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STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT AND COMPOUNDING COMMITTEE
MEETING MINTUES

DATE: June 24, 2015

LOCATION: DCA Headquarters, First Floor Hearing Room
1625 North Market Blvd.
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT:
Amy Gutierrez, PharmD, Chair, Professional Member
Greg Lippe, Vice Chair, Public Member
Greg Murphy, Public Member
Allen Schaad, RPh, Professional Member
Stanley C. Weisser, RPh, Professional Member

COMMITTEE MEMBERS NOT PRESENT: Rosalyn Hackworth, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Janice Dang, PharmD, Supervising Inspector
Laura Freedman, DCA Staff Counsel
Laura Hendricks, Administrative Analyst

Call to Order

Dr. Gutierrez, chair of the committee, called the meeting to order at 10:05 a.m.

Dr. Gutierrez welcomed those in attendance. Roll call of the board members present was taken and a quorum of the committee was established.

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

Dr. Raymond Pierson, an orthopedic surgeon, asked the committee to agendize a discussion on medical access in rural communities. Dr. Pierson explained that in his rural community he has experienced difficulty with patients receiving emergency medications after hours because they did not have access 24 hour pharmacies.

Aglaia Panos, representing the Marin County Public Health Office's initiative, "RX Safe Marin", requested time to provide an update on the Marin County initiative at the next meeting of the prescription medication abuse subcommittee.

Ms. Panos, representing Pharmacy Planning Service, also requested a hearing on prescription drug errors.

II. ENFORCEMENT MATTERS

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

Background

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

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

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

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

Discussion and Comment

Ruth Carter from the Drug Enforcement Administration (DEA) made a presentation regarding the DEA's regulations for the take back of prescription medications. Ms. Carter's presentation can be found at the end of this document.

In 2010, Congress passed the Secure and Responsible Drug Disposal Act (Act). The Act was passed to address the prescription medication epidemic in the United States. People had no legitimate way to dispose of their medications at the time, so they stored them in their

medicine cabinets at home. This led to easy access for everyone which made it difficult to combat the epidemic.

Because the public didn't have a way to dispose of their prescription medications, the DEA began hosting take back days in 2008. The take back days resulted in the collection of over 2,400 tons of pharmaceutical substances.

Other methods of disposing of pharmaceuticals, including flushing down a toilet, mixing with kitty litter or coffee grounds and placing the garbage, are still legal if the method is legal in the particular state.

The Act specifies that participation in the take back program is voluntary; the DEA cannot mandate that its registrants participate. However, regulations promulgated in response to the Act specify the manner by which pharmaceuticals must be destroyed or disposed by DEA registrants.

Law enforcement may continue take back events and maintain take back receptacles under their own authority. The only requirement for law enforcement is that they must maintain custody and control over the pharmaceuticals and/or controlled substances.

Regulations created a category titled "collection" which is defined as receiving a controlled substance from an ultimate user for the purpose of destruction. Controlled substances can be received from a person lawfully entitled to dispose of an ultimate user decedent's property or from a long term care facility on behalf of a resident. Also, if a person is indigent or has no family, individual state law may designate hospice as the entity legally authorized to dispose of his or her property and pharmaceuticals.

Mr. Weisser asked whether long term care facility patients would need to give approval to have their old medications disposed. Ms. Carter stated that the patient, if cognizant, would need to give their permission. Medications are technically the property of the patient and are being held in a custodial capacity by the long term care facility. The DEA regulations do not address the way in which long term care facilities should record the patients' approval.

Collection receptacles must be operated at the address of the registrant except in the case of long term care facilities. Ultimate users must place pharmaceuticals in the receptacles themselves. Controlled substances and non-controlled substances may be co-mingled but controlled substances can't be counted, sorted, inventoried, or otherwise individually handled by anyone.

Receptacles must be secured to a permanent structure, locked, and have a permanent outer container that will hold an inner liner. The outer structure should have an opening

that allows placing pharmaceuticals in the receptacle, but does not allow for someone to pull the contents out.

Liners must be waterproof, tamper-evident, tear-resistant, removable, sealable as soon as they are removed, must not allow the contents to be viewed, and must have the size of the bag and a permanent, unique identification number printed on the outside. When liners are collected, they must be sealed by two employees immediately upon removal from the receptacle.

Dr. Gutierrez asked whether pharmacy employees can remove and store a liner if it becomes full. Ms. Carter stated that the pharmacy can remove full liners, seal them, and keep them in a secure area prior to pick up.

Mr. Weisser asked whether there was a requirement to record the types and amounts of pharmaceuticals placed into receptacles. Ms. Carter answered that there is no federal requirement to document what goes into receptacles.

Ms. Carter specified that pharmacies can't put their expired inventory in a collection receptacle for destruction.

A pharmacist asked a clarifying question regarding the person responsible for pulling the liner from the receptacle. Ms. Carter answered that two pharmacy employees must remove and seal the liner. Reverse distributors are not authorized to remove liners from the pharmacy receptacles. Reverse distributors may only pick up sealed liners.

Jen Jackson, representing the City of San Francisco, stated that San Francisco has been operating a pilot take back program for the past three years and has collected 47,000 pounds of non-controlled substances. San Francisco has also passed a city ordinance which requires drug manufacturers to fund and operate take back programs. The new ordinance should be implemented within 18 to 24 months.

Ms. Jackson asked whether a contract carrier could haul away the liners with only one employee because they were not reverse distributors. Ms. Carter clarified that the term contract carrier refers to carriers with which the reverse distributor will contract to haul the liners. The liners can't be sent to a hazardous waste site; they need to be returned to the DEA registrant for destruction.

Ms. Jackson also asked the board to incorporate language in its regulations to allow hospitals to take back medications. She also urged the DEA to work with the Food and Drug Administration (FDA), Environmental Protection Agency (EPA), and Department of Transportation to address hazardous waste issues such as the ability to put chemotherapy drugs and auto injectors in take back receptacles. She felt that the receptacles were a

secure and appropriate place for that type of waste. Ms. Carter indicated that she believed the EPA would address that issue in its upcoming rule.

Dr. Gutierrez asked whether the City of San Francisco is seeing sharps in take back containers. Ms. Jackson stated the city had not heard about sharps in liners probably because the city has a sharps collection program. She encouraged the state to also pass legislation that would require manufacturers to take back their sharps so there are separate waste streams for sharps and pharmaceutical waste.

Heidi Sanborn, representing the California Product Stewardship Council, argued that the general public does not know the difference between different schedules of drugs and recommended that the board be clear in its education and labeling of the receptacles. She thanked the board for allowing pharmacies to participate in drug take back programs.

Wayman Wong, representing San Mateo County Environmental Health, asked whether there is a deadline for a reverse distributor to destroy the liners once they take control of them. Ms. Carter responded that the new regulation requires reverse distributors to destroy the pharmaceuticals within 30 days of taking control.

Mr. Wong also addressed Assembly Bill 45 (Mullin) and stated that he believed the bill, as it relates to possibly collecting controlled substances at the curb, is bad public health policy which would lead to increased diversion of medications. Ms. Herold stated that the board has spoken with the author regarding its concerns has taken an official position of "oppose unless amended."

Mr. Weisser asked Ms. Carter to clarify the 3-day requirement for long term care facilities to dispose of their medications. Ms. Carter stated that the 3-day rule applied to the length of time a liner can be stored once it's sealed. When a medication is placed in a receptacle, it might sit there for months before the liner is full. Once the liner is full, removed, and sealed, it can only be stored on premises for three days.

Janet Dumonchelle, pharmacist-in-charge at California State University Sacramento, stated that the university has hosted a take back receptacle in their pharmacy for 2 ½ years and has collected over 1000 pounds of expired and unused medications. Ms. Dumonchelle indicated that the university is having difficulty getting someone to transport the medications for destruction and asked about the process. Ms. Carter answered that if the university is collecting controlled substances, the liner would have to be picked up by a reverse distributor registered with the DEA. She suggested that any interested company contact the DEA to inquire about the requirements to become registered as a reverse distributor.

Dave Woods, chief pharmacy officer for the San Francisco Department of Public Health, applauded the board's efforts to address the take back of prescription medications.

Aglaia Panos, asked the board to address issues of liability and responsibility for the items that get placed in pharmacy receptacles. Ms. Herold answered that pharmacists are not responsible for the contents of the receptacles. Ms. Carter identified the few requirements for which pharmacists are responsible.

Dr. Gutierrez asked whether the DEA has funding to reimburse pharmacies for participating in the take back program. Jen Jackson from San Francisco stated that data from Canada indicates 99 percent of pharmacies voluntarily participate. In San Francisco, every major retail pharmacy supported the take back ordinance and they are just waiting for the board to issue regulations.

There were no additional questions or comments.

Dr. Gutierrez recessed for a break at 12:10 p.m.

The meeting reconvened at 12:20 p.m.

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

<u>Background</u>

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

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

At this meeting, the committee will resume work on the proposed regulation, following information provided by the DEA during its presentation earlier in the meeting. The plan is to draft the components of the proposed regulation and to bring for discussion at the July

Board Meeting. The board needs to complete work on this draft in the near future as many communities are establishing requirements for collection of unwanted pharmaceuticals.

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

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

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

1. Strength and tear resistance of the liners as sharps and other items may be placed in these collection receptacles, even if the public is advised not to make such deposits. Bags that can be punctured, torn or possibly leak will create a serious health risk to those who come in contact with the liners or near receptacles.

