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November 17, 2008

California Integrated Waste Management Board
1001 I Street
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SUBJECT: Consideration Of Model Programs And Procedures For
The Collection And Proper Disposal Of Pharmaceutical Waste
(Board Agenda Item No. 4)

Dear Members of the Board:

Thank you for the opportunity to comment on the Model Programs and Procedures for the Collection and Proper Disposal of Pharmaceutical Waste ("Procedures") that were developed by CIWMB staff for implementation of Senate Bill 966.

Tri-TAC is a technical advisory committee for Publicly Owned Treatment Works (POTWs) in California. Tri-TAC is jointly sponsored by the California Association of Sanitation Agencies, the California Water Environment Association, and the League of California Cities. The constituency base for Tri-TAC collects, treats, and reclaims more than two billion gallons of wastewater each day and serves most of the sewered population of California.

Tri-TAC's member agencies have been involved in the CIWMB stakeholder process for SB 966 implementation and have noted a vast improvement in the Procedures since a draft was provided to stakeholders at the August 25, 2008 stakeholder meeting. Between then and now, CIWMB clearly worked closely with the State Board of Pharmacy and Department of Public Health to reduce barriers to participation in model programs, including allowing pharmacies to collect unwanted pharmaceuticals and allowing collected material to be held for up to 90 days.

However, Tri-TAC is concerned that Procedures presented for the Board's review were not made available for review by all stakeholders until November 3, 2008. After an initial review, we have noted some deficiencies in the document that will continue to hamper voluntary participation in developing model programs.

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First, the Procedures include a goal (Additional Goal #5," p. 4-5) for the development of "a sustainable funding source for collection and disposal of pharmaceuticals, such as grants, utility funding, or ADFs placed on pharmaceuticals and local general funds or via (Extended Producer Responsibility) EPR funding framework." Other than an EPR funding framework, none of these sources represents a sustainable funding source. EPR was strongly supported by the stakeholders; furthermore, the document does not reflect the Board's Strategic Directive No. 5 and is contrary to the significant amount of focus the Board itself has given to this funding approach.

The highly successful Canadian pharmaceutical take-back program is fully funded by manufacturers, most of which are the same companies that sell pharmaceuticals in California. Tri-TAC members are not averse to being part of the solution, and in fact spearheaded the "No Drugs Down the Drain!" campaign in October 2008; however, relying on local government's shrinking funds as a sole source will result in too few collection programs.

Second, in several places the Procedures require that pharmaceutical waste must be managed according to the Medical Waste Management Act. This is a significant barrier to participation in the program, due to the high cost of handling Medical Waste; these costs are not acknowledged in the Procedures.

While a major improvement has been made to allow pharmacies and other appropriate collection sites to accept unwanted medication, these entities may be challenged in voluntary participation if they must use a Medical Waste transporter. Instead, numerous stakeholders have suggested that the use of a common carrier, such as U.S. Postal Service, would be much more cost effective. Many of these entities already use common carrier to mail new pharmaceuticals to recipients or to dispose of unsold medication; a provision allowing pharmacies and other appropriate collection sites to mail unwanted medication for incineration would reduce the cost of disposal and potentially greenhouse gas impacts due reduced trucking of these wastes.

Last, the Procedures would require HHW facilities to segregate pharmaceuticals from other waste streams as a way to facilitate quantifying pharmaceuticals received. While we understand the desire to measure how many pharmaceuticals are being disposed of properly, at HHW facilities, pharmaceuticals are in small packages that can easily be packed among

other poison solids to completely fill voids in containers. Segregating these wastes adds additional disposal costs and workload for HHW facilities.

Again, while we have some concerns about specific details in the Procedures, we do want to commend staff for having made significant strides in working through concerns held by the State Board of Pharmacy and the Department of Public Health. However, we believe that local government and other stakeholders also should have been included in the finalization of the procedures.

We have attached changes in the proposed Procedures. If you have any questions, please feel free to contact Jen Jackson at East Bay Municipal Utility District at 510-287-0818.

Sincerely,

A handwritten signature in cursive script that reads "Jim Colston". The signature is written in black ink on a white background.

Jim Colston
Chair, Tri-TAC

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Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs

Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007) requires the California Integrated Waste Management Board (CIWMB) to develop model programs for the collection from consumers and proper disposal of unused or expired home-generated pharmaceuticals¹. 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 it to the CIWMB. The purpose of the survey was to acquire information on existing home-generated pharmaceutical waste collection programs in California. From the survey results, the Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs (Procedures) were developed that would help organizations or local governments create programs through which the public may return unused or expired home-generated 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 of SB 966 and of the Pharmaceutical Working Group (staff from CIWMB, California Department of Public Health (CDPH), Board of Pharmacy, Department of Toxic Substances Control, and the State Water Resources Control Board).

