Enforcement Committee Report

Randy Kajioka, PharmD, Chair, Professional Member
Shirley Wheat, Public Member
Tappan Zee, Public Member
Rosalyn Hackworth, Public Member
Amy Gutierrez, PharmD, Professional Member


a. FOR DISCUSSION: Implementation of California’s Electronic Pedigree Requirements for Prescription Medication

During the December Enforcement Committee meeting, the board heard multiple very important presentations for the implementation of California’s law. The meeting minutes and the webcast of the meeting provide details about the findings and discussions with the committee.

There was a two-hour presentation on a manufacturer to pharmacy track and trace pilot underway at the US Veterans Administration. This pilot involves the drug Humira, manufactured by Abbot Laboratories (in the future to be called AbVie), distributed through McKesson and data systems of Global Healthcare Exchange (GHX). There was considerable discussion on this pilot and the findings to date.

A presentation was also made by HP Labs on various types of technology in use worldwide for tracking and tracing, and a short demonstration of the ability of a cell phone to read bar codes, a system that could read the serialized numeric identifier on a product or case.

There was a presentation on RFID technology by Intelliflex, and a presentation by SmartRmeds on packaging technology that would facilitate aggregation and thus permit inference for downstream partners.

2. Elements for Possible Regulation Requirements to Permit Inference as Provided by California Business and Professions Code Section 4163.3.

ATTACHMENT 1

On July 23rd, the board released a request for comments from interested parties on the need for inference. The solicitation request was developed by Deputy Attorney General Room and released via a subscriber alert, seeking comments from industry to gather the information the board needs to review to assess the conditions upon which inference may,
or may not, be used. Provisions in Business and Professions Code section 4163.3 direct the board to balance the need for inference with the risks of permitting inference.

As explained by Deputy Attorney General Room, California statute requires every trade partner who owns the product to verify the product at the unit level. In the absence of action by the board to allow for inference, verification is required at the unit level. The board needs to have data to support what types of inference industry wants.

Initially 18 comments were received from interested parties by the initial due date of September 1. During the meeting on September 11th, the committee discussed the comments received and Mr. Room emphasized that while grateful for the comments, we do not have the specificity needed to develop regulations. As such, the board released a second request for information on inference after the September Enforcement Committee Meeting. One additional comment has been received.

These comments and the specific notices seeking comments are provided in Attachment 1. Since July, we have received comments from companies and associations representing:

- 9 manufacturers
- 5 wholesalers
- 3 pharmacies
- 1 standards setter
- 1 aggregate group of manufacturers, wholesalers, and pharmacies

At the December meeting, staff was asked to do a summary of the comments. These are the elements requested:

1. Identifying and contact information for the submitting person or entity.

2. A description of the submitting party’s interest in this subject, including the submitting party’s role, if any, in the supply chain (e.g., manufacturer, repackager, distributor, or dispenser) or other basis for interest (e.g., vendor, consultant, standards body) and a brief description of the person, company, or other entity responsible for the submission.

3. If the submitting party is a supply chain participant, a detailed description of the means and methodology, including hardware and software specifications, processes, and data carrier(s), that the submitting party has deployed or intends to deploy to “verify and validate the delivery and receipt of dangerous drugs against [electronic] pedigrees at the unit level,” including specification of the means and methodology for certification.

4. If the submitting party is seeking a regulatory allowance for inference, a specific request for same along with a detailed description of the particular circumstance(s) and/or those transaction(s) under which or pursuant to which there is a perceived need for inference. Define the requested inference(s) as specifically as possible, and where possible provide a limiting descriptor for such transaction(s) that could be used in regulatory language. In addition, provide as much data as possible regarding the factual circumstance(s) and/or transaction(s) in question, including the number and percentage of transaction(s) to which such an inference might apply, both with regard to the submitting party and in the supply chain as a whole, and any trading partners that will be involved in the inference(s).
5. If the submitting party is opposed to a regulatory allowance for inference, either generally or with regard to particular circumstances/transactions, a detailed description of same that as closely as possible meets the requirements of item 4. above.

6. The detailed reason(s) that such an inference is necessary and/or advantageous, and either decreases risk(s) of diversion or counterfeiting (or other risk(s) in the supply chain), holds risk(s) constant, or does not unacceptably increase such risk(s). Or the detailed reason(s) any inference(s) is/are unnecessary, disadvantageous, or unacceptably increase(s) risk(s).

7. Proposed SOPs that incorporate and explain the use of the inference(s), and describe the proposed process for statistical sampling to ensure the accuracy of pedigree information.

8. A proposal for the allocation of any liability that may be incurred due to use of inference.

Provided below is a general summary of the responses:

Elements Requested:

- **Means and Methodology** to be used for e-pedigree: the few responders who responded specifically to this specific element (few actually did) stated that a line of sight read would be deployed, and most specifically mentioned 2-D bar code. Hardware and software specifications were not provided, nor was information submitted regarding certification. Multiple responders identified use of GS1 standards, although not all did.

- **Inference**: All 19 responders stated that inference is necessary; no responder identified inference as unnecessary.

Cardinal states that based on one of its pilots: 70 percent of its cases were inferred upon receipt from the manufacturer, but 98 percent of the items were actually shipped by Cardinal as individual units – they explained it is because they tend to sell product in the smallest quantity possible (and instead do multiple deliveries each day).

The Generic Pharmaceutical Association states that 75-90 percent of all cases it ships to a wholesaler are opened by the wholesaler at some point after receipt of a case by the wholesaler (or 10 -15 percent of the cases its members ship to a wholesaler are NOT opened by the wholesaler and shipped directly as an unopened case to the buyer (a pharmacy or pharmacy distribution center).

- **Detailed reasons for Inference:**
  The board received multiple reasons from responders, most lacking quantification, of why they needed inference. Most stated that opening each container to do line of sight reads of each saleable unit of a product would greatly increase the opportunity to expose products to possible diversion, eliminate covert and overt packaging by the manufacturer to protect products, permit adulteration and greatly slow the receipt and delivery of pharmaceuticals to downstream partners and patients.
• **Standard Operating Procedures:**
  Generally, no standard operating procedures were provided. At least two responders indicated they could not develop operating procedures until they routinely start receiving serialized product. Cardinal does discuss procedures on how it would ensure a manufacturer’s product has been accurately aggregated.

• **Assessing Liability:**
  Again, the specific responses are not responsive to the level of information sought or hoped for by the board in seeking industry comments on liability. When a responder addressed this issue, manufacturers generally indicated that they could be responsible for the product until it reaches the wholesaler -- then it was no longer within their control. Wholesalers generally responded each trading partner must be responsible for the information the partner represents as true, and for consequences that result from false or erroneous information. Pharmacies stated liability has little usefulness in the area of inference, and pharmacies should not be held responsible for the mistakes of wholesalers and manufacturers. They requested implementation of the law first, then the board should address the issue of liability in response to the problems that arise.

During this board meeting, the board will have an opportunity to further discuss inference and elements of an inference regulation based on the information submitted. Staff will bring components to this meeting.

3. **Minutes of the Meeting Held December 4, 2012**

  Attachment 2 contains the minutes from the December 4, 2012, meeting.

b. **FOR DISCUSSION AND POSSIBLE ACTION:** US DEA Notice of Proposed Rulemaking Related to Disposal of Controlled Substances, and Opportunity for Comment

  ATTACHMENTS 3 and 4

One of the causes mentioned for the growing incidence of prescription drug abuse is lack of appropriate methods for patients and others to dispose of unwanted or no longer needed prescription medication, specifically controlled substances. Existing law offers few options for proper disposal of controlled drugs.

Since 2008, the board has been working with various agencies on drug take back programs. Currently, California has guidelines for how these programs should work. These guidelines were developed through the work of multiple agencies. However, they are only guidelines; there are no requirements specified in law or regulation for drug take back programs. **Attachment 3** contains the last *The Script* article the board prepared alerting our licensees
about the components the board expects to see in drug take back programs particularly in pharmacies.

Part of the complexity to adopting rules or specific requirements for drug take back programs was waiting for the federal Drug Enforcement Administration to determine how federal law should be amended to permit the return and destruction of unwanted controlled substances. In mid December 2012, after a number of years of waiting, the federal Drug Enforcement Administration released the long-awaited proposal for drug take back and disposal of controlled substances. **Attachment 4** contains this proposal, and the background and rationale for its provisions. Comments are due February 19.

Given the high demand and street value of controlled substances, the growing number of prescription drug caused deaths, when coupled with the fact that the board regulates pharmacies and reverse distributors who would be permitted to establish prescription drug take back programs, staff believe that the board should provide comments regarding the provisions. During this meeting, staff will seek the board’s authorization to work with President Weisser on comments to this proposal based on California's current guidelines for disposal of unwanted pharmaceuticals.

c. **FOR INFORMATION: Future Meeting Dates Proposed for the Enforcement Committee**
   - March 14, 2013 – Southern California
   - June 4, 2013
   - September 10, 2013
   - December 3, 2013

d. **FOR INFORMATION: Enforcement Statistics**

   Attachment 6 will be made available at the board meeting.

e. **FOR INFORMATION: First Quarterly Report on the Committee’s Goals**
Comments re: Inference
Last call for comments on Inference:

The Board continues to seek detailed information from members of the pharmaceutical supply chain to build the elements for a possible regulation dealing with inference. These comments would be appreciated and most useful if received before the December 4th Enforcement Committee Meeting. To facilitate the expectations of the Board in requesting these comments, we are re-releasing the information provided below. Thank you and see you on December 4th.

At its September 11, 2012 meeting, the Enforcement Committee of the Board considered the submissions received in response to the "Opportunity to Submit Information Necessary to Possible Board Rulemaking On Inference and Certification of Individual Package Units Drug Pedigree Law" released/published July 23, 2012. A copy of the “Opportunity” document describing the parameters for submissions in support of a possible rulemaking is attached.

That request for information set a deadline of September 1, 2012 for such submissions. However, the discussion at the September 11, 2012 Enforcement Committee meeting made clear that greater specificity and greater participation by all segments of the supply chain is desirable to support a possible rulemaking.

Accordingly, the Board is extending the deadline for submissions in response to the "Opportunity to Submit Information Necessary to Possible Board Rulemaking On Inference and Certification of Individual Package Units – Drug Pedigree Law" to a new deadline date of **November 30, 2012**. Once again, please submit in hardcopy.

Any new or supplemental submission should pay careful attention to the descriptions of the information that would be helpful to the Board that are given in the attached.

In particular, submitting parties are directed to items 3, 4, and 6 in the attached, and to the detailed information outlined in those items.

The intended sequence is that any submitting party:

(a) identify the means and methodology, in as much detail as possible, that it will deploy to meet the pedigree requirements, including certification requirement(s);

(b) where an inference is requested, identify as specifically as possible the particular transaction(s) to which the inference is to be applied (e.g., a wholesaler requests an "inbound inference" that, upon receipt of sealed cases from a known and demonstrably reliable manufacturer trading partner, that are homogenous both in product/SKU and lot number, it be allowed to "infer" that the case identifier is accurately linked to the individual package serial numbers, so that it can receive and certify receipt of the individual items based on that parent-child relationship without opening the sealed case prior to accomplishing "receipt" of product)
and suggest regulatory language that can accurately and specifically describe the limited transaction(s) in question;

(c) supply data on how many units and/or percentage of the business that would be subject to this transactional inference, thereby helping to define potential increase in risk/decrease in unit-level tracking that is inherent in this inference; and

(d) describe and support with as much data as possible the perceived benefit of this inference, whether in terms of how much additional cost would be incurred and/or is being avoided by use of this inference, what is the increased risk that is avoided by not having these cases opened, or in other terms.

**Opportunity to Submit Information Necessary to Possible Board Rulemaking On Inference and Certification of Individual Package Units – Drug Pedigree Law**

Pursuant to Business and Professions Code section 4163.3 (see below), the Board of Pharmacy is confirming its willingness to receive information by written submission regarding supply chain participants’ ability to use or rely on inference(s) as to the contents of aggregate containers for purposes of certification of delivery or receipt of individual package units of dangerous drugs, as required by the California electronic pedigree law. (Bus. & Prof. Code, &sect;§ 4034, 4163 et seq.)

To be considered for purposes of developing a possible future Board rulemaking on this subject, we request that all written submissions contain at minimum the information outlined below, and be received by mail or personal delivery at the Board offices by no later than September 1, 2012.

**§ 4163.3. Legislative intent; maintaining integrity of pedigree system; use of inference**

(a) It is the intent of the Legislature that participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.

(b) To meet this goal, and to facilitate efficiency and safety in the distribution chain, the board shall, by regulation, define the circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.

(c) Manufacturers, wholesalers, and pharmacies opting to employ the use of inference as authorized by the board to comply with the pedigree requirements shall document their processes and procedures in their standard operating procedures (SOPs) and shall make those SOPs available for board review.

(d) SOPs regarding inference shall include a process for statistically sampling the accuracy of information sent with inbound product.
Liability associated with accuracy of product information and pedigree using inference shall be specified in the board's regulations.

Section 4163.3 affirms the base requirement of the California pedigree law that all participants in the dangerous drug supply chain will “verify and validate the delivery and receipt of dangerous drugs against [electronic] pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.” Accordingly, the subsequent direction to the Board, to issue regulations defining circumstances under which it would be permissible to substitute an inference as to the contents of an aggregate container for verification and validation of that container’s individual unit contents, is similarly limited. Any allowance for inference(s) cannot unacceptably increase supply chain risk(s).

To meet this standard, the Board must base any regulation permitting inference on supply chain information and data demonstrating that use or reliance on inference in specified settings and/or under particular transactional circumstances will not unacceptably increase supply chain risk(s).

At its public meetings, the Board has repeatedly stated its willingness to receive this information. This notification confirms that the Board will accept written submissions from interested parties, in support of or in opposition to permitting inference under specified circumstances, to develop the record necessary to any Board rulemaking on the subject of inference and/or certification.

Necessary Information in Submissions

Any submission by an interested party should include at least the following:

1. Identifying and contact information for the submitting person or entity.

2. A description of the submitting party’s interest in this subject, including the submitting party’s role, if any, in the supply chain (e.g., manufacturer, repackager, distributor, or dispenser) or other basis for interest (e.g., vendor, consultant, standards body) and a brief description of the person, company, or other entity responsible for the submission.

3. If the submitting party is a supply chain participant, a detailed description of the means and methodology, including hardware and software specifications, processes, and data carrier(s), that the submitting party has deployed or intends to deploy to “verify and validate the delivery and receipt of dangerous drugs against [electronic] pedigrees at the unit level,” including specification of the means and methodology for certification.

4. If the submitting party is seeking a regulatory allowance for inference, a specific request for same along with a detailed description of the particular circumstance(s) and/or those transaction(s) under which or pursuant to which there is a perceived need for inference. Define the requested inference(s) as specifically as possible, and where possible provide a limiting descriptor for such transaction(s) that could be used in regulatory language. In addition, provide as much data as possible regarding the factual circumstance(s) and/or transaction(s) in question, including the number and percentage of transaction(s) to which such an inference might apply, both with regard to the submitting party and in the supply chain as a whole, and any trading partners that will be involved in the inference(s).
5. If the submitting party is opposed to a regulatory allowance for inference, either generally or with regard to particular circumstances/transactions, a detailed description of same that as closely as possible meets the requirements of item 4., above.

6. The detailed reason(s) that such an inference is necessary and/or advantageous, and either decreases risk(s) of diversion or counterfeiting (or other risk(s) in the supply chain), holds risk(s) constant, or does not unacceptably increase such risk(s). Or the detailed reason(s) any inference(s) is/are unnecessary, disadvantageous, or unacceptably increase(s) risk(s).

7. Proposed SOPs that incorporate and explain the use of the inference(s), and describe the proposed process for statistical sampling to ensure the accuracy of pedigree information.

8. A proposal for the allocation of any liability that may be incurred due to use of inference.

Where and When to Submit

All written submissions should be mailed or delivered to Executive Officer Virginia Herold, Board of Pharmacy, 1625 N. Market Blvd., Suite N219, Sacramento, CA 95834. Materials received on or before September 1, 2012 will be considered by the Board in developing a possible rulemaking. These submissions will be considered at the Enforcement Committee meeting on September 11, 2012, and/or at the full Board meeting on October 25-26, 2012.

1 The Board expects that submissions will be made primarily by individual persons, companies, or other entities that are themselves involved in the supply chain and able to supply information and data specific to their own operations regarding the potential benefits and risks of inference(s). Although the Board also welcomes input from associations and other groups, it is most interested in the kind of detail that individual submissions can better provide. The Board is also interested in hearing from vendors, consultants, standards bodies, hardware and software providers, and other experts in the field, regarding their viewpoints on and experience(s) with the use of inference(s).

https://www.dca.ca.gov/webapps/pharmacy/subscribe.php
Opportunity to Submit Information Necessary to Possible Board Rulemaking On Inference and Certification of Individual Package Units – Drug Pedigree Law

Pursuant to Business and Professions Code section 4163.3 (see below), the Board of Pharmacy is confirming its willingness to receive information by written submission regarding supply chain participants’ ability to use or rely on inference(s) as to the contents of aggregate containers for purposes of certification of delivery or receipt of individual package units of dangerous drugs, as required by the California electronic pedigree law. (Bus. & Prof. Code, §§ 4034, 4163 et seq.)

To be considered for purposes of developing a possible future Board rulemaking on this subject, we request that all written submissions contain at minimum the information outlined below, and be received by mail or personal delivery at the Board offices by no later than September 1, 2012.

§ 4163.3. Legislative intent; maintaining integrity of pedigree system; use of inference
(a) It is the intent of the Legislature that participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.
(b) To meet this goal, and to facilitate efficiency and safety in the distribution chain, the board shall, by regulation, define the circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.
(c) Manufacturers, wholesalers, and pharmacies opting to employ the use of inference as authorized by the board to comply with the pedigree requirements shall document their processes and procedures in their standard operating procedures (SOPs) and shall make those SOPs available for board review.
(d) SOPs regarding inference shall include a process for statistically sampling the accuracy of information sent with inbound product.
(e) Liability associated with accuracy of product information and pedigree using inference shall be specified in the board's regulations.

Section 4163.3 affirms the base requirement of the California pedigree law that all participants in the dangerous drug supply chain will “verify and validate the delivery and receipt of dangerous drugs against [electronic] pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.” Accordingly, the subsequent direction to the Board, to issue regulations defining circumstances under which it would be permissible to substitute an inference as to the contents of an aggregate container for verification and validation of that container’s individual unit contents, is similarly limited. Any allowance for inference(s) cannot unacceptably increase supply chain risk(s).

To meet this standard, the Board must base any regulation permitting inference on supply chain information and data demonstrating that use or reliance on inference in specified settings and/or under particular transactional circumstances will not unacceptably increase supply chain risk(s).
At its public meetings, the Board has repeatedly stated its willingness to receive this information. This notification confirms that the Board will accept written submissions from interested parties, in support of or in opposition to permitting inference under specified circumstances, to develop the record necessary to any Board rulemaking on the subject of inference and/or certification.

Necessary Information in Submissions

Any submission by an interested party¹ should include at least the following:

1. Identifying and contact information for the submitting person or entity.

2. A description of the submitting party’s interest in this subject, including the submitting party’s role, if any, in the supply chain (e.g., manufacturer, repackager, distributor, or dispenser) or other basis for interest (e.g., vendor, consultant, standards body) and a brief description of the person, company, or other entity responsible for the submission.

3. If the submitting party is a supply chain participant, a detailed description of the means and methodology, including hardware and software specifications, processes, and data carrier(s), that the submitting party has deployed or intends to deploy to “verify and validate the delivery and receipt of dangerous drugs against [electronic] pedigrees at the unit level,” including specification of the means and methodology for certification.

4. If the submitting party is seeking a regulatory allowance for inference, a specific request for same along with a detailed description of the particular circumstance(s) and/or those transaction(s) under which or pursuant to which there is a perceived need for inference. Define the requested inference(s) as specifically as possible, and where possible provide a limiting descriptor for such transaction(s) that could be used in regulatory language. In addition, provide as much data as possible regarding the factual circumstance(s) and/or transaction(s) in question, including the number and percentage of transaction(s) to which such an inference might apply, both with regard to the submitting party and in the supply chain as a whole, and any trading partners that will be involved in the inference(s).

5. If the submitting party is opposed to a regulatory allowance for inference, either generally or with regard to particular circumstances/transactions, a detailed description of same that as closely as possible meets the requirements of item 4., above.

6. The detailed reason(s) that such an inference is necessary and/or advantageous, and either decreases risk(s) of diversion or counterfeiting (or other risk(s) in the supply chain), holds risk(s) constant, or does not unacceptably increase such risk(s). Or the detailed reason(s) any inference(s) is/are unnecessary, disadvantageous, or unacceptably increase(s) risk(s).

¹ The Board expects that submissions will be made primarily by individual persons, companies, or other entities that are themselves involved in the supply chain and able to supply information and data specific to their own operations regarding the potential benefits and risks of inference(s). Although the Board also welcomes input from associations and other groups, it is most interested in the kind of detail that individual submissions can better provide. The Board is also interested in hearing from vendors, consultants, standards bodies, hardware and software providers, and other experts in the field, regarding their viewpoints on and experience(s) with the use of inference(s).
7. Proposed SOPs that incorporate and explain the use of the inference(s), and describe the proposed process for statistical sampling to ensure the accuracy of pedigree information.

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August 31, 2012
Executive Officer Virginia Herold
Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

RE: Opportunity to Submit Information Necessary to Possible Board Rulemaking On Inference and Certification of Individual Package Units – Drug Pedigree Law; ISSUE DATE: July 23, 2012

Dear Madam:

Amgen discovers, develops, manufactures, and delivers innovative human therapeutics. A biotechnology pioneer since 1980 headquartered in Thousand Oaks, CA, Amgen was one of the first companies to realize the new science’s promise by bringing safe, effective medicines from lab to manufacturing plant to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease, and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people’s lives. (For more information, visit www.amgen.com)

Amgen is pleased to be afforded the opportunity to provide comments on the Opportunity to Submit Information Necessary to Possible Board Rulemaking on Inference and Certification of Individual Package Units – Drug Pedigree Law. Amgen endorses the Board’s commitment to ensuring the safety of patients and the drug supply. Amgen is committing major resources to the implementation of its serialization projects in order to play its part in building an interoperable system. While Amgen has not finalized all of the details of its serialization system, and many aspects of this system are proprietary and confidential, it offers the following comments:

- Aggregation and Inference are critical operational and inventory management elements in making serialization and interoperability a more cost-effective and impactful method to protect patients and the drug supply.
- As part of good manufacturing practices, Amgen actively takes precautions to ensure quality is maintained throughout the production and distribution of goods to our wholesalers and other authorized distributors. For example, our quality management system requires that equipment, information systems, and processes are tested and validated prior to their use for production. Automated verification is also built into the packaging process to confirm correct information is printed on the products and their secondary packaging. Sampling during production is performed to further verify that quality is sustained. Applicable staff are trained on and use standardized procedures where appropriate as part of this quality management system. We intend to use the quality management system to ensure serialization and aggregation attributes, like any other quality attributes, meet Amgen standards and comply with all applicable laws and regulations.
- Amgen recommends that regulators provide guidelines for the use of inference. However, these guidelines should not specify how an aggregation and inference process should be performed or what the acceptance criteria should be. Manufacturers and other supply chain members should be
allowed to determine how to perform quality checks and establish the appropriate criteria, in line with their existing quality practices.

Again, Amgen wishes to thank the Board of Pharmacy for receiving its comments on the important issue of inference.

Amgen is committed to work proactively with the Board of Pharmacy to enhance regulatory and compliance systems to secure the drug supply chain. We share the Board’s concern about the public health impact caused by diversion and counterfeiting and strive to meet our corporate mission of serving every patient, every time.

Sincerely yours,

Lewis T. Kontnik
Director, Brand Protection
August 24, 2012

California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento CA 95834

Dear Members of the California Board of Pharmacy,

Apotex welcomes the opportunity to comment on the Board’s request for information regarding the pharmaceutical supply chain’s use of inference in carrying out the requirements of California’s electronic pedigree law. Apotex believes an end-point model would most efficiently achieve the public policy objectives of an electronic track and trace system at the state and/or federal level, and that, under such a model, aggregation and inference would not be necessary. Unlike an end point system, however, California’s law requires the tracking and tracing at the unit of sale level. Under any such system requiring confirmation of serial numbers at each movement through the supply chain, it is essential, for efficiency and cost containment purposes, that inference be allowed. Requiring the scan of each unit will increase the cost of pharmaceuticals and introduce significant disruptions in product movement through the supply chain with potentially adverse impact on the public’s timely access to affordable medicine. Accordingly, Apotex strongly encourages the California Board of Pharmacy to permit the use of inference under its electronic pedigree law as currently proposed.

Apotex would also like to take the opportunity these comments provide to express its concerns about the ability of the entire supply chain to meet the deadlines for compliance with California’s electronic track and trace law. While Apotex will be ready to meet these deadlines, our ongoing preparations leave us with the view that the complexity of the task continues to pose significant challenges for compliance of the supply chain as a whole under the proposed deadlines. For example, there are some concerns that the effort required to establish e-pedigree connections to our customers will not occur in a timely manner to support the established deadlines. It is feared that, the time each connection is expected to take in conjunction with the anticipated last minute rush will leave some customers unable to conduct business under the new law. The sheer number of connections required in the greater supply chain is also a concern. Apotex therefore urges the Board to keep an open mind on the compliance timeline question as the Board continues to participate in the continuing discussions at the federal level about establishing a national system. Should such a system fail to be enacted this year, Apotex would similarly urge the Board to keep an open mind on the compliance timeline in any such discussions the supply chain should raise with the state.
1. Apotex Corporation (Corp) is the US Company that markets the products of Apotex Inc., the largest Canadian-owned manufacturer of prescription drugs. Apotex Inc. sells a portfolio of approximately 300 affordable medicines to 115 countries around the world. Through its sales and marketing offices in Weston, Florida, and operations center in Indianapolis, Indiana, Apotex Corp. is committed to providing safe and affordable generic medicines to the US market.

2. Apotex plans to address e-pedigree requirements via serialization of unit of sale, inner pack, case and pallet utilizing GS1 standard 2D Data matrix barcodes. Given that barcoding is a line of site technology, we plan to utilize inference to allow for aggregation of child serial numbers to parent serial numbers for inner pack, shipper case and pallet aggregation. Aggregation to higher pack formats would be electronically tracked and included in Advanced Ship Notice (ASN) and some Electronic Product Code Information Service (EPCIS) communications.

Apotex has partnered with industry leading solution providers to ensure appropriate, validated solutions are implemented to support the serialization and aggregation of our product, as well as the internal storage, tracking of serialized product to our customers down in the supply chain using Drug Pedigree Messaging Standard (DPMS) and EPCIS and to allow for tracing from our Third Party Suppliers.

Apotex is requesting a regulatory allowance for the use of inference from the Board. As described in our response to question 3, Apotex intends to use inference to aggregate child serial numbers for inner pack, shipper case, and pallet aggregation. Although we are not submitting regulatory language at this time, Apotex fully intends to work actively with all stakeholders on efforts to develop such language.

4. As described in the opening paragraph of these comments, Apotex is strongly in favor of the use of inference in any track and trace system that imposes unit-level tracking requirements. Inference is required to preserve efficiencies in the US Pharmaceutical Supply Chain while minimizing additional operational costs we expect to incur if inference is not permitted.

5. Inference is a mechanism that enables healthcare entities to conduct business in a manner that leverages best practices to meet the challenges associated with the distribution of serialized products. Inference enables the results of transactions conducted at the parent (case) packaging level to be automatically cascaded to all of the contents of that level automatically, without having to scan each individual unit packed within the parent. Apotex feels that inference is a part of the solution. Combining inference with validated serialization systems and revised Standard Operating Procedures would balance the need for efficiency with the underlying value of security.
If inference and aggregation are not accepted in practice, the US pharmaceutical supply chain would be forced into unit level verification at every exchange of ownership. This would, no doubt, lead to a severe and unacceptable increase in effort to process drugs through the supply chain. Subsequently, it would dramatically increase the potential for delays in patients obtaining much needed medicines. Additionally, in order to attempt to maintain throughput, many of our downstream partners would be forced to expend a significant amount of energy, time and resources, in sum, leading to an increase in costs which would need to be passed to the end consumer.

Since 2D barcoding has become the data carrier of choice for serialized products, line of sight will be required. If inference is not an accepted practice, it would be very costly to the supply chain and ultimately to the consumer. Having to manually scan each unit of sale shipped and received would result in a dramatic increase in man hours and would expect to lead to supply interruptions caused by the added delays at all levels of the supply chain.

It is our opinion that the acceptance of inference adds no additional risk to the security of product while helping to ensure minimal supply disruptions by maintaining a required level of efficiency in the Supply Chain. Utilizing inference would reduce the need for additional manual handling of units which by its nature could lead to unnecessary human error and additional costs incurred as a result of the additional handling.

It is felt that inference allows for balance in the Supply Chain by maintaining efficient delivery of product down to the end consumer while allowing the various partners to stay true to the intent of the legislation to ensure a more secure Supply Chain for the enhanced safety of all Americans.

6. Apotex is in the process of finalizing its implementation program. While it is understood this new technology will require changes to Standard Operating Procedures, it is too early to identify the magnitude and specifics of the changes required. We can infer however, that the majority of any SOD changes will be found in the operating of packaging and distribution systems as well as the exchange of information with Third Party partners and customers.

7. Apotex does not feel there should be any allocation of liability. Inference, along with serialization, is intended to provide for an increase in security while minimizing disruption in the pharmaceutical supply chain. Whilst all supply chain partners appear to be working diligently to implement serialization and e-pedigree solutions, we all do so in good faith. In the unlikely event there is a challenge due to inference, we feel this would need to be handled on a case by case basis, allowing for flexibility to resolve the issue at hand. Instituting liability language, in our viewpoint, would undermine the cooperative spirit of the newly secured Supply Chain in the US. Further, it is felt that free market should determine liability, once again, on a case by case basis.
At this time, Apotex would like to take the opportunity to have the Board provide further clarification on grandfathering of existing stock during the transition period. We would also strongly suggest the Board formally support the widely expected use of EPCIS as the primary messaging standard for pedigree. By providing clearer direction on these two critical items the supply chain can focus on implementing the needed systems to support the looming deadlines.

We appreciate the opportunity to provide our perspective on these issues and will continue to work collaboratively with our various trade organizations to support increasing security in our supply chain.

Thank You,

John J. Flinn

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August 30, 2012

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

Dear Ms. Herold:

The undersigned organizations (BayBio, BIOCOM, and CHI) are California’s leading life science associations, representing more than 2,400 biotechnology, pharmaceutical, medical device, diagnostics, research tools, and bioagricultural companies. California is home to the oldest, largest and most productive life science clusters in the world, employing more than 268,000 people statewide. The total economic impact of the life sciences in California is greater than either Hollywood’s vaunted entertainment industry or our world renowned wine industry. We appreciate the opportunity to comment on the Board’s “Opportunity to Submit Information Necessary to Possible Board Rulemaking on Inference and Certification of Individual Package Units – Drug Pedigree Law” in our role as general representatives for many companies who would be the source point for much of the supply which will enter the system discussed.

Inference is an absolutely critical component to a viable and effective track and trace system. In order to produce a system that does not interrupt and delay the access to medications and other therapies for patients, regulations should encourage use of inference to the maximum extent possible. BayBio, BIOCOM and CHI are concerned that a system without strong utilization of bundling and inference will inevitably create supply stream bottlenecks, delaying the delivery of medications to the consumer and placing great numbers of patients at unnecessary risk. Additionally, it will likely require significant increases in workforce to manage the greatly increased administrative workload. The specific proprietary methods to be used to establish pedigree across our combined memberships will vary, and so we are unable to comment on specific means and methodology to be used by our members. The mere fact that this variance will exist illustrates the complexity faced by our member companies, downstream suppliers, and the Board of Pharmacy in ensuring a fully interoperable system.

Another issue we would like to bring to the Board’s attention on behalf of our memberships is that of liability. Manufacturers should not be liable for the actions of those not under their direct control. Once a product has been transferred from the manufacturer’s jurisdiction, a manufacturer cannot reasonably be expected to be able to insure or affect its safety and security. Provided all relevant statutes and regulations have been adhered to and packaging is not compromised, liability should follow the product and be conveyed to the parties accepting the product throughout the supply chain. A manufacturer cannot be reasonably held responsible for the actions of downstream participants with whom they have no direct contact or control over independent supply chain actors.

BayBio, BIOCOM and CHI greatly appreciate the opportunity to submit comment in this matter. If we may answer any questions on behalf of our respective associations, please feel free to contact us at the numbers or email addresses below.

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September 6, 2012

Virginia Herold, Executive Officer
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1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

Re: Opportunity to Submit Information Necessary to Possible Board Rulemaking on Inference and Certification of Individual Package Units – Drug Pedigree Law (July 23, 2012)

Dear Ms. Herold:

Please accept this letter as Cardinal Health’s response to the Board of Pharmacy’s Opportunity to Submit Information Necessary to Possible Board Rulemaking On Inference and Certification of Individual Package Units – Drug Pedigree Law, published July 23, 2012. Headquartered in Dublin, Ohio, Cardinal Health helps pharmacies, hospitals, ambulatory surgery centers and physician offices focus on patient care while reducing costs, enhancing efficiency, and improving quality. Cardinal Health is an essential link in the health care supply chain, providing pharmaceuticals and medical products to more than 60,000 locations each day. The ability to use inference in meeting the obligations under the California pedigree law will be a critical process in maintaining efficiency for Cardinal Health and our customers.

Overview of California pharmaceutical distribution business
Cardinal Health has two pharmaceutical distribution centers in California. Our locations in Elk Grove and Valencia service over 3,000 customers; providing pharmacies, hospitals, ambulatory surgery centers and physician’s offices with access to over 57,000 items including 20,000 prescription (dangerous) drugs.

The below statistics highlight the approximate volume of annual operational activities for our two California pharmaceutical distribution centers. These numbers illustrate the magnitude of serial number management that will be required for compliance with California pedigree law:

- Receipts: 55 million pieces; 2 million cases
- Shipments: 55 million pieces (75% of which are Rx) contained within 4 million totes
- Returns: 3% of pieces originally shipped
Cardinal Health has been engaged in pilot activities to support implementation of the California pedigree law for more than five years. One of our California distribution centers is currently engaged in pilot activities with several drug manufacturers to build effective controls to comply with the law while ensuring business efficiencies.

**Inference definition**

Inference can be defined as a conclusion drawn from evidence or reasoning. For the purposes of pedigree, inference is a process that supply chain partners use to electronically match expected receipts and shipments with the physical product actually received or shipped without physically reading each unique serial number within a packaging unit.

Cardinal Health believes that inference, when used responsibly in the receiving and shipping processes, will support efficient operations and will not increase the risk of diversion or counterfeiting within the pharmaceutical supply chain.

**Circumstances where inference is necessary**

California pedigree law evidences the legislative intent in statute. The Legislature intended that all participants in the supply chain “verify and validate the delivery and receipt of dangerous drugs against those [electronic] pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.” See B&PC §4163.3(a). Inference is an essential operational process that must be allowed in order to comply with the law. The Legislature recognizes this as they included §4163.3(b) the requirement that the Board of Pharmacy, by regulation, shall “define the circumstances under which participants in the distribution chain may infer…”. See §4163.3(b).

To aid the Board in drafting those regulations, the following circumstances are those which Cardinal Health would like to utilize inference:

- Distributor’s receipt of sealed full case(s) when electronic data has been received from the supplier prior to receipt of the physical product. The electronic data received must provide the unit to case relationship.
- Distributor’s receipt of full pallet(s) when electronic data has been received from the supplier prior to the receipt of the physical product. The electronic data received must provide the unit to case and case to pallet relationship.
- Distributor’s shipment of sealed full case quantities when electronic data has been delivered, prior to the recipient’s receipt of the physical product, from the distributor. The electronic data much provide the recipient with unit to case relationship.
- Inference shall not be allowed on receipt of a product through the returns process.

Cardinal Health requests that the Board of Pharmacy draft regulations allowing inference in these above circumstances.

Because Cardinal Health strives to fulfill customers’ needs immediately, we ship daily (sometimes twice daily) to customers. These order quantities tend to be single units. Data over a one year period for six serialized NDCs shows that although 70% of products were received
during this period with inference, 98% of units (serial numbers on an individual unit) shipped were physically read upon receipt, shipment, or both. The 2% of units not scanned at the unit level are scanned at the case level. Both receipt and shipment serial numbers for these case level scans are recorded as transferring ownership based on verification of the original electronic transmission provided by the supplier. See chart below for actual pilot statistics in 2011:

### Procedures to use inference
Cardinal Health has established documented procedures in our distribution center engaged in pedigree pilot activities. Although these procedures may be revised with increased product volume, the major components of the procedures will remain the same and are as follows:

- Supplier must provide electronic transmission via AS2 secured transaction (using either a serialized Advanced Ship Notice, DPMS pedigree, or EPCIS transaction) that provides hierarchy for serialized products
- Procedures are defined to determine which suppliers can be trusted to provide accurate and complete data:
  - Physical verification of a defined number of consecutive receipts
  - 100% match of electronic transmission with physical serial numbers received
  - No manual intervention other than product scans
  - Approval of trusted status by local compliance manager
  - Signed documentation of process compliance
- Random audits performed to ensure ongoing accuracy of electronic transmissions
  - Conducted according to ANSI/ASQZ1.4-2008, using Special Level S-1 and the single sampling plan for normal inspections
Safety of inference
Prescription drug manufacturers have overt and covert methods for securing their products. One of the overt methods is the case seal or tape. The security of the case is compromised when that seal is broken and product continues to move in its original carton through the supply chain. California regulation requires that all materials be examined upon receipt or before shipment. See CCR 1780(d). Our distribution centers examine product to ensure there is no evidence of tampering, such as a broken seal on a manufacturer’s case. The ability to infer the contents and leave the cases sealed either until the entire case is sold or until a single unit is needed for a customer, would create a more secure supply chain.

Operationally, inference is preferred because opening every case in an effort to read the individual units would have a significant negative impact on productivity and may lead to overall increased cost to distribute in California. In addition, the use of inference expedites the receiving process, resulting in product being readily available to ship to dispensers that have patients in need of those prescription drugs.

Liability
Each trading partner should be responsible for information they represent as true and for the consequences that result if such information is found to be false or erroneous. Consideration should be given to whether the error was intentional or due to human error or mistake, as well as the seriousness of the resulting consequence.

Parties should be liable for their own actions, but mitigating factors such as properly vetting trading partners, due diligence, long-standing relationships, and past experience (good or bad) with a certain entities should be taken into consideration when determining any liability resulting from reliance on inference as a result of manufacturer provided product and shipment information.

Conclusion
The safety and security of our nation’s pharmaceutical supply is one of Cardinal Health’s top priorities. We take this responsibility very seriously, as a safe and reliable drug supply is central to our customers’ business and critical to the health and well being of patients. We are committed to complying with pedigree laws, including serialization requirements, in the most efficient manner possible. If you have any further questions, please do not hesitate to contact us.

Sincerely,

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August 29, 2012

Virginia Herold  
Executive Officer, California State Board of Pharmacy  
1625 North Market Blvd, Suite N219  
Sacramento, CA 95834

Dear Ms. Herold;

Thank you for the opportunity to comment on the Drug Pedigree Law as it relates to inference and certification of individual package units.

As licensed healthcare practitioners in California, we support the Board’s decision on moving forward with Pedigree Law to protect the public from counterfeit medications and minimize drug diversion. Furthermore, we concur with the California Society of Health-System Pharmacists (CSHP) Policy on E-Pedigree and Tracking of the Medication Supply Chain (see Attachment 1). While many of the processes for ordering, receiving, and inventorying of pharmaceuticals are shared across pharmacy practice settings (community, hospital, retail, etc.), the Pedigree Law will create unique challenges and opportunities for hospital pharmacists. We wish to elucidate the specific implications of the Pedigree Law on inpatient pharmacy practice.

To facilitate electronic inference, it is expected that all firms fulfilling orders of dangerous drugs in aggregate containers will assign serial numbers to their containers as below:

- The aggregate is identified with a unique serial number and each unit/item in the aggregate is also identified with a unique serial number. For example, if medications are received in a pallet, then each pallet will have unique serial number, each tote on the pallet will have a unique serial number, and each unit in the tote will have its own unique serial number.
- All serial numbers are associated with the aggregate in a hierarchical relationship.
- Electronic communication identifies each item in the aggregate.
- Pharmacies will have assurance that the integrity of the aggregate has remained intact since leaving the last supply chain partner and can confirm the integrity of the aggregate has not been compromised.

1) Risks Associated with Open Cases

We support a regulatory allowance that would allow individual pharmacies to choose to infer the contents of aggregate containers for the purposes of certification of delivery or receipt of individual package units for all dangerous drugs. Inference supports patient safety, security and efficiency in the supply chain distribution process (i.e., products move faster in the supply chain). Opening containers to verify the individual package can lead to:
- Delayed delivery of medications to patients
- Introduction of error into the system
- Tampering
- Theft
- Product mix-up

The security and integrity of medications may be compromised if security seals or tamper evident packages are not left intact. For example, open packages of controlled substances may lead to tampering or theft.