2. Possible placement of hazardous drugs in receptacles could require special consideration: are specialty liners needed for all receptacles that can handle antineoplastic drugs (to prevent exposure to hazardous drugs).

   For example,

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

Discussion and Comment

Jan Harris, Director of Environmental Health and Safety at Sharps Compliance, presented information about their receptacle take back system. Ms. Harris's presentation can be found at the end of this document.

Mr. Weisser asked about the cost of the Sharps Compliance program and Ms. Harris stated that the cost is based on usage and can range from $65 to $200 per month. Mr. Weisser also asked about the cost of the receptacles and whether they are sold or leased. Ms. Harris indicated most receptacles are leased because, for example, the pharmacy would not be stuck with a non-compliant receptacle if the DEA changes it regulations. Ms. Harris didn't know the costs of the receptacles or whether there were costs in addition to the $65 to $200 per month.

Ms. Harris referred to the NIOSH list and stated that, when referring to a list an ultimate user would utilize, there are very few hazardous drugs. However, if someone puts hazardous waste in a receptacle, that waste would fall under the household hazardous waste exemption.

There were no additional questions or comments.

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

Background

The Drug Quality Security Act (DQSA) preempted California's e-pedigree law, and instead established national requirements for tracking drugs through the supply chain. The first round of tracking requirements became effective January 1 with requirements for drug wholesalers. The second part of the requirements for pharmacies are is to take effect July 1.

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

Discussion and Comment

Scott Moody, an employee of McKesson, made a presentation on the requirements and ramifications of the DQSA at the invitation of the Healthcare Distribution Management Association. Mr. Moody's presentation can be found at the end of this document.

Drug Supply Chain Security Act (DSCSA) is the second title of part of a larger bill (DQSA) passed by Congress in 2013 and signed into law November 27, 2013. There are two parts to the law: Title I which deals with drug compounding and outsourcing facilities, and Title II which deals with the supply chain as it relates to distribution and pharmacy.

Title I affects distribution by creating a new class of outsourcing facility that requires regulation by the FDA, but there is a prohibition on conventional distributors being able to participate in distribution through the supply chain. The distribution of anything that an outsourcing facility creates has to be handled by the outsourcing facility because they're not allowed to use a conventional distributor to facilitate the movement of goods or facilitate financial transactions.

The two primary goals of Title II are national traceability systems and standards and a revision of the state wholesaler licensing requirements for consistency across all fifty states.

Title II established national traceability requirements which will result in a system where, within 10 years, each container will have a serial number which will be a sub part of a lot that will be traceable through the supply chain from its introduction into commerce to the point where it is delivered to a pharmacy. The ten-year evolution has a variety of steps along the way that require active participation from every participant in the supply chain.

DQSA sets a floor and a ceiling for state licensing activities. In November, it is anticipated that the FDA will publish their licensing requirements that the states will then need to adopt.

DQSA traces who owns the product and follows changes of ownership through the supply chain; it does not track physical custody of the product. There are several times when the custody of a product might go in one direction and the ownership might go in another direction.

Changes of ownership must be documented; however, the law doesn't require documentation about the location from which a product is shipped or stored as long as the ownership remains constant. While a business entity has ownership of a product, it may move and store it at any warehouse within its distribution system without having to trace its location. It's only when ownership changes from one entity to another, that traceability requirements must be applied.

Similarly, as long as they are under common ownership, health systems and pharmacies may move product between different locations without having to trace its location.

The DQSA defines drugs subject to traceability as "finished human Rx drugs." Animal products made exclusively for animals are not subject to traceability. Human drugs that

cross into the veterinary space are subject to traceability until they cross into the custody of a veterinarian or veterinary supply company.

Many drugs don't meet the definition of being a "finished" drug. If a drug is not suitable to be administered to a patient in the form in which the manufacturer sells it, it doesn't meet the definition of "finished" and is not then subject to traceability.

Traceability begins with the manufacturer at the point where the product is finished, packaged and ready to be sold. Additionally, a manufacturer may also have an exclusive relationship with a distributor and sell its product to the distributor for introduction into the market. At that point, the distributor may be the starting point in the supply chain for that product and traceability would begin there. Lastly, a re-packager who purchases directly from the manufacturer may be the third point of introduction into the supply chain and subject to traceability.

Under the DSCSA, when a transaction occurs, traceability data is provided to the party making the purchase. The purchaser is responsible for maintaining the purchase data for six years.

A contract pharmacy that has received product without taking ownership of it, is challenged because the DSCSA has a confidentiality clause that says you can't disclose information to the contract pharmacy without written permission from the covered entity (owner).

An exception request has been made to the FDA by ASHP, NACDS, NCPA, and HGMA asking the FDA to give a general exception that would allow traceability data to be sent to the contract pharmacy. The FDA has yet to rule on the exception request.

Mr. Weisser asked about distributors who never take ownership of the product. Mr. Moody explained that the DSCSA splits distributors and third party logistic providers (3PLs) and they have separate activities under the law. A 3PL can't be a distributor. If a manufacturer/owner sends product to a 3PL and the 3PL doesn't acquire ownership of the product, the 3PL doesn't need to provide traceability data to anyone, but the owner must still maintain traceability data whenever a 3PL transacts a product on the owner's behalf. The 3PL is the contracted agent to the manufacturer so the manufacturer retains accountability for the 3PL's activities.

Traceability data between the manufacturer and distributor will mainly be electronic. Between the distributor and pharmacy, the FDA did not specify a format, but Mr. Moody believed that data will be provided to the pharmacy via a proprietary portal. Portals will generally be able to store the traceability data for six years as required. For most pharmacies, storing data will be a service provided by the distributor.

Manufacturers and distributors were required to maintain inbound data and generate outbound data as of January 1, 2015. Beginning July 1, 2015, pharmacies will also be required to maintain inbound data and generate outbound data.

As of January 1, 2015, pharmacies were required to have a procedure or policy for detecting suspicious or illegitimate drugs and then initiating an investigation upstream and downstream in the supply chain. When an illegitimate drug is positively identified, pharmacies, distributors, and manufacturers are required to notify the FDA on a form 3911. Samples of the illegitimate drug must be maintained in quarantine until the FDA issues a clearance letter at the conclusion of its investigation.

If audited, pharmacies, distributors and manufacturers are required to maintain audit information for six years from the date of the audit.

Beginning November 27, 2017, any new product that's packaged after that date, will be required to have a new 2D data matrix barcode attached for the commercial unit of sale. The barcode will still contain the NDC number but will also contain three new data elements: A machine-readable version of the lot number, the serial number of the product, and the expiration date of the product. Repackagers will be required to have the new barcode in place by 2018.

In 2019, distributors will have to begin shipping products with the new barcodes. Also in 2019, when returning product, there will need to be proof that the entity to which the product is being returned was actually the original seller. Returns will also require verification of a legitimate lot number and serial number.

Dr. Gutierrez asked if reverse distributors were exempt because the product is not returning to the supply chain. Mr. Moody verified that unsalable product is exempt from traceability because the product is no longer considered fit for human consumption.

In November 2020, pharmacies will not be able to transact product without a new barcode. Any entity using scanners that shoot a straight red line, a linear digital scanner, will need to replace/upgrade its scanners to read the new barcodes.

Pharmacies are subject to providing traceability information when selling a drug; however, there are several exceptions that exclude most pharmacy sales from traceability. First, any drug going to a patient at the pharmacy is not considered a distribution under the law.

Second, if transferring/selling product to another pharmacy, you can make the transfer subject to a specific patient need. If there is an identified patient on the other end awaiting the prescription, you can transfer the product with no traceability requirements.

Transferring product proactively in anticipation of someone needing it, doesn't qualify under this exception. There must be a specific patient need.

Emergency medical reasons are another exception to the rule. This exception deals with life and death situations; a supply shortage does not rise to the level of a life and death situation under the law.

The most interesting exception is the one that says the distribution from a pharmacy of a minimal quantity to a licensed practitioner for office use is exempt from traceability. Questions regarding this exemption include the definitions of a minimal quality and a licensed practitioner. Mr. Moody believed the individual states will probably need to define these terms.

Ms. Herold asked for clarification regarding the process for documenting a pharmacy to pharmacy sale of medication. Mr. Moody stated that the selling pharmacy must create a traceability document which includes the current transaction but which also includes the upstream data with all the previous transactions. For example, assume manufacturer A sells product to distributor B, and distributor B sells product to pharmacy C. When pharmacy C sells to pharmacy D, the traceability document must include the current transaction (pharmacy to pharmacy) as well as data showing the transactions between manufacturer A and distributor B and distributor B and pharmacy C. Additionally, because pharmacy C is not a direct purchase distributor, the product lot number must also be identified in the traceability data.

Ms. Sodergren asked whether an internal pharmacy reference number would suffice in lieu of a lot number. Mr. Moody stated that the legislation specifically states that a secondary distributor must include the lot number in the transaction.

Further, Mr. Moody clarified that there is no difference in how the law treats pharmacies and distributors if they're in a position as a secondary distributor. All secondary distributors are required to create the traceability purchase document and capture the lot number.

Tony Wong, of Kaiser Permanente, asked about returns and how a scenario would play out with one hospital returning product to another sister hospital. The hospital returning the product may not be returning the exact vial or lot number, but might be returning the same type of product once they get a shipment. Mr. Moody indicated that the scenario was not defined in law.

There were no additional comments or questions.

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

Background

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

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

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

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

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

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

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

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

1715.55 Reconciliation and Inventory Report of Controlled Substances

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances.

