

January 25, 2011

Comments on CalRecycle Background Paper

Evaluation of Home-Generated Pharmaceutical Programs in California

Issued July 12, 2010

It is acknowledged that the staff at CalRecycle responsible for drafting this report has completed a difficult task that may represent the first evaluation of programs to take back home-generated pharmaceuticals in the country. They are commended for providing those of us involved in this field with a document to critique. Since this draft document will provide the foundational material for CalRecycle's report to the Legislature in December 2010, the following comments are offered to assist in the development of the final report to the Legislature.

1. Several parts of the report list CDPH-registered hauler as a guideline criteria. Specifically, Figures 5-8 display this requirement and the first paragraph on page 25 under the heading "Registered Waste Haulers & Disposal Facility Options" mentions that nine pharmacies used "mailback" boxes but that this method did not use a registered waste hauler. A review of the California Medical Waste Management Act will show that there is no requirement for home-generated pharmaceuticals to be transported by a CDPH-registered hauler. Unlike the home-generated sharps requirements in the Medical Waste Management Act that require CDPH-registered haulers be used to transport the sharps once they are consolidated; no such requirement exists for home-generated pharmaceutical wastes. This appears to be acknowledged on page 28 under the section: California Department of Public Health (CDPH), where it states that: "...CDPH does not have statutory authority to regulate home-generated pharmaceutical wastes. Instead, CDPH applies a best waste management policy consistent with current, existing waste collection models for home-generated pharmaceutical wastes." By making a registered hauler requirement in your guidelines and finding programs not to be in compliance when using common carriers; CalRecycle has joined with CDPH in creating an "underground" regulation that will most likely not stand up in court and may not be well received by the Legislature.
 - a. It is recommended that the requirement for a CDPH-registered hauler be removed from the evaluation criteria since the use of common carriers to transport home-generated pharmaceutical wastes is legal. This will require the document to be edited and the statistics adjusted to show that programs using common carriers are in compliance.
 - b. If CDPH-registered haulers are desired to transport home-generated pharmaceutical wastes, a recommendation for such a legislative remedy should be made to amend the California Medical Waste Management Act.
2. Section on Cost Effectiveness, page 16: Limitations; second and third paragraphs state that in many cases staff time was not tracked and provided. The mailback program uses very little staff time as the participant loads the mailback and mails it. This may show an unfair

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comparison when ranking programs on cost per pound. The report also states that the cost data varied significantly within the program types. Additionally, when analyzing the data on an average cost per pound it skirts the issue that getting the pharmaceuticals out of the medicine cabinet in the home and removing the temptation for diversion by teenagers outweighs any cost per pound. Using a \$3.65 mailback just might save the life of a teenager or the start of an addictive lifestyle.

- a. It is recommended that the cost calculations shown in the report for the mailback be reviewed with representatives from Sharps Compliance, Inc. so that an understanding of how the high costs per pound were determined and refined if necessary.
 - b. It is recommended that the cost effectiveness data and tables be removed from this section as the report indicates that the data varied significantly. By commenting about the findings without the comparisons might be better understood and accepted.
3. Option 2: States that the Legislature should direct CalRecycle or another state agency to develop regulations based on the guidelines...
- a. It is recommended that Option 2 be changed to state “The Legislature should introduce legislation to direct CalRecycle or another state agency to develop regulations. This would provide clear statutory authority for developing the regulations.
4. Options 3 and 4: These options focus on the pharmaceutical industry.
- a. It is recommended that the healthcare industry that writes the prescriptions and treats patients using pharmaceuticals; as well as the insurance providers be included in these options as they play a role as does the pharmaceutical manufacturers.

Comments submitted by Jack McGurk, President and CEO, Systems Improvement Initiators, Inc.