

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

Comment	Commenter	Draft Response to Comment in Document
A. Management of Pharmaceuticals		
<p>1. Develop sustainable funding for collection/disposal via EPR framework policies as stated in Board's Strategic Directive 5. Delete grants, ADF and utility funding as sustainable.</p>	<p>CA Product Stewardship Council City of Los Angeles Orange County Tri-TACⁱ Los Angeles County Sanitation Districts ESJPA Pharmaceutical Committeeⁱⁱ City of San Jose Waste Management Calaveras County</p>	<p>Page 2 #5 – CIWMB staff suggests that EPR should be included in the document and grants and fees shouldn't be deleted just because they may not be sustainable. Grants and fees could be reclassified as alternative funding.</p>
<p>2. Use a common carrier to reduce costs as many pharmacies and other entities use common carriers to mail new pharmaceuticals or dispose of unsold pharmaceuticals.</p>	<p>City of L.A. Calaveras County Pharmaceutical Committee Tri-TAC</p>	<p>Page 2, # 8 – Statutes enforced by CDPH require 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. This includes all statutory requirements for storage and handling, and transportation. Therefore, common carriers cannot be used.</p>
<p>3. Better define consolidation points and collection points.</p>	<p>Tri-TAC</p>	<p>The definition on Page 18, #6 is consistent with the provisions in SB 966.</p>
<p>4. Procedures require that pharm waste be managed according to MWMA.</p>	<p>Tri-TAC L.A. County Sanitation District Pharmaceutical Committee ESJPA</p>	<p>Page 2, #8 – Statutes enforced by CDPH require 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. This means that it must be transported as such.</p>
<p>5. Procedures require segregation of pharmaceuticals from other waste streams, which would be difficult, costly, and time consuming.</p>	<p>Tri-Tac L.A. County Sanitation District City of Los Angeles ESJPA</p>	<p>Page 4, #5 – Statutes enforced by CDPH require that 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.</p>
<p>6. HHW generated pharm waste does not need to be managed as HHW in CA. How does this differ from DTSC's statement that collected pharmaceuticals are HHW.</p> <p>7. Pharmacies should be able to charge for the collection costs.</p>	<p>CPSC City of San Jose</p> <p>Board of Pharmacy</p>	<p>Board staff will consult with DTSC staff regarding this comment and amend the procedures as deemed appropriate.</p> <p>PRC 47122 (b), (1) requires that the take back should be at no cost to the consumer. Any collection charges would conflict with existing law.</p>

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8. Every operator of a model program must have written policies and procedures to document their operations and compliance with the guidelines.	Board of Pharmacy	Page 2, #9 includes the requirement that collection locations have written policies and procedures to document their operations and compliance with this home-generated pharmaceutical waste collection program.
B. How Will Pharmaceuticals Be Collected		
1. Procedures don't show differences between collecting at a pharmacy and at an HHW facility.	City of L.A.	Comment noted.
2. At HHW facilities and mobile events, consumers can't get out of their vehicle to place in bins as required in procedures.	City of L.A. City of San Jose Pharmaceutical Committee	Page 5, #6 – Board of Pharmacy requested that staff of the collection sites not to assist consumers in placing home-generated pharmaceuticals in the bins. This seems unreasonable, so CIWMB staff will recommend revisions to the document allowing collection staff to assist consumers in placing home-generated pharmaceuticals in the bins.
3. Need to develop permanent collection programs to change long term habits.	Orange County	Page 2, #6 - CIWMB is in agreement with this comment.
4. Where home-generated pharmaceuticals are commingled in a plastic bag, staff may place them in the secure bin.	Pharmaceutical Committee	Page 5, #6, a – Board of Pharmacy recommends that collection site staff may assist a consumer in opening a container but shall not otherwise assist consumers in placing pharmaceutical waste into the bins. CIWMB staff recommends that collection site staff may assist consumers in placing pharmaceutical waste into the bins.
5. All pharmaceuticals should stay in their original containers. This should not be a requirement as some residents may consolidate pills into one large plastic bag or container.	City of San Jose Pharmaceutical Committee	Page 8, #11, b and Page 11, #11, b - It may not be possible or practical to have the pharmaceuticals in their original containers, so the reference to the pharmaceuticals staying in their original container will be deleted.
6. The burden of removing personal data should not be on the collection program.	ESJPA	Page 11, #5 –The procedures do not place the burden on the program operator, other than providing that signage advises consumers to remove personal information from the medicine containers. CIWMB staff recommends no change in guidelines.
7. Provide clearer direction on whether or not a pharmacist can assist in the collection.	City of San Jose	Page 6, #7, a – This provision is confusing and CIWMB staff will work with the Board of Pharmacy to clarify this issue.
8. Restricting access to the area may not be possible.	City of San Jose	Page 9, #1 - Collection Site – The intent of this provision is to provide a measure of security to prohibit unauthorized access. This would be consistent with HHW programs where access is restricted to only those authorized areas. CIWMB staff recommends no change in guidelines