(b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section.

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

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

(e) Adjustments to the Inventory Report shall be made following reconciliation, only after the reporting and documenting of any losses or accounting made for overages.
    (1) Each adjustment to the Inventory Report made to correct the stock on hand count shall be annotated to show any adjustment in the number of controlled substances on hand in the pharmacy or clinic, and who made the annotation, and the date.
    (2) The pharmacist-in-charge or consultant pharmacist shall countersign the adjusted Inventory Report.
    (3) The original Inventory Report and amended Inventory Report following reconciliation shall be readily retrievable in the pharmacy or clinic for three years.

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

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

Discussion and Comment

Ms. Hendricks explained that she surveyed other states regarding the frequency for which they require their pharmacies to perform an inventory. Ms. Hendricks was able to obtain information from 25 states and found the following:

- Six states require an annual inventory
- Four states require a perpetual inventory – the board highlighted two of those states that specifically require a reconciliation of the inventory
- Fifteen states require a biennial inventory (the minimum as mandated by the DEA)

Ms. Hendricks' presentation can be found at the end of this document.

Dr. Gutierrez recessed for a break at 2:40 p.m.

The meeting reconvened at 2:46 p.m.

Rebecca Cupp, representing Ralph's, made a presentation on Ralph's policies and procedures for conducting inventories of controlled substances.

Ms. Cupp reported that Ralph's conducts an annual inventory of its controlled substances and anytime there is a change of pharmacist-in-charge (PIC). The new PIC and a representative from pharmacy management must conduct the inventory together.

Ralph's also conducts a quarterly reconciliation for all schedule II controlled substances. In addition, Ralph's contracts with a company that will conduct surprise audits on the entire pharmacy operation. Roughly ten percent of Ralph's pharmacies get surprise audits each year.

Ms. Cupp recommended that the board consider having a list of controlled substances for which reconciliation is required, but also requiring a random drug in the reconciliation which can be changed annually or every quarter based on diversion data. Including a random drug in the reconciliation process would make it more difficult for persons attempting to divert drugs from the pharmacy because they wouldn't know exactly which drug might be included in the next reconciliation.

Steve Gray, Kaiser Permanente, commented that when trying to account for liquids, it's important to keep in mind that a pharmacy will lose a significant number of milliliters by just what sticks to the side of the bottle. He recommended making a good faith estimate for liquids and thought that would make the reconciliation process more practical and more efficient.

Mr. Gray then asked that the board discuss and clarify whether hospitals would be required to inventory and/or reconcile the entire hospital or just the pharmacy.

Ms. Herold read the committee's new proposed language. The committee discussed its options and decided to require a physical count of schedule II controlled substances every quarter. The committee also decided to recommend adding language to require an additional drug, identified by the board on an annual basis, be counted when conducting the inventory/reconciliation.

The committee also discussed requiring an inventory every time there is a change of PIC. Mr. Weisser expressed his concern about the practicality of requiring an inventory every time there is a PIC change. Supervising Inspector Dang explained that one major advantage of conducting an inventory at the time of a PIC change is that there is an inventory baseline and no question about who is responsible from that point forward.

Mr. Weisser also questioned the language in section (g) which would require a pharmacy to install cameras, move the controlled substances to a more secure location and perform

daily inventory counts. Dr. Gutierrez stated that the board should leave the language open ended and give pharmacies the freedom to decide how to improve their own security.

Steve Gray commented that the board should consider amending section (a) to include "pharmacies, hospitals, and clinics" because hospitals without pharmacies are still dispensing controlled substances.

Additionally, Mr. Gray said that while teaching pharmacy law at UC San Diego, he recommends that an inventory be conducted by the departing PIC and by the incoming PIC. He believes it would be a good idea to write the language to make it the permit holder's responsibility to conduct an inventory when there's a PIC change.

Committee Recommendation:

Motion: Recommend that staff revise the language based on the committee's comments and bring it back to the full board for review/approval.

M/S: Weisser/Murphy
Support: 5 Oppose: 0 Abstain: 0

Supervising Inspector Dang commented that the inspectors have found that some pharmacies conduct their inventory throughout the day. Federal law recommends conducting inventories at the beginning of the day. SI Dang recommended that the committee consider adding a similar provision to the new language.

There were no additional comments or questions.

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

Surescripts issued its 2014 National Progress Report which indicated a 19% growth in overall e-prescriptions. Additionally, although e-prescriptions for controlled substances increased 400 percent to 1.67 million, only 1.4 percent of providers were enabled to participate.

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

There were no comments or questions.

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

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

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

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

<u>Discussion and Comment</u>
Ms. Herold provided a brief overview and advised the committee to recommend that the board advance the proposed language to a 45-day comment period and initiate rulemaking. She also advised that the committee pull back the self-assessment process and wait until the regulations are in place.

<u>Committee Recommendation:</u>

Motion: Initiate the 45-day comment period without the self-assessment form.

M/S: Weisser/Lippe
Support: 5 Oppose: 0 Abstain: 0

There were no additional comments or questions.

Mr. Lippe left the meeting at 3:56

g. DISCUSSION: <u>Update on CURES 2.0</u>

Discussion and Comment

Ms. Herold provided an update on the latest iteration of the Controlled Substance Utilization Review and Evaluation System (CURES) and indicated that the Department of Justice (DOJ) wants to implement the new CURES system on June 30, 2015 despite some problems with the transition. DOJ wants to initiate the transition period and run both CURES systems (1.0 and 2.0) concurrently while they continue to build and augment the new system.

Ms. Herold stated that users might have difficulty accessing CURES 2.0 if they don't have current versions of internet browsers such as Chrome, Firefox, and Internet Explorer. She cited a Los Angeles Times article titled, "Tech Problems May Crimp Launch of State's New Prescription Drug Database." Ms. Herold clarified that the problems are not due to a failure to create a working database, but will still require more time to implement effectively.

Ms. Herold sits on the CURES 2.0 Executive Steering Committee which has three members from the Department of Consumer Affairs and three from DOJ. Her view is that the June 30, 2015 implementation date is premature, but that everyone should still be able to access CURES 1.0.

In addition to changes to the CURES system, Ms. Herold pointed out that the statute also required all pharmacists with active licenses to be enrolled in the system by January 1, 2016. She advised pharmacists who hadn't already enrolled to use the current enrollment method and not wait for the new method which might be plagued by delays.

Steve Gray, from Kaiser Permanente, said that a lot of pharmacy organizations don't have the latest version of the required internet browsers. He indicated that it is not as easy as just upgrading the browser because the browsers might be incompatible with a pharmacy's current software or might not even be compatible with other drug information websites that pharmacies use on a daily basis.

Mr. Gray also requested clarification for licensed pharmacists who don't fill prescriptions or prescribe. It was his understanding that if he registered for CURES then didn't use it, he would have to register again. Ms. Herold clarified that users have to sign in at least once every 30 days to maintain their registration.

There were no additional comments or questions.

III. COMPOUNDING MATTERS

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

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

The board reviewed a paper that explained the differences between traditional and outsourced compounding and described the key CGMP provisions that are critical to ensuring drug quality and patient safety when compounding occurs at a larger scale.

There were no comments or questions.

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

Background

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

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

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

Discussion and Comment

Ms. Herold stated that the bill stalled on the Senate Appropriations Committee calendar. The stall was political and not due to the strength or language of the bill itself. The bill might be picked up later in the year as an emergency bill if there is more than one

outsourcing facility affected and unable to do business in California. The bill most likely will be picked up next year as part of the board's sunset package.

Steve Gray, Kaiser Permanente, commented that the bill's language states that a location cannot be both a pharmacy and an outsourcing facility. It seems to imply that the state wouldn't allow an out-of-state location to be both a 503A and a 503B. Mr. Gray pointed out that many facilities outside California are licensed as both and asked whether those facilities would then be unable to do business in California if the bill passes.

Ms. Herold answered that when the board sponsored the bill, there was a discussion about whether it wanted to restrict to only outsourcers or compounders. The concern was that the services a pharmacy provides are much different than the patient care services an outsourcing facility provides and the state didn't want those locations co-licensed. However, if another state has already licensed a location in that manner, California will allow it and will move forward with a California outsourcing license and/or a pharmacy license depending on whether the location ships patient-specific drugs.

Glen Olsheim, of California Pharmacy and Compounding Center in Newport Beach, indicated that the California Pharmacy and Compounding Center is licensed as an outsourcing facility and a licensed sterile compounder under one roof. He asked for an explanation of the reasoning for prohibiting a location licensed as an outsourcing facility and sterile compounder in California.

Ms. Herold responded that the concerns were about patient care, patient tracking, patient consultations, and the liaison of the specific prescriber for a particular patient that the board expects of a pharmacy. With an outsourcer, the location becomes more impersonal and doesn't necessarily have those patient-specific services.

Mr. Olsheim indicated his facility follows pharmacy law standards as well as federal, CJMP, standards. He stated that his location had been inspected twice by the FDA and has had one sterile compounding inspection by the board of pharmacy. The licensing environment has become chaotic with different states asking for different types of licenses and different types of compliance.

Ms. Herold thought the board would benefit from hearing more from Mr. Olsheim. The bill was set up by looking at the dynamics of the federal law. Should there be demonstrated need to allow these types of businesses to become both pharmacies and outsourcers, the board will need to discuss allowing it provided the businesses can assure the board that patient-centered protections can be maintained in that environment.

There were no additional comments or questions.

