervise the removal, sealing, transfer, and storage of sealed inner liners at long-term care facilities. Collectors authorized to install, manage, and maintain collection receptacles at long-term care facilities shall comply with all requirements of this chapter, including §§ 1317.60, 1317.75, and 1317.80.

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

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

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

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

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

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

Subpart C—Destruction of Controlled Substances

§ 1317.90 Methods of destruction.

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

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

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

§ 1317.95 Destruction procedures.

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

(a) *Transfer to a person registered or authorized to accept controlled substances for the purpose of destruction.* If the controlled substances are transferred to a person registered or authorized to accept the controlled substances for the purpose of destruction, two employees of the transferring registrant shall load and

unload or observe the loading and unloading of any controlled substances until transfer is complete.

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

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

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

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

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

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

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

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

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

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

(d) *On-site destruction.* If the controlled substances are destroyed at a registrant's registered location utilizing an on-site method of destruction, the following procedures shall be followed:

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

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

Dated: August 25, 2014.

Michele M. Leonhart,

Administrator.

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BILLING CODE 4410–09–P

Attachment 2

DEA Drug Take Back Requirements

Virginia Herold

December 17, 2014

DEA Regulations

- Released in early September 2014.

Who May Donate Drugs to Take Back

- Patients
- Estate
- Long-Term Care

Generally

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

Who Can Operate Drug Take Back

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

Law Enforcement

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

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

Law Enforcement

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

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

Requirements

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

Collectors

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

Collection Receptacles

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

Location of Receptacles

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

Receptacles

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

Inner Liners

Must be:

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

Inner Liners

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

Mail Back

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

Mail Back

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

Collectors with Mail Back

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

Collection at Long-Term Care

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

Long-Term Care

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

  Or

  - 2 employees of the collector location

Long-Term Care

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

Reverse Distributors

- Requirements established for drugs collected from pharmacies (not take back from patients)

  These requirements are separate from drug take back requirements

- Requirements establish if Rev Dist. accept mail back packages and liners

Reverse Distributors

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

Record Keeping Requirements

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

Destruction

- 2 employees must load or unload any controlled substances until the transfer is complete
- When transferred to destruction location:

  2 employees must transport or

use of a common carrier

Miscellaneous & Generally

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

The Future

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

Proposed Additions and Deletions to the NIOSH Hazardous Drug List 2014						
Established Name	**Proprietary Name**	**Drug Class**	**Formulation(s)**	**Dosage**	**FDA pregnancy Category**	**Drug Package Insert**
Drugs Recommended by NIOSH to be Added to the 2012 Hazardous Drug List						
abacavir	Ziagen	antiviral	tablets, oral solution	600mg	C	PI
abiraterone acetate	Zytiga	antineoplastic; CYP17 inhibitor	tablets	1000mg	X	PI
apomorphine	Apokyn	dopamine agonist	SQ	2-6mg	C	PI
bevacizumab	Avastin	monoclonal antineoplastic	IV	5-15mg/kg	C	PI
crizotinib	Xalkori	antineoplastic	capsules	250mg	D	PI
deferiprone	Ferriprox	FE chelator	tablets	25-30mg/kg	D	PI
dexmedetomidine	Precedex	alpha andrenergic antagonist	IV	0.2-1mcg/kg	C	PI
eribulin mesylate	Halaven	antineoplastic; microtubule inhibitor	IV	1.4mg/m2	D	PI
erlotinib	Tarceva	antineoplastic	tablets	150mg	D	PI
ezogabine	Potiga	anticonvulsant	tablets	100-150mg	C	PI
fingolimod	Gilenya	biological response modulator; sphingosine-1 phosphate recpt. modulator	capsules	0.5mg	C	PI
fluconazole	Diflucan	antifungal	tablets, IV, oral suspension	100-400mg	C/D	PI
icatibant	Firazyr	bradykinin B2 recptor antagonist	SQ	30mg	C	PI

liraglutide recombinant	Victoza	antidiabetic agent	SQ	0.6-1.8mg	C	PI
misoprostol	Cytotec	prostaglandin analog	tablets, oral solution	100-200mcg	X	PI
nevirapine	Viramune	antiviral	tablets, oral solution	200mg	B	PI
propylthiouracil		antithyroid	tablets	100mg	D	PI
spironolactone	Aldactone	diuretic	tablets	25-200mg	C	PI
tesamorelin acetate	Egrifta	somatropin; GRF analog	SQ	2mg	X	PI
topiramate	Topamax	antiepileptic	tablets, sprinkle	25-400mg	D	PI
ulipristal acetate	Ella	contraceptive	tablets	30mg	X	PI
vemurafenib	Zelboraf	antineoplastic	tablets	960mg	D	PI
voriconazole	VFEND	antifungal	tabets, oral suspension, IV	4mg/kg IV, 200mg	D	PI
warfarin	Coumadin	anticoagulant	IV, tablets	2-10mg	X	PI
Drugs with Manufacturer's Safe Handling Guidelines that will be Added to the 2012 Hazardous Drug List						
brentuximab vedotin	Adcetris	antineoplastic; monoclonal	IV	1.8mg/kg	D	PI
cabazitaxel	Jevtana Kit	antineoplastic; microtubule inhibitor	IV	25mg/m2	D	PI
dexrazoxane	Zinecard	chelator	IV	250-500mg/m2	D	PI
vandetanib	Caprelsa	antineoplastic; kinase inhibitor	tablets	300mg	D	PI
Drug Recommended to be Removed from the 2012 Hazardous Drug List						
tetracycline		antibiotic	capsules	500mg	D	PI

Attachment 3

Track and trace: Is your pharmacy in compliance with the new law?

June 09, 2015

APhA reminds pharmacies of new regulatory requirements

Is your pharmacy ready for the new track-and-trace law? Under the Drug Supply Chain Security Act, January 1 and July 1 are the key dates in 2015 for new requirements for pharmacies.

Per the new law, as of January 1, 2015, pharmacies shall only accept drug products from authorized trading partners. Also, pharmacies are required to have processes in place to identify, quarantine, and investigate suspect products and determine whether products are illegitimate. By July 1, 2015, pharmacies must be able to capture and maintain transaction information (TI), transaction history (TH), and a transaction statement (TS)—sometimes referred to as "the three Ts"—for each drug product received for 6 years from the date of the transaction.

APhA is spreading the word to help pharmacies stay in compliance with the new law. Following up on January's ***Pharmacy Today*** article on the 2015 deadlines, this article ahead of the upcoming July issue features additional information as implementation is under way. In the days ahead, a printable compliance checklist for pharmacies will be posted on pharmacist.com.

Next deadline: July 1

Beginning July 1, pharmacies may not accept product from trading partners unless it is accompanied by the three Ts, and they must maintain these records for 6 years. Pharmacies could contract with their wholesale distributors to maintain the records electronically for them so long as the pharmacy can access and retrieve the data. FDA has clarified in draft guidance that "e-mail or Web-based platforms (such as Web portals)" are acceptable means to meeting the requirement of providing the TI, TH, and TS—as long as the information can be accessed by pharmacies and other required entities.

If pharmacies are contracting with wholesale distributors and/or cloud-based traceability vendors to maintain the three Ts, it is necessary that pharmacies have written agreements on record that reflect these new requirements, according to Michael H. Ghobrial, PharmD, JD, APhA Associate Director of Health Policy.

APhA member Travis Hale, PharmD, works for two different pharmacies in the small community of Remington, VA. At Remington Drug Co., he is a staff pharmacist in the process of buying the pharmacy along with a partner. He is also the Pharmacist in Charge at Family Care Remington Pharmacy, a long-term care pharmacy. "I had heard about track and trace and the basic idea of what was to be accomplished over the last year or 2, but not really any hard information as to how it was going to impact my stores or any specifics on day-to-day operations," Hale told ***Today***.

Real-world challenges

On June 1, APhA and other national pharmacy associations attended an FDA Drug Supply Chain and Security Act listening session. APhA articulated a number of concerns related to the impending July 1 deadline and the ability of wholesaler distributors to meet the requirement to provide access to the three Ts to pharmacies. APhA also discussed the concern that access to the three Ts may come at a cost in the future or may limit pharmacists' ability to switch wholesaler distributors.

Hale spoke at the FDA meeting as an APhA member. He described his experiences interfacing with the more than 10 primary and secondary wholesale distributors from which both pharmacies order medications fairly consistently. One of the wholesalers, he noted to ***Today,*** has always offered satisfactory customer service; but Hale has "not been able to get a lot of details on how things will work" with regard to providing the information so pharmacies can meet the July 1 requirements.

The biggest real-world challenge Hale faces with track and trace, he told ***Today***, "is going to be the management of all of this data as a single-store owner/manager when it is being held by potentially 10-plus wholesalers in different portals or clouds where we have 10-plus usernames and passwords."

He continued, "It has the potential to be a very time-consuming administrative task to add to the long list of administrative tasks that independent store owners are being asked to do as everything goes electronic." While Hale has no problem with going electronic, and actually welcomes it if efficiency and safety can be improved, he is concerned that "this could result in additional expense for the independent pharmacy owner."

Stay tuned

Watch for APhA's printable compliance checklist in the days ahead on pharmacist.com.

Diana Yap, Editorial Director

PharmacyToday

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TITLE II—DRUG SUPPLY CHAIN SECURITY

Drug Supply Chain Security Act.

SEC. 201. SHORT TITLE.

21 USC 301 note.

This title may be cited as the "Drug Supply Chain Security Act".

SEC. 202. PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN.

Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"Subchapter H—Pharmaceutical Distribution Supply Chain

21 USC prec. 360eee.

"SEC. 581. DEFINITIONS.

21 USC 360eee.

"In this subchapter:

"(1) AFFILIATE.—The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

"(A) one business entity controls, or has the power to control, the other business entity; or

"(B) a third party controls, or has the power to control, both of the business entities.

"(2) AUTHORIZED.—The term 'authorized' means—

"(A) in the case of a manufacturer or repackager, having a valid registration in accordance with section 510;

"(B) in the case of a wholesale distributor, having a valid license under State law or section 583, in accordance with section 582(a)(6), and complying with the licensure reporting requirements under section 503(e), as amended by the Drug Supply Chain Security Act;

"(C) in the case of a third-party logistics provider, having a valid license under State law or section 584(a)(1), in accordance with section 582(a)(7), and complying with the licensure reporting requirements under section 584(b); and

"(D) in the case of a dispenser, having a valid license under State law.

"(3) DISPENSER.—The term 'dispenser'—

"(A) means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and

"(B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).

"(4) DISPOSITION.—The term 'disposition', with respect to a product within the possession or control of an entity, means the removal of such product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other appropriate handling and other actions, such as retaining a sample of the product for further additional physical examination or laboratory analysis

of the product by a manufacturer or regulatory or law enforcement agency.

"(5) DISTRIBUTE OR DISTRIBUTION.—The term 'distribute' or 'distribution' means the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1) or the dispensing of a product approved under section 512(b).

"(6) EXCLUSIVE DISTRIBUTOR.—The term 'exclusive distributor' means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser.

"(7) HOMOGENEOUS CASE.—The term 'homogeneous case' means a sealed case containing only product that has a single National Drug Code number belonging to a single lot.

"(8) ILLEGITIMATE PRODUCT.—The term 'illegitimate product' means a product for which credible evidence shows that the product—

"(A) is counterfeit, diverted, or stolen;

"(B) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

"(C) is the subject of a fraudulent transaction; or

"(D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

"(9) LICENSED.—The term 'licensed' means—

"(A) in the case of a wholesale distributor, having a valid license in accordance with section 503(e) or section 582(a)(6), as applicable;

"(B) in the case of a third-party logistics provider, having a valid license in accordance with section 584(a) or section 582(a)(7), as applicable; and

"(C) in the case of a dispenser, having a valid license under State law.

"(10) MANUFACTURER.—The term 'manufacturer' means, with respect to a product—

"(A) a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;

"(B) a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C); or

"(C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B).

"(11) PACKAGE.—

"(A) IN GENERAL.—The term 'package' means the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product.

"(B) INDIVIDUAL SALEABLE UNIT.—For purposes of this paragraph, an 'individual saleable unit' is the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser.

"(12) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug for human use subject to section 503(b)(1).

"(13) PRODUCT.—The term 'product' means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but for purposes of section 582, does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021), imaging drugs, an intravenous product described in clause (xiv), (xv), or (xvi) of paragraph (24)(B), any medical gas (as defined in section 575), homeopathic drugs marketed in accordance with applicable guidance under this Act, or a drug compounded in compliance with section 503A or 503B.

"(14) PRODUCT IDENTIFIER.—The term 'product identifier' means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.

"(15) QUARANTINE.—The term 'quarantine' means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use or through other procedures.

"(16) REPACKAGER.—The term 'repackager' means a person who owns or operates an establishment that repacks and relabels a product or package for—

"(A) further sale; or

"(B) distribution without a further transaction.

"(17) RETURN.—The term 'return' means providing product to the authorized immediate trading partner from which such product was purchased or received, or to a returns processor or reverse logistics provider for handling of such product.

"(18) RETURNS PROCESSOR OR REVERSE LOGISTICS PROVIDER.—The term 'returns processor' or 'reverse logistics provider' means a person who owns or operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from an authorized trading partner such that the product may be processed for credit to the purchaser, manufacturer, or seller or disposed of for no further distribution.

"(19) SPECIFIC PATIENT NEED.—The term 'specific patient need' refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

"(20) STANDARDIZED NUMERICAL IDENTIFIER.—The term 'standardized numerical identifier' means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

"(21) SUSPECT PRODUCT.—The term 'suspect product' means a product for which there is reason to believe that such product—

"(A) is potentially counterfeit, diverted, or stolen;

"(B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

"(C) is potentially the subject of a fraudulent transaction; or

"(D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

"(22) THIRD-PARTY LOGISTICS PROVIDER.—The term 'third-party logistics provider' means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

"(23) TRADING PARTNER.—The term 'trading partner' means—

"(A) a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or

"(B) a third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.

"(24) TRANSACTION.—

"(A) IN GENERAL.—The term 'transaction' means the transfer of product between persons in which a change of ownership occurs.

"(B) EXEMPTIONS.—The term 'transaction' does not include—

"(i) intracompany distribution of any product between members of an affiliate or within a manufacturer;

"(ii) the distribution of a product among hospitals or other health care entities that are under common control;

"(iii) the distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

"(iv) the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1);

"(v) the distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with section 503(d);

"(vi) the distribution of blood or blood components intended for transfusion;

"(vii) the distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;

"(viii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

"(ix) the distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;

"(x) the dispensing of a product approved under section 512(c);

"(xi) products transferred to or from any facility that is licensed by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021);

"(xii) a combination product that is not subject to approval under section 505 or licensure under section 351 of the Public Health Service Act, and that is—

"(I) a product comprised of a device and 1 or more other regulated components (such as a drug/device, biologic/device, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

"(II) 2 or more separate products packaged together in a single package or as a unit and comprised of a drug and device or device and biological product; or

"(III) 2 or more finished medical devices plus one or more drug or biological products that are packaged together in what is referred to as a 'medical convenience kit' as described in clause (xiii);

"(xiii) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this clause as a 'medical convenience kit') if—

"(I) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 510(b)(2);

"(II) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

"(III) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit—

"(aa) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

"(bb) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

"(IV) in the case of a medical convenience kit that includes a product, the product is—

"(aa) an intravenous solution intended for the replenishment of fluids and electrolytes;

"(bb) a product intended to maintain the equilibrium of water and minerals in the body;

"(cc) a product intended for irrigation or reconstitution;

"(dd) an anesthetic;

"(ee) an anticoagulant;

"(ff) a vasopressor; or

"(gg) a sympathomimetic;

"(xiv) the distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

"(xv) the distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

"(xvi) the distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

"(xvii) the distribution of a medical gas (as defined in section 575); or

"(xviii) the distribution or sale of any licensed product under section 351 of the Public Health Service Act that meets the definition of a device under section 201(h).

"(25) TRANSACTION HISTORY.—The term 'transaction history' means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

"(26) TRANSACTION INFORMATION.—The term 'transaction information' means—

"(A) the proprietary or established name or names of the product;

"(B) the strength and dosage form of the product;

"(C) the National Drug Code number of the product;

"(D) the container size;

"(E) the number of containers;

"(F) the lot number of the product;

"(G) the date of the transaction;

"(H) the date of the shipment, if more than 24 hours after the date of the transaction;

"(I) the business name and address of the person from whom ownership is being transferred; and

"(J) the business name and address of the person to whom ownership is being transferred.

"(27) TRANSACTION STATEMENT.—The 'transaction statement' is a statement, in paper or electronic form, that the entity transferring ownership in a transaction—

"(A) is authorized as required under the Drug Supply Chain Security Act;

"(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

"(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

"(D) did not knowingly ship a suspect or illegitimate product;

"(E) had systems and processes in place to comply with verification requirements under section 582;

"(F) did not knowingly provide false transaction information; and

"(G) did not knowingly alter the transaction history.

"(28) VERIFICATION OR VERIFY.—The term 'verification' or 'verify' means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager, as applicable in accordance with section 582.

"(29) WHOLESALE DISTRIBUTOR.—The term 'wholesale distributor' means a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 503(e)(4), as amended by the Drug Supply Chain Security Act).

"SEC. 582. REQUIREMENTS.

Effective dates.
21 USC 360eee–1.
Compliance.

"(a) IN GENERAL.—

"(1) OTHER ACTIVITIES.—Each manufacturer, repackager, wholesale distributor, and dispenser shall comply with the requirements set forth in this section with respect to the role of such manufacturer, repackager, wholesale distributor, or dispenser in a transaction involving product. If an entity meets the definition of more than one of the entities listed in the preceding sentence, such entity shall comply with all applicable requirements in this section, but shall not be required to duplicate requirements.

"(2) INITIAL STANDARDS.—

Consultation.

"(A) IN GENERAL.—The Secretary shall, in consultation with other appropriate Federal officials, manufacturers, repackagers, wholesale distributors, dispensers, and other pharmaceutical distribution supply chain stakeholders, issue a draft guidance document that establishes standards for the interoperable exchange of transaction information,

transaction history, and transaction statements, in paper or electronic format, for compliance with this subsection and subsections (b), (c), (d), and (e). In establishing such standards, the Secretary shall consider the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the transaction information, transaction history, and transaction statement to the subsequent purchaser of a product and to facilitate the exchange of lot level data. The standards established under this paragraph shall take into consideration the standards established under section 505D and shall comply with a form and format developed by a widely recognized international standards development organization.

Compliance.

"(B) PUBLIC INPUT.—Prior to issuing the draft guidance under subparagraph (A), the Secretary shall gather comments and information from stakeholders and maintain such comments and information in a public docket for at least 60 days prior to issuing such guidance.

Time period.

"(C) PUBLICATION.—The Secretary shall publish the standards established under subparagraph (A) not later than 1 year after the date of enactment of the Drug Supply Chain Security Act.

Deadline.

"(3) WAIVERS, EXCEPTIONS, AND EXEMPTIONS.—

"(A) IN GENERAL.—Not later than 2 years after the date of enactment of the Drug Supply Chain Security Act, the Secretary shall, by guidance—

Deadline.
Guidance.

"(i) establish a process by which an authorized manufacturer, repackager, wholesale distributor, or dispenser may request a waiver from any of the requirements set forth in this section, which the Secretary may grant if the Secretary determines that such requirements would result in an undue economic hardship or for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act;

"(ii) establish a process by which the Secretary determines exceptions, and a process through which a manufacturer or repackager may request such an exception, to the requirements relating to product identifiers if a product is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with this section; and

"(iii) establish a process by which the Secretary may determine other products or transactions that shall be exempt from the requirements of this section.

"(B) CONTENT.—The guidance issued under subparagraph (A) shall include a process for the biennial review and renewal of such waivers, exceptions, and exemptions, as applicable.

"(C) PROCESS.—In issuing the guidance under this paragraph, the Secretary shall provide an effective date that is not later than 180 days prior to the date on which manufacturers are required to affix or imprint a product identifier to each package and homogenous case of product

intended to be introduced in a transaction into commerce consistent with this section.

"(4) SELF-EXECUTING REQUIREMENTS.—Except where otherwise specified, the requirements of this section may be enforced without further regulations or guidance from the Secretary.

"(5) GRANDFATHERING PRODUCT.—

"(A) PRODUCT IDENTIFIER.—Not later than 2 years after the date of enactment of the Drug Supply Chain Security Act, the Secretary shall finalize guidance specifying whether and under what circumstances product that is not labeled with a product identifier and that is in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of this section shall be exempted from the requirements of this section. Deadline. Guidance.

"(B) TRACING.—For a product that entered the pharmaceutical distribution supply chain prior to January 1, 2015—

"(i) authorized trading partners shall be exempt from providing transaction information as required under subsections (b)(1)(A)(i), (c)(1)(A)(ii), (d)(1)(A)(ii), and (e)(1)(A)(ii);

"(ii) transaction history required under this section shall begin with the owner of such product on such date; and

"(iii) the owners of such product on such date shall be exempt from asserting receipt of transaction information and transaction statement from the prior owner as required under this section.

"(6) WHOLESALE DISTRIBUTOR LICENSES.—Notwithstanding section 581(9)(A), until the effective date of the wholesale distributor licensing regulations under section 583, the term 'licensed' or 'authorized', as it relates to a wholesale distributor with respect to prescription drugs, shall mean a wholesale distributor with a valid license under State law. Definition.

"(7) THIRD-PARTY LOGISTICS PROVIDER LICENSES.—Until the effective date of the third-party logistics provider licensing regulations under section 584, a third-party logistics provider shall be considered 'licensed' under section 581(9)(B) unless the Secretary has made a finding that the third-party logistics provider does not utilize good handling and distribution practices and publishes notice thereof. Notice.

"(8) LABEL CHANGES.—Changes made to package labels solely to incorporate the product identifier may be submitted to the Secretary in the annual report of an establishment, in accordance with section 314.70(d) of chapter 21, Code of Federal Regulations (or any successor regulation).

"(9) PRODUCT IDENTIFIERS.—With respect to any requirement relating to product identifiers under this subchapter—

"(A) unless the Secretary allows, through guidance, the use of other technologies for data instead of or in addition to the technologies described in clauses (i) and (ii), the applicable data—

"(i) shall be included in a 2-dimensional data matrix barcode when affixed to, or imprinted upon, a package; and

"(ii) shall be included in a linear or 2-dimensional data matrix barcode when affixed to, or imprinted upon, a homogeneous case; and

"(B) verification of the product identifier may occur by using human-readable or machine-readable methods.

"(b) MANUFACTURER REQUIREMENTS.—

"(1) PRODUCT TRACING.—

"(A) IN GENERAL.—Beginning not later than January 1, 2015, a manufacturer shall—

"(i) prior to, or at the time of, each transaction in which such manufacturer transfers ownership of a product, provide the subsequent owner with transaction history, transaction information, and a transaction statement, in a single document in an paper or electronic format; and

Time period.

"(ii) capture the transaction information (including lot level information), transaction history, and transaction statement for each transaction and maintain such information, history, and statement for not less than 6 years after the date of the transaction.

Time period.

"(B) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a manufacturer shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request, or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction history, and transaction statement for the product.

"(C) ELECTRONIC FORMAT.—

"(i) IN GENERAL.—Beginning not later than 4 years after the date of enactment of the Drug Supply Chain Security Act, except as provided under clause (ii), a manufacturer shall provide the transaction information, transaction history, and transaction statement required under subparagraph (A)(i) in electronic format.

"(ii) EXCEPTION.—A manufacturer may continue to provide the transaction information, transaction history, and transaction statement required under subparagraph (A)(i) in a paper format to a licensed health care practitioner authorized to prescribe medication under State law or other licensed individual under the supervision or direction of such a practitioner who dispenses product in the usual course of professional practice.

"(2) PRODUCT IDENTIFIER.—

"(A) IN GENERAL.—Beginning not later than 4 years after the date of enactment of the Drug Supply Chain Security Act, a manufacturer shall affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce. Such manufacturer shall maintain the product identifier information for such product for not less than 6 years after the date of the transaction.

Time period.

"(B) EXCEPTION.—A package that is required to have a standardized numerical identifier is not required to have a unique device identifier.

"(3) AUTHORIZED TRADING PARTNERS.—Beginning not later than January 1, 2015, the trading partners of a manufacturer may be only authorized trading partners.

"(4) VERIFICATION.—Beginning not later than January 1, 2015, a manufacturer shall have systems in place to enable the manufacturer to comply with the following requirements:

"(A) SUSPECT PRODUCT.— Determination.

"(i) IN GENERAL.—Upon making a determination that a product in the possession or control of the manufacturer is a suspect product, or upon receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a manufacturer is a suspect product, a manufacturer shall—

"(I) quarantine such product within the possession or control of the manufacturer from product intended for distribution until such product is cleared or dispositioned; and Quarantine.

"(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product, which shall include validating any applicable transaction history and transaction information in the possession of the manufacturer and otherwise investigating to determine whether the product is an illegitimate product, and, beginning 4 years after the date of enactment of the Drug Supply Chain Security Act, verifying the product at the package level, including the standardized numerical identifier. Investigation.

"(ii) CLEARED PRODUCT.—If the manufacturer makes the determination that a suspect product is not an illegitimate product, the manufacturer shall promptly notify the Secretary, if applicable, of such determination and such product may be further distributed. Notification.

"(iii) RECORDS.—A manufacturer shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation. Time period.

"(B) ILLEGITIMATE PRODUCT.— Determination.

"(i) IN GENERAL.—Upon determining that a product in the possession or control of a manufacturer is an illegitimate product, the manufacturer shall, in a manner consistent with the systems and processes of such manufacturer—

"(I) quarantine such product within the possession or control of the manufacturer from product intended for distribution until such product is dispositioned;

"(II) disposition the illegitimate product within the possession or control of the manufacturer;

"(III) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the manufacturer; and

"(IV) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) upon request by the Secretary (or other appropriate Federal or State official), as necessary and appropriate.

"(ii) MAKING A NOTIFICATION.—

Deadline.

"(I) ILLEGITIMATE PRODUCT.—Upon determining that a product in the possession or control of the manufacturer is an illegitimate product, the manufacturer shall notify the Secretary and all immediate trading partners that the manufacturer has reason to believe may have received such illegitimate product of such determination not later than 24 hours after making such determination.

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

"(iii) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary or a trading partner that a determination has been made that a product is an illegitimate product, a manufacturer shall identify all illegitimate product subject to such notification that is in the possession or control of the manufacturer, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

Consultation.

"(iv) TERMINATING A NOTIFICATION.—Upon making a determination, in consultation with the Secretary, that a notification is no longer necessary, a manufacturer shall promptly notify immediate trading partners that the manufacturer notified pursuant to clause (ii) that such notification has been terminated.