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9. Having law enforcement be able to see the transfer of pharmaceuticals from vehicles is too restrictive.	City of San Jose	Page 9-10, # 1, c - The intent of this provision is to ensure that the controlled substances are indeed placed in a secure collection container and not diverted. CIWMB staff recommends no change in guidelines.
C. Types of Collection Locations		
1. Door to-door should be a permitted collection method.	CPSC Curbside Inc.	PRC 47121, c , does not specify door-to-door as a type of collection option. However, this could be an option of the One-time or Periodic Collection Events
2. Include those facilities that manufacture, distribute, and sell as part of the solution.	City of San Jose	Page 2-3, #1-1 lists examples of facilities that could be collection locations which include businesses, such as pharmacies that distribute and sell drugs. Mail-back programs are an example of program that could include manufacturers of drugs.
3. How will program hosts implement criteria if existing programs need to revise their activities to comply with model criteria?	City of San Jose	These criteria and procedures are for model programs as described in SB 966. If an existing program want to be considered a model program under SB 966 it will need to analyze which portions of their existing program do not meet these criteria and revise accordingly.
4. Delete #1 on Page 3 - Calls out specific facilities for pharm collection but doesn't include places that have historically collected. This should be a recommendation.	Calaveras County Pharmaceutical Committee	Page 2-3, #11 – CIWMB staff disagrees with the recommendation of deleting this paragraph. The facilities listed are examples of the types of facilities that could be collection locations. Feed stores and senior centers may be considered for selection if there is qualified staff to oversee the collection and if they adhere to proper procedures. CIWMB staff recommends no change in guidelines.
5. A list of those facilities that collect home-generated pharmaceutical waste shall be provided to the CIWMB. What is the penalty for not providing the information? Who is required to provide this list?	Pharmaceutical Committee ESJPA	Page 2-3, #1 - There is no penalty given if information is not provided. Page 2-3, #1 – The CIWMB, Board of Pharmacy, and CDPH are requiring that 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.
6. Recommends that only California-licensed pharmacies, government agencies, police or sheriff's offices, and licensed medication practitioners, and hazardous waste collection sites.	State Board of Pharmacy	Page 2-3, #1 - Comment noted.
7. Pharmacies should not be required to accept unused medications, because it would ultimately place consumers at risk and compromise the medication safety integrity currently established in both outpatient and inpatient pharmacies.	California Society of Health-System Pharmacists	The Board of Pharmacy recommends that California-licensed pharmacies should be authorized to operate pharm take-back programs; however this law does not <u>require</u> a pharmacy to accept unused medications. PRC 47122 (a) (2) requires an evaluation of a variety of models, such as pharmacies, used by other entities.