The minimum criteria of SB 966 and of the Pharmaceutical Working Group for home-generated pharmaceutical waste collection programs are -as follows:

1. Requires, at no additional cost to the consumer, the safe and environmentally sound take back and disposal of unused or expired home-generated pharmaceuticals;
2. Ensures protection of the public's health and safety and the environment;
3. Ensures protection of the health and safety of consumers, and employees;
4. Report to the Board the amounts of home-generated pharmaceutical waste collected for purposes of program evaluation for safety, efficiency, effectiveness and funding sustainability, and incidents of diversion of drugs for use or sale;
5. Protects against the potential for the diversion of drug waste for unlawful use or sale;
6. Provides notices and informational materials about potential impacts of improper disposal of pharmaceutical waste and options for proper disposal;
7. Subjects persons or businesses to consequences for failure to comply with model programs per SB 966 and related state and federal pharmaceutical and waste management statutes at the point of transportation, deposition, and consolidation;

¹ Throughout this document, the terms "home-generated pharmaceuticals" or "home-generated pharmaceutical waste" are used. Although the term does not appear in the law establishing this program, it is the term commonly used by stakeholders to refer to unused or expired pharmaceuticals in the possession of consumers.

8. Requires that once home-generated pharmaceutical waste has been consolidated at a facility or place of business, the waste **must be managed as medical or hazardous waste** [EPA is proposing a rule to deem this waste as universal waste; staff may want to reconsider this language. Propose change: *"must ultimately be disposed of as medical or hazardous waste; collection points are not considered the generator of the waste until consolidated at a consolidation point, such as a medical or hazardous waste handling facility or a reverse distributor."*]. This would include all statutory requirements for storage and handling as medical or hazardous waste, the use of registered medical or hazardous waste haulers and approved treatment technology for disposal; and
9. Requires collection locations to have written policies and procedures to document their operations and compliance with this home-generated pharmaceutical waste collection program.

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Additional goals of SB 966 and the Pharmaceutical Working Group include:

1. Provides for the collection of home-generated pharmaceuticals that is convenient for consumers
2. Maintains privacy of all participants;
3. Prevents the illegal collection of controlled substances through displaying signage or legally manages them if they are collected;
4. Ensures that medication information is legible, so that it can be identified in case of a poisoning;
5. Develops a sustainable funding source for collection and disposal of home-generated pharmaceuticals, ~~such as grants, utility funding, or advanced disposal fees placed on home-generated pharmaceuticals and local general funds or via~~ through extended producer responsibility funding framework in accordance with the CIWMB's adopted Strategic Directive #5. [Utilities and local government are not a viable long-term source of funding for a program. Producer responsibility needs to be ensured for this waste stream. Local government and utilities can be a part of the solution, especially for outreach vehicles (bill inserts, advertising, etc.).]
6. Strives to develop permanent collection programs rather than one-day events, so they will be more accessible to the public; and
7. Provides recommendations for implementation of a statewide program; and
8. Recommends statutory changes to, for example, the Medical Waste Management Act.

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The following Procedures have been extracted from both the Pharmaceutical Collection Programs Survey collection program information on the internet, and from the Pharmaceutical Working Group and are required for pharmaceutical collection programs. The Procedures are not only a tool to determine if a program meets the minimum criteria of model programs, but also can be used as a model to develop a collection and disposal program for unused/expired home-generated pharmaceuticals. The Procedures are broken down by (I) Permanent Home-Generated Pharmaceutical Waste Collection and Disposal Programs, (II) One-Time or Periodic Events, and (III) Mail Back Programs.

I. Procedures for Model Permanent Home-Generated Pharmaceutical Waste Collection and Disposal Programs

As mentioned in the previous section on goals, it is preferable that permanent home-generated pharmaceutical collection programs be developed to provide the public with consistently accessible and convenient venues to drop off unused or expired home-generated pharmaceuticals. The following procedures are basic steps that shall be taken to implement permanent collection programs at these types of facilities.

1. **Types of Collection Facilities** – Only the following may maintain permanent collection locations for home-generated pharmaceuticals: pharmacies with active unrestricted licenses from the California State Board of Pharmacy, police and sheriff's stations, public/environmental health agencies, physician and other licensed health care prescribers' offices, Household Hazardous Waste (HHW) facilities, and healthcare collection sites. Healthcare collection sites are physical locations licensed or operated by individuals or entities licensed by an agency within the Department of Consumer Affairs (DCA), with these locations electing to collect or take-back home-generated pharmaceutical waste and/or sharps, as applicable. Examples of healthcare collection sites include but are not limited to physicians and surgeons' offices, dentists, veterinary offices and pharmacies. If a DCA licensee has their license revoked, suspended, placed on probation or otherwise limited in any way, it shall not operate a healthcare collection site. If collection is at a police station, law enforcement must agree to and be able to collect the controlled substances and other home-generated pharmaceutical waste. Participation by any entity is voluntary and must be done in accordance with these provisions in these procedures in order to be considered a model program. Jurisdictions such as the City of Los Angeles, San Mateo County, Ventura County, Santa Cruz County, Marin County, Santa Clara County, and nonprofit groups such as the Teleosis Institute are current examples of entities implementing permanent and ongoing programs utilizing these types of venues.

A list of those facilities that collect home-generated pharmaceutical waste shall be provided to the CIWMB by the governmental entity, organization, or business that is implementing these programs. The list of collection facilities shall include the name, address, contact, and telephone number of the facility collecting and disposing of the home-generated pharmaceutical waste.