Time period.

"(v) RECORDS.—A manufacturer shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

Deadline.
Timeline.

"(C) REQUESTS FOR VERIFICATION.—Beginning 4 years after the date of enactment of the Drug Supply Chain Security Act, upon receiving a request for verification from

an authorized repackager, wholesale distributor, or dispenser that is in possession or control of a product such person believes to be manufactured by such manufacturer, a manufacturer shall, not later than 24 hours after receiving the request for verification or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, notify the person making the request whether the product identifier, including the standardized numerical identifier, that is the subject of the request corresponds to the product identifier affixed or imprinted by the manufacturer. If a manufacturer responding to a request for verification identifies a product identifier that does not correspond to that affixed or imprinted by the manufacturer, the manufacturer shall treat such product as suspect product and conduct an investigation as described in subparagraph (A). If the manufacturer has reason to believe the product is an illegitimate product, the manufacturer shall advise the person making the request of such belief at the time such manufacturer responds to the request for verification.

"(D) ELECTRONIC DATABASE.—A manufacturer may satisfy the requirements of this paragraph by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity. The owner of such database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a manufacturer of the requirement under this paragraph to respond to a request for verification submitted by means other than a secure electronic database.

Verification.

"(E) SALEABLE RETURNED PRODUCT.—Beginning 4 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), upon receipt of a returned product that the manufacturer intends to further distribute, before further distributing such product, the manufacturer shall verify the product identifier, including the standardized numerical identifier, for each sealed homogeneous case of such product or, if such product is not in a sealed homogeneous case, verify the product identifier, including the standardized numerical identifier, on each package.

"(F) NONSALEABLE RETURNED PRODUCT.—A manufacturer may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the information described in paragraph (1)(A)(i).

"(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

"(1) PRODUCT TRACING.—

Applicability.

"(A) IN GENERAL.—Beginning not later than January 1, 2015, the following requirements shall apply to wholesale distributors:

"(i) A wholesale distributor shall not accept ownership of a product unless the previous owner prior to,

or at the time of, the transaction provides the transaction history, transaction information, and a transaction statement for the product, as applicable under this subparagraph.

"(ii)(I)(aa) If the wholesale distributor purchased a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, then prior to, or at the time of, each transaction in which the wholesale distributor transfers ownership of a product, the wholesale distributor shall provide to the subsequent purchaser—

"(AA) a transaction statement, which shall state that such wholesale distributor, or a member of the affiliate of such wholesale distributor, purchased the product directly from the manufacturer, exclusive distributor of the manufacturer, or repackager that purchased the product directly from the manufacturer; and

"(BB) subject to subclause (II), the transaction history and transaction information.

"(bb) The wholesale distributor shall provide the transaction history, transaction information, and transaction statement under item (aa)—

"(AA) if provided to a dispenser, on a single document in a paper or electronic format; and

"(BB) if provided to a wholesale distributor, through any combination of self-generated paper, electronic data, or manufacturer-provided information on the product package.

"(II) For purposes of transactions described in subclause (I), transaction history and transaction information shall not be required to include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer (as defined in subparagraphs (F), (G), and (H) of section 581(26)).

"(iii) If the wholesale distributor did not purchase a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, as described in clause (ii), then prior to, or at the time of, each transaction or subsequent transaction, the wholesale distributor shall provide to the subsequent purchaser a transaction statement, transaction history, and transaction information, in a paper or electronic format that complies with the guidance document issued under subsection (a)(2).

"(iv) For the purposes of clause (iii), the transaction history supplied shall begin only with the wholesale distributor described in clause (ii)(I), but the wholesale distributor described in clause (iii) shall inform the subsequent purchaser that such wholesale distributor received a direct purchase statement from a wholesale distributor described in clause (ii)(I).

"(v) A wholesale distributor shall—

"(I) capture the transaction information (including lot level information) consistent with the requirements of this section, transaction history, and transaction statement for each transaction described in clauses (i), (ii), and (iii) and maintain such information, history, and statement for not less than 6 years after the date of the transaction; and

Time period.

"(II) maintain the confidentiality of the transaction information (including any lot level information consistent with the requirements of this section), transaction history, and transaction statement for a product in a manner that prohibits disclosure to any person other than the Secretary or other appropriate Federal or State official, except to comply with clauses (ii) and (iii), and, as applicable, pursuant to an agreement under subparagraph (D).

Confidentiality.

"(B) RETURNS.—

"(i) SALEABLE RETURNS.—Notwithstanding subparagraph (A)(i), the following shall apply:

Applicability.

"(I) REQUIREMENTS.—Until the date that is 6 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), a wholesale distributor may accept returned product from a dispenser or repackager pursuant to the terms and conditions of any agreement between the parties, and, notwithstanding subparagraph (A)(ii), may distribute such returned product without providing the transaction history. For transactions subsequent to the return, the transaction history of such product shall begin with the wholesale distributor that accepted the returned product, consistent with the requirements of this subsection.

"(II) ENHANCED REQUIREMENTS.—Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), a wholesale distributor may accept returned product from a dispenser or repackager only if the wholesale distributor can associate returned product with the transaction information and transaction statement associated with that product. For all transactions after such date, the transaction history, as applicable, of such product shall begin with the wholesale distributor that accepted and verified the returned product. For purposes of this subparagraph, the transaction information and transaction history, as applicable, need not include transaction dates if it is not reasonably practicable to obtain such dates.

"(ii) NONSALEABLE RETURNS.—A wholesale distributor may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, or to a person acting on behalf of such a person, including a returns

processor, without providing the information required under subparagraph (A)(i).

Time period.

"(C) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a wholesale distributor shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction history, and transaction statement for the product.

"(D) TRADING PARTNER AGREEMENTS.—Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act, a wholesale distributor may disclose the transaction information, including lot level information, transaction history, or transaction statement of a product to the subsequent purchaser of the product, pursuant to a written agreement between such wholesale distributor and such subsequent purchaser. Nothing in this subparagraph shall be construed to limit the applicability of subparagraphs (A) through (C).

"(2) PRODUCT IDENTIFIER.—Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act, a wholesale distributor may engage in transactions involving a product only if such product is encoded with a product identifier (except as provided pursuant to subsection (a)(5)).

"(3) AUTHORIZED TRADING PARTNERS.—Beginning not later than January 1, 2015, the trading partners of a wholesale distributor may be only authorized trading partners.

"(4) VERIFICATION.—Beginning not later than January 1, 2015, a wholesale distributor shall have systems in place to enable the wholesale distributor to comply with the following requirements:

Determination.

"(A) SUSPECT PRODUCT.—

"(i) IN GENERAL.—Upon making a determination that a product in the possession or control of a wholesale distributor is a suspect product, or upon receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a wholesale distributor is a suspect product, a wholesale distributor shall—

Quarantine.

"(I) quarantine such product within the possession or control of the wholesale distributor from product intended for distribution until such product is cleared or dispositioned; and

Investigation.

"(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product, which shall include validating any applicable transaction history and transaction information in the possession of the wholesale distributor and otherwise investigating to determine whether the product is an illegitimate product, and, beginning 6 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)),

verifying the product at the package level, including the standardized numerical identifier.

"(ii) CLEARED PRODUCT.—If the wholesale distributor determines that a suspect product is not an illegitimate product, the wholesale distributor shall promptly notify the Secretary, if applicable, of such determination and such product may be further distributed. Notification.

"(iii) RECORDS.—A wholesale distributor shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation. Time period.

"(B) ILLEGITIMATE PRODUCT.— Determination.

"(i) IN GENERAL.—Upon determining, in coordination with the manufacturer, that a product in the possession or control of a wholesale distributor is an illegitimate product, the wholesale distributor shall, in a manner that is consistent with the systems and processes of such wholesale distributor—

"(I) quarantine such product within the possession or control of the wholesale distributor from product intended for distribution until such product is dispositioned; Quarantine.

"(II) disposition the illegitimate product within the possession or control of the wholesale distributor;

"(III) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the wholesale distributor; and

"(IV) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) upon request by the manufacturer or Secretary (or other appropriate Federal or State official), as necessary and appropriate.

"(ii) MAKING A NOTIFICATION.—Upon determining that a product in the possession or control of the wholesale distributor is an illegitimate product, the wholesale distributor shall notify the Secretary and all immediate trading partners that the wholesale distributor has reason to believe may have received such illegitimate product of such determination not later than 24 hours after making such determination. Deadline.

"(iii) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary or a trading partner that a determination has been made that a product is an illegitimate product, a wholesale distributor shall identify all illegitimate product subject to such notification that is in the possession or control of the wholesale distributor, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

"(iv) TERMINATING A NOTIFICATION.—Upon making a determination, in consultation with the Secretary, that a notification is no longer necessary, a wholesale

distributor shall promptly notify immediate trading partners that the wholesale distributor notified pursuant to clause (ii) that such notification has been terminated.

Time period.

"(v) RECORDS.—A wholesale distributor shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

"(C) ELECTRONIC DATABASE.—A wholesale distributor may satisfy the requirements of this paragraph by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity. The owner of such database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a wholesale distributor of the requirement under this paragraph to respond to a verification request submitted by means other than a secure electronic database.

Requirements.

"(D) VERIFICATION OF SALEABLE RETURNED PRODUCT.—Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act, upon receipt of a returned product that the wholesale distributor intends to further distribute, before further distributing such product, the wholesale distributor shall verify the product identifier, including the standardized numerical identifier, for each sealed homogeneous case of such product or, if such product is not in a sealed homogeneous case, verify the product identifier, including the standardized numerical identifier, on each package.

"(d) DISPENSER REQUIREMENTS.—

"(1) PRODUCT TRACING.—

"(A) IN GENERAL.—Beginning July 1, 2015, a dispenser—

"(i) shall not accept ownership of a product, unless the previous owner prior to, or at the time of, the transaction, provides transaction history, transaction information, and a transaction statement;

"(ii) prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product (but not including dispensing to a patient or returns) shall provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product, except that the requirements of this clause shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need; and

Time period.

"(iii) shall capture transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintain such information, history, and statements for not less than 6 years after the transaction.

"(B) AGREEMENTS WITH THIRD PARTIES.—A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which

the third party confidentially maintains the transaction information, transaction history, and transaction statements required to be maintained under this subsection on behalf of the dispenser. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of the dispenser under this subsection.

Records.

"(C) RETURNS.—

"(i) SALEABLE RETURNS.—A dispenser may return product to the trading partner from which the dispenser obtained the product without providing the information required under subparagraph (A).

"(ii) NONSALEABLE RETURNS.—A dispenser may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, to a returns processor, or to a person acting on behalf of such a person without providing the information required under subparagraph (A).

"(D) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect or an illegitimate product, a dispenser shall, not later than 2 business days after receiving the request or in another such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction statement, and transaction history which the dispenser received from the previous owner, which shall not include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer unless such information was included in the transaction information, transaction statement, and transaction history provided by the manufacturer or wholesale distributor to the dispenser. The dispenser may respond to the request by providing the applicable information in either paper or electronic format. Until the date that is 4 years after the date of enactment of the Drug Supply Chain Security Act, the Secretary or other appropriate Federal or State official shall grant a dispenser additional time, as necessary, only with respect to a request to provide lot level information described in subparagraph (F) of section 581(26) that was provided to the dispenser in paper format, limit the request time period to the 6 months preceding the request or other relevant date, and, in the event of a recall, the Secretary, or other appropriate Federal or State official may request information only if such recall involves a serious adverse health consequence or death to humans.

Time periods.

"(2) PRODUCT IDENTIFIER.—Beginning not later than 7 years after the date of enactment of the Drug Supply Chain Security Act, a dispenser may engage in transactions involving a product only if such product is encoded with a product identifier (except as provided pursuant to subsection (a)(5)).

"(3) AUTHORIZED TRADING PARTNERS.—Beginning not later than January 1, 2015, the trading partners of a dispenser may be only authorized trading partners.

"(4) VERIFICATION.—Beginning not later than January 1, 2015, a dispenser shall have systems in place to enable the dispenser to comply with the following requirements:

"(A) SUSPECT PRODUCT.—

Determination.

"(i) IN GENERAL.—Upon making a determination that a product in the possession or control of the dispenser is a suspect product, or upon receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a dispenser is a suspect product, a dispenser shall—

Quarantine.

"(I) quarantine such product within the possession or control of the dispenser from product intended for distribution until such product is cleared or dispositioned; and

Investigation.

"(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product.

"(ii) INVESTIGATION.—An investigation conducted under clause (i)(II) shall include—

"(I) beginning 7 years after the date of enactment of the Drug Supply Chain Security Act, verifying whether the lot number of a suspect product corresponds with the lot number for such product;

"(II) beginning 7 years after the date of enactment of such Act, verifying that the product identifier, including the standardized numerical identifier, of at least 3 packages or 10 percent of such suspect product, whichever is greater, or all packages, if there are fewer than 3, corresponds with the product identifier for such product;

"(III) validating any applicable transaction history and transaction information in the possession of the dispenser; and

"(IV) otherwise investigating to determine whether the product is an illegitimate product.

Notification.

"(iii) CLEARED PRODUCT.—If the dispenser makes the determination that a suspect product is not an illegitimate product, the dispenser shall promptly notify the Secretary, if applicable, of such determination and such product may be further distributed or dispensed.

Time period.

"(iv) RECORDS.—A dispenser shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.

Determination.

"(B) ILLEGITIMATE PRODUCT.—

"(i) IN GENERAL.—Upon determining, in coordination with the manufacturer, that a product in the possession or control of a dispenser is an illegitimate product, the dispenser shall—

"(I) disposition the illegitimate product within the possession or control of the dispenser;

"(II) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the dispenser; and

"(III) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) upon request by the manufacturer or Secretary (or other appropriate Federal or State official), as necessary and appropriate.

"(ii) MAKING A NOTIFICATION.—Upon determining that a product in the possession or control of the dispenser is an illegitimate product, the dispenser shall notify the Secretary and all immediate trading partners that the dispenser has reason to believe may have received such illegitimate product of such determination not later than 24 hours after making such determination. Deadline.

"(iii) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary or a trading partner that a determination has been made that a product is an illegitimate product, a dispenser shall identify all illegitimate product subject to such notification that is in the possession or control of the dispenser, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

"(iv) TERMINATING A NOTIFICATION.—Upon making a determination, in consultation with the Secretary, that a notification is no longer necessary, a dispenser shall promptly notify immediate trading partners that the dispenser notified pursuant to clause (ii) that such notification has been terminated.

"(v) RECORDS.—A dispenser shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition. Time period.

"(C) ELECTRONIC DATABASE.—A dispenser may satisfy the requirements of this paragraph by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity.

"(5) EXCEPTION.—Notwithstanding any other provision of law, the requirements under paragraphs (1) and (4) shall not apply to licensed health care practitioners authorized to prescribe or administer medication under State law or other licensed individuals under the supervision or direction of such practitioners who dispense or administer product in the usual course of professional practice.

"(e) REPACKAGER REQUIREMENTS.—

"(1) PRODUCT TRACING.—

"(A) IN GENERAL.—Beginning not later than January 1, 2015, a repackager described in section 581(16)(A) shall—

"(i) not accept ownership of a product unless the previous owner, prior to, or at the time of, the transaction, provides transaction history, transaction

information, and a transaction statement for the product;

"(ii) prior to, or at the time of, each transaction in which the repackager transfers ownership of a product, provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product; and

"(iii) capture the transaction information (including lot level information), transaction history, and transaction statement for each transaction described in clauses (i) and (ii) and maintain such information, history, and statement for not less than 6 years after the transaction.

"(B) RETURNS.—

"(i) NONSALEABLE PRODUCT.—A repackager described in section 581(16)(A) may return a nonsaleable product to the manufacturer or repackager, or to the wholesale distributor from whom such product was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the information required under subparagraph (A)(ii).

"(ii) SALEABLE OR NONSALEABLE PRODUCT.—A repackager described in section 581(16)(B) may return a saleable or nonsaleable product to the manufacturer, repackager, or to the wholesale distributor from whom such product was received without providing the information required under subparagraph (A)(ii) on behalf of the hospital or other health care entity that took ownership of such product pursuant to the terms and conditions of any agreement between such repackager and the entity that owns the product.

Time period.

"(C) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a repackager described in section 581(16)(A) shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request or in other such reasonable time as determined by the Secretary, provide the applicable transaction information, transaction history, and transaction statement for the product.

"(2) PRODUCT IDENTIFIER.—

"(A) IN GENERAL.—Beginning not later than 5 years after the date of enactment of the Drug Supply Chain Security Act, a repackager described in section 581(16)(A)—

"(i) shall affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction in commerce;

Time period.

"(ii) shall maintain the product identifier information for such product for not less than 6 years after the date of the transaction;

"(iii) may engage in transactions involving a product only if such product is encoded with a product identifier (except as provided pursuant to subsection (a)(5)); and

"(iv) shall maintain records for not less than 6 years to allow the repackager to associate the product identifier the repackager affixes or imprints with the product identifier assigned by the original manufacturer of the product.

Records.
Time period.

"(B) EXCEPTION.—A package that is required to have a standardized numerical identifier is not required to have a unique device identifier.

"(3) AUTHORIZED TRADING PARTNERS.—Beginning January 1, 2015, the trading partners of a repackager described in section 581(16) may be only authorized trading partners.

"(4) VERIFICATION.—Beginning not later than January 1, 2015, a repackager described in section 581(16)(A) shall have systems in place to enable the repackager to comply with the following requirements:

"(A) SUSPECT PRODUCT.—

Determination.

"(i) IN GENERAL.—Upon making a determination that a product in the possession or control of the repackager is a suspect product, or upon receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a repackager is a suspect product, a repackager shall—

"(I) quarantine such product within the possession or control of the repackager from product intended for distribution until such product is cleared or dispositioned; and

Quarantine.

"(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product, which shall include validating any applicable transaction history and transaction information in the possession of the repackager and otherwise investigating to determine whether the product is an illegitimate product, and, beginning 5 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), verifying the product at the package level, including the standardized numerical identifier.

Investigation.

"(ii) CLEARED PRODUCT.—If the repackager makes the determination that a suspect product is not an illegitimate product, the repackager shall promptly notify the Secretary, if applicable, of such determination and such product may be further distributed.

Notification.

"(iii) RECORDS.—A repackager shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.

Time period.

"(B) ILLEGITIMATE PRODUCT.—

Determination.

"(i) IN GENERAL.—Upon determining, in coordination with the manufacturer, that a product in the possession or control of a repackager is an illegitimate product, the repackager shall, in a manner that is consistent with the systems and processes of such repackager—

"(I) quarantine such product within the possession or control of the repackager from product

Quarantine.

intended for distribution until such product is dispositioned;

"(II) disposition the illegitimate product within the possession or control of the repackager;

"(III) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the repackager; and

"(IV) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) upon request by the manufacturer or Secretary (or other appropriate Federal or State official), as necessary and appropriate.

Deadline.

"(ii) MAKING A NOTIFICATION.—Upon determining that a product in the possession or control of the repackager is an illegitimate product, the repackager shall notify the Secretary and all immediate trading partners that the repackager has reason to believe may have received the illegitimate product of such determination not later than 24 hours after making such determination.

"(iii) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary or a trading partner, a repackager shall identify all illegitimate product subject to such notification that is in the possession or control of the repackager, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

Consultation.

"(iv) TERMINATING A NOTIFICATION.—Upon making a determination, in consultation with the Secretary, that a notification is no longer necessary, a repackager shall promptly notify immediate trading partners that the repackager notified pursuant to clause (ii) that such notification has been terminated.

Time period.

"(v) RECORDS.—A repackager shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

Deadline.

"(C) REQUESTS FOR VERIFICATION.—Beginning 5 years after the date of enactment of the Drug Supply Chain Security Act, upon receiving a request for verification from an authorized manufacturer, wholesale distributor, or dispenser that is in possession or control of a product they believe to be repackaged by such repackager, a repackager shall, not later than 24 hours after receiving the verification request or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, notify the person making the request whether the product identifier, including the standardized numerical identifier, that is the subject of the request corresponds to the product identifier affixed or imprinted by the repackager. If a repackager responding to a verification request identifies a product identifier that does not correspond to that affixed or imprinted by the repackager, the repackager shall treat such product as suspect product and conduct an investigation as described in subparagraph (A). If the repackager

has reason to believe the product is an illegitimate product, the repackager shall advise the person making the request of such belief at the time such repackager responds to the verification request.

Requirements. Procedures.

"(D) ELECTRONIC DATABASE.—A repackager may satisfy the requirements of paragraph (4) by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity. The owner of such database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a repackager of the requirement under subparagraph (C) to respond to a verification request submitted by means other than a secure electronic database.

"(E) VERIFICATION OF SALEABLE RETURNED PRODUCT.—Beginning 5 years after the date of enactment of the Drug Supply Chain Security Act, upon receipt of a returned product that the repackager intends to further distribute, before further distributing such product, the repackager shall verify the product identifier for each sealed homogeneous case of such product or, if such product is not in a sealed homogeneous case, verify the product identifier on each package.

"(f) DROP SHIPMENTS.—

"(1) IN GENERAL.—A wholesale distributor that does not physically handle or store product shall be exempt from the provisions of this section, except the notification requirements under clauses (ii), (iii), and (iv) of subsection (c)(4)(B), provided that the manufacturer, repackager, or other wholesale distributor that distributes the product to the dispenser by means of a drop shipment for such wholesale distributor includes on the transaction information and transaction history to the dispenser the contact information of such wholesale distributor and provides the transaction information, transaction history, and transaction statement directly to the dispenser.

"(2) CLARIFICATION.—For purposes of this subsection, providing administrative services, including processing of orders and payments, shall not by itself, be construed as being involved in the handling, distribution, or storage of a product.".

SEC. 203. ENHANCED DRUG DISTRIBUTION SECURITY.

21 USC 360eee–1.

Section 582, as added by section 202, is amended by adding at the end the following:

"(g) ENHANCED DRUG DISTRIBUTION SECURITY.—

Effective date.

"(1) IN GENERAL.—On the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act, the following interoperable, electronic tracing of product at the package level requirements shall go into effect:

"(A) The transaction information and the transaction statements as required under this section shall be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of subsection (h), including any revision of such guidance issued in accordance with paragraph (5) of such subsection.

"(B) The transaction information required under this section shall include the product identifier at the package level for each package included in the transaction.

"(C) Systems and processes for verification of product at the package level, including the standardized numerical identifier, shall be required in accordance with the standards established under the guidance issued pursuant to subsection (a)(2) and the guidances issued pursuant to paragraphs (2), (3), and (4) of subsection (h), including any revision of such guidances issued in accordance with paragraph (5) of such subsection, which may include the use of aggregation and inference as necessary.

"(D) The systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.

"(E) The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required—

"(i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or

"(ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).

"(F) Each person accepting a saleable return shall have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement associated with that product.

"(2) COMPLIANCE.—

"(A) INFORMATION MAINTENANCE AGREEMENT.—A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party shall confidentially maintain any information and statements required to be maintained under this section. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of the dispenser under this subsection.

Records.

Determinations.

"(B) ALTERNATIVE METHODS.—The Secretary, taking into consideration the assessment conducted under paragraph (3), shall provide for alternative methods of compliance with any of the requirements set forth in paragraph (1), including—

"(i) establishing timelines for compliance by small businesses (including small business dispensers with

25 or fewer full-time employees) with such requirements, in order to ensure that such requirements do not impose undue economic hardship for small businesses, including small business dispensers for whom the criteria set forth in the assessment under paragraph (3) is not met, if the Secretary determines that such requirements under paragraph (1) would result in undue economic hardship; and

"(ii) establishing a process by which a dispenser may request a waiver from any of the requirements set forth in paragraph (1) if the Secretary determines that such requirements would result in an undue economic hardship, which shall include a process for the biennial review and renewal of any such waiver. Waiver.

"(3) ASSESSMENT.—

"(A) IN GENERAL.—Not later than the date that is 18 months after the Secretary issues the final guidance required under subsection (h), the Secretary shall enter into a contract with a private, independent consulting firm with expertise to conduct a technology and software assessment that looks at the feasibility of dispensers with 25 or fewer full-time employees conducting interoperable, electronic tracing of products at the package level. Such assessment shall be completed not later than 8½ years after the date of enactment of the Drug Supply Chain Security Act. Deadlines. Guidance.

"(B) CONDITION.—As a condition of the award of the contract under subparagraph (A), the private, independent consulting firm shall agree to consult with dispensers with 25 or fewer full-time employees when conducting the assessment under such subparagraph.

"(C) CONTENT.—The assessment under subparagraph (A) shall assess whether—

"(i) the necessary software and hardware is readily accessible to such dispensers;

"(ii) the necessary software and hardware is prohibitively expensive to obtain, install, and maintain for such dispensers; and

"(iii) the necessary hardware and software can be integrated into business practices, such as interoperability with wholesale distributors, for such dispensers.

"(D) PUBLICATION.—The Secretary shall— Public information. Deadlines.

"(i) publish the statement of work for the assessment under subparagraph (A) for public comment prior to beginning the assessment;

"(ii) publish the final assessment for public comment not later than 30 calendar days after receiving such assessment; and

"(iii) hold a public meeting not later than 180 calendar days after receiving the final assessment at which public stakeholders may present their views on the assessment.

"(4) PROCEDURE.—Notwithstanding section 553 of title 5, United States Code, the Secretary, in promulgating any regulation pursuant to this section, shall— Regulations.

"(A) provide appropriate flexibility by—

"(i) not requiring the adoption of specific business systems for the maintenance and transmission of data;

Determination.

"(ii) prescribing alternative methods of compliance for any of the requirements set forth in paragraph (1) or set forth in regulations implementing such requirements, including—

"(I) timelines for small businesses to comply with the requirements set forth in the regulations in order to ensure that such requirements do not impose undue economic hardship for small businesses (including small business dispensers for whom the criteria set forth in the assessment under paragraph (3) is not met), if the Secretary determines that such requirements would result in undue economic hardship; and

Waiver.

"(II) the establishment of a process by which a dispenser may request a waiver from any of the requirements set forth in such regulations if the Secretary determines that such requirements would result in an undue economic hardship; and

"(iii) taking into consideration—

"(I) the results of pilot projects, including pilot projects pursuant to this section and private sector pilot projects, including those involving the use of aggregation and inference;

"(II) the public meetings held and related guidance documents issued under this section;

"(III) the public health benefits of any additional regulations in comparison to the cost of compliance with such requirements, including on entities of varying sizes and capabilities;

"(IV) the diversity of the pharmaceutical distribution supply chain by providing appropriate flexibility for each sector, including both large and small businesses; and

"(V) the assessment pursuant to paragraph (3) with respect to small business dispensers, including related public comment and the public meeting, and requirements under this section;

Notice.
Records.