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D. Sharps		
1. Delete part about sharps and pharmaceuticals in separate containers, and instead allow sharps and pharmaceuticals to be combined only if transported by med waste hauler for incineration.	Calaveras County Pharmaceutical Committee	Page 5 #6, c and Page 4 #4, b – CIWMB staff agrees with this comment. The sharps and pharmaceuticals could be combined if CDPH’s more stringent requirement of incineration were adhered to.
2. Having consumer reload sharps into an approved sharps container is dangerous.	ESJPA	Page 5, #6, c and Page 12, #6, c – The Board of Pharmacy recommended that if the sharps are not brought in approved containers 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.
E. Government Agency Authorizations		
1. It should be specified as to whom should be notified. Recommend no permit fee and CDPH should provide a permit form in the appendix to be sent to CDPH or LEA. Want a streamlined permit approach.	Tri-TAC Pharmaceutical Committee City of San Jose Waste Management	Page 3, #2 - Statutes enforced by CDPH would need to be changed to provide a streamlined permit approach. This information was in general terms, because there are different requirements from one locale to another. Operators should check with their local authorities for specific requirements and fee waivers.
2. Provide generator exemption for collecting pharmaceutical waste.	Calaveras County	Page 3, #2 – These are statutes enforced by CDPH and would have to be changed in statute. This may require revising the MWMA which is beyond the scope of these procedures. Simple process is covered in current section via determining requirements for each collection point.
F. Storage Containers		
1. The type of equipment and supplies to use should be left to the discretion of the facility owner/operator.	City of L.A. Pharmaceutical Committee ESJPA	Page 7, #8 - Container Security –The Board of Pharmacy requires the entity overseeing the collection location to provide for the security of the collected home-generated pharmaceuticals. The Board of Pharmacy also requires that 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.
2. Longer storage time is essential in rural areas, since the cost of frequent pickups is prohibitive.	ESJPA	Page 12, #6, b – CIWMB staff believe there is ample storage time allowed. CDPH requires that 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.

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3. The two key bins should be suggestion not a requirement. These access and storage limitations don't allow for a common carrier shipment option, because for a common carrier or mail-back option for collection sites, site staff have to handle, seal, and move collection boxes and get them into the mail.	Pharmaceutical Committee	Page 7, #8 – The Board of Pharmacy recommended that 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. Page 3-4, #3 – CDPH requires by statute that 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 MWMA. To utilize common carriers for the transport of pharmaceutical waste would require changes to the MWMA. CIWMB staff recommends no change in guidelines.
4. Once a collection device becomes full, no pharmaceutical waste can be accepted until the waste hauler has removed the pharm waste.	City of San Jose	Page 7, #8 – The Board of Pharmacy recommended this security measure to ensure that the pharm waste is kept secure.
5. On one-day events, pharmaceutical waste must be picked up at the end of the day. It cannot be temporarily stored anywhere, even if the signs on the bins are removed.	Board of Pharmacy	Page 12, #6, b - The Board of Pharmacy would like the pharmaceutical waste to be immediately removed and disposed of by the hazardous or medical waste transporter to prevent the possibility of drug diversion.
G. Chain of Custody		
1. Delete the words-"becomes the owner of the pharmaceutical waste" and delete the words "in accordance with the MWMA."	Tri-TAC	Page 6, #6, d - Chain of Custody- CIWMB cannot suggest procedures that conflict with current statute. In addition, CDPH requires that 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.
2. Having pharmacies assume ownership of the waste would deter them from becoming a collection program due to liability concerns.	Pharmaceutical Committee	Page 6, #6, d – CDPH requires that 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 MWMA by a licensed medical waste or hazardous waste transporter. CIWMB staff recommends no change in guidelines.
3. Inventorying what is coming in via collection bins is a large amount of staff time. A weighed and sealed container is sufficient until the controlled substances are incinerated.	Pharmaceutical Committee City of San Jose	Page 6, #6, d – Comment noted.

