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SOLID WASTE MANAGEMENT COMMITTEE/
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May 18, 2016

Ms. Lori Martinez, Staff Manager
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, CA 95834

Dear Ms. Martinez:

**COMMENTS: BOARD OF PHARMACY PROPOSED REGULATIONS FOR
PRESCRIPTION DRUG TAKE-BACK PROGRAMS – APRIL 25, 2016**

The Los Angeles County Solid Waste Management Committee/Integrated Waste Management Task Force (Task Force) appreciates this opportunity to comment on the California Board of Pharmacy's (BOP) April 25, 2016 Proposed Regulations for Prescription Drug Take-Back Programs by adding Sections 1776 through 1776.6 to Article 9.1, Division 17 of Title 16 of the California Code of Regulations (Regulations). A link to the Proposed Regulations is provided below:

http://www.pharmacy.ca.gov/meetings/agendas/2016/16_apr_bd_mat_add_dtb.pdf

Protecting the health and safety of citizens is the most important responsibility for all levels of government and the proposed Regulations should help in addressing the prescription drug abuse epidemic, which plagues California and the nation. The Secure and Responsible Drug Disposal Act of 2010 and the United States Drug Enforcement Administration's (DEA) Regulations, which implement the Act, were established in order to provide citizens with increased access to properly dispose of medications classified as controlled substances. As indicated in the Task Force's previous comments, in many instances the proposed Regulations are needlessly more stringent than the DEA Regulations and will in all likelihood actually reduce access for citizens to properly dispose of unwanted medications. Accordingly, the Task Force submits the following comments for your consideration:

Pursuant to the California Integrated Waste Management Act of 1989 (Assembly Bill 939) and Chapter 3.67 of the Los Angeles County Code, the Task Force is responsible for coordinating the development of all major solid waste planning documents prepared for the County of Los Angeles and the 88 cities in Los Angeles County with a combined population in excess of ten million. Consistent with these responsibilities and to ensure a coordinated and cost-effective and environmentally sound solid waste management system in Los Angeles County, the Task Force also addresses issues

impacting the system on a countywide basis. The Task Force membership includes representatives of the League of California Cities-Los Angeles County Division, County of Los Angeles Board of Supervisors, City of Los Angeles, the waste management industry, environmental groups, the public, and a number of other governmental agencies.

General Comment:

There are references in the proposed Regulations which refer to “prescription” drugs as being the only type of drugs allowed to be placed into collection receptacles. While we do not believe it is the Board’s intention to not allow over-the-counter drugs to be deposited into collection receptacles, these references to “prescription” drugs may create confusion. We understand the Board’s jurisdiction is limited to “prescription drugs,” however, we recommend removing the references to “prescription” drugs throughout the document and/or clarify that over-the-counter drugs are allowed to be collected in drug take-back receptacles.

A. Section 1776 Prescription Drug Take-Back Programs: Authorization

“All board-licensed authorized collectors should be vigilant to prevent the public from disposing of prohibited items through drug take-back collection methods.”

Comment: Vigilance on the part of authorized collectors is inconsistent with the DEA’s Regulations that prohibit authorized collectors from handling and/or sorting through collected drugs. Moreover, it is contrary to the Board’s own proposed Regulation section 1776.1(e)(1) which states: “Pharmacy staff shall not review, accept, count, sort, or handle prescription drugs returned from the public.”

- **Recommendation:** modify text to read: All board-licensed authorized collectors should ~~be vigilant~~ take reasonable steps in a manner consistent with this chapter to prevent the public from disposing of prohibited items through drug take-back collection methods.

Section 1776.2 Mail Back Package and Envelope Services from Pharmacies

General Comment: As previously commented, this section appears to confuse two types of entities: authorized collectors and pharmacies which solely provide mail-back envelopes. As currently drafted, this section, as modified, could be construed to prohibit California pharmacies from conducting a mail-back program without being registered with the DEA as an authorized collector.

Recommendation: Replace the entire text of this Section, as modified April 25, 2016, with the following:

1776.2.1 Requirements for Pharmacies Which Conduct a Take-Back Program

- (a) Register with the DEA and the board as a collector.
- (b) Utilize mail-back envelopes and packages which meet the requirements of 21 CFR 1317.70(c) and make them available, for sale or for free, to the public directly or through another entity, including, but not limited to other pharmacies.
- (c) Follow the requirements of 21 CFR 1317.70(e) in conducting a mail-back program.
- (d) Have and utilize at their registered location a method of destruction which shall render the contents of the mail-back envelopes and packages non-retrievable.

