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Best Management Practices for the Collection of Unused and Expired Pharmaceuticals

Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007) requires the California Integrated Waste Management Board (CIWMB) to develop model programs for the collection and proper disposal of unused and expired pharmaceuticals. In developing model programs in California, the CIWMB is also required to evaluate programs used by other state, local, and other governmental entities. The CIWMB provided a survey to those entities that have collection programs and requested that they complete and return to the CIWMB. The purpose of the survey was to acquire information on existing pharmaceutical waste collection programs in California. From the survey results, Best Management Practices (BMPs) were developed that would help create model programs through which the public may return unused or expired pharmaceutical waste (typically a prescription drug dispensed to a consumer, or a non-prescription item, such as over the counter drugs, that are no longer wanted or needed by the consumer) and meet the following minimum criteria and goals from SB 966 and the Pharmaceutical Working Group (staff from CIWMB, California Department of Public Health, Board of Pharmacy, Department of Toxic Substances Control and State Water Resources Control Board):

1. Ensures the safe and environmentally sound disposal of pharmaceuticals;
2. Provides for the collection of pharmaceuticals that is convenient for consumers;
3. Provides the collection of pharmaceuticals at no additional cost to the consumer;
4. Ensures protection of public health and safety, the environment, and the health and safety of consumers and employees;
5. Provides a means to report to the Board the amounts and types of pharmaceutical waste collected for purposes of program evaluation for safety, efficiency, effectiveness and funding sustainability;
6. Protects against the potential for the diversion of drug waste for unlawful use or sale;
7. Provides notice and informational materials about potential impacts of improper disposal of pharmaceutical waste and options for proper disposal;
8. Maintains privacy of all participants;
9. Segregates medications into controlled and non-controlled substances;
10. Ensures that medication information is legible, so that it can be identified in case of a poisoning or to determine if it is a controlled substance or not;
11. Develops a sustainable funding source for collection and disposal of pharmaceuticals, such as grants, utility funding, advanced disposal fees placed on pharmaceuticals and local general funds;
12. Strives to develop permanent collection programs rather than one-day events, so they will be more accessible to the public; and

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13. Provides consequences for failure to comply with model programs at the point of transportation, deposition, and consolidation.

The following BMPs have been extracted from both the Pharmaceutical Collection Programs Survey and collection program information on the internet. These BMPs are not only a tool to determine if a program meets the minimum criteria of model programs, but also can be used to develop a collection and disposal program for unused/expired pharmaceuticals. The BMPs are broken down by (I) Ongoing Collection Programs, (II) One-Time or Periodic Events, and (III) Mail Back Programs.

I. Best Management Practices for the Collection of Unused and Expired Pharmaceuticals At Ongoing Collection Programs

As mentioned in the previous section on goals, it is preferable that permanent pharmaceutical collection programs be developed, in order to provide the public with consistently accessible and convenient venues to drop off unused and expired pharmaceuticals. Jurisdictions such as the City of Los Angeles, San Mateo County and Ventura County and nonprofit groups such as the Teleosis Institute are current examples of permanent and ongoing programs utilizing various types of venues. The following are basic steps that can be taken to implement permanent programs.

A. Ongoing Collection Program Requirements

The following collection program requirements need to be adhered to at locations collecting pharmaceutical waste from the public:

1. What Will Be Collected - These programs provide for the collection and disposal of prescription drugs dispensed to a consumer, or a non-prescription item, such as over the counter drugs, and veterinary medications. Medical waste such as blood samples, vaccines and serum, and trauma scene waste will not be accepted. In addition, controlled substances should not be collected by these programs unless law enforcement is available to properly collect, conduct inventory, and dispose of them.

2. Controlled Substances - Controlled substances are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines and methamphetamines). If a medication is not identifiable, it should be assumed to be a controlled substance and handled accordingly. Controlled substances should not be collected except at police stations or at least in the presence of law enforcement.

