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

To: **Board Members**

Subject: **Agenda Item XV – Proposed Regulations for the Take Back of Prescriptions Medication**

Background

Since the July 2015, board meeting, the board has continued to refine the board's proposed requirements for drug take back programs.

Meanwhile, additional counties have established requirements to permit or require take back of unwanted pharmaceuticals from the public. This often involves pharmacies.

On September 26, the Drug Enforcement Administration (DEA) conducted another national Drug Take Back day. The board released a subscriber alert and posted information about this collection day on the board's web site.

Recommendation

After discussion at the September 9, 2015, Enforcement Committee meeting the committee made the following recommendation: Direct staff to complete work on the proposed regulation, including the policy comments made by the committee, and bring the proposed regulation to the board for possible initiation of a rulemaking.

The proposed regulation language and excerpt from the September 9 Enforcement Committee meeting minutes are provided immediately following this memo.

Medication Article 9.1

Prescription Drug Take-Back Programs

Section 1776

Pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board and licensed skilled nursing facilities may offer, under the requirements in this article, specified prescription drug-take back services to the public to provide options for the public to destroy unwanted, unused or outdated prescription drugs. Each of these entities must comply with regulations of the federal Drug Enforcement Administration and the Board of Pharmacy regulations contained in this article.

All board-licensed authorized collectors should be vigilant to prevent patients or their agents from disposing of prohibited items through drug take-back collection methods. Federal, state and other laws prohibit the deposit in drug take-back receptacles of the following: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, hazardous medications (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers).

Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board and also registered with the Drug Enforcement Administration as collectors may participate in drug take back programs authorized under this article.

Section 1776.1 Pharmacies

(a) Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.

(b) Pharmacies may provide take-back services to patients as provided in sections 1776 - 1776.4. Retail pharmacies and hospital/clinics with onsite pharmacies may establish collection receptacles in their facilities. Pharmacies may operate collection receptacles as specified in in section 1776.4 in skilled nursing facilities licensed under Health and Safety Code section 1250(c).

(c) There are multiple federal and state requirements governing the collection and destruction of dangerous drugs. Pharmacies are expected to know and adhere to these requirements when operating a prescription drug take-back program.

(d) For purposes of this article, prescription drugs means dangerous drugs as defined by California Business and Professions Code section 4022, including controlled substances. Controlled substances may be commingled in collection receptacles or mail back packages or envelopes with other dangerous drugs. Once drugs are deposited into a collection receptacle or mail back envelope or package by a patient, they are not to be separated by pharmacy staff or others.

(e) The following dangerous drugs and devices are expressly prohibited from collection in

a pharmacy's collection receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers). Signage shall be placed on collection receptacles as referenced in section 1776.3.

(f) Prescription drugs that are eligible for collection in drug take-back programs operated by pharmacies are only those prescription drugs that have been dispensed by a pharmacy or practitioner to a patient or patient's agent. Dangerous drugs that have not been dispensed to patients (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected in pharmacy drug take-back programs.

1. Pharmacy staff shall not review, accept, count, sort, or handle prescription drugs returned from the public.
2. A pharmacy shall not accept or possess prescription drugs returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities.
3. A pharmacy shall not dispose of quarantined, recalled or outdated prescription drugs from pharmacy stock in a drug take-back collection receptacle. Instead the pharmacy must return these items to a reverse distributor.

(g) A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for purposes of operating a prescription drug take-back program. Such pharmacies cannot employ anyone convicted of a felony related to controlled substances, or anyone who has had a DEA permit denied, surrendered or revoked.

(h) Any pharmacy that operates a drug take-back collection program as authorized in this article shall notify the board on a form designated by the board within 30 days of establishing the collection program. Additionally:

1. Any pharmacy that ceases to operate a drug take-back program shall notify the board within 30 days on a form designated by the board.
2. Any pharmacy operating a mail back program or maintaining collection receptacles shall identify to the board that it provides such services annually at the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.
3. Any tampering with a storage receptacle or theft of deposited drugs shall be reported to the board with 14 days.
4. Any tampering, damage or theft of a removed liner shall be reported to the board within 14 days.