1776.2.2 Requirements for Pharmacies Which Distribute Mail-Back Envelopes and Packages

- (a) Ensure that any mail-back envelopes or packages made available to the public are preaddressed to a location that complies with DEA and board requirements.
- (b) Direct the public to take mail-back envelopes or packages and their contents to common carrier or contract carrier indicated on the envelope or package.

1776.3 Collection Receptacles in Pharmacies

(a) "... During hours when the pharmacy is closed, the collection receptacle shall not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit slot on the collection receptacle and physically block the public from access to the collection receptacle by some means."

Comment: This requirement goes beyond the DEA regulations, and could be a burden to pharmacies. The DEA Rule states that the receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present.

Recommendations:

- 1) Remove language about physically blocking patient access, and
- 2) Revert to DEA language in order to avoid requiring independent pharmacies to lock the collection receptacle when they lock the designated pharmacy area within the building/facility.

1776.3(b) *" . . . The receptacle shall be installed in an inside location, within the pharmacy premise, where the receptacle is visible to pharmacy employees, but not located in or near emergency areas."*

Comment: The DEA specifies that the receptacle shall be inside a collector's registered location. The DEA does not specify that employees must be employed in the

pharmacy. The reference to “emergency areas,” is likely only applicable to pharmacies located within a hospital or clinic and is proposed in the following paragraph.

Recommendation: Delete “pharmacy,” “within the pharmacy premises,” and “but not located in emergency areas.”

1776.3 (c) “... When the supervising pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle. When the collection receptacle is locked, the supervising pharmacy shall ensure that the collection receptacle is also physically blocked from public access by some means.”

Recommendation: Change above text to read: The collection receptacle shall be locked or made otherwise inaccessible to the public when not being regularly monitored by an employee so that drugs may not be deposited into the collection receptacle.

1776.3(h) “... All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste.”

Comment: There is a lot of confusion around the definition of medical waste; home-generated pharmaceutical waste is not currently defined as medical waste (see CA Health & Safety Code Section 117700).

Recommendation: Delete “for transport of medical waste.”

1776.3 (k)(5) “... If a common carrier is used to transport the liner to the reverse distributor, the company used, the signature of the driver, and any related paper (invoice, bill of lading) must be recorded.”

Comment: The DEA does not require any of these records when registrants use a common carrier to transport inner liners to a reverse distributor. We foresee some possible issues with obtaining the signature of the common carrier driver, in the case where some companies may prohibit their drivers from signing anything or the driver does not feel comfortable signing any forms.

Recommendation: Delete “the signature of the driver.”

The Task Force appreciates the difficult task the Board has undertaken to develop and revise the proposed Regulations. The general purpose of these comments are intended to bring to light provisions in the proposed Regulations which the Task Force believes afford no added benefit to the health and safety of residents and in most cases make it more difficult to provide convenient access for residents to properly dispose of unwanted drugs. It is hoped that the Board consider the purpose of drug take-back programs, which is to provide increased convenience for proper disposal and revise the Regulations to be as closely aligned with the DEA Regulations as possible.

Ms. Lori Martinez

May 18, 2016

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If you have any questions, please contact Mr. Mike Mohajer of the Task Force at MikeMohajer@yahoo.com or (909) 592-1147.

Sincerely,



Margaret Clark, Vice-Chair
Los Angeles County Solid Waste Management Committee/
Integrated Waste Management Task Force and
Mayor, City of Rosemead

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cc: Each member of the California Board of Pharmacy
Executive Director of the Board of Pharmacy
California State Association of Counties
League of California Cities, Los Angeles Division
California Product Stewardship Council
Each member of the Los Angeles County Board of Supervisors
Los Angeles County Department of Public Health
Los Angeles County Department of Public Works
San Gabriel Valley Council of Governments
South Bay Cities Council of Governments
Gateway Cities Council of Governments
Westside Cities Council of Governments
Each City Mayor and City Manager in the County of Los Angeles
Each City Recycling Coordinator in Los Angeles County
Each Member of the County Sanitation Districts of Los Angeles County
Each Member of the Los Angeles County Integrated Waste Management Task Force