

**From:** Billy Puk [cpuk@recology.com]  
**Sent:** Monday, August 16, 2010 1:21 PM  
**To:** Lucy, Burke; PharmaSharps  
**Subject:** comment on the Pharmaceutical Waste Programs in CA

To whom it may concern:

I greatly appreciated that CalRecycle has stepped up to draft a model program moving forward. To prevent any unintended consequences down the road, I have the following comments regarding to the CalRecycle Background Paper for July 20, 2010 Workshop. I will group them from general to specific to the section of this Background Paper.

**General:**

- 1) Who would define the performance goal to measure success? CalRecycle or private sectors? Or both? What are the potential performance goal?
- 2) What does CalRecycle's decision on prioritizing the 4 criteria (Safety (security), Accessibility, Cost Effectiveness, Efficacy)? Which of these four criteria should be the first, second, third, and last priority? Essentially, what is the ranking of these 4 criteria for CalRecycle to determine a model program?
  - a. Are these four criteria really essential to be a model program? What if some of the 4 criteria would be enough depending on where the program is developed and utilized?
  - b. How flexible CalRecycle is on this issue?
- 3) "Accessibility is a very subjective measure." Is there a boundary to draw to make this criterion to be objective? Like population density vs. total population vs. population per square mile? Or is this measurement really necessary tool when we are trying to develop a model program that would serve more than 80% of population in the big cities? Can CalRecycle develop a substitute criterion for that 20% of underserved population to meet the model program standard?
- 4) How would CalRecycle to draw a line between cost effectiveness and efficacy? Frequently, these two criteria come hand-in-hand. If the cost is not effective, efficacy would often be minimized.
- 5) What does the position of CalRecycle hold right now on the proper disposal (or treatment) of home-generated pharmaceutical wastes? What are the preferred options – incineration, landfill, recycling, resale, if only if the medication is not expired and the medicine is in the original packaging from the manufacturer?
- 6) Incineration sounds like one of the acceptable options that CalRecycle is inferring to as a proper disposal option based on the six model programs in the Paper because of most registered Medical Waste Transporters with CDPH currently would choose incineration over other methods of disposal. If so, why doesn't CalRecycle permit a medical waste incinerator in the State of California again? Or can California build a pharmaceutical waste-only incinerator? The funding for building a medical waste or pharmaceutical waste-only incinerator can be a joint effort between governmental bodies and private sectors. Generally speaking, hazardous waste incinerator, which meets all the criteria to be a medical waste incineration due to its capability to have even higher temperature treatment than medical waste incinerator, is harder to be permitted in the US where medical waste incinerator is relatively easier. However, the pharmaceutical waste-only incinerator has not been explored as far as my current

knowledge goes.