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3. How Will Pharmaceuticals Be Collected - Signage or literature informing customers that the program cannot accept controlled substances should be visible and available to the public. The pharmaceuticals should be kept in their original container with personal information removed or marked out. Labels should not be removed. The containers and pharmaceuticals can then be given to the collection program for collection and disposal. The collection location must ensure that the pharmaceuticals are destroyed. In a retail setting, no collected pharmaceuticals can be resold or reused.

A. Pack pharmaceutical waste (controlled and non-controlled substances) in their original containers.

B. Packing Controlled Substances - This is at the discretion of the law enforcement agency. The signed inventory must accompany the medications and must stay with them in the evidence storage locker and through the point of destruction. Before the medications are destroyed, the contents are checked against the inventory to ensure that there has been no diversion. This is US Drug Enforcement Agency law.

C. Storage - Never store collected pharmaceuticals at a HHW facility or any other setting, other than in the secure containers or in the custody of law enforcement due to the risk of theft or accidents.

D. Sharps - Be prepared for sharps by having sharps containers that can be mailed back to a sharps management company for disposal after the event.

4. Security - Containers with a lockable cage can be purchased for additional security. Containers with pharmaceutical waste should be locked in a closet preventing the public and staff from gaining access. Other security measures can be taken including video surveillance, limiting access, providing drop-off containers at police stations or utilizing mail-back envelopes. If not accepting controlled substances provide a flyer as to where they can be disposed.

5. Signage - Provide signage regarding what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.).

6. Data Collection - Itemize amounts and types of pharmaceuticals collected so the information can be used for further study and recommendations for future collection. Examples of collection forms can be accessed at www.teleosis.org/pdf/Medicine_Return_Form.pdf or www.comofcom.com.

7. Education - Provide education about the problem of pharmaceutical waste entering waterways and drinking water to the community and customers dropping off pharmaceuticals.

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8. Site Visits to Collection Sites - Visit collection locations often to help assure that procedures are being maintained and help maintain lasting relationships. An example of this is the Teleosis Institute that makes routine site visits by the staff person that oversees the Teleosis Institute's pharmaceutical take back program.

B. Logistics and Equipment

1. Type of Collection Location - There is a wide variety of facilities that can collect pharmaceuticals-pharmacies, police stations, retirement and convalescent homes, public health agencies, clinics, and HHW facilities. The best facilities would be those that are convenient to the public, can continue collection for a long period of time, and are willing to collect.

A. Collection at Law Enforcement Facilities - If collection is at a police station, law enforcement must be able to collect the materials, document the amounts collected, and place in an area to be accumulated and destroyed.

B. HHW Collection Site - If you use a collection site at the HHW facility, the site must have access to electricity, room for the hazardous waste containers, and room for workstations.

2. Government Agency Authorization - Determine if additional permits or approval are needed for pharmaceutical collection. All relevant agencies and programs have to authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health agencies, California Department of Public Health, local hazardous waste departments, and zoning departments for use permits.

3. Budget - A budget estimate should be developed and the **program should be free to the public to dispose of unused and unwanted pharmaceuticals at the point of disposal**. It needs to be determined who will be paying for the collection and disposal of pharmaceuticals and whether there are sufficient funds to pay for any large increases in rates or in amounts collected.

4. Hazardous Waste Hauler/Disposal Arrangements - Advance arrangements should be made with the hazardous waste hauler on the fee schedule, hazardous waste incineration, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers.

5. Advertising - Provide advertising which could include internet, web site ads, newspaper ads, fliers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual pictures distributed in utility bills

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in participating cities, movie ads, movie theatre ads shown in theaters, ads on buses and at bus stops, print ads in recycling guides, English and Spanish PSA's in video and audio. Advertising may be the most expensive part of the collection program, so for the most effective means for advertising the program, people that would be disposing of pharmaceuticals should be targeted. These populations could include people at convalescent homes and people that are purchasing new prescriptions.