2) Statistical Sampling

We support statistical sampling of incoming shipments from trusted members of the supply chain rather than conducting 100% inspection of all incoming items to assess the presence and integrity of the products. We do not support regulatory language which would require pharmacies to perform sampling for chemical analysis of medications; rather, sampling should be limited to product or package confirmation. We would recommend each Pharmacist in Charge (PIC) be responsible for delineating within their own Standard Operating Procedures (SOPs):

- Frequency and amount of sampling performed.
- Situations in which 100% of the shipment should be inspected if there is reason to be suspicious about the integrity of an incoming shipment.

Manufacturers and distributors/wholesalers should have additional responsibility for conducting more frequent statistical sampling (based on the Acceptable Quality Level [AQL]) and periodic chemical analysis before medications are shipped to pharmacies. Pharmacies should not be liable for receiving counterfeit or mishandled medications during transportation.

3) Technology and Manual Pedigree

We anticipate the Board will receive comments from other supply chain participants and technology vendors with specific hardware, software, and data carrier recommendations to facilitate the passing of electronic pedigree information among supply chain participants. We believe the system used for tracking E-Pedigree should be harmonized with internationally recognized standards for such an identifier (e.g., Radio Frequency Identification [RFID], Serialized Global Trade Item Number [SGTIN]). We urge the Board to recognize there will be situations which will require manual tracking of pedigree information (e.g., during hardware/software downtime, emergency situations). We suggest each hospital should define within their SOPs their process for manual pedigree tracking. Ideally, in the future, one machine-readable code would contain a product's expiration date, lot number, and NDC number which would be then tracked through pedigree.
4) Exception for Using Electronic Pedigree (Risk Assessment)

While the comments above are specific to the use of inference of aggregate package contents, the situations in which an electronic pedigree must be passed between supply chain participants impacts and will be impacted by the decision to use inference. Because of the difficulties associated with passing an E-pedigree, the relationships hospital pharmacies have with the entities below, and the minimal risk of tampering, fraud or errors, we recommend against the use of electronic pedigrees in the following situations:

- The ability for pharmacies to procure essential medication from another pharmacy to avoid patient harm (i.e., emergency loan and borrow)
- Sales/transfers to another pharmacy under common control
- Sales/transfers to authorized providers (e.g., sales to private doctors’ offices)
- Medication shipments approved by the FDA and received from outside of the United States due to critical drug shortages (e.g., methotrexate from Europe)
- Reverse distributor transactions (e.g., for expired and recalled medications)
- Compounded medications from contracted pharmacies that have a quality assurance program built in as part of their contracted relationship with the pharmacy (e.g., outsourced parenteral nutrition compounding company)
- Existing medication inventory

Finally, we would appreciate the opportunity to address these issues at an upcoming Board meeting.

Founded in 1962, CSHP represents over 4,500 pharmacists, student pharmacists, pharmacy technicians, and associates who serve patients and the public through the promotion of wellness and rational drug therapy. CSHP members practice in a variety of organized healthcare settings – including, but not limited to, hospitals, integrated healthcare systems, medication therapy management clinics, home healthcare and ambulatory care settings.

If you have any questions and/or comments, please do not hesitate to contact me or CSHP Legislative and Regulatory Analyst Jonathan Nelson at (916) 447-1033 ext. 105 or jonathan@cshp.org.

Sincerely,

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Attachment 1

California Society of Health-System Pharmacists (CSHP) Policy on E-Pedigree and Tracking of the Medication Supply Chain

CSHP advocates for improved processes to assure the integrity of medications throughout the supply chain, specifically to eliminate or minimize the persistent and increasing threat from counterfeit, misbranded, adulterated, or diverted drugs.

1. Support the California State Board of Pharmacy in development of a comprehensive electronic pedigree system to track and trace the passage of medications through the entire supply chain.
2. Require the technology and process implemented be compatible with national and international standards so as not to impede the supply of medications.
3. Require the technology(s) adopted must be a single, shared interoperable system to allow health-systems to receive medications from all sources in a single process.
4. Advocate that the technology developed has the future ability to extend the validation of the pedigree to the level of patient administration throughout the continuum of care.
5. Assure that health-systems be an active participant in the development of technology, process design and implementation.
6. Advocate that the implementation deadlines for the supply chain be a phased in approach allowing health-systems time to implement after the deadlines for manufacturers and distributors.
7. Require that "grandfathered" inventory be addressed in the implementation plan to minimize inventory losses.
8. Advocate for a streamlined process to allow medication returns and "emergency" borrowing of medications within the documentation process.
Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd, Suite N219
Sacramento, CA 95834

Dear Board of Pharmacy,

Re: Inference and Certification of Individual Package Units – Drug Pedigree Law

EMD Serono, Inc., the U.S. biopharmaceutical subsidiary of Merck KGaA, Darmstadt, Germany, a global pharmaceutical and chemical group, would like to thank the California Board of Pharmacy for their dedication to protecting the citizens of California though their tireless pursuit of electronic pedigree legislation. Like the California Board of Pharmacy, EMD Serono’s goal is to protect patients from unauthentic products and we continue to take an active role in ensuring the safety and integrity of our products.

The industry moves approximately 9 million units per day* making unit level serialization without inference extremely challenging. EMD Serono thanks the California Board of Pharmacy for the opportunity to participate in the creation of practical inference guidelines. As many industry members have stated in previous letters and board meetings, if the industry is required to scan each individual unit throughout the supply chain, the additional burden would be devastating to the industry.

Description of EMD Serono’s interest in serialization / inference

In 2002, EMD Serono implemented a secured distribution model including a track and trace program for Serostim® [somatropin for injection], a recombinant human growth hormone. Shipments of Serostim® are restricted to contracted pharmacies that participate in this program. Each Serostim® unit is uniquely serialized and can be tracked to the patient level. In 2003 the FDA stated that the Serostim® tracking program is an effective solution.

Since the California Board of Pharmacy proposed the electronic pedigree and serialization legislation in 2004, EMD Serono has been diligently working on implementing an interoperable system using the GS1 standards and initiating pilot programs with wholesalers. Currently, EMD Serono has two pilot programs underway with two of its three major wholesalers.

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EMD Serono is an affiliate of
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www.emdserono.com
Description of the means and methodology that have been deployed by EMD Serono

As noted in previous submissions to the California Board of Pharmacy, in order to implement serialization, EMD Serono had to establish a cross-function team including: Supply Chain, IT, Packaging, Manufacturing, Quality Assurance, Regulatory Affairs, Government Affairs, Legal and Procurement. This global team was successful in completing the following projects:

- Packaging modifications to add 2D barcodes and serial numbers,
- An application to capture and track all serial number events,
- State license processing and validation upgrades to include on the ePedigree,
- An upgrade to our 3PL interfaces to capture all data fields required for the ePedigree
- And finally the ePedigree solution.

All projects were completed by 2008 and we continue to make enhancements and phase in serialization. Currently we have eight out of eighteen major products serialized and plan to have all products serialized by 2015. The current system design is made up of four levels.

- Level 1: Devices and Printers
- Level 2: Line Controller
- Level 3: Site Application
- Level 4: Enterprise Application

As you see in the flow below, each level is essential to the serialization process.

<table>
<thead>
<tr>
<th>Devices scan and capture the unit serial numbers and the shipper case serial numbers</th>
<th>Line manager counts # of units required for case and builds inference between items and shipper cases</th>
<th>Site Application generates serial numbers and then stores inference data until product ships to US</th>
<th>Enterprise Application sends file to US with unit to case inference and stores all T&amp;T events</th>
</tr>
</thead>
</table>
| Product marking at MFG | Each unit has a 2D barcode with the sGTIN encoded. (In 2015, each unit will have the sGTIN, lot and expiration date encoded into the 2D barcode.) | Data capture and Uniqueness check | Each unit is read immediately before being packaged into the case to ensure the following:
1) There are no duplicate serial numbers
2) The correct serial numbers are placed into the case
3) The correct item serial numbers are aggregated with the correct case serial number |

EMD Serono is an affiliate of Merck KGaA Darmstadt, Germany.
### Aggregation file building at MFG

All aggregated unit and case serial numbers are stored in the system as a "manufactured lot".

### Product shipped to 3PL

A file with the unit to case association is sent to the 3PL for verification upon receipt.

### In-bound at 3PL

Product is received and placed into quarantine until all verifications are complete, including quality and quantity checks.

### Out-bound from 3PL

Product is scanned on the outbound, captured and passed via an electronic pedigree to the downstream trading partners.

### Other inbound at 3PL

Product which is moved to retain or reject is captured and stored as product that will never ship to trading partners.

### Returns

Product returns are captured as returned and sent for destruction.

(Redistribution of returns is extremely rare and would need to go through extensive quality checks prior to placing product back to stock.)

---

EMD Serono has taken a number of steps to ensure the correct serial numbers are placed into the correct case. For example, our system logic will not allow a case to be completed and sealed until the serial numbers match the total case quantity. In addition, our manufacturing sites make sure item serial numbers are only scanned once the items are placed into the shipper case and also ensure the correct case label is applied to the correct shipper case.

Furthermore, our cases are packaged using branded tape. Therefore, any case that has been opened will be apparent. Less than full case quantities will invalidate the case serial number, requiring the case to be opened and all items within scanned individually.

Our final check is with our 3rd party logistics company. Upon arrival the product is placed into quarantine until all necessary quality and quantity checks are complete. For serialized product the quantity is validated against the serialized aggregated file received from the manufacturing site. If there is a discrepancy, each unit is scanned on the inbound to ensure the file is correct prior to shipping product to our trading partners. In addition, we have a final check on the outbound, which ensures there are no duplicate serial numbers within the file.

**Reasons that inference is necessary and advantageous**

Each supply chain step, starting from the goods outbound from the manufacturing site, requires identification of the shipped or received items. This operation cannot be managed without inference:
Having no inference would mean that every single item should be read/scanned individually, which would represent hundreds of thousands of scanning operations. Not only would this dramatically slow down the goods movements at each node, but it would also significantly increase the risk of error in the scanning operations.

We therefore believe that inference clearly decreases risks of diversion of counterfeiting, and is necessary and advantageous in order to:

- Ensure the ability to track all individual serial numbers of a shipment within a reasonable time frame
- Maintain a seamless flow of goods through the supply and distribution chain
- Decrease the risk of error in the code reading operations and thereby minimizing the opportunity of counterfeit product entering the legitimate supply chain.

EMD Serono has taken great strides in serialization and has taken great efforts in ensuring the integrity of case inference. We have system checks, manual checks, clear Standard Operating Procedures and multiple checks prior to shipping product to our trading partners. In addition, in February 2012 our global team kicked off a new project to enhance the systems to reduce manual checks and further streamline the processes for global efficiencies.

As mentioned above, EMD Serono applauds the California Board of Pharmacy and other relevant Federal and State agencies for their continued efforts to ensure that measures remain in place by law to prevent counterfeiting and diversion throughout the United States. We have and will continue to work closely with the Federal and State authorities to ensure that our genuine medicines will reach patients for whom they are intended and will continue to advocate for a national standard. EMD Serono remains committed to assessing, testing and incorporating potential new technological advances in product tracking and distribution as they become practically available.

**Date of Submission**
August 30, 2012

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* Source: HDMA
RESPONSE TO CALIFORNIA BOARD OF PHARMACY

RE: INFEERENCE

Thank you for the opportunity for GPhA to comment on inference and its role in compliance with the California Pedigree Law. The generic pharmaceutical industry is committed to providing safe and effective products to US consumers and believes that maintaining and improving the safety of the US supply chain are important components of achieving that goal.

The Generic Pharmaceutical Association (GPhA) represents manufacturers of generic drugs. Generic medicines now fill 80% of the prescription drugs dispensed in the US yet account for only 25% of the total cost. Over three billion of the four billion units sold in this country are generic. Given the enormous volume, compliance to the California ePedigree law by the mandated dates represents a large, complex and costly challenge to our members.

GPhA understands inference, within the context of the California law, to mean the ability of a downstream partner to infer, or assume, the contents (units) of an aggregate container (i.e., case or pallet) from information provided by the prior owner of the product, without necessarily opening that aggregate container. The ability to infer in this fashion, assumes that the prior owner has done aggregation, or created a parent-child data relationship (between the pallet - case – unit) and passed that data in a pedigree document to a downstream partner. Generic manufacturers are having great difficulty with meeting a certifiable aggregation requirement due to:

- Limits of aggregation technology and applications.
- Cost of aggregation.
- The value of manufacturer aggregation to increasing patient safety through increased supply chain security.
- Difficulties with data integrity and certification.
- Liability of data errors.

Aggregation Technology

The data carrier used by most, if not all, manufacturers planning to comply with California is the 2D barcode. 2D is readily available, has very high reliability and is relatively inexpensive. An interoperable system must enable downstream partners to infer the contents of aggregate containers. Because 2D barcode is a line-of-sight technology, establishing an accurate parent/child relationship between units, cases and pallets (i.e., aggregation) relies on cumbersome, inaccurate and expensive technology.

In a 2D scenario, manufacturer aggregation requires 360 degree visioning systems stationed in front of an automated case packing machine. Each serialized unit is scanned using optical character recognition technology as it is packed into a new case. This process varies from line to line depending on the presence of automated case packers, palletizers, different package types - i.e., tubes, cartons, bottles - which sometimes results in units needing to be turned, tilted or manipulated robotically to allow the
scan of the label at high speeds. Once the appropriate number of units has been packed into a case and that case is sealed, the system at the line level virtually creates that case with those specific units inside. In turn, when cases are stacked onto pallets, the cases typically must be hand-scanned, unless a palletizer is present. That step would complete the aggregation of units to cases, and then cases to pallets. The ability to get accurate scans while operating at production speeds, while also accounting for all of the different misfeeds, sampling for quality assurance, line stoppages, etc., makes this process cumbersome and very expensive. Errors are a certainty, potentially caused by any number of factors from packaging types and shapes, to equipment issues and technology limitations, to line exceptions.

The Value of Manufacturer Aggregation

75%-90% of cases, and virtually 100% of pallets are opened or divided and the units subsequently placed in a new aggregate container by the first supply chain customer, thereby obviating the manufacturers aggregation information for those affected units. The lion’s share of generic Rx products are sold through the "big 3" wholesalers. Most of these cases are opened and the units piece-packed at the wholesaler for subsequent sale. The net effect of this repackaging after one "hop" in the supply chain is that units would likely need to be "re-aggregated" to their new containers at the wholesale/distributor stage in order to allow inference further down the supply chain.

Given this value proposition for manufacturers aggregation, it is important to look at the costs:

Costs for Manufacturers Aggregation (Industry estimate)

Assumptions:

- Assumes 2D barcode as data carrier
- This model does not include cost for line shutdowns, re-engineering due to speeds or space constraints.
- This model does not include cost for returns or shipment refusals due to lack of certification, etc.

<table>
<thead>
<tr>
<th></th>
<th><strong>No aggregation</strong></th>
<th><strong>With aggregation</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of drug manufacturers serving the US market</td>
<td>425</td>
<td></td>
</tr>
<tr>
<td>Number of production / packaging lines - industry aggregate</td>
<td>$3,250</td>
<td></td>
</tr>
<tr>
<td>Typ. Cost per production / packaging line with serialization, but no aggregation</td>
<td>$125,000</td>
<td></td>
</tr>
<tr>
<td>Typ. Cost per production / packaging line with serialization and aggregation</td>
<td>$750,000</td>
<td></td>
</tr>
<tr>
<td>Typ. Cost of Database / EPCIS/ Pedigree and integration</td>
<td>$2,000,000</td>
<td></td>
</tr>
<tr>
<td><strong>Total cost of production / packaging lines</strong></td>
<td><strong>$406,250,000</strong></td>
<td><strong>$2,437,500,000</strong></td>
</tr>
<tr>
<td><strong>Total cost of database and integration</strong></td>
<td><strong>$850,000,000</strong></td>
<td><strong>$850,000,000</strong></td>
</tr>
<tr>
<td><strong>(One time) Simple CapEx subtotal</strong></td>
<td><strong>$1,256,250,000</strong></td>
<td><strong>$3,287,500,000</strong></td>
</tr>
<tr>
<td><strong>Annual OpEx (Maintenance / Updates)</strong></td>
<td><strong>$251,250,000.0</strong></td>
<td><strong>$657,500,000</strong></td>
</tr>
</tbody>
</table>
So, the net value of a $3.3 billion manufacturer investment, and annual maintenance of $658 million in aggregation technology is the transmission of a parent/child relationship for only one step in the supply chain in most cases. GPhA believes that in order to allow the entire supply chain to infer the contents of aggregate containers (cases and pallets), it would be necessary for serialization of the new containers (totes, etc.) plus "re-aggregation" of the units to those totes, increasing the costs detailed above in total industry terms.

**Difficulties with Certification Mandates in California's law**

An important aspect of California's law is the certification of the accuracy of pedigree information with every change of title in the supply chain. Given the description of the manufacturers aggregation process as detailed above, GPhA believes that it would be very difficult, if not impossible, for a manufacturer to certify aggregation information for 100% of product. The available technology and processes are simply not 100% accurate in scale and at production speeds with different product and package types.

Another complication in the certification aspect of California's law is the common use of third party manufacturers. Under California's law, the ANDA holder in the case of a generic, is the manufacturer, meaning that company must create a certifiable pedigree. In the case of a contract manufacturer relationship, which all of the large generic manufacturers have, much of the industry will be in the position of certifying aggregation information that is not under the manufacturer’s direct control.

**Potential Liability for errors in inferred data**

GPhA believes that the vision systems currently available for the aggregation of serialized units fall short of 100% reliability. Therefore, a certain percentage of system error is unavoidable for aggregated data regardless of standard operating procedures. Further, manufacturers cannot be held responsible for the operating processes and procedures of other supply chain participants and their handling of data. GPhA urges the board to take this into consideration and establish liability rules only to the company holding title to a product at the time of an incident.

Thank you very much for the opportunity to provide comments on inference. GPhA looks forward to participating in this process with the ultimate goal of an achievable, reliable and cost-effective system which results in a safer supply chain for all.
August 30, 2012

Virginia Herold  
Executive Officer  
California State Board of Pharmacy  
1625 N. Market Blvd., Suite N219  
Sacramento, CA 95834

Re: Opportunity to Submit Information Necessary to Possible Board Rulemaking on Inference and Certification of Individual Package Units – Drug Pedigree Law (July 23, 2012)

Dear Ms. Herold:

On behalf of the Healthcare Distribution Management Association (HDMA) and its members serving California, I appreciate the opportunity to respond to the Board of Pharmacy’s request for comments regarding inference and its use in the context of California’s electronic pedigree law. The framework set forth by this law will result in operational and technological changes unlike any the industry has experienced to date. Inference will be an integral part of any implementation strategy for pharmaceutical distributors, and its allowance by the Board is necessary for distributors to meet the goals and requirements of the California law.

HDMA is the national association representing primary healthcare distributors, the vital link between the nation’s pharmaceutical manufacturers and healthcare providers. Nearly 90 percent of the prescription drugs in the U.S. are stored, managed, and delivered by our primary distributor members. Every day, HDMA member companies collectively ensure that nearly 9 million prescription medicines and healthcare products are delivered safely and efficiently to nearly 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. In California, our members serve over 32,000 customers.

We appreciate and support the Board of Pharmacy’s request for comments from individual companies. As you know, HDMA also has been significantly involved in the development of the California pedigree law and offers a unique and critical viewpoint on implementation. We hope that this perspective is helpful to the Board as it moves toward 2015 and beyond.
Background

Inference in the context of electronic pedigree and track-and-trace has essentially the same meaning as it does in the English language – an assumption that a proposition is true based on the occurrence of some other fact or assumption. For example, Wholesale Distributor XYZ received ten individual units in a sealed case (A) from the manufacturer of a product, along with a communication stating that these ten units were numbered 1 through 10 in case A. Because the manufacturer provided this information, and the same manufacturer sent Wholesale Distributor XYZ the case, XYZ can infer that what the manufacturer sent to it is what was stated by the manufacturer – without requiring Wholesale Distributor XYZ to open the case to confirm.

The concept of inference first emerged in discussions among pharmaceutical supply chain partners approximately five years ago, when the current iteration of the California pedigree law was being drafted by the Legislature. Historically, California’s law has been silent on the specific type of technology and/or data carrier required to satisfy the provisions of the law, but the concept of unit level track-and-trace was based originally on the capabilities of radiofrequency identification (RFID) technologies. In 2007 or 2008, it became clear that manufacturers overwhelmingly believed that unit level serialization was more practical and economically feasible through the use of two dimensional (2D) data matrix bar codes. Because 2D bar codes utilize “line of sight” technology, an individual must scan each bar code in order to capture product information.

On an average day, a typical HDMA member distribution center handles almost 2,000 customer orders, and picks (or processes) an average of 95,000 product units. Due to this high volume and the associated need for efficiencies of scale, scanning individual units on receipt is not always practical or economically feasible. The Legislature understood the need for supply chain members to avoid having to unnecessarily open every single case of product.

In recognition of this concern, the Legislature’s solution was the allowance for inference as described in California Bus. & Prof. Code § 4163.3. HDMA reads the statutory language regarding inference as requiring the Board of Pharmacy to issue regulations that define circumstances in which inference may be used. The need for inference still exists today, and without it, primary distributors will have incredible difficulty with implementation, potentially slowing movement of product and bringing the distribution chain to a halt in California.

Below are HDMA’s responses to a number of the Board of Pharmacy’s specific requests for information.

I. Process and Technology Recommendations

HDMA and its members have been working on implementation issues related to California’s pedigree law since before the 2008 law was enacted. Our members have engaged staff and
outside consultants in exploring existing and developing technology solutions in order to help
them comply with the California law. Some members have also engaged in pilot programs that
will help inform more specific solutions and data exchange between trading partners.

In addition, HDMA members have been participating in the development of GS1 standards and
piloting use of those standards. Significant efforts have been put forth and progress has been
made; though, there is still more work to be done before the standards are complete and ready
for application throughout the supply chain.

It should be noted, however, that the ability of HDMA primary distributor members to comply
with the California law is heavily dependent upon manufacturer compliance beginning in
January 2016. A future that includes serialized product, use of track-and-trace technologies,
and electronic pedigree data exchange is one that has been contemplated, but we cannot yet
fully understand or anticipate how such changes will require modifications to our members’
operational and logistics functions.

The impact of these changes extends beyond the boundaries of the state’s day-to-day product
demands, affecting the ability to move product within complex, national, distribution networks,
and creating a need for new contingencies for moving product into the state during times of
emergency or shortage. Without a critical mass of serialized product entering the supply chain,
with unit-to-case aggregated product information (individual SNIs associated to case),
distributors will have significant difficulty maintaining their current levels of efficiency, which
may adversely affect the availability of drug products in California.

II. Circumstances In Which Inference is Necessary

As primary distributors, HDMA members will be receiving the vast majority of product
shipments directly from manufacturers. HDMA believes that inference would be appropriate
and should be permitted under the following circumstances:

1) Recipient places an order for product with the shipper, with whom the recipient has
   a business relationship; and
2) A sealed homogenous (same lot, same product) case is sent by the shipper directly
   to the recipient; and
3) The shipper and recipient have technology solutions to provide electronic business-
   to-business transactional security; and
4) The shipper sends – in advance of, or in conjunction with shipment – information
   about the items/contents of such case, including the items’ serial numbers and
   pedigree information related to each specific case; and
5) The recipient receives the case and the product information from the shipper.
HDMA Response to
California Board of Pharmacy
August 30, 2012

Although the frequency of receiving sealed homogenous cases as described above may vary depending on the manufacturer, product and customer orders, we anticipate that the vast majority of inbound shipments received by primary distributors consist of sealed homogeneous cases.

Please note that most individual units received by primary distributors using case inference will in fact be scanned individually as the units are prepared for shipment to the pharmacy setting. Exceptions to this procedure will occur when distributors ship to large volume customers, such as mail order pharmacies, regional or national pharmacy warehouses, warehousing health systems, or government agencies.

III. Safety Benefits / Advantage to Allowing Inference

Allowing inference by distributors as described above would help to facilitate implementation of the provisions of California’s pedigree law. Most important, inference will enable compliance with the spirit and the intent of the law – to employ technology and processes in the supply chain to permit electronic track-and-trace for the first time. Simply put, without inference, such technologies and processes might not be successfully deployed. The use of inference by distributors will help to ensure that California providers and patients have continued access to life saving medicines, while increasing the security of the supply chain. It is anticipated that adoption of track-and-trace and electronic pedigree will create new procedural and logistical burdens for distributors; however, the allowance of inference will at least enable some efficiencies to be maintained.

Successful deployment of electronic track-and-trace technologies and processes is expected to decrease the risk of counterfeiting and diversion within the supply chain. As to the benefit of inference specifically, the use of inference in distribution centers will limit the number of open cases in a warehouse or on a receiving platform, thereby limiting the number of personnel handling product, and thus creating fewer opportunities for diversion, theft or contamination. If the scope of permitted inference is limited as described in section II above, HDMA does not believe that inference would be disadvantageous or introduce unacceptable increases in risk.

IV. SOPs and Statistical Sampling

As a preliminary matter, it is important to note that the statute does not require the Board to promulgate regulations addressing the content of Standard Operating Procedures (SOPs) covering the use of inference. The spirit of the governing statutory provision was to require each company to develop a compliance plan and SOP language compatible with its own processes and implementation plan.
HDMA Response to
California Board of Pharmacy
August 30, 2012

HDMA believes that each individual company opting to use inference should have the flexibility to tailor SOPs to its specific operations, while making such SOPs available to the Board of Pharmacy for review upon request.

If the Board believes that it is necessary to provide greater uniformity among supply chain members in their SOP development, HDMA suggests that the Board limit its guidance to several general factors or categories that could be considered in developing appropriate SOPs.

V. Allocation of Liability

HDMA suggests that each trading partner should be liable for the information that they introduce into the marketplace and for the actions/consequences that result if such information is found to be false or erroneous. Further, when assessing liability, the Board should consider whether the error was made with intent or due to mistake as well as the seriousness of the resulting consequence. (e.g., different treatment by the Board for systems malfunctions than for an intentional falsification or negligent assertion.)

For example, in the instance of a manufacturer stating that specific serialized items are shipped to a distributor, labeled with serial numbers 1-20 and contained in a manufacturer’s sealed homogenous case, the manufacturer should bear responsibility for the accuracy of that information. For its part, the distributor should be responsible for complying with the state’s requirements (including having appropriate SOPs), but the distributor should be able to rely on the information and assertions made by manufacturer, and should be held liable only for violations within its control.

In other words, parties should be liable for their own actions, but mitigating factors such as properly vetting trading partners, due diligence, long-standing relationships or experience with certain entities should be taken into consideration when determining any liability resulting from reliance on inference as a result of manufacturer-provided product and shipment information.

Conclusion

HDMA respectfully submits the above comments in response to the Board’s request. The use of inference does not reduce the integrity of the pedigree system nor does it create an increase in the risk of diversion or counterfeiting. As we have stated, inference is a necessary part of implementation of California’s pedigree law for distributors, as we expect manufacturers to be employing 2D bar codes to meet their serialization requirements. Without the ability to infer the contents of sealed homogenous cases based on information supplied about the products shipped within those cases, distributors would have severe difficulties complying with the requirements of California’s pedigree law.
HDMA Response to
California Board of Pharmacy
August 30, 2012

Please contact me should you have any questions or need additional information. HDMA appreciates this opportunity to provide input and we look forward to working with you on this important issue.

Sincerely,

Elizabeth A. Gallenagh
Vice President, Government Affairs & General Counsel
Healthcare Distribution Management Association
August 29, 2012

Executive Officer Virginia Herold
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, California 95834

Re: §4163.3. Legislative Intent; maintaining integrity of pedigree system; use of inference

Dear Ms. Herold:

On behalf of the Health Industry Distributors Association (HIDA), I am submitting information necessary to possible rulemaking on inference and certification of individual package units as related to the California drug pedigree law. We respectfully request that the California State Board of Pharmacy (the Board) allow through regulation for supply chain trading partners to infer the contents of sealed containers from an associated serialized numerical identifier (SNI).

HIDA is the professional trade association that represents the interests of over 600 medical-surgical products distributor companies operating throughout the United States. Our members deliver life-saving healthcare products to more than 290,000 points of care including over 210,240 physician offices, 6,512 hospitals, 44,061 assisted living and nursing homes and 33,722 medical facilities. While our members primarily carry medical-surgical products they may also deliver low-risk, high-volume pharmaceutical products used in everyday medical interactions, such as topical anesthetics and flu vaccines.

As the implementation of the California electronic pedigree law approaches, a variety of HIDA distributor members have been challenged with establishing the definitive means and methodology needed to “verify and validate the delivery and receipt of dangerous drugs against electronic pedigrees at the unit level.” Specifically, the deployment of hardware, software, and processes associated with these functions (that is, verification, validation, and certification of dangerous drugs at the unit level) is difficult until more guidance is available from supply chain partners and the Board regarding compliance requirements. For example, the scope of a regulatory allowance for the use of inference for the purposes of certification of individual units of drug products will influence certain wholesaler decisions.

Regulatory allowance for inference is a necessity for wholesale distributors to maintain the efficiency of the supply chain. The prevalence of two-dimensional (2D) barcodes as the carrier technology for serial numbers, for example, will require “line-of-sight” scanning capabilities on the part of wholesale distributors to validate serialized numerical identifiers (SNI) on individual units. Opening sealed containers and scanning individual units to validate the contents of each and every container will add significant costs in labor, technology, and time to the supply chain. As such, inference should be allowed for supply chain participants in the following circumstances:

- Upon the receipt of product in a sealed container (e.g., pallet, case, package) with an associated SNI; and
Upon the sale of product when the container’s seal remains intact and when the contents within a container remain sealed with an associated SNI (e.g., a sealed case contained within a pallet).

Ensuring patient safety remains the priority of medical-surgical products distributors and the use of inference can be used toward that end. By preserving the original seal of a container, and in some cases tamper-evident packaging, downstream trading partners are provided an additional mechanism for assuring the contents are not illegitimate product.

Thank you for the opportunity to submit information on the need for inference in the healthcare supply chain. Please contact Ashley Palmer, palmer@HIDA.org or (703) 838-6113, if you have any questions regarding HIDA’s comments to the Board.

Sincerely,

[Signature]

Linda Rouse O’Neill
Vice President, Government Affairs
Health Industry Distributors Association
August 31, 2012

Virginia Herold, Executive Officer  
Board of Pharmacy  
1625 N. Market Boulevard  
Suite N219  
Sacramento, CA 95834

Dear Ms. Herold:

On behalf of the Johnson & Johnson companies affected by the California Drug Pedigree Law, we appreciate the opportunity to provide information to the California Board of Pharmacy on the possible rulemaking on inference and certification of individual package units as it pertains to the California Drug Pedigree Law. Johnson & Johnson is the world’s most diverse and largest health care company - actually a family of 250 companies producing pharmaceuticals, biologics, medical device and diagnostics and consumer health products, with operations in 60 countries (including 15 companies in California). Looking at only the pharmaceutical and biologics portions of the company, we are the eighth-largest pharmaceutical company and the fifth-largest biologics company in world.

1. **Efforts of Johnson & Johnson Companies.**
   
   Johnson & Johnson companies take a variety of approaches to identify and mitigate the risks of counterfeit health care products. They include a range of product and packaging security measures that help distinguish the authentic product from a counterfeit, and aid in minimizing the potential for tampering. Affected companies within the Johnson & Johnson family are working earnestly to be in compliance with the California pedigree law when it becomes effective on January 1, 2015. This involves a significant undertaking to outfit our global packaging network with capability to apply the FDA’s Standardized Numerical Identifier (SNI); upgrading our U.S. distribution centers to handle SNI labeled product; working with our external contract manufacturers to ensure they can apply SNI’s to products that they manufacture for us; and upgrading our business and IT capabilities to support the new processes. As we are working to implement these capabilities needed to comply with the California pedigree law, we must also ensure that all our processes and systems are GXP compliant and that we maintain uninterrupted patient access to our products.

2. **Use of Inference.**
   
   Fundamentally, Johnson & Johnson believes that inference is important to maintaining the uninterrupted supply of pharmaceutical products to patients and caregivers. We employ inference when moving product through our supply chain and fulfilling customer orders. Once SNI’s have been applied to our products, we intend to maintain the association between the lot number and each individual SNI within that specific lot so that we are able to use inference in our distribution centers when we pick, pack, verify, and ship SNI labeled product to fulfill a customer’s order.
We have a number of U.S. customers who distribute product to California-based pharmacies who will need processes and capabilities to exchange SNI’s and business event related information. Our intent is to provide information to our trading partners via a system that conforms to GS1’s Electronic Product Code Information System (EPCIS) standards.

3. **Need for Regulatory Action.**

While we fully expect that all legitimate companies interested in continuing to do business in California will seek to comply with the e-pedigree, there are substantial challenges in doing so. As such, it is critical to establish an interoperable electronic system that connects all trading partners and allows for the reliable and efficient exchange of e-pedigree data in order for companies to be able to comply with the CA law. In spite of the efforts being made by the Johnson & Johnson companies, as well as other industry leaders, California’s law cannot be successfully implemented unless the Board and the FDA provide guidance and possibly regulations in several areas. These include:

a) **Interoperable Electronic System Requirements and Regulations** – over the last several years, the Johnson & Johnson companies have worked with the Global Health Exchange (GHX) and several trading partners to understand an option for sharing SNI related information. Although it is very preliminary, our work with GHX demonstrates the challenges with exchanging SNI related information between trading partners. We encourage the Board and the FDA to provide guidance to the industry by publishing regulations that define clearly the expectations for interoperability. Before the stakeholders within the pharmaceutical supply chain can successfully comply with the CA pedigree law, a number of key areas require resolution with respect to interoperability, including the following:

I. **Interoperable Electronic System Specifications** – Will a single industry solution or will multiple solutions be acceptable? What will be the planned architecture – e.g., centralized, semi-centralized, distributed/de-centralized? What are the data specifications that are required to ensure interoperability across trading partners – e.g., field lengths and formats?

II. **Document Pedigree Model System (DPMS) vs. Electronic Product Code Information System (EPCIS)** – Can a pedigree on request model using the EPCIS standards be used instead of the document based DPMS? Are physical pedigree documents required? What are the requirements for system availability? Can a pedigree document be electronically generated at the time of the inquiry? Are electronic signatures required to verify the authenticity of a product’s pedigree?

III. **Management and Accountability for the Interoperable Electronic System** – Who is responsible for funding, managing and operating the interoperable system? Who is tasked with running the interoperable system on a day-to-day basis? Who is responsible for data integrity within the interoperable system?
b) **Phased Implementation and Enforcement Discretion** – Since California's pedigree law requires interoperability across the industry, we recommend that the Board formally state that it will exercise its discretion when enforcing the provisions contained across the phases and milestones as defined by the law, until the Board verifies that the majority of supply chain participants can exchange SNI related information.

c) **Liability** – With respect to liability, as stated previously, we intend to make information available through an EPCIS compatible system so that our trading partners can verify our product's SNI and the relevant business event information related to our products. We intend to certify the accuracy of the information related to our outbound shipments, and to certify the authenticity of an SNI on request.

However, we believe that manufacturers should not be held liable and, indeed, cannot be held liable for actions by our downstream participants, and for those participants who do not verify pedigree information. In particular, we should not be held liable to certify to the accuracy of a pedigree once legal title has been transferred to another entity.

We support the comments made in the submission by the Pharmaceutical Research and Manufacturers of America (PhRMA). Specifically, PhRMA's views related to liability and the challenges with achieving a "zero defect system" for the purposes of certification.

Thank you again for the opportunity to provide feedback on the Board's request for information on inference. If you have any questions or comments regarding the points raised in this letter, please feel free to contact me at (510) 248-2362.

Sincerely,

Nancy Noe
Manager, State Government Affairs & Policy
September 1, 2012

Ms. Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

Re: Opportunity to Submit Information Necessary to Possible Board Rulemaking on Inference and Certification of Individual Package Units – Drug Pedigree Law (July 23, 2012)

Dear Ms. Herold:

On behalf of McKesson Corporation (“McKesson”), I appreciate the opportunity to respond to the State of California’s Board of Pharmacy (“Board”) request for comments regarding inference and its use in the context of California’s electronic pedigree law.

For 179 years, McKesson has led the industry in the delivery of medicines and healthcare products to drug stores. Today, a Fortune 14 corporation, we deliver vital medicines, medical supplies, care management services, automation, and health information technology solutions that touch the lives of over 100 million patients in healthcare settings that include more than 25,000 retail pharmacies, 5,000 hospitals, 200,000 physician practices, and over 10,000 extended care facilities and 700 home care agencies. McKesson delivers medicines to the entire Department of Veterans Affairs system, as well as to a significant number of Department of Defense and other government facilities. McKesson is also one of the nation’s largest distributors of biotechnology and specialty pharmaceutical products and services for providers and patients.

Based on our expertise in pharmaceutical distribution and our history of providing recommendations to the Food and Drug Administration and selected states on technologies and standards to further secure the drug supply chain, we are pleased to provide comments on inference relative to the California drug pedigree law.

Below are responses to the information needed for possible Board rulemaking.

1. **Identifying and contact information for the submitting person or entity.**
   Mr. Ron Bone, Senior Vice President, Distribution Operations, McKesson Pharmaceutical at 415-983-7613 or ron.bone@mckesson.com

   Mrs. Ann Richardson Berkey, Senior Vice President, Public Affairs, McKesson at 415-983-8494 or ann.berkey@mckesson.com
2. A description of the submitting party’s interest in this subject, including the submitting party’s role, if any, in the supply chain (e.g., manufacturer, repackager, distributor, or dispenser) or other basis for interest (e.g., vendor, consultant, standards body) and a brief description of the person, company, or other entity responsible for the submission.

McKesson is a national pharmaceutical and medical supply wholesale distributor with two pharmaceutical distribution centers and two medical-surgical distribution centers located in the state of California. We have two pharmaceutical supply distribution centers located in Denver, CO and Olive Branch, MS which supply these California facilities.

Mr. Ron Bone has represented McKesson in GS1 Standards and Traceability standard setting efforts for the past eight years and has been participating regularly in federal and state discussions regarding serialization, traceability and pedigree.

3. If the submitting party is a supply chain participant, a detailed description of the means and methodology, including hardware and software specifications, processes, and data carrier(s), that the submitting party has deployed or intends to deploy to “verify and validate the delivery and receipt of dangerous drugs against [electronic] pedigrees at the unit level,” including specification of the means and methodology for certification.

McKesson seeks to protect the integrity of the pharmaceutical supply chain while ensuring the delivery of safe medicines to patients. We scrutinize our trading partners and hold trusted relationships with these manufacturers. Today, McKesson initiates the purchase of product through the issuance of a purchase order (PO) with the manufacturer. Upon receipt, we confirm the physical order and the data feed associated with that specific product order.

It is our expectation that manufacturers will provide products to McKesson with GS1 compliant 2D Barcodes. McKesson has deployed a GS1 compliant traceability solution in the two California pharmaceutical distribution centers and is installing the same solution in the rest of the distribution network. We are currently using this system in the pilot projects we are conducting with manufacturers and supplying feedback to GS1 on system enhancements that should be included in the standard. This system will compare the serial numbers from the data collected from the manufacturer to the serial numbers on the products picked for the customer. Only products that have a match in our data system will be allowed to be shipped to the customer. Any products that do not match will be isolated in a quarantine area for further investigation by the shipper.

4. If the submitting party is seeking a regulatory allowance for inference, a specific request for same along with a detailed description of the particular circumstance(s) and/or those transaction(s) under which or pursuant to which there is a perceived need for inference. Define the requested inference(s) as specifically as possible, and where possible provide a limiting descriptor for such transaction(s) that could be used in regulatory language. In addition, provide as much data as possible regarding the factual circumstance(s) and/or transaction(s) in question, including the number and percentage of transaction(s) to which such an inference might apply, both with regard
to the submitting party and in the supply chain as a whole, and any trading partners that will be involved in the inference(s).

Inference is an important element of any implementation strategy for pharmaceutical distributors and its allowance by the Board is essential to enable distributors to meet the goals and requirements of the California law.

McKesson intends to comply with all applicable laws and plans to utilize inference in its receipt and shipment of serialized product into our distribution centers. We encourage the Board to allow us to scan the case label of a manufacturer’s sealed case and match that serial number to the data provided by the manufacturer. When we have a match, we want to be able to infer that the unit serial numbers (SNI) that the manufacturer linked to the case serial number are correct. We further want to ship this sealed case to a customer’s or to another McKesson distribution center using inference and without a requirement to break the sealed case and read the unit level serial numbers. The vast majority of our inbound shipments come to McKesson in the manufacturers’ sealed cases.