(i) Before establishing a collection receptacle, the pharmacy must obtain collector status from the federal Drug Enforcement Administration. If the pharmacy later ceases to operate the collection receptacle, the pharmacy must notify the Drug Enforcement Administration within 30 days.

1776.2 Mail Back Package and Envelope Services from Pharmacies

(a) Pharmacies that provide prescription drug take-back services may do so by establishing mail back services, whereby the public may obtain from the pharmacy

preaddressed mailing envelopes or packages for returning prescription drugs to a destruction location.

(b) All envelopes and packages must be preaddressed to a location registered with the Drug Enforcement Administration as a collector that has onsite a method appropriate to destroy the prescription drugs. The pharmacy is responsible for ensuring that all preaddressed envelopes and packages it makes available to the public are preaddressed to be delivered to facilities that comply with this section.

(c) The preaddressed envelopes and packages must be water and spill proof, tamper evident, tear resistant and sealable. The exterior shall be nondescript and not include markings that indicate the envelope or package contains prescription drugs. Postage shall be prepaid on each envelope or package.

(d) The preaddressed envelope and package shall contain a unique identification number for each envelope and package, and certain instructions for users to mail back drugs.

(e) The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.5.

(f) Individuals who mail back prescription drugs as provided in this section do not need to identify themselves as the senders.

(g) Once filled with unwanted prescription drugs, the mail back packages or envelopes shall be mailed and not accepted by the pharmacy for return, processing or holding.

1776.3 Collection Receptacles in Pharmacies

(a) Pharmacies that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby the public may deposit their unwanted prescription drugs for destruction. The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removal inner liner.

(b) The pharmacy operating the collection receptacle must securely install the receptacle so it cannot be removed. The receptacle shall be installed in an inside location, where the receptacle is visible to pharmacy employees, but not located in emergency areas. In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by employees and not in the proximity of emergency or urgent care.

(c) The receptacle shall include a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner.

(d) In hours when the pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle.

(e) The pharmacy is responsible for the management and maintenance of the receptacle. Pharmacy staff shall not accept, count, sort or handle prescription drugs returned from the public, but instead direct the public to deposit the drugs into the collection receptacle themselves.

(f) The receptacle shall be locked and have a removable inner liner to contain the deposited prescription drugs.

(g) A liner as used in this article shall be made of material used and rated to contain chemotherapy waste. The liner shall be yellow and labeled with the words "chemotherapy waste."

(1) The liner shall waterproof, tamper evident and tear resistant.

(2) The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer.

(h) The liner shall be removable as specified in this section. The receptacle shall allow the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed or counted.

(i) A liner may be removed from a locked receptacle by two employees of the pharmacy who shall immediately seal the liner and record in a log their participation in the removal of each liner from a collection receptacle. Removed liners shall not be opened, x-rayed, analyzed or penetrated.

(j) Immediately after a liner is removed from a collection receptacle, the liner shall be placed for storage, handling, and transport in a rigid container that may be disposable, reusable, or recyclable. Containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. Containers may be of any color and shall be labeled with the words "Chemo Waste" so the sides may be visible from any lateral direction.

(l) Liners that have been filled and removed from a collection receptacle, and stored in a rigid container must be stored in a secured, locked location in the pharmacy no longer than three days.

(m) The pharmacy shall maintain a log to record information about all liners that have been placed into or removed from a collection receptacle. The log shall contain:

1. The unique identification numbers of all unused liners in possession of the pharmacy
2. The unique identification number and dates a liner is placed in the collection receptacle,
3. The date the liner is removed from the collection receptacle and placed in a rigid container,
4. The names and signatures of the two pharmacy employees who removed and witnessed the removal of a liner from the collection receptacle, and
5. The date the liner was provided to a licensed DEA-registered reverse distributor for destruction, and the signature of the two pharmacy employees who witnessed the delivery to the reverse distributor.

