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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 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.**SUPPLEMENTARY INFORMATION:****Outline**

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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. 21 CFR 1317.65, 1317.70, and 1317.75. Pharmaceutical controlled substances collected by collectors may not be individually counted or inventoried. 21 CFR 1317.75. This rule also imposes various registration, security, and recordkeeping requirements.

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

authorized registrants that choose to administer mail-back programs may gain from the opportunity to distribute to consumers promotional, educational, or other informational materials with the mail-back packages.

DEA Registrant Disposal

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

Reverse Distributors

The DEA is providing regulations for entities that reverse distribute that are clear and consistent. Entities that reverse distribute are often the last registrant to possess controlled substances prior to destruction; however, the recordkeeping safeguards that exist when controlled substances are distributed between registrants are not present when these registrants destroy controlled substances. Because reverse distributors routinely acquire controlled substances for destruction from other registrants and may also be authorized as collectors, reverse distributors accumulate greater amounts of controlled substances that are destined for destruction in comparison to other registrants. The DEA is defining “reverse distribute;” revising the definition of “reverse distributor;” (21

CFR part 1300) outlining security (21 CFR part 1301), inventory, recordkeeping requirements, and other procedures that reverse distributors must follow to acquire controlled substances from registrants and to destroy such acquired substances. 21 CFR part 1304. The DEA also is clarifying that these security, inventory, and recordkeeping requirements apply to certain specified entities that reverse distribute but are not registered as reverse distributors. *See, e.g.*, 21 CFR 1304.11(e)(3) (“each person registered or authorized to reverse distribute”). The DEA believes that these regulations will help all registrants that reverse distribute comply with the CSA in a manner that decreases the risk of the diversion of controlled substances during the disposal process.

Return and Recall

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

Methods of Destruction

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

As explained above under “Compliance Date,” this final rule supersedes all existing MOAs and MOUs that registrants may have

pursuant to § 1307.21, including MOAs and MOUs pertinent to storage of controlled substances. The DEA retains in the new part 1317 the ability for practitioners to request assistance from the local Special Agent in Charge (SAC) regarding the disposal of controlled substances. 21 CFR 1317.05. Practitioners may request a new MOA or MOU pursuant to the new § 1317.05(a)(5).

C. Summary of the Changes in the Final Rule

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).

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).

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

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).

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

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 Terms⁶ (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

⁶Definitions 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 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 without 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 sewerage 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-Retrieveable Destruction Standard

[1] Issue: Forty commenters asked the DEA to outline performance standards and parameters for the "non-retrieveable" 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-retrieveable."

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-retrieveable

standard. The preamble of the NPRM states that sewerage (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 sewerage and landfill disposal in the text of the regulation. These commenters applauded the DEA for stating that sewerage 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 sewerage 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 sewerage 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 comingling 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 Conservation 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 2001⁷ 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

⁹The 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 comeingle 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 comeingled, 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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