2. **Government Agency Authorization** – Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection. All relevant agencies and programs must authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health departments, California Department of Public Health Medical Waste Management Program, local hazardous waste departments, and zoning departments for use permits. [It seems that to reduce barriers to participation, it should be specified as to whom should be notified, and also determined here whether there is any permit fee. Recommend no permit fee, and DPH should provide a permit form in the appendix that can be filled out and sent to DPH or the LEA. Upshot – specify the procedure here, so that more will participate.] As an example, medical waste generator permits are a requirement for collection

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programs, and are issued by local enforcement agencies, which can be the local environmental health department or the California Department of Public Health. ~~The volume of pharmaceuticals collected will determine if a small quantity generator or large quantity generator permit is required.~~ [Facilities that are not currently generators, should not trigger generator status if they are collection points. Rather they should be called "collection points" and then where the material is taken is the consolidation point. Upon receipt at a consolidation point, the material is then considered a waste and triggers the generator status.]

~~3.2.~~

3. **Medical/Hazardous Waste Hauler/Disposal Arrangements** - Advanced arrangements shall be made with the medical or hazardous waste hauler on the fee schedule, medical or hazardous waste incineration options, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers. All home-generated pharmaceutical waste transported to an offsite waste treatment facility shall be transported by a medical waste or -hazardous waste transporter that has been issued a registration certificate in accordance with the Medical Waste Management Act, or via common carrier, such as USPS, UPS or FedEx to an appropriate disposal site or consolidation facility such as a medical or hazardous waste facility or pharmaceutical reverse distributor. A complete list of approved medical waste transporters can be found on the CDPH webpage at <http://www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/Haulist.pdf>. A medical or hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. It is the responsibility of the collection site to ensure that all home-generated pharmaceutical waste is appropriately picked up and transported by registered waste haulers. Detailed information about each pickup from a collection site and invoices for these services shall be retained by the collection site for three years. [Using USPS, UPS or FedEx and sending via mail to a reverse distributor may be much less expensive. Haz waste handling is very expensive and pharmacies and other medical offices may choose not to participate due to the expense. Providing an alternative means, such as sending to a reverse distributor, might be a more cost effective option.]

4. What Can and Cannot Be Collected

- a. Home-generated prescription drugs dispensed to a consumer, or a non-prescription item in the possession of a consumer, such as over the counter drugs, vitamins and supplements, and veterinary pharmaceutical waste, may be accepted.
- b. Sharps in approved containers may be accepted at collection sites, but shall not be placed in the same containers as the home-generated pharmaceutical waste.
- c. Medical waste such as human surgery specimens, blood samples, vaccines and serum, trauma scene waste, human surgery specimens, cultures from pathology laboratories, items containing human fluid blood vaccines, and serum shall not be accepted.

d. **Controlled Substances** - Controlled substances cannot be collected by these programs unless a sworn law enforcement officer is onsite to take custody of, document, and dispose of these controlled substances. Controlled substances are a specific category of prescription drugs and are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples of controlled substances include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines). If a medication is not identifiable, it shall be assumed to be a controlled substance and handled accordingly.

5. Signage – Signage must be provided regarding what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.), as well as the hours during which collection is permitted. Home-generated pharmaceutical wastes shall be segregated for storage and when placed in a container or secondary container, that container shall be labeled with the words “INCINERATION ONLY” or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction. A stand alone sign may be provided by the consolidation point (facility) which further describes the container as a waste pharmaceutical consolidation container. This sign shall be located in close proximity to the container to direct consumers to the container location. During periods of non-operation this sign shall be removed and the container shall be stored in a secure intermediate storage area.

Signage should also show how to deposit pharmaceuticals into the secured container, since staff cannot assist the consumers. The signage should also advise consumers to remove personal information from the medicine containers. In addition, the signage should mention that the consumer must not be charged for this service, nor shall any collection site pay a consumer to participate in a take back program.

6. How Home-Generated Pharmaceuticals Shall Be Collected - If home-generated pharmaceuticals are kept in the original, labeled container, personal information shall be removed or marked out. The containers and home-generated pharmaceuticals can then be placed in separate collection bins by the consumer for proper management. Staff of the collection site are not to assist consumers in placing home-generated pharmaceuticals in the bins. This is the obligation of the consumer. The collection location must ensure that the home-generated pharmaceutical licensed waste hauler or handler transports the home-generated pharmaceutical for proper destruction. Collected home-generated pharmaceuticals shall not be resold or reused. No individual or collection site shall purchase or offer to purchase home-generated pharmaceutical waste from consumers, nor shall such returned waste be sold, donated, or provided to anyone other than a registered waste hauler as specified in these procedures.

a. **Packing Home-Generated Pharmaceutical Waste and Controlled Substances** – If Home-generated pharmaceutical waste, pills, liquids or other materials are not kept in their original container, they shall be emptied from their containers by the consumer into the secured bin/container. Collection site staff may assist a consumer in opening a container but shall not otherwise assist consumers in placing pharmaceutical

waste into the bins. With respect to controlled substances, the law enforcement agency whose officers are onsite have discretion over the exact details regarding the handling of controlled substances.

b. Storage – A collection site shall not allow storage of pharmaceutical waste outside of the collection containers, and shall not allow commingling of the pharmaceutical waste with active drug stock stored elsewhere on the premises. Home-generated pharmaceutical waste shall not be placed or commingled with expired, recalled or other quarantined drugs in the possession of a collection site. Collected home-generated pharmaceuticals may only be stored in the secure sealed containers or in the custody of law enforcement. Once collected, home-generated pharmaceutical waste may be stored at an onsite location for not longer than 90 days when the container is ready for disposal. In certain circumstances, additional storage time may be obtained with prior written approval from the enforcement agency or the CDPH. The container shall be emptied at least once per year unless prior written approval from the enforcement agency or the CDPH is obtained.

