

Pharmaceutical Disposal Advisory Group Meeting #2

Date: February 26, 2010

Time: 9:00am – 12:30pm

Location: TCEQ Austin, Bldg F, RM 2210

Minutes

Sign-in took place from approximately 8:30am to 9:00.

TCEQ Study Team Staff in Attendance: Elston Johnson, Jessica Huybregts, Eric Beller, Angela Curry, Shannon Herriott, Jeff Horvath, Tom Harrigan, Daniel Ingersoll, Clyde Bohmfalk.

Total Attendees: A total of approximately 55 people attended in person (including TCEQ staff) and 24 people attended via LiveMeeting for a total of 79 participants.

See attached list of attendees (in person) and LiveMeeting participants.

Today's Powerpoint presentations will be available on the Pharmaceutical Disposal Advisory Group webpage by March 12:

http://www.tceq.state.tx.us/permitting/water_supply/pdw/pdagroup

Time (am) Event

9:06 Meeting called to order by Elston Johnson (hereby EJ).

9:08 Opening remarks and welcome by EJ. EJ asked people who were not present for the first meeting to introduce themselves, both onsite and LiveMeeting participants.

9:15 EJ displayed slides depicting a summary of the study goals. EJ displayed the agenda for today's meeting.

9:20 Presentation of Slideshow #1: Emerging Contaminants by Timothy Oden, United States Geological Survey.

9:42 Questions were asked of Timothy Oden as follows.

{Stakeholder in audience} asked a question about the presence of ECs in lined landfills compared to unlined.

Oden answered that according to preliminary information, similar compounds have been found in lined landfills both within the landfill and external to the landfill.

Selin Hoboy with Stericycle asked a question about a landfill study in Maine.

Oden answered that he is not familiar with this study but will do some checking. If USGS was involved, he can find the information.

{Stakeholder in audience} asked a question about testing active metabolites separately.

Oden answered that this is done by the USGS where possible.

Irina Cech, University of Texas School of Public Health asked a question about the need for blanks every fifth sample compared to every ten samples for pesticides.

Oden answered that this is done by the USGS due to issues with self contamination when testing for ECs.

9:50 Presentation of Slideshow #2: TCEQ Regulations Relating to Pharmaceutical Disposal in Texas, Part 1 by Eric Beller: Municipal Solid Waste Current Regulations and Waste Classification.

{Stakeholder in audience} asked a question about regulatory guidelines for pharmaceutical collections events.

Beller answered that currently there is no regulatory instrument to allow for non-hazardous waste collection. All waste from Household Hazardous Waste (HHW) collection must be handled as hazardous waste.

{Stakeholder in audience} asked a question about laws regarding controlled substances.

Beller answered that there are specific requirements for controlled substances. Some events have had law enforcement and pharmacists present. Jessica Huybregts stated she will address controlled substances in the next presentation.

Charlotte Smith from PharmEcology indicated that only a small percentage of pharmaceuticals are controlled substances (approximately 10%).

{Stakeholder on LiveMeeting} asked a question about guidance for municipalities and law enforcement that have pharmaceutical collection events.

Beller answered that he does not know of current written guidance. TCEQ Small Business and Environmental Assistance Division handles HHW events. Shannon Herriott added that household hazardous waste collection guidance is available, that pharmaceuticals can be collected and would be added to the HHW notification paperwork. However, if

pharmaceuticals are collected at an HHW event all other regulations must be met, including for controlled substances.

10:05 Presentation of Slideshow #2: Regulations Relating to Pharmaceutical Disposal in Texas, Part 2 by Jessica Huybregts (hereby JH): Non-Waste Regulations both state and federal. JH asked for input from stakeholders regarding this subject.

10:20 Questions were asked of JH as follows.

Selin Hoboy with Stericycle asked a question about prohibition for pharmacies to take back drugs from the public.

JH answered that this is not a TCEQ rule. Charlotte Smith with PharmEcology added that a consultant pharmacist can dispose of drugs from an assisted living facility but cannot remove them.

Gay Dodson, Texas State Board of Pharmacy added that reverse distribution is used at nursing homes. Pharmacies cannot accept drugs back for resale.

{Stakeholder in audience} added that rules were changed to allow disposal into waste containers for incineration by contract.

