



Date: September 26, 2017
To: Contra Costa Board of Supervisors
From: Daniel Peddycord, Public Health Director
Marilyn Underwood PhD, Environmental Health Director
Subject: Report on Safe Drug Disposal Program

Background:

On December 13, 2016, the Contra Costa Board of Supervisors introduced Ordinance No. 2016-24 ("Ordinance"), the Safe Drug Disposal Ordinance. Final adoption occurred on December 20, 2016. The Ordinance, which is similar to ordinances adopted by other counties, requires drug manufacturers to establish and pay for a system to collect and dispose of unwanted pharmaceutical drugs. The goal is to establish at least three drop-off sites in each of the five supervisorial districts in locations that allow for convenient and equitable access by residents of the unincorporated areas of those districts. Preference is given for establishing drop-off sites in pharmacies and law enforcement agencies as these are the only two entities that can legally accept controlled drugs, such as opioid based pain medications. In the event that achievement of this goal is not logistically feasible in a particular supervisorial district, the stewardship program would need to establish a mail-back provision in addition to hosting periodic drug take-back events that are at least 6 hours in length, held at least once per quarter and located in at least three separate locations in the district. In addition, mail-back services would need to be made available to individuals who are disabled or homebound. During the introduction of the Safe Drug Disposal Ordinance No. 2016-24, Supervisor Mary Piepho requested the following actions be taken as further considerations for implementation of the new program and for possible future amendments to the program itself:

- The Public Health Director will report back to the Board in 6 months with an update on implementation as well as the following additional considerations.
- Advise the Board on whether to establish additional requirements on the drug stewardship organization, specifically in terms of how it is organized as an entity.
- Advise the Board regarding opportunities to include Hospitals as drop-off sites versus limiting drop-off sites to retail pharmacies and law enforcement.
- Advise the Board on the advisability of including sharps as part of the program.
- Update the Board on the County's progress to seek adoption of similar ordinances in each city within the County.
- Include a Public Awareness Campaign that will increase awareness of the program and provide useful information to pharmacies, law enforcement, cities and citizens, hazardous material collectors, and sanitation districts, and include an update in the report.

The report is intended to address these requests and advise the Board on proposed amendments to the program that would support participation by those city jurisdictions that are interested in aligning with the product stewardship strategy put forward by the County.

Progress to Date on Implementing the Ordinance:

Following final adoption of the Ordinance, the Public and Environmental Health Divisions of Contra Costa Health Services (EH) endeavored to contact pharmaceutical wholesalers to alert them to the new Ordinance, to request information confirming that they sell prescription and/or over-the-counter drugs in Contra Costa County, and to provide the names and manufacturers of all covered drugs that the drug wholesaler sells or distributes in the unincorporated area of the county. By mid-February, letters had been sent to over 3,000 purported drug wholesalers. The list of purported drug wholesalers was obtained from Bay Area counties that were further along in the implementation of their respective ordinances and had already completed this step. This list was an amalgam of purported drug wholesalers from all those counties' efforts. Many of the companies on the list had more than one location listed. For instance, McKesson had 32 locations and Cardinal Health had 46 locations on the list. EH was therefore not expecting a response from each addressee, as one would suspect that a company may send one response representing their overall wholesaler operation. One-hundred-twenty-two of the letters were returned for incorrect addresses, location moves, etc.

In the letter, EH asked each addressee to respond by visiting one of two websites, using links EH provided. One website was to be completed by those companies who were not drug wholesalers in Contra Costa County. Ninety five (95) respondents completed the information requested on this website, indicating they were exempt from the requirements of the Ordinance related to being a drug wholesaler in Contra Costa County. Below is a depiction of the exemption options and in the brackets next to the option is the number of respondees that selected that option.