(n) The pharmacy shall ensure the sealed inner liners and their contents are shipped to a distributor's registered location by common or contract carrier (such as UPS, FEDEX or

USPS) or by licensed distributor pick-up at the licensed pharmacy's premises.

(o) The collection receptacle shall contain signage developed by the board advising the public that it is permissible to deposit Schedule II-V drugs into the receptacle, but not Schedule I drugs. Labeling shall also identify that medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) may not be deposited into the receptacle. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.

(p) The board shall develop signage to appear on the collection receptacle to provide consumer information the collection process.

1776.4 Collection in Skilled Nursing Facilities

Skilled nursing facilities licensed under Health and Safety Code section 1250(c) may participate in drug take-back programs as authorized by this article.

(a) Skilled nursing facility personnel may dispose of a current resident's unwanted or unused prescription drugs by using mail back packages or envelopes and packages based upon a request by the resident patient. Mail back envelopes and packages shall conform to the requirements specified in section 1776.1. Records shall be kept by the skilled nursing facility noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent.

(b) Only retail pharmacies and hospitals/clinics with onsite pharmacies may establish collection receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted prescription drugs.

1. Any pharmacy and hospital/clinic with an onsite pharmacy operating collection receptacles in skilled nursing facilities shall be registered and maintain registration with the DEA as collectors.
2. Any pharmacy or hospital/clinic with an onsite pharmacy that operates a collection receptacle at a skilled nursing facility shall notify the board within 30 days of establishing a collection receptacle on a form designated by the board.
3. Any pharmacy or hospital/clinic with an onsite pharmacy that ceases to operate a collection site at a skilled nursing facility shall notify the board within 30 days on a form designated by the board.
4. Any pharmacy operating a collection site at a skilled nursing facility shall list all collection receptacles it operates annually at the time of renewal of the pharmacy license.

(c) When a pharmacy or hospital/clinic with an onsite pharmacy installs a collection receptacle in a skilled nursing facility, only the pharmacy shall remove, seal, transfer, and store or supervise the removal, sealing, transfer and storage of sealed inner liners at long-term care facilities as specified in this section.

(d) Every pharmacy and hospital/clinic pharmacy that operates a collection site at any

skilled nursing facility shall notify the board within 14 days of any loss from the collection receptacle or secured storage location for the storage of removed liners.

(e) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded prescription drugs into a collection receptacle. Records of such deposit shall be made in the patient's records, with the name and signature of the employee discarding the drugs.

(f) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.

(g) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be removed.

(h) The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removal inner liner.

(i) The outer container shall include a small opening that allows deposit of drugs into the inside of the outer container and directly into the inner liner.

(j) The outer container shall prominently display a sign indicating that prescription drugs and controlled drugs in Schedules II – V may be deposited. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.

(k) Once deposited, the prescription drugs shall not be counted, inventoried or otherwise individually handled.

(l) A liner as used in this article shall be made of material used and rated to contain chemotherapy waste. The liner shall be yellow and labeled with the words "chemotherapy waste."

1. The liner shall waterproof, tamper evident and tear resistant.
2. The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the manufacturer.

(m) The installation, removal, transfer and storage of inner liners shall be performed only by:

1. One employee of the authorized collector and one supervisory level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector, or
2. By or under the supervision of two employees of the authorized collector pharmacy.

(n) Upon removal from the collection receptacle, the liner shall be immediately sealed, and placed for storage, handling, and transport in a rigid container that may be disposable, reusable, or recyclable. Containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. Containers may be of any color and shall be labeled with the words "Chemo Waste" so the sides may be visible from

any lateral direction.

(o) Sealed inner liners that are placed in a container may be stored at the skilled nursing facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction.

(p) Liners housed in a container may be delivered to a reverse distributor for destruction by two pharmacy employees delivering the sealed inner liners and their contents directly to a reverse distributor's registered location, or by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.

(q) Records of the destruction shall be maintained that provide the date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and if applicable, the names and signatures of the two employees who transferred each liner.

1776.4 Reverse Distributors

(a) A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section.