c. Sharps - Sharps may be accepted only if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point. Sharps and sharps in approved containers, cannot be combined in collection bins with home-generated pharmaceutical waste. If the sharps are not brought in approved container and the collection site is willing to accept sharps, the consumer must place them in an approved sharps disposal container. Never have employees touch the sharps or assist in this process.

d. Chain of Custody- When the home-generated pharmaceutical waste is collected by the facility, the facility ~~becomes the owner of the pharmaceutical waste and~~ is responsible for assuring that it is stored, transported, and disposed ~~of in accordance with the Medical Waste Management Act~~ by a licensed medical waste or hazardous waste transporter or sent via common carrier to a medical or hazardous waste facility or reverse distributor. [This wording is a problem for HHW facilities, which would handle as hazardous waste, not medical waste and would not be knowledgeable necessarily about MW requirements. Recommend removing "in accordance with MWMA." Adding common carrier language will allow small pharmacies and medical offices to reduce costs by sending collected material to a proper disposal site.]. Detailed information and invoices about each pick up from a home-generated pharmaceutical collection site shall be retained in a log by the collection site for three years after the life of the collection device. Each collection location must keep a log specific to that collection device. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection device; (b) the address, phone number and location number where device is located; (c) the date the collection device was installed at the location (d) the dates for every opening of the device and purpose of opening; (e) the names of the two persons that accessed the device (one column for collection site's personnel, and one column for the waste hauler); (f) the weight of home-generated pharmaceutical waste removed from the device; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals from the device. The log should indicate the name, address and hauler number of the waste hauler taking the drugs.

~~For controlled substances, the signed inventory must accompany the pharmaceutical waste and must stay with law enforcement in the evidence storage locker and through the point of destruction~~ (this will be a big barrier for law enforcement – inventorying what’s coming in via collection bins is a large amount of staff time and is not under the purview of CIWMB. Law enforcement has its own regulations with regard to maintaining security of the collected material before destruction). ~~Before the home-generated pharmaceutical waste is destroyed, the contents must be checked against the inventory to ensure that there has been no diversion. This is a U.S. Drug Enforcement Agency law.~~ [Suggest changing language as previously stated: *“With respect to controlled substances, participating law enforcement agencies shall handle controlled substances per their regulatory authority.”*]

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7. Staffing - The following staff are recommended at collection programs to implement the specified tasks:

a. Pharmacist (at pharmacies) – The pharmacist may or may not be able to assist any consumer who brings in home-generated pharmaceutical waste or review each consumer’s deposit into the collection bin. No pharmacist or pharmacy staff shall accept home-generated pharmaceutical waste directly from consumers. The consumer shall deposit the items into the secured locked container. A pharmacist, if he or she chooses, to assist consumers with the identification of drugs that are unidentified, shall treat those drugs as controlled substances and consumers shall be referred to an appropriate collection location for those items. Alternatively, signage could be displayed stating that the pharmacy will not accept controlled substances for collection and disposal. Additional items that shall not be accepted into the pharmaceutical collection containers include sharps, medical waste and other items identified in the definition section of these procedures.

b. Law Enforcement –If a permanent home-generated pharmaceutical waste collection program decides to collect controlled substances, a police officer or other law enforcement officer is required to be present to monitor and collect the controlled substances.

c. Hazardous Waste Company Personnel (for collection at HHW facilities) - Hazardous waste personnel will provide drums/containers for collection of non-controlled substances, seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove home-generated pharmaceutical waste, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances at a licensed hazardous waste incinerator, provide a certificate of destruction, and provide weight of materials collected. Do not allow home-generated pharmaceutical wastes that are hazardous waste (e.g. chemotherapy drugs) to be stored longer than 90 days at the facility as required for the management of hazardous waste.

d. Medical Prescriber Staff - No physician, dentist, veterinarian or other prescriber or the staff in these offices may accept home-generated pharmaceutical waste directly from consumers. It is the consumer’s

responsibility to deposit the items into the secured locked container. A prescriber may assist consumers with the identification of drugs.

8. Container Security – It is the responsibility of the entity overseeing the collection location to provide for the security of the collected home-generated pharmaceuticals. The home-generated pharmaceutical waste must be deposited into secured containers to limit diversion and theft opportunities and not allow staff or the entity overseeing the program from having access to the contents. Containers at permanent locations shall either be locked and positioned so they are not moveable or -stored in an area that is either locked or under direct supervision or surveillance. The collection device must be within the physical plant of a pharmacy, prescriber's office, police department, or government agency operating the device so that it can only be accessed during operating hours.

The bins shall require two keys-one in the possession of the collection site's designated responsible person and the other in the possession of the licensed hauler who will pick up the contents for appropriate destruction. Containers may be stored in the following manner: a lockable cage on the container, lockable collection bins or kiosks, or lockable closets. Intermediate storage areas shall be marked with the international biohazardous symbol. These warning signs shall be readily legible from a distance of five feet.