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

Background

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

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

Committee Recommendation:

Motion: Provide comments regarding the FDA's draft guidance.

M/S: Weisser/Murphy

Support: 4 Oppose: 0 Abstain: 0

There were no additional comments or questions.

d. REVIEW: Sterile Compounding Licensure Statistics

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

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

Supervising Inspector Janice Dang presented information regarding 2014 sterile compounding inspections. 1,394 sterile compounding sites were inspected in 2014. Of those, 683 were issued at least one violation. Altogether, 1,746 individual violations or corrections were ordered.

The majority of violations were related to poor facility and equipment standards, lack of or poor self-assessments and/or compounding records, and lack of an active quality assurance program.

The majority of citations issued and cases referred to the Attorney General's office were for poor compounding records.

Ms. Dang's presentation can be found at the end of this document.

IV. REMAINING MEETING DATES FOR 2015

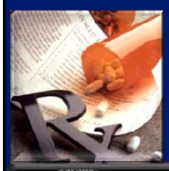
- September 2, 2015
- December to be determined

Dr. Gutierrez adjourned the meeting at 4:25 p.m.

DEA
U.S. Drug Enforcement Administration

Secure and Responsible Drug Disposal Act of 2010

California State Board of Pharmacy
Board Meeting



The United States Department of Justice
Drug Enforcement Administration

Ruth A. Carter, Chief
Liaison and Policy Section
Office of Diversion Control

The Problem: Easy Access

National Take Back Initiative

U.S. Drug Enforcement Administration
Office of Diversion Control

National Take Back Initiative

- First Eight DEA Take Back Days (Combined)
  - Collection of 2,100+ tons
- September 27, 2014
  - Ninth (Final) DEA Take Back Day, approximately 309 tons

U.S. Drug Enforcement Administration
Office of Diversion Control

Ultimate User Methods of Disposal Prior to Disposal Final Rule

Disposal in Trash (ONDCP method); or

Flushing (FDA opioids and select CSs)

National Take-back Event

Transfer to Law Enforcement (Police Station Receptacles or local Take-back events)

DEA

Secure and Responsible Drug Disposal Act of 2010

- CSA amended to provide ultimate users and LTCF with additional methods to dispose of unused, unwanted or expired controlled substance medication in a secure, safe and responsible manner
- Amendment authorizes DEA to inspect all collection facilities

21 USC §§ 822(f) and (g)

Secure and Responsible Drug Disposal Act of 2010

- Authorized DEA to promulgate regulations (Disposal Rule) that allow ultimate users to transfer pharmaceutical controlled substances to authorized entities for disposal
- Created an exception for long-term care facilities (LTCF) to transfer pharmaceutical controlled substances for disposal on behalf of patients who reside or have resided at that facility.

21 USC §§ 822(f) and (g)

Secure and Responsible Drug Disposal Act of 2010

- Regulations did not limit the ways that ultimate users may dispose of pharmaceutical controlled substances—they expanded them.
- Any method of pharmaceutical disposal that was valid prior to these regulations continues to be valid.

Secure and Responsible Drug Disposal Act of 2010

- Participation is voluntary.
- DEA may not require any person to establish or operate a disposal program.

21 USC §§ 822(g)(2)

Secure and Responsible Drug Disposal Act of 2010

- Disposal rule eliminated existing 21 CFR §§ 1307.12 and 1307.21
- New part 1317 contains the requirements on:
  - disposal procedures;
  - collection of pharmaceutical controlled substances from ultimate users;
  - return and recall; and
  - destruction of controlled substances

Ultimate User

Ultimate user means 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 a member of his household."

21 USC § 802(27)

Disposal 21 CFR § 1317

Law Enforcement

- Law enforcement continues to have autonomy with respect to how they collect controlled substances from **ultimate users**, including:
  - maintaining collection receptacles
  - conducting mail-back programs
  - conducting take-back events

21 CFR § 1317.35

Law Enforcement

- Law Enforcement may continue to conduct take-back events.
- Any person may partner with Law Enforcement.
- Law Enforcement shall maintain control and custody of collected substances until secure transfer, storage, or destruction has occurred.
- Authorized collection receptacles and inner liners "should" be used.

21 CFR §§ 1317.35 and 1317.65

Collection

Collection means 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
  and (54)
- LTCF on behalf of an ultimate user who resides or has resided at the facility.

21 USC § 822(g)(3) and (4)
21 CFR § 1300.01(b)

Authorized to Collection

Registrants authorized to collect:

- Manufacturers
- Distributors
- Reverse Distributors
- Narcotic Treatment Programs
- Hospitals/clinics with an on-site pharmacy
- Retail Pharmacies

21 CFR § 1317.40

Modification to Become Collector

- Must be registered to handle Schedule II - V
- Request modification in writing to the DEA or on-line at ww.DEAdiversion.usdoj.gov
- **No fee** is required for this modification request

21 CFR §§ 1301.51(b) and (c)

Collection at LTCF

- A registered hospital/clinic with an **on-site pharmacy** or a registered retail pharmacy may request modification of their registration to become an authorized collector to maintain a collection receptacle at a LTCF (§ 1317.80).
- Request must include:
  - Name and physical location of each LTCF at which a collection receptacle will be operated
- **No fee** is required for this modification request.

21 CFR §§ 1301.51(b)(2) and (c)

Collection Receptacles

Collection Receptacles

Collection receptacle

- Any authorized collector may operate a collection receptacle at their registered location

- Retail pharmacies and hospitals/clinics with an on-site pharmacy may manage collection receptacles at LTCFs

21 CFR §§ 1317.75 and 1317.80

Collection Receptacles

- Ultimate users *shall* put the substances directly into the collection receptacle.
- Controlled and non-controlled substances may be comingled.
- Collected substances shall not be counted, sorted, inventoried, or otherwise individually handled.
- Registrants **shall not dispose of stock/inventory** in collection receptacles.

21 CFR § 1317.75(b) and (c)

Design of Collection Receptacles

Design of Collection Receptacles

- Securely fastened to a permanent structure.
- Securely locked, substantially constructed container with permanent outer container and removable inner liner.
- Outer container must have small opening that allows for contents to be added, but does not allow for removal of contents.

21 CFR § 1317.75(e)

Design of Collection Receptacles

- Outer container must display a sign stating only Schedule II-V and non- controlled substances are acceptable substances.
- Substances Not Permitted to be collected:
  - Schedule I controlled substances,
  - Controlled substances that were not lawfully possessed by the ultimate user, and
  - All other illicit substances (including marijuana in states like CO and WA)

21 CFR § 1317.75(e)

Collection Receptacle Location

- Must be securely placed and maintained:
  - Inside **collector's registered location**
  - Inside law enforcement's physical location, or
  - **Inside an authorized LTCF**

Collection Receptacle Location

- Registered location – immediate proximity of designated area where controlled substances are stored and at which an employee is present.
- LTCF – located in secure area regularly monitored by LTCF employees.
- Hospital/clinic – located in an area regularly monitored by employees---**not** in proximity of where emergency or urgent care is provided.
- NTP – located in a room that does not contain any other controlled substances and is securely locked with controlled access.

21 CFR § 1317.75(d)

Collection Receptacle Inner Liner

- Waterproof, tamper-evident, and tear-resistant.
- Removable and sealable upon removal without emptying or touching contents.
- Contents shall not be viewable from the outside when sealed (i.e., can't be transparent).
- Size shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.).
- Outside of liner shall have permanent, unique ID number.

21 CFR § 1317.60(a)

Handling Inner Liners

- Only employees of the collector may access the inner liners.
- The inner liner shall be sealed by **two employees** immediately upon removal from the permanent outer container.
- Sealed inner liner ***shall not*** be opened, x-rayed, analyzed, or otherwise penetrated.
- Practitioners ***cannot*** transport collected controlled substances.

21 CFR §§ 1317.60(b) and (c), 1317.05(c)

Records for Collectors

Collection Receptacle Inner Liners Inventory

- For each unused inner liner on hand and sealed inner liner on hand:
  - Inventory date
  - Number and size of liners
  - Unique ID number for each liner

21 CFR § 1304.11(e)(7)

Records for Collectors

- Unused inner liners:
  - Date acquired, number acquired, unique ID number, and size
- Installed inner liners
  - Date, address where installed, unique ID number, size, DEA number of collector, and names and signatures of witnesses (**2 employees**)
- Inner liners removed and sealed
  - Date, address of removal location, unique ID number, size, DEA number of collector, names and signatures of witnesses (**2 employees**)

21 CFR § 1304.22(f)(2)

Records for Collectors

- Sealed inner liners transferred to storage
  - Date sealed and transferred to storage, unique ID number, size, names and signatures of witnesses (**2 employees**)
- Sealed inner liners transferred for destruction
  - Date transferred for destruction, address and DEA number of reverse distributor or distributor to whom transferred, unique ID number, size, names and signatures of witnesses (**2 employees**)
- Sealed inner liners destroyed on-site
  - The same information required of reverse distributors in § 1304.22(e)(4)(ii).

21 CFR § 1304.22(f)(2)

Mail-Back Programs

Mail-Back Program – Who is Authorized?

Any authorized collector that has and utilizes **at its registered location (on-site) a method of destruction consistent with § 1317.90**

21 CFR § 1317.70

Collection in LTCF

Collection at LTCF

- LTCF may dispose of a current or former resident's unwanted or unused controlled substances in a collection receptacle located at the LTCF.

  - Transfer is to be immediate, but no longer than **3** business days after discontinuation of use.
  - Discontinuation of use includes discontinuation directed by the prescriber, and as a result of patient transfer or death.

