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July 26, 2010

Mr. Burke Lucy
CalRecycle
via e-mail

Subject: Comments on the Evaluation of Home-Generated Pharmaceutical Programs in California Background Paper issued on July 12, 2010.

Dear Mr. Lucy

Thank you for the opportunity to comment on the subject Background Paper. The SLO County IWMA has yet to implement a pharmaceutical collection program. We see the following as barriers to implementation of a program:

- Pharmacy collection program. A take back program at pharmacies cannot include controlled substances. This represents about 10% of all drugs but more importantly these are the drugs with the highest potential for abuse. In our opinion, to be effective a collection program must include controlled substances. Thus, at this time a pharmacy collection program by its self is not viable solution.

- Household hazardous waste facility collection program. We believe this is not a viable option for the same reason as a collection program at pharmacies. These programs cannot include controlled substances.

- Law enforcement collection. This is a viable option if the law enforcement organization is willing to participate. Historically this has been a barrier, but we are currently in discussion with our law enforcement agencies and we are hopeful that they may agree to serve as collection locations.

- Mail back. While mail back is an option, it appears that the mail back programs cannot accept controlled substances. In addition these programs are very costly compared to collection sites.

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- One day event. While a one day event with law enforcement present would allow for the collection of all drugs, this is not a sustainable solution. A one day event is not convenient for the public and is a stop gap measure until a permanent solution could be found.

- Finally, there is no regulatory prohibition to flushing drugs down the drain or putting them in a garbage container. Thus, unlike with sharps, there is no regulatory mandate driving a change in current practices.

Law enforcement collection. Given the above barriers and in particular the prohibition on collecting controlled substances, there is currently, in our opinion, only one viable option, law enforcement collection. For this option to be used, a law enforcement agency must be wiling to participate in a collection program, which may or may not occur. Another barrier is that under this option local government becomes financially responsible for the collection and disposal of unused drugs.

Pharmacy collection. If the Federal Government removes the restriction on pharmacies collecting controlled substances, then pharmacy collection becomes the preferred option. All the foreign programs referenced in the document, France, Portugal, Spain, Sweden and Canada, rely on return to local pharmacies. If pharmacies are not allowed to take back controlled substances, then an alterative would be to allow the mail back of controlled substances in combination with a pharmacy take back program for non-controlled substances.

Finally I would like to comment on the four options presented in the Background Paper. While these are shown as four discrete options, they should be revised into regulatory, program and financing options.

Regulatory Approach. The first category is the regulatory approach. This encompasses options 1 and 2 in the background paper. These are combined under regulatory approach because these options impact how you would implement options 3 and 4.

There are two questions which need to be addressed. The first question is, should the current guidelines be revised? The second question is, should the guidelines be converted into regulations?

With regard to the first question, when 95% of the participating pharmacies are not in compliance with the current guidelines, there appears to be a problem. A study could be done to determine if the guidelines are overly restrictive or are the existing pharmacies operating programs that compromise safety. Given that the foreign programs operate with much less stringent guidelines (for example in British Columbia the drug collection box has no locking mechanism), it would appear that the existing guidelines are too stringent. This is especially true when the pharmacies are only handling non-controlled substances.

With regard to the second question, ultimately the collector is responsible for the safe management of the drugs, thus guidelines seen to be adequate along with a general regulation which places the responsibility on the collector to properly manage the collected drugs.

Program and Financial Approach. Options 3 and 4 in the Background Paper address program and financing options. Which is the best approach depends on which collection options are available and implemented.

Without change in Federal Law to allow pharmacies to collect controlled substances or at least to allow mail back of controlled substances, the only collection option is law enforcement. This program should be funded with advanced disposal fees collected by CalRecycle and provided to local government. This would be similar to the used oil payment program. Local government could then use the money to fund law enforcement collection and the necessary public outreach.

If Federal Law is changed to allow pharmacies to collect controlled substances, then the preferred collection option would be pharmacies. The pharmacies could directly collect the drugs or could provide a mail back option to its customers. With a mandatory retail take back program it would become the responsibility of the pharmacies to implement and fund the program. Thus, government would have minimal involvement.

Thank you for the opportunity to comment on the Background Paper.

Sincerely,

William A. Worrell, P.E.
Manager