Check the applicable box. Our company is not subject to the Ordinance because:

<input type="radio"/>	Our Company does not meet the definition of a Drug Wholesaler under the Ordinance. [15]
<input type="radio"/>	Our company DOES NOT currently sell any covered drugs in or into the county of Contra Costa. [52]
<input type="radio"/>	Our company DOES sell covered drugs in or into the county of Contra Costa, but they are not intended to be used in the home. [10]
<input type="radio"/>	Our company is a 3PL business, and reports to the FDA as a 3PL. [18]

The other website was for companies to complete if they did meet the definition of a drug wholesaler in Contra Costa County. Sixty (60) respondents completed the information requested on the website for non-exempt wholesalers. Addressees were asked to check the box next to the name of any drug manufacturers for whom they act as a wholesaler for that company's drugs in Contra Costa County. Again, the list of drug

manufacturers was obtained from a list created and expanded upon by the Bay Area Counties that are farther along on the implementation of their own similar ordinances. The list contained 3,050 manufacturer names and addresses and again, there are many manufacturing companies with multiple addresses on the list. If a drug manufacturer was not listed, EH asked the respondent to add the additional names and addresses at the bottom of the fillable list. The respondents collectively selected 1,317 listed manufacturer names/addresses and collectively added 189 additional manufacturer names/addresses to the list.

At that point, EH had 1,506 manufacturer names/addresses that potentially need to comply with the Ordinance. To summarize, as of May 1, 2017, 95 wholesalers have responded indicating that they are exempt from the Ordinance and 60 have responded confirming that they wholesale drugs in Contra Costa County.

EH also pursued action towards those purported drug wholesalers that did not respond to the first letter. According to data published about the drug wholesale business, in 2015, three Pharmaceutical Wholesale companies accounted for 85 to 90 percent of all drug distribution revenues in the United States: Amerisource Bergen Corporation, Cardinal Health, Inc., and McKesson Corporation. Of those three large product wholesalers, only Cardinal Health had responded to our request for information at the time this report was drafted.

- In the February mailing, EH had sent a letter to each of the 21 locations for Amerisource Bergen that were on the list. None of them were returned as undeliverable. Interestingly, none of the addresses that were on the list were located in Valley Forge, Pennsylvania which is supposedly the headquarters for the company.
- In the February mailing, EH sent a letter to each of the 31 locations for McKesson that were on the list. None of them were returned as undeliverable. Again, none of the addresses that were on the list were in San Francisco, California which is supposedly the headquarters for the company.
- Additionally, there were several other key wholesalers that did not respond to the February mailing that should have, including Smith Drug, CuraScript Specialty, and BDI Pharma.

On May 8, 2017, EH issued Notice of Violations to Amerisource Bergen, McKesson, Smith Drug, CuraScript Specialty, and BDI Pharma. By the end of May, all five drug wholesalers provided the list of drug producers that they work with in the county. These five respondents collectively selected an additional 70 listed manufacturer names/addresses and collectively added 56 manufacturer names/addresses to the list.

To summarize, 1,632 drug producers will be contacted about their potential responsibility to participate in the County's safe drug take-back ordinance. In practical terms, this likely leaves several hundred small to mid-size wholesalers we have been unable to contact; however, collectively those wholesalers probably represent less than 1 percent of the drug wholesale market.

In early June, EH sent a correspondence to the list of 1,632 drug producers who appeared to manufacture covered drugs sold in Contra Costa County. This letter refers to the Ordinance and relevant time lines and advised them of the deadline to provide a notice of intent to participate in the Pharmaceutical Product

Stewardship Work Group (PPSWG) program¹ or a different stewardship program. The deadline is 6 months after the effective date of the Ordinance. By October 2017, they will need to provide the name and contact information for the stewardship program in which they will be participating.

As of September 7, 2017, EH received responses from 81 producer letter recipients and an email from Med-Project (see next paragraph). Of the 81 responses, eight responded that they would be participating by working with Med-Project. One producer indicated they would be submitting a plan, not participating with Med-Project. The other 72 responded in the following manner: 48 indicated they do not see drugs that are used in the home; 30 responded that they do not sell in Contra Costa County, and 31 chose the “Other” category and provided a text response. The text responses most often stated that they were a distributor and not a producer or that they produced medical product by not a drug.

On June 30, 2017, EH received an email from Med-Project letting us know the drug producers for whom they would be submitting a plan. The email had an attachment containing a list of 378 producers/addresses. Many of the producers that were submitted by Med-Project are on the list to whom letters were sent. EH has also been in contact with the Plan Director for MED-Project, based in Washington, D.C.

Currently, the Ordinance requires pharmaceutical producers to submit a written product stewardship plan to the County Health Officer that conforms to the requirements set forth in the Ordinance and to notify retail pharmacies and law enforcement agencies of the opportunity to participate as collection sites. These two steps should be completed by January 2018.