21 CFR § 1317.80(a)

Collection at LTCF

Authorized retail pharmacies and hospitals/clinics with an on-site pharmacy may:

- Install, manage, and maintain collection receptacles at LTCFs.
- Remove, seal, transfer, store, or supervise the removal, sealing, transferring, and storage of sealed inner liners.
- Upon removal, sealed inner liners may be transferred for destruction, or stored at the LTCF for up to **3** business days.

21 CFR §§ 1317.80(b) and (d); 1317.05(c)

Collection at LTCF – Handling Liners

- Persons who can handle sealed inner liners:
  - 2 employees of the authorized collector, or
  - 1 employee of the authorized collector and 1 supervisory-level employee of the LTCF (e.g., charge nurse)
  - Sealed inner liner ***shall not*** be opened, x-rayed, analyzed, or otherwise penetrated
- Inner liners may be stored at LTCF for up to **3 business days** in a securely locked, substantially constructed cabinet or a securely locked room with controlled access, until transfer for destruction.

NOTE: Collectors shall NOT transport sealed liners from the LTCF for any purpose

21 CFR § 1317.80(c) and (d); 1317.05(c)

Collection at LTCF – Handling Mail-Back Package

- Any authorized collector may make mail-back packages available to ultimate users, and persons lawfully entitled to dispose of an ultimate user decedent's property
- LTCF personnel may dispose of a current resident's unwanted or unused controlled substances in a mail-back package based upon a request by the resident

21 CFR § 1317.70

Authorized Collector Physical Security

- Non-Practitioner

  Collected substances must be stored as a C-II

21 CFR § 1317.05(c)(1)(ii) and (c)(2)(ii)

- **Practitioner**

  Securely locked, substantially constructed cabinet, or a securely locked room with controlled access

21 CFR §§ 1317.05(c)(1)(ii) and (c)(2)(ii); 1317.80(d)
21 CFR § 1301.75(c)

Authorized Collector Personnel Security

- A Collector shall not employ, as an agent or employee who has access to or influence over controlled substances, any person who has:
  - A felony offense conviction related to controlled substances; or
  - Had a DEA application for registration denied, or had a DEA registration revoked, suspended, or surrendered for cause

21 CFR § 1301.71(f)

Termination of Authorization to Collect

Registrant shall notify the DEA in writing or online.

21 CFR §§ 1301.52(f) and 1317.70 (e)(3)

Registrant Disposal

Registrant Disposal
Destruction of Sealed Inner Liners

Practitioners & Non-Practitioners shall dispose of sealed inner liners by:

- Prompt on-site destruction
- Prompt delivery to reverse distributor by common or contract carrier or reverse distributor pick-up
- Deliver sealed inner liners to a distributor's registered location by common or contract carrier or distributor pick-up

Practitioner may **also** request assistance from the SAC -may not authorize destruction which in not in compliance with regulations

Non-Practitioner may also transport to reverse distributor

Freight forwarding facilities may NOT be used.

21 CFR § 1317.05(a) & (b) – Inventory; (c)(2)(iv) and (v) – Liners;

Pharmaceutical Wastage

Requirements for Destruction of Controlled Substances

Destruction of Controlled Substances

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

21 CFR § 1317.90

Destruction of Controlled Substances

Non-retrievable means the condition or state to which a controlled substance shall be rendered following a process that permanently alters the substance's physical or chemical condition or state through irreversible means, and thereby renders the controlled substance unavailable and unusable for all practical purposes.

21 CFR § 1300.05

Destruction of Controlled Substances

- Destruction shall be in accordance with the following requirements:
  - Transfer to registrant or person authorized to accept for destruction
  - On-site destruction

21 CFR § 1317.95

Destruction Procedures

- 2 employees of the registrant shall handle or observe the handling of any controlled substance until it is rendered non-retrievable, and
- 2 employees of the registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.

21 CFR § 1317.95(c) and (d)

DEA Form 41

- Form 41 shall be used to record the **destruction of all controlled substances, including controlled substances acquired from collectors.**
  - The Form 41 shall include the names and signatures of the two employees who witnessed the destruction.
  - Exceptions for DEA Form 41:
    - Destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (i.e. wastage) shall be properly recorded in accordance with § 1304.22(c), and such record **need not** be maintained on a Form 41
    - Transfers by registrant to a reverse distributor must be recorded in accordance with § 1304.22(c), and such record **need not** be maintained on a Form 41

21 CFR § 1304.21(e)

Thank You

Bringing It All Together

What to Look For in Disposal Solutions for Ultimate User Drugs

California State Board of Pharmacy Enforcement & Compounding Committee

June 24, 2015

SHARPS
Compliance, Inc.

Jan Harris, MPH
Director, Environmental, Health & Safety

Brandon Beaver
Sr. VP of Sales

Sharps Compliance
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SHARPS Compliance, Inc.

MedSafe “How To” Overview

Experience and Expertise

- History with pharmaceuticals and mailback
- History with dealing with materials from ultimate users – uncontrolled environment
- Processes in place
- Working a current program

It Starts with Security

Compliant signage

Instructions for Use

Small lockable opening that allows contents to be added without removal

Substantially constructed container with a permanent outer shell, e.g. 14-gauge powder-coated steel construction (UL Tested 291)

Securely fastens to the floor or wall

Two ultra high-security padlocks secure main door

Instructions for Use and Steps to Compliance

Sharps Compliance is a DEA registered reverse distributor. All MedSafe inner liners will be transported and transferred to its DEA registered facility, Sharps Environmental Services via common carrier in compliance with all applicable sections of § 1317.

medsafe
Safe Collection Proper Destruction

01 Pharmacy shall modify its DEA registration to become an authorized collector, and list locations of collection receptacles.

02 The MedSafe receptacle shall be securely fastened to a permanent structure so that it cannot be removed and can be seen from the pharmacy counter. Two authorized pharmacy employees shall install the Inner liner, and both sign the Step Log. Two authorized employees shall maintain keys for the receptacle in a safe location.

07 When the receptacle Inner liner is full, two authorized pharmacy employees shall remove, seal and package the liner immediately upon removal without emptying or touching the contents; and both shall sign the Step Log.

08 The Inner liner may be stored by two authorized employees in a securely locked, substantially constructed cabinet or securely locked room if necessary prior to transferring for disposal. Both employees shall sign the Step Log.

Types of Receptacles

From mailboxes to counter-top units

Inner Liner

Containment and Transport

- Waterproof, tamper-evident, and tear-resistant
- Double 200lb opaque corrugated boxes
- 4mil plastic liner with zip-tie and absorbent
- DOT drop/leak tested
- Removable without touching contents
- Size, unique ID, barcode - traceable
- Pre-paid, pre-addressed to reverse distributor with onsite destruction
- Instructions for use and step log

SHARPS Compliance, Inc.

Proper Documentation

medsafe
Safe Collection Proper Destruction

Inner Liner Step Log 38-Gallon

1. INSTALLATION (Place Inner Liner into Receptacle)

Date Inner Liner Received:_____ Inner Liner NO: _____

Date Inner Liner Installed into Receptacle: _____

Address where Inner liner Installed:

_____

_____

_____

Collector (Pharmacy) Registration NO: _____

1st Employee Name: _____

1st Employee Signature: _____

2nd Employee Name: _____

2nd Employee Signature: _____

2. REMOVAL (Remove and Seal Inner Liner)

Date Inner Liner Removed from Receptacle and Sealed: _____

1st Employee Name: _____

1st Employee Signature: _____

2nd Employee Name: _____

2nd Employee Signature: _____

3. STORAGE (Transfer to Storage)

Date Inner Liner Transferred to Storage: _____

1st Employee Name: _____

1st Employee Signature: _____

2nd Employee Name: _____

2nd Employee Signature: _____

4. DESTRUCTION (Ship for Destruction)

Date Inner Liner Transfered/Shipped for destruction: _____

1st Employee Name: _____

1st Employee Signature: _____

2nd Employee Name: _____

2nd Employee Signature: _____

Address (Reverse Distributor to which Inner Liner Transfered):

Sharps Environmental Services

1544 NE Loop, Carthage, TX 75633

Reverse Distributor Registration NO: RS0365800

100939 REV A

SHARPS Compliance, Inc.

Types of Inner liners

Mailback

- Reverse Distributor (RD) receives approval for packaging from common carrier/USPS
- RD updates registrant status with DEA to be collector
- Nondescript with unique ID#
- Instructions for Use
- Prepaid and preaddressed to RD
  - Documentation/ reconciliation maintained by RD
  - Inventory maintained by pharmacy
- Ultimate user mails to RD when full for disposal

Destruction and Documentation

- Inner liners and mailbacks are scanned, weighed and stored in Schedule II vault
- Destroyed within 30 days of receipt
- Incineration is currently the best method to assure unidentifiable and irretrievable, as required by DEA, but not required
- Electronic secure documentation, unique for each client:
  - DEA compliant
  - Outbound inventory
  - Returned inventory
  - Date of return
  - Condition of return
  - Weight of return
  - Current status of return (stored)
  - Date of destruction
  - Effectiveness check

SHARPS Compliance, Inc.