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4. Any system that results in the aggregation of pharmaceuticals is more susceptible to diversion, loss, or theft than is possible in a mail-back system.	Waste Management	Page 16 – Comment noted.
H. Controlled Substances		
1. Delete requirement for that signed inventory must accompany the pharmaceutical waste and must stay with law enforcement through the point of destruction. Delete requirement that contents must be checked against the inventory.	Tri-TAC	Page 6, #6, d – Deleting this requirement would conflict with U.S. DEA law. The U.S. DEA requires that 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.
2. Is a one-way drop container sufficient for controlled substances? Which law enforcement agent can take possession of controlled substances? Would an open drum qualify if the event is monitored by the police? Locking containers are not available through some local HHW programs. This would also limit ability to remove packing.	City of San Jose	Page 11, #4, d – A one-way drop container would be sufficient for controlled substances. The DEA requires that the person accepting controlled substances must be a sworn law enforcement officer. If a law enforcement officer were onsite, then an open drum would be sufficient.
3. Remove the requirement that if a medication is not identifiable, it shall be assumed to be a controlled substance.	Pharmaceutical Committee ESJPA	Page 11, #4, d – The Board of Pharmacy has stated that if a medication is not identifiable, it shall be assumed to be a controlled substance and handled accordingly.
I. Medical/Hazardous Waste Hauler/Disposal Options		
1. Manifesting presents a barrier by increasing costs. Do RCRA drugs need to be sorted separately?	City of San Jose	Page 3-4, #3 – CDPH regulations require that collected pharmaceuticals shall be handled as hazardous waste or medical waste. Deleting this provision would conflict with existing law.
2. Recommend removing "in accordance with MWMA". This would be a problem for pharmacies due to concerns over liability.	Pharmaceutical Committee	Page 3-4, #3, Page 7, #8 – Statutes enforced by CDPH require that collected pharmaceuticals shall be handled as hazardous waste or medical waste. Deleting this provision would conflict with existing law.

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3. The current language causes problems for sites that collect medications at several sites and consolidate at another site, e.g. San Mateo Sheriff and Palo Alto Medical.	Pharmaceutical Committee	Page 3, #3 – This language was included at the request of CDPH to ensure compliance with the MWMA. Deleting this provision would conflict with existing law.
J. Education and Advertising		
If participation is voluntary, making this a requirement seems to throw up a barrier to collection programs.	Tri-TAC Pharmaceutical Committee	Page 6, #7 – Staff disagrees and believes it is reasonable to require collection location operators to provide educational materials to the community and to consumers dropping off home-generated pharmaceuticals. The Board of Pharmacy requested that this be added and CIWMB believes it is important to educate the public about the proper and improper disposal of pharmaceuticals.
K. Staffing		
1. Suggest the following language: “The following staff are recommended at collection sites, and may be required if controlled substances are to be collected.”	Tri-TAC Pharmaceutical Committee	Page 6, # 7. Comment noted.
2. Having a pharmacist on site adds significant cost and complexity to a collection program.	ESJPA	Page 13, #7 c. CIWMB staff agrees that this would add significant costs and could be deleted from the procedures.
3. Having law enforcement on site adds extraordinary costs to the program and is not necessary for programs where the pharmaceuticals are placed directly into secure containers.	ESJPA	Page 13, #7, b - Per DEA laws, only law enforcement officers can accept controlled substances. If a permanent collection program opts to collect controlled substances, a police officer or other law enforcement officer is required to be present to monitor and collect the controlled substances. Deleting this provision would conflict with federal law.
4. How can pharmacists identify drugs if they are not supposed to handle them?	Pharmaceutical Committee	Page 13, #7, c – This provision will be deleted per Board of Pharmacy recommendation thus allowing a pharmacist to handle and identify drugs.
L. Signage		