In preparation for the practice of inference, McKesson will develop a detailed standard operating procedure (SOP) to ensure that the process meets specific criteria. As with all of our distribution processes, we employ Six Sigma methodology to minimize the occurrence of errors.

5. If the submitting party is opposed to a regulatory allowance for inference, either generally or with regard to particular circumstances/transactions, a detailed description of same that as closely as possible meets the requirements of item 4., noted above.

We are not opposed to regulatory allowance for inference.

6. The detailed reason(s) that such an inference is necessary and/or advantageous, and either decreases risk(s) of diversion or counterfeiting (or other risk(s) in the supply chain), holds risk(s) constant, or does not unacceptably increase such risk(s). Or the detailed reason(s) any inference(s) is/are unnecessary, disadvantageous, or unacceptably increase(s) risk(s).

Ensuring the integrity of the manufacturer’s case is an important safeguard. A number of our larger customers will only accept product from us in the manufacturer’s sealed case. In our distribution centers, the backup stock is kept in the manufacturer’s sealed case until it is brought to the picking area and prepared for picking for the customer order. When a customer orders items at the unit level, we will compare the unit serial number with the number provided to us by the manufacturer to be sure we have a valid item. Only products that have a match in our data system will be allowed to be shipped to the customer. Any products that do not match will be isolated in a quarantine area for further investigation by the shipper.
7. Proposed SOPs that incorporate and explain the use of the inference(s), and describe the proposed process for statistical sampling to ensure the accuracy of pedigree information.

The industry developed a document in conjunction with GS1 entitled “The Practice of Inference”, which was published in 2010 and is available on the GS1 website. McKesson will base the development of its detailed standard operating procedure (SOP) for inference on this document.

8. A proposal for the allocation of any liability that may be incurred due to use of inference.

A distributor should not be held financially liable for the accuracy of the electronic data that they receive from their supplier. Since it is likely not the intent of the packager or manufacturer of the product to improperly record the aggregation of pieces in the case, these ‘honest’ mistakes should be communicated to the original packager or manufacturer so that discrepancies can be addressed. When these problems are detected and a supply chain partner discovers that the serial number on the product that they currently possess does not have a proper ‘chain of custody’ (for example, they do not have a record that shows that they should have this product), this discrepancy must be reported to the relevant parties, including regulatory bodies. Appropriate action should be taken to either correct the situation or return the product to the manufacturer of the product.

Any financial liability should be directed to protecting the supply chain and the detection and elimination of adulterated and counterfeit product.

On behalf of McKesson, we appreciate this opportunity to provide comments to the Board and to share our perspective regarding the use of inference to track prescription drugs. McKesson seeks to protect the integrity of the pharmaceutical supply chain while ensuring the rapid and safe delivery of medicines to patients.

We look forward to working with the Board as rulemaking on inference is further developed. Should you have any questions, please contact me or Ron Bone, Senior Vice President, Distribution Operations, McKesson Pharmaceutical, at 415-983-7613 or ron.bone@mckesson.com.

Sincerely,

Ann Richardson Berkey
Opportunity to Submit Information Necessary to Possible Board Rulemaking
On Inference and Certification of Individual Package Units – Drug Pedigree Law

The following comments are submitted on behalf of Medline Industries, Inc. We appreciate the opportunity to express our views on the importance of inference in the California pedigree system. Should the Board have any questions, please do not hesitate to contact Rob Calia at the contact information detailed below.

1. Identifying and contact information for the submitting person or entity.

   Company: Medline Industries, Inc.
   Primary Contact: Rob Calia
   Address: One Medline Place
            Mundelein, IL 60060
   Phone: (847) 643-4249
   Email: rcalia@medline.com

2. A description of the submitting party’s interest in this subject, including the submitting party’s role, if any, in the supply chain (e.g., manufacturer, repacker, distributor, or dispenser) or other basis for interest (e.g., vendor, consultant, standards body) and a brief description of the person, company, or other entity responsible for the submission.

Medline manufactures and distributes more than 125,000 products (including prescription drugs) to hospitals, extended care facilities, surgery centers, physician offices and home care dealers. Medline has a network of 50 manufacturing and distribution centers worldwide, including three distribution centers in the state of California.

Our interest in this subject primarily relates to our role as a wholesale distributor of pharmaceuticals.

3. If the submitting party is a supply chain participant, a detailed description of the means and methodology, including hardware and software specifications, processes, and data carrier(s), that the submitting party has deployed or intends to deploy to “verify and validate the delivery and receipt of dangerous drugs against [electronic] pedigrees at the unit level,” including specification of the means and methodology for certification.

In the absence of further guidance and having not yet participated in or seen the results from successful, supply chain wide, pilots, we have not yet made final determinations on the specific means and methodology we will use to comply with California’s ePedigree requirements.

Medline currently uses a purchased software system to pass electronic pedigrees. We anticipate using a similar or upgraded version of this software to comply with California’s ePedigree requirements.

4. If the submitting party is seeking a regulatory allowance for inference, a specific request for same along with a detailed description of the particular circumstance(s) and/or those
transaction(s) under which or pursuant to which there is a perceived need for inference. Define the requested inference(s) as specifically as possible, and where possible provide a limiting descriptor for such transaction(s) that could be used in regulatory language. In addition, provide as much data as possible regarding the factual circumstance(s) and/or transaction(s) in question, including the number and percentage of transaction(s) to which such an inference might apply, both with regard to the submitting party and in the supply chain as a whole, and any trading partners that will be involved in the inference(s).

Because of the cost and unreliability of Radio Frequency Identification (RFID) technologies, we anticipate that the vast majority of manufacturers will serialize using two-dimensional matrix barcodes, which require a line of sight scan. If required to manually unpack each case and pallet and scan each individual unit, the entire pharmaceutical distribution chain will break down—endangering public health and safety by significantly exasperating drug shortages while drastically increasing the cost of pharmaceuticals for California consumers.

Therefore, we anticipate that the majority of our transactions will involve inference. We anticipate that we would utilize inference on approximately 70% of incoming product. We anticipate that we would utilize inference on approximately 15% of outgoing product.

On receipt of a product, we believe that scanning should occur at the level of product purchased (e.g. if Medline purchases a sealed case, we would scan the case and infer the Standardized Numerical Identifier (SNI) for each unit within the case). On sale of product, we believe scanning should occur at the level of product sold (e.g. if Medline sells a sealed case, the case would be scanned and inference would be used to collect the SNI for each unit within the sealed case).

With approximately 500 million prescription dispensed in California each year, we believe the only way the system can possibly function without significantly delaying the delivery of prescription drugs is to allow inference in this way.

Example 1: Medline purchases and then resells an entire pallet of drug X. Medline purchases a pallet of drug X from the manufacturer of drug X or an Authorized Distributor of Record (ADR) of drug X. Upon receipt of the pallet, Medline would use inference to collect the SNI for each individual unit contained within the pallet—leaving the pallet itself sealed. Upon resell of the sealed pallet, inference would again be used to capture the SNI from each outbound unit within the sealed pallet.

Example 2: Medline purchases a pallet of drug X, breaks down the pallet to the case level, and then sells a sealed case. Medline purchases a pallet of drug X from the manufacturer of drug X or an ADR of drug X. Upon receipt of the pallet, Medline would use inference to collect the SNI from each individual unit contained within the pallet—leaving the pallet itself sealed. When the pallet is opened for the sale of a sealed case contained within the pallet, inference would again be used to capture the SNI from each outbound unit within the sealed case.

Example 3: Medline purchases and then resells an entire case of drug X. Medline purchases a case of drug X from the manufacturer of drug X or an ADR of drug X. Upon receipt of the case, Medline would use inference to collect the SNI from each individual unit contained within the
case—leaving the case itself sealed. Upon sale of the sealed case, inference would again be used to capture the SNI from each outbound unit with the sealed case.

*Example 4: Medline purchases a case of drug X, breaks down the case to the unit level.* Medline purchases a case of drug X from the manufacturer of drug X or an ADR of drug X. Upon receipt of the case, Medline would use inference to collect the SNI from each individual unit contained within the case—leaving the case itself sealed. When the case is opened for the sale of an individual unit(s), individual units will be scanned to capture the SNI.

5. *If the submitting party is opposed to a regulatory allowance for inference, either generally or with regard to particular circumstances/transactions, a detailed description of same that as closely as possible meets the requirements of item 4., above.*

Medline supports the use of inference, as described above.

6. *The detailed reason(s) that such an inference is necessary and/or advantageous, and either decreases risk(s) of diversion or counterfeiting (or other risk(s) in the supply chain), holds risk(s) constant, or does not unacceptably increase such risk(s). Or the detailed reason(s) any inference(s) is/are unnecessary, disadvantageous, or unacceptably increase(s) risk(s).*

We believe that inference can be used in the ways described above without increasing the risk of diversion or counterfeiting (or other risks(s) in the supply chain) and may in fact reduce some supply chain risks.

7. *Proposed SOPs that incorporate and explain the use of the inference(s), and describe the proposed process for statistical sampling to ensure the accuracy of pedigree information.*

Our SOPs will be shaped by the statutorily mandated regulations under development by the Board. In the absence of these regulations and without a more complete understanding of how manufacturers will utilize inference and aggregation Medline is unable to craft detailed SOPs.

8. *A proposal for the allocation of any liability that may be incurred due to use of inference.*

We believe any liability that may be incurred due to the use of inference should be assumed by the aggregator—e.g. the manufacturer or repackager. The aggregator is the one who makes and certifies the aggregation which those further down the supply chain must rely upon. Should there be any issues with that initial aggregation/inference, the manufacturer or repackager who made it should be fully liable.
August 31, 2012

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

RE: Opportunity to Submit Information Necessary to Possible Board Rulemaking On Inference and Certification of Individual Package Units – Drug Pedigree Law

Dear Ms. Herold:

MERCK & CO., INC. appreciates the opportunity to provide information to the California Board of Pharmacy (the Board) in response to its request for information for a possible Board rulemaking on inference, pursuant to California Business & Professions Code § 4163.3. Merck is fully supportive of appropriate measures to increase supply chain security. The seriousness of pharmaceutical counterfeiting goes well beyond the financial impact that is experienced by other industries. When counterfeit pharmaceuticals are introduced into U.S. commerce, patient safety and confidence in our drug distribution system is compromised and the potential for patient harm, including even death exists. It is for this reason that we continue to believe that a national system should be developed, aligning all states with a system that is both technically viable and will foundationally support further enhancements, if required.

Merck is a global healthcare company working to help the world be well:

- We manufacture and provide innovative medicines, vaccines, biologic therapies and consumer and animal health products to help improve health and well-being;
- We work with customers in 140 countries to deliver broad-based healthcare solutions; and
- We demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships to help people around the world lead healthier lives.

Merck has been actively engaged in standard setting groups such as GS1 and currently co-chairs the National Council for Prescription Drug Programs (NCPDP) work group 17 on product traceability. As a global company, we have also been active in the European Federation of Pharmaceutical Industries and Associations (EFPIA) in the development of the European pharmaceutical authentication system and have successfully deployed serialized product in specific markets based on their requirements.
Merck has performed pilot programs and continues to make significant investments to prepare for the future supply of serialized product to the U.S. market. In fact, some earlier investments, such as in software as an example, may never be utilized since the method to communicate serial numbers has not been fully defined (i.e., DPMS electronic pedigree most aligned with current California law versus EPCIS track and trace aligned with the FDA vision).

Merck is supportive of inference. We believe it is necessary and should be permissible. Today, inference is widely and effectively used throughout the supply chain to ascertain key information (i.e., product, lot number and expiration date) regarding product in scaled, homogenous cases. Another example would be for supply of bulk tablets to off-site packaging operations. In this latter situation, appropriate controls are maintained when Merck fills drums of tablets to assure the identity of the product and the associated lot number are accurate. These scaled drums are then brought to a tablet filler, again through an appropriately controlled environment, allowing inference of the product and lot number in each bottle when packaged.

While we acknowledge the utility of inference, we also recognize its limitations. There are situations in which inference is not accurate enough. For example, the FDA requires that labeling use one-hundred percent electronic verification because using inference would not guarantee that a supply of labels from a supplier is homogeneous and the ramifications of a misbranded lot are serious enough to warrant recalls. Merck performs documented testing to prove the consistent reliability of these systems. This includes operator training, to ensure that each and every alarm is reviewed.

Further, inferring the serial number of each unit associated with each case is different than inference of tablets filled in bottles. First, each packaging line is different. Merck packages prescription drugs in various types of dosage forms, including, blisters, vials, tubes, and bottles - each with its own separate packaging process. Packaging is further complicated by the complexity of equipment, speed of the lines and available space to install new or additional equipment on existing lines, both at Merck facilities and/or at contract facilities. Exceptions in the packaging and distribution processes can have a dramatic impact on case accuracy. For example, if a machine stops, it may cause a change in the normal flow of product on a line impacting case accuracy. In the case of general business processes, the quality unit may sample from a selected case at any time while in our possession. If management of business processes after packaging are not managed correctly, such as the quality sampling example, case accuracy may also be impacted.

In distribution, product is picked into totes that will again have its content inferred. This is currently done for billing purposes and is managed in a similar way that lots are managed. However, transitioning the level of inference from its current use for billing purposes to inferring all serial numbers is a significant leap in technology and business processes for the quantities and varieties of packages required for the State of California.
This is another area that will take substantial efforts to improve if current error rates are not acceptable.

We respectfully submit that the Board considerations, include the level of accuracy required for serial number aggregation and whether that level of accuracy may be achieved through the varying processes within the supply chain. The example often cited by the California Board of Pharmacy is the ability to pick a product on the shelf and establish where it has been. What if this cannot be established because of a glitch in inference? In accordance with 4163.3 (c), what should be the disposition of that product and what supply chain partner should be responsible for the glitch?

Given the concerns regarding accuracy outlined above, Merck is also concerned with how statistical sampling may be applied to the inference process as requested in 4163.3 (d). If one was to use ANSI ASQ Z1.4 2008: Sampling Procedures and Tables for Inspection by Attributes, as an example, there would be a number of variables that all come back to the level of acceptable risk. Developing a sampling plan using this methodology requires understanding confidence limits, acceptable quality levels, lot size and sampling locations. From a manufacturer's perspective, each packaging line would represent a different process having its own unique operating curves. As the Board considers statistical sampling requirements, it should consider what the impact would be if a lot fails statistical evaluation? Would that product be acceptable for sale? Would it put into question other packages within that lot?

With respect to inference upon the effective date, Merck agrees that it:

- **Can** certify that the correct product, lot, and expiration date are aggregated to a sealed, homogeneous case allowing for accurate inference.
- **Can** certify that case and individual unit serial numbers are aggregated to a lot allowing for accurate inference.
- **Can** verify the serial number associated with sealed, homogeneous cases along with its recipient.

However, Merck **Cannot** certify the level of accuracy for individual unit serial numbers being aggregated to a case number. We will require considerable commercial operation, assessment time (not pilot) to fully evaluate every potential cause for variation and to understand the impacts of corrective actions.

Finally, with respect to responsibility, Merck should not be held responsible for downstream participants who do not verify pedigree information. Manufacturers can only reasonably be expected to certify to the accuracy of the information they generate with each outbound shipment, and to, with appropriate security controls in place, certify to the authenticity of particular standardized numerical identifiers, when requested. Once
a product is outside of a manufacturer's control, it is not reasonable or feasible to hold that manufacturer responsible.

In conclusion, Merck appreciates California's efforts to highlight this important national issue. We are committed to doing our part in enhancing supply chain security in a manner consistent with our capability and Merck will work to continually improve that capability. We believe that inference should be allowed based on both process capability and level of acceptable risk. It is critical that, for this system to meet safety objectives, the rule making process takes in all comments and considerations when establishing achievable expectations.

Merck appreciates the Board's leadership in protecting the public and providing us an opportunity to provide input on this important legislation. Please do not hesitate to contact me should you have any questions.

Sincerely,

Steve Drucker
Director, GPC Package Technologies
Reg. Compliance & Distribution Support
Merck
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steve.drucker@merck.com
August 29, 2012

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 North Market Blvd., Suite N219
Sacramento, CA 95834

RE: Comments regarding Inference and Certification of Individual Package Units – Drug Pedigree Law

Dear Executive Officer Herold:

The California Retailers Association (CRA), the California Pharmacist Association (CPhA) and the National Association of Chain Drug Stores (NACDS) thank the Board of Pharmacy (“Board”) for the opportunity to submit written comments in response to the Board’s request for information regarding supply chain participants’ ability to use or rely on inference(s) as to the contents of aggregate containers for purposes of certification of delivery or receipt of individual package units of dangerous drugs, as required by the California electronic pedigree law.

The retail community pharmacy industry is committed to maintaining and enhancing the safety and security of the U.S. drug distribution supply chain through feasible and workable means. We believe that the United States prescription drug distribution system is one of the safest in the world, if not the safest. A number of proactive safety measures in the private sector and a comprehensive set of federal and state laws and regulations contribute to this safety. We are proud of the private sector initiatives that our members have taken along with other industry stakeholders to enhance the security of the U.S. drug supply chain. Retail community pharmacies have made changes in their purchasing practices, such as requiring their wholesale distributors to purchase prescription drug products directly from manufacturers. This policy creates a secure system of distribution known as the “normal distribution channel” -- a direct flow of product from the manufacturer to the wholesale distributor, and to the pharmacy for dispensing.

Contact Information
The contact information for the submitting entities and persons are provided at the conclusion of this letter.

Submitting Parties’ Interest in this Subject
CRA is a statewide trade association representing all segments of the retail industry including chain drug stores. CPhA is the largest statewide pharmacy association in the country, with over 5,000 members practicing in all practice settings. Additionally, CPhA represents nearly 1,000 independent community pharmacies operating throughout California. NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 40,000 pharmacies and employ more than 3.5 million employees, including 130,000 pharmacists. Our members dispense over 2.6
billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. In the state of California, NACDS represents 20 companies operating 3,916 pharmacies.

### Reasons Inference is Necessary and Advantageous

While we continue to have concerns about the necessity and effectiveness of extending electronic pedigree requirements to individual community pharmacies, we believe that allowing inference is a significant and necessary component for maintaining supply chain integrity under California’s electronic pedigree law. Inference must be available for use by pharmacies and other supply chain participants. Allowing inference at the pallet, case, and tote levels is critical to preserve supply chain security and enhance patient safety by preserving the integrity of the pallet, case, tote or other aggregated distribution unit.

Without inference, it is highly likely that the aggregated product, e.g. pallets, cases, totes, would need to be opened, creating the potential for loss of product, diversion, and risks to the safety and security of the supply chain. We believe that inference has the potential to decrease the risk of diversion and enhance security and safety by maintaining the integrity of the aggregated containers.

Without inference, each pallet, case, or tote would have to be opened and each individual drug package scanned. This would lead to an inefficient, costly, and time consuming process that would cripple the entire drug distribution supply chain. Without inference, the supply chain will likely see insurmountable product delays from having to manually scan millions of products. As a result, pharmacies will have difficulties meeting the medication needs of their patients. Moreover, opening up the boxes or containers for scanning will destroy the security of the sealed containers. Imposing such an inefficient time-consuming system on pharmacies and other healthcare providers makes little sense.

### Proposed Standard Operating Procedures

At this time to our knowledge, due to the very limited availability and use of serialized prescription drug product packages, we believe that standard operating procedures are under development. As associations that representing retail community pharmacists and pharmacies, we look forward to the development and review of such procedures as they are made available. We defer our comment until that time.

### Liability

In regards to liability, we believe that liability has little usefulness in the area of inference. However, we certainly believe that pharmacies should not be held liable for inaccurate packing by the wholesaler or manufacturer. Rather, we believe that the better approach is to understand the complexities of this as yet untried and untested system, and therefore to allow supply chain stakeholders to exist in a learning environment. This system is not in use in California and is being built from the ground up. As such, we recommend that liability be forestalled as stakeholders learn this new system.

### Conclusion

Although our concerns remain about the feasibility and workability of California’s electronic pedigree law, we support inference and believe that it is a critical component of the electronic pedigree process. Please do not hesitate to contact Mandy Lee with the CRA at mlee@calretailers.com or 916-425-8481, Brian Warren with CPhA at bwarren@cpha.com or 916.779.4517, or Mary Staples with NACDS at mstaples@nacds.org or 817.442.1155 if we can provide further assistance.
Sincerely,

Mandy Lee                      Mary Staples
Director of Government Affairs  Director of Government Affairs
California Retailers Association National Association of Chain Drug Stores

Brian Warren
Director of Government & Professional Affairs
California Pharmacists Association
August 27, 2012

California State Board of Pharmacy
1625 N Market Blvd.
Suite N219
Sacramento, CA 95834

Re: Opportunity to Submit Information Necessary to Possible Board Rulemaking On Inference and Certification of Individual Package Units – Drug Pedigree Law

Dear Board of Pharmacy:

NCPDP is a non-profit ANSI-accredited Standards Development Organization consisting of more than 1,600 members who represent computer companies, drug manufacturers, pharmacy chains and independents, drug distributors, insurers, mail order prescription drug companies, pharmaceutical claims processors, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

NCPDP and its membership are interested in a safe, secure and efficient supply chain for drugs and biological products.

NCPDP Response:
The stated goal of the pedigree regulation is to establish and implement a system to ensure patient safety and improve the security of the drug supply chain against counterfeit, diverted, sub potent, substandard, adulterated, misbranded, or expired drugs. Inference is essential to the practical achievement of this goal.

Inference, as it is currently used within the supply chain, supports both the security of the product being shipped and the efficiency of the supply chain. The manufacturer/repackager, following established security protocols, seals and places the identifier on a case (or higher level shipping container) of medication prior to shipping. So long as that seal is unbroken, the downstream trading partners can trust, i.e. infer, that content received is the content packed by the manufacturer/repackager. If an error is found on opening the container at the point of use, then it can be reported back to the manufacturer/repackager and the product quarantined until the problem is resolved.

To not use inference, that is, to inspect the contents of every case as it moves through the supply chain, would dramatically slow the movement of products, but more importantly, it would substantially increase the opportunity for substitution and diversion. If a problem is found at the point of use, there is no way to pinpoint where it occurred since the integrity of the case was not maintained to the final destination.
Conclusion
Inference allows a reasonable level of security with a lower expenditure of resources and may even protect the supply chain from introduction of adulterated, misbranded or counterfeit product that could otherwise be missed due to the massive number of reviews that would be required. Therefore, the use of inference can provide the necessary protection while allowing the reasonable flow of product through the drug distribution chain.

Enhancing the safety and security of the prescription drug supply chain is of acute interest to NCPDP and its members. For the last four years NCPDP Work Group 17 Pharmaceutical Pedigree and Traceability has explored the many facets of pedigree, track and trace regulations and other potentially inter-related pharmacy technology initiatives. Based on our experience with the successful implementation of networked systems, NCPDP understands the magnitude of developing and implementing a track and trace system.

NCPDP stands ready to assist the CA Board of Pharmacy in achieving consensus and support within the pharmaceutical industry for the development and implementation regulations to enhance the safety and security of the drug supply chain.

Thank you for the opportunity to respond to this request for comments.

For direct inquiries or questions related to this letter, please contact
Sue Ann Thompson
Standards Advisor, NCPDP
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Sincerely,

Lee Ann C. Stember
President
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
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cc: NCPDP Board of Trustees
The Pharmaceutical Distribution Security Alliance
Response to the California State Board of Pharmacy
Regarding Inference and Certification of Individual Package Units

INTRODUCTION

The Pharmaceutical Distribution Security Alliance (PDSA) appreciates the opportunity to submit these comments in response to the request of the California State Board of Pharmacy (the Board) for information necessary to any Board rulemaking on inference and certification of individual package units – drug pedigree law (Bus. & Prof. Code, §§ 4034, 4163 et seq.).

PDSA’s mission is to develop and help enact a federal policy proposal that enhances the security and integrity of the domestic pharmaceutical distribution chain for patients, and to articulate a technical migratory pathway to implement such a policy. Our primary goal is ensuring patients have uninterrupted access to safe, authentic, U.S. Food and Drug Administration (FDA)-approved medicine. Membership of PDSA spans the entire spectrum of the U.S. pharmaceutical distribution chain, including manufacturers, wholesale distributors, third-party logistics providers, and pharmacies. Twenty-nine organizations are formal members of PDSA, while many other external stakeholders provide additional policy and technical support to the group. Please see the “About Us” document attached for more information about the submitting party, including contact information for PDSA.

While we are fortunate to live in a nation where the pharmaceutical distribution chain is relatively safe, grave threats from sophisticated criminal elements still exist, and are becoming more severe. PDSA appreciates the efforts of the Board to protect California consumers by preventing, assessing, and responding to threats of prescription drug counterfeiting and diversion in the state supply chain. We agree with the Board, FDA and other stakeholders that more must be done to protect U.S. patients from these public health threats.

RESPONSE¹

The ability to use or rely on inference(s) as to the contents of aggregate containers for purposes of certification of delivery or receipt of individual package units of prescription drugs is operationally essential to facilitate the efficient movement of prescription drugs in California.

We encourage the Board to carefully consider the technical input from the many diverse participants in the distribution chain, whose abilities and needs may vary depending on the nature and scope of their operations and the California populations they serve. PDSA, with membership representing a broad spectrum of distribution chain participants, fully appreciates the difficulty of crafting policies and rules that will be feasible for all stakeholders – but striking this balance is essential when seeking to craft a comprehensive supply chain security system, as the chain is only as strong as its weakest link. We encourage the Board to remain highly attuned to this challenge as it considers possible rulemaking.

The California statute will require the creation of a substantial interoperable electronic system to connect the thousands of unique participants in the pharmaceutical distribution chain to enable tracking and tracing all individual prescription drug product packages at the smallest saleable unit (“unit”) through use of “electronic pedigrees” (e-pedigree) showing the full distribution history of each

¹ Separate and distinct from these comments, PDSA members may also opt to respond to the Board’s request for information in their individual capacity. Any such response should not be construed to reflect the views of PDSA.
individual unit sold in the state. Creating such a system that consistently and efficiently works for the thousands of small and large entities in the distribution chain – including drug manufacturers, wholesale distributors, third-party logistics providers, and retail, independent, hospital and clinic pharmacies – is a novel, complex, expensive, and highly technical undertaking. Accordingly, PDSA appreciates the Board’s recognition that technical input from distribution chain participants is essential to the development and implementation of a new pharmaceutical distribution system.

While we fully expect that all legitimate companies interested in continuing to do business in California will seek to comply with the e-pedigree law, we recognize the substantial challenges in doing so. As such, it is critical to establish an interoperable electronic system that meets an industry accepted standard that connects all trading partners and allows for the reliable and efficient exchange of e-pedigree data in order for companies to be able to comply with the California law.

A. Compliance with the California Law Requires a Workable Interoperable Electronic System

Functional technology and interoperability is the foundation of the envisioned California e-pedigree system, and is the essential first step for companies seeking to comply with the law. While regulations on inference and certification are important to creating a functional e-pedigree system, without a workable interoperable electronic system as the starting point, even the most consensual driven regulations would be of limited utility.

To enable companies to comply with the California law, the interoperable electronic system must function for every one of the thousands of entities in the pharmaceutical distribution chain operating and doing business in California. Unless all can do it, the ability of only some (or even most) companies and healthcare entities to exchange e-pedigree data will be negate the intended results as the required chain of ownership would be broken in many instances. Simply put, unless the e-pedigree system works for all of us, it works for none of us, and interoperable exchange of e-pedigree data is the keystone to the CA system.

B. Concerns with the Current State of E-Pedigree Technology and Interoperability

The envisioned California e-pedigree system relies on an interoperable electronic system(s) that connects all trading partners and ensures an efficient and secure exchange of e-pedigree information. Though efforts to create such a system are ongoing, no such system currently exists for all participants in the chain, and industry discussion and debate about the most efficient and effective model continues. This creates significant compliance challenges that cannot quickly or easily be overcome:

- The development of standards for information exchange and business process for data management (including protocols regarding master data and exceptions management), and the reliable use of vendor systems takes time and testing. Even if these pieces were in place for manufacturers, all downstream partners must also have an interoperable system including the availability and testing of the necessary standards in place to exchange serial numbers, e-pedigrees, and associated transaction information (i.e. from shipments, receipts, returns, etc).

- Despite many stakeholders’ attempts to build systems to comply with the e-pedigree law, there is very little data to estimate expected failure rates. As an example: for just one company, even a 99% accuracy rate would result in exceptions impacting 550,000 units each year, meaning approximately 2,201 items per day could enter the supply chain and would be inaccurate, thereby compromising the integrity of the system. Moreover, any of the errors that surface could sit in quarantine awaiting resolution. If each company along the supply chain experiences 1% or even higher failure rates, the amount of possibly inaccurate and possibly quarantined...
product is further increased. If current pilot projects’ accuracy rates do not improve, the
distribution of many thousands of products would be inaccurate and could be delayed. Such
findings highlight the need for extensive testing of this functionality across all products, all
trading partners, and all shipping/receiving points well in advance of the effective date of such a
requirement.

➢ In another company’s pilot, the inference concept was tested in small application, using
transactions containing roughly 10,000 serialized units. The pilot used 2D and 1D GS1 standards
barcodes with aggregation of unit to case, case to pallet relationships. When the data
exchanged were 100% accurate to the labels for the product, inference did work. However,
when technical exception issues occurred – which many did – it either took tremendous time to
correct the problem or it could not be corrected at all. In this pilot, most of transactions
required some level of human intervention to correct technical issues; less than 10% went
through without error.

➢ Implementation of an interoperable electronic system is complicated by the fact that many
trading partners have varying legacy systems, different solutions providers, and significantly
different resources and capabilities to effectively deploy and test such a system.

While it is concerning that liabilities may be imposed on legitimate pharmaceutical distribution chain
participants not capable of meeting unproven expectations, technical challenges are not merely issues
that impact corporate compliance. Accuracy and interoperability – and in this case the lack thereof –
can compromise the integrity of the system and potentially impact patient access to medication and the
public health. According to IMS 2010 data, approximately 638,400,000 prescriptions are dispensed to
patients in California each year, and these products reach consumers through many more millions of
transactions in the pharmaceutical distribution chain. If any part of the complex e-pedigree process fails
– even if only for technological reasons – the prescription drug cannot be distributed, resulting in
possibly dangerous delays or limited supplies in medications available to patients due to slower
distribution schedules and large-scale product returns. We trust that all stakeholders will actively work
to avoid such outcomes that endanger the public health while also seeking to comply with the California
law.

CONCLUSION

While we agree with the Board’s intent to enhance patient safety, PDSA respectfully urges the Board to
consider the important prerequisite of proving the functionality and reliability of the interoperable
electronic system for all participants in the pharmaceutical distribution chain. Such is the essential first
step for companies seeking to comply with the California law and is critical for ensuring system accuracy
and integrity so that patients will continue to have timely, efficient access to prescription medications.

Thank you for your consideration.

The Pharmaceutical Distribution Security Alliance

Attachment: PDSA “About Us” Document
Pharmaceutical Distribution Security Alliance (PDSA)

Our Mission
The Pharmaceutical Distribution Security Alliance’s (PDSA) mission is to develop and help enact a federal policy proposal that enhances the security and integrity of the domestic pharmaceutical distribution system for patients, and to articulate a technical migratory pathway to implement such a policy. Our primary goal is ensuring patients have uninterrupted access to safe, authentic, FDA-approved medicine.

About Us
The Pharmaceutical Distribution Security Alliance is a multi-stakeholder and interdisciplinary initiative. Membership spans the entire spectrum of the U.S. pharmaceutical distribution system, including manufacturers, wholesale distributors, third-party logistics providers, and pharmacies. More than 20 companies are formal members of PDSA, while many other external stakeholders provide additional policy and technical support to the group.

Membership

For more information about the PDSA or this document, please contact:

Vince Ventimiglia
FaegreBD Consulting
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Liz Wroe
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August 30, 2012

California State Board of Pharmacy
1625 N. Market Boulevard, Suite N219
Sacramento, CA 95834

Re: Pfizer Inc.'s Submission Regarding Possible Rulemaking on Inference and Certification of Individual Package Units – Drug Pedigree Law (Bus & Prof Code § 4163.3)

To the Members of the California State Board of Pharmacy:

Pfizer Inc respectfully responds to the California State Board of Pharmacy’s (“the Board’s”) invitation to provide written comments regarding inference and certification of individual package units. (Bus. & Prof. Code, § 4034, 4163 et seq.)

As one of the world’s leading pharmaceutical manufacturers, Pfizer remains strongly committed to providing patients with safe and effective medications of the highest quality. We share the Board’s concern for the risk to patient health posed by counterfeit drugs, and welcome the opportunity to work with the Board and other stakeholders to develop effective mechanisms for preventing the insinuation of counterfeit drug products into the U.S. drug distribution system.

Pfizer believes that counterfeiting issues must be addressed on many fronts, including enhanced business practices, regulatory and legislative solutions, heightened enforcement, and employment of technology.

With this in mind, Pfizer respectfully offers the following comments:

**General Comments on Inference**

As a general matter, Pfizer believes that a single, federal serialization and traceability law is preferred to the existing patchwork of state pedigree requirements. While Pfizer continues to invest in serialization and works diligently toward compliance with the California pedigree law, we recognize that a phased-implementation approach is necessary. A migration path that begins with implementation of item-level serialization and deployment of the required IT infrastructure is a practical step toward the implementation of an item-level track-and-trace solution. To implement the California requirements, Pfizer strongly supports the need for inference.

www.pfizer.com
The use of inference implies the need for aggregation (associating serialized items to a serialized case, for example) and we believe an item-level track-and-trace solution will require aggregation. Aggregation requires a means to exchange information regarding the aggregated items (the serialized units contained in a serialized case). With respect to the exchange of serialized pedigree information, California's electronic pedigree law requires an interoperable electronic system. As a threshold matter, it must be emphasized that such an interoperable electronic system does not yet exist. As a result, Pfizer recommends the Board work with industry stakeholders, standards bodies, and the U.S. Food and Drug Administration (FDA), to define and enable such an interoperable electronic system on a national basis.

Industry is currently assessing three potential electronic systems or models: centralized, decentralized, and semi-centralized. In this context, "system," is used to mean a network that connects all the necessary stakeholders and provides a means for the secure, reliable, timely and cost-effective exchange of information. The nature of the ultimate "system" design and data requirements will impact the need for inference as well as the associated rules.

Since 2005, Pfizer has been working with industry stakeholders, solution providers and standards bodies to deploy and test our serialization capabilities, including our ability to aggregate individual serialized items to higher levels of logistical units (item to cases and cases to pallets) and to successfully exchange the associated data with our trading partners. We have implemented a drug pedigree messaging standard (DPMS) solution and are currently testing an EPCIS "event-based" pedigree model.

In order to align ourselves with where we believe industry is trending, Pfizer has recently made a decision to utilize 2D bar codes going forward as the primary data carrier for serialization, with linear and/or human readable back-up when possible. Pfizer's decision to use 2D bar codes is globally harmonized with initiatives in the EU and elsewhere; it is also aligned with the direction many other pharmaceutical manufacturers are pursuing in the U.S.

The use of 2D technology and the California requirement for item-level tracking necessarily requires the use of inference, given that it is not practical or advisable for others in the supply chain to open sealed cases from the manufacturer for the sole purpose of the confirming serial numbers. In fact, to require sealed manufacturer's cases be opened to scan serial numbers would destroy tamper evident tape and other features designed to alert supply chain participants to potential issues with the package. Indeed, opening cases that are outside the manufacturers' control, as a normal course of business, would increase supply chain risk by increasing the opportunity for theft, diversion and tampering that would then go unnoticed as opening and resealing cases would become common place.

**Pedigree Certification**

With respect to pedigree certification, based on our pilot experience, we believe unavoidable aggregation errors will sometimes occur, especially in the early stages of adoption of an item-level track-and-trace system. We also believe that other
mistakes are likely to occur, such as shipping errors and master data management issues. As a result, the Board should allow for reasonable accommodations to be made for these situations.

For example, the Board should recognize that if a rigid certification requirement is mandated, which does not allow for exceptions or unintentional errors, the inability to provide an unrestricted certification will likely impede the flow of goods. The inability to resolve these unavoidable errors and exceptions in a timely manner due to strict certification requirements, may impede the flow of goods and prevent them from reaching patients when needed.

**Allocation of Liability**
Concerning the allocation of liability that may be incurred due to the use of inference, Pfizer believes that provisions or allowance should be made in the Board’s rulemaking process to distinguish between unintentional shipping or technology/data errors and intentional misrepresentations of information for the purpose of introducing counterfeit or diverted product into the legitimate supply chain. More specifically, it would be unreasonable to expect that there will never be inadvertent or unintentional errors with physical shipments, whose errors are then captured in a pedigree. It is our belief that the intent of the California law is not to prosecute individuals or organizations for unintentional shipping errors. Nor, do we believe the unintended consequence of unnecessary delays in the delivery of important medications to patients should be permitted as a result of unintentional shipping errors.

As a result, the requirements for certification relating to pedigrees should reflect this reality and provide that inadvertent and unintentional errors would not render a certification to be considered false. Further, at best, any entity within the supply chain can only certify as to the information that such entity provides. Entities should not be liable for the accuracy of information that the entity cannot itself verify, e.g., information supplied by participants further down the supply chain. This should be clarified through the rulemaking process.

Regarding liability associated with the accuracy of pedigree information using inference, we believe the Board should clarify that provided there are processes and procedures in place to ensure a reasonable degree of accuracy with respect to information contained in a pedigree based on the use of inference, no liability should flow from the reasonable and intended use of inference. To the extent any liability should be associated with the accuracy of pedigree information, it should be determined based on the intentional misrepresentation of information.

**Conclusion**
Finally, Pfizer supports the use of inference and believes it should be permissible in an item-level track-and-trace system. In fact, given the industry movement toward adoption of 2D bar code technology, we believe the use of inference is a necessity. We are committed to working with the California Board of Pharmacy, the FDA and other industry stakeholders to develop the requirements around its use. However, before the inference rules can be written, additional details about the item-level track-
and-trace system to be utilized are needed. There should be a better understanding of the complete process, including the system architecture and data requirements and how exceptions will be resolved in order to inform decisions around inference rules. For example, whether an item was read or "inferred" upon receipt will impact how an exception is resolved. The entire process is inextricably linked and must be defined before Inference rules can be determined.

Pfizer is committed to working with the Board, GS1, and others to further assess various system architecture models (the GS1 network centric e-pedigree models) and to address exception handling issues. We are actively engaged at this time in the work being done by GS1 Healthcare US to address the resolution of exceptions and in documenting findings from our pilot activities in the GS1 Implementation Guide, “Applying GS1 Standards to U.S. Pharmaceutical Supply Chain Business Processes”. We look forward to sharing this work with the Board when complete.

Pfizer appreciates the opportunity to provide this input to the Board and looks forward to working with you in the future. Please contact me at (212) 573-3192 if you have any questions.

Sincerely,

[Signature]

Tom McPhillips
Vice President
US Trade Group
Virginia Herold  
Executive Officer  
California State Board of Pharmacy  
1625 N. Market Blvd., Suite N219  
Sacramento, CA 95834  

Re: Use of Inference  

Dear Ms. Herold:  

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide information to the California Board of Pharmacy (the Board) in response to its request for information for a possible Board rulemaking on inference, pursuant to California Business & Professions Code § 4163.3. PhRMA represents the country’s leading innovative biopharmaceutical companies, who operate globally. PhRMA member companies are committed to researching and developing new medicines to help patients live longer, healthier lives.  

While PhRMA recognizes that the Board specifically requested input on inference, the Board’s request for information touches on key aspects of an interoperable electronic pedigree system that must first be defined, in order to fully evaluate inference. PhRMA also continues to believe that a national system is preferable to any one state system. Nonetheless, we remain committed to helping California implement its law, and encourage the Board to define the data elements, system architecture, and other infrastructure necessary to achieve an interoperable electronic system.  

Since California amended its law in 2008, PhRMA members have engaged in a number of pilot activities and have learned a great deal about data exchange and the elements and steps necessary to achieve an interoperable electronic pedigree system. The pilot work completed to date suggests that an item-level track and trace system as envisioned under California law is not the most effective electronic system to prevent diversion and counterfeiting of finished pharmaceutical products in the finished product distribution chain. The only known way to currently achieve an item level track and trace model is to use the Drug Pedigree Messaging Standard (DPMS). However, the pilots conducted to date suggest that the DPMS model...
introduces unrealistic supply chain risks because it requires a high degree of accuracy that has not
been proven in pilot work conducted.

More precisely, in order for any electronic pedigree system to function as intended, the pedigree
information must be exchanged electronically between trading partners, and these electronic data
exchanges must match the physical flow of the product. Both pieces must work together to allow
uninterrupted movement of pharmaceuticals through the distribution chain. However, the pilot
experiences with DPMS to date demonstrate that when exceptions or errors in the data exchange
occur, the physical flow of the product stops. PhRMA members are greatly concerned about the
cumulative impact of this phenomenon on the ability of patients to obtain their medicine. If,
when the system envisioned in California is fully operational, exceptions or errors in data
exchange halt the further distribution of products, this will have a negative impact on product
supply and patient care. And, the cumulative effect of these errors will have a ripple effect
throughout the distribution chain.