"(B) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

Time period.
Public comments.

"(C) provide a period of not less than 60 days for comments on the proposed regulation; and

Federal Register, publication.
Deadline.

"(D) publish in the Federal Register the final regulation not less than 2 years prior to the effective date of the regulation.

"(h) GUIDANCE DOCUMENTS.—

"(1) IN GENERAL.—For the purposes of facilitating the successful and efficient adoption of secure, interoperable product tracing at the package level in order to enhance drug distribution security and further protect the public health, the Secretary shall issue the guidance documents as provided for in this subsection.

"(2) SUSPECT AND ILLEGITIMATE PRODUCT.—

Deadline.

"(A) IN GENERAL.—Not later than 180 days after the date of enactment of the Drug Supply Chain Security Act, the Secretary shall issue a guidance document to aid

trading partners in the identification of a suspect product and notification termination. Such guidance document shall—

"(i) identify specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain;

"(ii) provide recommendation on how trading partners may identify such product and make a determination on whether the product is a suspect product as soon as practicable; and

"(iii) set forth the process by which manufacturers, repackagers, wholesale distributors, and dispensers shall terminate notifications in consultation with the Secretary regarding illegitimate product pursuant to subsections (b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B).

"(B) REVISED GUIDANCE.—If the Secretary revises the guidance issued under subparagraph (A), the Secretary shall follow the procedure set forth in paragraph (5).

"(3) UNIT LEVEL TRACING.—

"(A) IN GENERAL.—In order to enhance drug distribution security at the package level, not later than 18 months after conducting a public meeting on the system attributes necessary to enable secure tracing of product at the package level, including allowing for the use of verification, inference, and aggregation, as necessary, the Secretary shall issue a final guidance document that outlines and makes recommendations with respect to the system attributes necessary to enable secure tracing at the package level as required under the requirements established under subsection (g). Such guidance document shall— Deadline.

"(i) define the circumstances under which the sectors within the pharmaceutical distribution supply chain may, in the most efficient manner practicable, infer the contents of a case, pallet, tote, or other aggregate of individual packages or containers of product, from a product identifier associated with the case, pallet, tote, or other aggregate, without opening each case, pallet, tote, or other aggregate or otherwise individually scanning each package;

"(ii) identify methods and processes to enhance secure tracing of product at the package level, such as secure processes to facilitate the use of inference, enhanced verification activities, the use of aggregation and inference, processes that utilize the product identifiers to enhance tracing of product at the package level, including the standardized numerical identifier, or package security features; and

"(iii) ensure the protection of confidential commercial information and trade secrets.

"(B) PROCEDURE.—In issuing the guidance under subparagraph (A), and in revising such guidance, if applicable, the Secretary shall follow the procedure set forth in paragraph (5).

"(4) STANDARDS FOR INTEROPERABLE DATA EXCHANGE.—

"(A) IN GENERAL.—In order to enhance secure tracing of a product at the package level, the Secretary, not later than 18 months after conducting a public meeting on the Deadline.

interoperable standards necessary to enhance the security of the pharmaceutical distribution supply chain, shall update the guidance issued pursuant to subsection (a)(2), as necessary and appropriate, and finalize such guidance document so that the guidance document—

"(i) identifies and makes recommendations with respect to the standards necessary for adoption in order to support the secure, interoperable electronic data exchange among the pharmaceutical distribution supply chain that comply with a form and format developed by a widely recognized international standards development organization;

"(ii) takes into consideration standards established pursuant to subsection (a)(2) and section 505D;

"(iii) facilitates the creation of a uniform process or methodology for product tracing; and

"(iv) ensures the protection of confidential commercial information and trade secrets.

"(B) PROCEDURE.—In issuing the guidance under subparagraph (A), and in revising such guidance, if applicable, the Secretary shall follow the procedure set forth in paragraph (5).

"(5) PROCEDURE.—In issuing or revising any guidance issued pursuant to this subsection or subsection (g), except the initial guidance issued under paragraph (2)(A), the Secretary shall—

Notice. Federal Register, publication. Time period. Web posting.

"(A) publish a notice in the Federal Register for a period not less than 30 days announcing that the draft or revised draft guidance is available;

"(B) post the draft guidance document on the Internet Web site of the Food and Drug Administration and make such draft guidance document available in hard copy;

"(C) provide an opportunity for comment and review and take into consideration any comments received;

"(D) revise the draft guidance, as appropriate;

Notice. Federal Register, publication. Time period. Web posting.

"(E) publish a notice in the Federal Register for a period not less than 30 days announcing that the final guidance or final revised guidance is available;

"(F) post the final guidance document on the Internet Web site of the Food and Drug Administration and make such final guidance document available in hard copy; and

Effective date.

"(G) provide for an effective date of not earlier than 1 year after such guidance becomes final.

"(i) PUBLIC MEETINGS.—

"(1) IN GENERAL.—The Secretary shall hold not less than 5 public meetings to enhance the safety and security of the pharmaceutical distribution supply chain and provide for comment. The Secretary may hold the first such public meeting not earlier than 1 year after the date of enactment of the Drug Supply Chain Security Act. In carrying out the public meetings described in this paragraph, the Secretary shall—

Deadline.

"(A) prioritize topics necessary to inform the issuance of the guidance described in paragraphs (3) and (4) of subsection (h); and

"(B) take all measures reasonable and practicable to ensure the protection of confidential commercial information and trade secrets.

"(2) CONTENT.—Each of the following topics shall be addressed in at least one of the public meetings described in paragraph (1):

"(A) An assessment of the steps taken under subsections (b) through (e) to build capacity for a unit-level system, including the impact of the requirements of such subsections on—

"(i) the ability of the health care system collectively to maintain patient access to medicines;

"(ii) the scalability of such requirements, including as it relates to product lines; and

"(iii) the capability of different sectors and subsectors, including both large and small businesses, to affix and utilize the product identifier.

"(B) The system attributes necessary to support the requirements set forth under subsection (g), including the standards necessary for adoption in order to support the secure, interoperable electronic data exchange among sectors within the pharmaceutical distribution supply chain.

"(C) Best practices in each of the different sectors within the pharmaceutical distribution supply chain to implement the requirements of this section.

"(D) The costs and benefits of the implementation of this section, including the impact on each pharmaceutical distribution supply chain sector and on public health.

"(E) Whether electronic tracing requirements, including tracing of product at the package level, are feasible, cost effective, and needed to protect the public health.

"(F) The systems and processes needed to utilize the product identifiers to enhance tracing of product at the package level, including allowing for verification, aggregation, and inference, as necessary.

"(G) The technical capabilities and legal authorities, if any, needed to establish an interoperable, electronic system that provides for tracing of product at the package level.

"(H) The impact that such additional requirements would have on patient safety, the drug supply, cost and regulatory burden, and timely patient access to prescription drugs.

"(I) Other topics, as determined appropriate by the Secretary.

"(j) PILOT PROJECTS.—

"(1) IN GENERAL.—The Secretary shall establish 1 or more pilot projects, in coordination with authorized manufacturers, repackagers, wholesale distributors, and dispensers, to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain. Such projects shall build upon efforts, in existence as of the date of enactment of the Drug Supply Chain Security Act, to enhance the safety and security of the pharmaceutical distribution supply chain, take into consideration any pilot projects conducted prior to such date of enactment, including any pilot projects that use aggregation and inference, and inform the draft and final guidance under paragraphs (3) and (4) of subsection (h).

"(2) CONTENT.—

"(A) IN GENERAL.—The Secretary shall ensure that the pilot projects under paragraph (1) reflect the diversity of the pharmaceutical distribution supply chain and that the pilot projects, when taken as a whole, include participants representative of every sector, including both large and small businesses.

"(B) PROJECT DESIGN.—The pilot projects under paragraph (1) shall be designed to—

"(i) utilize the product identifier for tracing of a product, which may include verification of the product identifier of a product, including the use of aggregation and inference;

"(ii) improve the technical capabilities of each sector and subsector to comply with systems and processes needed to utilize the product identifiers to enhance tracing of a product;

"(iii) identify system attributes that are necessary to implement the requirements established under this section; and

"(iv) complete other activities as determined by the Secretary.

"(k) SUNSET.—The following requirements shall have no force or effect beginning on the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act:

"(1) The provision and receipt of transaction history under this section.

"(2) The requirements set forth for returns under subsections (b)(4)(E), (c)(1)(B)(i), (d)(1)(C)(i), and (e)(4)(E).

Applicability.

"(3) The requirements set forth under subparagraphs (A)(v)(II) and (D) of subsection (c)(1), as applied to lot level information only.

"(l) RULE OF CONSTRUCTION.—The requirements set forth in subsections (g)(4), (i), and (j) shall not be construed as a condition, prohibition, or precedent for precluding or delaying the provisions becoming effective pursuant to subsection (g).

Effective date.
Time period.

"(m) REQUESTS FOR INFORMATION.—On the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act, the timeline for responses to requests for information from the Secretary, or other appropriate Federal or State official, as applicable, under subsections (b)(1)(B), (c)(1)(C), and (e)(1)(C) shall be not later than 24 hours after receiving the request from the Secretary or other appropriate Federal or State official, as applicable, or in such other reasonable time as determined by the Secretary based on the circumstances of the request.".

SEC. 204. NATIONAL STANDARDS FOR PRESCRIPTION DRUG WHOLESALE DISTRIBUTORS.

(a) AMENDMENTS.—

(1) REQUIREMENT.—Section 503(e) (21 U.S.C. 353(e)) is amended by striking paragraphs (1), (2), and (3) and inserting the following:

"(1) REQUIREMENT.—Subject to section 583:

"(A) IN GENERAL.—No person may engage in wholesale distribution of a drug subject to subsection (b)(1) in any State unless such person—

"(i)(I) is licensed by the State from which the drug is distributed; or

"(II) if the State from which the drug is distributed has not established a licensure requirement, is licensed by the Secretary; and

"(ii) if the drug is distributed interstate, is licensed by the State into which the drug is distributed if the State into which the drug is distributed requires the licensure of a person that distributes drugs into the State.

"(B) STANDARDS.—Each Federal and State license described in subparagraph (A) shall meet the standards, terms, and conditions established by the Secretary under section 583.

"(2) REPORTING AND DATABASE.—

"(A) REPORTING.—Beginning January 1, 2015, any person who owns or operates an establishment that engages in wholesale distribution shall— Effective date.

"(i) report to the Secretary, on an annual basis pursuant to a schedule determined by the Secretary—

"(I) each State by which the person is licensed and the appropriate identification number of each such license; and

"(II) the name, address, and contact information of each facility at which, and all trade names under which, the person conducts business; and

"(ii) report to the Secretary within a reasonable period of time and in a reasonable manner, as determined by the Secretary, any significant disciplinary actions, such as the revocation or suspension of a wholesale distributor license, taken by a State or the Federal Government during the reporting period against the wholesale distributor.

"(B) DATABASE.—Not later than January 1, 2015, the Secretary shall establish a database of authorized wholesale distributors. Such database shall—

"(i) identify each authorized wholesale distributor by name, contact information, and each State where such wholesale distributor is appropriately licensed to engage in wholesale distribution;

"(ii) be available to the public on the Internet Web site of the Food and Drug Administration; and Public information. Web posting.

"(iii) be regularly updated on a schedule determined by the Secretary.

"(C) COORDINATION.—The Secretary shall establish a format and procedure for appropriate State officials to access the information provided pursuant to subparagraph (A) in a prompt and secure manner. Procedure.

"(D) CONFIDENTIALITY.—Nothing in this paragraph shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

"(3) COSTS.—

"(A) AUTHORIZED FEES OF SECRETARY.—If a State does not establish a licensing program for persons engaged in the wholesale distribution of a drug subject to subsection License.

(b), the Secretary shall license a person engaged in wholesale distribution located in such State and may collect a reasonable fee in such amount necessary to reimburse the Secretary for costs associated with establishing and administering the licensure program and conducting periodic inspections under this section. The Secretary shall adjust fee rates as needed on an annual basis to generate only the amount of revenue needed to perform this service. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

"(B) STATE LICENSING FEES.—Nothing in this Act shall prohibit States from collecting fees from wholesale distributors in connection with State licensing of such distributors.".

(2) WHOLESALE DISTRIBUTION.—Section 503(e) (21 U.S.C. 353(e)), as amended by paragraph (1), is further amended by adding at the end the following:

Definition.

"(4) For the purposes of this subsection and subsection (d), the term 'wholesale distribution' means the distribution of a drug subject to subsection (b) to a person other than a consumer or patient, or receipt of a drug subject to subsection (b) by a person other than the consumer or patient, but does not include—

"(A) intracompany distribution of any drug between members of an affiliate or within a manufacturer;

"(B) the distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;

"(C) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

"(D) the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b)(1);

"(E) the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;

"(F) the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

"(G) the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

"(H) the distribution of a drug by the manufacturer of such drug;

"(I) the receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;

"(J) a common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

"(K) the distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with section 582(e);

"(L) salable drug returns when conducted by a dispenser;

"(M) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this subparagraph as a 'medical convenience kit') if—

"(i) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 510(b)(2);

"(ii) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

"(iii) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit—

"(I) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

"(II) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

"(iv) in the case of a medical convenience kit that includes a product, the product is—

"(I) an intravenous solution intended for the replenishment of fluids and electrolytes;

"(II) a product intended to maintain the equilibrium of water and minerals in the body;

"(III) a product intended for irrigation or reconstitution;

"(IV) an anesthetic;

"(V) an anticoagulant;

"(VI) a vasopressor; or

"(VII) a sympathomimetic;

"(N) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

"(O) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

"(P) the distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

"(Q) the distribution of medical gas, as defined in section 575;

"(R) facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or

"(S) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in section 581(16)(B) and registered under section 510 for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.".

(3) THIRD-PARTY LOGISTICS PROVIDERS.—Section 503(e) (21 U.S.C. 353(e)), as amended by paragraph (2), is further amended by adding at the end the following:

"(5) THIRD-PARTY LOGISTICS PROVIDERS.—Notwithstanding paragraphs (1) through (4), each entity that meets the definition of a third-party logistics provider under section 581(22) shall obtain a license as a third-party logistics provider as described in section 584(a) and is not required to obtain a license as a wholesale distributor if the entity never assumes an ownership interest in the product it handles.".

(4) AFFILIATE.—Section 503(e) (21 U.S.C. 353(e)), as amended by paragraph (3), is further amended by adding at the end the following:

Definition.

"(6) AFFILIATE.—For purposes of this subsection, the term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

"(A) one business entity controls, or has the power to control, the other business entity; or

"(B) a third party controls, or has the power to control, both of the business entities.".

(5) STANDARDS.—Subchapter H of chapter V, as added by section 202, is amended by adding at the end the following:

Regulations.
21 USC
360eee–2.
Deadline.

"SEC. 583. NATIONAL STANDARDS FOR PRESCRIPTION DRUG WHOLESALE DISTRIBUTORS.

"(a) IN GENERAL.—The Secretary shall, not later than 2 years after the date of enactment of the Drug Supply Chain Security Act, establish by regulation standards for the licensing of persons under section 503(e)(1) (as amended by the Drug Supply Chain Security Act), including the revocation, reissuance, and renewal of such license.

Applicability.

"(b) CONTENT.—For the purpose of ensuring uniformity with respect to standards set forth in this section, the standards established under subsection (a) shall apply to all State and Federal licenses described under section 503(e)(1) (as amended by the Drug Supply Chain Security Act) and shall include standards for the following:

"(1) The storage and handling of prescription drugs, including facility requirements.

"(2) The establishment and maintenance of records of the distributions of such drugs.

"(3) The furnishing of a bond or other equivalent means of security, as follows:

"(A)(i) For the issuance or renewal of a wholesale distributor license, an applicant that is not a government owned and operated wholesale distributor shall submit a surety bond of $100,000 or other equivalent means of security acceptable to the State.

"(ii) For purposes of clause (i), the State or other applicable authority may accept a surety bond in the amount of $25,000 if the annual gross receipts of the previous tax year for the wholesaler is $10,000,000 or less.

"(B) If a wholesale distributor can provide evidence that it possesses the required bond in a State, the requirement for a bond in another State shall be waived.

"(4) Mandatory background checks and fingerprinting of facility managers or designated representatives.

"(5) The establishment and implementation of qualifications for key personnel.

"(6) The mandatory physical inspection of any facility to be used in wholesale distribution within a reasonable time frame from the initial application of the facility and to be conducted by the licensing authority or by the State, consistent with subsection (c).

"(7) In accordance with subsection (d), the prohibition of certain persons from receiving or maintaining licensure for wholesale distribution.

"(c) INSPECTIONS.—To satisfy the inspection requirement under subsection (b)(6), the Federal or State licensing authority may conduct the inspection or may accept an inspection by the State in which the facility is located, or by a third-party accreditation or inspection service approved by the Secretary or the State licensing such wholesale distributor.

"(d) PROHIBITED PERSONS.—The standards established under subsection (a) shall include requirements to prohibit a person from receiving or maintaining licensure for wholesale distribution if the person—

"(1) has been convicted of any felony for conduct relating to wholesale distribution, any felony violation of subsection (i) or (k) of section 301, or any felony violation of section 1365 of title 18, United States Code, relating to product tampering; or

"(2) has engaged in a pattern of violating the requirements of this section, or State requirements for licensure, that presents a threat of serious adverse health consequences or death to humans.

"(e) REQUIREMENTS.—The Secretary, in promulgating any regulation pursuant to this section, shall, notwithstanding section 553 of title 5, United States Code—

"(1) issue a notice of proposed rulemaking that includes a copy of the proposed regulation; Notice.

"(2) provide a period of not less than 60 days for comments on the proposed regulation; and Time period.

"(3) provide that the final regulation take effect on the date that is 2 years after the date such final regulation is published.".

(b) AUTHORIZED DISTRIBUTORS OF RECORD.—Section 503(d) (21 U.S.C. 353(d)) is amended by adding at the end the following:

"(4) In this subsection, the term 'authorized distributors of record' means those distributors with whom a manufacturer Definition.

has established an ongoing relationship to distribute such manufacturer's products.".

21 USC 353 note.

(c) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) shall take effect on January 1, 2015.

SEC. 205. NATIONAL STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS; UNIFORM NATIONAL POLICY.

Subchapter H of chapter V, as amended by section 204, is further amended by adding at the end the following:

21 USC 360eee–3.

"SEC. 584. NATIONAL STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS.

"(a) REQUIREMENTS.—No third-party logistics provider in any State may conduct activities in any State unless each facility of such third-party logistics provider—

"(1)(A) is licensed by the State from which the drug is distributed by the third-party logistics provider, in accordance with the regulations promulgated under subsection (d); or

"(B) if the State from which the drug distributed by the third-party logistics provider has not established a licensure requirement, is licensed by the Secretary, in accordance with the regulations promulgated under subsection (d); and

"(2) if the drug is distributed interstate, is licensed by the State into which the drug is distributed by the third-party logistics provider if such State licenses third-party logistics providers that distribute drugs into the State and the third-party logistics provider is not licensed by the Secretary as described in paragraph (1)(B).

Effective date.

"(b) REPORTING.—Beginning 1 year after the date of enactment of the Drug Supply Chain Security Act, a facility of a third-party logistics provider shall report to the Secretary, on an annual basis pursuant to a schedule determined by the Secretary—

"(1) the State by which the facility is licensed and the appropriate identification number of such license; and

"(2) the name and address of the facility and all trade names under which such facility conducts business.

"(c) COSTS.—

License.

"(1) AUTHORIZED FEES OF SECRETARY.—If a State does not establish a licensing program for a third-party logistics provider, the Secretary shall license the third-party logistics provider located in such State and may collect a reasonable fee in such amount necessary to reimburse the Secretary for costs associated with establishing and administering the licensure program and conducting periodic inspections under this section. The Secretary shall adjust fee rates as needed on an annual basis to generate only the amount of revenue needed to perform this service. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

"(2) STATE LICENSING FEES.—

"(A) STATE ESTABLISHED PROGRAM.—Nothing in this Act shall prohibit a State that has established a program

to license a third-party logistics provider from collecting fees from a third-party logistics provider for such a license.

"(B) NO STATE ESTABLISHED PROGRAM.—A State that does not establish a program to license a third-party logistics provider in accordance with this section shall be prohibited from collecting a State licensing fee from a third-party logistics provider.

"(d) REGULATIONS.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Drug Supply Chain Security Act, the Secretary shall issue regulations regarding the standards for licensing under subsection (a), including the revocation and reissuance of such license, to third-party logistics providers under this section. Deadline.

"(2) CONTENT.—Such regulations shall—

"(A) establish a process by which a third-party accreditation program approved by the Secretary shall, upon request by a third-party logistics provider, issue a license to each third-party logistics provider that meets the requirements set forth in this section;

"(B) establish a process by which the Secretary shall issue a license to each third-party logistics provider that meets the requirements set forth in this section if the Secretary is not able to approve a third-party accreditation program because no such program meets the Secretary's requirements necessary for approval of such a third-party accreditation program;

"(C) require that the entity complies with storage practices, as determined by the Secretary for such facility, including—

"(i) maintaining access to warehouse space of suitable size to facilitate safe operations, including a suitable area to quarantine suspect product;

"(ii) maintaining adequate security; and

"(iii) having written policies and procedures to—

"(I) address receipt, security, storage, inventory, shipment, and distribution of a product;

"(II) identify, record, and report confirmed losses or thefts in the United States;

"(III) correct errors and inaccuracies in inventories;

"(IV) provide support for manufacturer recalls;

"(V) prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood;

"(VI) ensure that any expired product is segregated from other products and returned to the manufacturer or repackager or destroyed;

"(VII) maintain the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory; and

"(VIII) quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency;

"(D) provide for periodic inspection by the licensing authority, as determined by the Secretary, of such facility warehouse space to ensure compliance with this section;

"(E) prohibit a facility from having as a manager or designated representative anyone convicted of any felony violation of subsection (i) or (k) of section 301 or any violation of section 1365 of title 18, United States Code relating to product tampering;

"(F) provide for mandatory background checks of a facility manager or a designated representative of such manager;

"(G) require a third-party logistics provider to provide the applicable licensing authority, upon a request by such authority, a list of all product manufacturers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services at such facility; and

"(H) include procedures under which any third-party logistics provider license—

"(i) expires on the date that is 3 years after issuance of the license; and

"(ii) may be renewed for additional 3-year periods.

"(3) PROCEDURE.—In promulgating the regulations under this subsection, the Secretary shall, notwithstanding section 553 of title 5, United States Code—

Notice.
Records.

"(A) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

Time period.
Public comments.

"(B) provide a period of not less than 60 days for comments on the proposed regulation; and

Effective date.

"(C) provide that the final regulation takes effect upon the expiration of 1 year after the date that such final regulation is issued.

License.

"(e) VALIDITY.—A license issued under this section shall remain valid as long as such third-party logistics provider remains licensed consistent with this section. If the Secretary finds that the third-party accreditation program demonstrates that all applicable requirements for licensure under this section are met, the Secretary shall issue a license under this section to a third-party logistics provider receiving accreditation, pursuant to subsection (d)(2)(A).

21 USC 360eee–4.
Effective date.

"SEC. 585. UNIFORM NATIONAL POLICY.

"(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.

Effective date.

"(2) STATE REGULATION OF THIRD-PARTY LOGISTICS PROVIDERS.—No State shall regulate third-party logistics providers as wholesale distributors.

"(3) ADMINISTRATION FEES.—Notwithstanding paragraph (1), a State may administer fee collections for effectuating the wholesale drug distributor and third-party logistics provider licensure requirements under sections 503(e) (as amended by the Drug Supply Chain Security Act), 583, and 584.

"(4) ENFORCEMENT, SUSPENSION, AND REVOCATION.—Notwithstanding paragraph (1), a State—

"(A) may take administrative action, including fines, to enforce a requirement promulgated by the State in accordance with section 503(e) (as amended by the Drug Supply Chain Security Act) or this subchapter;

"(B) may provide for the suspension or revocation of licenses issued by the State for violations of the laws of such State;

"(C) upon conviction of violations of Federal, State, or local drug laws or regulations, may provide for fines, imprisonment, or civil penalties; and

"(D) may regulate activities of licensed entities in a manner that is consistent with product tracing requirements under section 582.

"(c) EXCEPTION.—Nothing in this section shall be construed to preempt State requirements related to the distribution of prescription drugs if such requirements are not related to product tracing as described in subsection (a) or wholesale distributor and third-party logistics provider licensure as described in subsection (b) applicable under section 503(e) (as amended by the Drug Supply Chain Security Act) or this subchapter (or regulations issued thereunder).".

SEC. 206. PENALTIES.

(a) PROHIBITED ACT.—Section 301(t) (21 U.S.C. 331(t)), is amended—

(1) by striking "or" after "the requirements of section 503(d),"; and

(2) by inserting ", failure to comply with the requirements under section 582, the failure to comply with the requirements under section 584, as applicable," after "in violation of section 503(e)".

(b) MISBRANDING.—Section 502 (21 U.S.C. 352), as amended by section 103, is further amended by adding at the end the following:

"(cc) If it is a drug and it fails to bear the product identifier as required by section 582.".

SEC. 207. CONFORMING AMENDMENT.

(a) IN GENERAL.—Section 303(b)(1)(D) (21 U.S.C. 333(b)(1)(D)) is amended by striking "503(e)(2)(A)" and inserting "503(e)(1)".

21 USC 333 note.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on January 1, 2015.

21 USC 331 note.

SEC. 208. SAVINGS CLAUSE.

Except as provided in the amendments made by paragraphs (1), (2), and (3) of section 204(a) and by section 206(a), nothing in this title (including the amendments made by this title) shall be construed as altering any authority of the Secretary of Health and Human Services with respect to a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)) under any other provision of such Act or the Public Health Service Act (42 U.S.C. 201 et seq.).

Approved November 27, 2013.