McKESSON

Drug Supply Chain Security Act (DSCSA):
Final Preparation for July 1st

Partnering for Better Health

AGENDA

- Overview of the Drug Supply Chain Security Act (DSCSA)
- Key Requirements & Terms
- DSCSA Timeline
- Executing DSCSA Requirements
- Customer Resources

DSCSA Overview

Drug Quality & Security Act - DQSA

Two titles in Act address three primary topics

Act was signed by President on Nov 27th, 2013

Title 1
Drug Compounding – Pharmacy Only

Title 2
Drug Supply Chain Security Entire Supply Chain

- National Traceability
- Wholesaler Licensing

4

Title I: Drug Compounding

- [illegible] compounding to [illegible] specific for [illegible]
- Creates Outsourcing Facility for Non Patient Specific
- Requirements for Outsource Facility
  - Must register with [illegible]
  - Direct Distribution to [illegible]
  - or Other Dispenser [illegible]
  - No Third Party Distribution

5

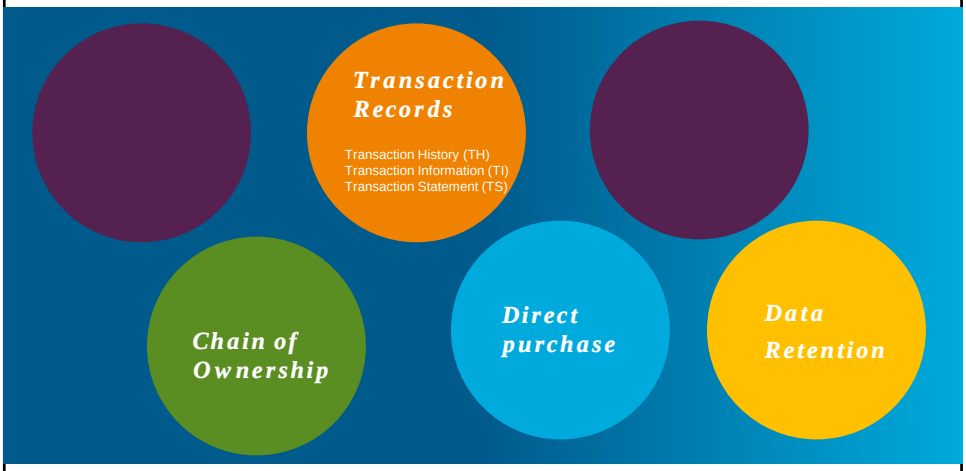
Title II: Drug Supply Chain Security

- [illegible] *uniform* traceability requirements
- [illegible] immediately any/all State requirements that differ from Federal language
- [illegible] evolution to *Lot based tracing* and then to *serialized item traceability* [illegible] the next 10 years
  - [illegible] involves all participants in the supply chain
- [illegible] Federal licensure standards for wholesalers
  - [illegible] floor and ceiling standards the States must follow to license wholesalers
  - [illegible] creates a Federal license for States that opt not to conform and license on their own

6

Key Requirements and Terms

Key Requirements &Terms



8

Traceability

- Finished Human Rx Drugs
- Only with the Manufacturer
- Includes Direct Purchase Repackager & Exclusive Distributor as part of supply chain

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Chain of Ownership

- Track Ownership as opposed to Possession
- Must be tracked through entire supply chain
- Transaction detail must be presented at point of receipt

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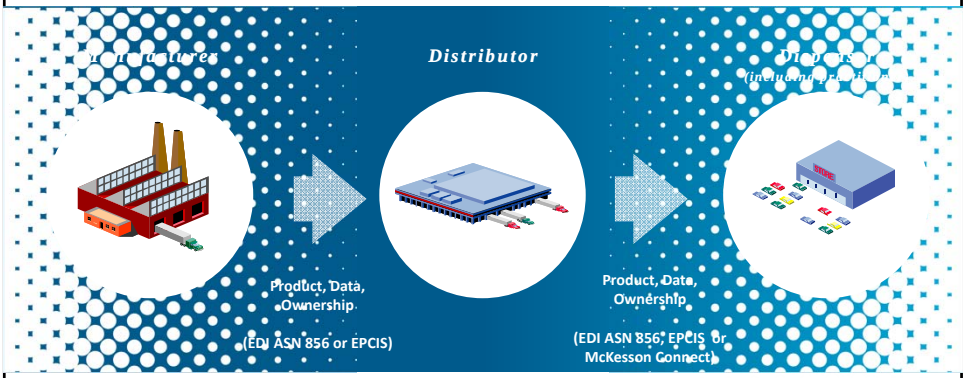
Transaction Records

- **Transaction History (TH)**
  - Who has owned the product?
- **Transaction Information (TI)**
  - What is the product?
    - Product Description, NDC, Lot #, # of containers etc…
- **Transaction Statement (TS)**
  - Statement attesting to transaction being correct and that the information is accurate

11

Direct Purchase



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DSCSA Requirements

Distributors:

- Retain inbound and outbound DSCSA data for six years
- Respond to FDA investigations within 24 hours

Dispensers:

- Program for Detection and Notification of Suspicious and Illegitimate Drugs
- Retain inbound and outbound DSCSA data for six years
- Respond to FDA investigation within 48 hours

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Transaction Record Data Retention

McKesson's Commitment to Records Retention

•We will retain our customers' Transaction Record data for six years, for ***McKesson DC purchases only.***

•Transaction Records retained by McKesson can be accessed via the Traceability Report in McKesson Connect which is at the bottom of the **Reports and Analysis tab**.

•Customers will need to identify a separate data storage solution for ***non-McKesson DC purchases*** which includes drop shipments and any product they purchased elsewhere.

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What happens if you are audited?

Key	Narrative (Example Scenario)	Time Period
A	Your pharmacy purchases and receives a product from a McKesson DC in 2015. McKesson retains the associated Transaction Record data for 6 years, through 2021.	2015-2021
B	Your pharmacy is audited by the FDA in 2017. The audit requires you to provide the products' transaction record data specified in the audit, in this case a product purchased in 2015. You obtain the required Transaction Data from McKesson Connect.	(audit) 2017
C	Due to the audit, the data retention period of the audited information begins in 2017 (audit completion year), and extends for another 6 years. The data to be retained now includes the 2017 audit file *plus* the transaction records associated with the 2015 product which was audited.	2017-2023 + Audit File

Note:

1. *The customer is responsible for retaining their complete audit file.**
2. *McKesson's original commitment to Transaction Record data retention for the customer ends in 2021 (see point A). Therefore, the customer must identify another data retention solution from 2021 through 2023.*

* Refer to FDA guidance for instructions on retaining the audit file and associated transaction records.

Audit Scenario: DSCSA Data Retention

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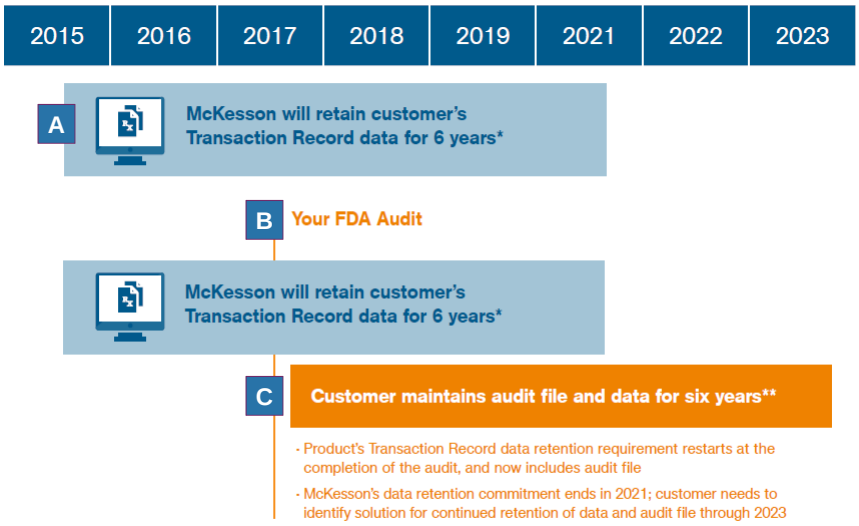

* McKesson will retain customer's Transaction Record data for products purchased from McKesson DCs. Customers will need to identify a data storage solution for products obtained from non-McKesson DCs.
** Refer to FDA guidance for instructions on retaining the audit file and associated Transaction Records.

DSCSA Timeline

DSCSA Implementation Timeline

	November 27, 2013		Jul
Manufacturer	State pedigree and traceability laws pre-empted	Must send to distributor TH – Transaction history TI – Transaction information TS – Transaction statement	• Manufacturers serialize product • TH, TI, TS –electronic
Distributor		• Distributors receive TH, TI, TS • Distributors ship only to authorized trading partner • Provide TH, TI, TS to dispenser • Lot # provided only for non-direct purchases	
Pharmacy			

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DSCSA Implementation Timeline

	November 2018	November 2019	November 2020 *	November 2023
Manufacturer				Unit Level Traceability for All Supply Chain
Repackagers	Serialize product			
Distributor		• Receive product with identifier • Receive and maintain TH, TI, TS electronically • Returns only with TI, TS		
Pharmacy			• Receive only product 2D identifiers	

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Executing DSCSA's Requirements

DSCSA Complexities

- Distributors who sell product purchased direct from manufacturer, exclusive distributor or repackager who sourced direct do not need to forward:
  - Original transaction dates
  - Lot numbers
- Drop shipments required to have TI, TH and TS provided by the SHIPPER and not the distributor
- 340B Covered Entities are the purchaser and will get the DSCSA data instead of the Contract Pharmacies
- Returns that are restocked begin their transaction history anew with the distributor and do not show that they previously had been sold and returned.