The pilot work conducted to date has also involved distributed database models. PhRMA
members believe that pilots of other database models, to assess both patient access and product
protection, are necessary, and we are willing to work with the Board and others to conduct such
pilots.

Notwithstanding this fact, PhRMA members remain committed to helping the state implement its
law. As such, PhRMA members are beginning to serialize products at the item level, and to
create databases containing information about those products at the item level that will allow for
downstream supply chain participants to authenticate or verify those item numbers. These
activities will facilitate the exchange of item level information in the supply chain, but they do
not lead to the creation of an interoperable electronic system required under California law.
Thus, this is where the Board must exercise its leadership to develop such an interoperable
system.

Given that it’s unclear what type of interoperable pedigree system will be developed nationwide
or in California, developing regulations on inference at this time could be premature.
Manufacturers need to know what type of interoperable system will be established to enable
supply chain participants to meet the state’s interoperable pedigree requirements. Will California
establish a centralized system, a semi-centralized system, or a de-centralized system? As stated
above, pilot work completed to date have only tested the distributed or de-centralized model.
Moreover, under California law, the exchange of pedigree information throughout the distribution chain is not complete until 2017. As downstream supply chain participants begin to receive and exchange pedigree information, a host of unanticipated outcomes that can’t be predicted today should be expected. A “detailed description of the means and methodology, including hardware and software specifications, processes, and data carrier(s), that the submitting party has deployed or intends to deploy,” is not possible today. Moreover, hardware and software specifications, processes, means and methodologies cannot be known today as they likely haven’t been built, and once designed, built, and tested, will be modified and adopted over time.

No matter what interoperable electronic system is ultimately adopted, PhRMA members believe inference is necessary and should be permissible. To manufacturers, “inference” consists of one or more steps that allow a person to infer the contents of a collection of containers as it moves through the supply chain, without having to separately verify each unit or item within the individual collection. As the Board considers these issues, a GS1 document from May 2010 entitled, “The Practice of Inference in the Pharmaceutical Supply Chain,” could be helpful to the Board. As product flows through the supply chain, homogenous cases from a manufacturer are broken down and further distributed into secondary packages and containers. In fact, manufacturers believe that very few of their original packaging configurations remain intact throughout the supply chain to a dispensing location. The Board will need to understand the impact of these activities on the use of inference and on product supply and patient access to medicines. Additionally, standard operating procedures (SOPs) to accomplish inference do not presently exist within many manufacturers.

Finally, with respect to liability, manufacturers should not be liable for downstream participants who do not verify pedigree information. Further, the California law requires a certification that the information contained in a pedigree is true and accurate. As the Board considers issues around certification and liability, it should consider the appropriateness of requiring such certifications in each instance. For example, how can an entity certify to the accuracy of a pedigree once legal title to the product has transferred to another entity? This is especially true in the case of returns, which must be documented on the same pedigree as the original transaction. Manufacturers can only reasonably be expected to certify to the accuracy of the information they generate with each outbound shipment, and to, with appropriate security controls in place, certify to the authenticity of a particular standardized numerical identifier when requested. Manufacturers generally understand that achieving a zero defect system may not be expected for the purposes of certification, and that business rules may be used to manage exceptions.
Thank you again for the opportunity to provide input into the Board’s request for information on inference. Should you have any questions or comments regarding the issues raised in this letter, please feel free to contact me at 202-835-3549.

Sincerely,

Kendra Martello
Assistant General Counsel
November 20th, 2012
California State Board of Pharmacy
1625 N Market Blvd.
Suite N219
Sacramento, CA 95834

Re: Opportunity to Submit Information Necessary to Possible Board Rulemaking on Inference and Certification of Individual Package Units – Drug Pedigree Law

Dear Board of Pharmacy:

Thank you for the opportunity to comment on the proposed rulemaking regarding inference and certification of individual drug package units. The Independent Pharmacy Cooperative (IPC) represents the interests of pharmacist owners, managers, and employees of more than 450 independent owned community pharmacies in the State of California. These pharmacies in many cases are the most accessible health care providers in their local communities. Importantly, IPC is also one of the largest member-owned wholesale drug distributors in the nation.

The Case for Inference

The California drug pedigree law requires recipients of drugs to certify that they received specific drug items at a unit level based on unique serial numbers. However, to be able to certify that you have received a given set of serialized units one would have to open, scan the units and reseal every case. This requirement would be very labor intensive, costly and inefficient. Currently, the Independent Pharmacy Cooperative brings cost effective drug wholesale solutions to independent owned pharmacies that allows them to better compete with large chain pharmacies. The significant costs associated with a strict unit level certification, which we estimate to be in excess of $1.15 million dollars per year for our operation, would jeopardize our ability to continue this business model.

Today, when a drug wholesaler receives a full case of drugs they normally do not open the container, instead they confirm that it contains exactly what the case label says; including, NDC, quantity and lot number. This type of inference is standard operating procedure across the entire supply chain. If case inference is not allowed, it would dramatically slow the movement of products, but more importantly, it would substantially increase the opportunity for substitution and diversion possibly resulting in adulterated, misbranded or counterfeit product entering the distribution channel.

Solution

The above mentioned security concerns are one of the drivers behind the practice of inference, under which companies use other evidence, rather than opening outer containers and scanning each individual item, in order to verify the integrity of a shipment. This aligns with the Agency’s description: "Inbound inference" that upon receipt of sealed cases from a known and demonstrably reliable manufacturer
trading partner, that are homogenous both in product/SKU and lot number, it be allowed to "infer" that the case identifier is accurately linked to the individual package serial numbers, so that it can receive and certify receipt of the individual items based on that relationship without opening the sealed case.

Proposed Standard Operating Procedures

At this time there is very limited availability and use of serialized prescription drug product packages. It is our understanding that FDA is working on a standard Serialized Numerical Identifier (SNI). Standard Operating Procedures will be tailored to the SNI when made available.

Conclusion

Inference allows a reasonable level of security with a lower expenditure of resources and may even protect the supply chain from the introduction of adulterated, misbranded or counterfeit product that could gain entry due to the massive number of open container events that would be required. Therefore, the use of inference can provide the necessary protection while allowing for the efficient flow of drug product through the drug distribution supply chain.

For direct inquiries or questions related to this letter, please contact

Mark Kinney R.Ph
Vice President of Government Affairs
Independent Pharmacy Cooperative
15550 Columbus Street
Sun Prairie, WI 53590
4163.1. (a) For purposes of Sections 4034 and 4163, "drop shipment" means a sale of a dangerous drug by the manufacturer of the dangerous drug whereby all of the following occur:

(1) The pharmacy, or other person authorized by law to dispense or administer the drug, receives delivery of the dangerous drug directly from the manufacturer.

(2) The wholesale distributor takes ownership of, but not physical possession of, the dangerous drug.

(3) The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.

(b) The board may develop regulations to establish an alternative process to convey the pedigree information required in Section 4034 for dangerous drugs that are sold by drop shipment.
AGENDA ITEM XI

ATTACHMENT 2
MINUTES
Enforcement Committee and E-Pedigree Public Meeting
September 11, 2012

COMMITTEE MEMBERS PRESENT:
Randy Kajioka, Vice-President, Chair
Tappan Zee, Public Member
Rosalyn Hackworth, Public Member
Amy Gutierrez, PharmD
Shirley Wheat, Public Member

STAFF MEMBERS PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistance Executive Officer
Carolyn Klein, Legislation and Regulations Manager
Susan Cappello, Enforcement Manager
Kristy Shellans, DCA Senior Counsel
Joshua Room, Deputy Attorney General

The meeting was Webcast at http://www.pharmacy.ca.gov/meetings/current_webcasts.shtml

The meeting was called to order at 9:37 and called for a moment of silence in respect for the September 11 events. Roll call taken and quorum established.

I. Enforcement Committee Issues:

(a) Discussion Regarding the Process under Which the Board May Accept the Surrender of a License from a Licensee on Probation with the Board.

Ms. Cappello provided an overview of the voluntary surrender requirements and the benefits of having a document by which a licensee could submit to the board as well as an implementation strategy. Once the surrender is approved, the signed form would be attached as an addendum to the disciplinary order.

Ms. Shellans provided the committee with additional information on how the proposal would work and what action can or cannot be taken.

Dr. Gutierrez asked if the forms would also apply to wholesalers and non-resident pharmacies. Ms. Shellans indicated that it would.

Motion: (Wheat / Hackworth) – Motion to move to accept the forms as presented and delegate the acceptance of the surrender to the Executive Officer.
Vote: 5-0

(b) Discussion Regarding Electronic Prescribing of Controlled Substances in California, Including a Request for Proposals by the California HealthCare Foundation for a Pilot Study in Ambulatory Provider Settings.

Ms. Herold provided an overview of the issues with e-prescribing. One principal impediment is that the DEA is unable to provide a list of certified and authenticated pharmacies to post on the board’s Website. Ms. Herold advised the committee that board inspectors have been instructed to request a copy of the auditing certification approval when inspecting pharmacies that are using e-prescribing for controlled substances.

Public Comment: Al Carver, representing Walgreens, advised the committee that a copy of the certification with DEA auditing requirements can be provided when requested by an inspector. Mr. Carver stated that Walgreens has difficulty confirming if the prescriber is also certified and indicated that currently Walgreens is relying on SureScripts to identify whether the prescriber’s system meets the requirements because SureScripts will not transmit an e-prescription from an uncertified system. Those scripts sent from a non-authorized prescriber are returned back to the prescriber with a notice indicating that the prescription cannot be filled.

Dr. Kajioka requested clarification of information that Walgreens received from SureScripts about the number of prescribers that have been approved consistent with the rule.

Mr. Carver advised the committee that Walgreen’s does have such a list and will provide it to the board for information purposes.

Ms. Herold also advised the committee about funding for pilot projects available through the California HealthCare Foundation and referred to materials in the committee meeting’s packet.

(c) Request for Clarification Regarding 16 California Code of Regulations Section 1707.5(d) Involving Availability of Interpreters for Patients with Limited English Speaking Skills in a Nuclear Pharmacy.

Dr. Kajioka provided a brief overview of the issues involving patient-centered label regulations and if the translation requirement would apply to a nuclear pharmacy.

Ms. Shellans advised the committee that the requirement does not apply because the medicine is not dispensed to the patient.

No public comment was provided.

II. Discussion on the Implementation of California’s Electronic Pedigree Requirements for Prescription Medication

(a) Presentations and Questions from the Pharmaceutical Supply Chain on Their Readiness to Meet California’s Staggered E-Pedigree Implementation Schedule.
Dr. Kajioka welcomed those who had traveled to attend the meeting. Dr. Kajioka noted that Brazil now has electronic serialization requirements.

No public or board comment was provided.

(b) **Update on the Status of Proposed Regulations to Specify a Unique Identification Number for Prescription Medication, and “Grandfathering” Provisions for Non-Pedigreed Dangerous Drugs.**

Ms. Herold stated that the regulation specifying the requirements for serialized numbers as well as the grandfathering provisions were finalized at the July Board Meeting and that the proposed regulations had been released for the required 45-day comment period. Ms. Herold provided a brief timeline for the regulation and advised all present the process to request a regulation hearing if one is requested.

No public or board comment was provided.

(c) **Discussion Concerning Elements for Possible Regulation Requirements to Permit Inference as Provided by California Business and Professions Code Section 4163.3.**

Dr. Kajioka provided an overview of the board’s desire to document the need for inference. In July the board released a request for comments on inference seeking specific elements from industry. Dr. Kajioka underscored that consumer protection cannot be compromised with the use of inference but that board recognizes the requests of the supply chain to use inference. Dr. Kajioka provided a brief synopsis of the comments provided.

Dr. Gutierrez also spoke in favor of the comments and encouraged everyone to submit their comments.

Mr. Room indicated that the comments received were very general in nature and did not provide the board with sufficient information to develop regulations at this point. He requested that more detailed information be provided. Mr. Room also highlighted that one submission indicated that the cost of aggregation was too high to implement. Mr. Room pointed out that inference cannot be achieved unless aggregation occurs.

Mr. Room also indicated that some of the comments included statements that industry is looking to the board or FDA to identify who will manage the data, and what type of solutions should be employed. These topics are outside the scope of this information request.

Ms. Herold advised the committee that comments submitted from two organizations seemingly did not make it to the board’s office. Ms. Herold advised all present that if comments were not included in the meeting materials packets that they can be sent via scanned letter attached to an e-mail to Ms. Herold.
Bill Fletcher - Pharmacy Logistics Solutions. (PowerPoint presentation provided at the end of these minutes) Mr. Fletcher indicated that he was presenting to the board to share some of the lessons learned as well as a reminder to all present why the law is on the books. Mr. Fletcher commented that by complicating the issue, it just delays the implementation and provided some examples. Mr. Fletcher indicated that the cost for implementation of the electronic pedigree is primarily on the manufacturer. Mr. Fletcher highlighted several other industries that serialize products and infer serialized products moving through the supply chain including auto parts distributors, electronic component distributors as well as consumer electronics.

Mr. Fletcher advised the committee that inference is widely used. Mr. Fletcher indicated that nonconformance issues are detected at the point of sale, when the detected saleable item is removed from the container and scanned at checkout. Mr. Fletcher noted that if a drug serial number is checked against trade documents like a pedigree when the item is removed from the case, bad products would never move through the supply chain.

Mr. Fletcher provided an overview of the Good Manufacturing Practices (GMP) as it relates to determining the confident of the contents of a sealed box. GMPs used in the pharmacy industry validate requirements and ensure consistent procedures are followed.

Mr. Fletcher highlighted some of the problems experienced with implementation as well as some of the risks of a limited solution. Mr. Fletcher indicated that some manufacturers have made the integration of the serialized product more complicated than necessary and indicated that tracking of the serialized number should not begin until the point of aggregation.

Mr. Fletcher discussed some of the other technologies used including electronic data interchange (EDI) advanced shipping notices (ASN) as well as GS1 identifiers.

Mr. Fletcher provided examples of advanced shipping notices offered for automotive parts. Mr. Fletcher underscored that the concept is not new and provided a chart documenting that 50% of the pharmacy supply chain are already using ASNs.

Mr. Fletcher indicated that EDI can comply with the “certification” requirement provided for in the law and provided the committee with the basic premise upon how that is done.

No public or committee comments were provided.
Bob Celeste - GS1 (PowerPoint presentation provided at the end of these minutes)
Mr. Celeste provided the committee with an update on the progress of the standards setting work being
done by his organization. Mr. Celeste provided an overview of the standards in healthcare used to identify,
capture and share information with trading partners. Mr. Celeste indicated that the GS1 standards ensure
barcode quality to ensure it can be read at the end of the supply chain through all of the processing shipping
and handling.

Mr. Celeste discussed the development of an implementation guide done through the Secure Supply Chain
Task Force. Mr. Celeste discussed the current status of the development and the timeline for finalization of
the guideline. Mr. Celeste highlighted the areas that will be covered in the guideline document.

Mr. Celeste discussed standards activities with respect to inference and advised the committee that GS1
worked with Stanford University to develop a statistical sampling paper. Mr. Celeste indicated that the
inference paper may be revised to include the statistical sampling information developed by Stanford
University after further vetting. A copy of this document is in the meeting materials.

Mr. Celeste advised the board that GS1 continues to hold conference calls to discuss physical vs. virtual
accountability. Mr. Celeste highlighted what is happening next including traceability adoption.

Dr. Kajioka asked for clarification on the inference document, specifically to clarify at what point a sealed
case should be opened and read. Mr. Celeste indicated that when a case unit is naturally opened that is
when the item should be read. This ensures that an item is not unnecessarily opened.

There was no additional committee or public comment.

Lynn Paulson - speaking on behalf of CSHP.
Dr. Paulson asked the board to provide some guidance on what it is expected for a hospital to comply. Dr.
Paulson indicated that a hospital could receive up to 80 totes a day that are mixed lots. Hospitals need a
workable system that includes just one reader irrespective of the company providing the totes. In addition,
Dr. Paulson indicated that a hospital needs to maintain the box intact as a way to reduce diversion. Dr.
Paulson advised the committee that there are a lot of challenges to implementing the e-pedigree
requirements and getting some of these requirements to work in a real world scenario. Dr. Paulson
suggested a two-day collaborative meeting to develop solutions to these changes.

Mr. Room asked Dr. Paulson about the inference requirements and was advised by Dr. Paulson that the
cases would be scanned when received and inventoried. Mr. Room clarified that hospitals are requesting
inference when a case is involved - - that the item can be inferred until the case is opened.

Ms. Herold asked if Dr. Paulson was interested in engaging in a pilot project and was advised that yes Dr.
Paulson is interested in pilot projects with wholesalers.

There was no additional committee or public comment.
Liz Gallenagh – HDMA (PowerPoint presentation provided at the end of these minutes)

Ms. Gallenagh indicated that inference is key to the implementation strategy of e-pedigree. Ms. Gallenagh provided a brief overview of the HDMA organization and its members. In addition she provided an overview of the suppliers they receive products from as well as the types of settings that they provide products to.

Ms. Gallenagh stated that the need for inference of serialized products is needed due to use of 2D barcode because such a barcode requires “line of sight” technology to read the information.

Ms. Gallenagh provided a scenario of how inference would be used including the use of an ASN as well as what factors would be present. Ms. Gallenagh indicated that without inference, technologies and processes will be difficult or impossible to successfully deploy. Ms. Gallenagh spoke of the benefits to the use of inference including increased security of the supply chain by limiting the number of open cases in a warehouse.

Mr. Room asked for clarification on what HDMA is requesting -- inbound inference only and if so, is it time-based? Mr. Room asked what percentage of a wholesaler’s shipment is homogenous and was advised that it depends on the size of the wholesalers, but indicated that it could be 75-85 percent of the shipments received by the large wholesalers, but would likely be a smaller percentage for smaller wholesalers.

General discussion indicated that about 2 percent of cases are never opened by a wholesaler and remain intact through the supply chain to the pharmacy.

Ms. Gallenagh indicated that the comments she provided were specific to inbound shipments. She requested flexibility on the elements that must be included in company SOPs to allow for the different ways business is conducted by large wholesalers and suggested that perhaps the board should identify the factors that must be addressed in the SOPs rather than prescribing the SOPs themselves.

Ms. Herold asked about what happens if a package is inferred inbound and outbound, what is the role of the wholesaler if a problem is identified at the end of the chain at a pharmacy. Julie Kuhn of Cardinal Health responded with a real world scenario when a case was received by the manufacturer without any record of the shipment. Ms. Kuhn indicated that exception processing needs to be undertaken but indicated that the general process would be expected that the pharmacy would work with the wholesaler to resolve the issue.

Ms. Herold asked about information surrounding the use of the advanced shipping notice and asked what the process is now if a shipment is received without an ASN. Ms. Gallenagh advised that the shipment is always in response to the wholesaler placing an order and as such there is always a PO or other sort of documentation. The committee was advised that such a scenario needs to be vetted through the exception process and that work is just beginning in this area.

Dr. Gutierrez asked for clarification on how drop shipments are being handled. Dr. Gutierrez was advised that the issue of drop shipments needs to be further discussed because of the unique scenario where the wholesaler takes ownership but never takes possession of the products.
No additional public or committee comment was provided.

Steve Gray – Representing Kaiser Permanente and as an individual
Dr. Gray stated that many of the board members are new to the issue and underscored that the intent of e-pedigree is patient protection. Dr. Gray asked the board to focus on the top priority – protection of the public via enforcement against the bad players. Dr. Gray stated that if a true track and trace model is being employed, then inference is essential given technology limitations. Dr. Gray indicated that inference must then be done at the pallet level and case level as well as the need to have inference for a shelf packet as well (especially for hospitals and wholesalers). Dr. Gray discussed the complexity of the supply chain and various business settings and suggested that multiple solutions may be necessary when defining inference.

Dr. Gray advised the board that the use of EDI has occurred for at least a decade and indicated that the EDI needs to be incorporated into the pedigree. Dr. Gray indicated that the issue of drop shipment needs to be discussed and the solution will require some flexibility. Dr. Gray also advised the committee that one of the SOPs needed are to address the scenario where the receiver is on site at the shipping site and accepts ownership of the product immediately.

No public or committee comments were provided.

Ruby Raley - Axway
Ms. Raley spoke to the needs of independent pharmacies and the fact that many wholesalers act as the warehouse for such pharmacies and this must be considered when developing the inference rules. Ms. Raley also indicated that information technology should not drive implementation but it should be driven by the regulators and industry. Ms. Raley indicated that the committee needs to discuss the forensics and what tools are needed by the regulator or QA personnel to identify what went wrong and where the hole in the process occurred. Also, what type of recording is sufficient to meet the forensic needs and that the exceptions need to be vetted and how that should be included in the SOPs.

Dr. Gray recommended to the committee that the database of information should be maintained by a quasi-government organization to protect the proprietary information. Kaiser is opposed to making such information public and indicated that this needs to be considered by the board.

Steve Drucker - Merck
Mr. Drucker thanked the committee for the work in the area of e-pedigree. Mr. Drucker indicated that costs of the solution must be considered to ensure that the costs are associated with value. Mr. Drucker spoke in support of e-pedigree and indicated that Merck is interested in moving forward. Items that should be included in the inference discussion are the level of accuracy, what can industry commit to, what is the risk involved - - what is acceptable risk, and last, what is the impact to the supply chain. Mr. Drucker referenced
the PDSA efforts and the areas that all supply chain members could agree with including barcoding lot leveling tracking first.

No public or committee comments were provided.

(d)  **General Discussion**

There was no additional discussion

(e)  **2013 Future Meetings**

Dr. Kajioka confirmed the next enforcement committee meeting is December 4, 2012.

Dr. Kajioka discussed future Enforcement Committee dates.

- March 5 - Bay Area
- June 4 – possibly southern CA
- September 10 -
- December 3

(f)  **Closing Comments**

Dr. Kajioka summarized some of the comments from the public speakers.

III.  **Public Comment on Items Not on the Agenda/Agenda Items for Future Meetings**

No public comment was provided.

Dr. Kajioka adjourned the meeting at approximately 2:00 p.m.
Eureka! A Pragmatic Implementation of California e-Pedigree Law
Introduction

- **California e-pedigree projects with 15 global life sciences companies.**
  - Over 29 years of industry experience.
  - Plus dozens of projects with life sciences companies and validated systems spanning 20 years.
  - Over 10 years working with many of the world’s largest companies on logistics and supply chain systems.

- **Consultant** specializing in solutions for global drug serialization, traceability and supply chain, including:
  - strategy,
  - requirements,
  - vendor selection,
  - pilots and
  - implementation.

- I don’t sell hardware or software.
- Projects have included solutions from multiple vendors.
- Member GS1 US Healthcare.
Why am I here?

“Any intelligent fool can make things bigger and more complex... It takes a touch of genius - and a lot of courage to move in the opposite direction.”

Albert Einstein

“I wish to help the industry by challenging conventional thinking and presenting time-tested standards-based solutions for complying with California law.

Pharma Logic Solutions and Bill Fletcher have helped 15 global life sciences companies develop solutions to comply with California law and would like to share the lessons learned with other life sciences companies.”
Remembering the victims

- Let’s remember the victims of drug counterfeiting and related crimes, who suffered through no action of their own and whose loved ones suffer today.

- The US pharmaceutical supply chain is likely the safest in the world.
  - But it is ironic we lack systems to better measure supply chain integrity.
  - Complicated requirements can only delay implementation and the realization of the benefits.
  - Pedigree is the most costly to manufacturers and provides fewer benefits than other supply chain tracking solutions – hampering the brand owner’s awareness and ability to respond to threats.

- Let’s never forget the intent of the law.
Which industries already track serial numbers and infer serialized contents?

- Auto parts
- Electronic Component distributors
- Consumer electronics
- High value consumer goods
What’s in the box

- The practice of inferring the serialized contents in a sealed serialized logistics container, such as a shipping case, using electronic information is a commonly accepted practice in many industries.

- Nonconformance is detected when a saleable item is removed from the container and scanned.
  - Most high value goods with unverifiable serial numbers are returned and an alternate item given to the consumer.
  - Automotive and electronic parts are returned.
  - If drug serial numbers are checked against trade documents like a pedigree when the item is removed from the case and shipped further or dispensed, the patient would never be exposed to the nonconforming item.
    - Why impose fines if process prevents harm?
    - Trade will keep this in check and consistent failures will result in no future trade with that company.
    - The law could require the nonconformance to be reported for possible investigation.
How can we be confident we know what is in the sealed box?

- Good Manufacturing Practices (GMP) are widely used in the pharmaceutical industry to validate requirements and ensure consistent procedures.
  - GMP practices take time and have a cost.
  - There is a cost in ensuring safety.

- Inference is widely used in life sciences today.
  - What’s in the bottle or vial before the label goes on?

- Supply chain procedures relating to verifying the serial numbers of items as they are removed from shipper cases and then updating pedigree will catch errors before dispensing.
What technology solutions are used?

- **Electronic data interchange (EDI)** advanced shipping notices (ASN), have supported hierarchical parent/child serialization for over 2 decades.
  - EDI supports EPC (electronic product code) encoding and GLN (global location number) locations.
  - EDI supports pedigree indication.
  - EDI and ASN guidance is available from leading life sciences trade organizations, including HDMA.
  - Hundreds of thousands of EDI ASN transmissions occur daily.

- **GS1 identifiers**, such as the global trade item number (GTIN) and related application identifiers (AI) are ubiquitous, time-tested, globally acceptable and used in most industries.
  - GTIN and GS1 serial number AI are included in FDA guidance.
  - GS1 encoding is supported around the world.
A commercial off-the-shelf (COTS) system provides pedigree tracking for Automotive Parts to improve quality control and brand protection from parts manufacturing to installation in a vehicle.
EDI in Life Sciences

- Pharma Logic Solutions has helped leading life sciences companies map business processes, including order-to-cash, into EDI and leverage multiple EDI transaction sets, including but not limited to:
  - Serialized Advanced Ship Notice
  - Purchase Order
  - Order Adjustments
  - Invoice
  - Item Maintenance
  - Warehouse Shipping Order
  - Goods Receipt
  - Inventory Status Change
  - Transaction confirmations

- EDI communication are secured using digital certificates and AS2 protocol, including delivery receipt via MDN.
EDI ASN for California Law

- Some say it cannot support “certification under penalty of perjury.”
  - GMP Validation ensures the accuracy and repeatability of the processes used to collect and manage serialization information – the same way it would for e-pedigree.
  - EDI with hierarchical serialization is no more or less accurate than Drug Pedigree Messaging Standard (DPMS).
    - Many enterprise business system support EDI and serialization.
    - For example, SAP has integrated EDI ASN into its latest Aii serialization solution. Axway, Oracle, IBM and others support EDI and serialization.
  - Transmission via secure (digital certificate controlled) AS2 protocol, with active message delivery notification (MDN), ensures that trade agreements are established in advance and provides proof of delivery.
EDI ASN for California Law

- EDI is said not to be “created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.”

  - DPMS pedigree is a file, digitally signed and transmitted to the next trading partner. It is not “interoperable” such that previous trading partners, or the manufacturer cannot interoperate with it and gain new/current information.

  - EDI, via AS2 with active MDN, is communicated via secure, digital certificate controlled, pre-established electronic channels, to the receiving trading partner.
    - MDN receipts may be maintained as proof of delivery.
    - EDI functional acknowledgement messages may also be used.
    - Secured trade channels provide a history of trades for investigational or forensic needs.

  - EDI is ubiquitous and available from dozens of solutions provides and Value Added Networks (VAN) as a cloud-based hosted solution.
EDI ASN for California Law

- EDI does not meet the requirement for “a record, in electronic form containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering or dispensing the dangerous drugs.”

- EDI ASN via AS2 with MDN does provide a chain of previously established trades, secured via digital certificates to authenticate the trade partner, with proof of delivery. This controlled trade channel could provide verified trades from manufacturer to dispensing.

- EDI is time-tested and available from many solution providers and is often provided as a subscription service.
Discovering Inference Errors

- As serialized items are traded, they will eventually reach a point where the saleable unit is removed from a shipping case and identity/serialization no longer inferred.

- When the recipient tries to update a pedigree for a new trade or dispensing, they will discover the serial number is not part of the pedigree that was provided to them.

- They will return the item to the company they purchased it from.

- The item will reverse back up the supply chain until the trader where the aggregation error occurred is identified. They will not be able to return it further and will need to correct the error against the pedigree they received. The cost of inference errors is with the entity who caused the error.

- Traders will establish agreements regarding the integrity of sealed serialized containers and will reject items from traders who have a poor record of supplying accurate serialization information.

- Dispensing nonconforming serialized goods will be stopped because a pedigree will not be able to be updated because the number will not be in the document.
So why do I mention of EDI?

- EDI via AS2, where identity must be established in advanced and secured via digital certificate, will limit elicit trade and diversion.
  - Require retention of EDI and proof or delivery.
  - Require unit serialization and invoice reference.
  - EDI includes support for DEA, HIN, D-U-N-S and related numbers.

- EDI ASN and related EDI Transaction sets provide a widely-used, time-tested, commercial off-the-self or hosted solution for exchanging serialization information and serialized hierarchy with trading partners.
  - Secure via AS2 with active MDN (proof of deliver) and functional acknowledgments.
  - Trade connections established in advance, and digital certificates exchanged, to ensure the identity of trading partners.
So why do I mention of EDI?

- EDI is ubiquitous while systems to support electronic DPMS pedigree are limited.
  - DPMS may pose a challenge for many distributors and pharmacies.
  - EDI is widely available today as a hosted or cloud-based solution.

- EDI supports many transactions to automate and record trade exceptions, errors, adjustments and movement between contracted organizations (where “ownership” may not change but goods physically move and could be altered).

- The California Board of Pharmacy could greatly reduce the implementation burden by considering EDI via AS2 and MDN, along with record retention rules, as an alternative.
Why haven’t you heard this before?

- Solution provider are motivated to sell systems and may not share lower cost, less complicated solutions offered by a larger set of competitors, such as EDI.

- Many life sciences companies seek advice from solution providers who are motivated to sell solutions.

- The fact that standards for sharing hierarchical parent/child serialization have been around for decades, well before discussion in life sciences, tells us that other industries use it – otherwise, why was it created and perpetuated?
What others may say.

- Pharmaceuticals are not computer chips.
  - Yet faulty counterfeit or mishandled chips can cause death.

- Other industries do not impose fines for aggregation errors.
  - When the item pedigree is updated, and the serial number is not correct (due to an aggregation error or counterfeit), it will be caught and not dispensed.
  - Trade will correct issues because traders will reject goods from companies who cannot reliably aggregate.

- The industry has already discussed and rejected EDI.
  - EDI is time-tested and has shown to be a reliable method for exchange trade information, including serial numbers and aggregation.
  - The use of secure electronic trade and requiring positive message delivery notification and retention of records provides the information needed for investigation.
  - It may have been rejected to foster the development of a new standard – DPMS.
What others may say.

- Other industries don’t aggregate.
  - The EDI ASN standard has included hierarchical serialization for two decades.
  - As presented earlier, solutions used in other industries support track & trace, pedigree and parent/child serial number management.

- EDI doesn’t support recording the entire trading history.
  - Yet it is widely used in other industries to control trade and secure trade information (via AS2).
So what’s my point?

- Aggregation and inference errors can be caught before dispensing using process and trade documents.
- If the process is not established to catch aggregation errors, then counterfeits could easily be injected into the supply chain and be dispensed.
  - So why not consider more widely used, time-tested standards for trade control and communication?
- Fines are not needed for inference errors.
  - Trade will handle it because of the cost of returns.
- EDI as an alternative to pedigree could be established to support the needs of the California Law and represents an alternative for US Federal Law.
- Companies who are concerned with their ability to comply with California Law may wish to have their projects reviewed by a subject matter expert to gain a new unbiased perspective.
- Smaller distributors and Pharmacies will benefit from hosted EDI services.
Questions?

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CALIFORNIA BOARD OF PHARMACY ENFORCEMENT COMMITTEE

GS1 TRACK AND TRACE STANDARDS AND IMPLEMENTATION
CONTENTS

• Update on Standards

• Guideline Development

• Activities to support industry in preparing for 2015

• Certification
GS1 STANDARDS

GS1 Standards for identifying, capturing, and sharing information - about products, business locations, and more - make it possible for companies to speak the same language, connect with each other, and move their business forward.
GS1 STANDARDS IN HEALTHCARE

ITEM

Barcodes
Carries a Global Trade Item Number® (GTIN®)

EAN/UPC
GS1-128

GS1 DataMatrix
GS1 DataBar™

GS1-128
Carries a GTIN

Carries a GTIN with extended data or a Serial Shipping Container Code (SSCC)

OR

EPC-ENABLED RFID
Carries a Serialized GTIN (SGTIN)

CASE

ITF-14
Carries a GTIN

PALLET

ITF-14
Carries a GTIN

OR

EPC-ENABLED RFID
Carries a GTIN or SSCC

AND

EPC-ENABLED RFID
Carries an SGTIN or SSCC

AND

EPC-ENABLED RFID
Carries an SGTIN or SSCC
GS1 STANDARDS IN HEALTHCARE

IDENTIFY: GS1 SYSTEM IDENTIFICATION NUMBERS

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<th>GTIN</th>
<th>GTIN</th>
<th>SSCC</th>
<th>GLN</th>
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CAPTURE: GS1 SYSTEM DATA CARRIERS

BARCODES

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<td><img src="image5.png" alt="GS1 DataMatrix Barcode" /></td>
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EPC-ENABLED RFID TAGS

SHARE: GS1 INTERFACE STANDARDS FOR ELECTRONIC COMMERCE

MASTER DATA GLN Registry for Healthcare, Global Data Synchronization Network™ (GDSN™), TRANSACTIONAL DATA eCom/EDI, PHYSICAL EVENT DATA EPC Information Services

INTEROPERABILITY

ITEM DATA Location Data Purchase Order Shipping Notice Invoice Product Recall/Withdrawal Pedigree Track & Trace
APPLYING GS1 STANDARDS TO SERIALIZATION AND PEDIGREE
ENSURING BARCODE QUALITY
CONFORMANCE TEST CARDS & DECODE AND ANALYSIS REPORT

GS1 DATA MATRIX
CALIBRATED CONFORMANCE STANDARD TEST CARD

Serial Number: 1121
Date Processed: 11/18/2009

Symbol: 1:4.0 (A)
Symbol: 2:1.0 (B)
Symbol: 3:1.0 (C)
Symbol: 4:1.0 (D)
Symbol: 5:4.0 (A)
Symbol: 6:2.0 (C)
Symbol: 7:2.0 (C)

Wavelength: 690nm
Synthetic Aperture: 0.8 x Dilm

Analysis Report

Decoding Passphrase: 90
Data Words: 91
Corrected Data Words: 91
Global Threshold: 6.432
Contract Uniformity: 0.016

Analysis Details

Symbol: 1:4.0 (A)
Symbol: 2:1.0 (B)
Symbol: 3:1.0 (C)
Symbol: 4:1.0 (D)
Symbol: 5:4.0 (A)
Symbol: 6:2.0 (C)
Symbol: 7:2.0 (C)

2D JUDGE CERTIFIED

GS1 US
THE GLOBAL LANGUAGE OF BUSINESS

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SECURE SUPPLY CHAIN TASK FORCE
IMPLEMENTATION GUIDE

Contents of the guideline:

- Identifying Trade Units (Products, Cases, and Kits):
- Identifying Logistics Units (Cases, Pallets, and Totes)
- Identifying Parties & Locations
- Encoding GS1 Data Carriers
- Translating Captured Data
- Master Data Management (product and location data)
- Applying GS1 Standards for Event Data
- Supply Chain Events to be Captured for Pedigree
- Additional Supply Chain Events for Track & Trace
- Exceptions Processing
- Pilot learnings / best practices
- Forward Logistics Examples
- Reverse Logistics Examples
- Potential Architectural Models
SECURE SUPPLY CHAIN TASK FORCE
IMPLEMENTATION GUIDE - TIMELINE

• Release 1.0
  – Technical Review – Complete
  – Readability Adjustments – Complete
  – 2nd Technical Review - Complete
  – Comment Resolutions – 10/5/2012 – 10/24/2012
    • GS1 Healthcare US Fall Forum: 10/1/2012 – 10/3/2012
    • GS1 Healthcare US approval 10/30/2012
  – Publish –

• Release 2.0:
  – Exception Processing
  – Forward Logistics (drop shipments, repackaging, kitting)?
  – Reverse Logistics (Returns, Recalls, Withdrawals, Refusals)?
STANDARDS ACTIVITIES WITHIN THE U.S.

INFERENCE
STANDARDS ACTIVITIES WITHIN THE U.S.
IMPLEMENTATION SUPPORT - STATISTICAL SAMPLING MODEL

Statistical Sampling Paper and Model review period:
9/6/2012 – 9/20/2012
STANDARDS ACTIVITIES WITHIN THE U.S.
INERENCE PAPER – POSSIBLE V2 UPDATE
## Traceability Pilots Task Force

### Pilot Panel Calls

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<td>Master Data Management</td>
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<td>6/13/2012</td>
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<td>RFID Bar Code Interoperability - GS1 Guideline Translations between different formats</td>
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<td>10/17/2012</td>
<td>Inference and Aggregation</td>
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<td>10/31/2012</td>
<td>Implementation Guideline</td>
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TRACEABILITY PILOTS TASK FORCE

PILOT PANEL CALLS

Workshop Dates:
- October 16
- November 13

Info Webinar Dates:
- Sept 13
- Sept 27
- October 11
- October 23
- November 1
Contents of the guideline:

• Identifying Trade Units (Products, Cases, and Kits):
• Identifying Logistics Units (Cases, Pallets, and Totes)
• Identifying Parties & Locations
• Encoding GS1 Data Carriers
• Translating Captured Data
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• Applying GS1 Standards for Event Data
• Supply Chain Events to be Captured for Pedigree
• Additional Supply Chain Events for Track & Trace
• Exceptions Processing
• Pilot learnings / best practices
• Forward Logistics Examples
• Reverse Logistics Examples
• Potential Architectural Models
TRACEABILITY ADOPTION

WHAT’S NEXT?

- Call for participation!

Conformance Test Criteria Task Force
- 9/19/2012

Certification
- 1Q, 2013
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Connect with the GS1 US community on

LinkedIn  Twitter  YouTube
Inference: Key to CA Pedigree Implementation

California Board of Pharmacy Enforcement Committee Meeting
September 11, 2012
Burlingame, CA
HDMA – Who We Represent

• Active members include 33 primary healthcare distributors – national, regional and specialty.

• HDMA’s members offer value-added services that help ensure safe and timely delivery of nearly 9 million healthcare products to over 200,000 pharmacy and healthcare settings nationwide.

• Nearly 90 percent of all U.S. pharmaceutical sales go through HDMA distributors.

The Role of Distributors in the U.S. Healthcare Industry (2011)
HDMA member database
The Vital Link in a Sophisticated Supply Chain

MANUFACTURERS
- Branded
- Generic
- Biologic
- Specialty
- OTC
- Medical and Surgical Device

Primary Healthcare Distributors (Traditional and Specialty)

Hospitals, HMOs, Clinics and Nursing Homes
- Chain Pharmacies and Food Stores
- Chain Warehouses
- Independent Pharmacies
- Mail Order
- Physicians Offices
- Specialty Pharmacies
- Others

Healthcare Distributors

Typical companies inventory more than nearly 56,000 healthcare products from an average of 1,100 different manufacturers.

The average distribution center picks more than 95,000 items each day to fulfill nearly 2,000 customer orders.

Distributors deliver consolidated products on a next-day basis in low units of measure.

The typical distribution center serves nearly 1,200 customers and nearly 1,300 ship-to locations.

HDMA in California

• California Customers: HDMA members deliver lifesaving medicines to approximately 32,000 customer locations in California.

• Jobs in California: HDMA member companies directly employ more than 6,600 California residents and contract for transportation and other services that support hundreds of additional jobs.
HDMA in California

- **AmerisourceBergen Corporation**
  - Corona, Orange, Sacramento, San Bruno, Valencia

- **Cardinal Health, Inc.**
  - Elk Grove, Valencia

- **H. D. Smith**
  - Carson

- **McKesson Corporation**
  - City of Industry, Ontario, San Francisco, Santa Fe Springs, West Sacramento, Visalia

- **Valley Wholesale Drug Company**
  - Stockton
Inference - Background

• First emerged during development of the California pedigree law.
• The concept of unit level track-and-trace was based originally on the capabilities of RFID technologies.
• In 2007 or 2008, it became clear that manufacturers overwhelmingly believed that unit level serialization was more practical and economically feasible through the use of two dimensional (2D) data matrix bar codes. This was confirmed through HDMA’s 2010 track and trace survey.
• 2D bar codes utilize “line of sight” technology, thus, an individual must scan each bar code in order to directly capture product information.
Inbound Cases & Pallets
Inbound Cases & Pallets
Inbound Cases & Pallets
Case Level Bar Code Label
Distributor Volume

- On an average day, a typical HDMA member distribution center handles almost 2,000 customer orders, and picks (or processes) an average of 95,000 product units. Receipts come in from @ 1100+ mfrs.