LEGISLATIVE HISTORY—H.R. 3204:

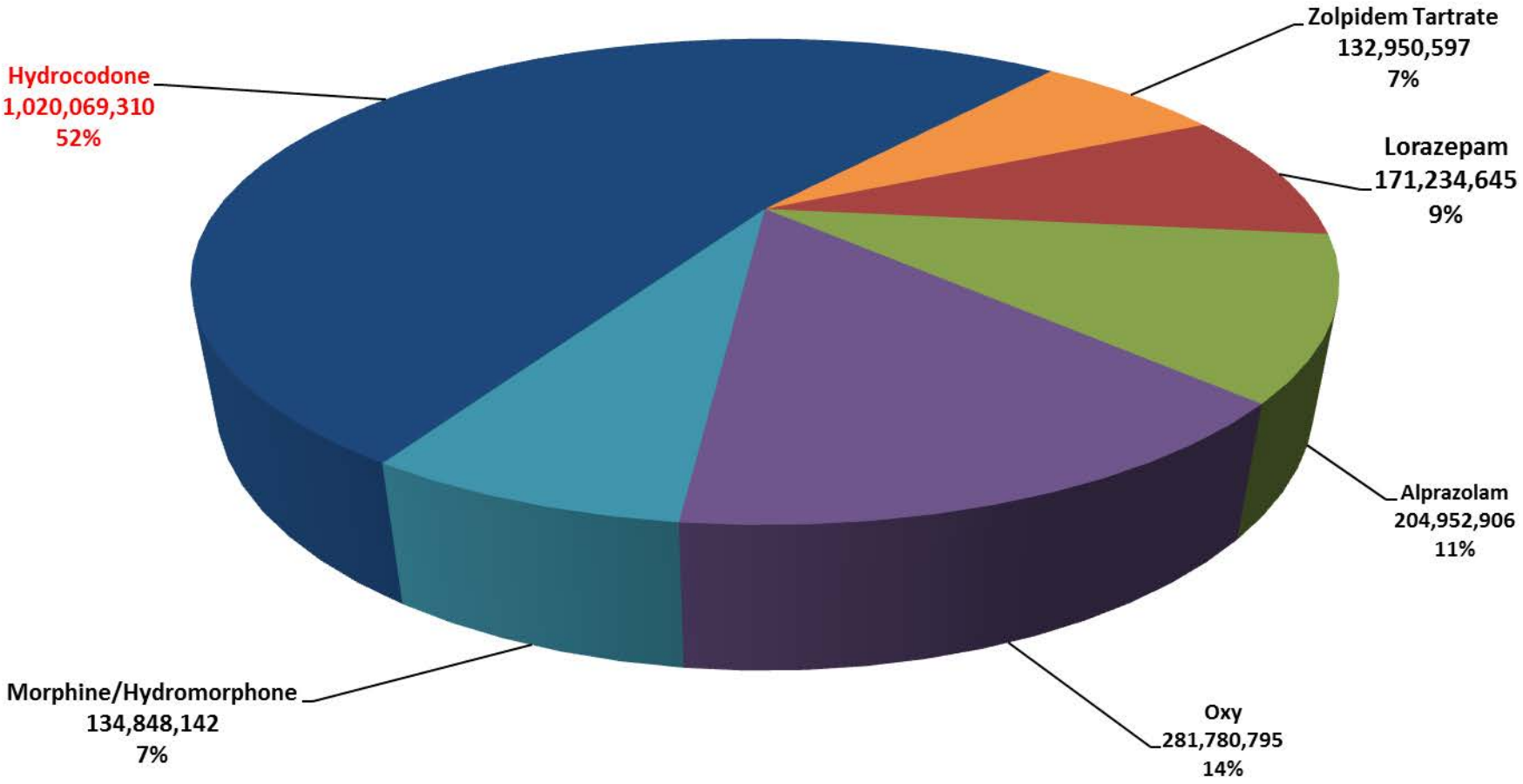
CONGRESSIONAL RECORD, Vol. 159 (2013):
Sept. 28, considered and passed House.
Nov. 14, 18, considered and passed Senate.

○

Attachment 4

Medications Dispensed In California
2013-2014
Total Dispensed: 1,945,836,395

*** Data From CURES**



Top 10 Controlled Substances Reported Lost or Stolen In 2014

Drug Name	Count	Transit Loss Adjustment	Adjusted Count
Hydrocodone/Acetaminophen (tab/cap)	746,587	15,022	731,565
Promethazine/Codeine (liq)	695,009	5,861	689,148
Alprazolam (tab/cap)	186,237	639	185,598
Carisoprodol (tab)	81,727	719	81,008
Oxycodone (tab/cap)	57,280	3,745	53,535
Hydrocodone/Homatropine (liq)	39,927	250	39,677
Acetaminophen/Codeine (tab/liq)	37,267	2,350	34,917
Oxycodone/Acetaminophen (tab/cap)	36,036	1,673	34,363
Lorazepam (tab)	23,515	1,254	22,261
Guaifenesine Phosphate/Codeine (liq)	23,370	1,571	21,799
Totals	**1,926,956**	**33,085**	**1,893,871**

DEA 106 Reports by License Category

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

Proposed Language from the September 2014 Committee Meeting

Proposed Language - September 2014 Committee Meeting
1715.65 Monthly Inventory Counts of Fastest Moving Controlled Substances

(a) Every June 30th, each pharmacy and clinic licensed by the board shall identify its top 10 controlled substances dispensed by the licensee as measured in dosage units in the prior 12 months (July 1 – June 30).

(b) Effective July 1 and each month thereafter until the next June 30 (for a total of 12 months), the pharmacy or clinic shall count and reconcile the inventory of the top 10 controlled substances identified pursuant to subdivision (a). This reconciliation shall include for each of the controlled substances:

(1) The inventory recorded on the first of the preceding month

(2) The additions to inventory made in the preceding month (e.g., purchases, transfers in, will-call items that were never handed out that were counted as dispositions the prior month)

(3) The dispositions (e.g., dispensing, saleable returns to a wholesaler, drugs provided to a reverse distributor for destruction) from inventory made in the preceding month

(4) The drugs in quarantine waiting for the reverse distributor,

(5) The final inventory count on the first of the month

(6) The pharmacy shall attempt to reconcile overages or shortages. Shortages must be reported to the board.

(7) The name of the individual conducting the inventory and date the inventory required by this subdivision was performed

(c) Losses of controlled substances identified from the monthly audit shall be reported to the board as required by section 1716.5 and Business and Professions Code section 4104.

(d) The pharmacist-in-charge or consultant pharmacist for the clinic shall sign each monthly inventory performed under this section indicating he or she has reviewed the inventory taken.

(e) The pharmacist-in-charge or consultant pharmacist shall perform a quality assurance review of the monthly and annual inventories to establish secure methods to prevent losses of all dangerous drugs.

Proposed Language from the December 2014 Committee Meeting

Proposed Language – December 2014 Committee meeting
1715.65 Monthly Inventory Counts of Fastest Moving Controlled Substances

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

Proposed Language from the March 2015 Committee Meeting

Proposed Language – March 2015 Committee Meeting
1715.65 Monthly Inventory Counts of Fastest Moving Controlled Substances

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

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

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

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

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

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

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

Proposed Language from the April 2015 Board Meeting

Proposed Language – April 2015 Board Meeting
1715.65 Monthly Inventory Counts of Fastest Moving Controlled Substances

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

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

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

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

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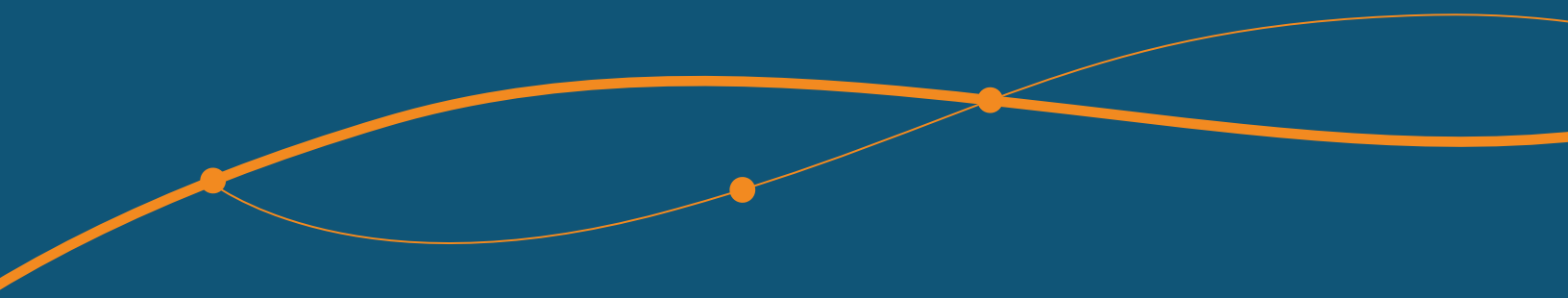
(f) The pharmacist-in-charge or consultant pharmacist for the clinic shall sign and date each monthly reconciliation within 14 days of completion. These signed reconciliations shall be retained by the licensed premises for three years and be readily retrievable for review by the board.

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

Attachment 5

2014 **National Progress Report**

More Connected Than Ever Before.



surescripts®
How Healthcare Gets Connected™

900,000 healthcare professionals

45 immunization registries

3,300 hospitals

230 million patients

71% of US population[1]

The Surescripts network is **more connected than ever.**

Day in and day out, massive amounts of private and secure healthcare data are exchanged across the country. By connecting to the Surescripts network, doctors, pharmacists, and others can fill electronic prescriptions, review patient medication histories, report immunization records and exchange patient records. Each day, providers nationwide exchange valuable information through a single point of connectivity using our vendor neutral technology.

In 2014, the Surescripts network continued to grow, connecting more providers and exchanging more information than ever before.

32 state and regional networks

40,000 | 98%
chain pharmacies[2]

21,000 | 88%
independent pharmacies[2]

700
EHR software applications

"Walgreens is committed to enabling a connected patient experience. This means creating a connected health ecosystem that supports good clinical care collaboration. Our focus on connected health includes clinical interoperability, clinical portals and apps, care management, and connected devices for clinical care, to bridge gaps in care and provide vital information to care providers at the point of care and beyond. We utilize Surescripts clinical messaging and HISP services that are seamlessly integrated into this infrastructure.

Venk Reddy, Senior Director, Connected Health, Walgreens

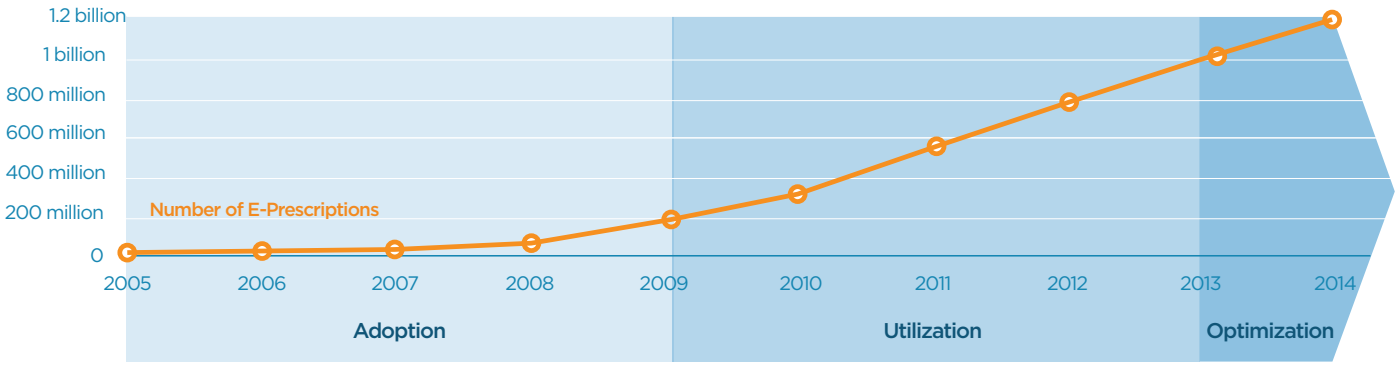
Massive amounts of private and secure health data crossed the Surescripts network in 2014.

1.2 billion E-prescriptions	**764 million** Medication histories	**7.4 million** Clinical messages
19% growth y/y	**9%** growth y/y	**1,300%** growth y/y
67% of all new prescriptions	**44%** hospital adoption[3]	

More than
6.5 billion transactions

Improving Data Quality
One Prescription at a Time.

A connected network is only as good as the information exchanged, so the quality and accuracy of the data on the Surescripts network, particularly prescription data, is critically important. Given the progress we have made driving adoption and utilization of e-prescribing, we are now uniquely positioned to optimize the process. We're doing this by adding new functionality, like electronic prior authorization, and by improving the quality of the data that flows over the network, to increase customer satisfaction and drive growth.



"Increased connectivity in healthcare means providers have access to exponentially more clinical data. But to fulfill the promise of improved patient care through safer prescribing, reduced medication errors, and improved medication adherence, clinical data must be accurately and reliably captured."

Shane Stenner, MD, MS, Program Director,
RxStar,Vanderbilt University Medical Center

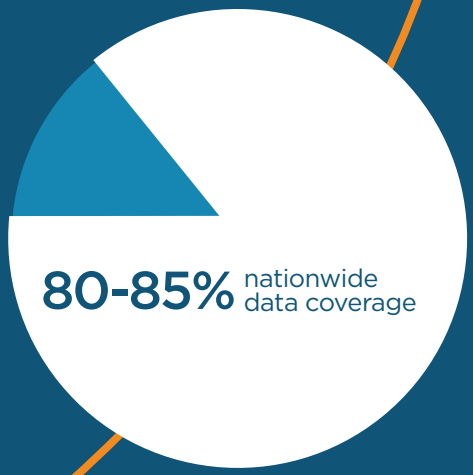
Interoperability **Reduces Costs, Saves Time and Improves Care.**

A seamless, connected healthcare experience is an increasing expectation for patients and providers. Interoperability between providers is a critical step in creating a more efficient and quality-driven healthcare system. Surescripts has been working on interoperability for more than a decade. With more than half of all prescriptions routed electronically, we're moving from adoption to optimization. We're expanding our network to enable integrated electronic solutions for prior authorization, controlled substances, clinical messaging, and medication adherence. By increasing access to accurate and complete medication information, we can add more value for providers and improve the patient experience.

What is medication history worth to a hospital?

The process of reconciling a patient's medication history has traditionally been very time consuming and inaccurate. The growth in electronic prescribing has made real-time access to medication information at the point-of-care possible. This is particularly true in acute settings, such as a hospital emergency room, where a patient may be unconscious or unable to tell the doctor what medications they are on. In the case of medication reconciliation, interoperability between different technology systems is critical to realizing the true value of a connected healthcare system.

SMALL 100 Bed Hospital	MEDIUM 200 Bed Hospital	LARGE 500 Bed Hospital	VERY LARGE 1,000 Bed Hospital[4]
3 Less Patient Adverse Drug Events	5 Less Patient Adverse Drug Events	13 Less Patient Adverse Drug Events	26 Less Patient Adverse Drug Events
4 Prevented Patient Readmissions	9 Prevented Patient Readmissions	22 Prevented Patient Readmissions	43 Prevented Patient Readmissions
3,331 Unnecessary Staff Hours Cut	6,663 Unnecessary Staff Hours Cut	16,657 Unnecessary Staff Hours Cut	33,315 Unnecessary Staff Hours Cut
SAVINGS **$110,704 per year**	SAVINGS **$221,409 per year**	SAVINGS **$553,522 per year**	SAVINGS **$1,107,045 per year**



Hospitals are increasingly dependent upon Surescripts for patient medication history data in acute settings.

2.15 billion
medication records
7.5% growth y/y

84.7 million
medication history transactions by hospitals
75% growth y/y

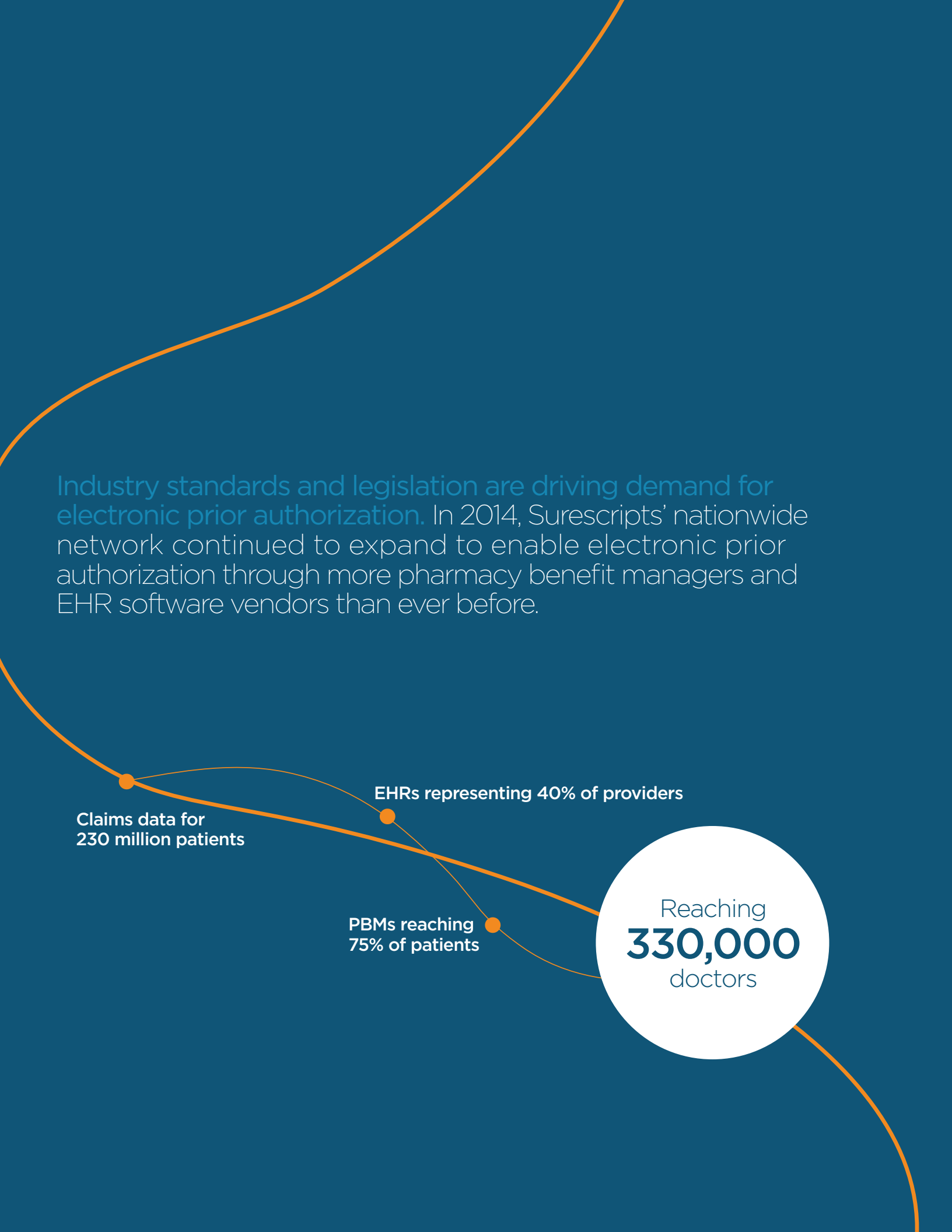
Medication claims data for
230 million patients

Adopted in approximately
44% of U.S. hospitals[5]

Approx.
2,500 Hospitals

Approx.
370,000 Beds

Industry standards and legislation are driving demand for electronic prior authorization. In 2014, Surescripts' nationwide network continued to expand to enable electronic prior authorization through more pharmacy benefit managers and EHR software vendors than ever before.



Electronic prior authorization saves time & money while increasing medication adherence.

Prior authorization is an important yet inefficient administrative task that costs providers precious time and money while increasing wait time for patients to receive their much needed medication. In fact, **20 – 30% of patients abandon their prescribed medications** at the pharmacy due to prior authorizations6.

Surescripts CompletEPA® connects physicians with patients' health plans to help them realize the benefits of prior authorization without enduring the pain of using outdated and slow phone, fax and portal systems. Surescripts simplifies the prior authorization process by using the software systems providers are already familiar with and leveraging the existing e-prescribing process. The **single point of contact** through the Surescripts network allows providers to complete the prior authorization process accurately and efficiently, in many cases before the patient leaves the office.

Manual prior authorization is costly and time-consuming.

4 hours
Per pharmacist each week

$11k
Per pharmacist each year

5-8 hours
Per physician each week

$14k
Per physician each year[7]

Clinical messaging **increases workflow efficiency and connects providers** nationwide.

Exchanging clinical data, such as discharge and visit summaries, patient charts, and referral orders, is not just a regulatory requirement to improve care coordination, but it makes good business sense. Surescripts Clinical Messaging can help meetMeaningful Use requirements for transitions of care and helps hospitals and other healthcare organizations improve patient outcomes.

In the past three years, Surescripts has built the nation's largest physician directory, connecting more than 160,000 providers, so they can exchange patient-specific clinical information electronically.

"Prior authorization has been a pain point for providers and patients alike. Through our collaborative efforts with Surescripts, we are providing the industry with the tools necessary to alleviate this frustration while saving time and resources. Integrating CompletEPA into our application will provide our clients with automated, real-time electronic prior authorization processes enabling them to focus less on administrative functions and more on providing better patient care."

Michael Lovett, Executive Vice President
& General Manager NextGen

Clinical messaging, while still in the adoption phase, is beginning to take off.

7.3 million
clinical messages

1,300%
growth y/y

18%
of all staffed beds in the country

974
hospitals

2,000
provider organizations

160,000
providers connected
400% growth y/y

"HITECH led directly to our Epic project and to participation in the Meaningful Use Program. All of our eligible providers and hospitals have successfully participated in Stage 1, and in 2014 98% of our 500 Stage 2 providers and one Stage 2 hospital successfully attested. Surescripts was critical to that success, providing infrastructure that supported our Transitions of Care strategy.

Dr. Lynn Witherspoon, SVP & CMIO,
Ochsner Health System

Improving Public Health By Combating Prescription Fraud and Abuse.

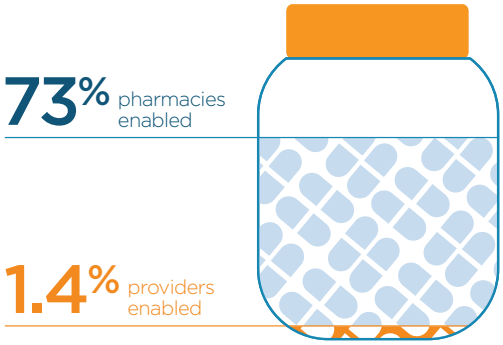
In 2013, more than two million Americans abused prescription painkillers such as hydrocodone, oxycodone and methadone.[8] Since 1999, overdose deaths involving prescription painkillers have quadrupled, and by 2007 they outnumbered heroin and cocaine overdoses.[9]

The rescheduling of hydrocodone to a Schedule II drug has made the need for safe and secure electronic prescriptions for controlled substances even greater. By eliminating the paper prescription and connecting physicians and pharmacists electronically, there is an opportunity to improve care, reduce fraud, and identify potential instances of abuse.

"The ability to communicate easily and efficiently ensures that all of our physicians and health care providers will be armed with the right information at the right time to make the right decisions for our patients. To advance healthcare interoperability we need to move faster as an industry, and the changes in the delivery model that are being thrust upon us are going to necessitate that we do it quicker.

Chuck Fennell, CIO, St. Joseph's - Syracuse

E-prescribing of controlled substances increased by 400% in 2014, but adoption among providers is still low.



Legal in 49 states and D.C.

1.67 million
controlled substance e-prescriptions

Almost
400% y/y growth

Top 10 States E-Prescribing Controlled Substances[10]

1 **Nebraska**
2 **California**
3 **Michigan**
4 **Massachusetts**
5 **Delaware**
6 **Illinois**
7 **Iowa**
8 **Rhode Island**
9 **Arizona**
10 **Minnesota**

State	% Prescribers Enabled	% Pharmacies Enabled	% EPCS Transactions
NE	8.11%	75.90%	6.81%
CA	8.58%	71.20%	4.26%
MI	9.07%	65.90%	2.57%
MA	4.91%	80.60%	2.72%
DE	1.39%	87.90%	3.37%
IL	2.76%	78.80%	2.19%
IA	3.31%	75.30%	1.99%
RI	2.30%	91.40%	1.15%
AZ	2.24%	87.20%	1.03%
MN	2.99%	64.10%	1.63%
OR	1.74%	81.80%	1.15%
TX	1.59%	81.30%	1.21%
NH	0.90%	89.10%	1.07%
MD	1.61%	77.20%	1.28%
WY	1.92%	72.90%	0.78%
CO	1.47%	82.40%	0.38%
OK	1.18%	84.20%	0.44%
DC	1.39%	75.70%	0.87%
IN	0.99%	85.70%	0.29%
OH	1.01%	77.70%	0.87%
NY	1.84%	70.30%	0.77%
VA	0.81%	78.80%	0.75%
NV	1.29%	80.30%	0.12%
NC	1.04%	78.30%	0.44%
CT	0.74%	81.10%	0.46%
NM	0.81%	78.70%	0.43%
ME	0.53%	79.60%	0.53%
ID	1.18%	68.10%	0.82%
WA	0.98%	71.70%	0.55%
NJ	0.61%	77.40%	0.36%
FL	1.57%	68.40%	0.17%
AK	0.73%	75.80%	0.22%
TN	1.19%	67.60%	0.33%
PA	0.51%	71.90%	0.52%
LA	0.49%	74.60%	0.20%
WI	0.33%	70.70%	0.56%
WV	0.48%	69.00%	0.39%
SC	0.20%	73.90%	0.04%
KS	0.45%	71.30%	0.03%
GA	0.55%	69.40%	0.08%
KY	0.51%	60.80%	0.54%
AL	0.79%	63.00%	0.15%
MS	0.61%	62.80%	0.14%
AR	0.86%	60.80%	0.04%
UT	0.61%	57.80%	0.09%
VT	0.34%	56.20%	0.10%
HI	0.05%	56.00%	0.00%
MO	0.47%	42.40%	0.09%
SD	0.20%	45.30%	0.02%
MT	1.68%	25.50%	0.00%
ND	0.00%	26.50%	0.00%

"EPCS is one example of how our customers can achieve interoperability, resulting in increased practice efficiency and patient convenience, not to mention improved patient safety and medication adherence.

George Cuthbert, Vice President, MEDENT

"I see the physical and emotional toll that opioid abuse takes on patients and their families every day in the emergency room. EPCS can be an effective tool in fighting that abuse. Physicians are eager to embrace technology – as long as it is good technology that speeds our workflows and allows us to make better informed decisions that increase patient safety. What we don't want is bad technology that slows us down, costing us minutes that impact the health and well-being of our patients. As a healthcare community, we need to work together to deliver integrated, usable systems; good technology that prescribers want to use. EPCS can help with that.