(b) A licensed reverse distributor may not count, inventory or otherwise sort or x-ray the contents of inner liners. All liners shall be incinerated by an appropriately DEA-licensed distributor.

(c) Two employees of the reverse distributor shall pick up or accept the receipt of inner liners from DEA registrants.

(d) A reverse distributor shall not employ as an agent or employee who has access to or influence over controlled substances, any person who has been convicted of any felony offense related to controlled substances or who at any time had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause.

(e) Each reverse distributor with an incineration site shall maintain a record of the destruction on DEA form 41. The records shall be complete, accurate, and include the name and signature of the two employees who witness the destruction.

(f) For each sealed liner or mail back package received from collectors or law enforcement pursuant to federal CFR section 1317.55, the reverse distributor shall maintain records of the number of sealed inner liners or mail back envelopes/package, including the:

1. Date of acquisition
2. Number and the size (e.g., five 10-gallon liners, etc.)
3. Inventory number of each liner or envelope/package
4. The date and place and method of destruction
5. Number of packages and inner liners received
6. Number of packages and inner liners destroyed
7. The number and signature of the two employees of the registrant that witnessed the destruction.

1776.5 Record Keeping Requirements for Board Licensees Providing Drug Take-Back Services

Each entity authorized by this article to collect unwanted prescription drugs from patients shall maintain the following records.

(a) When obtaining unused mail-back packages and envelopes for future distribution:

1. The collector pharmacy shall maintain records that identify: the date the envelope or package was obtained by the pharmacy, the number of packages/envelopes made available to the public, and the unique identification number of each package.
2. For unused packages and envelopes provided to a skilled nursing facility or third party to make available to patients and other authorized individuals: the name of the third party and physical address of the location receiving the unused packages, date sent, and the number of unused packages sent with the corresponding unique identification number.

(b) For each mail-back package or envelope distributed by a pharmacy, the pharmacy shall record the serial number of each package or envelope distributed and the date distributed.

(c) For sealed mail-back packages received by the reverse distributor: the date of receipt and the unique identification of the individual package or envelope,

(d) For sealed mail back packages destroyed onsite by the reverse distributor collector: number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witness the destruction.

(e) For pharmacies using collection receptacles, for each liner:

1. Date each unused liner is acquired, its unique identification number and size (e.g., five gallon, 10-gallon). The pharmacy shall assign the unique identification number if the liner does not already contain one.
2. Date each liner is installed in a receptacle, the address of the location where each liner is installed, the unique identification and size (e.g., five gallon, 10-gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation.
3. Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each removal.
4. Date each sealed inner liner is transferred to storage, the unique identification and size (e.g., 5-gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage.
5. Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each

sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor.

(f) For each reverse distributor (wholesaler or third-party logistics provider) accepting liners, immediately upon receipt of a liner:

1. The date of receipt of each liner, the unique serial number of the liner, the pharmacy from which the liner was received, the method by which the liner was delivered to the reverse distributor (e.g., personal delivery by two pharmacy staff, shipping via common carrier).
2. For each liner destroyed by the reverse distributor collector: the method and date of destruction, listed by the unique identification number of liner and other items required by (f)(1), and the names and signatures of the two employees of the registrant who witness the destruction.

September 9, 2015 Enforcement Committee

Meeting Minutes Excerpt

Steven Gray representing Kaiser requested that the DOJ attend the California Society Hospital Pharmacists (CSHP) seminar to conduct CURES enrollment. Mr. Gray was asked to submit details of the meeting for consideration. Ms. Herold offered to help with CURES enrollment at this meeting.

There were no additional comments from the committee or public.

b. Update by the University of California, San Diego on Its Pilot Program to Permit Patients to Access Medication from an Automated Storage Device not Immediately Adjacent to a Pharmacy

Background

At the Board of Pharmacy's April 2015 Board Meeting, the board approved an 18-month pilot study under the auspices of the UCSD School of Pharmacy involving use of an automated storage device for prescription medication for which staff and their families of a Sharp Hospital in San Diego, who opt in, may pick up their outpatient medications from this device located in a hospital, instead of having to go to the community pharmacy. Consultation will be provided via telephone before medication can be dispensed to a patient.