- Scanning individual units on receipt is not practical or economically feasible.

- The Legislature understood the need for supply chain members to avoid having to unnecessarily open every single case of product.
Distributor Volume - Receiving
Distributor Volume - Receiving
Inference Example

• Wholesale Distributor XYZ orders and receives ten individual units in a sealed case (A) from the manufacturer of a product, along with a communication stating that these ten units were numbered 1 through 10 in case A. Because the manufacturer provided this information, and the same manufacturer sent Wholesale Distributor XYZ the case, XYZ can infer that what the manufacturer sent to it is what was stated by the manufacturer – without requiring Wholesale Distributor XYZ to open the case to confirm.
Handheld Scanner
Product Cases
Product Cases
Open Product Case
Individual bottles in case
Major Changes in Operations

• The ability of HDMA primary distributor members to comply with the California law is heavily dependent upon manufacturer compliance beginning in January 2016.

• A future that includes serialized product, use of track-and-trace technologies, and electronic pedigree data exchange is one that has been contemplated, but we cannot yet fully understand or anticipate how such changes will require modifications to our members’ operational and logistics functions.
Use of Inference When . . .

• Recipient places an order for product with the shipper, with whom the recipient has a business relationship; and

• A sealed homogenous (same lot, same product) case is sent by the shipper directly to the recipient; and

• The shipper and recipient have technology solutions to provide electronic business-to-business transactional security;
. . . all of these factors are present.

- And, the shipper sends – in advance of, or in conjunction with shipment – information about the items/contents of such case, including the items’ serial numbers and pedigree information related to each specific case; and

- The recipient receives the case and the product information from the shipper.
Inference is Necessary

- Allowing inference by distributors is necessary to help facilitate implementation of California’s pedigree law.

- Allowance of inference is consistent with the spirit and the intent of the law – to employ technology and processes in the supply chain to permit electronic track-and-trace for the first time.

- Without inference, such technologies and processes will be difficult or impossible to successfully deploy.
Safety, Efficiency and Access

• Inference will help to ensure that California providers and patients have continued access to life saving medicines.

• Inference will actually help ensure increased security of the supply chain by
  – Limiting open cases in a warehouse receiving area;
  – Limiting personnel handling items; and
  – Limiting opportunities for diversion, theft or contamination.

• Successful deployment of electronic track-and-trace technologies and processes is expected to decrease the risk of counterfeiting and diversion within the supply chain.
Inference: Key to CA Implementation

• Successful deployment of electronic track-and-trace technologies and processes is expected to decrease the risk of counterfeiting and diversion within the supply chain.

• **Without inference**, such technologies and processes will be difficult or impossible to successfully deploy.
Thank You

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Guidelines for Drug Take-Back Programs

Prescription drug abuse is soaring. Today more people die from prescription drug overdoses than from automobile accidents. Part of the problem may be the availability of unwanted pharmaceuticals in homes and other locations, drugs that need to be discarded and destroyed.

But law has not kept up with the issue nor with consumer demand to provide environmentally appropriate ways to dispose of the medication. Much work remains to be done to develop a strong take-back program for consumers that will protect the environment and not contribute to drug diversion for collection sites.

For the last two years, the federal Drug Enforcement Administration has held twice annual drug take-back days so consumers can dispose of their unwanted medication in environmentally safe ways. The next of these days is April 28 (see article on Page 22), and the collection of controlled substances will be accepted at these specific events.

In 2008, the Board of Pharmacy worked with the then California Integrated Waste Management Board (now CALRecycle) and several other public agencies to develop guidelines for take-back programs for the disposal of prescription drugs that have been dispensed to patients. The guidelines address parameters for both permanent and occasional take-back event collection sites. There is also a mail-back component, where the patient can purchase or obtain a preaddressed, postage paid mailer to send unwanted medication through the mail to a licensed waste hauler.

A copy of the full approved guidelines can be obtained from the board’s Web site at: www.pharmacy.ca.gov. (Note, there are other prior versions of the guidelines available on the CalRecycle Web site—the final version adopted by the Integrated Waste Management Board was approved on February 24, 2009. To get the approved version of the guidelines, make certain you use the link above, and not a search function on the CalRecycle Website.

These guidelines are complex and must be read carefully.)

What Can and Cannot Be Collected

a. Home-generated prescription drugs dispensed to a consumer, or a non-prescription item in the possession of a consumer, such as over-the-counter drugs, vitamins and supplements, and veterinary pharmaceutical waste, may be accepted.

b. Sharps in containers approved by the local enforcement agency may be accepted at collection sites, but shall NOT be placed in the same containers as the home-generated pharmaceutical waste.

c. Medical waste such as human surgery specimens, blood samples, vaccines and serum, trauma scene waste, human surgery specimens, cultures from pathology laboratories, items containing human fluid blood and vaccines, and serum shall NOT be accepted.

d. Controlled Substances - Controlled substances cannot be collected by these programs unless a sworn law enforcement officer is onsite to take custody of, document, and dispose of these controlled substances. Controlled substances are a specific category of prescription drugs and are defined as any substance listed in Sections 1053-11058 of the California Health and Safety Code. Some examples of controlled substances include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines).

Signage

Signage must be provided regarding what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.), as well as the hours during which collection is permitted.

Home-generated pharmaceutical wastes are generally classified as household waste and as such can be commingled in containers with other household waste or hazardous waste. However, if home-generated pharmaceutical wastes are mixed with other medical waste or managed as medical waste, the waste shall be segregated for storage in a separate container or secondary container, and that container shall be labeled with the words “INCINERATION ONLY” or other label approved by the California Department of Public Health on the lid and sides, so as to be visible from any lateral direction.

How Home-Generated Pharmaceuticals Shall Be Collected

The consumer, not the pharmacy staff, should empty home-generated pharmaceuticals from their original prescription containers into the secured container at the collection location. Then the consumer will place the empty container into a separate collection bin for proper management.

The pharmacy must ensure that the home-generated pharmaceutical licensed waste hauler or handler transports the home-generated pharmaceuticals for proper destruction. Collected home-generated pharmaceuticals shall not be resold or reused. No individual or collection site shall purchase or offer to purchase home-generated pharmaceutical waste from consumers, nor shall such returned waste be sold, donated, or provided to anyone other than a registered medical or hazardous waste hauler as specified in these procedures.

Storage

In accordance with Board of Pharmacy specifications, collection sites located in pharmacies shall not commingle pharmaceutical waste with expired, recalled or other quarantined drugs that...
Drug Take-Back Programs
Continued from Page 23

have never been dispensed. Collected home-generated pharmaceuticals may only be stored in the secure sealed containers or in the custody of law enforcement. Once collected, home-generated pharmaceutical waste may be stored at an onsite location for not longer than 90 days when the container is ready for disposal. In certain circumstances, additional storage time may be obtained with prior written approval from the enforcement agency or the California Department of Public Health.

Container Security

It is the responsibility of the pharmacy overseeing the collection location to provide for the security of the collected home-generated pharmaceuticals. The home-generated pharmaceutical waste must be deposited into secured containers to prevent diversion and theft opportunities and not allow staff at the pharmacy overseeing the program from having access to the contents. Containers at permanent locations such as pharmacies shall be locked and stored in an area that is either locked or under direct supervision or surveillance. The collection device must be within the physical plant of a pharmacy, so that it can only be accessed during operating hours.

Bins located at pharmacies shall have a two-key security system—one in the possession of the pharmacy’s designated responsible person and the other in the possession of the licensed waste hauler who will pick up the contents for appropriate destruction. Containers may be stored in the following manner—a lockable cage on the container, lockable collection bins or kiosks, or lockable closets. Intermediate storage areas shall be marked with the international biohazardous symbol. These warning signs shall be readily legible from a distance of five feet.

Home-generated pharmaceutical waste may not be removed from a collection device and stored in a pharmacy, medical office or any other location. Instead, once the pharmaceuticals are removed by the waste hauler, they must be taken by the hauler. When a collection device becomes full, no more pharmaceutical waste can be accepted from consumers at the collection site until a waste hauler has removed the pharmaceutical waste and re-stocked the collection device with an empty container. Any theft of or loss from the collected home-generated pharmaceutical shall be reported within 24 hours to the local police department, California Department of Public Health, California State Board of Pharmacy, and other agencies that have authorized the collection program.

Record Keeping

Detailed information and invoices about each pick up from a home-generated pharmaceutical collection site shall be retained in a log by the collection site for three years after the life of the collection device and readily retrievable at the request of a government enforcement agency. Each collection location must keep a log specific to that collection device and contain:

- The name, address, phone number, and title of the collection site person authorized for the collection device;
- The address, phone number, and location number where device is located;
- The date the collection device was installed at the location;
- The dates for every opening of the device and purpose of opening;
- The names of the two persons that accessed the device (one column for collection site’s personnel and one column for the medical or hazardous waste hauler);
- The weight of home-generated pharmaceutical waste removed from the device;
- Additional columns for the final disposition of the drugs and other security measures implemented to prevent unauthorized removals from the device; and
- The name, address, and registration number of the waste hauler taking the drugs.

In late 2009, the Board of Pharmacy adopted the policy that if a pharmacy wishes to establish a prescription drug take back program, the collection should comply with the guidelines excerpted below. Before instituting a home-generated take-back program, be familiar with all the components in the guidelines above.
AGENDA ITEM XI

ATTACHMENT 4
DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR PARTS 1300, 1301, 1304, 1305, 1307, 1317, and 1321

[Docket No. DEA-316]

RIN 1117-AB18

Disposal of Controlled Substances

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

ACTION: Notice of Proposed Rulemaking.

SUMMARY: This rule proposes requirements to govern the secure disposal of controlled substances by both DEA registrants and ultimate users. These regulations would implement the Secure and Responsible Drug Disposal Act of 2010 (Pub. L. 111-273) by expanding the options available to collect controlled substances from ultimate users for purposes of disposal to include: take-back events, mail-back programs, and collection receptacle locations. These proposed regulations contain specific language to continue to allow law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection receptacles. These regulations propose to allow authorized manufacturers, distributors, reverse distributors, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles. In addition, this proposed rule expands the authority of authorized retail pharmacies to voluntarily maintain collection receptacles at long term care facilities.
This proposed rule also reorganizes and consolidates existing regulations on disposal, including the role of reverse distributors.

DATE: Electronic comments must be submitted and written comments must be postmarked on or before [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESS: To ensure proper handling of comments, please reference “Docket No. DEA-316” on all electronic and written correspondence. DEA encourages all comments to be submitted electronically through http://www.regulations.gov using the electronic comment form provided on that site. An electronic copy of this document is also available at the http://www.regulations.gov website for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to http://www.regulations.gov will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Office of Diversion Control (OD/DX), 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION, CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 307-4654.

SUPPLEMENTARY INFORMATION
Posting of Public Comments:

Please note that all comments received are considered part of the public record and are made available for public inspection online at http://www.regulations.gov and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you would like to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you would like to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the
agency's public docket file in person by appointment, please see the "For Further Information" paragraph.

OUTLINE

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EXECUTIVE SUMMARY

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 controlled substance pharmaceuticals had limited disposal options. The Controlled Substances Act (CSA) only permitted ultimate users to destroy those substances themselves, for example by flushing or discarding, or to dispose of such substances by surrendering them to law enforcement or by seeking assistance from the U.S. Drug Enforcement Administration (DEA). These restrictions resulted in the accumulation of controlled substances in household medicine cabinets that were available for abuse, misuse, and accidental ingestion. The Disposal Act amended the CSA to authorize ultimate users to deliver their 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) and 828(b)(3). The Attorney General delegated responsibility for promulgating the Disposal Act implementing regulations to DEA. These proposed regulations expand the entities to which ultimate users may transfer unused, unwanted, or expired controlled substances for the purpose of disposal, as well as the methods by which such controlled substances may be collected. Specified entities may voluntarily administer any of the authorized collection methods in accordance with these proposed regulations.

Summary of the Major Provisions of the Regulatory Action

DEA is proposing new regulations for the disposal of controlled substances by ultimate users in accordance with the Disposal Act. In drafting the implementing
regulations, DEA considered the public health and safety, ease and cost of program implementation, and participation by various communities. To this end, 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 (e.g., ultimate users). The reverse distributor registration category, which is pertinent to the process of registrant disposal, was included in this comprehensive review. These regulations will be incorporated into a new part 1317 on disposal.

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

_Ultimate User Disposal_

This rule proposes three voluntary options for ultimate user disposal: (1) take-back events, (2) mail-back programs, and (3) collection receptacles. In addition to ultimate users, individuals lawfully entitled to dispose of ultimate user decedent's
property are authorized to dispose of the ultimate user’s substances by utilizing any of the three options for disposal. All of the proposed collection methods are voluntary and no person is required to establish or operate a disposal program.

DEA proposes specific language that will continue to authorize federal, state, tribal, and local law enforcement agencies, either independently or in partnership with private entities or community groups, to voluntarily hold take-back events and administer mail-back programs. DEA also proposes to authorize certain registrants (manufacturers, distributors, reverse distributors, and retail pharmacies) to be “collectors,” with authorization to conduct mail-back programs. All mail-back programs must provide specific mail-back packages to the public, either at no cost or for a fee, and collectors that conduct mail-back programs must have and utilize an on-site method of destruction.

Finally, DEA proposes that law enforcement agencies voluntarily maintain collection receptacles at that agency’s physical location and to authorize collectors to maintain collection receptacles at their registered location. Retail pharmacies that are authorized to be collectors may maintain collection receptacles at long term care facilities (LTCFs). LTCFs are permitted to dispose of controlled substances on behalf of an ultimate user that resides or has resided at that LTCF only through a collection receptacle that is maintained by a retail pharmacy at that LTCF.

DEA proposes to allow all controlled substances collected through take-back events, mail-back programs, and collection receptacles to be comingled with non-controlled substances. Controlled substances collected by collectors may not be individually counted or inventoried. In addition, DEA proposes various collection security and recordkeeping requirements.
DEA appreciates that there is a cost to voluntarily providing these methods of collection and destruction. DEA notes 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 benefit the public by decreasing the supply of controlled substances available for misuse, abuse, and accidental ingestion, and protect the environment from potentially harmful contaminants. 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, the proposed regulation specifies that mail-back program collectors may partner with third parties to make mailers 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 mailers.

Registrant Disposal

DEA proposes to delete the existing rule related to registrant disposal, 21 CFR 1307.21, and incorporate similar requirements on proper disposal procedure, security, and recordkeeping in a new part 1317 on disposal. DEA proposes these changes in order to provide consistent disposal procedures for each registrant category, regardless of geographic location. In addition, DEA proposes to modify 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.

*Reverse Distributors*

DEA proposes revised regulations for reverse distributors that are clear, consistent, and consolidated into one part. Reverse distributors are often the last registrant to possess controlled substances prior to destruction because they are at the end of the closed system and the same recordkeeping safeguards that exist when controlled substances are distributed between registrants are not present. 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. DEA believes that the proposed regulations will help reverse distributors comply with the Controlled Substances Act in a manner that effectively decreases the risk of the diversion of controlled substances during the disposal process. DEA proposes to revise the definition of reverse distributor in addition to proposing new procedures that reverse distributors must follow to acquire controlled substances from registrants and other security and recordkeeping requirements.

*Return and Recall*

DEA proposes to delete the existing rule on return and recall, 21 CFR 1307.12, and incorporate into a new part 1317 clarified and separate return and recall requirements for registrants and non-registrants.

*Methods of Destruction*

DEA proposes a standard of destruction — non-retrievable — for persons that
intend to destroy controlled substances. In particular, 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.

Background

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and the Controlled Substances Import and Export Act (21 U.S.C. 801-971), as amended, and referred to as the Controlled Substances Act (CSA). 1 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 purposes. 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 based on their use and importance to the manufacture of controlled substances

1The Attorney General’s delegation of authority to DEA may be found at 28 CFR 0.100.
(List I or List II chemicals). 21 U.S.C. 802(33) – (35).

The CSA establishes a closed system of distribution that requires 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 controlled substances is essential to preventing the diversion of controlled substances into the illicit market.

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

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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 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 controlled substances, if they distribute (i.e., deliver or transfer) such controlled substances without the appropriate registration, they are in violation of the CSA. Such unlawful distribution includes the transfer of controlled substances for the purpose of disposal.

On October 12, 2010, the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act) was enacted (Pub. L. 111-273, 124 Stat. 2858). The Disposal Act amended the CSA to allow an ultimate user to “deliver” a controlled substance “to another person for the purpose of disposal” if the person receiving the controlled

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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 these terms are not defined. For example, in the CSA, see 21 U.S.C. 822(g); 824(f) and (g); 826(c), (e), and (f); 827(a)(3) and (d)(1); 842(a)(7); 853(n); 880(a)(2); 881(e)(1); and 958(d)(6); and in the CFR, see 21 CFR 1307.21(b). 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.” 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 Notice of Proposed Rulemaking, 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. When necessary to specify a particular activity within the disposal process, the particular activity is identified, e.g., transfer, deliver, collect/collection, return, recall, destroy/destruction.
substance is authorized to receive that substance and the disposal takes place in accordance with regulations issued by the Attorney General to prevent the diversion of controlled substances. 21 U.S.C. 822(g)(1). The Attorney General delegated responsibility for promulgating the Disposal Act implementing regulations to DEA.

In addition to authorizing ultimate users to deliver their controlled substances to another person for the purpose of disposal, the Disposal Act also authorized any person lawfully entitled to dispose of an ultimate user decedent’s property to deliver the ultimate user’s controlled substance to another person for the purpose of disposal if the ultimate user dies while in lawful possession of the controlled substance. The Disposal Act also gave DEA the ability, by regulation, to authorize long term care facilities (LTCFs) to dispose of controlled substances on behalf of ultimate users who reside or have resided at the LTCF. Congress directed 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.

History of Disposal of Controlled Substances

In 1970, Congress created the CSA after consolidating more than 50 laws related to the control of narcotics and dangerous drugs. The statute was “designed to improve the administration and regulation of the manufacturing, distribution, and dispensing [and import/export] of controlled substances by providing for a ‘closed’ system of drug distribution for legitimate handlers of such drugs” with criminal penalties for transactions
outside the legitimate chain.\textsuperscript{5} With the enactment of the CSA, the Attorney General delegated the responsibility for promulgating the CSA’s implementing regulations to DEA’s predecessor, the Bureau of Narcotics and Dangerous Drugs (BNDD).\textsuperscript{6}

BNDD recognized that to maintain the closed system of distribution, secure avenues for the destruction of controlled substances were essential. The implementing regulations specifically addressed the issue of the disposal of controlled substances (36 FR 7776, April 24, 1971). In particular, the implementing regulations outlined a process under which any person lawfully in possession of a controlled substance could distribute such substance to the person from whom he/she obtained it or return it to the manufacturer or the manufacturer’s registered agent, and created procedures for any person in possession of a controlled substance, with instruction from DEA, to either deliver or transfer the substance to another for destruction, or to destroy that substance themselves. 21 CFR 1307.12 and 1307.21. These procedures have changed little since 1971.

\textit{DEA Registrant Disposal – Reverse Distributors}

Through the mid-1990s, DEA accepted controlled substances from registrants for destruction or authorized registrants to destroy controlled substances pursuant to 21 CFR 1307.21. Manufacturers also accepted returns of controlled substances from their customers as an additional service. Eventually, a group of brokers emerged with the sole purpose to collect controlled substances from registrants for destruction pursuant to the

\textsuperscript{6} In 1973, the BNDD was abolished and all BNDD functions were transferred to DEA. Reorganization Plan No. 2 of 1973, 38 FR 18380 (July 2, 1973).
procedures outlined in DEA's regulations. Initially, this group registered with DEA as distributors and called the services that they provided "reverse distribution." At about the same time, another group emerged called "inventory control processors/auditors" whose primary purpose was to identify expired substances in a registrant's inventory and prepare them for disposal by the registrant pursuant to 21 CFR 1307.21, or return to the person from whom it was obtained or to the manufacturer. This group was not required to register with DEA in order to conduct their activities because they did not take possession of the substances. Any inventory control processors/auditors that wanted to take possession of controlled substances were required to register with DEA as distributors. To reduce the risk of diversion from these activities, and ensure accountability during the disposal process, DEA and the registered distributors entered into memorandums of understanding (MOUs) that outlined acceptable disposal procedures until permanent regulations were finalized.

Initially, DEA proposed to codify these MOUs by issuing a Notice of Proposed Rulemaking to define and register a new category of manufacturer registration called "disposers" that would authorize those registrants to receive controlled substances for the primary purpose of destruction (60 FR 43732, August 23, 1995). This rule was never finalized. In 2003, DEA readdressed the issue of registrant disposal in an Interim Final Rule (IFR) to define and register "reverse distributors" (68 FR 41222, July 11, 2003). In 2005, DEA published a final rule, thereby finalizing a new category of distributor registration called "reverse distributors" (70 FR 22591, May 2, 2005). The final rule authorized reverse distributors to acquire controlled substances from DEA registrants for

7 The procedures are found today in 21 CFR 1307.21.
the purpose of return to the manufacturer or manufacturer's agent or for processing those substances for disposal in accordance with 21 CFR 1307.21. The final rule also codified security, recordkeeping, reporting, and order form requirements applicable to reverse distributors.

Non-Registrant Disposal

As discussed above, prior to passage of the Disposal Act, the CSA did not address the disposal of controlled substances by ultimate users. 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.). The CSA did not, however, account for circumstances in which controlled substances were lawfully dispensed to and possessed by an ultimate user, but not fully used. To this end, the CSA did not authorize the ultimate user to transfer unwanted and unused controlled substances to another person for the purpose of disposal.

Moreover, the CSA did not address the disposal of controlled substances by long term care facilities (LTCFs). DEA defines a LTCF as "a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients." 21 CFR 1300.01(b). Generally, controlled substances are prescribed by a LTCF resident's physician and dispensed by the resident's pharmacist; such controlled substances are owned by the resident. This is in contrast with patients in a hospital where controlled substances are dispensed dose by dose and remain under the possession and control of the registered dispenser, the hospital. Accordingly, a LTCF may secure its residents' controlled substances for custodial purposes only. The controlled substances
remain in the lawful possession of the resident, the ultimate user. As with any other ultimate user, prior to the enactment of the Disposal Act, a LTCF resident in lawful possession of dispensed controlled substances could not distribute those substances to another person, even for the purpose of disposal.

In anticipation of the growing need of ultimate users and LTCFs to dispose of unused and unwanted controlled substances, DEA published an Advance Notice of Proposed Rulemaking to solicit information on the disposal of controlled substances by ultimate users and LTCFs (74 FR 3480, January 21, 2009). Subsequently, as discussed above, on October 12, 2010, the Secure and Responsible Drug Disposal Act of 2010 was enacted.

Existing DEA Regulations

Existing DEA regulations on the disposal of controlled substances are codified at 21 CFR 1307.12 and 1307.21. The process for returns is outlined in 21 CFR 1307.12 and permits any person in lawful possession of a controlled substance to distribute that substance, without being registered to distribute, to the person from whom the substance was obtained or to the manufacturer or manufacturer’s registered agent.

The procedure governing the transfer of controlled substances for disposal is outlined in 21 CFR 1307.21. In the existing regulations, any person in possession of any controlled substance that desires or is required to dispose of such substance may request authority and instructions for disposal from the DEA Special Agent in Charge (SAC) in the region in which they are located. The SAC must authorize and instruct applicants to dispose in one of four ways, by: (1) transfer to a DEA registrant authorized to possess the substance; (2) delivery to an agent of DEA or to the nearest DEA office; (3) destruction
in the presence of an agent of DEA or other authorized person; or (4) such other means that the SAC determines to assure that the substance does not become available to unauthorized persons. 21 CFR 1307.21(b).

Registrants requesting authority and instructions from the SAC to dispose of controlled substances must submit to the SAC three copies of DEA Form 41 listing the controlled substances that the registrant would like to dispose. 21 CFR 1307.21(a).

Registrants required to regularly dispose of controlled substances may ask the SAC for authorization to dispose of those substances without prior approval from DEA in each instance if the registrant agrees to keep records of disposal. Further, the SAC may place additional conditions upon the ongoing approval to dispose. 21 CFR 1307.21(c).

*Reverse Distributors*

DEA currently defines a reverse distributor as “a registrant who receives controlled substances acquired from another DEA registrant for the purpose of—(1) Returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer’s agent; or (2) Where necessary, processing such substances or arranging for processing such substances for disposal.” 21 CFR 1300.01(b). Reverse distributors are required to meet general security requirements, the security requirements applicable to non-practitioners, and specific inventory, recordkeeping, and reporting requirements. DEA registrants are authorized to distribute their lawfully possessed controlled substances to a registered reverse distributor to the extent authorized by their registration and in conformity with the CSA and its implementing regulations. 21 U.S.C. 822(b) and 958(g); See, e.g., 21 CFR 1301.13(e) and 1307.11. Manufacturers, distributors, importers, and practitioners are currently authorized to distribute their
lawfully possessed controlled substances to a reverse distributor without prior authorization from the SAC in the region they are located. 21 CFR 1301.13(e)(i), (ii), (viii) and 1307.11(a)(2).

Law Enforcement Agencies and Ultimate User Take-Back Events

Until DEA finalizes the implementing regulations for the Disposal Act and expanded options for disposal are available, ultimate users may not deliver their lawfully obtained controlled substances to any other person for the purpose of disposal other than by surrender to law enforcement or under the direction of the DEA Special Agent in Charge in the area in which the person is located. In the interim, DEA has established National Take-Back Days. DEA organized these nationwide one day events as a collaborative effort with state and local law enforcement agencies. The National Take-Back Days provide the public with a convenient and secure way to surrender pharmaceutical controlled substances to law enforcement for destruction.

Prescription Drug Abuse Epidemic

Before the Disposal Act, the CSA did not address the disposal of controlled substances by ultimate users. To dispose of their controlled substances, ultimate users were permitted to destroy the substances themselves (e.g., mix the substances with coffee grounds, place in a plastic bag, and throw into the garbage or flush) or surrender the substances to law enforcement or DEA. There is concern, however, that throwing controlled substances into the garbage or flushing them can contribute to harming the environment. Because the public has limited options for disposal, outdated and unwanted

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9 DEA registrants are not authorized to dispose of controlled substances at these events; DEA registrants must comply with the current DEA regulations regarding disposal of controlled substance stock/inventory.
controlled substances often accumulate in medicine cabinets, easily within reach of children and teenagers. In passing the Disposal Act, Congress recognized that the secure disposal of controlled substances is important because of the significant prescription drug abuse problem in the United States. The Centers for Disease Control and Prevention declared prescription drug overdoses an epidemic. Studies show the adverse consequences associated with the substantially high levels of abuse and misuse (non-medical use) of prescription drugs.

The availability of outdated or unwanted prescription drugs is problematic because there is a concern that young people may perceive prescription and/or over-the-counter drugs as “safer” than illegal drugs because of their intended, legitimate medical use. This misperception may be shared by parents. Over 20 percent of parents believe that it is acceptable to give a teen a prescription drug that was not prescribed to them. The 2010 National Survey on Drug Use and Health (NSDUH) indicates that over 70 percent of Americans twelve and older who used pain relievers non-medically in the previous year obtained the drugs from a friend or relative. Another study found that more than 50 percent of teens obtained prescription drugs from their own family’s

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13 The National Survey on Drug Use and Health (NSDUH) is an annual survey of the civilian, non-institutionalized, population of the United States aged twelve or older. The survey is conducted by the Department of Health and Human Services Office of Applied Studies, Substance Abuse and Mental Health Services Administration (SAMHSA).
medicine cabinet.\textsuperscript{15}

The prevalence of controlled substance prescription drug abuse among teenagers is right behind their abuse of marijuana (to include organic marijuana and synthetic cannabinoids). The 2011 “Monitoring the Future” survey of teenagers found that 8.1 percent of high school seniors reported non-medical use of Vicodin (a brand name for Schedule III hydrocodone combination products) in the past year, and 4.9 percent reported non-medical use of OxyContin (a brand name for Schedule II oxycodone sustained release products) in the past year.\textsuperscript{16} This is consistent with reports by high school students of increased non-medical use of painkillers in the past five years.\textsuperscript{17} According to a 2009 survey by the Partnership at Drugfree.org, more than 50 percent of teenagers (grades 9-12) believe that prescription drugs are easier to obtain than illegal drugs.

Prescription drug abuse is the fastest growing drug problem in the United States. Findings from the 2010 NSDUH estimate that 7.0 million persons aged twelve or older used prescription-type psychotherapeutic drugs – pain relievers, anti-anxiety medications, stimulants, and sedatives – non-medically in the previous month.\textsuperscript{18} This represents 2.7 percent of the U.S. population.\textsuperscript{19} In 2010, 2 million persons aged twelve or older used

\textsuperscript{15} Partnership for a Drug-Free America and MetLife Foundation, “2010 Partnership Attitude Tracking Study,” April 6, 2011.


\textsuperscript{19} These estimates were similar to those from the 2009 survey but 13 percent higher than those from the 2008 survey.
pain relievers non-medically for the first time.\textsuperscript{20} On average, every day 2,046 12 to 17-year-olds abuse a prescription pain reliever for the first time.\textsuperscript{21}

Non-medical prescription drug use, particularly among young adults, is having a devastating effect on the United States. According to the Centers for Disease Control and Prevention, poisoning deaths, which include drug overdoses such as those from prescription drugs, are the leading cause of injury death in the United States; nearly nine out of ten poisoning deaths are caused by drugs and more than 40\% of those involve opioid analgesics.\textsuperscript{22} According to SAMHSA’s latest Drug Abuse Warning Network (DAWN) data, of the 4.6 million emergency department visits in 2009 associated with drug use, about 1.2 million visits involved the non-medical use of pharmaceuticals.\textsuperscript{23} Emergency department visits involving non-medical use of pharmaceuticals (misuse or abuse) almost doubled between 2004 and 2009 from 627,291 in 2004 to 1,244,679 visits in 2009 (a 98.4 percent increase).\textsuperscript{24} About half of the 2009 emergency department visits related to misuse or abuse of pharmaceuticals involved painkillers and more than one-third involved drugs to treat insomnia and anxiety.\textsuperscript{25}

\textbf{Scope of Proposed Rule}

In response to this growing problem, DEA is proposing new, expanded regulations for the disposal of controlled substances by ultimate users in accordance with

\textsuperscript{20} Id.
\textsuperscript{21} Substance Abuse and Mental Health Services Administration, 2010 National Survey on Drug Use and Health.
\textsuperscript{24} Id. at 4.
\textsuperscript{25} Id. at 3.
the Disposal Act. These regulations will provide ultimate users with more options for
disposal of their controlled substances so that the controlled substances will not
accumulate and be available for misuse, abuse, and accidental ingestion by children and
the elderly. In drafting the implementing regulations, DEA considered the public health
and safety, ease and cost of program implementation, and participation by various
communities. To this end, 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 (e.g., ultimate users). The reverse
distributor registration category, which is pertinent to the process of registrant disposal,
was included in this comprehensive review.

As discussed above, DEA currently regulates the disposal of controlled
substances by registrants and other persons in accordance with 21 CFR 1307.21 and
regulates the returns process through 21 CFR 1307.12. The existing disposal regulation
gives DEA Special Agents in Charge (SACs) the discretion to authorize disposal in a
manner that reduces the risk of diversion from this activity on a case-by-case basis.
These regulations have changed little since the CSA was enacted. While this approach is
effective, with the enactment of the Disposal Act and the increasing need for the
responsible disposal of controlled substances by registrants and non-registrants alike,
DEA believes that in order to securely and effectively dispose of unwanted or unused
controlled substances, consistent nationwide standards on disposal are necessary. As a

DEA does not address the proper disposal of listed chemicals by DEA registrants in this rulemaking.
result, DEA proposes to delete 21 CFR 1307.12 on “Distribution to supplier or
manufacturer” and 21 CFR 1307.21 on “Disposal of controlled substances” and
promulgate a new part 1317 that will expand available disposal options, establish
nationwide standards for the disposal of controlled substances, and comprehensively
outline the process and procedure for the disposal of controlled substances by registrants,
ultimate users, and other non-registrants such as long term care facilities.27

The goal of this proposed new part on disposal, consistent with Congress’s goal in
passing the Disposal Act, is to set controlled substance diversion prevention parameters
that will allow public and private entities to develop a variety of methods for collecting
and destroying controlled substances in a secure, convenient, and responsible manner.
DEA believes that the new part on disposal will provide registrants and non-registrants
alike clear and consistent requirements for the disposal of controlled substances. It is
intended to maximize cost efficiency, voluntary participation, and public accessibility
while simultaneously promoting the secure and responsible disposal of controlled-
substances in order to prevent diversion.

In accordance with the changes described above, DEA proposes to delete any
reference to 21 CFR 1307.12 and 1307.21 and replace it with a reference to the new 21
CFR part 1317, where appropriate.28 DEA also proposes to revise 21 CFR

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27 Any previous waivers, MOUs, and MOAs issued in accordance with 21 CFR 1307.21 shall be
superseded by this rulemaking on the “Disposal of Controlled Substances” if and when it is finalized.
28 DEA proposes in 21 CFR 1301.76 to delete reference to 1307.12 and replace it with reference to 21 CFR
part 1317; in 21 CFR 1304.11(e) and the introductory paragraph of 1304.22 to delete reference to 21 CFR
1307.12; in 21 CFR 1301.25(i), 1301.52(c), and 1307.13 to delete reference to 21 CFR 1307.21 and replace
it with reference to 21 CFR part 1317; in 21 CFR 1304.25(a)(9) and 1304.25(b)(9) to delete reference to 21
CFR 1307.22 and replace it with reference to 21 CFR part 1317; and in 21 CFR 1304.04(a) to add reference
to 21 CFR part 1317. DEA also proposes in 21 CFR 1307.22 to delete reference to 21 CFR 1307.21, and
replace it with reference to 21 CFR part 1317. DEA proposes to revise the title of 21 CFR 1307.22 to
“Delivery of surrendered and forfeited controlled substances” for clarity.
1301.13(e)(1)(i) to delete reference to a disposer category of registration in the coincident activity column for manufacturers. A disposer category of registration was proposed by DEA in 1995, but was never finalized (60 FR 43732, August 23, 1995). Reference to a disposer category was inadvertently included in a previous rulemaking (68 FR 58587, October 10, 2003).

January 19 – 20, 2011 Public Meeting

On January 19 and 20, 2011, DEA held a well-attended public meeting to receive information from interested parties and the public and gather ideas for drafting regulations for the newly enacted Disposal Act. (The Notice of Meeting was published in the Federal Register on December 22, 2010, 75 FR 80536.) This meeting provided an opportunity for all interested persons — the general public, including ultimate users, parents, pharmacies, waste management companies, long term care and pharmaceutical related industries, as well as federal, state, and local agencies, including law enforcement personnel, and others — to express their views regarding safe and effective methods of disposal of controlled substances consistent with the CSA. Representatives of various industries and organizations as well as federal, state, and local agencies made presentations at the meeting and many submitted written comments prior to the meeting.

In drafting the Disposal Act implementing regulations, DEA gathered information about disposal from the more than 70 written comments and 44 oral presentations that were submitted and transcribed from the two day public meeting. Information and experience resulting from pilot projects around the United States involving mail-back programs, take-back events, and collection receptacles for pharmaceuticals were shared and helped inform this proposed rule. Representatives of law enforcement agencies
provided information on their experience, existing procedures, and perspective, particularly with respect to take-back events as a method of collection. Representatives from DEA registrant and other affected groups, such as pharmacies, reverse distributors, and the waste management industry, provided insights on technology and existing destruction procedures. Presentations by the Environmental Protection Agency, the Food and Drug Administration, the U.S. Postal Service, the U.S. Army, and state and local agencies provided information on relevant federal, state, and local laws and procedures pertaining to the disposal and transportation of controlled substances, particularly pharmaceuticals. DEA appreciated and considered all information provided at or submitted in response to the Notice of Meeting in drafting this NPRM.

**Proposed Disposal Act Implementing Regulations**

**Disposal of Controlled Substances by Ultimate Users – Authorized Persons**

In accordance with the Disposal Act, DEA proposes new regulations for the disposal of controlled substances by ultimate users and other non-registrants – in particular: (1) persons lawfully entitled to dispose of ultimate user decedent’s property and (2) LTCFs on behalf of ultimate users that reside or have resided at that LTCF. In drafting these proposed implementing regulations, DEA considered the public health and safety, ease and cost of program implementation, and participation by various communities. To this end, DEA proposes three options for ultimate users to dispose of controlled substances: (1) take-back events; (2) mail-back programs; and (3) collection receptacle locations. These proposed options are voluntary and no person is required to establish or operate a disposal program, although any person who chooses to do so and is authorized by DEA to do so must adhere to the final regulations.
DEA proposes to authorize ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property to deliver lawfully possessed controlled substances in Schedules II, III, IV, and V to law enforcement agencies through take-back events, mail-back programs, and collection receptacles, and to authorized collectors through mail-back programs and collection receptacles. DEA is also proposing to authorize LTCFs, on behalf of an ultimate user that resides or has resided at that LTCF, to deliver a resident's lawfully possessed controlled substances in Schedule II, III, IV, or V to certain on-site collection receptacles operated by a registered retail pharmacy that is an authorized collector. The collection of Schedule I controlled substances is not permitted because, generally, ultimate users cannot lawfully possess Schedule I substances unless they are participating in an investigational use of drugs pursuant to 21 U.S.C. 355(i) and 360b(j). For ultimate users in lawful possession of Schedule I substances for investigational use, DEA proposes that they follow the disposal procedures in 21 CFR 1317.85(b). Furthermore, the proposed collection methods are intended for the collection and destruction of lawfully possessed controlled substances, not as an avenue for the disposal of substances that were illegally obtained.

DEA proposes in sections 1317.65 – 1317.80 that controlled substances collected from ultimate users and other authorized non-registrant persons may be comingled with non-controlled substances – both controlled and non-controlled substances may be collected together so long as the requirements outlined for controlled substances are followed. Comingling reduces the risk of diversion and is practical, efficient, and economical. Members of the public cannot easily identify the difference between controlled and non-controlled substances. As collection pilot programs demonstrate, the
requirement that controlled and non-controlled substances be collected separately is
expensive, time-consuming, and hampers the collection process. In addition, conmingling
controlled substances is another way to minimize the risk of diversion of collected
controlled substances. For example, many pharmacies and institutional practitioners
disperse controlled substances throughout the stock of non-controlled substances in order
to deter the theft or diversion of the controlled substances. See 21 CFR 1301.75(b).

DEA proposes in section 1317.30 that federal, state, tribal, and local law
enforcement agencies continue with authority to collect ultimate user controlled
substances, and that certain registrants authorized by DEA to be a “collector” be
authorized to collect controlled substances from ultimate users, persons lawfully entitled
to dispose of ultimate user decedent’s property, and, in some circumstances, long term
care facilities. DEA is authorizing certain registrant categories to be “collectors” so that
DEA can ensure sufficient physical security controls are in place, thereby minimizing the
risk of diversion. Registrants are subject to controls related to their DEA registration.
These pre-existing controls will protect against the diversion of controlled substances in
the process of ultimate user collection.

Possession for Disposal

Once a controlled substance is lawfully dispensed to an ultimate user, the ultimate
user is in possession of that substance. Only the ultimate user or other authorized persons
(i.e., persons lawfully entitled to dispose of an ultimate user decedent’s property and, in
some cases, the LTCF where the ultimate user resides or has resided) may dispose of
such controlled substances in accordance with DEA’s proposed ultimate user disposal
regulations. In contrast, a controlled substance dispensed for immediate administration
pursuant to an order for medication in an institutional setting remains in the possession of that registered institution, even if 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). Such remaining substance must be properly recorded, stored, and destroyed in accordance with DEA regulations, and all applicable federal, state, tribal, and local laws and regulations. These same principles would apply to hospice settings, which may be registered by DEA as an institutional practitioner or may be unregistered like many LTCFs.

*Law Enforcement Agencies*

DEA proposes specific language in section 1317.35 to continue to authorize law enforcement agencies, on a voluntary basis, to collect controlled substances from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property through: (1) take-back events, (2) mail-back programs, and (3) collection receptacles located at the law enforcement agency's physical address.

DEA recommends that law enforcement agencies electing to participate in ultimate user disposal maintain any records of receipt or collection in a manner that is consistent with that agency's recordkeeping requirements for illicit controlled substance evidence handling and store any controlled substances collected in a manner that reasonably prevents the diversion of controlled substances and is consistent with that agency's standard procedures for storing illicit controlled substances. Destruction of controlled substances must be in accordance with applicable federal, state, tribal, and local laws and regulations. DEA recommends that law enforcement agencies also keep a record of any transfer of controlled substances to reverse distributors for destruction; such
records may assist DEA in ensuring that reverse distributors are keeping proper records of those controlled substances they acquire from law enforcement agencies that conduct ultimate user disposal activities. DEA recognizes that law enforcement agencies have existing procedures regarding the handling, storage, or transfer for destruction of controlled substances. These proposed rules do not require changes to those procedures. DEA anticipates that those existing procedures will provide the necessary security to prevent the diversion of controlled substances.