Exceptions for Pharmacy Sales

- Dispensing pursuant to a prescription.
- Pharmacy sale to another pharmacy for a "specific patient need" does not require DSCSA transaction data to be sent. Specific patient needs means an identified patient exists and does not include transfers "for the purpose of increasing or replenishing… in anticipation of a potential need".
- Emergency medical reasons including public health emergency "except that a drug shortage… shall not constitute an emergency medical reason."
- Distribution of minimal quantities to a licensed practitioner for office use.

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DSCSA Customer Resources

BUSINESS CARE CONNECTIVITY

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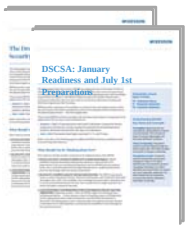
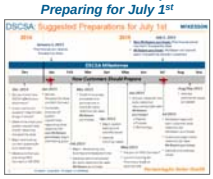
DSCSA Customer Communications

DSCSA Customer Education Materials



Customer Roadmap: Preparing for July 1st



"DSCSA: What to Expect and How to Prepare"

McKesson Connect Program Page

Contents

- DSCSA Overview
- Actions to Consider
- Major Milestones
- Preparing for Upcoming Milestones
- Suggested Roadmap
- Transaction Data Views
- FAQs
- FDA Resources

- DSCSA Milestones
- Suggested Activities to Prepare for July 1st DSCSA Milestone

- DSCSA Overview
- Upcoming Milestones
- January: What to Expect
- Transaction Data Preview
- Preparing for July 1st
- What Customers Should Do
- Preview of Upcoming Collateral

- DSCSA Overview
- DSCSA Collateral from McKesson
- Milestones & Timelines
- FDA Resources

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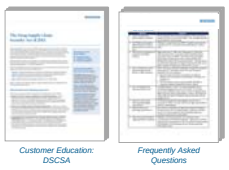
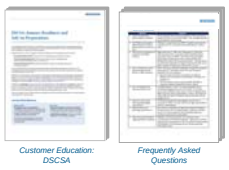
Resources: Customer Support Collateral

McKesson continues to distribute collateral to support our customers through the DSCSA milestones.



Content in Fall Collateral:
- DSCSA Overview
- Key Terms/Concepts
- What to Think About Now
- FDA's Milestones
- FAQs



Content in Winter Collateral:
- January 1st Readiness
- Impacts to Pharmacy Distributors
- Transaction Record Data Views
- Preparing for July 1st
- FDA Resources
- FAQs

Spring Collateral Covers:
- McKesson's Data Retention Efforts
- Impact of an Audit on Data Retention
- What to Think About Now
- Guide to Preparing for July 1st
- FDA Resources
- FAQs

Customer Roadmap: Preparing for July 1st

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2014

January 1, 2015
Pharmacies can receive Traceability Data

2015

July 1, 2015
Customers must begin retention of Transaction Record data for all purchases for all sources. McKesson will retain data for purchases made from McKesson Distribution Centers for 6 years.

DSCSA Milestones

Dec | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep

Go Live — Go Live

How Customers Should Prepare

Dec 2014
- *Do you know how DSCSA affects your pharmacy?*
- *Is your policy on suspect/ illegitimate drugs in place?*
- *Determine what your system capabilities are for receiving traceability data*
- *Begin evaluating current systems for July readiness*
- *Make sure that you are using McK Connect or EDI 856*

Jan 2015
- *Review Traceability Data via McKesson Connect*
- *Complete analysis of system capabilities regarding data retention; begin addressing gaps*

Feb 2015
- *Begin developing July business processes/policies*
- *Develop technical plan(s) for data retention*

Mar 2015
- *Confirm business processes and policies are in place for data retention*

Apr 2015
- *Begin system testing and address issues*
- *Identify training needs*

May 2015
- *Are you on McKesson Connect?*
- *Launch training for Pharmacy Staff, as appropriate*

Jun 2015
- *Are you ready for the data retention requirement?*
  - *People*
  - *Process*
  - *Technology*

Jul 2015
- *Customers begin data retention for all purchases*
- *McKesson begins 6-year customer data retention **for McKesson Distribution Center** purchases*
- *Identify and address issues*

Aug/Sep 2015
- *Address additional issues as needed*

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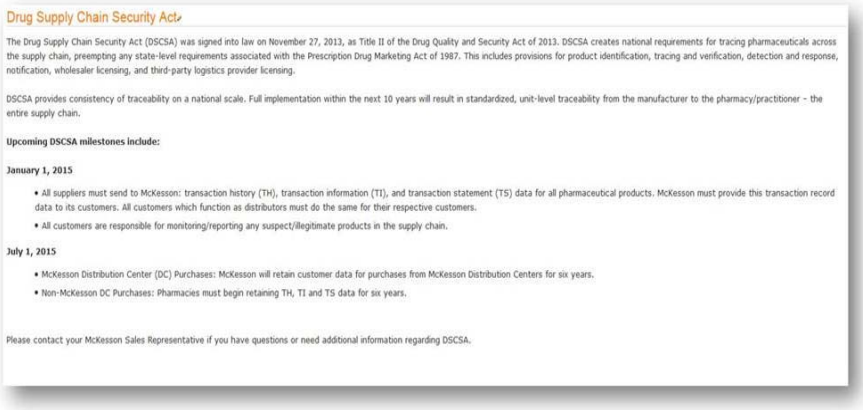
McKesson Connect: DSCSA Customer Resource

McKesson launched a Program Page on McKesson Connect, dedicated to DSCSA.



Drug Supply Chain Security Act

The Drug Supply Chain Security Act (DSCSA) was signed into law on November 27, 2013, as Title II of the Drug Quality and Security Act of 2013. DSCSA creates national requirements for tracing pharmaceuticals across the supply chain, preempting any state-level requirements associated with the Prescription Drug Marketing Act of 1987. This includes provisions for product identification, tracing and verification, detection and response, notification, wholesaler licensing, and third-party logistics provider licensing.

DSCSA provides consistency of traceability on a national scale. Full implementation within the next 10 years will result in standardized, unit-level traceability from the manufacturer to the pharmacy/practitioner - the entire supply chain.

Upcoming DSCSA milestones include:

January 1, 2015

- All suppliers must send to McKesson: transaction history (TH), transaction information (TI), and transaction statement (TS) data for all pharmaceutical products. McKesson must provide this transaction record data to its customers. All customers which function as distributors must do the same for their respective customers.
- All customers are responsible for monitoring/reporting any suspect/illegitimate products in the supply chain.

July 1, 2015

- McKesson Distribution Center (DC) Purchases: McKesson will retain customer data for purchases from McKesson Distribution Centers for six years.
- Non-McKesson DC Purchases: Pharmacies must begin retaining TH, TI and TS data for six years.

Please contact your McKesson Sales Representative if you have questions or need additional information regarding DSCSA.

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Upcoming Customer Education Events

McKesson ideaShare2015
San Diego, CA | June 24 – 28

Business, networking and innovative ideas come together at McKesson ideaShare

- Thursday, June 25th: DSCSA Workshop
  - Drug Supply Chain Security Act (DSCSA): Preparing Pharmacy for July 1, 2015
- ideaShare DSCSA Booth

- Recorded Customer Webcast Posted to McKesson Connect
  - Drug Supply Chain Security Act (DSCSA): Preparing Pharmacy for July 1, 2015

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Drug Supply Chain Security Act (DSCSA): *Final Preparation for July 1st*

Partnering for Better Health

2014 Compounding Statistics

Violations of Pharmacy Law

2014 Compounding Inspections

- 1,394 sites were inspected for sterile compliance in 2014.
- 683 (49%) of the sites inspected in 2014 had one or more violations.
- In 2014 there were 1,746 violations or corrections ordered.

Violations by License Type

License Type	Number of Violations
Clinic	5
Hospitals	642
LSC	520
Non-Resident Pharmacy	123
Pharmacy	456
Total	1,746

2014 Top 5 Violations

Type of Violation	Example	Total Violations
Compounding Limitations and Requirements; Self Assessment – CCR 1735.2	Failure to complete a self-assessment	257
Sterile Injectable Facility and Equipment Standards – CCR 1751.4	Failure to maintain or meet Facility and Equipment Standards Examples: 1) No cleaning and disinfecting weekly 2) No designated area for compounding 3) Cleanroom made from material that is not easily cleaned and disinfected	231
Compounding Records Requirements – CCR 1735.3	Failure to have all the required records for a compounded product (compounding log)	213
Sterile Injectable Quality Assurance and Process Validation – CCR 1751.7	Failure to have a Quality Assurance policy or failure in following a Quality Assurance policy. Examples: 1) Not having documented PATT tests for sterile compounding employees. 2) Not having documented end product testing for a batch- produced sterile injectable drug product, PRIOR to use. 3) No recall policy and procedures.	195
Compounding Policies and Procedures – CCR 1735.5	Failure to have one or more required Polices and Procedure, or failure to required Polices and Procedure 1) No recall policy and procedures. 2) No Annual review of P&P	138