Opportunities to work with Hospitals:

A number of years ago, Contra Costa Regional Medical Center, in cooperation with the Contra Costa County Sheriff, established a drug disposal Kiosk near the Emergency Department at the hospital campus in Martinez. This site is associated with the Hospital inpatient pharmacy. CCRMC closed their outpatient/clinic pharmacies in 2006.

In addition, Kaiser Permanente hospital system has begun to establish drop off locations in several of their bay area locations as a pilot program. As Kaiser is a member-based health care organization, these locations would be intended to serve Kaiser Members versus the general public. However, this is an important

¹ A mechanism by which to contact and work with the wholesalers and drug manufacturers is via the PPSWG and MED-Project. PPSWG is a membership association for drug manufacturers and marketers. The group was formed to address the complexities and uncertainties of new laws that govern the disposal of unused and unwanted pharmaceutical products. PPSWG provides “members with a platform to organize and present science-based data about safe pharmaceutical disposal practices. PPSWG also coordinates the industry’s efforts to raise awareness about appropriate disposal methods, and to respond to disposal laws.” MED-Project is the name for the PPSWG’s activity on the drug take-back front. There is a website that they have developed to disseminate information about drug disposal, and they add information about each of the jurisdiction’s that have programs as implementation unfolds: <http://www.med-project.org/locations>

contribution as the Kaiser system is somewhat unique in that they direct their patients to their own internal pharmacy system versus out to retail pharmacies. It is our understanding that pilot programs have been established at Kaiser Antioch and Kaiser Vallejo as well as at least one location in Alameda County.

Sutter Delta does not currently have a collection bin on site for the disposal of unwanted medications or sharps. We have been informed that due to security and space issues that they are not able to consider being part of a stewardship program at this time. John Muir Health provides information on their web site regarding the safe disposal of unwanted medication at local law enforcement agencies and sanitation districts.

It may also be important to distinguish a hospital-based pharmacy as different, or not, from a retail pharmacy open to the general public. To the extent that a hospital or health care system related pharmacy is considered and operated as a retail pharmacy, it would appear to be included in the current Ordinance and could volunteer to be a disposal site under the larger product stewardship umbrella. Board of pharmacy rules allow hospitals and clinics with onsite pharmacies to maintain drug collection receptacles in their facilities. These too may fall under the umbrella of the current ordinance, but a bit more research needs to be done to make that determination.

Nature of the Drug Stewardship consortium:

The Ordinance currently allows drug producers to meet the Ordinance's drug disposal requirements by participating in a stewardship organization, which is an organization established to implement a program for collecting, transporting, and disposing unwanted drugs generated by County residents.

While staff was planning to introduce the Ordinance in 2016, representatives from the California Product Stewardship Council, as well as Sue Stevenson from the Dublin San Ramon Services District, requested that the County consider requiring stewardship organizations to be organized as a tax-exempt entity under Section 501(c)(3) of the Internal Revenue Code, versus allowing them to be organized as a tax-exempt entity under Section 501(c)(6) of the Internal Revenue Code. The Ordinance is silent on how stewardship organizations must be organized for tax purposes. In general, 501(c)(3)s are organized primarily for charitable, scientific, educational, religious, and certain other purposes, while 501(c)(6)s are business leagues or associations that are organized primarily to promote the common business interests of its members.

The concern expressed in 2016 was connected to the notion that if the stewardship organization was set up as a 501C6, the organization could more effectively act on behalf of the interest of the industry it represents than the public benefit it is intended to serve by lobbying and taking actions that are adversarial to the intention and implementation of the Ordinance.

The PPSWG is set up as a 501C6 member benefit organization. The members are primarily pharmaceutical manufacturers. MED-Project is established as a Limited Liability Organization working on behalf of the Product Stewardship Work Group.

It is unknown what, if any, impact this requirement might have on the implementation of the Ordinance in Contra Costa County or the growing number of counties that have already established a working relationship with Med-Project, the industries' product stewardship liaison organization. However, in speaking with staff

from other Counties that have adopted Safe Drug Disposal ordinances, they strongly endorse this concept but believe it may be better handled by the State, should the State adopt legislation in support of county efforts. It is recommended that this idea be studied more before any action is taken.

Including Sharps Disposal as a component of the Safe Drug Disposal Program:

State law prohibits the disposal of home-generated sharps medical waste into any container used for private or commercial collection of solid waste, recyclable materials, or green waste. Sharps must be placed in an approved container and disposed of at a waste management facility or an approved collection site, which could include pharmacies, hospitals, household hazardous waste facilities, police stations, fire stations, other public sites or an approved mail-back system. There are currently 26 sites in the county that have been identified as collecting home-generated sharps from the public, and eight available mail-back systems.