Ken Diehl with San Antonio Water System (SAWS) asked a question about the status of proposed federal regulations, HB 1191 and 1359 that may amend the controlled substances act.

JH answered that we will base the study on what is applicable now. Selin Hoboy added that the bills are probably two years from being considered.

10:22 JH presented an update on the questionnaires.

There are now a total of 12 questionnaires, one each for 12 groups. The questionnaires have been reviewed by volunteers in each group. The TCEQ is now considering the edits and the questionnaires will be sent out again to the original reviewers for final (second) review. The TCEQ is focusing on getting the correct questions. The survey will be on Survey Monkey and the link will be provided to Advisory Group members to forward on to appropriate parties.

10:30 Break

10:51 Return from Break

10:52 EJ introduced the break-out discussion groups to discuss disposal methods. Questions have been prepared for each group to answer and present to the advisory group. JH discussed details of participation in the groups, or

forming a group on the side for academics. JH introduced the groups and the associated TCEQ study team members.

The meeting participants gathered in the following 12 groups with TCEQ facilitators shown following:

- Group 1: Health-care Providers: Jessica Huybregts
- Group 2: Veterinary Providers: Jeff Horvath
- Group 3: Pharmacies/Pharmacists: Shannon Herriott
- Group 4: Waste Management/Disposal Operators: Eric Beller
- Group 5: Pharmaceutical Manufacturers: Daniel Ingersoll
- Group 6: Ranchers/Farmers: Clyde Bohmfalk
- Group 7: End Users/Consumers: Angela Curry
- Group 8: In-Home Care Providers: Angela Curry
- Group 9: Water and Wastewater Utilities: Elston Johnson
- Group 10: Local Governments (incl. COGs): Thomas Harrigan
- Group 11: Law Enforcement: Thomas Harrigan
- Group 12: Educational/Research Institutions: Clyde Bohmfalk

The questions provided in writing to each group for discussion are as follows.

Group 1: Health-care Providers

1. Most common types of unused pharmaceuticals waste in your profession (e.g. controlled, hazardous, non-hazardous non controlled, bulk chemotherapy, for non-controlled pharmaceuticals: prescription vs over the counter)
2. Top 3 most common methods of disposing of unused pharmaceuticals
3. Top 3 Advantages of the current disposal methods used
4. Top 3 Constraints/disadvantages of the current disposal methods used
5. What is the one take-home comment about unused pharmaceutical disposal in your profession?
6. If you have time, you can discuss the questionnaire or other topics related to current methods for disposing of unused pharmaceuticals. (eg. gaps in the rules, who education needs to focus on)

Group 2: Veterinary Providers

1. Most common types of unused pharmaceuticals waste in your profession (e.g. controlled, hazardous, non-hazardous non controlled, bulk chemotherapy, for non-controlled pharmaceuticals: prescription vs over the counter)
2. Top 3 most common methods of disposing of unused pharmaceuticals
3. Top 3 Advantages of the current disposal methods used
4. Top 3 Constraints/disadvantages of the current disposal methods used
5. What is the one take-home comment about unused pharmaceutical disposal in your profession?
6. If you have time, you can discuss the questionnaire or other topics related to current methods for disposing of unused pharmaceuticals. (eg. gaps in the rules, who education needs to focus on)

Group 3: Pharmacies/Pharmacists

1. Most common types of unused pharmaceuticals waste in your profession (e.g. controlled, hazardous, non-hazardous non controlled, bulk chemotherapy, for non-controlled pharmaceuticals: prescription vs over the counter)
2. Top 3 most common methods of disposing of the unused pharmaceuticals
3. Top 3 Advantages of the current disposal methods used (or what is allowed under the rules)
4. Top 3 Constraints/disadvantages of the current disposal methods used (or what is allowed under the rules)
5. What is the one take-home comment about unused pharmaceutical disposal in your profession?
6. If you have time, you can discuss the questionnaire or other topics related to current methods for disposing of unused pharmaceuticals.

Group 4: Waste Management/Disposal Operators

1. How do you usually dispose of/destroy unused pharmaceuticals collected?
2. Do you receive unsolicited returns of unused pharmaceuticals?
 - (a) If so, from what kinds of entities?
 - (b) What do you do with them?
3. Top 3 advantages/benefits from your perspective for how unused pharmaceuticals are currently handled and disposed of.
4. Top 3 limitations/issues from your perspective for how unused pharmaceuticals are currently handled and disposed of.
5. What is the one take-home comment about unused pharmaceutical disposal in your profession?
6. If you have time, you can discuss the questionnaire or other topics related to current methods for disposing of unused pharmaceuticals.