2014 Top Citations

Code Section	Description	Total
1735.3A	COMPOUNDING RECORD REQUIREMENT	26
1735.2H	COMPOUNDED DRUG; EXP DATE REQ	21
1735.2	COMPOUNDING LIMITATIONS & REQ	17
1735.5	COMPOUNDING P&P	15
1751.7C	END PRODUCT TESTING	10
1751.4	PROTECTIVE CLOTHING	9
1751.3	STERILE COMPOUNDING POLICY AND PROCEDURES	9
1751.7A	CLEANING AND SANITIZATION	8
1735.6	COMPOUNDING FACILITIES	7
1751.6	DISPOSAL OF WASTE MATERIAL	6
1735.7	TRAINING OF COMPOUNDING STAFF	6
1751.7D	STORAGE OF COMPOUNDED PRODUCTS	4
1735.8A	COMPOUNDING Q&A; WRITTEN P&P	4
1735.8C	COMP. Q&A;QUALITATIVE/QUANTATV	4
1751.B	WALLS AND FLOORS	3
1735.4	LABELING OF COMPOUNDED DRUG	2
1735.1	COMPOUNDING DEFINITIONS	2
1751.1	LAMINAR FLOW BIO SAFETY CABIN.	2
1735.8D	COMP. Q&A;BELOW MIN STANDARDS	2
1751.7B	TESTING DOCUMENTED IN WRITING	2
Grand Total		159

2014 Attorney General Cases

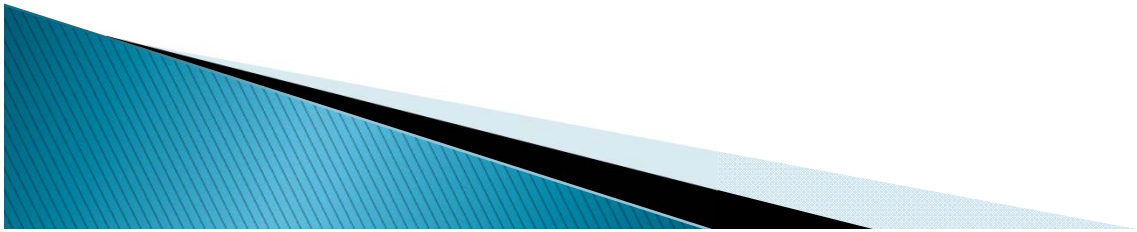
Code Section	Description	Total
1735.3A	COMPOUNDING RECORD REQUIREMENT	9
1735.2	COMPOUNDING LIMITATIONS & REQ	6
1751.7C	END PRODUCT TESTING	5
1735.5	COMPOUNDING P&P	4
1751.7	QUALITY ASSURANCE	3
1751.1	LAMINAR FLOW BIO SAFETY CABIN.	3
1735.8	COMPOUNDING QUALITY ASSURANCE	3
1735.6	COMPOUNDING FACILITIES	2
1751.3	RECORDKEEPING REQUIREMENTS	2
1751.7A	CLEANING AND SANITIZATION	2
1751	COMPOUNDING AREA 4 PARENT. SOL	2
1751.4	PROTECTIVE CLOTHING	2
4127	CORPORATE FORM NOT REQUIRED	1
1751.7D	STORAGE OF COMPOUNDED PRODUCTS	1
1735.2H	COMPOUNDED DRUG; EXP DATE REQ	1
4127.1	LICENSE TO COMPOUND INJ DRUGS	
1735.4	LABELING OF COMPOUNDED DRUG	1
1735.7	TRAINING OF COMPOUNDING STAFF	
Grand Total		50

Controlled Substance Inventory

Requirements by State

Summary

- Information was gathered from 25 states.
- Information was gathered from board web sites, law books and email/phone calls with board staff.
- 6 states require annual inventory
- 15 states require biennial inventory
- 4 states require a perpetual inventory
  - Note: some of the states specifically require *reconciliation* of the inventory



State	Requirement
Alabama	Annual - By January 15 or alternate Board approved date
Arizona	Annual - By May 1 or alternate date filed with Board
Arkansas	Biennial
Connecticut	Biennial
Delaware	Biennial - with PIC doing annual self-inspection report
Georgia	Biennial - Board has discussed the possibility of changing
Idaho	Annual inventories for controlled substance registrants
Illinois	Biennial
Iowa	Biennial
Kansas	Annual
Kentucky	Biennial
Louisiana	Annual - For all schedules of controlled substances

State	Requirement
Maine	Perpetual inventory records for Schedule II
Michigan	Biennial
Minnesota	Biennial
Nebraska	Annual
Nevada	Biennial and within 48 hours of a pharmacy manager change
New Jersey	Biennial
New York	Biennial
Rhode Island	Biennial
Texas	Biennial
Vermont	Perpetual inventory for Schedule II, documented every 30 days
	al inventory for Schedule II, reconciled once a quarter

Maine

Perpetual Inventory

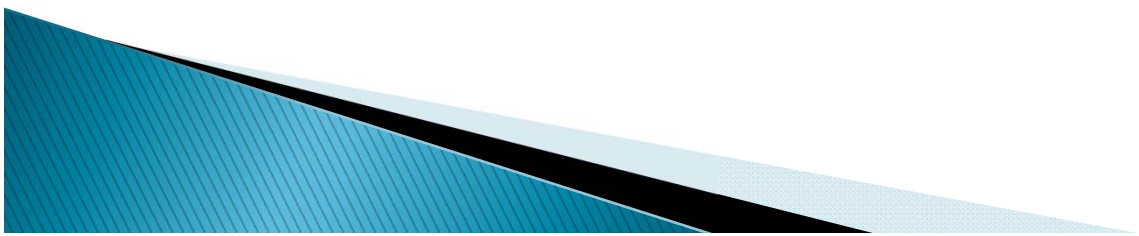
A retail pharmacy that dispenses Schedule II controlled substances shall maintain perpetual inventory records. These records shall indicate all receipts and dispersals of Schedule II controlled substances and shall state at any point in time the current inventory quantities of each such drug on hand. The perpetual inventory shall be maintained contemporaneously and shall be made available for inspection by the board at the pharmacy for a period of 5 years.

Perpetual Inventory

A perpetual inventory shall be maintained for at least two years for all Schedule II controlled substances. Electronic versions may be permitted if they provide a secure audit trail of entries.

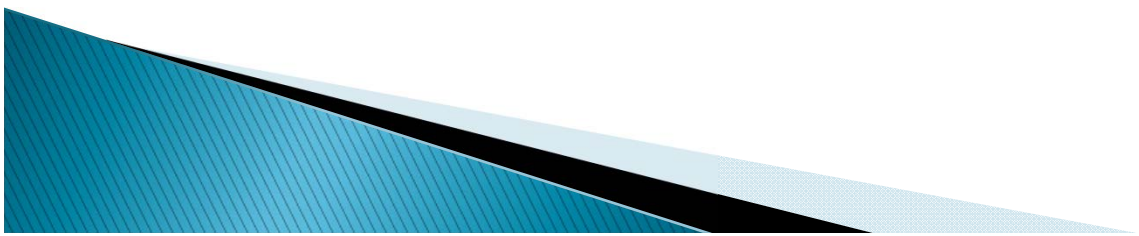
Schedule II Inventory

All Schedule II controlled substances must be physically inventoried and documented at least once every thirty (30) days.



Virginia

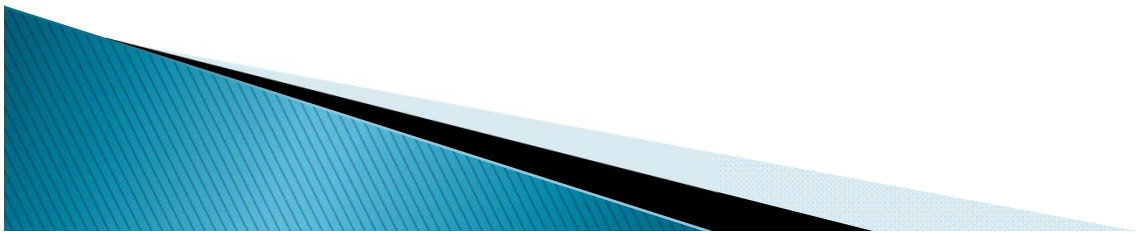
Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy. Each pharmacy shall maintain a perpetual inventory of all Schedule II drugs received and dispensed, with reconciliation at least monthly. Electronic monitoring at the pharmacy or by another entity that provides alerts for discrepancies between drugs received and drugs dispensed is acceptable provided such alerts are reviewed at least monthly.



Wyoming

Each registered pharmacy shall maintain inventories and records of controlled substances as follows:

- Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file in consecutive numbers.
- Inventories and records of controlled substances listed in Schedules III - V shall be maintained separately from all other records of the pharmacy and prescriptions for such substances shall be maintained in separate prescription files for controlled substances in consecutive numbers.
- All invoices for controlled substances shall be dated and signed when received by the pharmacist in charge or his/her designated agent. Invoices shall be maintained on file for two years and readily available for inspection by the board.



Wyoming Continued…

- All retail and institutional pharmacies shall maintain a perpetual inventory for all schedule II controlled substances. This inventory shall be reconciled no less than once a quarter. Discrepancies discovered during reconciliation shall be reported to the board within 10 calendar days of discovery. Only those discrepancies, which are considered a significant loss or gain shall be reported. For the purpose of this section a significant loss or gain shall exist whenever the actual inventory differs from the recorded inventory by more than five percent (5%) for any drug product.

Additionally

- The Board shall be notified within seven (7) days of every change in PIC. A controlled substance inventory is required when there is a change in PIC, at the time of the change. This inventory shall include the signatures of both the outgoing and incoming PIC, and the date and time the inventory was taken. If the inventory cannot be conducted with both pharmacists, then the incoming PIC shall conduct an inventory. A copy of the controlled substance inventory and signed Certification of Responsibilities as Pharmacist-in-Charge (PIC) shall be forwarded to the Board office within fifteen (15) days of conducting the inventory.