6. Essential Equipment and Supplies

- A. Pharmacies - Lockable secure containers with a wire cage around them, black markers to cover up personal data, a form to track types and amounts of pharmaceuticals collected and signage informing the public about what can be collected. The containers should be located behind the counter.
- B. Police Stations - Refurbished containers with an inside collection container located near the building entrance or in the lobby that allows people to dump off pharmaceuticals and not be able to get them out again. Refurbished mail boxes, as an example, can be used to prevent theft.
- C. Permanent HHW Collection Facilities - 4 container types (55 gallon lab packing containers, 30-gal cardboard with plastic liner, a 5-gal plastic container for inhalers, and a 5-gal plastic container for mercury items), gloves, indelible markers, and mail back sharps disposal kits.

C. Staffing

1. Staffing for Ongoing Collection Programs - The following staff are recommended at collection programs to implement the specified tasks:

- A. Pharmacist (at pharmacies) - The pharmacist will determine if a pharmaceutical is a controlled substance, identify non-labeled medications, inventory controlled substances, witness, and sign the inventory.
- B. Hazardous Waste Company (for HHW facilities) - The Hazardous Waste Company will provide drums/containers for collection of non-controlled substances, seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove medications, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances in licensed hazardous waste incinerator, provide certificate of destruction, and provide weight of materials collected. Do not allow medications to be stored longer than 90 days at the facility.
- C. Law Enforcement - If an ongoing collection program decides to collect controlled substances, a police officer or other law enforcement is required to be present to monitor and collect the controlled substances.

2. Staffing for Programs That Don't Collect Controlled Substances-recommended:

- A. Pharmacist (at pharmacies)

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B. Hazardous Waste Company (for HHW facilities)

II. Best Management Practices for the Collection of Unused and Expired Pharmaceuticals At One Time or Periodic Collection Events

Although permanent and ongoing collection programs are the preferred way to collect and dispose of pharmaceuticals, there will be instances when conducting one time or periodic events are necessary. Jurisdictions currently conducting one time/periodic events include Tuolumne County, East Bay Municipal Utility District and Fresno County. These events are held at local street fairs, festivals, city halls, water district facilities, and household hazardous waste temporary collection events. The following are steps to take in conducting one time/periodic events.

A. Collection Event Operation Requirements

During the collection event, the following requirements need to be adhered to:

1. **Critical Information for the Event** - The following items are critical to assure that the public and the event staff are safe and that no medications are diverted from the collection event:
 - A. Medications stay in their original containers.
 - B. Personal information can be crossed out, but keep information about medication legible.
 - C. Do not remove labels.
 - D. No sharps.
 - E. No thermometers.
 - F. No medical waste, such as biohazardous waste, sharps waste, or medicinal preparations made from living organisms.
 - G. Medications will be destroyed.
 - H. If in a retail setting, no refunds and medications will not be resold or used.
 - I. Provide where, when, hours of operation, and who to contact for more information.
 - J. No cost to participate.
2. **What Will Be Collected** - All prescription medications should be accepted, including veterinary medications. It is recommended to accept over-the-counter medications.
3. **Personal Protective Equipment** - Wear gloves (latex or non-latex) at all times when handling medications. The containers may be powdery, sticky, and dirty. Accidental ingestion (even through skin or breathing) should be avoided. Wearing facemasks should be considered, especially for the pharmacist who is doing the physical inventory of the medications. Do not eat or drink directly in the area that the medications are being collected. Discard used gloves.

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4. Packing Pharmaceutical Waste - Controlled and non-controlled substances should be packed separately and in their original containers.

A. Packing of Non-Controlled Substances

- 1). No loose pills should be placed in the hazardous waste container. A pharmacist should make a best faith effort to identify the medication. This will include using reference materials. Once identified, put the medication in a Ziploc® bag and mark the bag with an indelible marker indicating the type of medication and dosage. If the tablets remain unidentifiable, mark the bag "unknown."
- 2). Two types of containers must be provided for certain items: items under pressure and certain mercury-containing medications.