Dr. Sean Kelly, FACEP, CMO, Imprivata and an emergency physician at Beth Israel Deaconess Medical Center

National Progress Report
Data Set

	2014	2013
Healthcare professionals	900,000	700,000
Health data transactions	6,500,000,000	6,000,000,000
Hospitals	3,300	n/a
Patients	230,000,000	210,000,000
EHR Applications	700	600
Chain pharmacies	40,000	40,000
Independent pharmacies	21,000	21,000
Number of state and regional networks (HIEs)	23	21
Electronic Prescribing		
Electronic prescriptions	1,200,000,000	1,040,000,000
Percentage of new e-prescriptions	67%	58%
Prescribers utilizing	56%	55%
Clinical messages	7,400,000	509,000
Hospitals utilizing	974	400
Provider addresses	160,000	32,000
Medication History		
Medication history transactions	764,000,000	699,000,000
Medication history transactions by hospitals	84,700,000	48,000,000
Hospitals utilizing	2,500	1,200
Patient data coverage	80-85%	66%
Electronic Prescribing of Controlled Substances (EPCS)		
EPCS transactions	1,670,000	340,000
Percentage of pharmacies enabled	73%	40%
Percentage of providers enabled	1.40%	n/a

Virginia
2800 Crystal Drive
Arlington, VA 22202
Fax: 1-703-921-2191

Minnesota
920 2nd Avenue South
Minneapolis, MN 55402
Fax: 1-651-855-3001

1. U.S. Census Bureau, 2014
2. NCPDP
3. AHA, http://www.aha.org/research/rc/stat-studies/fast-facts.shtml
4. http://surescripts.com/hospitalvalue
5. AHA, http://www.aha.org/research/rc/stat-studies/fast-facts.shtml
6. http://content.healthaairs.org/content/28/4/w533.full
7. Health Aairs July/August 2009 vol. 28 no. 4 w533-w543 http://content.healthaairs.org/content/28/4/w533.abstract?ijkey=0ea98293a5c04485a869a0310555efbdfc387258&keytype2=tf_ipsecsha
8. Centers for Disease Control and Prevention, http://www.cdc.gov/drugoverdose/data/index.html
9. National Institute on Drug Abuse
10. Based on pharmacy and provider enablement, and prescription volume

Attachment 6

Article 10. ~~Wholesalers~~ Dangerous Drug Distributors

1780. Minimum Standards for ~~Wholesalers.~~

The following minimum standards shall apply to all wholesale and third-party logistics provider establishments for which permits have been issued by the Board:

(a) A wholesaler and a third-party logistics provider shall store dangerous drugs in a secured and lockable area.

(b) All wholesaler and third-party logistics provider premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale and third-party logistics provider premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the United States Pharmacopeia Standards (1990, 22nd Revision).

(c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(1) All facilities shall be equipped with an alarm system to detect entry after hours.

(2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(3) The outside perimeter of the wholesaler premises shall be well-lighted.

(d) All materials must be examined upon receipt or before shipment.

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.

(1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.

(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets appropriate United States Pharmacopeia Standards (1990, 22nd Revision).

(f) Policies and procedures must be written and made available upon request by the board.

(1) Wholesale and third-party logistics provider drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

(2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.

(3) Wholesale and third-party logistics provider drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of ~~wholesale~~ drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

(4) Each wholesaler and third-party logistics provider shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.

(g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4051, 4053, 4054, 4059, 4120, 4160, 4161 and 4304, Business and Professions Code.

1780.1. Minimum Standards for Veterinary Food-Animal Drug Retailers.
Not relevant to third-party logistics providers

1781. Exemption Certificate.
A registered pharmacist, ~~or an~~ designated representative or designated representative –3PL certified in accordance with Section 4053, 4053.1 or 4054 of the Business and Professions Code shall be present and in control of a manufacturer's ~~or~~ ,wholesaler's or a third-party logistics provider's licensed premises during the conduct of business.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4053, 4053.1 or 4054, Business and Professions Code.

1782. Reporting Sales of Drugs Subject to Abuse.
All manufacturers, ~~and~~ wholesalers and third-party logistics providers shall report to the Board or its designee, up to twelve (12) times a year, all sales of dangerous drugs subject to abuse as designated by the Board for reporting, in excess of amounts to be determined by the Board from time to time. Reports shall be made within thirty (30) days of the request in the form specified by the Board.

Authority cited: Section 4005, Business and Professions Code; and Section 26692, Health and Safety Code. Reference: Sections 4081 and 4332, Business and Professions Code; and Section 26692, Health and Safety Code.

1783. Manufacturer, ~~or~~ Wholesaler or Third-Party Logistics Provider Furnishing Drugs and Devices.
(a) A manufacturer, ~~or~~ wholesaler or third-party logistics provider shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer, ~~or~~ wholesaler or third-party logistics provider shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.
(b) “Authorized person” means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. “Authorized person” also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer or wholesaler furnishing to such person shall, prior to

furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.
(c) Dangerous drugs or devices furnished by a manufacturer, ~~or~~ wholesaler or third-party logistics provider shall be delivered only to the premises listed on the permit; provided that a manufacturer, ~~or~~ wholesaler or third-party logistics provider may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer, ~~or~~ wholesaler if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer, ~~or~~ wholesaler or third-party logistics provider by the next business day after the delivery to the pharmacy receiving area.
(d) A manufacturer, ~~or~~ wholesaler or third-party logistics provider shall not accept payment for or allow the use of an entity's credit to establish an account for the purchase of dangerous drugs or devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief financial officer listed on the permit for the authorized person; and (2) on an account bearing the name of the permittee.
(e) All records of dangerous drugs or devices furnished by a manufacturer, ~~or~~ wholesaler or third-party logistics provider to an authorized person shall be preserved by the authorized person for at least three years from the date of making and shall, at all times during business hours, be open to inspection by authorized officers of the law at the licensed premises. The manufacturer, ~~or~~ wholesaler or third-party logistics provider shall also maintain all records of dangerous drugs or devices furnished pursuant to this section for at least three years from the date of making and shall, at all times during business hours, keep them open to inspection by authorized officers of the law at the premises from which the dangerous drugs or devices were furnished.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4059, 4059.5, 4080, 4081, 4120, 4160, 4161, 4163 and 4304, Business and Professions Code; and Section 11209, Health and Safety Code.

1784. Self-Assessment of a Wholesaler by the Designated Representative-in-Charge.

This section will be modified to also establish a self assessment process for the third-party logistics provider by the responsible manager. The changes have not been incorporated below

(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:
(1) A new wholesaler permit is issued, or
(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.
(3) There is a change in the licensed location of a wholesaler to a new address.
(c) The components of this assessment shall be on Form 17M-26 (Rev. 01/11) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the licensed wholesale premises for three years after it is completed.
(e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5,4043, 4053, 4059, 4120, 4160, 4161, 4201, 4301 and 4305.5, Business and Professions Code.

California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, California 95834
(916) 574-7900 FAX (916) 574-8618

Third-Party Logistics Provider
DANGEROUS DRUGS & DANGEROUS DEVICES SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page 21.

All references to "drugs" throughout this self-assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B&PC) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

Third-Party Logistics Provider's Name _____

Address _____

Phone _____

Third-Party Logistics Provider's e-mail address _____

Ownership: Please mark one

☐ sole owner ☐ partnership ☐ corporation ☐ LLC

☐ non- licensed owner ☐ Other (please specify) _____

CA 3PL Permit #_____ Expiration Date_____

Other Permit #_____ Expiration Date_____
(Use additional sheets if needed.)

DEA Registration #_____ Expiration Date_____

VAWD Accreditation # _____ Expiration Date _____

Date of most recent DEA Inventory _____

Hours: Weekdays_____Sat_____ Sun_____ 24 Hours_____ ☐

Responsible Manager / pharmacist (RPH) _____

Responsible Manager's Designated Representative – 3PL License # / RPH
License#_____
Expiration Date_____
Website Address (optional): _____

Licensed 3PL Staff (designated representative -3PL (DR-3PL), pharmacist):

1. _____ DR-3PL#/RPH#_____ Exp. Date _____

2. _____ DR-3PL#/RPH#_____ Exp. Date _____

3. _____ DR-3PL#/RPH#_____ Exp. Date _____

4. _____ DR-3PL#/RPH#_____Exp. Date _____

5. _____ DR-3PL#/RPH#_____ Exp. Date _____

6. _____ DR-3PL#/RPH#_____ Exp. Date _____

7. _____ DR-3PL#/RPH#_____Exp. Date _____

8. _____ DR-3PL#/RPH#_____ Exp. Date _____

9. _____ DR-3PL#/RPH#_____Exp. Date _____

10_____ DR-3PL#/RPH#_____Exp. Date _____

Please mark the appropriate box for each question. If "NO," enter an explanation on the "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes No N/A

☐ ☐ ☐ 1.1. Review the current third-party logistics provider permit for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (B&PC 4160[a][c][f]) **Attach a copy of the notification letter to the board to this document.**

☐ ☐ ☐ 1.2. Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. ~~(CCR~~ (CCR 1780[f][3]) **Please attach a copy of the list to this document.** (This list should be dated.)

Note: Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (B&PC 4082)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

2. Facility

2.1. Premises, fixtures and equipment:

Yes No N/A

☐ ☐ ☐ 2.1.1. Are clean and orderly

☐ ☐ ☐ 2.1.2. Are well ventilated

☐ ☐ ☐ 2.1.3. Are free from rodents and insects

☐ ☐ ☐ 2.1.4. Are adequately lit

☐ ☐ ☐ 2.1.5. Have plumbing in good repair

☐ ☐ ☐ 2.1.6. Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see USP 1990 22nd Edition) (CCR 1780[b])

☐ ☐ ☐ 2.2. Is there a quarantine area for outdated, damaged, deteriorated, or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs safety, identity, strength, quality or purity? (CCR 1780[e])

Yes No N/A

☐ ☐ ☐ 2.3. Are dangerous drugs and dangerous devices stored in a secured and locked area? (CCR 1780[a])

☐ ☐ ☐ 2.4. Is access to areas where dangerous drugs are stored limited to authorized personnel? (CCR 1780[c])

List personnel with keys to the area(s) where drugs are stored (list by name or job title):

_____

_____

_____

Yes No N/A

☐ ☐ ☐ 2.5. Does this business operate only when a designated representative -3PL or pharmacist is on the premises? (CCR 1781)

2.6. The third-party logistic provider's premises is equipped with the following specific security features:

☐ ☐ ☐ 2.6.1. There is an alarm to detect after-hours entry. (CCR 1780[c][1]).

☐ ☐ ☐ 2.6.2. The outside perimeter of the building is well lit (CCR 1780[c][3]).

☐ ☐ ☐ 2.6.3. The security system provides protection against theft and diversion including tampering with computers and or electronic records. ~~(CCR~~ (CCR 1780[c][2]).

Explain how your security system complies with these requirements.

_____

_____

Yes No N/A

☐ ☐ ☐ 2.7. Is this business a "reverse distributor," that is, does the business act as an agent for pharmacies, drug wholesalers, manufacturers and others, by receiving, inventorying and managing the disposition of outdated or nonsalable drugs? (B&PC 4040.5, 4044.5) List Code section

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Yes No N/A
☐ ☐ ☐ 2.8. The facility is subscribed to the board's e-mail notifications. (B&PC 4013)

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Yes No N/A
☐ ☐ ☐ 2.9. The facility receives the board's e-mail notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for distribution of controlled substances – these additional requirements are in Section 11 of this document.

3. Designated Representative-in-Charge - 3PL / Owner Responsibilities

Yes No N/A
☐ ☐ ☐ 3.1. The responsible manager of the third-party logistics provider is licensed as a designated representative -3PL and maintains this licensure while serving as the responsible manager of the third-party logistics provider premises. (B&PC 4060[e])

Yes No N/A
☐ ☐ ☐ 3.2. The owner and the responsible manager are both equally responsible for maintenance of the records and inventory. (B&PC 4081[b])

☐ ☐ ☐ 3.3. The responsible manager is at least 18 years of age and is responsible for the third- party logistic provider's compliance with all state and federal laws for the distribution of drugs? The responsible manager may be a pharmacist. (B&PC 4160[e])

☐ ☐ ☐ 3.4. The owner must notify the board within 30 days of termination of the responsible manager or pharmacist. (B&PC 4305.5[a])

☐ ☐ ☐ 3.5. The owner must identify and notify the board of the appointment of a new responsible manager within 30 days of the termination of the former responsible manager. (B&PC 4160[g], 4331[c]) The appropriate form for this notification is a "Change of Facility Manager for Third-Party Logistics Provider Premises," which is available on the board's website.

Yes No N/A

☐ ☐ ☐ 3.6. The responsible manager who ends his or her employment at a third-party logistics provider, must notify the board within 30 days. (B&PC 4305.5[c], 4101[c]). This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN _____

_____

4. Designated Representative-3PL/Pharmacist

Yes No N/A

☐ ☐ ☐ If a designated representative -3PL or pharmacist changes his/her name or personal address of record, he/she must notify the board in writing within 30 days. (B&PC 4100, CCR 1704)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

☐ ☐ ☐ 5.1. Are drugs obtained only from a business licensed by this board or from a licensed manufacturer? (B&PC 4163[b], 4169)

☐ ☐ ☐ 5.2. If drugs are returned to your premises by a business to whom you had shipped the drugs, you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (B&PC 4081, 4332)

☐ ☐ ☐ 5.3. For license verification, the third-party logistics provider may use the licensing information displayed on the board's Internet web site. (B&PC 4106)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for handling controlled substances – these additional requirements are in Section 11 of this document.

6. Receipt of Drugs by this Business

Yes No N/A

☐ ☐ ☐ 6.1. When drugs are received by your business, are they delivered to the licensed secured premises of the third-party logistics provided, and received by and signed for only by a designated representative -3PL or a pharmacist? (B & P 4059.5[a])

☐ ☐ ☐ 6.2. When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for handling controlled substances – these additional requirements are in Section 11 of this document.

7. Drug Stock

Yes No N/A

☐ ☐ ☐ 7.1. Is all drug stock open for inspection during regular business hours? (B&PC 4081[a])

☐ ☐ ☐ 7.2. Are all drugs you receive and store maintained in a secure manner at your licensed third-party logistics provider premises? You cannot order, obtain or receive drugs that you are not able to store on your licensed premises. (B&PC 4167)

☐ ☐ ☐ 7.3. Do all drugs you distribute conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B&PC 4342[a])

☐ ☐ ☐ 7.4. Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)

☐ ☐ ☐ 7.5. Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)

☐ ☐ ☐ 7.6. Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR1307.21)

Yes No N/A

☐ ☐ ☐ 7.7. When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e], CFR 1307.21)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for distributing controlled substances – these additional requirements are in Section 11 of this document.

8. Sale or Transfer of Drugs by this Business

Yes No N/A

☐ ☐ ☐ 8.1. Are drugs sold distributed only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

8.2. Describe how you verify a business or person is appropriately licensed. (B&PC 4059.5[a][b][d], B&PC 4169) \

_____

_____

8.3. List any businesses or individuals that order drugs from you that are not licensed according to the list above:

_____

_____

Yes No N/A

☐ ☐ ☐ 8.4. Are drugs only furnished by your business to an authorized person? (B&PC 4166[b]) Note: An authorized person can be a business or natural person.

8.5. Does your business only receive drugs from a pharmacy if:

☐ ☐ ☐ 8.5.1. the pharmacy originally purchased the drugs from you?

☐ ☐ ☐ 8.5.2. your business is a "reverse distributor"?

☐ ☐ ☐ 8.5.3. the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (B&PC 4126.5[a])

Yes No N/A

☐ ☐ ☐ 8.6 Are all drugs that are acquired by your business acquired from another business that is appropriated licensed?

☐ ☐ ☐ 8.6.1. transacted with a business licensed with this board as a manufacturer, wholesaler or pharmacy?

☐ ☐ ☐ 8.6.2. free of adulteration as defined by the CA Health & Safety Code section 111250?

☐ ☐ ☐ 8.6.3. free of misbranding as defined by CA Health & Safety Code section 111335?

☐ ☐ ☐ 8.6.4. **confirmed** to not be beyond their use date (expired drugs)? (B&PC 4169)

8.7. List any incidents where adulterated, misbranded or expired drugs were received, shipped, stored or transferred by this business in the past 2 years.

_____

_____

8.8. If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes No N/A

☐ ☐ ☐ 8.8.1. comply with all CA pharmacy laws related to the distribution of drugs?

☐ ☐ ☐ 8.8.2. comply with the pharmacy law of the receiving state within the United States?

☐ ☐ ☐ 8.8.3. comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the distribution of drugs?

☐ ☐ ☐ 8.8.4. comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?

☐ ☐ ☐ 8.8.5. comply with all applicable federal regulations regarding the exportation of dangerous drugs?

8.9. Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B&PC 4059.5[e])

_____

_____

Yes No N/A

☐ ☐ ☐ 8.10. When you are not an authorized distributor for a drug, a pedigree must accompany the product when sold, traded, or transferred (Prescription Drug Marketing Act of 1987).

Yes No N/A

☐ ☐ ☐ 8.11. If preferentially priced drugs are sold by your business, that sale complies with the Prescription Drug Marketing Act of 1987 and CA Pharmacy Law. (B&PC 4380)

~~Yes No N/A~~

☐ ☐ ☐ 8.12. Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B&PC 4341, B&PC 651, CCR 1766)

☐ ☐ ☐ 8.13. Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (B&PC 650)

_____

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

9. Outgoing Shipments of Drugs

Yes No N/A

☐ ☐ ☐ 9.1 Before you ship drugs to a purchaser, do you inspect the shipment to assure the drugs were not damaged while stored by your business? (CCR 1780[d][2])

☐ ☐ ☐ 9.2. Does your business use a common carrier (a shipping or delivery company — UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (B&PC 4166[b])

9.3 List the common carriers (shipping or delivery companies) you use.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

10. Delivery of Drugs

Yes No N/A

☐ ☐ ☐ 10.1 Are all drugs ordered by a pharmacy or another wholesaler delivered to the address of the buyer's licensed premises and signed for and received by a pharmacist or designated representative where allowed? (B&PC 4059.5[a])

Yes No N/A

☐ ☐ ☐ 10.2. Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (B&PC 4059.5[d])

☐ ☐ ☐ 10.3. All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (B&PC 4059.5[c])

☐ ☐ ☐ 10.4 If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (B&PC 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

11. Controlled Substances

Yes No N/A

☐ ☐ ☐ 11.1. Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

☐ ☐ ☐ 11.2. Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

☐ ☐ ☐ 11.3. Are DEA requirements for storage of Schedule ~~III~~ III, IV and V controlled substances being met? (specific requirements are listed in CFR 1301.72[b])

☐ ☐ ☐ 11.4. Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a][c][e])

☐ ☐ ☐ 11.5. Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])

☐ ☐ ☐ 11.6. Does the biennial inventory record document that the inventory was taken at the "close of business" or "opening of Business." (CFR 1304.11)

☐ ☐ ☐ 11.7. Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.05)

11.7.1. List the individuals at this location authorized by power of attorney to order controlled substances.

_____

_____

Yes No N/A

☐ ☐ ☐ 11.8. Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)

☐ ☐ ☐ 11.9. If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability, you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)

☐ ☐ ☐ 11.10. Are all controlled substances stored and shipped by your business, done so for legitimate medical purposes? (H & S 11153.5[a][b][c])

☐ ☐ ☐ 11.11. If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances (CFR 1301.74[f])

☐ ☐ ☐ 11.12. If a person attempts to purchase or secure a shipment of controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. (CFR 1301.74 [a], 4166)

☐ ☐ ☐ 11.13. Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

Yes No N/A

☐ ☐ ☐ 11.14. If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances. (CFR 1301.74[f])

☐ ☐ ☐ 11.15. If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[e])

☐ ☐ ☐ 11.16. Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)

☐ ☐ ☐ 11.17. When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 from? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.13 [b])

☐ ☐ ☐ 11.18. If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.15)

☐ ☐ ☐ 11.19. When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? ~~(CFR 1309.13[b])~~ (CFR 1305.13[b])

☐ ☐ ☐ 11.20. For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received and the number of containers received? (CFR 1305.13[e])

☐ ☐ ☐ 11.21. Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances? (CFR 1305.21, 1305.22)

☐ ☐ ☐ 11.22. Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.16(a))

☐ ☐ ☐ 11.23. Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the making? (B&PC 4081, CCR 1718, ~~CFR 1305.09[d],~~ CFR 1305.17[c], 1305.17[a][b], and ~~H & S~~ H&SC 11252, 11253, 1304.03)

Yes No N/A

☐ ☐ ☐ 11.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])

☐ ☐ ☐ 11.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])

☐ ☐ ☐ 11.26. Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.75[g], 1305.16[b])

☐ ☐ ☐ 11.27. Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? ~~(CFR 1305.16)~~ (CFR 1305.17[d])

☐ ☐ ☐ 11.28. Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])

☐ ☐ ☐ 11.29. Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

12. Policies and Procedures

12.1. Does this business maintain and adhere to policies and procedures for: (CCR 1780[f])

Yes No N/A

☐ ☐ ☐ 12.1.1. Receipt of drugs?

☐ ☐ ☐ 12.1.2. Security of drugs?

☐ ☐ ☐ 12.1.3. Storage of drugs? (including maintaining records to document proper storage)

☐ ☐ ☐ 12.1.4. Inventory of drugs? (including correcting inaccuracies in inventories)

☐ ☐ ☐ 12.1.5. Distributing drugs?

☐ ☐ ☐ 12.1.6. Identifying, recording and reporting theft or losses?

☐ ☐ ☐ 12.1.7. Correcting errors and inaccuracies in inventories?

Physically quarantining and separating:

☐ ☐ ☐ 12.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs?

☐ ☐ ☐ 12.1.9. drugs that have been partially used?

☐ ☐ ☐ 12.1.10. drugs where the outer or secondary seals on the container have been broken?

☐ ☐ ☐ 12.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug?

☐ ☐ ☐ 12.1.12. drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity? (CCR 1780[e][f])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

14. Training

Yes No N/A

☐ ☐ ☐ 13.1 Are training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

14. Record Keeping Requirements

Yes No N/A

☐ ☐ ☐ 14.1. Do your business records for receipt, storage and shipping of dangerous drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (B&PC 4081)

☐ ☐ ☐ 14.2 Are acquisition and shipping records for all transactions retained on your licensed premises for 3 years from the date of making? (B&PC 4081[a], 4105[c], 4081, 4332) Note: A drug pedigree is considered to be a part of the records of purchase and sale and must be retained for three years from the making.

☐ ☐ ☐ 14.3 Are all purchase, receipt and shipping sales records retained in a readily retrievable form? (B&PC 4105)

☐ ☐ ☐ 14.4. Is a current accurate inventory maintained for all dangerous drugs? (B&PC 4081, 4332, 1718)

☐ ☐ ☐ 14.5 If you temporarily remove acquisition or disposition records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (B&PC 4105[b])

☐ ☐ ☐ 14.6 Are required records stored off-site only if a board issued written waiver has been granted?

☐ ☐ ☐ 14.7 If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address_____

Yes No N/A

☐ ☐ ☐ 14.8 Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

☐ ☐ ☐ 14.9 If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

☐ ☐ ☐ 14.10. Can the records that are retained electronically be produced immediately in hard copy form by any designated representative – 3PL, if the responsible manager is not present? (B & P 4105[d])

☐ ☐ ☐ 14.11. Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

Yes No N/A

☐ ☐ ☐ 14.12 Has this licensed premises, or the designated representative-in-charge - 3PL or pharmacist, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so list each incident with a brief explanation (B&PC 4162[a][4]):

_____

_____

Yes No N/A

☐ ☐ ☐ 14.13 Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (B&PC 4083)

☐ ☐ ☐ 14.14 Has this business received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (B&PC 4315[e])

14.15 If this business dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

15. Reporting Requirements to the Board

Yes No N/A

☐ ☐ ☐ 15.1 A responsible manager who terminates employment at this business, must notify the board within 30 days of the termination (B&PC 4101[b], 4305.5[c].

☐ ☐ ☐ 15.2 The owner must report to the board within 30 days the termination of the responsible manager or pharmacist (B&PC 4305.5[a])

☐ ☐ ☐ 15.3The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)

☐ ☐ ☐ 15.4 The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])

Yes No N/A

☐ ☐ ☐ 15.5 Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)

☐ ☐ ☐ 15.6 The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (B&PC 4201[i], CCR 1709[b])

☐ ☐ ☐ 15.7 When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (B&PC 4164[a])

☐ ☐ ☐ 15.8 I understand that this wholesaler license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (B&PC 4201[g])

15,9 The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)

☐ ☐ ☐ 15.10 If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

CORRECTIVE ACTION OR ACTION PLAN _____

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~~17.~~ 18. Additional Licenses/Permits Required

18.1. List all licenses and permits required to conduct this business, including local business licenses, wholesale licenses held in other states, permits or licenses required by foreign countries or other entities (B&PC 4059.5[e], 4107, CFR 1305.11[a]) Use additional sheets if necessary.

_____

_____

Add requirements for wholesalers and 3PLs co-located.