This study was planned to start in June or July, 2015. However, in scheduling items for this committee meeting, we learned that the project is running a bit behind.

Discussion and Comment

At this meeting, via telephone, Dr. Hirsch delivered a presentation on the implementation of this program, which she anticipates will start in December 2015.

There were no comments from the public or committee.

A copy of this presentation can be found at the end of this document.

c. Discussion Regarding the Board's Proposed Regulations for the Take Back of Prescription Medication

Background

Since the July board meeting, work has continued to refine the board's proposed requirements for drug take back programs.

Meanwhile, additional counties have established requirements to permit or require take back of unwanted pharmaceuticals from the public. This often involves pharmacies.

On September 26, the Drug Enforcement Administration (DEA) will conduct another national Drug Take Back day. The board has released a subscriber alert and posted information about this collection day on the board's web site.

Board staff agreed to incorporate comments from this meeting into a draft and bring it to the October Board Meeting.

Board staff respectfully suggested a motion from this meeting for a recommendation that staff complete work on the proposed regulation, including incorporating comments made at this meeting, and bring the draft to the board meeting with a recommendation for the board to initiate a rulemaking by releasing the requirements for the 45-days of public comment.

Discussion and Comment

Ms. Freedman, board counsel, suggested that the committee focus on policy of the regulation and allow the board to tweak the language.

Heidi Sandborn, representing the California Product Stewardship Council, thanked the committee and stated the number one concern with this regulation is funding. She requested that the mandate be modified to include both a sharps container and a drug bin. She states that will provide more flexibility to local governments.

The San Mateo Department of Public Health expressed concerns with the sharps requirement and stated that this requirement may hinder pharmacies participation.

Mr. Weisser inquired into the cost of sharps disposal.

Jenn Jackson from San Francisco County voiced concern about the cost of sharps disposal. While she agreed it is necessary, she asked for clarification as to how existing pharmacies that do not take back controlled drugs would register.

The proposed regulations require pharmacies to register with the DEA. Ms. Jackson offered to provide the committee with information about the Health and Safety Code that allows for the co-mingling of sharps and drugs.

Mr. Weisser asked that a future agenda item include the manufacturer responsibility of drug take back.

A representative of the City of Santa Rosa agreed with comments made by previous speakers and requested clarification on several items including why inhalers are excluded. He requested that the committee remain cognizant of the impact the regulations may have on existing programs. Ms. Herold responded that pharmacies are DEA registrants and must comply with the DEA requirements irrespective of what the board does. The representative of Santa Rosa requested that the committee consider maximum flexibility and questioned about how the use of a common or contract carrier can ensure the chain of custody. He also asked if the language can reference “bags” instead of “liners”.

It was noted that the committee should consider is if there is value in the board creating a standardized sign for all drug take back.

Dr. Gutierrez discussed the need to educate pharmacies about the DEA requirements to register as a collector.

Brian Ward of CSHP thanked the committee for moving forward with these regulations. He informed the committee that the Environmental Protection Agency (EPA) just released information about their requirements for drug take back. He encouraged the committee to ensure that the board's regulations are consistent with EPA requirements.

Dr. Gutierrez sought clarification from counsel on whether the board's regulation indicated that drug take back is not required in our regulation but is required by a local ordinance, which one supersedes the other. Counsel indicated she would research the issue.

Dr. Gutierrez recessed for a break at 11:17 a.m.

The meeting reconvened at 11:27 a.m.

Dr. Gray representing Kaiser made several suggestions:

- He stated that the term "tampering" is ambiguous and suggested that the committee provide a definition of this term.
- He suggested that the regulation require that the liner material be made of antineoplastic material.
- He suggested that the board clarify the definition of controlled substances to include the state and federal schedules.
- He asked for the purpose of the signage requirement and whether this posting provides safe harbor if a consumer places a prohibited item in the bin.
- He requested that the board pursue legislation to create the safe harbor.
- He asked for clarification on the placement of the bin and stated that it is ambiguous.
- He suggested that the board clarify the documentation requirement when the mail back option is provided to the consumer.