Every collection site that provides for home-generated pharmaceutical waste collection shall keep contracts or ownership information for the collection device used for the program. These documents must be retained for the life of the device plus three years following discontinuation or replacement of the collection device. These records shall be readily retrievable at the request of a government enforcement agency.

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

9. Essential Equipment and Supplies

a. Pharmacies, Physicians, Veterinarians and Other Prescribers' Offices and Police Stations – The following are examples of the types of equipment and supplies that shall be provided: caged, lockable secure containers, lockable kiosks, lockable steel bins, refurbished lockable mail boxes with an internal container. These types of collection containers shall be located near a building entrance or in a lobby that allows people to drop off home-generated pharmaceuticals and not be able to retrieve them, in order to prevent theft. Other supplies include black markers to cover up personal data, signage informing the public about what can and shall not be collected.

b. Permanent HHW Collection Facility Equipment – The following equipment and supplies shall be provided: four container types (55 gallon lab packing containers, 30-gal cardboard with plastic liner, a 5-gal plastic container for inhalers, and a 5-gallon plastic container for mercury items), gloves, indelible markers, and sharps container and/or mail back sharps disposal kit.

10. **Budget** – In order to ensure that the program is properly run, a budget estimate should be developed so that the program is free for the public to dispose of unused and unwanted home-generated pharmaceuticals at the point of disposal. **In doing so the facility will need to determine who will pay for the collection and disposal of home-generated pharmaceuticals and whether there are sufficient funds to pay for any large increases in rates or in amounts collected.** [CIWMB has espoused Producer Responsibility. It seems that this is an opportunity to work with manufacturers to ensure collection of pharmaceuticals, rather than saddling our local governments with this.]

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11. **Education and Advertising** - Collection locations operators shall provide educational materials to the community and to consumers dropping off home-generated pharmaceuticals. Educational materials must include information about the problem of pharmaceutical waste entering waterways and drinking water and accidental poisoning from home-generated pharmaceuticals. Operators shall develop and distribute materials advertising the availability of permanent collection programs. Examples of such advertising could include internet web site ads, newspaper ads, flyers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual flyers distributed in utility bills in participating jurisdictions, movie theater advertisements, advertisements on buses and bus stops, print ads in recycling guides, or English and multi-lingual public service announcements. [If participation is voluntary, making this a requirement seems to throw up a barrier to collection programs. Once collection programs become required of pharmaceutical manufacturers, then this kind of requirement may make sense.]

Collection location operators shall provide instructions and information for consumers to use as they prepare to bring items to the collection location:

- a. List what will and will not be accepted (address at a minimum the following: non-prescription drugs, prescription drugs, controlled substances, sharps, thermometers, medical waste).
- b. All home-generated pharmaceutical waste must stay in their original containers; and
- c. Patient name and any other personal information must be rendered unreadable on the prescription label, before turning items in for collection. Blacking out with a Sharpie or other marker is suggested. Leave the name of the drug on the container.

12. Data Collection - Data shall be kept on the total number of pounds collected, the number of residents utilizing the collection facility where possible (some facilities may not be able to monitor exact numbers of users), and when possible, the types of materials collected for further study and analysis. Examples of collection forms can be accessed at www.teleosis.org/pdf/Medicine_Return_Form.pdf or www.comofcom.com. Security and confidentiality measures must be taken when retaining this data.

13. Site Visits to Collection Sites –For programs developed and overseen by public entities, those public entities shall visit collection locations periodically to help assure that procedures are being adhered to. A collection site shall make its premises available for inspection by government agencies with jurisdiction in this area.

II. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs at Government-Sponsored One Time or Periodic Collection Events

Although permanent collection programs are the preferred method to collect and properly manage home-generated pharmaceuticals, some jurisdictions such as Tuolumne County, Fresno County, City and County of Santa Cruz, and the City of Watsonville provide One-time or Periodic Collection Events. Jurisdictions offering one-time events shall adhere to the following requirements:

1. Collection Site - Access to the location must be restricted to only consumers dropping off home-generated pharmaceuticals. The designated operator shall observe consumers dropping off home-generated pharmaceuticals and shall ensure that none of the home-generated pharmaceutical wastes are stolen. If any theft is observed or suspected, the operator shall contact the appropriate law enforcement agency and the Local Enforcement Agency of CDPH.

- a. Pharmacist (if a 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.
- b. Dedicated Collection Area - If the collection site is at an HHW facility, the facility must provide room for additional hazardous waste containers.
- c. Law Enforcement - Law enforcement may participate in a collection event to provide security for event personnel; this is optional at the discretion of collection organizers and not required for all events. A law enforcement officer is required to attend and participate in a collection event only if controlled substances are to be accepted at the event. Only a law enforcement officer may accept controlled substances from the consumer. If controlled substances will be accepted, the operator of the event shall ask the law enforcement agency that is providing the officer if the agency has any specific requirements that the event must adhere to. For example, the law enforcement agency may specify the type of packaging that the drugs must be contained in to be accepted into their evidence locker, or if the containers the collection event will provide, are adequate for the law enforcement agency purposes. For controlled substances only, law enforcement must be on site at all times be and -able to see the collection and movement of the home-generated pharmaceutical wastes from the public to the collection location. Law enforcement must be able to see the transfer of home-generated pharmaceutical wastes from vehicles to the collection containers. The operator shall coordinate with law enforcement to determine the appropriate position for law enforcement to be stationed.