DESIGNATED REPRESENTATIVE-IN-CHARGE / PHARMACIST CERTIFICATION:

I, (please print) _____, DRIC# / RPH # _____ hereby certify that I have completed the self-assessment of this wholesale business of which I am the designated representative-in-charge (DRIC) / pharmacist (RPH). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Pharmacist (RPH)

ACKNOWLEDGEMENT BY OWNER, PARTNER OR CORPORATE OFFICER:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ Date _____

Legal References

The following Legal References are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet Web sites:

California Code of Regulations (CCR), Title 16, unless otherwise noted

Business and Professions Code (B&PC), Chapter 9, Division 2, unless otherwise noted

Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act

Health and Safety Code (H&SC), Division 104, Part 5, Sherman Food, Drug and Cosmetic Laws

United States Code of Federal Regulations (CFR), Title 21, Chapter II, Part 1300, Drug Enforcement Administration, Food and Drugs and Codified Controlled Substances Act (CSA)

California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

Pharmacy Law may be obtained by contacting:
LawTech Publishing Co.
1060 Calle Cordillera, Suite 105
San Clements, CA 92673
Phone: (800) 498-0911 Ext. 5
www.lawtechpublishing.com

Pharmacist Recovery Program
Phone: (800) 522-9198 (24 hours a day)

Prescriber Boards:

Medical Board of California
2005 Evergreen St., Suite 1200
Sacramento, CA 95815
Phone: (800) 633-2322
Phone: (916) 263-2382
Fax: (916) 263-2944
http://www.mbc.ca.gov

Dental Board of California
2005 Evergreen St., Suite 1550
Sacramento, CA 95815
Phone: (916) 263-2300
Fax: (916) 263-2140
http://www.dbc.ca.gov

Board of Registered Nursing
1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
Phone: (916) 322-7697
Fax: (916) 574-8637
http://www.rn.ca.gov/

Board of Optometry
2420 Del Paso Road, Suite 255
Sacramento, CA 95834
Phone: (916) 575-7170
Fax: (916) 575-7292
http://www.optometry.ca.gov/

Osteopathic Medical Board of California
1300 National Drive, Suite 150
Sacramento, CA 9583~~4~~
Phone: (916) 928-8390
Fax: (916) 928-8392
http://www.ombc.ca.gov

Physician Assistant Committee
2005 Evergreen St., Suite 1100
Sacramento, CA 95815
Phone: (916) 561-8780
Fax: (916) 263-2671
http://www.pac.ca.gov

Board of Podiatric Medicine
2005 Evergreen St., Suite 1300
Sacramento, CA 95815
Phone: (916) 263-2647
Fax: (916) 263-2651
http://www.bpm.ca.gov

Veterinary Medical Board
2005 Evergreen St., Suite 2250
Sacramento, CA 95815
Phone: (916) 263-2610
Fax: (916) 263-2621
http://www.vmb.ca.gov

Federal Agencies:

Food and Drug Administration – Industry Compliance
http://www.fda.gov/oc/industry/centerlinks.html#drugs

The **Drug Enforcement Administration** may be contacted at:

DEA Website:
http://www.deadiversion.usdoj.gov
Online Registration – New Applicants:
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm
Online Registration - Renewal:
www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm
Registration Changes (Forms):
http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html
Online DEA 106 Theft/Loss Reporting:
https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp
Controlled Substance Ordering System (CSOS): http://www.deaecom.gov/

DEA Registration Support (all of CA):
(800) 882-9539

DEA - Los Angeles
255 East Temple Street, 20th Floor
Los Angeles, CA 90012
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (213) 621-6942

DEA – San Francisco
450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251
Theft Reports or Diversion: (415) 436-7900

DEA - Sacramento
4328 Watt Avenue
Sacramento, CA 95821
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (916) 480-7250

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (951) 328-6200

DEA - Fresno
2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (559) 487-5406

DEA – San Diego and Imperial Counties
4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

DEA – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251
Diversion or Investigation: (510) 637-5600

DEA – San Jose
One North First Street, Suite 405
San Jose, CA 95113
Registration: (888) 304-3251
Diversion or Investigation: (408) 291-2631

DEA – Redding
310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or (415) 436-7900
Diversion or Investigation: (530) 246-5043

Attachment 7

Quality Standards for Large Scale Sterile Compounding Facilities

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Introduction

Legislation has established a new regulatory category for pharmaceutical compounders that supply healthcare providers with prepared non-patient specific medicines for use in hospitals, offices and clinics. These "outsourcing facilities" will be subject to more rigorous quality and safety standards modeled after the Current Good Manufacturing Practices (CGMPs)[1] that apply to pharmaceutical manufacturers. In light of the new law, this paper reviews the differences between traditional and outsourced compounding and describes the key CGMP provisions that are critical to ensuring drug quality and patient safety when compounding occurs at a larger scale. The scope and magnitude of sterile compounding has changed dramatically over the past three decades and includes many large scale commercial compounding operations providing compounded sterile preparations (CSPs) without the traditional benefit of a patient-specific prescription. This sector has outgrown existing traditional compounding standards of practice necessary to ensure product quality and sterility as well as added capacity. While outsourcing facilities will be subject to CGMPs, all large scale sterile compounding should meet more rigorous quality standards regardless of participation in the new regulatory category.

The Emergence of the Outsourced Compounding Sector

Pharmacy compounding is the historical cornerstone of the pharmacy profession. According to a 1949 text, it is the "task in which all the scientific knowledge, professional skill and sense of responsibility . . . must find their expression and justification."[2] Traditionally, compounding is the extemporaneous preparation and dispensing of medications in various dosage forms to meet the medical needs of patients pursuant to a prescription written by an authorized prescriber. The pharmacy profession, most notably hospital pharmacy, has redefined itself over time, and its focus has moved from production and distribution to clinical patient management.[*] As

[*] This transformation was fostered by the 1985 Hilton Head invitational consensus-conference facilitated by the American Society of Health-System Pharmacists (formerly known as the American Society of Hospital Pharmacists) which shifted departmental pharmacy practice from the provision of discrete clinical services (e.g., aminoglycoside pharmacokinetic dosing services) to a comprehensive clinical enterprise where pharmacists take on a larger role in the safe and appropriate use of medications. Examples of the services currently provided by pharmacy

the institutional practice of pharmacy shifted away from compounding, commercial business enterprises found opportunities to fill this void.[3] Examples include manufacturers of automated medication dispensing cabinets and pharmacies specializing in extemporaneous compounding.

Drug manufacturers were some of the first to enter the outsourced compounding space specifically to service the hospital market. In July 1982, Baxter Healthcare began operations of the Travenol Regional Compounding Center (TRC) business,[4] first opening a center in Morton Grove, Illinois and later adding a second in Bridgeport, New Jersey. The TRC program was designed to operate on a large scale to transform commercially available drug powders and concentrates into dosage packages suitable for immediate administration to patients[†] without further aseptic manipulation at hospitals or other provider sites. Baxter and other companies that followed their approach argued that this service was an extension of the hospital's compounding operation.

Though a commercial success, the TRC program drew the attention of the FDA, which alleged that the TRC activities violated the Food, Drug and Cosmetic Act (FDCA). FDA believed the drug packages produced at the TRCs were new drugs, which must be separately tested for safety and efficacy,[5] and further that Baxter was creating new dosage forms of other pharmaceutical companies' proprietary medications. Subsequently, they intervened, issuing a consent decree that prohibited Baxter from providing these services without significant financial and punitive penalties.[6] As a result, Baxter closed these operations.

Hospitals, however, were still looking to outsource the compounding of certain products, such as parenteral nutrition. The preparation of parenteral nutrition is complex and requires specialized facilities that maintain optimal states of environmental control, trained personnel and costly equipment. In all but the biggest hospitals, the cost associated with compounding parenteral nutrition using these systems was prohibitive. In 1991, Central Admixture Pharmacy Services (CAPS), a division of B Braun Medical, started to provide hospitals with ready-to-use, patient-specific bags of parenteral nutrition.[7] This allowed hospitals that did not have the

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departments include anticoagulation dosing services, immunization tracking and administration and recently, new prescribing roles.

[†] Many drugs are not produced by drug manufacturers in the final form needed for patient administration. They are purchased in either lyophilized (freeze-dried) or liquid concentrate form. Hospitals have commonly responded to the need to prepare these drugs for administration to patients by operating their own centralized drug preparation programs for the reconstitution, dilution, and repackaging, of drugs.

resources to prepare this type of compounded sterile preparation (CSP) to purchase them on an as needed basis, freeing up both fiscal and human resources.

The CAPS locations providing this service were state licensed pharmacies. Since nutrition was one of Baxter's core products (they manufactured or distributed various parenteral nutrition components such as amino acids, dextrose, water and fat emulsions and offered a state of art automated compounding device that improved the safety profile of preparing these complex formulations), they wanted to re-enter the outsourced compounding business. Baxter sought and received FDA permission to provide compounding services but with the provisos that the Baxter facilities (then known as the COMPASS program which later became PharMEDium when divested by Baxter)[8] be registered with the FDA, employ pharmacists and pharmacy technicians, and meet a limited number of quality requirements from the CGMPs – the robust quality requirements for commercial pharmaceutical manufacturing – dictated by the FDA. Baxter was also required to provide these compounded solutions of parenteral nutrition in a patient-specific manner. (Personal Communication, John L. Quick-former Corporate VP of Quality and Regulatory Affairs, Baxter Healthcare, May 2, 2014). The FDA never formalized these expectations in a Compliance Policy Guide or any other written document.[9] At about the same time, the FDA required the CAPS program facilities to become registered establishments, so they operated as both licensed pharmacies and FDA registered establishments.

Over time, COMPASS and CAPS expanded their extemporaneous compounding services to include non-patient-specific cardioplegia, anesthesia syringes, antibiotics and narcotic dosage forms. The FDA exercised its enforcement discretion with these companies allowing them to provide these non-patient specific doses since they were under the purview of the Agency, however there was an expectation that these organizations had the ability to ultimately track the compounded medication to the patients for which they were used.[10,11]

In addition to outsourced compounding for hospitals, a second market began to emerge to serve physician office practices and ambulatory care clinics looking for certain medication doses to keep on site for use in those entities. In some cases these drugs were in short supply from the pharmaceutical companies, in other cases pharmacies identified commonly-prescribed compounded dosage forms and marketed their ability to supply them to prescribers regionally or nationally.

While COMPASS and CAPS had mainly prepared new dosage forms from packaged FDA-approved medicines, the new compounders entering this new market were

producing large quantities of non-patient-specific sterile injectable drugs from non-sterile bulk chemicals and they were not registered with the FDA. Compounding sterile preparations from non-sterile ingredients is a high risk activity that requires significantly more rigorous controls to ensure the quality and sterility of the final formulation versus those required by compounders using only commercially available FDA approved products as their starting materials.

Additional factors continued to drive demand for outsourced sterile preparation services. New standards for sterile compounding issued by the United States Pharmacopeial Convention (USP) – discussed below – presented compliance challenges for pharmacies, despite the fact that these standards were considered minimum practice for sterile compounding as early as 1995 in USP Chapter <1206>, Sterile Drugs for Home Use (which was replaced in 2004 by the new USP Chapter <797> Pharmaceutical Compounding – Sterile Preparations).

Federal attention to the changing landscape of pharmaceutical compounding grew throughout this period. In the 1990s, the FDA became increasingly concerned with the expansion of this sector and grappled with how to appropriately regulate larger-scale compounding pharmacies that were operating like manufacturers. In 1992, the FDA published a non-binding Compliance Policy Guidance 460.200 that established nine criteria that the Agency used to determine when a pharmacy preparing large quantities of non-patient specific medications exceeded the traditional activities of a pharmacy and should be regulated under CGMPs. The compounding pharmacy industry, led by organizations like the Professional Compounding Centers of America (PCCA) and the International Academy of Compounding Pharmacists (IACP), battled with the FDA over their perceived right to compound medications to meet the growing demand for sterile injectable drugs, which included those kept in stock in physician office practices.[12]

In 1997 this regulatory gap prompted Congress to modify Section 503A of the FDCA to create a safe harbor for pharmacists who were compounding medications pursuant to physician's order. The Food and Drug Administration Modernization Act (FDAMA) section 127 amended the FDCA by adding section 503A (21 U.S.C. 353a), which governs the application of Federal law to pharmacy compounding. Under section 503A(a) of the act, a compounded drug product is a drug product made in response to, or in limited quantities in anticipation of, receipt of a valid prescription order or a notation on a valid prescription order from a licensed practitioner that states the compounded product is necessary for the identified patient. Compounded drug products are exempt from three key provisions of the act:

1. *Adulteration* provision of section 501(a)(2)(21 U.S.C. 351(a)(2)(B)) (current good manufacturing practice [CGMP] requirements);

2. *Misbranding* provision of section 502(f)(1) (21 U.S.C. 352(f)(1)) (labeling of drugs with adequate directions for use);

3. New drug provision of section 505 (21 U.S.C. 355) (…use of drugs under Investigational New Drug Applications (INDs), New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs).[13]

This law was almost immediately challenged by various compounding pharmacists who argued that the inclusion of a prohibition on advertising and promotion was an unconstitutional violation of free speech. A decision in the United States Court of Appeals for the Ninth Circuit held that the restriction on advertising and promotion was unconstitutional and further that the unconstitutional provision was not severable from the rest of section 503A.[14] The Supreme Court reviewed the case and in 2002 affirmed the ruling of unconstitutionality, but did not review the question of severability.[15] Following this decision the FDA assumed that section 503A was not enforceable and issued a second Compliance Policy Guide on how it would use its underlying authority to control certain compounding activities.[16] In 2008, the United States Court of Appeals for the Fifth Circuit held that the restriction on advertising and promotion *was* severable and thus that the rest of section 503A was enforceable.[17] These conflicting rulings resulted in inconsistent legal status of the law in different parts of the country and affected the FDA's perception of its authority to regulate pharmacies that they believed were acting more like manufacturers.

Compounding Quality Failures and Patient Harm

Alongside growth of the compounding sector and oversight challenges came high-profile incidents of contaminated drugs harming patients. The 1980s and 1990s saw a number of cases of contaminated sterile preparations involving eye drops,[18] parenteral nutrition solutions[19] and cardioplegia.[20] Because of these tragic and well-publicized sterile compounding failures, some FDA officials suggested banning certain types of pharmacy compounding under the FDA's discretionary authority to regulate

compounded preparations as unapproved new drugs under the adulteration and misbranding provisions of the FD&C Act. The following summarizes the FDA perspective at that time:

> "Generally, FDA will defer to state authorities regarding less significant violations of the Act related to pharmacy compounding of human drugs. However, when the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the Act, FDA has determined that it should seriously consider enforcement action."[21]

One of the first major catastrophic compounding incidents occurred in 2001 when a generic sterile injectable drug went into short supply after the pharmaceutical company production line was shut down due to CGMP compliance deficiencies. The drug, betamethasone injectable suspension, was compounded by a community pharmacy and one lot of 60 vials was not terminally sterilized. The result was distribution of vials contaminated with a highly pathogenic gram negative microorganism.[22] Several patients were hospitalized and treated and three patients died as a result of the contamination.

The 2012 national fungal meningitis outbreak linked to contaminated medications prepared by the New England Compounding Center brought widespread attention to compounding quality. As of October 23, 2013, when the Centers for Disease Control and Prevention (CDC) last updated their data, the total adverse event case count was 751, with 64 deaths.[23] But while larger than other outbreaks, this was not an isolated event. Between January 2000 and 2012, eleven other outbreaks were identified, involving 207 infected patients and 17 deaths after exposure to other contaminated compounded drugs.[24] The past several years have also seen harm caused by other errors, such as super-potency. Three patients died in 2007 after receiving a dose of colchicine made by a compounding pharmacy that was eight-times stronger than the labeled concentration.[25]

In recent years the FDA has increased its inspections of compounding pharmacies and registered establishments that were known to have had quality issues or that in the Agency's opinion posed a potential risk to patient safety. Since 2012, over 90 pharmacies have been inspected by the FDA and many were issued inspection reports known as "483s" which document and communicate observed conditions that may constitute violations of the FD&C Act.[26]

Compounding Quality Standards

The incidences of injuries and deaths to patients during the late 1980s and early 1990s from pharmacy compounded injections, ophthalmic solutions and organ transplant baths became a call to action[27,28] prompting US-based professional and standards organizations to develop better quality guidelines.

In the early 1990s, both the American Society of Health-System Pharmacists[‡] (ASHP) and the USP issued voluntary standards for sterile compounding. ASHP published a Technical Assistance Bulletin (TAB) to help pharmacists and pharmacy technicians produce sterile preparations of higher quality.[29] Both the ASHP TAB and USP Chapter <1206>, Sterile Drug for Home Use, served as a foundation for USP General Chapter <797>[§] issued in 2004 — the first U. S. national practice standard for sterile compounding that was enforceable by the U. S. Food and Drug Administration (FDA) and the State Boards of Pharmacy. Chapter <797> was developed by an expert General Committee, now called the Compounding Expert Committee (2010-2015), which updates the standard as needed.

The objective of Chapter <797> is to describe conditions and practices to prevent harm, including death, to patients that could result from:

(1) microbial contamination (nonsterility),

(2) excessive bacterial endotoxins,

(3) variability in the intended strength of correct ingredients that exceeds either monograph limits for official articles[**] (see “official” and “article” in the General Notices and Requirements) or 10% for nonofficial articles,

(4) unintended chemical and physical contaminants and

(5) ingredients of inappropriate quality in CSPs.

[‡] Then called the American Society of Hospital Pharmacists

[§] USP sets standards in its drug and drug dosage form monographs, General Chapters numbered lower than 1000, and General Notices, which are legally enforceable under the 1938 FD&C Act by FDA, state regulatory boards, Joint Commission, etc., but USP per se lacks enforcement authority.

[**] An article is a substance and an official article is an article that is recognized in USP or NF via monograph

Importantly, USP Chapter <797> describes *minimum* practice and quality standards for CSPs of drugs and nutrients based on current scientific information and best known sterile compounding practices.[30] The Chapter was never intended to describe the quality system requirements for large scale compounding practices described previously that are outside the traditional compounding role of pharmacists as defined Section 503A. Chapter <797> was last revised in June 2008. Its next revision – expected in the coming year or two – should reflect advances of science and industry understanding of best practices learned over the past several years, as well as lessons learned from the national fungal meningitis contamination event. These standards have historically been intended for traditional pharmacy compounding practices only. The quality system described in USP General Chapter <797> was not created to ensure drug quality and patient safety at the scales of large compounding facilities.

USP Chapter <797> - Good But Not Sufficient for Large Scale Compounding

USP General Chapter <797> has advanced compounding practice and describes a standardized compounding quality system as well as the expectations for personnel who compound and the processes needed to engender a quality CSP. But the Chapter leaves room for pharmacists and pharmacy technicians to exercise professional discretion. Unfortunately this discretion has at times resulted in a lack of compliance with standards of practice.[31] Additionally, lack of critical oversight by state boards of pharmacy, failure of accreditation organizations to establish an expectation of compliance and inadequate knowledge and expertise explain the profession's slow pace of adoption of effective compounding quality systems. In 2007, one study showed that only one in six pharmacists was prepared for sterile compounding work.[32] The results of a 2013 national survey of compliance with USP General Chapter <797> has showed little to no significant improvement in the overall scores of participating organizations over time despite the extensive and protracted educational efforts of professional and private organizations since 2004.[33]

The misapplication of professional discretion relative to sterile compounding practice has at times yielded inconsistent quality. This presents a much greater public threat when compounders operate on a large scale and their products can reach hundreds of patients across the country. Preparing medicines in large volumes necessitates much more robust quality assurance practices, such as those described under CGMPs. For

example, one element central to the CGMP approach is the focus upon building quality into the overall process and the prevention of problems. Quality is consistently producing products or services that the customer wants while simultaneously decreasing errors. Though quality can represent a measurement at a defined instance, it is better explained as a dynamic process leading to continual improvement of the output to customers over time. Systematic evaluation and elimination of variability within a manufacturing process is a cornerstone of predictable quality outcomes. The practice of large scale sterile compounding is no different and the absence of these concepts in large scale compounding was starkly illustrated by the national fungal meningitis outbreak and other such events.[34]

The current Chapter <797> does not adequately address large scale sterile compounding, whether it is done at an outsourcing facility without prescriptions, or at a large compounding pharmacy that aggregates many prescriptions and produces high volumes of sterile drugs. While the later example of compounding may be considered patient-specific – a criteria commonly used to differentiate traditional from non-traditional compounding – the sheer volume of drugs made by these prescription aggregator pharmacy operations most certainly exceed the *traditional* patient-specific compounding practices that Chapter <797> was intended to cover. Despite this, many large scale pharmacies that dispense patient-specific formulations will continue to operate under state board of pharmacy oversight, and therefore will still only be required to meet USP Chapter <797> or other similar standards set by the state.

USP Chapter <797> is currently under revision. The USP Compounding Expert Committee should add a more robust set of quality requirements to Chapter <797> to address high volume compounding pharmacy practices. Though it may be challenging to develop metrics based on volume and scale of production, they are nonetheless needed – the risk of patient exposure to potentially unidentified safety problems at high volume compounding pharmacies demands it. More robust sterile compounding quality systems must be adopted for all outsourcing facilities as well as for large scale compounding pharmacies that remain under state oversight.

Current Good Manufacturing Practices

Compounding pharmacies that meet federal requirements under 503A are not required to establish drug efficacy and safety, obtain FDA approval, or comply with manufacturing and labeling standards. This assumes that compounded drugs are

prepared as result of (or in limited quantities in anticipation of) the receipt of a valid prescription for an identified patient.

In contrast, drug manufacturers prepare large amounts of identical medicines for wide distribution. The pharmaceutical industry, unlike pharmacies that compound medication, is subject to rigorous regulations – CGMPs[††] – that are enforced by the FDA and define and safeguard critical aspects employed in the manufacture of all drugs. CGMPs are minimum guidelines for practice in the manufacture, processing, packing or holding of drug products to be administered to humans or animals. Their purpose is to ensure that all pharmaceutical products are produced in such a manner as to ensure consistent quality and integrity. CGMPs establish the "what to do" not the specific elements of "how to do." In addition to the CGMPs, the FDA has published a Guidance for Industry document titled "Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice." That document reflects the Agency's current thinking about the specific application of CGMPs to sterile production.

Exhibit 1 compares traditional pharmacy compounding, large scale compounding, and manufacturing based on certain central attributes. Large scale outsourced compounding shares elements of both categories. But as the scale of production grows, so does the public health risk when quality errors occur, underscoring the need for robust quality system requirements.

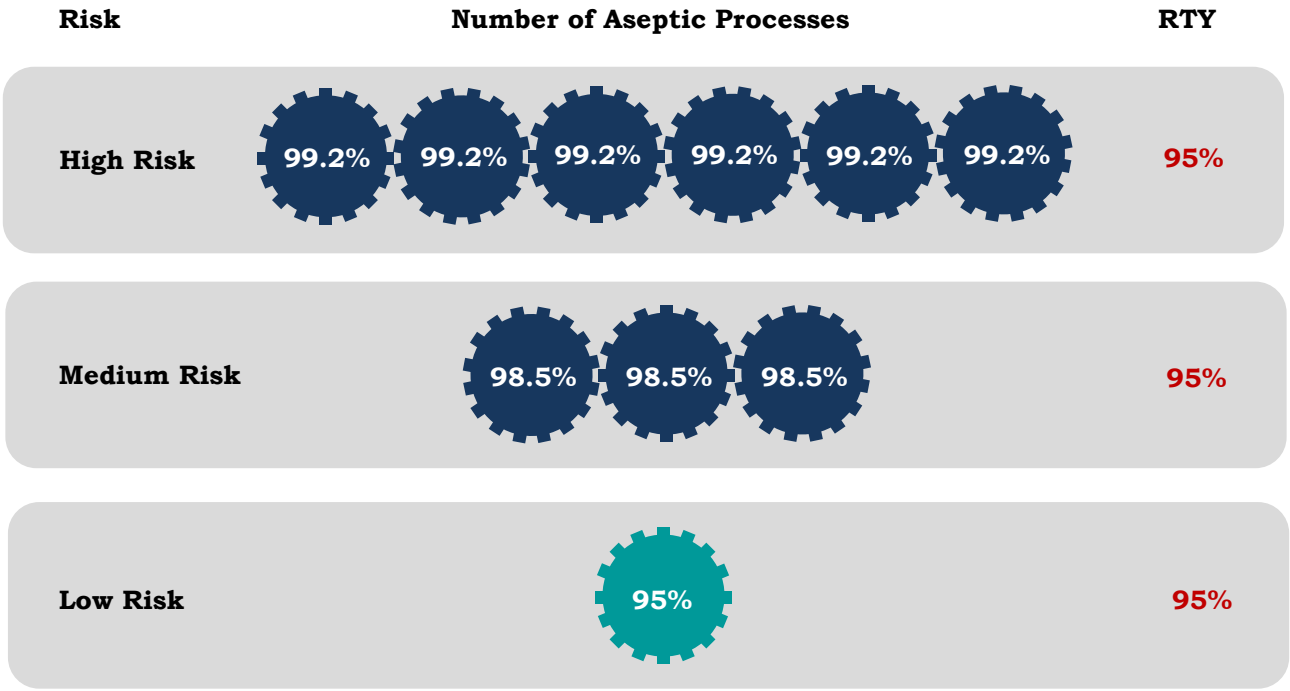
[††] 21 Code of Federal Regulations (CFRs) Part 210 and 211

Exhibit 1: Comparison of Traditional and Large Scale Compounding with Drug Manufacturing[35]

Attribute	Traditional Compounding	Large Scale Outsourced Compounding	Drug Manufacturing
Who is the Customer?	The patient upon receipt of a valid prescription from an authorized prescriber.	Hospitals, home infusion entities and prescribers.	Pharmacies, wholesalers and prescribers upon receipt of an order.
Therapeutic Paradigm	Matches drug to patient at the time of receipt of valid prescription.	Matches drug to customer requirement. Customers match drug to patient at the time of receipt of a valid prescription.	Matches patient to drug based on FDA approved indications.
Public Health Risk from Deviations in Quality System (Contamination or Ingredient Error)	Can be limited or significant: Typically only one patient is exposed when drug is prepared in response to a specific patient prescription. But large scale batch compounding, even when in anticipation of a prescription, increases the risk of exposure when errors occur.	Significant: Drug is produced in larger volumes than a traditional pharmacy but less than traditional manufacturing.	Significant: Drug is mass produced in response to market demand.
Main Regulatory Oversight	State Board of Pharmacy Rules and Regulations.	US Food and Drug Administration.	US Food and Drug Administration.
Published Quality System	USP General Chapter <797> Pharmaceutical Compounding-Sterile Preparations.	21 Code of Federal Regulations Parts 210 and 211 (CGMPs) and anticipated guidance.	21 Code of Federal Regulations Parts 210 and 211 (CGMPs).
Degree of Enforcement	Low to moderate: 21 states require compliance with the published quality system.	High: FDA is inspecting all establishments registering as outsourcing facilities.	High: All registered establishments can expect to be periodically inspected.

Strong quality systems are important for high-volume compounding, but also for higher risk compounding activities such as compounding sterile drugs from non-sterile bulk ingredients. The concept of Rolled Throughput Yield (RTY) is a helpful way to understand this. RTY is the probability that a single unit can pass through a series of process steps free of defects. The fewer the number of steps, the lower the potential for defects or points of failure. As the number of units in a batch increases or the number of steps in a process increases, the greater the chance of error, thus the precision of the process must improve. Exhibit 2 below represents three different processes and their relative risk based on the complexity of the relative compounding or manufacturing processes.

Exhibit 2: Rolled Throughput Yield (RTY). As a process becomes more complex, the accuracy and precision of each process step needs to improve



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In low and medium-risk level compounding as defined by USP Chapter <797>, compounders use FDA approved, commercially available, sterile release materials (e.g., medications and diluents), sterile components (e.g., tubing, syringes and needles) and packaging (e.g., empty IV bags, cassettes and elastomeric devices) as starting materials. During the aseptic processing of low and medium-risk level CSPs, the sterility of the materials, components and packaging is maintained by using proper aseptic technique — highly technical work that requires meticulous attention to detail.

In high-risk compounding as described in Chapter <797>, *nonsterile* materials, components or packaging and the final product are required to undergo some form of individual sterilization (filtration, steam, dry-heat or irradiation) prior to being compounded and subsequently released for use by patients. However, USP Chapter <797> only requires sterility testing according to USP Chapter <71> for batches of 25 or more or when the default beyond-use dates (BUDs) set based on risk-level in USP Chapter <797>, are exceeded. Otherwise compounders rely solely on careful aseptic processing to ensure sterility when manipulating commercially available, FDA approved sterile drugs and solutions. According to the FDA's guidance on drugs produced by aseptic processing:

> "Any manual or mechanical manipulation of the sterilized drug, components, containers or closures prior to or during aseptic assembly poses the risk of contamination and thus necessitates careful control. A terminally sterilized drug product, on the other hand, undergoes final sterilization in a sealed container, thus limiting the potential for error."‡‡ [36]

CGMP contains rigorous requirements for terminal sterilization, as discussed below. High-risk compounding involves numerous steps, each with a higher degree of complexity and therefore the precision, accuracy and effectiveness of each step must be more robust in order to ensure a predictable and acceptable outcome. Each individual process requires validation and control, as each can introduce error that could result in a contaminated medicine.