B. Packing Controlled Substances-This is at the discretion of the law enforcement agency. The signed inventory must accompany the medications and must stay with them in the evidence storage locker and through the point of destruction. Before the medications are destroyed, the contents are checked against the inventory to ensure that there has been no diversion. This is federal DEA law. If a medication is not identifiable, it should be assumed to be a controlled substance and handled accordingly.

C. Storage - Never store collected controlled substances at a HHW facility or any other setting, other than in the custody of law enforcement due to the risk of theft or accidents.

5. Security - Containers with a lockable cage can be purchased for additional security. Containers with pharmaceutical waste should be locked in a closet preventing the public and staff from gaining access. Other security measures can be taken including video surveillance, limiting access, providing drop-off containers at police stations or utilizing mail-back envelopes. If not accepting controlled substances provide a flyer as to where they can be disposed.

6. Signage - Provide signage regarding what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.).

7. Data Collection - Itemize amounts and types of pharmaceuticals collected so the information can be used for further study and recommendations for future collection.

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8. Medication Containers - These containers can be shredded for recycling. They should have the personal data marked out with a permanent marker.

9. Education - Have educational material available to be utilized by local government to educate the community about unused and expired pharmaceuticals.

10. Site Visits to Collection Sites - Local environmental health or similar program staff should conduct site visits to help assure that procedures are being maintained and help maintain lasting relationships.

B. Pre-Event Logistics

1. Government Agency Authorization - All relevant agencies and programs should have authorized the collection and its procedures at the collection event.

2. Budget - An estimate of the budget should be developed and the program should be free to the public to dispose of unused and unwanted pharmaceuticals.

3. Collection Site - Provide a location that restricts entering and exiting the facility to people dropping off pharmaceuticals. This will allow those in charge to watch people dropping off pharmaceuticals to assure that none of the medications are stolen.

4. Agreement With Law Enforcement - A peace officer is required to attend and participate in a collection event only if controlled substances are to be accepted at the event. Only a peace officer may accept controlled substances, not collection event personnel. If controlled substances will be accepted, confirm with law enforcement agency providing peace officer for the event, whether they have requirements for the type of packaging the drugs must be contained in to be accepted into their evidence locker, or if containers the collection event will provide are adequate for the law enforcement agency purposes. Law enforcement may participate in a collection event to provide security for event personnel; this is optional at the discretion of collection organizers, not required for all events.

5. Advertising - Provide advertising which could include internet, web site ads, newspaper ads, fliers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings. Multi-lingual pictures distributed in utility bills in participating cities, movie ads, movie theatre ads shown in theaters, ads on buses and at bus stops, print ad in recycling guides, English and Spanish PSA's in video and audio. Since

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advertising may be the most expensive part of the collection, people who would be disposing of pharmaceuticals should be targeted. These populations could include people at convalescent homes and people that are purchasing new prescriptions.

6. Pharmacist (if one day event is at a facility other than a pharmacy)-Pharmacists are recommended to be present at the event and must be licensed and in good standing with the California State Board of Pharmacy.

7. Hazardous Waste Hauler/Disposal Arrangements - Advance arrangements should be made with the hazardous waste hauler on the fee schedule, hazardous waste incineration, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers.

8. Dedicated Collection Area at the HHW Facility - If you use a collection site at the HHW facility, the site must have access to electricity, room for the hazardous waste containers, and room for workstations.

9. Law Enforcement Location - At one time events, law enforcement must be positioned to be able to see the collection and movement of the medications from the public to the workstation. Law enforcement must be able to see the transfer of medications from vehicles to the greeter. Determine a good position for law enforcement to be stationed.