2. Government Agency Authorization- [See suggested changes in #2, page 3.] Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection. All relevant agencies and programs must authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health departments, California Department of Public Health Medical Waste Management Program, local hazardous waste departments, and zoning departments for use permits. As an example, medical waste generator permits are a requirement for collection programs, and are issued by local enforcement agencies, which can be the local environmental health department or the California Department of Public Health. The volume of pharmaceuticals collected will determine if a small quantity generator or large quantity generator permit is required.

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3. Medical/Hazardous Waste Hauler/Disposal Arrangements - [See suggested changes in #3, page 4.] Advanced arrangements shall be made with the medical or hazardous waste hauler on the fee schedule, medical or hazardous waste incineration options, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers. All home-generated pharmaceutical waste transported to an offsite waste treatment facility shall be transported by a medical waste or hazardous waste transporter that has been issued a registration certificate in accordance with the Medical Waste Management Act. A complete list of approved medical waste transporters can be found on the CDPH webpage at <http://www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/Haulist.pdf>. A medical or hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste

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transporter registration certificate in the transporter's possession while transporting medical waste. It is the responsibility of the collection site to ensure that all home-generated pharmaceutical waste is appropriately picked up and transported by registered waste haulers. Detailed information about each pickup from a collection site and invoices for these services shall be retained by the collection site for three years.

4. What Can and Cannot Be Collected

- a. These programs provide for the collection and disposal of home-generated prescription drugs dispensed to a consumer, or a non-prescription item in the possession of a consumer, such as over the counter drugs, vitamins and supplements, and veterinary pharmaceutical waste.

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

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

- c. Controlled Substances - Controlled substances cannot be collected by these programs unless a sworn law enforcement officer is onsite to properly collect, document, and dispose of these controlled substances. Controlled substances are a specific category of prescription drug and are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples of controlled substances include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines). If a medication is not identifiable, it shall be assumed to be a controlled substance and handled accordingly.

5. Signage – Signage must be provided regarding what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.) Home-generated pharmaceutical wastes shall be segregated for storage and, when placed in a container or secondary container, that container shall be labeled with the words "INCINERATION ONLY" or other labels approved by the CDPH on the lid and on the sides, so as to be visible from any lateral direction. A stand alone sign may be provided by the consolidation point (facility which further describes the container as a waste pharmaceutical consolidation container. This sign shall be located in close proximity to the container to direct consumers to container location. During periods of non-operation this sign shall be removed and the container shall be stored in a secure intermediate storage area.

Signage should also show how to deposit pharmaceuticals into the secured container, since staff cannot assist the consumers. The signage should also advise consumers to remove personal information from the medicine containers. In addition, the signage should mention that the consumer must not be charged for this service, nor shall any collection site pay a consumer to participate in a take back program.

6. How Home-Generated Pharmaceuticals Shall Be Collected

~~Advertise where the event will take place, when it will take place, the hours of the event, and who to contact for more information.~~ [this should be in the recommendations under #11, Education and Advertising] If home-generated pharmaceuticals are kept in the original, labeled container, personal information shall be removed or marked out. The containers and home-generated pharmaceuticals can then be placed in separate collection bins by the consumer for proper management. Staff of the collection site are not to assist consumers in placing home-generated pharmaceuticals in the bins. This is the obligation of the consumer. The collection location must ensure that the home-generated pharmaceutical licensed waste hauler or handler transports the home-generated pharmaceutical for proper destruction. Collected home-generated pharmaceuticals shall not be resold or reused. No individual or collection site shall purchase or offer to purchase home-generated pharmaceutical waste from consumers, nor shall such returned waste be sold, donated, or provided to anyone other than a registered waste hauler as specified in these procedures.

a. Packing Home-Generated Pharmaceutical Waste and Controlled Substances – If Home-generated pharmaceutical waste, pills, liquids or other materials are not kept in their original container, they shall be emptied from their containers by the consumer into the secured bin/container. Collection site staff may assist a consumer in opening a container but shall not otherwise assist consumers in placing pharmaceutical waste into the bins. With respect to controlled substances, the law enforcement agency whose officers are onsite have discretion over the exact details regarding the handling of controlled substances.

b. Storage – A collection site shall not allow storage of pharmaceutical waste outside of the collection containers, and shall not allow commingling of the pharmaceutical waste with active drug stock stored elsewhere on the premises. Home-generated pharmaceutical waste shall not be placed or commingled with expired, recalled or other quarantined drugs in the possession of a collection site. Collected home-generated pharmaceuticals may only be stored in the secure sealed containers or in the custody of law enforcement. Once collected, home-generated pharmaceutical waste may be stored at an onsite location for not longer than 90 days when the container is ready for disposal. In certain circumstances, additional storage time may be obtained with prior written approval from the enforcement agency or the CDPH. The container shall be emptied at least once per year unless prior written approval from the enforcement agency or the CDPH is obtained.

c. Sharps - Sharps may be accepted only if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point. Sharps and sharps in approved containers, cannot be combined in collection bins with home-generated pharmaceutical waste. If the sharps are not brought in approved container and the collection site is willing to accept sharps, the consumer must place them in an approved sharps disposal container. Never have employees touch the sharps or assist in this process.