Exhibit 3 provides a comparison of selected quality system requirement attributes of CGMPs and USP General Chapter <797> that illustrates key differences between these standards.

‡‡ According to the FDA, nearly all drugs recalled due to nonsterility or lack of sterility assurance in the period spanning 1980-2000 were produced via aseptic processing

Exhibit 3: Comparison of Selected Quality System Requirement Attributes of CGMPs and USP General Chapter <797>

Quality System Requirement	CGMP	USP General Chapter <797>
Engineering Control Smoke Studies To Assess Proper Air Flow	Yes[§§]	Yes
Inbound Component ID Test	Yes	No[***]
Stability Testing of Formulation via Stability Indicating Method to Assign Expiration / Beyond Use Date	Yes	No[†††]
Sterility Testing as Release Test (USP General Chapter <71>)	Yes	Limited[‡‡‡]
Cleaning Validation	Yes	No
Continuous Particle Count	Yes	No
Use of Sterile Disinfectants	Yes	Only Isopropyl Alcohol
Environmental Monitoring During Production	Yes (Air, surface, personnel)	No
Frequency of Environmental Monitoring	Daily (Air, surface, personnel)	Air-twice yearly Surface-routinely Personnel-initially and 1-2 /year
Sterile Garb	Yes	Only sterile gloves
Reserve Samples	Yes	No

[§§] Critical to demonstrate that unidirectional first-air is delivered from the HEPA filter through the critical site and out of the device without refluxing or rollout into the critical site.
[***] There is no requirement for direct testing of bulk non-sterile active pharmaceutical ingredients (API). Certificate of Analysis from FDA registered supplier is acceptable if component is part of a FDA approved drug.
[†††] Peer-reviewed literature acceptable
[‡‡‡] Only w/extended dating & High-Risk batches > 25

Drug Quality and Security Act

In 2013, Congress passed the Drug Quality and Security Act, which was signed into law by President Obama on November 27. Title I of the Act addresses compounding and eliminates the unconstitutional provisions of Section 503A of the FDCA, effectively reinstating Section 503A as a safe harbor for traditional compounding practices. Though it exempts traditional compounders from complying with CGMPs, it does require compliance with general chapters on compounding (specifically Chapters <795> and <797> as well as other applicable USP chapters).[37]

The law also creates a new section of the FD&C Act - Section 503B - that recognizes pharmacies that engage in the manufacture and shipment of larger quantities of compounded drugs without prescriptions. These organizations, called outsourcing facilities, may receive exemptions from the drug approvals and labeling requirements of the FDCA if they voluntarily register with the Agency. Under the law such facilities are subject to the CGMPs, risk-based inspections and other standards to be defined by the agency with guidance from the FDA Pharmacy Compounding Advisory Committee.

As of this writing, over forty establishments have voluntarily registered with the FDA as Section 503B facilities. The FDA has yet to issue specific CGMP guidance for 503B facilities, but has indicated they will do so.[38] Lack of guidance creates a compliance challenge for 503B registrants.

In addition to the application of the CGMPs, additional guidance should be offered by the Agency similar to that in the FDA Aseptic Processing Guidance Document.

The section below describes key CGMP concepts that should be applied by 503B facilities, given their larger scale and non-patient specific operations, to ensure drug quality and patient safety. In addition, the appendix to this paper contains a crosswalk between the CGMPs and USP General Chapter <797> Pharmaceutical Compounding - Sterile Preparations, highlighting the detailed differences between these two quality standards.

Key CGMP Concepts for 503B Outsourcing Facilities

The central tenet articulated in the CGMP regulations and in robust modern-day quality systems is that quality must be built into the product and that testing alone cannot be relied upon to ensure quality. This Quality by Design[39] concept has been missing from the compounding regulatory schema that were intended for traditional pharmacy activities, not large scale compounding.

Through the lifecycle of a compounded sterile medication from receipt of raw materials to the point of administration, there are several key areas where the CGMPs provide a more robust way to ensure product quality and patient safety compared to USP General Chapter <797>, especially when large quantities of sterile products are made.

They are:

1. CGMP Mindset

CGMPs are a set of requirements from the U.S. FDA that serve as the cornerstone for assuring quality. This regulation is considered the premier quality model and has been adopted globally in the pharmaceutical industry. The "CGMP Mindset" is a term used to describe a desired attitude and vigilant adherence to detail that is harmonized with a set of actions and behaviors in the manufacturing process. This mindset must be fostered by organizational culture that embraces CGMP compliance, provides clear, understandable, consistent direction to all employees and decreases production errors and costs.

Another driver of the CGMP mindset is the dynamic tension that the FDA creates through their inspection process. The Agency holds organizational leadership accountable for complying with the CGMPs. A healthy respect for oversight has been absent in pharmacy compounding but is beginning to gain traction in state-based inspection models conducted by some State Boards of Pharmacy.

2. An Autonomous Quality Unit (QU)

The Quality Unit (QU) within a drug manufacturing operation is responsible for ensuring that the various operations associated with all systems are appropriately

planned, approved, conducted and monitored. The QU must review production records to ensure that no errors have occurred and has the authority to reject any product. In properly managed CGMP programs, manufacturing error and deviation rates are low. When mistakes are made or deviations occur, a robust quality system facilitates effective error tracing. Quality Units typically have no production responsibilities thereby insulating quality decision-makers from either financial or production pressures. Their decisions to accept or reject products are based instead upon a comprehensive set of predetermined specifications. This type of organizational check and balance is not an absolute expectation of USP General Chapter <797>. The Chapter states "when time and personnel availability so permit, compounding manipulations and procedures are separated from post compounding quality inspection and review before CSPs are dispensed."

3. Receipt and Release of Non-Sterile Ingredients, Materials, Supplies and Packaging

Confirming the identity and quality of starting materials is fundamental to building quality into the manufacturing process. Allowing ingredients, supplies and packaging that may not meet predefined specifications into production potentially introduces variability that may affect drug quality and patient safety. 503B entities need to establish a process to receive, evaluate and release non-sterile ingredients, materials, supplies and package components against predetermined acceptance specifications. This includes identity testing and assessing the degree of bioburden – the type and amount of microbial contamination present before sterilization. The microbiological quality of active pharmaceutical ingredients (APIs) and other components will have an impact on the effectiveness of sterilization methods.

USP General Chapter <797> does not identify specific requirements to determine this quality parameter stating "nonsterile active ingredients and added substances or excipients for CSPs should preferably be official General or NF articles. When nonofficial ingredients are used, they shall be accompanied by certificates of analysis from their suppliers to aid compounding personnel in judging the identity, quality and purity in relation to the intended use in a particular CSP."

Relying on a certificate of analysis for bulk APIs used in a larger-scale production process is not sufficient as API repackagers are not required to perform any qualitative assessment of these substances. USP General Chapters on compounding do not adequately address this regulatory gap. Analysis of bulk substances must be

performed to verify their identity and quality. Materials that fail to meet all pre-defined specifications must be rejected. Vendors of bulk APIs, other ingredients and components need to be qualified by the 503B entity and appropriately registered with the FDA. In addition, a system must be developed and maintained to track the lot numbers of non-sterile ingredients, materials, supplies and packaging components based on the date received ensuring they are used on a first in/first out basis.

4. Receipt and Release of Sterile Ingredients, Materials, Supplies and Packaging

Some 503B entities use only FDA approved, commercially available, sterile ingredients, materials, supplies and packaging in their operation, which have already undergone the necessary release testing by the original manufacturer. Despite the known quality of these items, 503B entities of this type must ensure the pedigree of their ingredients, materials, supplies and packaging. Mechanisms must be established to obtain certificates of analysis from the original manufacturers to confirm ingredient identity and the sterility. Predetermined specifications for all sterile ingredients, packaging and components must be developed and used to release these items. Should any of the material fail to meet these predetermined specifications, they must be rejected.

5. Buildings and Facilities and Environmental Monitoring

Any quality manufactured medication must be produced in a suitable environment that controls the risk of contamination and error. The CGMPs describe the critical elements of a suitable environment; but the specific criteria required are dependent on the organization's processes and must focus on the anticipated exposure of the materials, components and packaging to the immediate environment during each processing step. The buildings and facilities should be of suitable size for the activities performed and constructed of suitable materials and in a manner to facilitate cleaning, maintenance and proper operations. A well-designed, one-way flow of traffic for personnel, materials and equipment will reduce the risk of processing errors. All areas of a sterile production must be maintained in a strict and sanitary manner to prevent infestation, cross-contamination or damage to incoming / in-process materials and finished products.

Each of the defined areas of operation in an aseptic processing facility must be controlled for suitable air quality depending on the nature of the operation, equipment

and products. This involves ensuring microbiological and particle contaminants do not exceed set minimum levels, such as those in ISO[§§§] classifications for air cleanliness. Air quality should be measured during initial qualification studies performed under as-built, static conditions, but ongoing sampling must also occur during routine aseptic operations to ensure an environmental state of control. Frequent sampling under dynamic operating conditions facilitates the early identification of drift from a state of control and permits timely investigation and remedial action before product quality is compromised.

The environmental sampling program described in the current USP General Chapter <797> is considered inadequate for traditional pharmacy sterile compounding practices and is grossly inadequate for large scale compounding outsourced operations. The limited data collection required is insufficient to establish a microbial state of control, and it is certainly not able to detect any drift from that state of control in a timely fashion.

The quality of the environment and the interaction of human operators with the product during aseptic filling operations can affect the microbial quality of product being manufactured. The elements of comprehensive environmental monitoring program must include air sampling, surface sampling and personnel sampling (e.g., sterile gloves and other sterile garb) during each compounding session. 503B facilities must monitor both viable and non-viable particle counts during any aseptic processing procedures, which is the expectation under CGMPs. Environmental monitoring data also must be considered in conjunction of other quality data for product release.

Organizations must respond to data indicating an unfavorable trend away from the state of control. The FDA 4803 observations from the inspection of New England Compounding Center (NECC) showed that NECC was conducting more frequent environmental monitoring than what was required in Chapter <797>, but they failed to act upon that troubling data to eliminate the presence of unacceptable levels of microbial bioburden.[40]

6. Standard Operating Procedures (SOPs)

In order to ensure process uniformity within an organization and maintain it consistently, standard operating procedures are critical. Properly designed SOPs

[§§§] ISO (International Organization for Standardization) is a large developer of widely-used voluntary international standards.

clearly articulate the steps to ensure product consistency and quality. To develop effective SOPs that meet an organization's requirements, consensus must be achieved between production and quality control units and there must be an understanding of the activities necessary to consistently bring about the desired outcome. Though SOPs are required by Chapter <797>, compliance has been imperfect. The detailed process understanding needed to write SOPs is often lacking in organizations that function out of verbal tradition rather than from a well-defined and disciplined quality system. Unfortunately this paradigm is all too common within pharmacy compounding operations and it represents a failure of leadership. For example, only 48% of pharmacies surveyed in 2013 responded that they had a detailed written policy and procedure on all aspects of surface and viable air sampling which includes preparation of plates, labeling of plates according to the Environmental Sampling Plan, reading plates; documentation of result as well as procedure for sending them to contracted lab (in the event that is applicable).[41]

Subsequent to the development of detailed SOPs, is training of staff in the SOPs. Compounding staff must also be involved in the ongoing development and revision of SOPs. SOPs can and should be living documents that are refined continually as potential points of failure are identified. In a true quality system, the staff is encouraged to identify instances of "close calls" where mistakes were almost made. As issues and variances are identified, solutions are found and tested. When solutions are successful, the changes to the SOP are made permanent and the personnel are again retrained. This type of process and these expectations are self-evident in organizations that comply with CGMPs.

7. Personnel Training, Qualification and Monitoring

The personnel working in an aseptic processing area are the greatest source of both microbial and particulate contamination. Traditional pharmacy compounding is almost exclusively a manual process involving a significant human presence. This presence creates an increased risk in large scale compounding operations, as a greater number of products may be affected by contamination introduced by humans.

USP General Chapter <797> requires that "Compounding personnel are adequately skilled, educated, instructed and trained to correctly perform and document the following activities in their sterile compounding duties:

a. perform antiseptic hand cleansing and disinfection of non-sterile compounding surfaces;

b. select and appropriately don protective garb;

c. maintain or achieve sterility of CSPs in ISO Class 5 (see Table 1) PEC devices and protect personnel and compounding environments from contamination by radioactive, cytotoxic and chemotoxic drugs

d. identify, weigh and measure ingredients; and

e. manipulate sterile products aseptically, sterilize high-risk level CSPs and label and quality inspect CSPs."

These requirements for traditional compounding practices lack the qualitative and quantitative specificity and rigor needed for large scale compounding operations. For example, proper sterile garbing is critical to preventing microbial contamination, especially for entities that produce large scale batched products. USP General Chapter <797> describes the minimum garbing requirements but does not provide any qualitative guidance on this topic. In CGMP facilities, operators working in the aseptic processing area may not have any exposed skin and personnel in critical processing areas (e.g., ISO 5) must be vigilant about how they move and work within the critical filling zones.

Ideally, any aseptic processing procedures must minimize the presence of humans and maximize the use of automated equipment that has been validated to not add bioburden to the process. CGMP manufacturing operations have worked diligently to automate aseptic processing as much as possible, greatly reducing the risk of contamination. These commercial scale manufacturers employ automated sterilization / decontamination cycles to eliminate contamination from inbound ingredients, materials, supplies and packaging. USP General Chapter <797> relies on a manual decontamination and there is no requirement to validate the effectiveness of that decontamination.

Chapter <797> lacks a clear and comprehensive list of personnel training core elements. By contrast, the FDA Aseptic Processing Guidance used in the CGMP context states "Appropriate training should be conducted before an individual is permitted to enter the aseptic manufacturing area. Fundamental training topics should include aseptic technique, cleanroom behavior, microbiology, hygiene, gowning, patient safety hazards posed by a non-sterile drug product and the specific written procedures covering aseptic manufacturing area operations. After initial training, personnel should participate regularly in an ongoing training program. Supervisory personnel should routinely evaluate each operator's conformance to

written procedures during actual operations. Similarly, the quality control unit should provide regular oversight of adherence to established, written procedures and aseptic technique during manufacturing operations."

8. Stability Program and Expiration Dating

CGMPs require a program to determine the stability characteristics and shelf-life for each product. Chapter <797>, however, does not provide sufficient guidance for 503B facilities on robust methodology for establishing compounded drug stability and beyond-use dates (i.e. expiration dates). In fact, the Chapter permits individuals to use their professional judgment to assign this critical date. Chapter <797> states:

> "To ensure consistent practices in determining and assigning beyond-use dating (BUDs), the compounding facility should have written policies and procedures governing the determination of the BUDs for all compounded products. When attempting to predict a theoretical BUD, a compounded or an admixed preparation should be considered as a unique system that has physical and chemical properties and stability characteristics that differ from its components."
>
> "Compounding personnel who assign BUDs to CSPs when lacking direct chemical assay results must critically interpret and evaluate the most appropriate available information sources to determine a conservative and safe BUD."

503B facilities must have a more robust stability program that uses appropriate and validated methods and procedures to determine the stability characteristics of the manufactured product and to establish appropriate storage conditions and expiration dates. Stability is specific to the ingredients, materials and containers used in the manufacturing process and must be demonstrated through objective qualitative and quantitative data derived by validated scientific tests.

Some compounders use contract testing laboratories to conduct stability studies, but the methods and procedures used by contract testing laboratories have recently come under scrutiny. Several contract testing laboratories were issued 483s by the FDA calling into the question the veracity of the systems needed to support compounding practices when drug strength, sterility and endotoxin testing is required.[42]

Under a CGMP model, an organization's stability program is fully articulated within the organization's standard operating procedures. SOPs will describe the sample size, test intervals, storage conditions and test methods to determine stability, as well as the number of batches to evaluate each the formulations manufactured.

9. Cleaning and Disinfecting; Equipment Use Logs

Under CGMP regulations, facilities and equipment must be qualified, calibrated, cleaned and maintained to prevent contamination and mix-ups. Properly maintaining facilities and equipment is critical to ensure suitability and fitness of use. USP General Chapter <797> states the importance of cleaning and disinfecting, but it lacks specificity. Additional detail is necessary to describe proper cleaning and disinfection activities as well as how to inspect for adequacy.

As required under CGMP, only sterile chemical agents should be used to clean and disinfect facilities where sterile products are manufactured and these agents must be validated against the microbial bioburden of the facility to determine their effectiveness. USP General Chapter <797> does not require validated cleaning methods, but relies on limited environmental sampling alone to demonstrate that microbial bioburden is being appropriately controlled.

As a subset of cleaning and disinfecting procedures, all equipment (e.g., primary engineering controls, autoclaves, pumps, scales and other items that influence the quality of the product) must have operating SOP, maintenance, cleaning and use logs. Equipment must also be properly identified for tracking purposes – each product batch record must document the equipment used.

10. Process Validation

The effectiveness of any procedure used to sterilize or assure the quality / stability of a manufactured product must be established through process validation. Process validation is defined as the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product. Process validation involves a series of activities that take place over the lifecycle of the product and process.[43] Although Chapter <797> requires that "sterilization methods achieve sterility of CSPs while maintaining the labeled strength of active ingredients and the physical integrity of packaging," it lacks specific guidance in how to determine that this standard has been met.

Each 503B entity must establish validated methods to ensure quality and sterility within their processes and not merely rely on documentation provided by companies that sell bulk chemicals and other services to the compounding industry. Quality cannot be adequately assured merely by in-process and finished-product checks, which is the present-day model used under Chapter <797>.

11. Equipment Calibration, Validation and Preventative Maintenance System

A robust process validation system requires a clear understanding of how equipment will be used to achieve the quality, integrity, strength and sterility of each batch. Each piece of processing equipment used in batch manufacturing must be shown to be operating within its predetermined specifications.

A fundamental failure discovered in many compounding contamination events is the ineffective and improper use of equipment and procedures to terminally sterilize the CSPs. These critical quality assurance procedures were not validated and the sterility of the final product was not assured.

SOPs must define a calibration program that identifies the necessary steps to ensure the precision and accuracy of equipment. This includes all production and laboratory equipment that perform quantitative measurements, such as balances, thermometers, pipettes and temperature sensing devices in autoclaves or dry-heat ovens. Each piece of equipment or group of equipment requires a calibration log that specifies the frequency of calibration, points where calibration is checked and its acceptable operating range. Calibrated equipment should be tagged or labeled to show who performed the calibration, the date of the calibration and the scheduled date of the next calibration.

12. Area Clearance and Label Accountability System

This quality system element prevents product mix-ups and mislabeling. Area clearance applies to procurement, control and segregation of supplies and components and documentation throughout the manufacturing process. To reduce the risk of error, the manufacturing of a specific formulation occurs in a segregated area with assigned personnel working on only one formulation at a time. Strict control of all product labels must be in place to prevent errors in product labeling. This concept is not described in USP General Chapter <797>.

Area clearance and a label accountability program is a required element of the organization's SOPs. Whenever product is labeled, it must be performed in a cleared area free from label materials or documentation from other batches. An individual different from the person preparing the formulation should examine the labels to assure that the correct label is affixed to its corresponding product and that it properly identifies the product. This individual must also reconcile the quantity of labels issued vs. the quantity of labels used. Any discrepancies in the label reconciliation process must be fully investigated before the batch released. Any excess batch labels should be destroyed to prevent mislabeling.

Labels need to be stored in a manner to prevent mix-up and within a labeling area or room where labels are inspected prior to performing the labeling operation. An area clearance should be conducted to assure that all labels from the previous labeling operation are removed before bringing in the next batch to be labeled.

13. Change Control

Change control is another well-known CGMP concept that focuses on managing change to prevent unintended consequences. The system must manage the end-to-end change control process including initiating, reviewing, approving, distributing and storing the history of changes in procedures, processes, testing, formulations and other critical tasks that can impact product quality or regulatory filings. It captures the relevant information about the objective, nature and scope of change. A well-managed change control program can provide evidence of CGMP compliance to the FDA. A 503B entity would require a robust change control policy to ensure drug quality and patient safety. The CGMP regulations provide for change control primarily through the assigned responsibilities of the quality unit. Effective change control activities (e.g., quality planning and control of revisions to specifications, process parameters, procedures) are key components of any quality system.

14. Finished Product Release System

Required under CGMPs, a finished product release system assures that each batch of product conforms to predetermined specifications. Written procedures for the release of finished products must include an established sampling plan for testing the completed batch of finished product. Products failing to meet established specifications must be rejected. Products that can be reprocessed must again be sampled, tested and meet the established specifications before release. All products

need to be quarantined according to written procedures until released by the quality unit.

USP General Chapter <797> does not require a formal finished product release system. The standard does require sterility testing, but only when the default beyond-use dating of compounded medications made from sterile ingredients is exceeded; and for high-risk CSPs, such as those made from non-sterile bulk ingredients, and only for batches of larger than 25.

15. Operational Variances and Complaint System/Corrective and Preventive Action (CAPA)

A compliance system that tracks and trends feedback to improve the manufacturing process is a cornerstone of CGMP quality systems. A Corrective and Preventive Action (CAPA) system focuses on the systematic investigation of discrepancies (failures and/or deviations) in an attempt to prevent their reoccurrence (corrective action) as well as eliminate the cause of potential nonconforming product and other quality problems (preventive action).

To ensure that corrective and preventive actions are effective, failures must be systematically investigated and corrective actions must be standardized and integrated into the SOPs.

Performance feedback may be manufacturing process data on operational variances, or may come from customer complaints. A robust CAPA system must include a written SOP about how complaints are handled as well as a written record of each complaint. If the complaint requires an investigation, the investigation must be documented and made readily available in the CAPA record.

Summary

The uninterrupted availability of sterile formulations is an important part of delivering comprehensive pharmaceutical care to patients. The passage of the Drug Quality and Security Act provides the FDA, USP, State Boards of Pharmacy and various stakeholders with the opportunity to rethink the resources, standards and requirements necessary to ensure availability of manufactured/compounded drug

with suitable quality for patient safety. USP General Chapter <797> provides minimum practice and quality standards for traditional pharmacy sterile compounding activities. It does not describe nor was it intended to describe an appropriate quality system for large scale compounding activities. Producing large scale sterile batches requires a higher degree of discipline consistent with the approach described in the Current Good Manufacturing Practices. As Chapter <797> is revised, it should also address large scale sterile compounding activities and identify higher quality standards where necessary, even for compounders that ultimately link drugs to individual patient prescriptions. The description of key GMP concepts for large scale compounding listed in this paper may be useful in that effort. Regardless of the standard applied, a robust, detailed timely quality oversight process is required to drive meaningful compliance. The state boards of pharmacy are working to ensure that their inspectors are adequately skilled, educated and trained to enforce the requirements of Chapter <797>.[44] Large scale operations working within the provisions of Section 503B of the Drug Quality and Security Act must be regulated and inspected by the U.S. Food and Drug Administration. The FDA and State Boards of Pharmacy must work together to identify non-traditional compounding facilities that have not registered with the FDA as a 503B entity in order to ensure that they receive appropriate regulatory oversight. Only when all compounding facilities are held fully accountable to appropriate quality systems can drug quality and patient safety be assured.

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Attachment 8

AMENDED IN SENATE APRIL 6, 2015

SENATE BILL No. 619

Introduced by Senator Morrell
(Coauthor: Senator Stone)

February 27, 2015

~~An act to amend Section 14105.455 of the Welfare and Institutions Code, relating to Medi-Cal.~~ *An act to amend Section 4400 of, to add Section 4034 to, and to add Article 7.7 (commencing with Section 4129) to Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacy, and making an appropriation therefor.*

LEGISLATIVE COUNSEL'S DIGEST

SB 619, as amended, Morrell. ~~Medi-Cal.~~ *Pharmacy: outsourcing facilities: licensure.*

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists and pharmacy corporations in this state by the California State Board of Pharmacy. The law prohibits a pharmacy from compounding sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the board, and prohibits the board from issuing or renewing that license until the board has, among other things, reviewed a current copy of the pharmacy's procedures and policies for sterile compounding. Existing law provides that fees collected on behalf of the board are credited to the Pharmacy Board Contingent Fund, a continuously appropriated fund.

This bill would require the board to license an outsourcing facility, as defined, and would prohibit an outsourcing facility to be concurrently licensed with the board as a sterile compounding pharmacy at the same location. The bill would require an outsourcing facility to be licensed with the board before doing business within or into the state, and would

require an outsourcing facility to, among other things, notify the board of any disciplinary or other action taken by another state or the federal Food and Drug Administration within 10 days of the action. The bill would require the board to, among other things, inspect the location of an outsourcing facility to ensure that the outsourcing facility is in compliance with all laws and regulations before issuing or renewing an outsourcing facility's license. The bill would make a violation of any of these provisions or regulations adopted thereto punishable by a fine of up to $5,000 per occurrence. The bill would, on or after January 1, 2018, require the board to provide a report, as specified, to the Legislature regarding the regulation of nonresident outsourcing facilities. The bill would also authorize the board to collect a fee of $780 for the issuance and renewal of an outsourcing license and a fee of $715 for a temporary license, as specified. By increasing the amount of money deposited into a continuously appropriated fund, the bill would make an appropriation.

~~Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services, under which qualified low-income individuals receive health care services, including pharmacy services and drugs. Existing law requires pharmacy providers to submit their usual and customary charge when billing the Medi-Cal program for prescribed drugs.~~

~~This bill would make a technical, nonsubstantive change to that provision.~~

Vote: majority. Appropriation: ~~no~~ *yes*. Fiscal committee: ~~no~~ *yes*. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 4034 is added to the Business and Professions Code, to read:

4034. "Outsourcing facility" means a facility that meets all of the following:

(a) Is located within the United States of America at one address that is engaged in the compounding of sterile drugs and nonsterile drugs.

(b) Has registered as an outsourcing facility with the federal Food and Drug Administration under Section 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353b).

(c) Is doing business within or into California.

(d) Is licensed with the board as an outsourcing facility.

SEC. 2. Article 7.7 (commencing with Section 4129) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.7. Outsourcing Facilities

4129. (a) An entity licensed as an outsourcing facility with the federal Food and Drug Administration (FDA) shall be concurrently licensed with the board as an outsourcing facility if it compounds sterile medication or nonsterile medication for patients or practitioners within or into California. A product compounded by an outsourcing facility shall be distributed without a patient-specific prescription.