<u>Committee Policy Discussion</u>
Question: Should we assume that all medications being brought in are controlled substance?
Answer: Yes.

Question: Do we want to differentiate between sharps vs. other mail bins?
Answer: The committee recommended removing the sharps requirement.

The committee stated that pharmacies shall not be required to participate in drug take back programs and that pharmacies on probation is prohibited from participating in this program.

The committee stated that pharmacies participating in drug take back programs should not be prohibited from receiving reimbursement.

It was noted that the committee should focus on where the bins can be located and find other ways to prevent a consumer from dropping off medications when a pharmacy is closed. It was also noted that bins should be lockable when the pharmacy is closed.

The committee questioned whether there should be common signage and agreed that the board should develop a sign for posting.

Public Comment on Committee Policy

Heidi Sandborn expressed concern that some capacity will be lost if the board follows the DEA regulations because some pharmacies do not want to handle controlled substances.

Brian Warren sought clarification as to whether counsel will be researching drug take back, sharps take back or vs. both. Counsel advised that the current draft calls for both.

The Marin County Pharmacist Association recommended that the committee keep the focus on getting drugs out of the home to prevent drug abuse and overdose.

The City of Santa Rosa concurred with comments by Heidi Sandborn and expressed concern about the cost.

Tim James from the California Grocers Association is trying to determine how all of the different pieces will work together, including the technical aspects of the regulations. They are concerned that this program could compromise food safety. His association will provide written comments in the next few days.

Committee Recommendation:

Motion: Recommend that staff complete work on the proposed regulation, including the policy comments, and bring the proposed regulation to the board for possible initiation of a rulemaking.

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

There were no additional comments or questions.

Dr. Gutierrez recessed for a 30-minute lunch break at 12:24 p.m.

The meeting reconvened at 1:02 p.m.

The New York Times | http://nyti.ms/1VLfC9W

U.S.

D.E.A. Effort to Curb Painkiller Abuse Falls Short at Pharmacies

By **ALAN SCHWARZ** OCT. 10, 2015

When the Drug Enforcement Administration announced last year that pharmacies nationwide could accept and destroy customers' unwanted prescription drugs, experts in substance abuse called it a significant step toward easing the painkiller and heroin epidemic.

One year later, however, the response has been insignificant, dismaying optimists and leaving communities searching for other strategies. Only about 1 percent of American pharmacies have set up disposal programs, with none of those belonging to the two largest chains, CVS and Walgreens, which have balked at the cost and security risks, according to government and industry data.

Countless unused prescription pills like oxycodone and Xanax linger in household medicine cabinets, in easy reach of addicted adults and experimenting adolescents. People who develop painkiller dependencies often move on to heroin, which is considerably cheaper and provides a stronger high. About 23,000 Americans died of prescription-drug overdoses in 2013, more than twice the number from 2001, according to the National Institute on Drug Abuse.

Flushing unwanted medications down the toilet is legal but discouraged because they can pollute water sources; throwing them in household garbage that eventually reaches landfills creates similar environmental concerns.

The D.E.A. decided to allow retail pharmacies to collect unwanted drugs — generally in secure, mailboxlike receptacles — because the locations are convenient

for the public and already feature safeguards for the medicines, some of which can be worth $40 per pill on the street. Pharmacies within hospitals and clinics are also eligible.

But participation is voluntary, and leaves pharmacies with the costs of collecting, safeguarding and incinerating the pills. In addition, at least eight states, including New York, have laws that forbid pharmacies to take back controlled substances.

A Walgreens spokesman said the company had not authorized any of its 8,200 locations to take back prescription drugs from customers. If someone asks to have unwanted medicine destroyed, he said, the store offers a do-it-yourself kit, for $3.99, in which the pills are mixed with water and other substances to render their contents inactive.

“We consider this the safest and most convenient way to dispose of unused medications,” the spokesman, James Graham, said in a statement.