A report released in May 2017 by the California State Auditor found that the vast majority of Contra Costa residents live within a 20-minute drive of a sharps collection site. Eight mail-back programs have also been identified that are generally available to county residents. Some pharmaceutical manufacturers selling injectable medications also provide mail-back programs to users of their products.

The report also found that, because no agency has responsibility for coordinating collection of sharps, information in the state databases is infrequently updated and may contain inaccurate or outdated information concerning where to dispose of home-generated sharps. Similarly, because there isn't one agency responsible for coordinating sharps collection in Contra Costa County, information on websites belonging to various local agencies is not consistent either. CCHS will be reviewing information on its website to ensure accuracy.

In addition, the county has a long standing needle exchange program that addresses disease transmission among at-risk groups. Since 2013, the management of needle exchange services has been contracted out to HIV Education and Prevention Project of Alameda County (HEPPAC), which provides weekly services in West and East County. The agency exchanges an average of 250,000 needles per year through a one-for-one exchange model (one clean needle for one dirty needle).

There are a number of potential issues with embedding sharps disposal into the medication disposal program:

- The disposal receptacles for sharps should be kept separate from those for medications. This is due to the practical issue of the relatively higher cost and more rigorous handling and disposal requirement for medications vs. sharps. Sharps, once disposed of in an appropriate sealed container can be handled by a waste hauler or contractor for terminal disposal.
- If Sharps were to be included in the medication disposal program, pharmaceutical companies may seek to assure that they are not paying for the disposal of products manufactured by other entities. Hence, the County could seek to extend the product responsibility for the disposal of sharps onto those who produce those products.

- Aligning medication disposal with sharps under a common product stewardship organization may prove challenging, given that PPSWG and its implementation arm MED-Project are a collection of pharmaceutical manufacturers, not general medical product manufacturers.
- The justifications or findings that gave cause to assigning pharmaceutical producers extended producer responsibility for the life-cycle cost of their products are a bit different from that of sharps. While inappropriate disposal of sharps does present a potential public health threat, the level of threat, at this time, would be described as substantially less than for the inappropriate disposal of pharmaceuticals.

With respect to these potential challenges, several counties in the Bay Area have included or are considering including the disposal of sharps under their rubric of product stewardship initiatives. Santa Cruz has included sharps as a component of their drug stewardship ordinance. Alameda County has drafted a separate ordinance to address sharps disposal. Solano County is evaluating whether to include sharps as a component of their drug disposal ordinance versus drafting a separate ordinance. Santa Clara County just recently decided to pursue drafting a separate ordinance to address sharps. While study of this issue remains early, there appear to be some sensible reasons to address the two products in separate programs versus tying the two products together.

Opportunities to Work with Cities:

Numerous individuals, including Hedi Sandborn, Director of the California Product Stewardship Council and April Rovero, Founder and Executive Director of the National Coalition Against Prescription Drug Abuse and Chair of the Contra Costa MEDS (Medication Education and Disposal Safety) Coalition have advocated that the Ordinance be drafted in such a way that cities could participate without having to establish a separate product stewardship program for the safe disposal of unwanted medications. This idea is also favorable to staff. On April 13, 2017, the Public Health Director provided an overview to the Contra Costa Public Managers Association in regards to the scope of the morbidity and mortality associated with prescription drug misuse and the need for creating a system for the safe disposal of unwanted medications that often accumulate in households. The Ordinance was discussed as well as how other cities could participate. Interested cities were asked to contact the Public Health Division. To date, the City of Danville has expressed their interest in learning more and potentially participating in the County program.

In addition, in Dr. Underwood's annual Environmental Health Update letter to city mayors and managers, the new Ordinance was mentioned along with an invitation to participate. The cities of Clayton and San Pablo responded indicating they have some opportunities for drug disposal at their city police stations. EH will have ongoing communication with the cities to inform them of the Ordinance and the concept of product stewardship where the producers of covered drugs assume greater responsibility for the life-cycle cost of their products, specifically safe and effective disposal.