d. Chain of Custody- [See suggested changes in Section D, page 6.]When the home-generated pharmaceutical waste is collected by the facility, the facility becomes the owner of the pharmaceutical waste and is responsible for assuring that it is stored, transported, and disposed of ~~in accordance with the Medical Waste Management Act~~ by a licensed medical waste or hazardous waste transporter [This wording is a problem for HHW facilities, which would handle as hazardous waste, not medical waste and would not be knowledgeable necessarily about MW requirements.]. Detailed information and invoices about each pick up from a home-generated pharmaceutical collection site shall be retained in a log by the collection site for three years after the life of the collection device. Each collection location must keep a log specific to that collection device. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection device; (b) the address, phone number and location number where device is located; (c) the date the collection device was installed at the location (d) the dates for every opening of the device and purpose of opening; (e) the names of the two persons that accessed the device (one column for collection site's personnel, and one column for the waste hauler); (f) the weight of home-generated pharmaceutical waste removed from the device; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals from the device. The log should indicate the name, address and hauler number of the waste hauler taking the drugs.

For controlled substances, the signed inventory must accompany the pharmaceutical waste and must stay with law enforcement in the evidence storage locker and through the point of destruction. Before the home-generated pharmaceutical waste is destroyed, the contents must be checked against the inventory to ensure that there has been no diversion. This is a U.S. Drug Enforcement Agency law.

7. Staffing

The following staff are required at collection sites to implement the specified tasks: [this is awkward, makes it sound like you have to have law enforcement and pharmacist, which I think it's meant to say only that they are required if the tasks are to be completed – i.e. if you're collecting controlled, then you need to have law enforcement. If you're not taking controlled, then law enforcement and pharmacist are ostensibly not required.]
Recommended change: *"The following staff are recommended at collection sites, and may be required if controlled substances are to be collected."*

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a. Greeter - direct people to the collection location and answer questions. Greeters can also screen incoming people and wastes for problems. If the event is large enough, radios are useful.

b. Law Enforcement Staff - to provide security, take possession of controlled substances after determination by a pharmacist, transport controlled substances to evidence storage locker, document the collection of controlled substances, and arrange for and ensure U.S. Drug Enforcement Agency authorized witnessed destruction of controlled substances. Law enforcement staff can also provide crowd control and

watch for problem people. A law enforcement officer is required to attend and participate in a collection event only if controlled substances are to be accepted at the event. Only a law enforcement officer may accept controlled substances, not collection event personnel. If controlled substances will be accepted, confirm with the law enforcement agency providing an 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 and not required for all events.

c. Pharmacist - to determine if a medication is a controlled substance, identify non-labeled home-generated pharmaceutical waste, inventory controlled substances, witness, and sign the inventory.

d. Hazardous Waste Personnel - Provide drums/containers for collection of non-controlled substances. Seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove pharmaceutical waste 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, provide weight of materials collected, and complete data entry.

8. Container Security – It is the responsibility of the entity overseeing the collection event to provide for the security of the collected home-generated pharmaceuticals. The home-generated pharmaceutical waste must be deposited into secured containers to limit diversion and theft opportunities and not allow staff or the entity overseeing the event from having access to the contents. The collection device must be within the physical plant of a pharmacy, prescriber's office, police department, or government agency operating the device so that it can only be accessed during operating hours.

Every collection event that provides for home-generated pharmaceutical waste collection shall keep contracts or ownership information for the collection device used for the program. These documents must be retained for the life of the device plus three years following discontinuation or replacement of the collection device. These records shall be readily retrievable at the request of a government enforcement agency.

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

9. Essential Equipment and Supplies

- a. Tools for counting home-generated pharmaceutical waste (pharmacist should provide this);
- b. Hazardous waste containers;
- c. Gloves (Disposable latex or non-latex);
- d. Sealable plastic bags (One-gallon and snack size, with external slide mechanism);
- e. Extension cords, grounded;
- f. Survey forms (examples can be found at www.teleosis.org/pdf/Medicine_Return_Form.pdf or www.comofcom.com);
- g. Indelible markers;
- h. Packing tape;
- i. Containers- Check with your contracted medical or hazardous waste hauler for appropriate containers; and
- j. Sharps disposal container -Provide sharps containers to collect sharps if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point.
- k. Personal protective equipment – All staff must wear gloves (latex or non-latex) at all times when handling pharmaceutical waste. This is important as the containers may be powdery, sticky, and dirty. Accidental ingestion (even through skin or breathing) must be avoided. Wearing facemasks should be considered, especially for the pharmacist who is doing the physical determination of the home-generated pharmaceutical waste. Do not eat or drink directly in the area that the home-generated pharmaceutical wastes are being collected. Discard used gloves.

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

11. Education and Advertising – [See comment #11, page 9.]Collection event operators shall provide educational materials to the community and to consumers dropping off home-generated pharmaceuticals. These materials must include information about the problem of pharmaceutical waste entering waterways and drinking water and accidental poisoning from home-generated pharmaceutical waste. Event operators shall develop and distribute materials advertising for the collection event. Examples of such advertising could include internet web site ads, newspaper ads, flyers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual flyers distributed in utility bills in participating cities, movie theatre advertisements, advertisements on buses and at bus stops, print ads in recycling guides or English and multi-lingual public service announcements.