(b) A facility premises licensed with the board as a sterile compounding pharmacy shall not be concurrently licensed with the board as an outsourcing facility at the same location. A sterile compounding pharmacy compounds and dispenses pursuant to a prescription.

(c) The board may adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.

(d) The board shall review any formal requirements or guidance documents developed by the FDA regarding outsourcing facilities within 90 days after the release in order to determine whether revisions are necessary for any regulations.

(e) An outsourcing facility licensed by the board shall not perform the duties of a pharmacy, such as filling individual prescriptions for individual patients, within the outsourcing facility. Patient-specific compounding shall be performed only by a licensed pharmacy. An outsourcing facility shall not be located in the same licensed premises as a pharmacy.

4129.1. (a) An outsourcing facility that is licensed with the FDA and with an address in this state shall also be licensed by the board as an outsourcing facility before doing business within or into this state. The license shall be renewed annually and is not transferable.

(b) An outsourcing facility shall compound all sterile products and nonsterile products in compliance with current federal good manufacturing practices.

(c) An outsourcing facility license shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(d) An outsourcing facility license shall not be issued or renewed until the board does all of the following:

(1) Reviews a current copy of the outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.

(2) Is provided with copies of all inspection reports of the outsourcing facility's premises conducted in the prior 12 months.

(3) Receives a list of all sterile drugs and nonsterile drugs compounded by the outsourcing facility as reported to the FDA in the last 12 months.

(e) An outsourcing facility licensed pursuant to this section shall provide the board with all of the following:

(1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.

(2) Notice within 24 hours of any recall notice issued by the outsourcing facility.

(3) Notice within 24 hours after learning of adverse effects reported or potentially attributable to an outsourcing facility's products.

4129.2. (a) An outsourcing facility that is licensed with the FDA as an outsourcing facility and has an address outside of this state but in the United States of America is a nonresident outsourcing facility. A nonresident outsourcing facility shall not compound sterile drug products or nonsterile drug products for shipment into this state without an outsourcing license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A nonresident outsourcing facility shall compound all sterile products and nonsterile products in compliance with current federal good manufacturing practices.

(c) A license for a nonresident outsourcing facility shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident outsourcing facility shall reimburse

the board for all actual and necessary costs incurred by the board in conducting an inspection of the nonresident outsourcing facility at least once annually pursuant to subdivision (x) of Section 4400.

(d) A license for a nonresident outsourcing facility shall not be issued or renewed until the board:

(1) Reviews a current copy of the nonresident outsourcing facility's policies and procedures for sterile compounding and nonsterile compounding.

(2) Is provided with copies of all inspection reports of the nonresident outsourcing facility's premises conducted in the prior 12 months.

(3) Receives a list of all sterile drug products and nonsterile drug products compounded by the pharmacy as reported to the FDA within the prior 12 months.

(e) A nonresident outsourcing facility licensed pursuant to this section shall do all of the following:

(1) Provide the board with a copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.

(2) Provide the board notice within 24 hours of any recall notice issued by the nonresident outsourcing facility.

(3) Advise the board of any complaint it receives from a provider, pharmacy, or patient in California.

(f) A nonresident outsourcing facility shall provide to the board notice within 24 hours after learning of adverse effects reported or potentially attributable to a nonresident outsourcing facility's products.

4129.3. (a) On or before January 1, 2018, the board shall provide a report to the Legislature regarding the regulation of nonresident outsourcing facilities. The report shall be submitted to the Legislature in the manner required pursuant to Section 9795 of the Government Code. At a minimum, the report shall address all of the following:

(1) A detailed description of board activities related to the inspection and licensure of nonresident outsourcing facilities.

(2) Whether fee revenue collected pursuant to subdivision (x) of Section 4400 and travel cost reimbursements collected pursuant to subdivision (c) of Section 4129.2 provide revenue in an amount sufficient to support the board's activities related to the inspection and licensure of nonresident outsourcing facilities.

(3) The status of proposed changes to federal law that are under serious consideration and that would govern outsourcing facilities and compounding pharmacies, including, but not limited to, legislation pending before Congress, administrative rules, regulations, or orders under consideration by the FDA or other appropriate federal agency, and cases pending before the courts.

(4) If applicable, recommended modifications to the board's statutory duties related to nonresident outsourcing facilities as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.

(b) The requirement for submitting a report imposed under subdivision (a) is inoperative on January 1, 2022, pursuant to Section 10231.5 of the Government Code.

4129.4. (a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that an outsourcing facility compounding sterile drug products or nonsterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the outsourcing facility to immediately cease and desist compounding sterile drug products or nonsterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

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

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

(d) Failure to comply with a cease and desist order issued pursuant to this section is unprofessional conduct.

4129.5. Notwithstanding any other law, a violation of this article, or regulation adopted pursuant thereto, may subject the person or entity that committed the violation to a fine of up to five thousand dollars ($5,000) per occurrence pursuant to a citation issued by the board.

4129.6. For purposes of this article, "sterile compounded products" means compounded preparations for injection administration into the eye, or inhalation.

4129.8. The board, at its discretion, may issue a temporary license to an outsourcing facility when the ownership of the outsourcing facility is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary license fee shall be required as specified in subdivision (w) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon the earlier of personal service of the notice of termination upon the licenseholder or service by certified mail with return receipt requested at the licenseholder's address of record with the board. The temporary licenseholder shall not be deemed to have a vested property right or interest in the license for purposes of retaining a temporary license or for purposes of any disciplinary or license denial proceeding before the board.

4129.9. (a) An outsourcing facility licensed pursuant to Section 4129.1 or 4129.2 that issues a recall notice for a sterile drug or nonsterile drug compounded by the outsourcing facility, in addition to any other duties, shall contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 24 hours of the recall notice if both of the following apply:

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

(b) A recall notice issued pursuant to subdivision (a) shall be made as follows:

(1) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber and the prescriber shall ensure the patient is notified.

(2) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy and that pharmacy shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.

SEC. 3. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be four hundred dollars ($400) and may be increased to five hundred twenty dollars ($520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(c) The fee for the pharmacist application and examination shall be two hundred dollars ($200) and may be increased to two hundred sixty dollars ($260).

(d) The fee for regrading an examination shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars ($150) and may be increased to one hundred ninety-five dollars ($195).

(f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than

two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars ($125) and may be increased to one hundred sixty-five dollars ($165).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, or as a designated representative-3PL pursuant to Section 4053.1, shall be three hundred thirty dollars ($330) and may be decreased to no less than two hundred fifty-five dollars ($255).

(2) The fee for the annual renewal of a license as a designated representative or designated representative-3PL shall be one hundred ninety-five dollars ($195) and may be decreased to no less than one hundred fifty dollars ($150).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be three hundred thirty dollars ($330) and may be decreased to no less than two hundred fifty-five dollars ($255).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred ninety-five dollars ($195) and may be decreased to no less than one hundred fifty dollars ($150).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section

4161 shall be seven hundred eighty dollars ($780) and may be decreased to no less than six hundred dollars ($600).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(*l*) The fee for an intern pharmacist license shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars ($25) and may be increased to thirty dollars ($30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars ($400) and may be increased to five hundred twenty dollars ($520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325) for each license.

(r) The fee for the issuance of a pharmacy technician license shall be eighty dollars ($80) and may be increased to one hundred five dollars ($105). The fee for renewal of a pharmacy technician license shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred five dollars ($405) and may be increased to four hundred twenty-five dollars ($425). The annual renewal fee for a veterinary food-animal drug retailer license shall be two

hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(u) The fee for issuance or renewal of a nongovernmental sterile compounding pharmacy license shall be six hundred dollars ($600) and may be increased to seven hundred eighty dollars ($780). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715).

(v) The fee for the issuance or renewal of a nonresident sterile compounding pharmacy license shall be seven hundred eighty dollars ($780). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

~~(w) This section shall become operative on July 1, 2014.~~

(w) The fee for issuance or renewal of a nongovernmental outsourcing facility license shall be seven hundred eighty dollars ($780). The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars ($715).

(x) The fee for the issuance or renewal of a nonresident outsourcing facility license shall be seven hundred eighty dollars ($780). In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice

for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

~~SECTION 1. Section 14105.455 of the Welfare and Institutions Code is amended to read:~~

~~14105.455. (a) Pharmacy providers shall submit their usual and customary charge when billing the Medi-Cal program for prescribed drugs.~~

~~(b) "Usual and customary charge" means the lower of either of the following:~~

~~(1) The lowest price reimbursed to the pharmacy by other third-party payers in California, excluding Medi-Cal managed care plans and Medicare Part D prescription drug plans.~~

~~(2) The lowest price routinely offered to any segment of the general public.~~

~~(c) Donations or discounts provided to a charitable organization are not considered usual and customary charges.~~

~~(d) Pharmacy providers shall keep and maintain records of their usual and customary charges for a period of three years from the date the service was rendered.~~

~~(e) Payment to pharmacy providers shall be the lower of the pharmacy's usual and customary charge or the reimbursement rate pursuant to subdivision (b) of Section 14105.45.~~

~~(f) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, or make specific this section by means of a provider bulletin or notice, policy letter, or other similar instructions, without taking regulatory action.~~

O

Attachment 9

Contains Nonbinding Recommendations

Draft — Not for Implementation

#230

Guidance for Industry
Compounding Animal Drugs from Bulk Drug Substances

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact Eric Nelson (CVM) at 240-402-5642, or by e-mail at eric.nelson@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine (CVM)

May 2015

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Contains Nonbinding Recommendations

Draft — Not for Implementation

Guidance for Industry[1]

Compounding Animal Drugs from Bulk Drug Substances

This draft guidance, when finalized, represents the Food and Drug Administration's (FDA or Agency) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind 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 draft guidance using the contact information on the title page of this guidance.

I. INTRODUCTION AND SCOPE

This draft guidance sets forth the Food and Drug Administration's ("FDA") policy regarding compounding animal drugs from bulk drug substances[2] by state-licensed pharmacies, licensed veterinarians, and facilities that register with FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b). This guidance reflects FDA's current thinking regarding compounding animal drugs from bulk drug substances and describes the conditions under which FDA generally does not intend to take action for violations of the following sections of the FD&C Act: section 512 (21 U.S.C. 360b), section 501(a)(5) (21 U.S.C. 351(a)(5)), section 502(f)(1) (21 U.S.C. 352 (f)(1)), and, where specified, section 501(a)(2)(B) (21 U.S.C 351(a)(2)(B)), when a state-licensed pharmacy, licensed veterinarian, or an outsourcing facility[3] compounds animal drugs from bulk drug substances.

This draft guidance only addresses the compounding of animal drugs from bulk drug substances. It does not apply to the compounding of animal drugs from approved new animal or new human drugs. Such compounding can be conducted in accordance with the provisions of section 512(a)(4) and (5) of the FD&C Act (21 U.S.C. 360b(a)(4) and (5)) and 21 CFR part 530. In addition, this draft guidance does not address the compounding of drugs intended for use in

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[1] This draft guidance has been prepared by the Center for Veterinary Medicine (CVM) in consultation with the Center for Drug Evaluation and Research (CDER) and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

[2] FDA regulations define "bulk drug substance" as "any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances." 21 CFR 207.3(a)(4). "Active ingredient" is defined as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." 21 CFR 210.3(b)(7). Any component other than an active ingredient is an "inactive ingredient." See 21 CFR 210.3(b)(8). Inactive ingredients used in compounded drug products commonly include flavorings, dyes, diluents, or other excipients.

[3] "Outsourcing facility" refers to a facility that meets the definition of an outsourcing facility under section 503B(d)(4) of the FD&C Act. See draft guidance for industry *For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.* http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm434171.pdf.

humans, which is addressed in other guidances.[4] Further, the draft guidance does not address new animal drugs for investigational use. See 21 CFR part 511.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Regulatory Framework

To be legally marketed, new animal drugs must be approved under section 512 of the FD&C Act, conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc), or included on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species under section 572 of the FD&C Act (21 U.S.C. 360ccc-1). The FD&C Act does not generally distinguish between compounding and other methods of animal drug manufacturing. Animal drugs that are not approved or indexed are considered "unsafe" under section 512(a)(1) of the FD&C and adulterated under section 501(a)(5) of the FD&C Act.

Although sections 503A (21 U.S.C. 353a) and 503B of the FD&C Act provide certain statutory exemptions for compounded human drugs, these sections do not provide exemptions for drugs compounded for animal use. The compounding of an animal drug from bulk drug substances results in a new animal drug that must comply with the FD&C Act's approval/indexing requirements.[5] Further, all animal drugs are required to, among other things, be made in accordance with current good manufacturing practice (cGMP) requirements (section 501(a)(2)(B)) of the FD&C Act and 21 CFR parts 210 and 211) and have adequate directions for use (section 502(f)(1) of the FD&C Act).

Sections 512(a)(4) and (5) of the FD&C Act provide a limited exemption from certain requirements for compounded animal drugs made from already approved animal or human drugs. Such use is considered an extralabel use and the FD&C Act provides an exemption from the approval requirements and requirements of section 502(f) of the FD&C Act for extralabel uses that meet the conditions set out in the statute and FDA regulations at 21 CFR part 530. Among other things, these regulations specify that nothing in the regulations should be construed as permitting compounding animal drugs from bulk drug substances.

In 1996, FDA announced the availability of a CPG (section 608.400) entitled, "Compounding of Drugs for Use in Animals" (61 FR 34849, July 3, 1996), to provide guidance to FDA's field and headquarters staff with regard to the compounding of animal drugs by veterinarians and pharmacists. An updated CPG was made available on July 14, 2003 (68 FR 41591). This draft guidance supersedes that CPG, which has now been withdrawn.

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[4] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm166743.htm.

[5] See *Medical Center Pharmacy v. Mukasey*, 536 F.3d 383, 394 (5th Cir. 2008).

B. Compounding Animal Drugs

Numerous drugs are approved or indexed for use in animals. However, there are many different species of animals with different diseases and conditions for which there are no approved or indexed animal drugs. In some cases, approved human drugs can be used to treat an animal under the extralabel use provisions of the FD&C Act and FDA regulations (sections 512(a)(4) and (a)(5) of FD&C Act and 21 CFR part 530). For example, various chemotherapeutic drugs approved for humans are used to treat cancer in dogs and cats. FDA recognizes that there are circumstances where there is no drug available to treat a particular animal with a particular condition, because either no drug is approved for a specific animal species or no drug is available under the extralabel drug use provisions. In those limited circumstances, an animal drug compounded from bulk drug substances may be an appropriate treatment option.

However, FDA is concerned about the use of animal drugs compounded from bulk drug substances, especially when approved alternatives exist that can be used as labeled or in an extralabel manner consistent with the requirements of FDA's extralabel provisions. Compounded drugs have not undergone premarket FDA review of safety, effectiveness, or manufacturing quality. The unrestricted compounding of animal drugs from bulk drug substances has the potential to compromise food safety, place animals or humans at undue risk from unsafe or ineffective treatment, and undermine the incentives to develop and submit new animal drug applications to FDA containing data and information to demonstrate that the product is safe, effective, properly manufactured, and accurately labeled.

III. POLICY

As discussed above, animal drugs are generally subject to the adulteration, misbranding, and approval provisions of the FD&C Act. Generally, FDA does not intend to take action under sections 512(a), 501(a)(5), 502(f)(1) and 501(a)(2)(B) of the FD&C Act if a state-licensed pharmacy or a licensed veterinarian compounds animal drugs from bulk drug substances in accordance with the conditions described below, and the drug is not otherwise adulterated or misbranded. In addition, FDA generally does not intend to take action under sections 512(a), 501(a)(5), and 502(f)(1) of the FD&C Act if an outsourcing facility compounds animal drugs in accordance with all of the applicable conditions described below, and the drug is not otherwise adulterated or misbranded.

FDA's decision not to take enforcement action depends on its ability to evaluate whether the compounding of animal drugs is in accordance with the conditions below. Therefore, entities compounding animal drugs should keep adequate records to demonstrate that they are compounding such drugs in accordance with all of the applicable conditions described below.

The conditions referred to above are as follows:

A. If the animal drug is compounded in a state-licensed pharmacy:

1. The drug is compounded by or under the direct supervision of a licensed pharmacist.

2. The drug is dispensed after the receipt of a valid prescription from a veterinarian for an individually identified animal patient that comes directly from the prescribing veterinarian or from the patient's owner or caretaker to the compounding pharmacy. A drug may be compounded in advance of receipt of a prescription in a quantity that does not exceed the amount of drug product that the state-licensed pharmacy compounded pursuant to patient-specific prescriptions based on a history of receipt of such patient-specific prescriptions for that drug product over any consecutive 14-day period within the previous 6 months.

3. The drug is not intended for use in food-producing animals, and the prescription or documentation accompanying the prescription for the drug contains the statement "This patient is not a food-producing animal." For purposes of this draft guidance, all cattle, swine, chicken, turkey, sheep, goats, and non-ornamental fish are always considered to be food-producing animals regardless of whether the specific animal or food from the specific animal is intended to be introduced into the human or animal food chain (e.g., pet pot-bellied pigs and pet chicks are always considered to be food-producing animals). In addition, for purposes of this draft guidance, any other animal designated on the prescription or in documentation accompanying the prescription by the veterinarian as a food-producing animal, regardless of species, is considered to be a food-producing animal (e.g., rabbits, captive elk, captive deer).

4. If the drug contains a bulk drug substance that is a component of any marketed FDA-approved animal or human drug:

    a. there is a change between the compounded drug and the comparable FDA-approved animal or human drug made for an individually identified animal patient that produces a clinical difference for that individually identified animal patient, as determined by the veterinarian prescribing the compounded drug for his/her patient under his/her care, and
    b. the prescription or documentation accompanying the prescription contains a statement that the change between the compounded drug and the FDA-approved drug would produce a clinical difference for the individually identified animal patient. For example, the veterinarian could state that, "Compounded drug X would produce a clinical difference for the individually identified animal patient because the approved drug is too large a dose for the animal and cannot be divided or diluted into the small dose required."

5. If there is an FDA-approved animal or human drug with the same active ingredient(s), the pharmacy determines that the compounded drug cannot be made from the FDA-approved drug(s), and documents that determination.

6. The pharmacy receives from the veterinarian (either directly or through the patient's owner or caretaker), in addition to any other information required by state law, the following information, which can be documented on the prescription or documentation accompanying the prescription:

    a. Identification of the species of animal for which the drug is prescribed; and,
    b. The statement "There are no FDA-approved animal or human drugs that can be used as labeled or in an extralabel manner under section 512(a)(4) or (5) and 21 CFR part 530 to appropriately treat the disease, symptom, or condition for which this drug is being prescribed."

7. Any bulk drug substance used to compound the drug is manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360) (including a foreign establishment that is registered under section 510) and is accompanied by a valid certificate of analysis.

8. The drug is compounded in accordance with Chapters <795> and <797> of the United States Pharmacopeia and National Formulary (USP—NF)[6] (e.g., a sterile drug is compounded in an area with air quality that meets or exceeds ISO Class 5 standards (see USP—NF Chapter <797>, Table 1)).

9. The drug is not sold or transferred by an entity other than the entity that compounded such drug. For purposes of this condition, a sale or transfer does not include administration of a compounded drug by a veterinarian to a patient under his or her care.

10. Within 15 days of becoming aware of any product defect or serious adverse event associated with animal drugs it compounded from bulk drug substances, the pharmacy reports it to FDA on Form FDA 1932a. Form FDA 1932a can be downloaded at http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/animaldrugforms/ucm048817.pdf.

11. The label of any compounded drug indicates the species of the intended animal patient, the name of the animal patient and the name of the owner or caretaker of the animal patient.

B. If the animal drug is compounded by a licensed veterinarian:

1. The drug is compounded and dispensed by the veterinarian to treat an individually identified animal patient under his or her care.

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[6] Chapters <795> *Pharmaceutical Compounding—Nonsterile Preparations* and <797> *Pharmaceutical Compounding—Sterile Preparations* can be found in the combined *United States Pharmacopeia and National Formulary (USP-NF)*, available at http://www.usp.org.

2. The drug is not intended for use in food-producing animals as defined in section III.A.3 of this guidance.

3. If the drug contains a bulk drug substance that is a component of any marketed FDA-approved animal or human drug, there is a change between the compounded drug and the comparable FDA-approved animal or human drug made for an individually identified animal patient that produces a clinical difference for that individually identified animal patient, as determined by the veterinarian prescribing the compounded drug for his/her patient under his/her care.

4. There are no FDA-approved animal or human drugs that can be used as labeled or in an extralabel manner under sections 512(a)(4) and (5) of the FD&C Act and 21 CFR part 530 to appropriately treat the disease, symptom, or condition for which the drug is being prescribed.

5. The drug is compounded in accordance with USP—NF Chapters <795> and <797> (e.g., a sterile drug is compounded in an area with air quality that meets or exceeds ISO Class 5 standards (see USP—NF Chapter <797>, Table 1)).

6. Any bulk drug substance used is manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360) (including a foreign establishment that is registered under section 360(i)) and is accompanied by a valid certificate of analysis.

7. The drug is not sold or transferred by the veterinarian compounding the drug. For purposes of this condition, a sale or transfer does not include administration of a compounded drug by the veterinarian to a patient under his or her care, or the dispensing of an animal drug compounded by the veterinarian to the owner or caretaker of an animal under his or her care.

8. Within 15 days of becoming aware of any product defect or serious adverse event associated with animal drugs the veterinarian compounded from bulk drug substances, he or she reports it to FDA on Form FDA 1932a. Form FDA 1932a can be downloaded at http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/animaldrugforms/ucm048817.pdf.

9. The label of any compounded drug indicates the species of the intended animal patient, the name of the animal patient and the name of the owner or caretaker of the animal patient.

C. If the animal drug is compounded by an outsourcing facility:

1. The drugs are compounded only from bulk drug substances appearing on Appendix A of this draft guidance.

2. The drug is compounded by or under the direct supervision of a licensed pharmacist.

3. The drug is not intended for use in food-producing animals, as defined in Section III.A.3 of this guidance, and the prescription or order, or documentation accompanying the prescription or order, for the drug contains the statement, "This drug will not be dispensed for or administered to food-producing animals."

4. The drug is compounded in accordance with cGMP requirements.[7]

5. Any bulk drug substance used is manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360) (including a foreign establishment that is registered under section 360(i)) and is accompanied by a valid certificate of analysis.

6. The drug is not sold or transferred by an entity other than the outsourcing facility that compounded such drug. For purposes of this condition, a sale or transfer does not include administration of a compounded drug by a veterinarian to a patient under his or her care.

7. Within 15 days of becoming aware of any product defect or serious adverse event associated with animal drugs it compounded from bulk drug substances, the outsourcing facility reports it to FDA, on Form FDA1932a. Form FDA 1932a can be downloaded at http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/animaldrugforms/ucm048817.pdf.

8. All drugs compounded for animals by an outsourcing facility are included on the report required by section 503B of the FD&C Act to be submitted to the Food and Drug Administration each June and December identifying the drugs made by the outsourcing facility during the previous 6-month period, and providing the active ingredient(s); source of the active ingredient(s); NDC number of the source ingredient(s), if available; strength of the active ingredient(s) per unit; the dosage form and route of administration; the package description; the number of individual units produced; and the NDC number of the final product, if assigned.[8] The outsourcing facility should identify which reported drugs were intended for animal use.

9. The veterinarian's prescription or order states that the drug is intended to treat the species and condition(s) for which the substance is listed in Appendix A.

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[7] FDA intends to determine whether this condition is met by evaluating whether the facility complies with FDA regulations applicable to cGMPs for compounding of human drugs by outsourcing facilities. *See, e.g.*, draft guidance for industry, *Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act* (July 2014), at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM403496.pdf

[8] FDA has issued a draft guidance for industry, *Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act* (November 2014), which prescribes how human drug compounding facilities are to submit drug product reports to FDA. Available at http://www.fda.gov/downloads/Drugs/NewsEvents/UCM424303.pdf. Although this guidance addresses reporting of compounded human drug products, outsourcing facilities should follow the same procedure to electronically report the animal drug products they compounded.

10. The label of the drug includes the following:

    a. Active ingredient(s).
    b. Dosage form, strength, and flavoring, if any.
    c. Directions for use, as provided by the veterinarian prescribing or ordering the drug.
    d. Quantity or volume, whichever is appropriate.
    e. The statement "Not for resale."
    f. The statement "For use only in [fill in species and any associated condition or limitation listed in Appendix A]."
    g. The statement "Compounded by [name of outsourcing facility]."
    h. Lot or batch number of drug.
    i. Special storage and handling instructions.
    j. Date the drug was compounded.
    k. Beyond use date (BUD) of the drug.
    l. Name of veterinarian prescribing or ordering the drug.
    m. The address and phone number of the outsourcing facility that compounded the drug.
    n. Inactive ingredients.
    o. The statement "Adverse events associated with this compounded drug should be reported to FDA on a Form FDA 1932a."
    p. If the drug is compounded pursuant to a patient specific prescription, the species of the animal patient, name of the animal patient, and name of the owner or caretaker of the animal patient.

APPENDIX A[9]

LIST OF BULK DRUG SUBSTANCES THAT MAY BE USED BY AN OUTSOURCING FACILITY TO COMPOUND DRUGS FOR USE IN ANIMALS

This Appendix, when finalized, will contain a list of bulk drug substances that may be used by facilities registered under section 503B as outsourcing facilities to compound animal drugs pursuant to a prescription from a veterinarian for an individually identified animal patient or pursuant to an order from a licensed veterinarian for veterinarian office use, and in accordance with any specified limitations or conditions.

This list will be developed with public input; the process for nominating bulk drug substances for this list is described in the Federal Register notice soliciting nominations for such bulk drug substances. FDA intends to limit the bulk drug substances in this Appendix to address situations where all of the following criteria are met:

- there is no marketed approved, conditionally approved, or index listed animal drug that can be used as labeled to treat the condition;
- there is no marketed approved animal or human drug that could be used under section 512(a)(4) or (a)(5) and 21 CFR Part 530 (addressing extralabel use of approved animal and human drugs) to treat the condition;
- the drug cannot be compounded from an approved animal or human drug;
- immediate treatment with the compounded drug is necessary to avoid animal suffering or death; and
- FDA has not identified a significant safety concern specific to the use of the bulk drug substance to compound animal drugs (under the listed conditions and limitations).

FDA intends to review the nominated bulk drug substances on a rolling basis and to periodically update this Appendix.

LIST:

[9] To submit nominations for this list, refer to the Federal Register notice entitled, "List of Bulk Drug Substances That May be Used by an Outsourcing Facility to Compound Drugs for Use in Animals," published May 19, 2015. After the period for nominations closes, you may petition FDA under 21 CFR 10.30 to add or remove specific listings.