10. Essential Equipment and Supplies

- a. Tools for counting medications (pharmacist should provide this);
- b. Reference documents for researching unknown tablets (book or CD format);
- c. Hazardous waste containers;
- d. Gloves (Disposable non-latex preferably; Have at least two sizes, small and large);
- e. Ziploc® bags (One-gallon and snack size, with external slide mechanism);
- f. Laptop(s) (With spreadsheet software and compatible printer);
- g. Back-up memory (e.g. memory stick, CD);
- h. 1 Printer (Compatible with laptop. Be sure there is enough ink and paper);
- i. Extension cords, grounded;
- j. Survey forms (examples can be found at www.teleosis.org/pdf/Medicine_Return_Form.pdf or www.comofcom.com);
- k. Indelible markers (such as SHARPIE®);
- l. Packing tape;
- m. Containers-3 types of containers (30-gal cardboard with plastic liner, a 5-gal plastic container for inhalers, and a 5-gal plastic container for mercury items); and
- n. Mail back sharps disposal kits, in case some sharps do come into the event.

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C. Staffing

1. Staffing for Events that Also Collect Controlled Substances - The following staff are recommended at collection sites to implement the specified tasks:

A. Greeter - direct people to the collection location and answer questions.

B. Law enforcement staff - to provide security, take possession of controlled substances after determination by a pharmacist, transport controlled substances to evidence storage locker, inventory controlled substance, and arrange for and ensure USDEA authorized witnessed destruction of controlled substances.

C. Pharmacist - to determine if a medication is a controlled substance, identify non-labeled medications, inventory controlled substances, witness, and sign the inventory.

D. Data Entry Person - Enter inventory of medications into computer.

E. Hazardous Waste Company - Provide drums/containers for collection of non-controlled substances. Seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove medications on the same day as the event, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances in licensed hazardous waste incinerator, provide certificate of destruction, and provide weight of materials collected.

2. Staffing for Events That Don't Collect Controlled Substances -The following staff are recommended at collection sites:

A. Greeter

B. Pharmacist

C. Data Entry Person

D. Hazardous Waste Company

III. Best Management Practices for the Collection of Unused and Expired Pharmaceuticals Through a Mail Back Program

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In some jurisdictions mailing back used and unused pharmaceuticals may be the only or most convenient option to disposing of those items. An example is the State of Maine, which uses pre-paid mailing envelopes available at pharmacies, doctors' offices and post offices. In addition, some pharmaceutical companies will take back their own drugs via mail. An example of this is Celgene, who allows patients to return unused drugs purchased from the company, such as thalidomide, via UPS at no shipping cost to the patient. The following are some guidelines to look at when undertaking such a program:

1. Determine locations where pharmaceuticals can be mailed to for proper management. These facilities must be able to accept controlled substances for destruction. In addition, these facilities must be able to provide data on the amounts of pharmaceuticals received and destroyed.
2. Obtain self-sealing pre-addressed and pre-stamped envelopes that are durable enough to be mailed to a destruction center. The envelopes should also include an instruction sheet on how to package and send the pharmaceuticals.
3. Provide postage-paid envelopes to pharmacies to be provided to customers that will be utilized for the mailing and destruction of unused and expired pharmaceuticals.
4. The envelopes should be tracked to assure that all envelopes are used for their intended purposes and that all of the pharmaceuticals get to the destruction facility.
5. Advertise the program at pharmacies, convalescent homes, and retirement homes to assure the program is not underutilized.
6. As the program's success increases, expand to more age groups and to more sites that distribute the envelopes.

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7. Review data on the amounts of pharmaceuticals collected to assure that the amounts are increasing. Make changes as needed to the program to assure continued growth.

Additional Best Management Practices

For additional best practices, contact the Northeast Recycling Council at www.nerc.org. If you have some additional practices for conducting an event that would be beneficial to other collection programs, please e-mail those practices to James Cropper at jcropper@ciwmb.ca.gov.

Sources

Rubinstein, Lynn, Northeast Recycling Council, Inc., Operating Unwanted Medication Collection-A Legal and Safe Approach, www.nerc.org, September, 2006.

Bay Area Pollution Prevention Group, Report on the San Francisco bay Area's Safe medicine Disposal Days, August 2006.

Community Medical Foundation for Patient Safety, www.comofcom.com.