Public Awareness and Notifying Key Stakeholders:

The Ordinance requires the producers of covered drugs to provide written notice to all retail pharmacies located in the County and law enforcement agencies with jurisdiction in the County regarding the

opportunity to participate as collectors and to continue to do so, on an annual basis. The notice must explain the process for entering into an agreement to participate in the stewardship program. Contra Costa Health Services will also communicate with these key stakeholders to better inform them about the opportunity to participate as collectors.

Providing public notice of the availability of drug collection services through postings at collection sites and advertising in local media is also a required feature of the product stewardship plan that must be submitted by pharmaceutical producers.

Contra Costa Health Services maintains a web page with information for the public regarding the safe disposal of unwanted medications: <http://cchealth.org/safe-drug-disposal/>

In addition the California Product Stewardship Council maintains a web page of resources regarding the safe disposal of unwanted medications. The website is informative and includes packing instructions and a bin finder. <https://dontrushtoflush.org/>

Other related activity:

The U.S Drug Enforcement Administration (DEA) continues to sponsor their periodic drug take-back events, the most recent being held on Saturday April 29th, 2017 in several locations across the County.

Nationally with some 4,200 of its law enforcement and community partners this single nationwide event collected more unused prescription drugs than at any of the 12 previous National Prescription Drug-Take Back Day events. The Saturday, April 29, 2017, event brought in 900,386 pounds (450 tons) at close to 5,500 sites across the nation. Marking the 13th National Prescription Take-Back Day since September 2010, these events have altogether collected 8,103,363 pounds (4,052 tons) of prescription drugs. The DEA's next National Prescription Take-Back Day is Saturday, October 28, 2017.

In addition, Walgreens has taken the lead as the nation's first large retail pharmacy chain to establish a drug take-back program. From the program's inception in February 2016 to April 2017, the retailer installed disposal kiosks in more than 600 of their pharmacies located in 45 states. They collected 72 tons of unwanted medications. The Company prioritized their 24-hour stores and those stores with higher volumes of prescription drug sales for this initial rollout. The cost of the program, which is not insignificant, is borne by Walgreens directly, as their program is not affiliated with the PPSWG and MED-Project. It is important that we consider corporate efforts like these when establishing our local convenience standards for the number of drop-off locations to be established across the County. Walgreens has informed us that they are in support of their kiosk counting towards the Counties convenience standards for the number of drop-off sites, even if they are not a direct participant in the product stewardship organization. Walgreens has also made Naloxone available, without a prescription, in more than 7,600 of their stores.

Recently Rockland County, New York, joined the 13 counties, two cities, and two states that require pharmaceutical manufacturers to fund and manage drug take-back programs. This is the first jurisdiction on the East Coast to establish a pharmaceutical stewardship ordinance. Rockland's law is unique in that it

requires pharmacies to participate as collection locations, but only those chains with three or more U.S. stores. This provision will significantly increase the number of pharmacy collection locations in the County and provide greater convenience to residents.

On August 30, 2017, the Rite Aid Foundation announced the launch of its KidCents Safe Medication Disposal Program. The program aims to reduce drug accessibility, medication misuse, and accidental poisoning among children and adolescents. The initiative provides law enforcement agencies in communities served by Rite Aid with free medication disposal unit for individuals to safely dispose of unwanted or expired prescription and OTC medications. However, the initiative does not provide funding for terminal disposal of the medications. At present, more than 40 law enforcement agencies across the country participate in the KidCents Safe Medication Disposal Program, with 76 units available in 14 states. <http://tinyurl.com/ycd6lrs4>

Considerations for Proposed Amendments to the Program:

- In consideration of the opportunity to include cities, amend the convenience standards for the number of drop-off sites. The number of drop-off sites shall be no less than 1 per 20,000 residents or fraction thereof, accounting for both residents in the unincorporated County and any city or township that chooses to participate in this program. At no time shall there be less than 3 drop off-sites in each supervisorial district.
- Require the producer or their stewardship organization to make free mail-back services available to the general public and describe the methods and locations for doing so, and require the producer or their stewardship organization to describe how mail-back services will be made available to county residents who are disabled or homebound.
- Add hospital-based pharmacies to the list of preferred collectors, noting that serving as a collector remains entirely voluntary.

Next steps in implementation:

The current ordinance requires the producers, or the stewardship organization, to submit their stewardship plan for disposal of covered drugs by January of 2018. The producer is required to implement the plan by commencing operations within 90 days after the Health Officer's approval of the plan.

Attachment—Safe Drug Disposal Ordinance. No. 2016-24