DEA proposes that law enforcement agencies that choose to conduct mail-back programs within their jurisdiction must make available to ultimate users packages described in proposed section 1317.70. Such packages may, however, be made available pursuant to a partnership or other agreement between the law enforcement agency and another person for the purpose of funding, dissemination, production, or other non-collection activity meant to facilitate the law enforcement agency’s mail-back program. Such standards will help to alleviate the primary security concerns related to mail-back programs. As explained below, many such concerns exist regardless of the destination of the mail-back packages; thus, security standards related to the mail-back packages must be maintained even if the program is conducted by a law enforcement agency. DEA emphasizes, however, that the authority of law enforcement agencies to conduct ultimate user disposal programs is not a mechanism by which registrants may circumvent these proposed regulations or any other applicable laws or regulations. Any person, group, or entity that partners with a law enforcement agency to implement an ultimate user disposal program must comply with all applicable laws and regulations. In specific terms, any authorized collector that partners with a law enforcement agency to jointly conduct a
collection program must adhere to these proposed regulations and any other applicable laws and regulations.

DEA appreciates that implementing some of the proposed disposal methods may present challenges to some state, tribal, and local law enforcement agencies. When implementing any new community service, all government agencies must balance available resources against established priorities. DEA hopes that these regulations will provide flexibility and opportunities for communities, interest groups, registrants, and law enforcement agencies to partner together to provide cost effective, safe, and convenient methods of ultimate user disposal. DEA looks forward to receiving suggestions from state, tribal, and local law enforcement agencies concerning its proposed regulations for the disposal of controlled substances by law enforcement agencies.

Collectors

DEA proposes in section 1300.01(b) to define a “collector” as a registered manufacturer, distributor, reverse distributor, or retail pharmacy that is authorized to receive a controlled substance for the purpose of destruction from an ultimate user, person lawfully entitled to dispose of an ultimate user decedent’s property, or a long term care facility on behalf of an ultimate user that resides or has resided at that facility. In section 1317.40(a), DEA proposes that registered manufacturers, distributors, reverse distributors, and retail pharmacies may obtain authorization from DEA to be a collector. No manufacturer, distributor, reverse distributor, or retail pharmacy is required to be a collector.

In proposing which DEA registrants could become authorized collectors, DEA
considered public health and safety, diversion control, and convenience and accessibility. In particular, DEA is proposing to authorize registered retail pharmacies to become collectors because such registrants are open to the public and have theft and loss prevention measures within the pharmacy processing area as well as outside the confines of the prescription processing and pick-up area, which easily lends itself to secure collection receptacle placement. Retail pharmacy personnel also routinely handle controlled substances intended for the ultimate user in a public setting while keeping such substances secure, and they have experience comingling controlled and non-controlled substances in the receipt and storage process. As public retail establishments, retail pharmacies generally have experience with the general public as customers and routinely implement theft and loss prevention measures.

For the foregoing reasons, retail pharmacies co-located with hospitals may be authorized to maintain collection receptacles in accordance with these regulations. Registered hospitals themselves, however, may not be authorized as collectors. This should have limited adverse impact on the ability of hospital patients to participate in ultimate user disposal because DEA believes many hospitals are co-located with registered retail pharmacies as a convenient service for outpatients. DEA proposes to restrict hospitals from being authorized collectors because they do not generally operate under the same business model or with similar theft and loss prevention procedures as retail pharmacies. For example, the general public is expected to enter retail pharmacies for short durations in order to conduct retail business. The physical layout of retail pharmacies is designed for open, clearly observable common areas and practically no areas 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; they are much larger than retail pharmacies and many interactions occur behind closed doors without routine theft and loss prevention measures; and foot traffic is not routinely monitored for unlawful purposes. These differences reduce the effectiveness of the proposed regulation's diversion control mechanisms and substantially increase the risk of diversion at hospitals if hospitals were authorized as collectors.

The above discussed risks in allowing hospitals as collectors are not necessary in light of the many other options available to ultimate users to dispose of unwanted or unused controlled substances.

In addition to the increased risk of diversion at hospitals, there is a risk of inadequate recordkeeping if hospitals are permitted as collectors. Unlike retail pharmacies, registered hospitals do not dispense controlled substances to ultimate users pursuant to legitimate prescriptions. Rather, registered hospitals administer controlled substances to inpatients dose by dose, and the controlled substances remain within the possession and control of the registered dispenser, the hospital. As such, registered hospitals may not dispose of controlled substances in collection receptacles, but must follow the revised regulations for registrant destruction, and keep records of such destruction.

DEA is also proposing to allow retail pharmacies to operate collection receptacles in LTCFs under certain circumstances, as discussed below, because—unlike hospitals—LTCFs “face a distinct set of obstacles to the safe disposal of [ultimate user] controlled substances.”
substances due to the increased volume of controlled substances they handle.” Pub. L. 111-273, 2, 124 Stat. 2858. DEA is further proposing to authorize registered manufacturers, distributors, and reverse distributors to become collectors because, although such registrants have registered locations that generally are not open to the public, they do have heightened security requirements and are accustomed to receiving, securing, and distributing large amounts of controlled substances on a daily basis. DEA believes that expanding collector authorization to these registrants will provide the necessary convenience and accessibility to the public while ensuring the public health and safety and minimizing potential diversion.

To obtain authorization to be a collector, a manufacturer, distributor, reverse distributor, or retail pharmacy must apply for a modification to their registration in accordance with 21 CFR 1301.51, which DEA is proposing to revise in order to reflect these changes. Upon DEA approval of this modification in registration, each authorized registrant’s DEA Certificate of Registration will specify that registrant’s status as a “collector” and the location(s) approved for collection. Once approved to be a collector, the option for renewal will be available to authorized registrants when they renew their registration.

DEA proposes in section 1317.40(a) that if the registrant that is authorized to collect ceases activities as a collector, such registrant must modify their registration in accordance with 21 CFR 1301.51 to indicate that they no longer collect. In accordance with 21 CFR 1301.52, the registration of any person and any modifications, including authorization to be a collector, terminates if and when such person dies, ceases legal existence, discontinues business or professional practice, or surrenders a registration.
Any registrant that ceases legal existence or discontinues business or professional practice must notify the Administrator promptly of such fact. 21 CFR 1301.52(a).

Additionally, a registrant’s authorization to collect is dependent upon the registration status of the manufacturer, distributor, reverse distributor, or retail pharmacy. Accordingly, the expiration, revocation, suspension, or surrender of a DEA registration will also result in the loss of the registrant’s authorization to be a collector.

DEA proposes in section 1317.40(c) that authorized collectors may conduct the following activities: (1) receive mail-back packages from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent’s property if the collector has and utilizes an on-site method of destruction; (2) install, manage, and maintain collection receptacles at locations for which the registrant is authorized to collect; and (3) promptly dispose of sealed inner liners and their contents as provided for in § 1317.05(c)(2). DEA proposes in section 1317.40(b) that collection may occur only at the registered locations of manufacturers, distributors, reverse distributors, and retail pharmacies that are authorized to collect at those locations and at long term care facilities (LTCFs) at which registered retail pharmacies are authorized to maintain a collection receptacle (see discussion on LTCFs below).

DEA proposes to authorize as collectors those persons already registered as manufacturers, distributors, reverse distributors, and retail pharmacies because, as registrants, these persons are accountable, have experience handling large volumes of controlled substances on a routine basis, and they are subject to controls related to their DEA registration. These pre-existing controls also protect against the diversion of controlled substances in the process of ultimate user collection. Further, DEA believes
that ultimate user collection should occur at DEA registered locations because these premises are subject to DEA inspection, security, and other controls.29 Such requirements ensure that proper security and other controls are in place to minimize the risk of diversion from the collection of controlled substances. Finally, with the passage of the Disposal Act, Congress did not provide DEA the authority to register persons specifically for the purpose of collecting and disposing of controlled substances from ultimate users. DEA is therefore restricted to operating within its previously existing statutory authority with regard to registration.

In section 1317.45, DEA proposes that authorized collectors employ as an agent or employee with access to or influence over controlled substances acquired pursuant to their status as a collector, only those persons that have never been convicted of any felony offense related to controlled substances and have never, 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. DEA is proposing security requirements for collectors in order to strengthen the accountability of the ultimate user collection process, which occurs outside the closed system of distribution, by ensuring that only those employees that have met certain employee screening requirements have access to or influence over controlled substances collected from ultimate users. This requirement is similar to the employee screening requirements for registered practitioners in 21 C.F.R. 1301.76, where there is also a high risk of diversion.

29 In accordance with the Disposal Act, which permitted DEA to, by regulation, authorize LTCFs to dispose of controlled substances on behalf of ultimate users that reside or have resided at the LTCF (see 21 U.S.C. 822(g)(3)), DEA is also proposing to authorize the collection of controlled substances at those LTCFs for which a registered retail pharmacy is authorized to maintain a collection receptacle (see discussion of LTCFs below).
The information that collectors must maintain in their records is proposed in section 1317.50. In accordance with the CSA, every DEA registrant must 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). These records must be maintained separately from all other records of the registrant or, alternatively, in the case of non-narcotic controlled substances, be in such a form that required information is readily retrievable from the ordinary business records of the registrant. 21 U.S.C. 827(b)(2). The records must be kept and be available for at least two years for inspection and copying by officers or employees of the Attorney General. 21 U.S.C. 827(b)(3). DEA may promulgate regulations that specify the information that registrants are required to maintain in their records. 21 U.S.C. 827(b).

To this end, DEA is proposing information that collectors must record based on the particular ultimate user collection method utilized (i.e., mail-back program or collection receptacle). The inner liners and mail-back packages that DEA proposes to be utilized in the collection of ultimate user controlled substances are intended for the disposal of controlled substances. As a result, DEA is requiring that collectors make an inventory of all inner liners and mail-back packages and maintain records on the use and destruction of such liners and packages in order to properly account for the disposal of controlled substances in accordance with the CSA. Once sealed, inner liners and mail-

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30 The recordkeeping requirements differ depending on whether the records pertain to the registrant’s inventory or stock, or the registrant’s activities as an authorized collector. The requirements contained in the current regulations are those imposed on registrants with regard to their stock on hand (i.e., their inventory of controlled substances). Controlled substances collected from ultimate users are not part of a registrant’s inventory and would not be counted as such.
back packages shall not be opened, x-rayed, or otherwise penetrated and the substances contained in the inner liners and mail-back packages may not be individually handled, counted, inventoried, or otherwise discerned.

DEA is also proposing in section 1317.50 that collectors be exempt from the ARCOS requirements in 21 CFR 1304.33 and the order form requirements in 21 CFR part 1305 only when they collect controlled substances from ultimate users or other authorized non-registrant persons. Such substances are outside the closed system of distribution, and these tracking and accountability mechanisms are designed for substances within the closed system of distribution.

*Registered Reverse Distributors and Distributors*

DEA appreciates that law enforcement agencies and authorized collectors may not have the resources to destroy controlled substances received from ultimate users. Such persons may use the services of a registered reverse distributor for this purpose. DEA proposes in section 1317.55(a) to authorize registered reverse distributors to acquire for purposes of destruction controlled substances that have been collected by: (1) law enforcement agencies; and (2) authorized collectors through collection receptacles. DEA also proposes in section 1317.55(b) to authorize registered distributors, in addition to registered reverse distributors, to acquire for purposes of destruction controlled substances collected by authorized collectors through collection receptacles.\(^\text{31}\) DEA is proposing in section 1317.55(c) that registered reverse distributors and registered distributors that choose to acquire such collected controlled substances from authorized distributors or collectors may acquire controlled substances that have been collected by collection receptacle at either an authorized collector’s registered location or, pursuant to sections 1317.75(g) and 1317.80(d), at a long term care facility for which a registered retail pharmacy is authorized to collect. See subsequent discussion for more detail on reverse distributors.

\(^{31}\) Reverse distributors or distributors may acquire controlled substances that have been collected by collection receptacle at either an authorized collector’s registered location or, pursuant to sections 1317.75(g) and 1317.80(d), at a long term care facility for which a registered retail pharmacy is authorized to collect. See subsequent discussion for more detail on reverse distributors.
collectors do so in the manner prescribed for acquiring registrants' controlled substance inventory for purposes of disposal. This consistent procedure will help provide certainty in the disposal process, and help prevent errors during the acquisition process. Such acquisitions may be made pursuant to pick-up by the reverse distributor or distributor at the registrant's registered or authorized collection location, by delivery by common or contract carrier to the reverse distributor's or distributor's registered location, or by direct delivery from a non-practitioner to the reverse distributor's or distributor's registered location.

DEA proposes that authorized collectors that conduct mail-back programs must have and use an on-site method of destruction, and, as a result, these collectors will not be authorized to deliver or transfer those substances to a registered reverse distributor or distributor. The requirement to destroy on-site would not apply to law enforcement agencies that conduct mail-back programs; law enforcement agencies may continue to transfer any collected substance to an authorized reverse distributor.

Registered reverse distributors and distributors do not have to be authorized collectors to acquire collected controlled substances from law enforcement agencies or authorized collectors. In such circumstances, the substances being acquired have already been collected by law enforcement agencies and authorized collectors and should already be securely sealed in an inner liner or mail-back package in accordance with sections 1317.65 – 1317.80.

DEA also proposes in section 1317.55(c) that those registered reverse distributors and distributors that acquire controlled substances from law enforcement agencies and authorized collectors must destroy such controlled substances or securely transfer and
store the controlled substances utilizing applicable procedures described in section 1317.15(c) until timely destruction can occur. In addition, reverse distributors and distributors must destroy the controlled substances as soon as practicable but no later than fourteen calendar days of pick-up or delivery, pursuant to proposed section 1317.15(d).

Consistent procedures for the acquisition and disposal of registrant inventory and ultimate user collected controlled substances will streamline practices and help prevent confusion and error in the transfer, storage, and destruction processes. Any storage of such substances at the registered location of the reverse distributor or distributor must be in a manner consistent with the security requirements for Schedule II controlled substances. This is to minimize the risk of diversion because inner liners and mail-back packages shall not be opened once they are sealed and their contents will not be known, and, as a result, such liners and packages should be stored as though each contains a Schedule II controlled substance.

DEA also proposes in sections 1317.55(d) and 1317.100 to require that these reverse distributors and distributors keep records regarding the receipt, storage, transfer, and destruction of those controlled substances acquired from law enforcement agencies and authorized collectors.32 Such records will help to ensure that the collected substances are accounted for and properly destroyed.

Finally, DEA proposes in section 1317.55(e) and (f) to exempt reverse distributors and distributors that acquire collected controlled substances from law enforcement agencies or authorized collectors from the ARCOS requirements in 21 CFR 1304.33 and the order form requirements in 21 CFR part 1305, only when they acquire

32 For clarity, DEA proposes in 21 CFR 1304.11(e)(2) and 1304.22(h) to cross reference these reverse distributor and distributor recordkeeping requirements covered by 21 CFR 1317.55.
controlled substances that have been collected from ultimate users by law enforcement agencies or authorized collectors. Such substances are outside the closed system of distribution, and these tracking and accountability mechanisms are designed for substances within the closed system of distribution.

**Disposal of Controlled Substances by Ultimate Users – Authorized Methods**

**Take-Back Events**

The first method of collection that DEA proposes, in section 1317.65, is take-back events. Ultimate users and persons lawfully entitled to dispose of an ultimate user decedent’s property would be authorized to utilize a take-back event in accordance with 1317.65 to dispose of their controlled substances in Schedules II, III, IV, and V. As mentioned above, DEA is proposing specific language that will continue to authorize law enforcement agencies to conduct take-back events. DEA believes that take-back events should be conducted only by law enforcement agencies because such events are highly publicized, are often held at easily accessible locations within a community, and do not have the same security controls as permanent collection locations. As such, take-back events are more vulnerable to diversion. Although only law enforcement agencies would continue to be authorized to conduct take-back events, DEA proposes in section 1317.65(a) that private entities or community groups may continue to partner with law enforcement to hold community take-back events, thereby allowing for greater community involvement, education, and outreach, while minimizing the risk of diversion.

Many of the provisions that DEA proposes in section 1317.65, with respect to take-back events, are recommendations ("should" instead of "shall") because DEA has no intent to change existing law enforcement procedures regarding the handling, storage,
transfer, or destruction of controlled substances. DEA is, however, proposing some requirements that law enforcement agencies must follow in order to hold a take-back event. For example, in section 1317.65(b), DEA proposes that any law enforcement agency that conducts a take-back event shall appoint a law enforcement officer, who must be employed full time by the agency, to oversee the collection. Further, law enforcement officers employed and authorized by the law enforcement agency conducting the take-back event must 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 or destruction has occurred. DEA believes that designated law enforcement officers should be required to maintain control and custody of the controlled substances at all times in order to protect against theft and diversion.

Take-back events provide ultimate users the opportunity to dispose of Schedule II, III, IV, and V controlled substances, which they legally possess, at a designated place and time. DEA proposes in section 1317.65(c) that each take-back event should have at least one receptacle for the collection of permitted substances. Although this is only a recommendation for law enforcement agencies that conduct take-back events, DEA believes that optimal security and protection of public health and safety can be achieved if controlled and non-controlled substances are collected in a collection receptacle that is

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33 DEA proposes in section 1317.02 to define "law enforcement officer" for the purpose of 21 CFR part 1317. In order to prevent the appearance that a third party has access to or influence over controlled substances, for example by directly or indirectly funding law enforcement disposal activities, DEA is requiring the law enforcement officer to be directly employed full time by a law enforcement agency, be under the direction and control of the federal, state, tribal, or local government, be acting in the course of their official duty, and be duly sworn and given the authority by the federal, state, tribal, or local government to: (1) carry firearms; (2) execute and serve warrants; (3) make arrests without warrant; and (4) make seizures of property.
securely locked and substantially constructed with an outer shell and removable inner liner.

DEA also proposes in section 1317.65(e) that only an ultimate user or person lawfully entitled to dispose of an ultimate user decedent's property may transfer controlled substances to the law enforcement agency during the take-back event. No other person, such as a take-back event volunteer, may handle or touch the controlled substances at any time. DEA is proposing this requirement to limit the number of hands through which the substances pass because the risk of diversion increases each time a controlled substance is transferred to a new person.

*Mail-Back Programs*

The second method of collection that DEA proposes, in section 1317.70, is mail-back programs. Ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property are authorized to utilize a mail-back program in accordance with 1317.70 to dispose of their controlled substances in Schedules II, III, IV, and V. DEA proposes in section 1317.70(a) specific language to continue to authorize law enforcement agencies to voluntarily conduct mail-back programs; and mail-back programs may be conducted by registered manufacturers, distributors, reverse distributors, or retail pharmacies that: (1) are authorized as collectors; and (2) have and utilize an on-site method of destruction at their registered location. The security requirements proposed with respect to the other proposed collection methods (take-back events and collection receptacles) are adequate to ensure that controlled substances are collected and maintained in a manner that prevents diversion until transfer and destruction can occur. Designing regulations that ensure the security of controlled
substances in the context of mail-back programs is challenging because, unlike take-back events and collection receptacle locations, there is a third party who handles the controlled substances as they are transferred from the ultimate user to the authorized collector in mail-back programs – the mail system. This unique circumstance provides opportunities for diversion that do not exist with the other collection methods, thus requiring more stringent controls than the other methods. As a result, DEA proposes to allow mail-back programs to be voluntarily conducted by DEA registrants that are authorized collectors that have and utilize an on-site method of destruction and by law enforcement agencies in order to minimize the transfer of controlled substances between various locations. This is intended to minimize the risk of diversion.

DEA also proposes in section 1317.70(c) that any authorized collector or law enforcement agency that conducts a mail-back program must produce and provide specified packages, either at no cost or for a fee, to ultimate users for the collection of controlled substances through the mail, and may do so in partnership with third parties for convenience, funding, or any other lawful purpose. One example of such a partnership would be when an authorized collector with an on-site method of destruction (e.g., a DEA-registered reverse distributor) produces appropriate mail-back packages, and allows a third party business partner that is frequently accessed by the public (e.g., a retail pharmacy) to provide these packages to patronizing customers. In this circumstance, the registered reverse distributor would be responsible for operating the mail-back program, including recordkeeping and security, and it must receive the mail-back packages directly at its registered location for on-site destruction. DEA proposes that packages used for collection by mail-back must meet certain specifications. The proposed package
requirements include only those specifications necessary to ensure that controlled substances sent through the mail, outside of the closed system of distribution, can be tracked with a high degree of confidence in their security. These requirements are intended to protect public health and safety and prevent the diversion of controlled substances.

In particular, the packages are proposed to be postage paid (e.g., business reply), preaddressed to the authorized mail-back location, nondescript, tamper-evident and tear-resistant, among other things. This is to ensure that the mailers are not delayed or diverted through address changes, theft, or because the package has inadequate postage. Such mailers must be addressed to the authorized collector’s registered location with the on-site method of destruction or to the law enforcement agency’s physical address and cannot be addressed to any other location, such as a post office box.

DEA is also proposing to require that each package must have a unique identification number so that each package can be tracked. In an effort to increase the ease of program implementation and to enhance the security of the mail-back option, DEA is also proposing that each package include instructions for the user that indicate the process for mailing back the package, the permitted substances that can be sent, and notice that only packages provided by the authorized collector will be accepted for destruction.

DEA considered requiring registrants to establish a system that would allow ultimate users to notify the collector when the ultimate user mailed back a package containing controlled substances, similar to pilot projects described in the public hearing. However, the burden of requiring a notification system outweighed the benefits of such a
system, particularly when other security-enhancing measures are proposed. DEA believes that the collector inventory and recordkeeping requirements – that a collector conducting a mail-back program must keep inventory of mailers created and record the unique identification number of each mail-back package received – coupled with the stringent package specifications – for example the package must be postage paid and preaddressed – are sufficient controls to help protect against diversion while minimizing the burden on ultimate users. However, while DEA is not proposing to require collectors to create and maintain a notification system, such a system is not prohibited by the proposed regulations. To ensure privacy, the proposed language of section 1317.70(d) specifies that the public cannot be required to provide any personally identifiable information when mailing back controlled substances to an authorized collector.

DEA proposes in section 1317.70(e) that the authorized collector shall accept for the purpose of on-site destruction only those packages that they made available, directly or in partnership with a third party, for the collection of controlled substances. This requirement is designed so that authorized collectors, who control the production of uniform mail-back packages that are both nondescript and not readily identified as containing controlled substances, can easily identify authorized packages and thereby increase the likelihood that they accept only those packages that they are authorized to accept.

If the authorized collector inadvertently and unknowingly accepts controlled substances from an ultimate user in a package that they did not make available for the collection of controlled substances, the authorized collector shall notify the DEA office in their area of the receipt of the package within three business days of receipt and store the
package, in a manner consistent with the routine mail-back package storage requirements discussed below, until the collector receives further instructions from DEA.

The “three business day” requirement allows the registrant enough time to process the packages received while still ensuring that DEA is notified of the incident in a timely manner thus allowing further investigation if necessary. The requirements for postage paid and preaddressed packages are designed to reduce the likelihood that authorized collectors will receive unauthorized controlled substances via mail-back programs because the sender would have to address such package and pay for postage. Ultimate users will likely not engage in such inconveniences when postage paid and preaddressed mailers are available.

DEA proposes in section 1317.70(f) that law enforcement officers employed by the law enforcement agency and “authorized employees” of a collector be the only individuals permitted to handle packages collected through a mail-back program. Under the proposed definition in 1317.02(a), an “authorized employee” is a person directly employed by the registrant full time (i.e., not employed as a contractor or agent of a third party) and must not have been convicted of any felony offense related to controlled substances and not have had at any time an application for registration with DEA denied, had a DEA registration revoked or suspended, or surrendered a DEA registration for cause. These enhanced security requirements are proposed consistent with existing security screening procedures for employees of certain registrants and will strengthen the integrity of the mail-back process by ensuring that only trusted employees have access to or influence over controlled substances.

DEA proposes in section 1317.70(f) that upon receipt of a package through a
mail-back program, an authorized collector shall not open the package, x-ray, analyze, or otherwise penetrate the package. DEA proposes in section 1317.05(c)(1) that the authorized collector must promptly destroy the package on-site or securely store the package until prompt on-site destruction or timely notification to DEA of receipt of an unauthorized package in accordance with 1317.70(e) can occur. DEA is proposing the flexible “prompt” destruction and secure storage standard for collectors rather than a specific time frame to ensure that controlled substances do not accumulate while pending destruction or secure storage and are destroyed in a prompt manner, thus reducing the opportunities for diversion, while still accounting for the individual circumstances of registrants that destroy controlled substances. If the authorized collector is a reverse distributor, however, such destruction must occur as soon as practicable but no later than fourteen calendar days of receipt in accordance with proposed section 1317.15(d), which is discussed below.

Mail-back programs provide a convenient means of disposal for ultimate users who may not otherwise have access to a safe method of disposal. Mail-back programs are valuable because they may be made available to a large number of ultimate users regardless of geographic location. Because this method of ultimate user disposal presents high risks of diversion, DEA has carefully weighed many options and proposes the outlined requirements. The proposed requirements may limit the number of persons authorized to conduct a mail-back program; however, a single authorized mail-back program is capable of receiving packages from any location within the U.S.\textsuperscript{34} The mail-

\textsuperscript{34} Mail-back programs are restricted to the receipt of mailers initiated within the U.S. in order to be consistent with the import requirements of the CSA as provided in Subchapter II of Chapter 13 of Title 21 of the U.S. Code (21 U.S.C. 951 et. seq.).
back method of disposal for ultimate users is a valuable and convenient option, however, the high risk of diversion inherent to this method requires stringent controls, including post-collection tracking and accountability mechanisms, as well as on-site destruction by authorized collectors.

Collection Receptacles

The third voluntary method of collection that DEA proposes, in section 1317.75, is collection receptacles. DEA proposes specific language in section 1317.75(a) to continue authorization for any federal, state, tribal, or local law enforcement agency to maintain a collection receptacle at the law enforcement agency’s physical location as well as to authorize any DEA registered manufacturer, distributor, reverse distributor, or retail pharmacy authorized as a collector to maintain a collection receptacle at their DEA registered location. Collection receptacles may be located at a collector’s registered location (and certain authorized LTCFs, as discussed below) or at a law enforcement agency’s physical location – they may not be placed at non-registered locations such as libraries or community centers. DEA is proposing collection receptacles be placed at registered locations to ensure that controlled substances are collected at those locations that have existing security controls in place, with the exception of LTCFs, thereby reducing the risk of diversion while still providing for a convenient option for ultimate user disposal.

Like take-back events and mail-back programs, DEA proposes in sections 1317.75(b) and (c) and 1317.80(a) that the only persons that may transfer controlled substances to the authorized collector’s collection receptacle are the ultimate user, persons lawfully entitled to dispose of an ultimate user decedent’s property, and, as
discussed below, a LTCF on behalf of an ultimate user that resides or has resided at that LTCF when a collection receptacle is located at that LTCF. This requirement is proposed in order to limit the number of hands through which the substance passes because the risk of diversion increases each time a controlled substance is transferred to a new person.

The proposed collection receptacle requirements in section 1317.75(d) and (e) are intended to protect against diversion. In particular, DEA is proposing the minimum collection receptacle requirements necessary to protect against diversion while allowing flexibility. The collection receptacles used by authorized collectors must have a permanent outer container with a removable inner liner. The outer container must have an opening big enough to allow contents to be added to the inner liner, but small enough to prevent removal of the inner liner contents. The opening must be capable of being locked at times when an authorized employee is not present, unless the collection receptacle is located in a secured area of a long term care facility which is regularly monitored by LTCF personnel.

DEA defines an inner liner in section 1317.02 and proposes requirements for inner liners in section 1317.60. In particular, like the mail-back packages, the inner liner must be waterproof, tamper-evident, and tear-resistant. The inner liner must be removable and sealable immediately upon removal without emptying or touching the contents and the contents of the inner liner shall not be viewable from the outside when sealed. The size of the inner liner must be clearly marked on the outside of the liner, for example, be clearly marked “5 gallon” or “10 gallon.” Finally, the inner liner must bear a permanent, unique identification number that enables the liner to be tracked. DEA is proposing these inner liner requirements to ensure that controlled substances are collected
and destroyed in an accountable, secure, and convenient way in order to both prevent the diversion of controlled substances and to protect public health and safety.

In an effort to increase the ease of program implementation, to increase the security of collection by collection receptacle and to remind the public that illicit substances shall not be collected, DEA is also proposing that the outer container prominently display a sign indicating that only non-controlled drugs and Schedule II, III, IV, or V controlled substances are acceptable for collection. DEA seeks comment on the value and utility of requiring that a specific, uniform symbol be placed on each collection receptacle.

DEA is also proposing other security measures, including the requirement that collection receptacles be securely fastened to a permanent structure such as a wall, floor, or immovable countertop so that they cannot be removed. At a registered location, the collection receptacle must be located within the immediate proximity of a designated area where controlled substances are stored and where an authorized employee is present. At a long term care facility, the collection receptacle must be located in a secured area monitored by personnel of that long term care facility. In addition, access to the inner liner is restricted to authorized employees. Containers secured in compliance with the proposed requirements are intended to deter and prevent theft and pilferage.

DEA proposes in section 1317.75(g) that the removal of the inner liner of the collection receptacle shall be performed by or under the supervision of at least two authorized employees of the authorized collector. To this end, a registered reverse distributor or distributor is permitted to remove and take the inner liner of the collection receptacle for destruction so long as the removal is performed under the supervision of at
least two authorized employees of the authorized collector. In accordance with section 1317.05(c)(2), upon removal of the inner liner of the collection receptacle, the authorized collector shall promptly: (1) destroy the inner liner and its contents; or (2) store the inner liner and its contents at the collector’s registered location in a manner consistent with the security requirements for Schedule II controlled substances until prompt destruction can occur.

Authorized collectors who are registered practitioners\textsuperscript{35} shall dispose of the sealed inner liners and their contents in one of the following ways: (1) promptly destroy the sealed inner liners and their contents, using an on-site method of destruction in accordance with Subpart C of part 1317 of this chapter; (2) promptly deliver the sealed inner liners and their contents by common or contract carrier to the registered location of a reverse distributor or distributor for destruction, or by reverse distributor pick-up at the collector’s registered or authorized location; or (3) request assistance from the Special Agent in Charge of the Administration in the area in which the practitioner is located by submitting one copy of DEA Form 41 identifying what is to be disposed.

Authorized collectors who are not registered practitioners\textsuperscript{36} shall dispose of the sealed inner liners and their contents in one of the following ways: (1) promptly destroy the sealed inner liners and their contents, using an on-site method of destruction in accordance with Subpart C of part 1317 of this chapter; (2) promptly deliver the sealed inner liners and their contents by common or contract carrier to the registered location of

\textsuperscript{35} The basis for distinguishing between practitioners and non-practitioners when specifying disposal procedures is explained in detail below under the discussion of controlled substance inventory disposal, beginning on page 61.

\textsuperscript{36} The basis for distinguishing between practitioners and non-practitioners when specifying disposal procedures is explained in detail below under the discussion of controlled substance inventory disposal, beginning on page 61.
a reverse distributor or distributor, or by reverse distributor pick-up at the collector’s registered or authorized location; or (3) promptly transport the sealed inner liners and their contents by the collector’s own means to the registered location of a reverse distributor or distributor, or to the location of destruction. DEA is proposing the flexible “prompt” destruction, transfer, and storage standard for collectors rather than a specific time frame to ensure that controlled substances do not accumulate while pending destruction, transfer, or storage, while still accounting for the individual circumstances of registrants that operate and maintain collection receptacles. If the authorized collector is a reverse distributor, however, such destruction must occur as soon as practicable but no later than fourteen calendar days of receipt in accordance with proposed section 1317.15(d), which is discussed below.

Long Term Care Facilities

The Disposal Act authorized the Attorney General to develop regulations to permit long term care facilities to dispose of controlled substances on behalf of ultimate users who reside or have resided at such facilities in a manner that provides effective controls against diversion and is consistent with public health and safety. As such, DEA proposes in section 1317.80 to allow collection receptacles to be placed at long term care facilities for the disposal of controlled substances in accordance with outlined requirements.

DEA is proposing that only a registered retail pharmacy that receives authorization to collect at a specific long term care facility may manage and maintain collection receptacles at that long term care facility and remove or supervise the removal of the inner liner of the collection receptacles at that long term care facility. Such
registered retail pharmacies that desire to operate a collection receptacle at a long term care facility must apply to modify their registration in accordance with 21 CFR 1301.51 and include in their application for modification in registration the physical location of each long term care facility at which the registered pharmacy intends to operate a collection receptacle. If the retail pharmacy that is authorized to collect ceases activities as a collector, such registrant must modify their registration in accordance with 21 CFR 1301.51 to indicate that they no longer collect or have ceased collection at a particular physical location. The requirements in 21 CFR 1301.52(a) related to the termination of registration also apply.

A registered retail pharmacy authorized to maintain a collection receptacle at a long term care facility shall comply with the proposed requirements in 21 CFR 1317.75 that govern collection receptacles. At a long term care facility, the collection receptacle must be located in a secured area monitored by personnel of that long term care facility. In addition, access to the inner liner is restricted to authorized employees of the registered retail pharmacy. Because an authorized employee must be employed full time by the registrant, employees of the long term care facility will not have access to the inner liner of the collection receptacle, unless they are also a full time employee of the registered retail pharmacy that maintains that collection receptacle. In addition, DEA is proposing that two authorized employees of the retail pharmacy must remove or supervise the removal of the inner liner from the collection receptacle. In an effort to increase security and control of controlled substances collected, no employee of the long term care facility

37 For the purposes of 21 U.S.C. 880(a), collection receptacles at long term care facilities maintained by a registered retail pharmacy authorized as a collector is a “controlled premise” of that registered retail pharmacy.
will have access to or influence over the contents of the collection receptacle, except to
deposit controlled substances into it.

DEA is proposing that long term care facilities be permitted to dispose of
controlled substances in Schedules II through V on behalf of an ultimate user who resides
or has resided at such long term care facility. As with all other collection methods,
controlled and non-controlled substances may be comingled in the collection receptacle.
DEA proposes that the long term care facility be required to transfer controlled
substances into collection receptacles (on behalf of ultimate users who reside or have
resided at the long term care facility) immediately, but no longer than three business days
after it is determined that the ultimate user no longer needs or wants, or should
discontinue use of the controlled substance. DEA proposes this requirement on the
transfer of controlled substances at a long term care facility in an effort to prevent the
accumulation of ultimate user controlled substances at long term care facilities. DEA
believes that this requirement balances security concerns with the ease of long term care
facility participation by allowing these facilities to determine whether it is appropriate for
them to dispose on behalf of an ultimate user.

Pursuant to 21 U.S.C. 822(g)(3), DEA is proposing that a long term care facility
must dispose of those controlled substances only by depositing the substances into an
authorized collection receptacle at the long term care facility. The long term care facility
is not permitted to deliver or transfer the controlled substances off-site. If the long term
care facility does not have access to an on-site collection receptacle, they are not
otherwise permitted to dispose of a controlled substance on behalf of an ultimate user.
Rather, the ultimate user or persons lawfully entitled to dispose of ultimate user
decedent's property should dispose of those controlled substances. See 21 U.S.C. 822(g)(1) and 822(g)(4).

Because ultimate user medications are concentrated in and often administered by long term care facilities, DEA considered proposing to authorize long term care facilities to dispose of controlled substances on behalf of an ultimate user through mail-back programs and through take-back events. However, the majority of such facilities are not registered by DEA to handle controlled substances, and, therefore, do not have in place physical security controls and other requirements that minimize the risk of diversion such as the obligation to maintain effective controls against diversion, report thefts and losses, and screen certain employees for controlled substance-related felony convictions. DEA believes that only authorized DEA registrants and law enforcement agencies should be authorized to collect controlled substances from ultimate users because they have in place the proper security and other controls to help guard against diversion. Because long term care facilities are typically not registered with DEA and face the unique challenge of disposing of controlled substances on behalf of an ultimate user, DEA is proposing an option for LTCFs that balances convenience with security.

The on-site collection receptacles will reduce the risk that controlled substances may be removed from the facilities by employees (e.g., to transport substances to a take-back event for disposal) who will not be subject to the same screening procedures as employees of authorized collectors, such as the requirement that authorized employees who have access to or influence over controlled substances have no felony convictions related to controlled substances. Additionally, DEA believes that the mail-back option is not suitable because of the likelihood that long term care facilities may need to dispose of
large quantities of controlled substances or dispose of controlled substances on a frequent basis. One security aspect of the mail-back method of disposal is the requirement that mailers be non-descript, so as not to be readily identifiable as containing controlled substances. If a large number of such mailers are consistently sent from an unregistered facility whose residents are likely to possess controlled substances, such as a long term care facility, that security measure loses much of its efficacy, thereby increasing the risk of diversion, and may even have the unintended effect of making a long term care facility's mailing system a target for diversion. DEA is, therefore, proposing to only permit long term care facilities to use an on-site collection receptacle that is under the control of an authorized retail pharmacy registrant to dispose of controlled substances on behalf of an ultimate user. DEA believes that a secure on-site collection receptacle is the best method to protect against diversion and is consistent with public health and safety.

Although LTCFs may only dispose of their residents' controlled substances through collection receptacles at the LTCF, LTCF residents themselves may utilize any other disposal method available to ultimate users, including mail-back programs and take-back events. Care should be taken to ensure that LTCF residents' use of mail-back programs and take-back events does not result in the accumulation of controlled substances in a single location susceptible to internal or external diversion threats, as discussed above.

Additional Security Controls for the Collection of Controlled Substances through Mail-

38 Although reverse distributors and other collectors conducting mail-back programs will likewise receive a large number of mailers, DEA does not anticipate that the same risk exists. Collectors authorized to conduct mail-back programs will be DEA registrants that already routinely receive controlled substances and have in place security controls. A long term care facility, however, is likely not a DEA registrant, does not already routinely send out controlled substances, and will not have in place the same types of security controls.
Back Programs and Collection Receptacles

As discussed above, sealed mail-back packages and inner liners acquired by collectors and registered reverse distributors and distributors must be stored in a manner consistent with the physical security requirements for Schedule II controlled substances. Registered reverse distributors, distributors, and manufacturers authorized as collectors and that store mail-back packages and inner liners acquired from an ultimate user must follow the physical security controls for storing Schedule II controlled substances in accordance with 21 CFR 1301.72, which DEA proposes to revise. An authorized collector that is a retail pharmacy must follow the physical security controls for storing Schedule II controlled substances in accordance with 21 CFR 1301.75; however, such sealed mail-back packages and inner liners may not be dispersed through the practitioner’s stock of non-controlled substances as described in 21 CFR 1301.75(b), which DEA proposes to revise. DEA understands that storing sealed mail-back packages and inner liners as though they are Schedule II controlled substances is a stringent requirement; however the majority of authorized collectors, as registrants, are likely to already have these storage capabilities in place. DEA is proposing these physical security requirements because Schedule II is the highest schedule of controlled substances that is lawfully permitted to be included in the mail-back packages and inner liners. Because mail-back packages and inner liners may not be opened and their contents will not be known, such packages and liners should be stored as though each package and liner contains a Schedule II controlled substance.

In the event of theft, pilferage, or loss, registrants must notify DEA, in accordance with 21 CFR 1301.76(b) and 1301.74(c). DEA considers any theft or loss from a
collection receptacle or mail-back program to be a “significant loss” within the meaning of the regulation because such losses would be attributable to the unique activities involving the disposal of controlled substances. 21 CFR 1301.74(c)(3). Also, because the controlled substances collected cannot be individually handled or sorted, it must be assumed that the loss includes Schedule II controlled substances. 21 CFR 1301.74(c)(2) and 1301.76(b). Finally, collection receptacles and mail-back packages are likely candidates for diversion because these collection methods are highly publicized and accessible to the public, and, as a result, any theft or loss from these collection methods is considered significant. 21 CFR 1301.74(c)(5) and 1301.76(b)(5).

*Tracking Controlled Substances Collected from Ultimate Users and Other Authorized Non-registrants from Collection to Destruction*

In accordance with the closed system and the statutory framework of the CSA, DEA must ensure that all controlled substances collected from ultimate users are properly and promptly secured, stored, and destroyed. DEA considered allowing authorized persons to count or otherwise inventory controlled substances collected from ultimate users. Any effort to count, identify, or otherwise inventory the contents of sealed packages or inner liners, however, would require individualized identification of the contents, increase the number of hands through which controlled substances pass, and require that the packages and inner liners remain opened and exposed for extended periods of time. These factors greatly increase the risk of diversion and, when combined with the increased costs associated with such efforts, outweigh the potential benefit.