Group 5: Pharmaceutical Manufacturers

1. Most common types of unused pharmaceuticals waste in your profession (e.g. controlled, hazardous, non-hazardous non controlled, bulk chemotherapy, for non-controlled pharmaceuticals: prescription vs over the counter)
2. Top 3 most common methods of disposing of unused pharmaceuticals
3. Top 3 Advantages of the current disposal methods used
4. Top 3 Constraints/disadvantages of the current disposal methods used
5. What is the one take-home comment about unused pharmaceutical disposal in your profession?
6. If you have time, you can discuss the questionnaire or other topics related to current methods for disposing of unused pharmaceuticals.

Group 6: Ranchers/Farmers

1. Most common types of unused pharmaceuticals waste in your profession (e.g. controlled, hazardous, non-hazardous non controlled, bulk chemotherapy, for non-controlled pharmaceuticals: prescription vs over the counter)
2. Top 3 most common methods of disposing of unused pharmaceuticals

3. Top 3 Advantages of the current disposal methods used
4. Top 3 Constraints/disadvantages of the current disposal methods used
5. What is the one take-home comment about unused pharmaceutical disposal in your profession?
6. If you have time, you can discuss the questionnaire or other topics related to current methods for disposing of unused pharmaceuticals.

Group 7: Consumers

1. Top 2 most common methods of disposing of unused pharmaceuticals (in order)
2. Top 3 perceived advantages of the current disposal methods used
3. Top 3 perceived constraints/disadvantages of the current disposal methods used
4. What is the one take-home comment about unused pharmaceutical disposal?
5. If you have time, you can discuss the questionnaire or other topics related to current methods for disposing of unused pharmaceuticals.

Group 8: In-Home Care Providers

1. Most common types of unused pharmaceuticals waste in your profession (e.g. controlled, hazardous, non-hazardous non controlled, bulk chemotherapy, for non-controlled pharmaceuticals: prescription vs over the counter)
2. Top 3 most common methods of disposing of unused pharmaceuticals
3. Top 3 Advantages of the current disposal methods used
4. Top 3 Constraints/disadvantages of the current disposal methods used
5. What is the one take-home comment about unused pharmaceutical disposal in your profession?
6. If you have time, you can discuss the questionnaire or other topics related to current methods for disposing of unused pharmaceuticals.

Group 9: Water and Wastewater Utilities

1. What is the experience of Texas utilities in trying to identify PPCPs in their drinking water or wastewater? (max of 5 bullet points)
2. What public education initiatives have already been tried by Texas utilities? (3 bullet points)
3. Have any TX utilities hosted a pharmaceutical collection event? If so, why did you choose to conduct this event? (3 bullet points)
4. What is your one take-home comment about the general topic of unused pharmaceutical disposal?
5. If you have time, you can discuss the questionnaire or other topics related to current methods for disposing of unused pharmaceuticals.

Group 10: Local Governments

1. If you collect pharmaceuticals:
 - a. How do you collect pharmaceutical waste? (eg. pharm-only events, with HHW...)
 - b. Most common types of unused pharmaceutical waste collected

- c. Most common methods of disposal
 - d. Advantages of the current disposal methods used (5 bullet points)
 - e. Constraints/disadvantages of the current disposal methods used (5 bullet points)
2. If you do not collect pharmaceuticals, what are the reasons for not collecting them? (5 bullet points)
 3. Perceived benefits of pharmaceutical collection to your local/regional government?
 4. Perceived issues with collecting pharmaceuticals by your local/regional government?
 5. If you have time, you can discuss the questionnaire or other topics related to current methods for disposing of unused pharmaceuticals.

Group 11: Law Enforcement

1. How are controlled pharmaceuticals that you seize/posses usually disposed of by your profession?
2. For other pharmaceuticals you come across that may not be controlled substances, what do you do with them?
3. Top 3 Advantages of the current disposal methods used (or advantages of your SOP for how to deal with seized pharmaceuticals)
4. Top 3 Constraints/disadvantages of the current disposal methods used (or disadvantages of your SOP for how to deal with seized pharmaceuticals)
5. Have you ever participated, or been asked to participate, in a pharmaceutical collection event?
6. What is the one take-home comment about unused pharmaceutical disposal in your profession?