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1. Delete the section requiring signage that says, "Incineration only", because this is only necessary on containers used to transport the waste for disposal.	Pharmaceutical Committee	Page 4, #5 – Deleting this requirement would conflict with CDPH regulations.
2. Signage indicating pharmaceuticals are collected at this facility might encourage drug theft.	ESJPA	Page 4, #5 – CIWMB staff disagrees with this comment and believes it is important to provide proper instructions at the collection locations.
M. Data Collection		
1. Some facilities may not be able to monitor exact numbers of users.	City of San Jose Pharmaceutical Committee	Page 9, #12 - If the data is not available, the CIWMB would not require the data on the number of residents using the program. Programs would only be required to do the best they can to document this information as is done with the Form 303 for documenting HHW collected.
2. The data collection could be accomplished by providing a copy of the shipment document. Keeping the documents for 3 years is a barrier to becoming a collection site.	Pharmaceutical Committee	Page 15, #12 - CIWMB staff agree with the commenter regarding the data collection strategy but disagree that keeping documentation for 3 years is a barrier.
3. At one time events, does data collection refer to the event host agency or business?	City of San Jose	Page 2, #1 - The entities doing the actual collection would be responsible for data collection.
4. Identifying drugs is a difficult task and requires great expertise.	Pharmaceutical Committee	Page 15, #12 - Comment noted.
N. Mail Back		
1. The State needs to review mail back programs with CDPH to assure that it is legal to mail pharmaceuticals through a common carrier.	Pharmaceutical Committee	Page 16 and 17. The Criteria and Procedures were developed in conjunction with CDPH and Board of Pharmacy. As such procedures for mail-back programs were reviewed.
2. Is the only way to get a mail back envelope by going to a pharmacy as suggested by this section?	Pharmaceutical Committee	Page 17, #4 – Yes, because this would be the most logical place to get the mail back envelopes. There may be other options, but pharmacies would be the most logical and convenient location.
3. Waste pharmaceuticals should not be required to be tracked so meticulously.	Pharmaceutical Committee	Page 17, #5 - This provision is required by CDPH and Board of Pharmacy to ensure compliance with their laws and regulations. Any deviation from these requirements would conflict with existing law.

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4. Data should be reported by the facility receiving the mail-back envelopes.	Pharmaceutical Committee	Page 17, #7 – The CIWMB is requiring this provision in order to determine the effectiveness of various types of collection programs. This information will be used for the report required by SB 966 that is due in 2010.
5. Mail back programs are good methods to dispose of unwanted and expired pharmaceuticals, because it is convenient. They go directly to destruction repositories, easy to track and keep records on, and it is compliant with HIPA.	Waste Management	Page 16 - first paragraph - Board staff agrees with this comment.
O. Enforcement		
1. The document doesn't address who will perform enforcement actions.	Waste Management City of San Jose	Page 16, #2 - These facilities must be DEA-approved and able to accept controlled substances for destruction if controlled substances are mailed directly to the facility. Any enforcement actions would be carried out by the DEA or designated agency. Page 6, #6, d - These are DEA laws to be enforced by the DEA.
P. Container Security		
1. Thefts should be reported with 24 hours at least to the police, the Board of Pharmacy and the CDPH.	Board of Pharmacy	Page 7, #8 - This comment was already incorporated in the procedures.
Q. Additional Comments		
1. Add a section framing the issue of pharmaceuticals collection and disposal to include barriers, existing programs, controlled substances, and EPR funding.	City of San Jose Pharmaceutical Committee	Page 1 – CIWMB staff will add brief language to address suggested additions.
2. The proposed model is too restrictive and will discourage jurisdictions from developing model pharmaceutical collection programs. A model should serve as a guide allowing flexibility to adapt to their needs.	ESJPA	These procedures are in response to the requirements of SB 966 and are the culmination of comments from many diverse groups including state agencies, local governments, pharmaceutical manufacturers, and reverse distributors.
3. The document lacks specificity in areas such as the program approval process and is not in regulation and	City of San Jose Board of Pharmacy	This document provides information on what the procedures were attempting to accomplish and are only set up as a model as required in SB 966.

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will be difficult for the agencies involved. The enforcement procedures need augmentation and development.		
4. What is the timing of the effort?	City of San Jose	As stated in SB 966-these procedures were due Dec. 1, 2008 and an evaluation of the different programs is due to the Legislature in 2010.

Acronyms and Abbreviations Used

ADF-Advanced Disposal Fee

CDA – California Department of Consumer Affairs

CDPH-California Department of Public Health

CPSC – California Product Stewardship Council

DEA-Drug Enforcement Agency

DTSC-Department of Toxic Substances Control

EPR-Extended Producer Responsibility

ESJPA – Environmental Services Joint Powers Authority

HHW-Household Hazardous Waste

MWMA – Medical Waste Management Act

Pharms- Pharmaceutical Waste

PRC – Public Resources Code

ⁱ Tri-TAC is a technical advisory committee on POTW regulatory and policy issues

ⁱⁱ The Pharmaceuticals Working Group is an Ad Hoc committee of professionals from local government, non-profit and the pharmaceutical reverse distribution industries working towards pharmaceutical take-back programs.