Collection event operators shall provide instructions and information for consumers to use as they prepare to bring items to the collection event:

- a. List what will and will not be accepted (address at a minimum the following: non-prescription drugs, prescription drugs, controlled substances, sharps, thermometers, medical waste.
- b. All home-generated pharmaceutical waste must stay in their original containers.
- c. Event location, date, operating hours, and whom to call for more information.

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12. Data Collection - Determine amounts of home-generated pharmaceuticals (in pounds?) collected along with the number of **donators**, where possible [some facilities may have unmanned collection bins, such as at police stations and pharmacies and cannot tally the number of people who use the service]. If time allows, determine the types and amounts of home-generated pharmaceuticals collected. This information could be used for further studies and policy recommendations. Security and confidentiality measures should be taken when retaining this data.

Each collection event must have a log specific to that collection event. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection event (b) the address, phone number and location number where the event was located; (c) the date the collection event took place; (d) the names of at least one person from the event who witnessed the pickup by the licensed waste hauler (e) the name of the waste hauler's staff person who picked up the collected waste; (f) the weight of home-generated pharmaceutical waste removed from collection event; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals. The log should indicate the name, address and hauler number of waste hauler taking the drugs. These records shall be kept for 3 years after the life of the collection event by the host agency.

13. Site Visits to Collection Sites – The event organizer shall inspect the location to ensure compliance with all requirements. The CIWMB may request a report summarizing the activities of each collection location including amounts of home-generated pharmaceutical waste collected and the number of days in operation as a collection location for home-generated pharmaceuticals.

III. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs Through a Mail Back Program

In some jurisdictions mailing back used and unused home-generated pharmaceuticals may be the only or most convenient option for the proper management of these 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, such as Celgene, will take back their own home-generated pharmaceuticals via mail. Celgene allows patients to return unused drugs such as thalidomide purchased from the company, via UPS at no shipping cost to the patient. The following are some guidelines to look at when undertaking such a program:

Locations for Mail-Back Programs shall only be allowed if the following requirements are met:

1. Each entity overseeing either a Mail-Back Location or Mail-Back Program shall ensure that the home-generated pharmaceutical waste is destroyed in accordance with applicable regulations. CIWMB may request that each Mail-Back Location or Program provide information on the amounts of home-generated pharmaceuticals received and destroyed.

2. Determine locations where home-generated pharmaceuticals can be mailed for proper management and destruction. These facilities must be DEA-approved and able to accept controlled substances for destruction if controlled substances are mailed directly to the facility. In addition, these facilities must be able to provide data on the amounts of home-generated pharmaceuticals received and destroyed.

3. Operators of mail-back programs shall obtain self-sealing pre-addressed and pre-stamped envelopes that are approved by the U.S. Postal Service for containment and transportation of home-generated pharmaceutical waste. The envelopes shall also include an instruction sheet on how to package and send the home-generated pharmaceuticals.

4. Operators of mail back programs shall provide postage-paid envelopes to pharmacies to be provided to consumers that will be utilized for the mailing and destruction of unused and expired home-generated pharmaceuticals.

5. Envelopes shall be tracked to assure that all envelopes are used for their intended purposes and that all of the home-generated pharmaceuticals get to the destruction facility.

6. Operator shall advertise its mail back program at pharmacies, convalescent homes, and retirement homes in order to inform potential users of the program of its availability and requirements for participation. [seems like "shall" here is overkill. An operator may only want to work within a senior center, for example. Instead maybe this should be a recommendation.]

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7. The operator shall review data on the amounts of home-generated pharmaceuticals collected to assure that the amounts are increasing and shall make changes to the program as needed to the program to assure continued growth.

Appendix I-Definitions

1. Controlled Substance-any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the CA Health & Safety Code.

2. Event – Include programs and one- time events for the collection of home-generated pharmaceutical waste to assure appropriate disposal of these items.

3. Collection Programs – include permanent collection programs, temporary collection programs, and mail back collection programs

4. Model Program - CIWMB approved program through which the public may return unused or expired home-generated that meets statutory criteria.

5. Over the Counter Drug - a non-prescription drug as defined per CA Business & Professions Code Section 4025.1 which states "non-prescription drugs" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the laws and rules of this state and the federal government.

6. Collection Facility - any entity CIWMB finds appropriate to implement or evaluate a model home-generated pharmaceutical waste program. The participant must agree to participate as a model program. Entities that may qualify to participate:

- a. Governmental entities (includes police and sheriff's stations, public/environmental health agencies and HHW facilities);
- b. Pharmacies with active unrestricted licenses from the California State Board of Pharmacy;
- c. Other Physician and other licensed health care prescribers' offices; and
- d. Healthcare Collection Sites that are licensed by the Department of Consumer Affairs

7. Pharmaceutical Waste - In this document it is considered to be a prescription drug dispensed to a consumer or a non-prescription item, no longer wanted or need by the consumer and includes home-generated pharmaceuticals in many delivery systems, such as pills, liquids, and inhalers.

8. Prescription Drug - is a dangerous drug as defined per California Business and Professions Code Section 4022 which means any drug unsafe for self-use in humans or animals, without the oversight of a licensed prescriber and includes the following:

- (a) any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription, "Rx only", or words of similar import.
- (b) any other drug that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to CA Business & Professions Code Section 4006.