- a. Although there is a air and other environmental pollution concern, if we have a permitted medical waste incinerator in California, most of the pharmaceutical waste would be minimized to be diverted illegally through any mean of transportation. Chain of custody is shortened in both time and distance. Even with the DEA approved model on TakeAway Medicine Envelop program developed by Sharps Compliance, Inc., USPS has to deliver the envelops to the State of TX for incineration. Shorter distance travel to a treatment facility would dramatically reduce the cost of the program as well as minimizing the illegal diversion.
  - b. In addition to decrease accident and waste handling security probability, the trade-off advantage is that shorter distant travel to CA medical waste incinerator would cut down the carbon footprint due to interstate transportation, especially, crossing either deserts or mountain ranges.
- 7) From the Guideline, can CalRecycle be more specific on data collection and recordkeeping on the pharmaceutical waste that was collected, please? If packaging has to be eliminated on the sake of data collection of the pharmaceutical waste collected, such action would increase the chance of illegal diversion when staffing has to be increased to maintain the current check and balance status quo to meet the Guideline on Safety (or security). How would CalRecycle account for the packaging issue as whole in the recordkeeping? Should all future model pharmaceutical waste collection programs, assuming all collected pharmaceutical wastes have the packaging, use the recommended correction factor of 54% pharmaceuticals and 46% packaging as reference in this Paper?
- 8) How and which agency can Colorado State be granted federal funding to run its pilot program? If federal government can get involved, then why can't we as a State of California? This would solve much a problem on funding source issue.
- 9) Is CalRecycle going to apply for exemption or variance from USDOT-Pipeline & Hazardous Materials Safety Administration on behalf of the registered medical waste transporters on home-generated pharmaceutical wastes in general regardless the certain pharmaceuticals are under the governance of this federal agency to be considered as hazardous material, like chemotherapeutic drug? If not, the transportation services would lie on certain special DOT permitted transporters, which would significantly steer the market share towards those transporters for a total, one-stop shop service package, that undermines the competency of the market share and promotes monopoly.
- 10) How would CalRecycle handle (or does CalRecycle have a contingency plan for) financial mismanagement on any "Potential Option for further State Action"? As our current US economy is not as good as before, governments (for example, San Mateo County, City of Vallejo, etc.) and private pharmaceutical companies (for examples, Genentech, Chiron, etc.) have demonstrated their financial mismanagement that would lead to disastrous consequences. If we want our program to be a model, I would advise a sustainable check and balance system as State of California cannot print paper bill! To prevent any financial institution collapses that would impact the sustainable funding when CalRecycle and/or the manufacturers deposit the funding to such institution, can CalRecycle or State of California ask the Federal Reserve to secure a bond for our pharmaceutical waste program with product stewardship and sustainable funding from the manufacturers? This way CalRecycle or State of California would have already helped the nationwide push in developing a framework on product stewardship and sustainable funding for other type of products with the federal government involvement.
- 11) At last but not least, can California, as a state, to petition to federal government (i.e. DEA and FDA) to

apply for a variance as a statewide pilot program to collect all pharmaceutical wastes, including control substances, please?

**Specific:**

**HHW Facilities:**

- 1) As a model program in HHW facilities, since the permit for HHW facilities is governed by Permit-by-Rule (PBR), which has granted for one-year storage period, why does it not meet the criterion of "Permission to store longer than 90 days"? According to the Guideline on storage, "additional storage time may be obtained with prior written approval from the enforcement agency or the CDPH." Is DTSC considered enforcement agency in this case, which issues the PBR statewide?
  
- 2) Is there any legal reference from California and federal governments that the pharmaceutical waste cannot be treated when collected? Mixing coffee ground with pharmaceutical waste should be considered as on-site treatment. Therefore, why can't HHW minimize the cost by commingling the collected pharmaceutical waste into the poison waste stream to send off for destructive incineration, when there is no medical waste incinerator in California, to cut down the cost for the existing HHW program? Is security really important than cost effectiveness? HHW, legally speaking, becomes HW when HHW is sent off site for treatment disposal. HW has a more stringent rule on chain of custody as well as cradle-to-grave responsibility. The cradle-to-grave responsibility actually extends from first point of collection to the post-closure of a Treatment, Storage, and Disposal Facility (TSDF). So haven't we already have the framework to ensure the security of all HHW's in California? Why can't we incorporate the proposed pharmaceutical rule (or guideline) into the stringent HW rule instead of re-invent the wheel?
  - a. The other advantage of commingling pharmaceutical waste with poison is the elimination of CDPH registered medical waste transporter. This way the transportation market share would not fall only into this subset of HW transporters to do business with, in return to cut down the transportation cost as well as disposal cost, when the general HW transporters are already in a relatively saturated and competitive market. Generally speaking, when a container of waste is labeled poison, an average educated, normal person would not want to touch or to be nosy to open the containers to ensure the waste is actually poison unless you are working this field. Ultimately, the pharmaceutical wastes would surely be destructively incinerated at a even higher temperature when disposed through HW incineration.

**Law Enforcement:**

- 1) I always like the idea of law enforcement involved to meet the Control Substance Act. However, the involvement of law enforcement would sometimes impede CalRecycle desire target of collection rate. With the current state of economy, some agency might cut down its disposal cost budget to commingle the confiscated drugs, which may contain control substance, with voluntarily collected pharmaceutical wastes without control substances. The total collected waste pharmaceuticals may then be higher, which may fluctuate the total cost effectiveness (essentially, state targeted goal, if we have in the future) depending when the State would require the snapshot (reporting) of the law enforcement collection program and how much confiscated drugs are commingled.