Since 2010, the D.E.A. has held 10 so-called take-back days — with the latest on Sept. 26 — during which the police and other law enforcement groups encourage people to bring them unwanted medications for disposal. While these have collected 2,400 tons of pills, limited research suggests that the vast majority are noncontrolled medications like cholesterol drugs, antibiotics, and even aspirin and dietary supplements. One expert likened the effort to “trying to eliminate malaria in Africa by killing a dozen mosquitoes.”

A CVS spokesman, Michael DeAngelis, said the company did not allow its 7,800 pharmacies to accept controlled medications, although it held a pilot program at one of its stores. He would not disclose the location or results.

Mr. DeAngelis said CVS instead sought to address prescription drug abuse through other means. For example, it has expanded its program of selling naloxone, a medication that can avert opioid overdoses, to customers without a prescription. And it pays for receptacles, which cost about $800 each, that law enforcement officials use on the D.E.A.’s take-back days.

In some states, prescriptions for noncontrolled substances — those with vastly lower risks for misuse and addiction — are collected and redistributed to those in

need. Social services officials in Tulsa, Okla., have about 20 retired doctors who retrieve surplus prescription drugs from dozens of area long-term-care facilities and take them to a pharmacy where they are checked, sorted and donated to low-income residents.

Begun in 2004, the program has filled 180,000 prescriptions worth more than $35 million retail. But it does not handle controlled substances.

“They have such value on the street,” said Linda J. Johnston, the director of Tulsa County Social Services. “It’s not unusual to hear on the news about a pharmacy being robbed. It’s something we wanted to sidestep.”

While Ms. Johnston said she understood pharmacies’ concerns about security, both in guarding drop boxes and transferring their contents to disposal facilities, she expressed some skepticism for those who balk at the cost of destroying the substances. The drugs collected during Tulsa’s D.E.A. take-back day, and in about 20 other locations nationwide, are incinerated free by the local plant of Covanta, the waste and energy company.

Several West Coast counties, including Alameda (which includes Oakland, Calif.) and King (which includes Seattle), have passed ordinances to require the source of prescription medications — drug companies — to underwrite and manage take-back programs. The Pharmaceutical Research and Manufacturers of America, the industry’s main trade association, sued Alameda County over its law, but lost in the United States Court of Appeals for the Ninth Circuit. The Supreme Court declined to review the case in May, and the program could become the first to begin operation next year.

Scott Cassel, the chief executive of the Product Stewardship Institute, a nonprofit environmental group, said manufacturers in other industries had been required to handle the disposal of their own environmentally harmful products. For example, mattress makers in Connecticut are responsible for disposing of discarded mattresses because they are expensive to destroy or recycle.

"The mattress people were understandably not enthusiastic about picking up the cost," Mr. Cassel said, "but the idea is to protect the environment and to ask industries to handle the waste. Right now it's the taxpayers."

As for pharmacies, Mr. Cassel said that generally only small, independent locations had used the D.E.A.'s new guidelines to begin collecting controlled medications, partly out of civic responsibility but also as a means of getting more customers in the store.

The small number of participating pharmacies does not bode well for the future of the program, said Howard Weissman, the executive director of the St. Louis affiliate of the National Council on Alcoholism and Drug Dependence.

"People mean well and want to do the right thing, but in the same way we mean to bring our plastic bags back to grocery stores, we wind up just throwing them in the trash," Mr. Weissman said of unused drugs. "Until we figure out how to get people to understand how dangerous this stuff can be, parents are going to keep stocking their medicine cabinets with loaded revolvers."

Correction: October 13, 2015

Because of an editing error, an article on Sunday about a disposal system for unwanted prescriptions misstated, in some editions, part of the name of a group that has a St. Louis affiliate led by Howard Weissman, who commented on the practice. It is the National Council on Alcoholism and Drug Dependence (not Drug Abuse).

A version of this article appears in print on October 11, 2015, on page A18 of the New York edition with the headline: A Plan to Curb Pill Abuse Falls Short at Pharmacies .