As a result of these security and diversion prevention considerations, DEA is proposing a system of collection that requires the ultimate user or other authorized non-
registrant person in lawful possession of a controlled substance to personally handle such substance at all times until it is safely and securely placed in an authorized mail-back package or in an appropriate collection receptacle at an authorized location or at a take-back event. Additionally, an authorized collector would be required to collect items only in a collection receptacle with an inner liner or in a mail-back package, both of which must be uniquely identifiable, sealable, waterproof, tamper-evident, and tear-resistant. No person may open or otherwise access any secured mail-back package or inner liner.

DEA is proposing that each inner liner and mail-back package provided by an authorized collector must have a unique identification number that enables the liner and package to be tracked. The authorized collector must record the unique identification number located on the inner liner or mail-back package so that it can be properly tracked from collection to destruction. Law enforcement agencies are encouraged, but not required, to implement similar recordkeeping and tracking procedures. DEA believes that the proposed recordkeeping and tracking system is the most effective and efficient way to ensure that those controlled substances collected from ultimate users and other authorized non-registrants are secure until destruction, and are actually destroyed. DEA has proposed a rule that allows authorized collectors the flexibility to create a tracking system that is proportionate to the scope and method of their desired disposal program while also meeting the applicable security and control requirements proposed by DEA.

Disposal of Controlled Substances by Registrants

The procedures for the disposal of controlled substances by registrants are often determined on a case-by-case basis by the DEA Special Agent in Charge (SAC) in the area where the registrant is located. In many circumstances, the SAC has the discretion
to determine how to authorize and instruct registrants to dispose of controlled substances, including how the substances may be destroyed. 21 CFR 1307.21(a) and (b).

DEA proposes to expand the inventory\textsuperscript{39} disposal options available to registrants, delete the existing rule related to registrant disposal (21 CFR 1307.21), and incorporate similar requirements on proper disposal procedure, security, and recordkeeping into a new part 1317 on disposal. DEA is proposing these changes to ensure consistency in disposal procedures among registrant categories, regardless of geographic location. Such regulations will reduce the burden on registrants by eliminating the existing requirement for every registrant to contact the SAC in their area when they wish to destroy controlled substances. Also, the procedures and security and recordkeeping requirements that DEA proposes are intended to codify existing practice and to set singular and consistent procedures for DEA registrants in accordance with their authorized business activities while protecting the public health and safety and minimizing the risk of diversion.

Registration requirements and authorized activities vary depending on the type of controlled substance business activity in which a person is engaged. Accordingly, if a registrant desires to deliver controlled substances for any lawful purpose, the registrant must be authorized by his registration to conduct the delivery—the registrant must be authorized to engage in such conduct either as a business activity or coincident activity. This general rule also applies if a registrant desires to deliver controlled substances to an authorized person by transporting the substances itself and maintaining custody and control of the substances during transportation.

\textsuperscript{39} "Inventory" means "all factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor)." 21 CFR 1300.01(b).
Pursuant to the Controlled Substances Act, registration to distribute conveys broad authority to deliver controlled substances for a lawful purpose. "Distribute" means to "deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term 'distributor' means a person who so delivers a controlled substance or listed chemical." 21 U.S.C. 802(11). Accordingly, registrants authorized to distribute controlled substances (e.g., non-practitioners such as manufacturers, distributors, and reverse distributors) may themselves deliver such substances to authorized persons for the purpose of disposal in accordance with applicable security and recordkeeping procedures. In contrast, the Controlled Substances Act narrows the authorization of practitioners\(^4\) (e.g., physicians, pharmacies, and hospitals) to "dispense," which means "to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a substance . . . ." 21 U.S.C. 802(10) (emphasis added). Authorization to dispense does not include authorization to distribute and vice versa. See 21 U.S.C. 802(11) (specifically excluding "dispense" from the definition of "distribute"). As such, registration to dispense specifically conveys narrow authority to deliver a controlled substance to an ultimate user pursuant to the lawful order of a practitioner. Registrants who are only authorized to dispense controlled substances (e.g., practitioners) are therefore not authorized to deliver these substances themselves to any entity other than an ultimate user, even for the purpose of disposal. Instead, practitioners may only deliver

\(^4\) Defined by the CSA 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." 21 U.S.C. 802(21). Under the CSA, "[t]he Attorney General shall register practitioners . . . to dispense, or conduct research with, controlled substances . . . ." 21 U.S.C. 823(f).
these substances to authorized persons by common or contract carrier or by pick-up at the practitioner’s registered location.

As discussed, non-practitioners (e.g., manufacturers, distributors, and reverse distributors) are not similarly limited in their authority to lawfully deliver controlled substances. DEA therefore proposes in section 1317.05(b) to allow non-practitioners to deliver (i.e., transfer) controlled substances themselves for the purpose of disposal provided that such substances are transported directly to the destruction location and accompanied by two authorized employees. This proposed requirement is consistent with existing practices by registered manufacturers, distributors, and reverse distributors when transporting and disposing of controlled substances. These non-practitioners generally follow these procedures (in addition to various other procedures) as a counter-measure against theft and diversion. DEA proposes these procedures, along with the procedures set forth at section 1317.95, as the minimum required to help ensure the physical security of highly pilferable controlled substances and as a deterrent to theft and diversion.

Consistent with the requirements of the Controlled Substances Act, DEA proposes in section 1317.05(b) to authorize non-practitioners to dispose of their controlled substance inventory in one of four ways: (1) promptly destroy the substance using an on-site method of destruction in accordance with applicable federal, state, tribal, and local laws and regulations (as required by section 1317.90); (2) promptly deliver the substance to a registered reverse distributor at its registered location by common or contract carrier, or by reverse distributor pick-up; (3) for the purpose of return or recall, promptly deliver the substance by common or contract carrier or pick-up at the registrant’s registered location to the person from whom it was obtained, the registered
manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls; or (4) promptly transport the 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 the substance for the purpose of return or recall.

As discussed, a practitioner’s registration does not convey authority to distribute, deliver, or otherwise transfer controlled substances to any entity other than an ultimate user. Accordingly, DEA proposes in section 1317.05(a) to authorize practitioner registrants to dispose of their controlled substance inventory in one of four ways: (1) promptly destroy the substance using an on-site method of destruction in accordance with applicable federal, state, tribal, and local laws and regulations (as required by section 1317.90); (2) promptly deliver the substance to a reverse distributor at its registered location by common or contract carrier, or by reverse distributor pick-up;\(^{41}\); (3) for the purpose of return or recall, promptly deliver the substance to the registered person from whom the substance was obtained, the registered manufacturer of the substance, or another registrant authorized to accept returns or recalls by common or contract carrier or by pick-up at the registrant’s registered location; or (4) request assistance from the Special Agent in Charge of the Administration in the area in which the practitioner is located. DEA proposes to allow practitioner registrants to retain the existing ability to request assistance from the SAC in the area in which the practitioner is located to dispose of their controlled substances, similar to the existing provisions of section 1307.21, in

\(^{41}\) Current DEA regulations at 21 CFR 1307.11(a)(2) discuss practitioner distribution of controlled substances to a reverse distributor. DEA proposes to clarify that provision at the proposed section 1317.05. As such, DEA proposes to delete 21 CFR 1307.11(a)(2) to eliminate redundancy.
order to expand the options available for practitioners to destroy controlled substances or cause controlled substances to be destroyed. DEA proposes that the SAC in the practitioner’s area may authorize the practitioner to: transfer the controlled substances to a person registered under the Act and authorized to transport and destroy the substance; deliver the substances to an agent of the DEA or the nearest DEA office; or destroy the substances in the presence of an agent of the DEA or other authorized person. In circumstances in which a practitioner regularly destroys controlled substances, the practitioner may do so on a regular basis upon instructions from the relevant SAC.

Registrants that destroy controlled substances must do so promptly, unless otherwise specified. DEA is proposing the flexible “prompt” destruction standard rather than a specific time frame for destruction to ensure that controlled substances do not accumulate while pending destruction and are destroyed in a timely manner, while still accounting for the individual circumstances of registrants that destroy controlled substances.

For all registrants that destroy controlled substances or cause controlled substances to be destroyed (e.g., by transferring the substance to an authorized reverse distributor or transporting the substance to an off-site, unregistered location for destruction), DEA proposes in section 1317.95 that such registrants be required to follow certain security procedures related to employees, transportation, loading and unloading, handling, and destruction. DEA is proposing enhanced security requirements in order to strengthen the integrity of the disposal process, which has been expanded to include more disposal options and eliminates the requirement of prior notice of destruction to DEA, by filing DEA Form 41 prior to destruction, in every instance except when
practitioners seek disposal assistance pursuant to proposed section 1317.05(a)(4). When a DEA registrant that destroys or causes the destruction of controlled substances is the last registered person to possess such substances, the registrant must follow increased security measures at the point of destruction to ensure accountability and effectively minimize the risk of diversion.

For registrants that destroy controlled substances on-site, that maintain possession of controlled substances until they are rendered non-retrievable (e.g., when transporting substances to an unregistered location for destruction), or that transfer custody to an authorized person for disposal, DEA is proposing employee security requirements in section 1317.95 to ensure that only employees that have satisfied certain employee screening requirements are authorized to oversee the handling of controlled substances during the destruction process. Under the proposed definition in 1317.02(a), an "authorized employee" is a person directly employed by the registrant full time (i.e., not employed as a contractor or agent of a third party) who must not have been convicted of any felony offense related to controlled substances and not have had at any time an application for registration with DEA denied, had a DEA registration revoked or suspended, or surrendered a DEA registration for cause.

The proposed security measures include the requirement that two authorized employees load and unload (or observe the loading and unloading of) controlled substances during transfer of the substances to another registrant; and, if the substances are destroyed on a registrant’s registered premises, two authorized employees shall personally witness the destruction and shall handle (or observe the handling of) the substance until it is rendered non-retrievable. This two-person integrity requirement is
necessary because the destroying registrant is the last person authorized to handle the substance before destruction and this requirement will reduce the opportunity for diversion and help to ensure that the controlled substances are actually destroyed and not diverted to illicit use.

Additionally, DEA proposes in section 1317.100 that a registrant that destroys controlled substances or causes the destruction of controlled substances is required to maintain a record of the destruction in a form to be issued by DEA. This form will be DEA Form 41. At present, DEA Form 41 is used as a record of destruction by registrants. DEA is proposing to modify DEA Form 41 to act as the record of destruction, including the signature of the two authorized employees witnessing the destruction. In an effort to minimize the burden on registrants, and in accordance with the proposed comprehensive new part on disposal, registrants that destroy or cause the destruction of controlled substances and utilize DEA Form 41 will no longer be required to submit three copies of DEA Form 41 to the SAC in their area, except one copy shall be submitted by practitioners seeking assistance pursuant to section 1317.05(a). Rather, in accordance with the CSA, such registrants will be required to keep and make available that record, 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. Furthermore, all methods of destruction must be conducted in accordance with all applicable federal, state, local, and tribal laws and regulations.

**Reverse Distributors**

Reverse distributors are a unique group of registrants whose primary function is to possess controlled substances for the purpose of destruction or return. In this regard,
reverse distributors provide a valuable service to other registrants in the disposal process. In the distribution of controlled substances between registrants, each registrant serves as a check on the other and verifies whether the controlled substance has reached its lawful destination. This is accomplished through existing reporting, recordkeeping, and order form requirements. 21 U.S.C. 827 – 828; 21 CFR part 1304 and 21 CFR part 1305. However, a reverse distributor that acquires controlled substances from another registrant for destruction is the last person to possess such substance before destruction so there is no recipient to verify that the substance has been destroyed. Furthermore, reverse distributors accumulate greater amounts of controlled substances that are destined for destruction in comparison to other registrants. This is because reverse distributors routinely acquire controlled substances for destruction from other registrants and may also be authorized as collectors. As a result, DEA is proposing security and recordkeeping requirements that apply specifically to a reverse distributor’s unique function.

The existing regulations pertaining to reverse distributors are located in different parts of the CFR. DEA is proposing revised regulations for reverse distributors that are clear, consistent, and consolidated into one part.42 DEA believes that these proposed regulations will help reverse distributors comply with the Controlled Substances Act in a manner that effectively decreases the risk of diversion of controlled substances during the disposal process.

DEA proposes to revise the definition of reverse distributor in section 1300.01(b).

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42 While reverse distributor-specific regulations are consolidated into proposed new 21 CFR part 1317, registered reverse distributors will still be required to follow all other applicable regulations that fall outside 21 CFR part 1317.
In the existing regulations, a reverse distributor is permitted to acquire controlled substances from other registrants for the purpose of return to the manufacturer or manufacturer's agent, or "to process for or arrange the processing for" disposal. DEA proposes to revise the definition of "reverse distributor" by first defining "reverse distribute" to mean "to acquire controlled substances from another DEA registrant or a law enforcement agency for the purpose of: (1) return to the manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf, or (2) destruction." A "reverse distributor" is a person who reverse distributes a controlled substance.

In the existing definition of reverse distributor, a reverse distributor is permitted to acquire controlled substances from other registrants for the purpose of return to the manufacturer or manufacturer's agent. DEA proposes revising the definition to authorize a reverse distributor to acquire controlled substances from another DEA registrant for the purpose of return to the manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf. This revision is proposed so that the reverse distribute definition is consistent with the proposed revisions to return and recall in sections 1317.05 and 1317.85 (discussed below). DEA believes that this new definition clearly and accurately reflects the proper role of a reverse distributor.

DEA proposes in section 1317.15(b) to authorize registered reverse distributors to acquire controlled substances from other registrants in one of two ways: (1) pick-up the controlled substance from a registrant at the registrant's registered location ("pick-up"), or (2) receive the controlled substance from a registrant at the reverse distributor's registered location, delivered directly by a non-practitioner or by common or contract
carrier ("delivery"). Once en route from a registrant’s registered location to a reverse distributor’s registered location, shipments or packages of controlled substances may not be re-routed to another person or location, even if that person or location is registered with DEA. DEA believes that re-routing shipments or packages destined for one registrant to another registrant substantially increases the likelihood of diversion.

DEA proposes in section 1317.15(c) that upon acquisition of a controlled substance from a registrant, a reverse distributor must either: (1) immediately store the controlled substance at, or transfer the controlled substance to, the reverse distributor’s registered location for secure storage until timely destruction or timely return to the registered manufacturer of the substance can occur, (2) immediately deliver the controlled substance to the manufacturer or manufacturer’s agent, (3) timely destroy the controlled substance, or (4) immediately deliver the controlled substance to the place of destruction for timely destruction. The requirement for “immediate” transfer or delivery is intended to ensure that shipments or packages are continuously moving towards their ultimate, secure destination. Such continuous movement reduces the risk of diversion by limiting the opportunity for theft or loss. Consistent with 21 CFR 1301.12(b)(4) and the existing definition of “freight forwarding facility” in 21 CFR 1300.01(b), a reverse distributor may not operate freight forwarding facilities for purposes of transporting controlled substances. DEA proposes to clarify this by specifically excluding reverse distributors from the definition of “freight forwarding facility” in section 1300.01(b).

DEA is also proposing in section 1317.15(d) to require reverse distributors to destroy or cause the destruction of any controlled substances received for the purpose of destruction as soon as practicable but no later than within fourteen calendar days of pick-
up or delivery. A reverse distributor that acquires a controlled substance for destruction is the last person to possess such substance before destruction and, therefore, must follow increased security measures. The “as soon as practicable but no later than fourteen calendar day” requirement is unique to reverse distributors – other registrants that destroy must do so promptly and do not have to follow a specific time limit – because the primary business activity of reverse distributors, unlike other registrants, is to acquire controlled substances for the purpose of destruction or return. As a result, reverse distributors generally accumulate greater amounts of controlled substances that are destined for destruction in comparison to other registrants. They are typically the last registrant to handle the controlled substance with no other registrant reporting and recording receipt of the substance as a check against diversion. The “as soon as practicable but no later than fourteen calendar day” requirement will ensure that reverse distributors destroy or cause the destruction of controlled substances in a timely manner while also enabling them sufficient time to prepare the necessary records required for destruction. In addition, the “as soon as practicable but no later than fourteen calendar day” requirement will reduce the risk of diversion by limiting the opportunity for theft or loss. This is necessary because, just as there is a greater risk of diversion when controlled substances are being transported for the purposes of destruction, there is a greater risk of diversion the longer a substance destined for destruction remains in storage awaiting destruction.

DEA is proposing to specify a maximum time limit for reverse distributors to destroy or cause the destruction of any controlled substance received for the purpose of destruction—as soon as practicable but no later than fourteen calendar days of receipt.
(pick-up or delivery). While DEA believes that the majority of reverse distributors already destroy or cause the destruction of controlled substances received for the purpose of destruction as soon as practicable but no later than fourteen calendar days of receipt, DEA recognizes that some may not. For the reverse distributors that do not currently meet this standard, this requirement may cause these reverse distributors to incur additional costs through more frequent transportation of controlled substances to the point of destruction and destruction of partial loads. For purposes of this proposal, DEA assumes that some reverse distributors may have to adjust current business operations in order to comply with this new requirement, such as by restricting the receipt of deliveries to their registered location to specific days and/or amounts, or by changing pick-up routes to accommodate the requirement that any controlled substance received for the purpose of destruction be destroyed as soon as practicable but no later than fourteen calendar days of receipt.

DEA believes that the proposed "as soon as practicable but no later than fourteen calendar day" requirement is reasonable and will reduce the risks of diversion. However, DEA also acknowledges that there are assorted federal, state, and local transportation and environmental laws and regulations that reverse distributors must comply with in addition to those under the CSA and these proposed regulations. DEA also acknowledges that these proposed regulations may result in reverse distributors choosing to be responsible for much more controlled substances than they are currently responsible. Accordingly, DEA invites comments on the practicability of implementing the "as soon as practicable but no later than fourteen calendar day" requirement while also maintaining effective controls against diversion. Considering there are currently a limited number of registered
reverse distributors with significant variations in current business practices across the United States, DEA seeks information regarding how the "as soon as practicable but no later than fourteen calendar day" destruction requirement would impact business practices, if at all, with specific focus on the potential long-term and short-term costs of implementing this requirement, and whether such costs would be offset by other measures. DEA also invites comment regarding the effects that shorter and longer time limits for destruction—specifically, as soon as practicable but no later than seven calendar days or thirty calendar days for destruction—would have on current business practices, including the physical security controls and operating procedures that would be implemented or modified in order to guard against theft and diversion, and the potential costs that may be incurred as a result of alternative time limits.

DEA is also proposing in section 1317.20 enhanced employee security requirements for reverse distributors. DEA proposes that reverse distributors be prohibited from employing, as an agent or employee who has access to or influence over controlled substances, any person that has ever been convicted of any felony offense related to controlled substances or has ever had an application for registration with DEA denied, had a DEA registration revoked or suspended, or surrendered a DEA registration for cause. DEA is proposing these enhanced security requirements for reverse distributors in order to strengthen the integrity of the disposal process by ensuring that only certain employees are authorized to have access to or influence over controlled substances. This requirement is similar to existing employee security requirements for registered practitioners in 21 CFR 1301.76(a), where there is a high risk of diversion and limited physical security requirements.
DEA is also proposing in 1317.25 to streamline and clarify recordkeeping requirements for registered reverse distributors that acquire controlled substances from other registrants so that they are consistent and accurately reflect reverse distributor authorized activities in compliance with the Controlled Substances Act. These requirements are separate from the recordkeeping requirements for reverse distributors that acquire controlled substances from law enforcement agencies and authorized collectors, as discussed above, in proposed section 1317.55.

First, the existing regulations require registered reverse distributors to record in an inventory, information regarding specific quantities of controlled substances that is different from the information required in continuing records. 21 CFR 1304.11(e)(3) and 1304.22(e). To reconcile this discrepancy, DEA proposes in sections 1317.25(b) and (c) that in both inventory and continuing records, a reverse distributor must record the quantity of a controlled substance in both finished and bulk form, and the quantity contained in a commercial container, carton, crate, drum, or other receptacle that has been opened.

Second, in accordance with the CSA, every DEA registrant must 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). These records must be maintained separately from all other records of the registrant or, alternatively, in the case of non-narcotic controlled substances, be in such a form that required information is readily retrievable from the ordinary business records of the registrant. 21 U.S.C. 827(b)(2). The records must be kept and be available for at least two years for inspection and copying by officers or employees of the Attorney General. 21 U.S.C.
827(b)(3). Under its statutory authority, DEA may promulgate regulations that specify the information that registrants are required to maintain in their records. 21 U.S.C. 827(b).

To this end, DEA proposes in section 1317.25(c) to require registered reverse distributors to: (1) keep records regarding each controlled substance received from another registrant for the purpose of return to a manufacturer or, if designated, to another registrant authorized by the manufacturer to accept returns on the manufacturer’s behalf, and (2) keep records regarding each controlled substance destroyed, including information pertaining to the receipt and destruction of the controlled substance. These records, similar to the current requirements in 21 CFR 1304.22(e) that DEA proposes to delete, are necessary for inspection to maintain the integrity of the closed system and to assist in the detection and prevention of diversion.

DEA proposes in section 1317.25(c)(4) that for all controlled substance records, reverse distributors will be required to maintain the record of receipt with the corresponding record of return or destruction. By maintaining all relevant records together, DEA will be able to account for each substance received by a reverse distributor from its acquisition to its disposition, whether by destruction or return to the manufacturer. DEA also emphasizes that each registrant must prepare and maintain separate and independent records in order to ensure accountability of each registrant, and the integrity of the closed system of distribution.

Return and Recall

DEA is proposing to delete the existing rule on return and recall, 21 CFR 1307.12, and to clarify and separate the role of registrants and non-registrants in the
return and recall of controlled substances. This is because of the different circumstances surrounding registrant and ultimate user return and recall.

Return and Recall by Registrants

DEA proposes procedures for the return and recall of controlled substances by DEA registrants in sections 1317.05(a)(3), 1317.05(b)(3), and 1317.05(b)(4), and recordkeeping and order form requirements in a new section 1317.10, which are similar to the existing rule on return and recall in 21 CFR 1307.12. The proposed new sections, however, clarify which registrants are authorized to distribute and receive returns and recalls and clarifies the recordkeeping and order form requirements. DEA proposes in sections 1317.05(a)(3), 1317.05(b)(3), and 1317.05(b)(4) that registrants in lawful possession of a controlled substance may return that substance for the purpose of return or recall to: (1) the registered person from whom it was obtained; (2) the registered manufacturer of the substance; or (3) another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer’s behalf. The procedures governing return of the substance are determined by the returning registrant’s authorization as a practitioner or non-practitioner, as discussed above. This is consistent with the intent of the Controlled Substances Act to prevent opportunities for diversion because the substances are being transferred within the closed system of distribution for the purpose of disposal (i.e., return or recall) without having left the closed system of distribution, and accountability is ensured by pertinent recordkeeping requirements.

DEA proposes in section 1317.10(a) information that must be maintained in the records of registrants returning controlled substances and registrants receiving returns. In addition, pursuant to proposed section 1317.10(b), DEA Form 222 must be used by each
registrant that distributes a controlled substance in Schedule I or II for the purpose of return and recall in accordance with 21 CFR part 1305. The freight forwarding provision of the existing rule is also retained in section 1317.10(c).

**Ultimate User Product Recall**

DEA proposes in section 1317.85 procedures for the recall or return of controlled substances by ultimate users. Currently, DEA authorizes ultimate user distribution for the purpose of recall under existing 21 CFR 1307.12, but the language in this section is overly broad. The proposed section 1317.85(a) reduces ambiguity that exists under current regulations by specifying to whom an ultimate user is permitted to deliver their recalled controlled substance and by outlining consistent and clear requirements for registrants authorized to receive those recalled substances from ultimate users.

In particular, DEA proposes in section 1317.85(a) to authorize an ultimate user in lawful possession of a controlled substance in Schedules II, III, IV, or V to deliver the recalled controlled substance to the manufacturer of the substance or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf. In the event of a product recall, the manufacturer of the recalled controlled substance or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf is authorized to receive recalled controlled substances from an ultimate user and does not need to be an authorized collector to do so. This is because the necessary security and experience in handling controlled substances is already in place. Recalled controlled substances received by authorized registrants from ultimate users are re-entering the closed system of distribution and must be handled (stored, destroyed, etc.), unless otherwise specified, in accordance with procedures that the
registrant is otherwise required to follow.

DEA proposes in 1317.85(a)(1) that registrants authorized to receive recalled controlled substances from ultimate users maintain a record of recalled controlled substances received from ultimate users. Those registrants, however, are exempted under section 1317.85(a)(2) from the requirements in 21 CFR part 1305 pertaining to DEA Form 222 for substances received from non-registrants. In accordance with the Disposal Act, the delivery of a Schedule II controlled substance for the purpose of disposal by an ultimate user, long-term care facility, or other person acting in accordance with the Disposal Act is exempt from order form requirements (i.e., an ultimate user or long-term care facility may transfer a Schedule II controlled substance to another person for the purpose of disposal without a written order of the person to whom such substance is transferred). 21 U.S.C. 828(b)(3). In other words, when an ultimate user delivers a recalled controlled substance to an authorized registrant for the purpose of disposal, in this case recall, such transactions are exempt from the requirements found in 21 CFR part 1305.

DEA is also proposing in section 1317.85(a)(3) that the authorized registrant report all recalled controlled substance acquisition transactions pursuant to 21 CFR 1304.33. Such registrants may report either each individual receipt or a single transaction that includes 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.

Finally, DEA proposes in 1317.85(b) that an ultimate user that 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 substance received as part of that research to the registered
dispenser from which it was obtained, 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).

Methods of Destruction:

DEA is proposing a standard of destruction—non-retrievable—for persons that
destroy or cause the destruction of controlled substances. Some examples of current
technology that may achieve the non-retrievable standard are incineration and chemical
digestion. Flushing and mixing controlled substances with coffee grounds or kitty litter
are examples of existing methods of destruction that do not meet the non-retrievable
standard. These examples are not exhaustive and DEA is not requiring, endorsing,
authorizing, or recommending any particular method of destruction so long as the desired
result is achieved and the method is compliant with all applicable federal, state, tribal,
and local laws and regulations. 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. DEA is
proposing a standard of destruction that provides communities the flexibility to tailor
disposal options to meet their resources and needs and allows for advances in technology.

Non-retrievable

Each controlled substance has its own inherent chemical and/or physical
properties. Accordingly, the objective of “destruction” is to render the substance no
longer susceptible to diversion for an illicit or non-medical use. DEA intends to provide
maximum flexibility to allow for technological innovation and development in controlled
substance destruction processes. As such, DEA solicits comments on the proposed requirement that all destruction processes be applied in such a manner that the controlled substances are rendered "non-retrievable."

Any destruction method applied to a controlled substance must render it "non-retrievable." The proposed definition of "non-retrievable" means to permanently alter any controlled substance's physical and/or chemical state through 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.

In the case of ultimate user disposal where most people are unable to differentiate between controlled and non-controlled substances and because cataloging or taking inventory of substances may be detrimental to efforts to prevent diversion, all of the proposed collection methods allow comingling of pharmaceuticals. As a result, this proposed rule would require a method of destruction sufficient to render all included controlled substances non-retrievable. Likewise, where the actual substances collected are unknown, but may reasonably include controlled substances, the proposed rule would require selection of a method of destruction sufficient to render non-retrievable any controlled substance likely to be present. Information received at the January 2011 public meeting held by DEA indicated that incineration in accordance with federal, state, and local law may be the currently most-used method of destruction to achieve this result. Even so, DEA is proposing a standard that allows flexibility so long as the desired result is achieved, thus allowing for technological innovation and development. Regardless of
the destruction method, the destruction must be conducted in accordance with all federal, state, tribal, and local laws and regulations.

**Environmental Considerations**

In passing the Disposal Act to provide those individuals seeking to dispose of unwanted or unused controlled substances in their household with more disposal options beyond discarding or flushing the substances, Congress expected that there would be fewer such substances introduced into the environment, particularly into the water.\(^{43}\) DEA also recognizes that the establishment of alternative, lawful means for disposing of unused or expired pharmaceutical controlled substances may alleviate some existing environmental concerns. For example, recent studies have reported on the presence of pharmaceutical chemicals in varying concentrations in water supplies. DEA is hopeful that the increased availability of methods for citizens to safely and securely dispose of unwanted prescription drugs will have a positive impact on reducing the introduction of chemical contaminants into the water supply. However, collection and destruction of unwanted and unused pharmaceuticals cannot and will not address water contamination that occurs from other means such as bodily elimination or excretion of such substances.

The requirements of this proposed rule only govern compliance with the Controlled Substances Act. Any selected method of destruction of controlled substances meeting the requirements of this proposed rule must also comply with all applicable federal, state, and local laws and regulations applicable at the time of the destruction. Because of the broad range of such environmental and other laws and regulations, this

\(^{43}\) See Findings, Sec. 2, Secure and Responsible Drug Disposal Act of 2010.
proposed rule does not purport to address what laws may or may not be applicable in a particular circumstance now or at some future date.

As DEA and public and private entities introduce proposed options for disposal of controlled substances to the general public and in specific communities, it is anticipated that the environmental benefits of proper collection and destruction will be emphasized in the public education and publicity surrounding the disposal of unwanted or unused controlled substances. Public health and safety is protected and improved both in preventing diversion of controlled substances during a national epidemic of pharmaceutical drug abuse and in providing options for collection that result in secure and environmentally sound destruction consistent with federal, state, tribal, and local laws and regulations.

Miscellaneous Changes

In accordance with the changes described above, DEA proposes to delete any reference to 21 CFR 1307.12 and 1307.21 and replace it with a reference to the new 21 CFR part 1317, where appropriate.\textsuperscript{44} DEA also proposes to revise 21 CFR 1301.13(e)(1)(i) to delete reference to a disposer category of registration in the coincident activity column for manufacturers. A disposer category of registration was proposed by DEA in 1995, but was never finalized (60 FR 43732, August 23, 1995). Reference to a disposer category was inadvertently included in a previous rulemaking (68 FR 58587, 1307.22 to delete reference to 1307.21 and replace it with reference to 21 CFR part 1317; in 21 CFR 1307.22 to delete reference to 21 CFR 1307.22; in 21 CFR 1301.25(i), 1301.52(c), and 1307.13 to delete reference to 21 CFR 1307.21 and replace it with reference to 21 CFR part 1317; in 21 CFR 1304.25(a)(9) and 1304.25(b)(9) to delete reference to 21 CFR 1307.22 and replace it with reference to 21 CFR part 1317; and in 21 CFR 1304.04(a) to add reference to 21 CFR part 1317. DEA also proposes in 21 CFR 1307.22 to delete reference to 21 CFR 1307.21, but not replace it with reference to 21 CFR part 1317. This revision to 21 CFR 1307.22 will allow existing practices for seizure and forfeiture to continue. DEA proposes to revise the title of 21 CFR 1307.22 to “Delivery of forfeited controlled substances” for clarity.
October 10, 2003).

**Regulatory Analyses**

**Regulatory Flexibility Act**

Under the Regulatory Flexibility Act of 1980 (RFA) (5 U.S.C. 601-612), federal agencies must evaluate the impact of rules on small entities and consider less burdensome alternatives. As discussed in the preceding sections of the regulatory preamble, DEA has considered numerous alternatives for each proposed requirement and method of collection and evaluated the impact of this proposed rule on small entities. DEA has concluded that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. An economic analysis of the Proposed Rule can be found in the rulemaking docket at http://www.regulations.gov.

In developing this proposed rule, DEA considered several options for both registrant and non-registrant disposal and reverse distributor destruction requirements. DEA analyzed alternative methodology approaches keeping in mind its statutory obligations under the CSA. DEA considered three options for non-registrant disposal: (1) Single Collection, which would authorize 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 DEA registrant; and (3) Multiple Collection, which would authorize non-registrants to utilize more than one method of collection to transfer controlled substances for purposes of disposal to law enforcement agencies and certain DEA registrants. In addition, DEA considered two options for registrant disposal: (1) Retain Existing Regulations, which would make no changes to
the existing registrant disposal regulations (21 CFR 1307.12 and 1307.21); and (2) Establish Consistent National Standards, which would delete existing regulations on the disposal of controlled substances (21 CFR 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, 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 timeline on when reverse distributors must destroy controlled substances acquired for destruction; and (4) As Soon As Practicable But No Later Than Fourteen Calendar Day Requirement, which would require reverse distributors to destroy controlled substances received for the purpose of destruction as soon as practicable but no later than fourteen calendar days of receipt. DEA performed a qualitative analysis of each of these alternatives and selected the “Multiple Collection” option for non-registrant disposal, the “Establish Consistent National Standard” option for registrant disposal, and the “As Soon As Practicable But No Later Than Fourteen Calendar Day Requirement” option for reverse distributors.

In accordance with the RFA, DEA evaluated the impact of this rule on small entities and anticipates that this rule will not have a significant economic impact on a substantial number of small entities. If promulgated, this proposed rule would affect all 1.4 million controlled substance registrants, which corresponds to approximately 381,386
businesses affected by the proposed rule. DEA estimates that 370,133 (97 percent) of the affected businesses are considered "small entities" in accordance with the RFA and Small Business Administration (SBA) standards. 5 U.S.C. 601(6) and 15 U.S.C. 632. DEA estimates that there should be minimal to no economic impact as a result of this proposed rule.

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

Executive Orders 12866 and 13563

This proposed rule was developed in accordance with the principles of Executive Orders 12866 and 13563. Based on an economic analysis, 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 Proposed Rule can be found in the rulemaking docket at http://www.regulations.gov. Public comment was received in public meetings held on January 19-20, 2011, to help inform and develop these proposed rules. Public comment is encouraged on this proposed rule through the internet with easy access to supporting information found at http://www.regulations.gov. Although not an economically significant rule, this proposed rule on the disposal of controlled substances has been reviewed by the Office of Management and Budget.
For DEA registrants that destroy controlled substances as described above, DEA anticipates that this rulemaking will have minimal or no economic impact and that modified DEA Form 41 could result in some level of cost savings. In addition, for registered reverse distributors, DEA anticipates that the security and recordkeeping requirements contained in the proposed rule will result in minimal or no costs.

DEA has determined that reverse distributors currently destroy controlled substances within the proposed “as soon as practicable but no later than fourteen 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 proposed requirement. For these instances, DEA believes reverse distributors will be able to make modifications to their pick-up/receipt and destruction schedule to accommodate the proposed requirements with minimal to no economic impact. Moreover, DEA conservatively estimates that the voluntary provisions for collectors, reverse distributors, distributors, and law enforcement agencies will have a net economic impact of nearly zero, and invites comment on this estimate. The proposed provisions that facilitate Non-Registrant Disposal are completely voluntary, not mandated. Any collector, reverse distributor, distributor, or law enforcement agency may 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, 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 its collection activities. Any collector, reverse

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distributor, distributor, or law enforcement agency that chooses to engage in these voluntary activities can decide to cease these activities at any time. Therefore, for the purposes of this analysis, DEA estimates that the voluntary provisions in this section have net zero economic impact on the regulated entities.

In summary, DEA estimates that there should be minimal to no annual total cost to the economy as a result of the proposed rule. Accordingly, 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.

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 and listed chemicals into the illicit market. The cost-benefit analysis uses the costs associated with the nonmedical use of prescription opioids, $8.6 billion in 2001\textsuperscript{45} and $53.4 billion in 2006.\textsuperscript{46} These are conservative estimates of the rapidly growing total cost associated with diversion of controlled substances and listed chemicals into the illicit market. As DEA has determined this rule poses minimal to no economic impact, DEA concludes that this rule reduces the growth in the cost of the diversion of controlled substances and listed chemicals into the illicit market, therefore, this rule will have a positive benefit for the health and safety of the citizens and residents of the United States.

\textsuperscript{45} Clin J Pain (The Clinical Journal of Pain), Volume 22, Number 8, October 2006.

Paperwork Reduction Act

Pursuant to Section 3507(d) of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 et seq.), DEA has identified the following collections of information related to this proposed rule on the disposal of controlled substances and has submitted these collection requests to the Office of Management and Budget (OMB) for review and approval. This proposed rule implements the Secure and Responsible Drug Disposal Act of 2010 (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 Controlled Substances Act (CSA), which establishes a closed system of distribution for all controlled substances, DEA 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). These records must be in accordance with and contain such relevant information as may be required by regulations promulgated by DEA. 21 U.S.C. 827(b)(1). In this rule, DEA proposes to revise existing and add a minimum amount of new registrant recordkeeping requirements, which are consistent with those requirements that are already required by statute and the proposed new part on disposal that creates a comprehensive regulatory framework for the destruction of controlled substances.

Title: Implementation of Registrant Recordkeeping Requirements Pursuant to the Controlled Substances Act, 21 U.S.C. 827

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

As discussed in the section on reverse distributors above, DEA is proposing to revise the information that registered reverse distributors are currently required to record consistent with previous requirements as well as a minimum amount of requirements under the proposed new comprehensive regulatory framework for the destruction of controlled substances. As discussed in more detail above, DEA proposes to modify the existing information that reverse distributors are required to record for clarity and consistency. In addition, DEA proposes that for all controlled substance records, reverse distributors will be required to maintain their existing business records so that the record of receipt is maintained with the corresponding record of return or destruction. By maintaining all relevant business records together, 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.

DEA estimates that there will be 60 respondents to this information collection and that their estimated frequency of response will vary. DEA estimates that the frequency of response will vary, because in accordance with 21 U.S.C. 827(a), 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. Because DEA is proposing recordkeeping requirements that registered reverse distributors are already required to maintain in accordance with 21 U.S.C. 827(a) and (b), DEA anticipates that the annual hour burden will not be increased by the proposed rule.
DEA is also proposing revised information that registrants are required to record in the return and recall process. DEA proposes to delete the existing rule on return and recall, 21 CFR 1307.12, and to implement separate rules on the return and recall of controlled substances for registrants and non-registrants. The return and recall recordkeeping requirements have been revised to reflect these changes.

DEA estimates that the universe of potential respondents to this information collection will be 68,344 respondents (Distributors - 828, Reverse Distributors - 60, Manufacturers - 522, Retail Pharmacies - 66,934). DEA estimates that the frequency of response will vary, because in accordance with 21 U.S.C. 827(a), 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. Because DEA is proposing recordkeeping requirements that registrants are already required to maintain in accordance with 21 U.S.C. 827(a) and (b), DEA anticipates that the annual hour burden will not be increased by the proposed rule.

DEA is proposing 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. To implement the Disposal Act, DEA is proposing to provide ultimate users, long term care facilities, and other non-registrants safe and convenient options to transfer controlled substances for purposes of disposal: take-back events, mail-back programs, and collection receptacle locations. In the proposed rule, registered manufacturers, distributors, reverse distributors, and retail pharmacies may obtain authorization from DEA to be a collector. A collector is a registered person authorized to receive a controlled substance for the purpose of disposal.
from non-registrants in lawful possession of controlled substances. DEA is proposing information that collectors must record based on the particular ultimate user collection method utilized (i.e., mail-back program or collection receptacle).

DEA estimates that the universe of potential participants to this information collection will be 68,344 respondents (Distributors - 828, Reverse Distributors - 60, Manufacturers - 522, Retail Pharmacies - 66,934).\(^\text{47}\) DEA estimates that the frequency of response will vary, because in accordance with 21 U.S.C. 827(a), 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. DEA notes, however, that the option to become an authorized collector is voluntary and no entity is required to establish or operate a disposal program as an authorized collector. The authorization to collect is a new activity and DEA has no criterion to determine the level of participation. As a result, the number of respondents is based on the current number of registrants which may request authorization to become a collector and the annual hour burden cannot be determined at this time. DEA will continue to monitor and analyze the potential burden of the new requirements imposed by this proposed rule and will review all comments submitted in response to this proposed rule and information collection request.

DEA is also proposing to authorize registered reverse distributors and distributors to acquire controlled substances from authorized law enforcement agencies and certain collectors that have acquired controlled substances from ultimate users and other non-registrants. DEA proposes to require these registered reverse distributors and distributors

\(^{47}\) The universe of potential participants includes all registrants that could potentially become authorized collectors. It is likely that this estimate will be adjusted downward once DEA obtains more information.
to maintain complete and accurate records of controlled substances received, delivered, or otherwise transferred for the purpose of destruction.

DEA estimates that the universe of potential respondents to this information collection will be 888 respondents (Distributors - 828, Reverse Distributors – 60). DEA estimates that the frequency of response will vary, because in accordance with 21 U.S.C. 827(a), 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. The authorization for reverse distributors and distributors to acquire controlled substances collected by law enforcement agencies and authorized collectors is new. As a result, DEA presently has no criterion to determine the level of participation and the annual hour burden cannot be determined at this time. DEA will continue to analyze the potential burden of the new requirements imposed by this proposed rule and review all comments submitted in response to this proposed rule and information collection request.

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

OMB Control Number: 1117-0007

Form Number: DEA Form 41

The recordkeeping requirements that DEA registrants are required to maintain pursuant to law are a vital component of DEA’s enforcement and control responsibilities – such records alert DEA to problems of diversion and ensure that the system of controlled substances distribution is open only to legitimate handlers of such substances. DEA is proposing information that registrants involved in the destruction of controlled substances must record. The record of destruction must include the signature of the two
authorized 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. DEA proposes to modify existing DEA Form 41 to reflect the proposed record of destruction for 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 OMB and assigned OMB control number 1117-0007.