**Pharmacies & Periodic/One-Day Collection Event:**

- 1) I speculate that if all pharmacies can meet the model program defined in the Guideline (only 5 out of 102 responded pharmacies are considered as model program in the Paper), there will definitely be a surge of lbs collected per site to show its efficacy like the Periodic/One-day collection events. Is there way that CalRecycle and/or Board of Pharmacy can do to guide the pharmacies to meet the Guideline?

If funding is the most hurdle for improvement, can CalRecycle and/or Board of Pharmacy come up with some grant money to assist individual pharmacies to promote the improvement?

**Mail-back:**

- 1) This program cannot be compared apple to apple from my point of view with other programs described in the Paper. The main reason is that this program would fail all 4 criteria defined by CalRecycle so far. Yes, DEA approves and trusts USPS employees to handle all pharmaceuticals (both virgin materials and waste) through the mail. Although Mail-back is using the DEA-approved USPS services, USPS actually contracts out to many third party transporters to do most of the transportation of mail in the United States. I really suspect USPS contractors even they are already granted by the Homeland Security and DOT clearance to work for the federal government. Although one may argue that the mail of pharmaceutical wastes compared to the total volume of regular mail is significantly low, and because the Mail-back envelopes are regular mail, the actual delivery time may vary or not even there. Have any of CalRecycle staffs lost something in the regular mail? Does it mean this program has a security flaw?
- 2) UPS and FedEx are doing similar delivery service business as well except for waste pharmaceuticals but with a better tracking system. However, UPS & FedEx are doing the same as USPS regarding to return pharmaceuticals. The analogy is that a consumer defines a mistaken delivered pharmaceuticals order as a waste, when the distributors or manufacturers mistakenly sent the wrong pharmaceuticals to this consumer. However, these pharmaceuticals are still considered as virgin materials to the distributors/manufacturers because the expired date is not due and the packaging is still intact. Keep in mind that most of the distributors/manufacturers would pay for the fastest and convenient delivery service back to their plant for this mistaken order of pharmaceuticals to be resale in the market. So does this analogy already set a precedence of breaking the rule of security but has already been practicing for quite some time in the free electronic commerce (e-commerce or online prescription order)?
- 3) Accessibility is hard to define when a person can even get a Mail-back envelope virtually any time after this person made a phone call and left a message to the Mail-back distributor, which is the procedure San Francisco is currently doing at least. A program coordinator will send a Mail-back envelope in the regular mail addressed to this person for his/her own pharmaceutical wastes.
- 4) Cost effective is hard to determine at this point as this is a relative infancy program.
- 5) A big drawback for the Mail-back program is that the whole program relies on the consumer to send the envelopes to the medical waste incinerator with unlimited time in possession of the envelope, which decreases the efficacy. So when the State requires a snapshot of this program, such program may not look as great. I do not foresee if there is any necessary reason for each consumer to mail the envelope back to the incinerator in a set time frame.
- 6) Packaging is also another major challenge. Does the State want to see the total weight capture in the future report, including all packaging like envelopes and aluminum foiled seal but contains no pill? Or use the same 54% pharmaceuticals conversion factor? Remember some liquid pharmaceuticals may have been evaporated during transportation due to temperature change.
- 7) At last but not least, the weight of collected waste is not at the point of collection (in the hands of USPS) but is at the end of life (in the hands of ultimate medical waste incinerator in TX). As a result, there is no way Mail-back data can use to compare with other programs when liquid and gas medications are potentially lost during transportation due to evaporation or slowly losing its pressure when gas expands, respectively.

In conclusion, I love the idea of Extended Product Responsibilities (EPR or product stewardship) to help in developing our statewide pharmaceutical waste take-back model. However, I hope that the incentive mentioned in Option 3 (Implement Product Stewardship) would not be through sale tax or other type of tax that would eventually benefit the producers but not the consumers. I wish that CalRecycle and CPSC can work together to develop a clear, strategic framework on such incentive. Like I mentioned earlier, if CalRecycle or State of California can get Federal Reserve to secure a bond program as a funding source under the umbrella of EPR, I'd speculate that our developed program would not easily be falling apart but a success.

Sincerely yours,

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