In accordance with the current 21 CFR 1307.21, a DEA registrant that desires to dispose of a controlled substance must submit three copies of DEA Form 41 to the Special Agent in Charge (SAC) in their area. DEA is proposing to delete 21 CFR 1307.21 and replace it with a comprehensive part 1317 on disposal. In an effort to minimize the burden on registrants and in accordance with the proposed comprehensive regulatory framework for disposal, registrants that destroy controlled substances and utilize DEA Form 41 will no longer be required to submit three copies of DEA Form 41 to the SAC in their area. Rather, in accordance with the CSA, such registrants 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).

DEA estimates that there will be 68,344 respondents (Distributors - 828, Reverse Distributors - 60, Manufacturers - 522, Retail Pharmacies - 66,934) to this information collection. The number of respondents (68,344) represents the total number of registrants in business activities that are most likely to destroy controlled substances. DEA
estimates that the frequency of response will vary, because in accordance with 21 U.S.C. 827(a), registrants 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. DEA estimates that the average time per response will be 30 minutes and that the total annual burden will be 34,172 hours.

Request for Comments Regarding the Proposed Information Collection

All estimates include the time for reviewing instructions; searching existing data sources; gathering or maintaining the needed data; and reviewing the information. DEA solicits comments concerning: whether these information collection requirements are necessary for the proper performance of the functions of DEA, including whether the information has practical utility; the accuracy of DEA’s estimates of the burden of the information collection requirements; the quality, utility, and clarity of the information to be collected; and whether the burden of collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology, may be minimized. For information or a copy of the paperwork package submitted to OMB, contact John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 307-4654.

Organizations and individuals desiring to submit comments on the collection of information requirements should direct them to Drug Enforcement Administration, Attention: Office of Diversion Control (OD/DX), 8701 Morrissette Drive, Springfield, Virginia 22152.
OMB is required to make a decision concerning the collection of information requirements contained in this proposed rule between 30 and 60 days after its publication in the Federal Register. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

DEA is not authorized to impose a penalty on persons for violating information collection requirements which do not display a current OMB control number, if required. DEA intends to obtain current OMB control numbers for any new information collection requirements resulting from this rulemaking action prior to the effective date of the final rule. The OMB control number, when assigned, will be announced by separate notice in the Federal Register.

Executive Order 12988

This proposed regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform 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 proposed 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 proposed rule establishes the legal requirements for the handling of controlled substances. Destruction of controlled substances must be consistent with federal, state, tribal and local laws and regulations.

DEA and the regulated community have disposed of controlled substances since passage of the CSA. DEA has published a categorical exclusion from further NEPA analysis for the storage and destruction of controlled substances. This proposed rule would not authorize any new methods of storage, transportation, or destruction of controlled substances, but is limited to the logistics and documentation of the collection of controlled substances for destruction. Accordingly, this proposed rule does not significantly affect the quality of the human environment. DEA has, therefore, determined that this proposed 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

This proposed rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $136,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small
governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C 1532.

Executive Order 13175

This proposed rule is required by statute, will not have tribal implications and will not impose substantial direct compliance costs on Indian tribal governments.

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, Reporting and recordkeeping requirements, Security measures.

For the reasons set forth above, DEA proposes to amend 21 CFR parts 1300, 1301, 1304, 1305, 1307, and 1317 as follows:

PART 1300—DEFINITIONS

1. 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).

2. Amend § 1300.01, in paragraph (b) by:

a. Alphabetically adding a definition of “collection”;

b. Revising the third sentence of the definition of “freight forwarding facility”;

c. Alphabetically adding definitions of “non-retrievable” and “reverse distribute”; and

d. Revising the definition of “reverse distributor”.

The additions and revisions read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * * *

(b) * * *

Collection means to receive a controlled substance for the purpose of destruction from an ultimate user, a person lawfully entitled to dispose of ultimate user decedent’s property, or a long term care facility on behalf of an ultimate user that resides or has resided at that facility. The term collector means a registered manufacturer, distributor, reverse distributor, 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.

* * *

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

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alters that controlled substance's physical and/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 and/or physical properties. A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical and/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.

*   *   *   *   *

Reverse distribute means to acquire controlled substances from another DEA registrant or a law enforcement agency 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 means a person who reverse distributes a controlled substance.

*   *   *   *

*   *   *   *   *

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

3. The authority citation for part 1301 continues to read as follows:


4. Amend § 1301.13 by revising paragraph (e)(1)(i) 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)

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<th>Business Activity</th>
<th>Controlled Substances</th>
<th>DEA Application Forms</th>
<th>Application Fee ($)</th>
<th>Registration Period (years)</th>
<th>Coincident Activities Allowed</th>
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<td>Schedules I-V</td>
<td>New–225 Renewal–225a</td>
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<td>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</td>
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5. Amend § 1301.25 by revising 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.

6. 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, to change his/her name or address, or in the case of retail pharmacies, manufacturers, distributors, and reverse distributors, to authorize such registrant to be a collector, by submitting a letter of 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.

(1) The letter 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, a request for authorization to collect and the type(s) of collection the registrant intends to conduct (collection receptacle or mail-back program), or the new name or address; and

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

(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.

(3) If a registered retail pharmacy is applying for a modification in registration to authorize such registrant to be a collector and maintain a collection receptacle at a long term care facility in accordance with § 1317.80 of this chapter, the registrant shall include the physical location of each long term care facility at which the registered pharmacy intends to operate a collection receptacle.

(b) No fee shall be required to be paid for modifications. The request for modification shall be handled in the same manner as an application for registration. If the modification in 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.

7. Amend § 1301.52 by revising paragraph (c) to read as follows:

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

* * * * * *

(c) Any registrant desiring to discontinue business activities altogether or with respect to controlled substances (without transferring such business activities to another person) shall return for cancellation his/her certificate of registration, and any unexecuted order forms in his/her possession, to the Registration Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for current mailing address. Any controlled substances in his/her possession may be disposed of in accordance with part 1317 of this chapter.

* * * * *

8. Amend 1301.72 by revising 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, and 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 FFDCA which shall be subject to the requirements of paragraph (b) of this section), in addition to sealed mail-back packages and inner liners collected in accordance with part 1317 of this chapter, shall be stored in one of the following secured areas:
9. Amend § 1301.75 by revising paragraph (b) to read as follows:

§ 1301.75 Physical security controls for practitioners.

(b) Controlled substances listed in Schedules II, III, IV, and V, in addition to sealed mail-back packages and inner liners collected in accordance with part 1317 of this chapter, shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances, excluding sealed mail-back packages and collection receptacle inner liners, throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

10. Amend § 1301.76 by revising paragraph (c) to read as follows:

§ 1301.76 Other security controls for practitioners.

(c) Whenever the registrant distributes a controlled substance (as permitted in §§ 1301.13(e)(1), 1307.11, 1317.05, and 1317.10 of this chapter), he/she shall comply with the requirements imposed on non-practitioners in § 1301.74(a), (b), and (c).

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

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

Authority: 21 U.S.C. 821, 827, 831, 871(b), 958(f) and (g), and 965, unless otherwise noted.
12. Amend § 1304.03 by revising the first two sentences of paragraph (a) to read as follows:

§ 1304.03 Persons required to keep records and file reports.

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

13. Amend § 1304.04 by revising paragraph (a) introductory text to read as follows:

§ 1304.04 Maintenance of records and inventories.

(a) Except as provided in paragraphs (a)(1) and (2) of this section, every inventory and other records required to be kept under this part and part 1317 of this chapter must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration.
*  *  *  *  *  *

14. Amend § 1304.11 by revising paragraph (e) introductory text, paragraph (e)(2), and paragraph (e)(3) introductory text to read as follows:

§ 1304.11 Inventory requirements.

*  *  *  *  *

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

* * * * * *

(2) Inventories of distributors. Except for reverse distributors covered by § 1317.25 of this chapter, 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 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:

* * * * * *

15. Amend § 1304.22 by revising the introductory text, paragraph (b), and removing paragraph (e).

The revisions read as follows:

§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers and exporters.

Each person registered or authorized (by §§ 1301.13(e), 1307.11, or 1307.13 of
this chapter) to manufacture, distribute, dispense, import, export, or conduct research
with controlled substances shall maintain records with the information listed below.

*  *  *  *  *  *

(b) Records for distributors. Except for reverse distributors covered by §§
1317.25 and 1317.55 of this chapter, each person registered or authorized to distribute
controlled substances shall maintain records with the same information required of
manufacturers pursuant to paragraphs (a)(2)(i), (ii), (iv), (v), (vii), (viii), and (ix) of this
section or, when applicable, § 1317.55 of this chapter.

*  *  *  *  *  *

16. Amend § 1304.25 by revising paragraphs (a)(9) and (b)(9) to read as follows:

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

*  *  *  *  *

(a)  *  *  *

(9) The quantity disposed of by destruction, including the reason, date and
manner of destruction. All other destruction of narcotic controlled substances shall
comply with part 1317 of this chapter.

(b)  *  *  *

(9) The number of units of finished forms and/or commercial containers
destroyed in any manner by the registrant, including the reason, the date and manner of
destruction. All other destruction of narcotic controlled substances shall comply with
part 1317 of this chapter.

PART 1305—ORDERS FOR SCHEDULE I AND II CONTROLLED
SUBSTANCES

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

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

18. Amend § 1305.03 by adding paragraph (e) to read as follows:

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

   *   *   *   *   *

   (e) Deliveries to an authorized DEA registrant pursuant to part 1317 of this chapter by an ultimate user, a long-term care facility on behalf of an ultimate user that resides or has resided at that facility, or a person authorized to dispose of the ultimate user decedent’s property.

PART 1307—MISCELLANEOUS

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

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

§ 1307.11 [Amended]

20. In § 1307.11, remove and reserve paragraph (a)(2).

§ 1307.12 [Removed]


22. 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]

23. Remove § 1307.21

24. Revise § 1307.22 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. See the Table of DEA Mailing Addresses in § 1321.01 of
this chapter for the current mailing address. The application shall show the name,
address, and official title of the person or agency to whom the controlled drugs are to be
delivered, including the name and quantity of the substances desired and the purpose for
which intended. The delivery of such controlled drugs shall be ordered by the
Administrator, if, in his opinion, there exists a medical or scientific need therefor.

25. Add part 1317 to read as follows:

PART 1317 – DISPOSAL

Sec.

1317.01 Scope.
1317.02 Definitions.

**SUBPART A - DISPOSAL OF CONTROLLED SUBSTANCES BY REGISTRANTS**

1317.05 Registrant disposal.
1317.10 Registrant return or recall recordkeeping and order form requirements.
1317.15 Reverse distributor registration requirements and authorized activities.
1317.20 Reverse distributor employee security requirement.
1317.25 Reverse distributor inventory, recordkeeping, reporting, and order form requirements.

**SUBPART B - DISPOSAL OF CONTROLLED SUBSTANCES BY ULTIMATE USERS AND OTHER NON-REGISTRANTS**

1317.30 Authorization to collect from non-registrants.
1317.35 Collection by law enforcement agencies.
1317.40 Registrants authorized to collect and authorized collection activities.
1317.45 Collector security requirements.
1317.50 Collector inventory, recordkeeping, reporting, and order form requirements.
1317.55 Registered reverse distributor and distributor acquisition of controlled substances from law enforcement agencies or authorized collectors.
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.
1317.100 Recordkeeping requirements.

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

§ 1317.01 Scope.

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

§ 1317.02 Definitions.

(a) As used in this part, the following terms shall have the meaning specified:

Authorized Employee means an individual employed full time by the registrant, who has not been convicted of a felony offense related to controlled substances and has not, 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.

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.

Inner liner means a liner that meets the specifications listed in § 1317.60 of this chapter and is used in the collection of controlled substances.

Law enforcement officer means a person that is:

(i) Employed full time by a law enforcement agency;

(ii) Under the direction and control of a federal, state, tribal, or local government;

(iii) Acting in the course of their official duty; and

(iv) Duly sworn and given the authority by any federal, state, tribal, or local government to carry firearms, execute and serve warrants, make arrests without warrant, and make seizures of property.

(b) Any other term contained in this part and not defined in paragraph (a) of this section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

SUBPART A - DISPOSAL OF CONTROLLED SUBSTANCES BY REGISTRANTS

§ 1317.05 Registrant disposal.

(a) Practitioner Inventory. Any DEA registered practitioner in lawful possession of a controlled substance in its inventory who 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) 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 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 applicant to dispose of the controlled substance in one of the following manners:

      (A) By transfer to a person registered under the Act and 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.

   (iii) 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)(2) 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 she/he deems
proper on practitioner procedures regarding the disposal of controlled substances.

(b) Non-practitioner inventory. Any DEA registrant who is a non-practitioner in
lawful possession of a controlled substance in its inventory who 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 the location of destruction, the non-practitioner shall follow the procedures set forth at § 1317.95(b).

(ii) If a non-practitioner transports controlled substances by its own means to a registered location for any other authorized purpose described in this paragraph (b)(4), transportation shall be directly to the authorized registered location and two authorized employees of the transporting non-practitioner shall accompany the controlled substances to the destination registered location.

(c) Collected Controlled Substances. Any authorized 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 authorized 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 in a manner consistent with the security requirements for Schedule II controlled substances until prompt on-site destruction can occur or, with regard to the receipt of unauthorized packages, until instructions from the Administration are received.

(2) Collection Receptacles. Upon removal from the permanent outer shell, the authorized collector shall promptly:

(i) Destroy the inner liner and its contents; or
(ii) Store the inner liner and its contents at the collector’s registered location in a manner consistent with the security requirements for Schedule II controlled substances until prompt destruction can occur.

(iii) **Practitioner Methods of Destruction.** Authorized collectors who are registered practitioners shall dispose of sealed inner liners and their contents by utilizing any method in § 1317.05(a)(1), (a)(2), or (a)(4), 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.

(iv) **Non-Practitioner Methods of Destruction.** Authorized collectors who are non-practitioners shall dispose of sealed inner liners and their contents utilizing any method in § 1317.05(b)(1), (b)(2), or (b)(4), 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. Except distributing registrants shall not utilize freight forwarding facilities to transfer sealed inner liners and their contents.

**§ 1317.10 Registrant return or recall recordkeeping and order form requirements.**

(a) Each registrant shall maintain a record of each return or recall transaction in accordance with part 1304 of this chapter.

(1) Each registrant that delivers a controlled substance to another registrant for the purpose of return or recall shall maintain a record pursuant to § 1304.22(b).

(2) Each registrant that receives a controlled substance for the purpose of return or recall shall maintain a record that includes the following information: the date of the
transaction; the name, form, and quantity of each controlled substance received; and the
name, address, and registration number of the delivering registrant from whom the
substance was received.

(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 prescribed 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 DEA as a reverse distributor, unless exempted by law or otherwise authorized
pursuant to this chapter.

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

(1) The registered reverse distributor may pick-up controlled substances from a
DEA registrant at the DEA registrant’s registered location; or

(2) The registered reverse distributor may receive controlled substances
delivered by common or contract carrier or delivered directly by a registrant who is a
non-practitioner.

(i) Delivery to the registered reverse distributor by an authorized DEA 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 registered reverse distributor shall be personally received by an authorized employee of the reverse distributor at the registered location.

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

(1) Immediately and securely store the controlled substance at the reverse distributor’s registered location, or immediately transfer the controlled substance to the reverse distributor’s registered location for secure storage until timely destruction or timely return of the substance to the registered manufacturer or other registrant authorized by the manufacturer to accept returns or recalls on the manufacturer’s behalf;

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

(3) Timely destroy the controlled substance in a manner prescribed in Subpart C of this part, or

(4) Immediately deliver the controlled substance to the location of destruction for timely destruction pursuant to paragraph (d) of this section.

(d) A registered reverse distributor shall destroy or cause the destruction of any controlled substance received for the purpose of destruction as soon as practicable but no later than fourteen calendar days of receipt.

§ 1317.20 Reverse distributor employee security requirement.
A registered 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 DEA denied, had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause.

§ 1317.25 Reverse distributor inventory, recordkeeping, reporting, and order form requirements.

(a) A registered reverse distributor that acquires controlled substances from a registrant shall maintain the records, reports, and order forms described in this section and part 1304 of this chapter, except that a reverse distributor that acquires controlled substances from law enforcement agencies or authorized collectors pursuant to subpart B of this part shall follow § 1317.55(d) through (f) of this chapter.

(b) Inventory requirements. Each person registered as a reverse distributor shall include the following information in the inventory records required by § 1304.11 of this chapter:

(1) The name of the substance; and

(2) The total quantity of the substance:

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

(ii) 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

(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.

(c) Record requirements. Each person registered as a reverse distributor shall maintain records with the following information required by § 1304.21 of this chapter:

(1) For return or recall to manufacturers:

(i) The date of receipt; the name and quantity of each controlled substance received; the name, address, and DEA 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 DEA number of the person from whom the substance was received; the name, address, and DEA number of the registrant to whom the substance was returned; and the method of return (e.g., common or contract carrier).

(2) For destruction:

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

(ii) The date of destruction; the method of destruction; the name and quantity of each controlled substance destroyed; the name, address, and DEA number of the person from whom the substance was received; the place of destruction; and the name and signature of the two authorized employees of the registered reverse distributor 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 all records, the record of receipt shall be maintained together with the corresponding record of return or destruction.
(d) **Reports to ARCOS.** Registered reverse distributors shall report acquisition/distribution transactions pursuant to § 1304.33 of this chapter.

(e) **Order forms.** Each person registered to reverse distribute controlled substances in Schedules I or II shall comply with the requirements in part 1305 of this chapter.

**SUBPART B - DISPOSAL OF CONTROLLED SUBSTANCES BY 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 DEA to be a collector pursuant to § 1317.40 of this chapter; and

(2) Any federal, state, tribal, or local law enforcement agency or any law enforcement officer employed thereby acting in the course of that person’s official duties and pursuant to § 1317.35 of this chapter.

(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 that 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 of this chapter only.

§ 1317.35 Collection by law enforcement agencies.

(a) A Federal, state, tribal, or local law enforcement agency 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 of this chapter;

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

(3) Collection receptacles located at the law enforcement agency's physical address and in accordance with § 1317.75 of this chapter.

(b) A law enforcement agency 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 a law enforcement agency 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 a law enforcement agency through a take-back event, mail-back program, or collection receptacle should be transferred to a destruction location in a manner that prevents diversion.
(e) A law enforcement agency 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 an inner liner as described in § 1317.60 of this chapter is used, the unique identification number of the inner liner transferred, the size of the 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 DEA 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, and retail pharmacies may apply to 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 who is authorized to collect ceases activities as a collector, such registrant shall apply to modify its registration in accordance with § 1301.51 of this chapter to indicate that the registrant no longer collects.

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

(1) Those registered locations of manufacturers, distributors, reverse distributors, and retail pharmacies that are authorized for collection; and

(2) Long term care facilities at which registered retail pharmacies are authorized to maintain collection receptacles.

(c) Authorized collectors may conduct the following activities:

(1) Receive mail-back packages at a registered location that has an on-site method of destruction pursuant to § 1317.70 of this chapter;
(2) Install, manage, and maintain collection receptacles located at their authorized collection location(s); and

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

§ 1317.45 Collector security requirements.

An authorized 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.

§ 1317.50 Collector inventory, recordkeeping, reporting, and order form requirements.

(a) Inventory record requirements. Each authorized collector shall maintain the following information in the inventory:

(1) 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:

(i) The date of the inventory;

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

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

(2) 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 inner liner on hand awaiting destruction:

(i) The date of the inventory;

(ii) The number of inner liners;

(iii) The unique identification number of each inner liner; and

(iv) The size (e.g., 5 gallon, 10 gallon, etc.) of each inner liner.

(b) Continuing record requirements. Each authorized collector shall maintain the following records:

(1) For registrants authorized to collect through a mail-back program, the record shall include the following:

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

(ii) For those unused packages provided to a third party to make available to ultimate users and other authorized non-registrants (e.g., a pharmacy, grocery store, etc.): 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) Upon receipt of a sealed package: the date of receipt and the unique identification number on the individual package; and

(iv) Upon destruction of a sealed package pursuant to Subpart C of this chapter: in accordance with the recordkeeping requirements in § 1317.100 of this chapter.

(2) For registrants authorized to collect through a collection receptacle, the record
shall include the following:

(i) Upon acquisition of each inner liner: the date the inner liner is acquired, the corresponding unique identification number of each inner liner, and the size (e.g., 5 gallon, 10 gallon, etc.) of each inner liner.

(ii) Upon installation of each inner liner in a collection receptacle: the date of installation, the address and DEA registration number of the location of the collection receptacle where the inner liner is installed, the unique identification number of the inner liner, the size of the inner liner (e.g., 5 gallon, 10 gallon, etc.), and the name of two authorized employees who witnessed the installation;

(iii) Upon removal of the inner liner: the date of removal, the address and DEA registration number of the collection location, the unique identification number of the inner liner, the size of the inner liner (e.g., 5 gallon, 10 gallon, etc.), and the name of two authorized employees who witnessed the removal;

(iv) Upon secure storage of a sealed inner liner: the date of the transfer to storage, the unique identification number of the inner liner stored, the size of the inner liner stored (e.g., 5 gallon, 10 gallon, etc.), and the name of two authorized employees who transferred the inner liner to secure storage;

(v) Upon transfer of a sealed inner liner to a reverse distributor or distributor: the date of the transfer, the address and DEA registration number of the reverse distributor or distributor to whom the inner liner was transferred, the unique identification number of the inner liner transferred, the size of the inner liner transferred (e.g., 5 gallon, 10 gallon, etc.), and the name of the two authorized employees who transferred the inner liner to the reverse distributor or distributor; and
(vi) Upon destruction pursuant to subpart C of this chapter: in accordance with the recordkeeping requirements in § 1317.100 of this chapter.

(c) Reports to ARCOS. Authorized collectors are exempt from the ARCOS reporting requirements in § 1304.33 of this chapter for controlled substances collected through mail-back programs and collection receptacles for the purpose of disposal.

(d) Order forms. Authorized collectors are exempt from the requirements in part 1305 of this chapter for controlled substances collected through mail-back programs and collection receptacles for the purpose of disposal.

§ 1317.55 Registered reverse distributor and distributor acquisition of controlled substances from law enforcement agencies or authorized collectors.

(a) A registered reverse distributor is authorized to acquire controlled substances from law enforcement agencies that collect controlled substances from ultimate users. A registered reverse distributor is authorized to acquire controlled substances from authorized collectors that collect controlled substances through a collection receptacle in accordance with §§ 1317.75 and 1317.80 of this chapter.

(b) A registered distributor is authorized to acquire controlled substances from authorized collectors that collect controlled substances through a collection receptacle pursuant to §§ 1317.75 and 1317.80 of this chapter.

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

(1) Acquire the controlled substances in the manner prescribed in § 1317.15(b) of this part;

(2) Dispose of the controlled substances in the following manner:
(i) Immediately and securely store the controlled substance at the reverse
distributor’s registered location, or immediately transfer the controlled substances to the
reverse distributor’s registered location for secure storage, until timely destruction; or

(ii) Immediately deliver the controlled substance to the location of destruction
for timely destruction.

(iii) Destroy, or cause the controlled substances to be destroyed, as soon as
practicable but no later than fourteen calendar days of receipt.

(iv) Destruction shall be in accordance with Subpart C of this part.

(3) Secure storage of the controlled substances shall be in a manner consistent
with the security requirements for Schedule II controlled substances until timely
destruction can occur.

(d) Record requirements. A registered reverse distributor or a registered
distributor that acquires controlled substances pursuant to paragraphs (a) or (b) of this
section shall maintain the following records:

(1) Upon receipt: the date of receipt; the name and address of the law
enforcement agency or the name, address, and DEA registration number of the authorized
collector from whom the inner liner (or mail-back package if from a law enforcement
agency) was received; the unique identification number of the inner liner (or mail-back
package if from a law enforcement agency) received; and the size of the inner liner
received (e.g., 5 gallon, 10 gallon, etc.);

(2) Upon transfer to secure storage: the date of storage; the address and DEA
number of the storage location; the unique identification number of the inner liner or
mail-back package stored (if available in the case of a law enforcement agency); and the

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size of the inner liner stored (e.g., 5 gallon, 10 gallon, etc.);

(e) Reports to ARCOS. Reverse distributors and distributors that acquire controlled substances pursuant to paragraphs (a) or (b) of this section are exempt from the ARCOS reporting requirements in § 1304.33 of this chapter with regard to any controlled substances acquired pursuant to paragraphs (a) or (b) of this section.

(f) Order forms. Reverse distributors and distributors that acquire controlled substances pursuant to paragraphs (a) or (b) of this section are exempt from the requirements in part 1305 of this chapter with regard to any controlled substances acquired pursuant to paragraphs (a) or (b) of this section.

§ 1317.60 Inner liner requirements.
For the purpose of part 1317 of this chapter, an inner liner shall fulfill the following requirements:

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

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

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

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

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

§ 1317.65 Take-back events.
(a) Any Federal, state, tribal, or local law enforcement agency 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 a law enforcement agency to hold a collection take-back event in accordance with this section.

(b) The law enforcement agency shall appoint a law enforcement officer employed full time by the agency to oversee the collection. Law enforcement officers employed and authorized by the law enforcement 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 substance has occurred.

(c) Each take-back event should have at least one receptacle for the collection of permitted substances. The collection receptacle should be a securely locked, substantially constructed container with an outer shell and a removable inner liner as specified in §1317.60 of this chapter. The outer shell 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.

(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 the law enforcement agency 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 any federal, state, tribal, or local law enforcement agency or any authorized collector. An authorized 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.

(c) A law enforcement agency or authorized collector that conducts 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 mail. Any person may partner with an authorized collector or law enforcement agency 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 authorized
collector’s registered address or the participating law enforcement agency’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 permitted substances that can be sent, and notice that only packages provided by the authorized 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 an authorized collector. The authorized collector or law enforcement agency 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 agency that they are sending one of the designated packages by giving the unique identification number on the package.

(e) An authorized 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.

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

§ 1317.75 Collection receptacles.

(a) Any federal, state, tribal, or local law enforcement agency or authorized collector may manage, maintain, and empty 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.

(c) Only ultimate users and other authorized non-registrant persons in lawful possession of a controlled substance in Schedule II, III, IV, or V may put such substances in a collection receptacle at a registered location (e.g., ultimate user cannot transfer such substance to pharmacy staff to put into a collection receptacle).

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

(1) At an authorized collector's registered location, which shall have proper building security in accordance with §§ 1301.71 to 1301.77 of this chapter;

(2) At a long term care facility in accordance with § 1317.80 of this chapter; or

(3) At a law enforcement agency's physical location.

(e) For authorized collectors, a controlled substance collection receptacle shall:

(1) Be securely fastened to a permanent structure so that it cannot be removed;
(2) At a registered location, be located in the immediate proximity of a designated area where controlled substances are stored and at which an authorized employee is present (e.g., can be seen from the pharmacy counter); or at a long term care facility pursuant to § 1317.80, be located in a secured area regularly monitored by personnel of that long term care facility;

(3) Meet the following design specifications:

(i) A securely locked, substantially constructed container with a permanent outer shell and a removable inner liner as specified in § 1317.60 of this chapter.

(ii) 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;

(iii) The outer container shall prominently display a sign indicating that only non-controlled drugs and Schedule II, III, IV, or V controlled substances are acceptable (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

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

(f) At a registered location, the small opening in the outer container of the collection receptacle shall be locked or made otherwise inaccessible to the public when an authorized employee is not present (e.g., when the pharmacy is closed).

(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 authorized employees of the authorized collector. The inner liner shall be sealed immediately upon removal from the permanent outer shell and the sealed inner liner shall not be opened, x-rayed,
analyzed, or otherwise penetrated.

§ 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 resided at such long term care facility when such disposal occurs immediately, but no longer than three business days after the discontinuation of use by the ultimate user. A long term care facility shall dispose of such controlled substances only by transferring those controlled substances into an authorized collection receptacle located at that long term care facility.

(b) Only a registered retail pharmacy authorized to collect at the long term care facility may manage and maintain collection receptacles at that long term care facility and remove or supervise the removal of the inner liner of the collection receptacles at that long term care facility in accordance with § 1317.75(g) of this chapter. The registered retail pharmacy shall comply with all other requirements in § 1317.75 of this chapter.

(c) A registered retail pharmacy that intends to operate a collection receptacle at a long term care facility shall apply to modify its registration in accordance with § 1301.51 of this chapter and shall include in the application for modification in registration the physical location of each long term care facility at which the registered pharmacy intends to operate a collection receptacle.

§ 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.

(1) **Continuing record requirements.** Such registrant accepting recalled controlled substances shall maintain a record of each recalled controlled substance received from an ultimate user, to include the following information: the date of receipt, and the name, form, and quantity of each controlled substance received.

(2) **Order forms.** Such registrant accepting recalled controlled substances is exempt from the requirements in part 1305 of this chapter for the receipt of recalled controlled substances from ultimate users.

(3) **Reports to ARCOS.** Such registrant accepting recalled controlled substances 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 pursuant to § 1304.33 of this chapter.

(b) An ultimate user that 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 shall be destroyed in compliance with applicable federal, state, tribal, and local laws and regulations and shall be rendered
non-retrievable.

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

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

§ 1317.95 Destruction procedures.
The destruction of any controlled substance shall be in accordance with the following requirements:

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

(b) If the controlled substances are transported by a registrant to the location of destruction, the following procedures shall be followed:

(1) Transportation shall be directly to the destruction location;

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

(3) Two authorized employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances;
(4) Two authorized 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 authorized employees of the transporting registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.

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

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

§ 1317.100 Recordkeeping requirements.

(a) In addition to any other recordkeeping requirements, 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 that includes the following information: the date of destruction; the method of destruction; the name and address of the place of destruction; the name and quantity of the controlled substances destroyed or the unique identification number of the inner liner or mail-back package destroyed; the size of the inner liner destroyed (e.g., 5 gallon, 10 gallon, etc.); and the name and signature of the two authorized employees who witnessed the destruction.

(b) If the controlled substances destroyed were received from another registrant, the registrant destroying the controlled substances shall maintain a copy of the record transferring the substances or a copy of the DEA Form 222.
December 17, 2012

Dated:

Michele M. Leonhart
Administrator

[FR Doc. 2012-30699 Filed 12/20/2012 at 8:45 am; Publication Date: 12/21/2012]
1A. Complete all desk investigations within 120 days.
   (Recorded as number of cases submitted)

1B. Open all consumer complaints within 10 days.
   (Recorded as number of cases opened)
1C. Review all investigations within 30 days.
(Recorded as number of cases reviewed)

1D. Complete all field investigations within 120 days.
(Recorded as number of cases submitted)
1E. Close all Board investigations and mediations within 180 days.
(Recorded as number of cases closed)

1F. Issue citations and fines within 30 days.
(Recorded as number of citations issued)
1G. Issue letters of admonishment within 30 days.
(Recorded as number of letters of admonishment issued)

1H. Complete all field investigations for cases involving drug abuse within 60 days.

Under development
1I. Refer all cases to the AG’s Office within 10 days.
(Recorded as number of cases referred)

1J. Secure pleadings from AG’s Office within 90 days after referral.
(Recorded as number of pleadings received)
1K. Inspect 100 percent of all licensed facilities once every three years by June 30, 2015.

1L. Review draft pleadings within 30 days.
(Recorded as number of pleadings filed)
1M. **Perform quarterly status reports for all referral cases pending.**
(Recorded as number of cases pending over 90 days.)

1N. **Secure mail votes on all decisions within 30 days of receipt.**
(Recorded as number of decisions received for mail vote)
10. Complete petitions to revoke probation within 30 days.
(Recorded as number of cases submitted)

1P. Quarterly evaluate 5% of the Pharmacist Recovery Program (PRP) participants to ensure the PRP Contractor is in compliance with the contract.
(Recorded as number of participants in the PRP.)
## Board of Pharmacy Enforcement Statistics
### Fiscal Year 2012/2013

<table>
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<th>Workload Statistics</th>
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| **Cases Assigned & Pending (by Team) at end of quarter** |           |         |         |          |             |
| Compliance Team    | 523       | 504     |         |          | 504         |
| Drug Diversion/Fraud | 380    | 321     |         |          | 321         |
| Probation/PRP       | 107       | 98      |         |          | 98          |
| Routine Inspection  | 296       | 477     |         |          | 477         |
| Mediation/Enforcement ** | 243 | 337     |         |          | 337         |
| Criminal Conviction | 644       | 625     |         |          | 625         |

| Application Investigations |           |         |         |          |             |
| Received                  | 220       | 177     |         |          | 397         |
| Closed                    |           |         |         |          |             |
| Approved                  | 162       | 144     |         |          | 306         |
| Denied                    | 41        | 31      |         |          | 72          |
| Total ***                 | 283       | 226     |         |          | 509         |
| Pending (at the end of quarter) | 235    | 191     |         |          | 191         |

| **Letter of Admonishment (LOA) / Citation & Fine** |           |         |         |          |             |
| LOAs Issued               | 53        | 19      |         |          | 72          |
| Citations Issued          | 249       | 284     |         |          | 533         |
| Total Fines Collected **** | $831,660.29 | $450,459.00 |         |        | $1,282,119.29 |

* This figure include reports submitted to the supervisor.
** This figure include reports submitted to the citation and fine unit, Supervising Inspector, AG referral, EO referral, as well as cases assigned to enf. staff
*** This figure includes withdrawn applications.
****Fines collected (through 12/31/2012 and reports in previous fiscal year.)
## Board of Pharmacy Enforcement Statistics
### Fiscal Year 2012/2013

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<th>Jan-Mar</th>
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## Workload Statistics

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## Immediate Public Protection Sanctions

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* This figure includes Citation Appeals

** This figure includes administrative penalties

## Probation Statistics

### Licenses on Probation

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| Probation Office Conferences | 21 | 26 | 47 |
| Probation Site Inspections  | 67 | 53 | 120 |
| Successful Completion      | 7  | 3  | 10 |
| Probationers Referred to AG for non-compliance | 4 | 3 | 7 |

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

As of December 31, 2012.
## SB 1441 – Program Statistics
Pharmacist Recovery Program (PRP)

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<td>3</td>
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</table>

| Total PRP Participants | 71 | 72 | N/A |
| Contracts Reviewed | 65 | 73 | 138 |
| Total Probationers | 125 | 118 | 243 |
| Inspections Completed | 84 | 79 | 163 |

### Referrals to Treatment

| Referrals to Treatment | 3 | 5 | 8 |
| Drug Test Ordered | 1175 | 1223 | 2398 |
| Drug Tests Conducted | 986 | 987 | 1973 |

### Relapsed

| Relapsed | 2 | 1 | 3 |

### Major Violation Actions

| Cease Practice/Suspension | 1 | 2 | 3 |
| Referral for Discipline | 4 | 4 |         |

### Exit from PRP or Probation

| Successful Completion | 9 | 6 | 15 |
| Termination - Probation | 1 | 2 | 3 |
| Voluntary Surrender | 8 | 5 | 13 |
| Surrender as a result of PTR | 1 | 1 |         |
| Public Risk | 1 |         |         |
| Non-compliance | 19 | 7 | 26 |
| Other | 1 | 1 | 2 |

### Number of Patients Harmed

### Drug of Choice at PRP Intake or Probation

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<tr>
<th>Pharmacists</th>
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<th>Ambien</th>
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<th>Oxycodone</th>
<th>Morphine</th>
<th>Benzodiazepines</th>
<th>Barbiturates</th>
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<td>Zolpidem Tartrate</td>
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<td>Hydromorphone</td>
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<td>Promethazine w/Codeine</td>
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<tr>
<td>Pharmacist Recovery Program</td>
<td>July-Sep</td>
<td>Oct-Dec</td>
<td>Jan-Mar</td>
<td>Apr-Jun</td>
<td>Total 12/13</td>
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<tr>
<td>Participant Files Audited</td>
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</tr>
</tbody>
</table>
Drug Of Choice - Data entered from July 2012 to June 2013

Pharmacist

Intern

Technician

1 Alcohol
2 Opiates
3 Hydrocodone
4 Oxycodone
5 Benzodiazepines
6 Barbiturates
7 Marijuana
8 Heroin
9 Cocaine
10 Methamphetamine
11 Pharmaceutical Amphetamine
AGENDA ITEM XI

ATTACHMENT 6
<table>
<thead>
<tr>
<th>Success Indicators</th>
<th>Related Performance Measures</th>
<th>Acceptance Parameters</th>
<th>Actual Percentage Green Light Status</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A Complete all desk investigations within 120 days.</td>
<td>[CP, CC, EF, QE, RC]</td>
<td>○ 93% ○ 75% ○ 74%</td>
<td>50%</td>
<td>Cases with multiple offenses take longer to investigate. In addition to relying on other agencies to provide documents as well as staff vacancies.</td>
</tr>
<tr>
<td>1B Open all complaints within 10 days.</td>
<td>[CP, CC, EF, QE, RC]</td>
<td>○ 90% ○ 76% ○ 75%</td>
<td>58%</td>
<td>Staff vacancy in complaint unit prevented the board from opening complaints within 10 days.</td>
</tr>
<tr>
<td>1C Review all investigations within 30 days.</td>
<td>[CP, CC, EF, QE, RC]</td>
<td>○ 97% ○ 94% ○ 93%</td>
<td>n/a</td>
<td>Under Development</td>
</tr>
<tr>
<td>1D Complete all field investigations within 120 days.</td>
<td>[CP, CC, EF, QE, RC]</td>
<td>○ 94% ○ 75% ○ 74%</td>
<td>44%</td>
<td>Inspector vacancies and new inspector training prevented inspector staff to complete investigations timely.</td>
</tr>
<tr>
<td>1E Close all Board investigations and mediations within 180 days.</td>
<td>[CP, CC, EF, QE, RC]</td>
<td>○ 97% ○ 94% ○ 93%</td>
<td>43%</td>
<td>Inspector vacancies and new inspector training prevented inspector staff to complete investigations timely.</td>
</tr>
<tr>
<td>1F Issue citations and fines within 30 days.</td>
<td>[CP, CC, EF, QE, RC]</td>
<td>○ 96% ○ 92% ○ 91%</td>
<td>73%</td>
<td>Due to the number of cases to be split and issued there was a delay in issuing citations.</td>
</tr>
<tr>
<td></td>
<td>Objective Description</td>
<td>Responsible Agencies</td>
<td>Progress</td>
<td>Status</td>
</tr>
<tr>
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<td>---------------------------------------------------------------------------------------</td>
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<tr>
<td>1G</td>
<td>Issue letters of admonishment within 30 days.</td>
<td>[CP, CC, EF, QE, RC]</td>
<td>98%</td>
<td>79%</td>
</tr>
<tr>
<td>1H</td>
<td>Complete all field investigations for cases involving drug abuse within 60 days.</td>
<td>[CP, HE, QE, RC]</td>
<td>90%</td>
<td>n/a</td>
</tr>
<tr>
<td>1I</td>
<td>Refer all cases to the AG’s office within 10 days.</td>
<td>[CP, QE, RC]</td>
<td>97%</td>
<td>44%</td>
</tr>
<tr>
<td>1J</td>
<td>Secure pleadings from AG’s office within 90 days after referral.</td>
<td>[CP, QE, RC]</td>
<td>96%</td>
<td>57%</td>
</tr>
<tr>
<td>1K</td>
<td>Inspect 100 percent of all licensed facilities once every three years by June 30, 2015.</td>
<td>[CP, QE, RC]</td>
<td>90%</td>
<td>n/a</td>
</tr>
<tr>
<td>1L</td>
<td>Review draft pleadings within 30 days.</td>
<td>[CP, QE, RC]</td>
<td>90%</td>
<td>35%</td>
</tr>
<tr>
<td>1M</td>
<td>Perform quarterly status reports for all referral cases pending.</td>
<td>[CP, QE, RC]</td>
<td>90%</td>
<td>5%</td>
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<tr>
<td></td>
<td>Strategic Planning: Enforcement</td>
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<tr>
<td>1N</td>
<td>Secure mail votes on all decisions within 30 days of receipt.</td>
<td>[CP, QE, RC]</td>
<td>☐ 97%</td>
<td>☐ 91%</td>
</tr>
<tr>
<td>1O</td>
<td>Complete petitions to revoke probation cases within 30 days.</td>
<td>[CP, QE, RC]</td>
<td>☐ 98%</td>
<td>☐ 95%</td>
</tr>
<tr>
<td>1P</td>
<td>Quarterly evaluate 5% of the Pharmacist Recovery Program (PRP) participants to ensure the PRP Contractor is in compliance with the contract.</td>
<td>[CP, QE, RC]</td>
<td>☐ 98%</td>
<td>☐ 95%</td>
</tr>
<tr>
<td>1Q</td>
<td>Pursue disciplinary action, within 10 days, on a licensee closed a public risk from the Pharmacists Recovery Program.</td>
<td>[CP, QE, RC]</td>
<td>☐ 98%</td>
<td>☐ 95%</td>
</tr>
</tbody>
</table>