Group 12: Educational Institutions (who don't dispose of pharmaceuticals)

1. Top 3 data gaps (if required, this could be on the generalized topic of pharmaceuticals, not necessarily disposal)
2. Top 3 considerations when assessing the effect of disposal practices on public health?
3. Top 3 considerations when assessing the effect of disposal practices on the environment?
4. If you have time, you can discuss other topics related to current methods for disposing of unused pharmaceuticals, or other issues you deem important in this study.

11:35 JH announced the conclusion of the discussion group time and short presentations were made by each group as follows.

Group 1: Health-care Providers: Jessica Huybregts, TCEQ

Dorothy Crawford and Ed Gruber represented long-term care facilities, Rod Hicks represented nurses, and Matt Wall represented hospitals.

Hospitals: All pharmaceuticals in a hospital fall under the Pharmacy rules. See 21 TAC 133.41. A hospital will hold a Class C Pharmacy license.

The most common types of unused pharmaceuticals in a health-care provider setting: Expired drugs in a hospital can be returned to the wholesaler. Unused unexpired pharmaceuticals will be either solid dose non-administered drugs (e.g. half of a solid pill), non-administered or partially used liquids (e.g. pre-manufactured syringes or leftover fluids in pre-filled IV bags), or leftover topicals. From a nurse's perspective, partially used fluids are the most common pharmaceutical requiring disposal, followed by unused solid doses. The fluids will usually be disposed of down the drain while the unused solid doses will be disposed of in the red-bag (medical/biohazard waste). The red-bags are convenient and accessible. For long-term care facilities, the most common type of unused pharmaceuticals requiring disposal are unused solid dosages (~90% of these are prescription/dangerous drugs, ~10% are controlled substances). These solid doses go unused mainly because they are discontinued, but also result when the patient dies or is discharged from the facility. For clinics (private physician offices), expired professional samples will usually be taken back by the vendor when they next visit. At clinics, unused pharmaceuticals may be solid or unused liquid. These will usually be disposed of in a biohazard box/red-bag and will be taken away for disposal by a waste management service, or may be transferred to another facility for later disposal. Unused liquids in clinics may be flushed down the drain.

Main advantage of the current methods of disposal: primarily, standardization and convenience are the most important advantages of using red-bag disposal (disposal as medical waste, treating all as medical waste and not segregating anything else). It means the nurse doesn't need to think about what to do with every medication leftover except to dispose of it in the red-bag.

Main disadvantages of the current methods of disposal: treating everything as medical waste is expensive, and when you collect medications at a central location there's always the potential for drug diversion.

One take-home comment: Regulations are fragmented. There needs to be some standardization among the professions and within the regulations.

Group 2: Veterinary Providers: Jeff Horvath, TCEQ

The most common types of unused pharmaceuticals are controlled, non-hazardous non-controlled and prescription. The three most common methods of disposal are incineration, trash, or disposal as medical hazardous waste. The advantages of these methods are ease of use and to meet current legal requirements. There were no constraints or disadvantages with these methods. The one take home comment was that the group wanted to avoid any additional costs associated with pharmaceutical disposal.

Group 3: Pharmacies/Pharmacists: Shannon Herriott, TCEQ

Goal of pharmacies is to have no unused pharmaceuticals, so no particular type is most common. Top three disposal methods are reverse distribution, contract for collection and disposal, and send back to warehouses for chain pharmacies.

Advantage to reverse distribution is that it is an established system that works well. Constraint is the cost and paperwork. Take home comments are 1)the cost of disposal is high and adding additional costs would be problematic and 2)pharmacies have a system to prevent unused pharmaceuticals from entering wastewater, but once they are dispensed to consumers, they have no control over disposal, but would like to have more resources to offer consumers.

Group 4: Waste Management/Disposal Operators: Eric Beller, TCEQ

Most pharmaceuticals that are segregated are going to incineration, but not all incinerators are the same. Red bagged pharmaceuticals may go to autoclave/landfill. Encapsulating in concrete was tried, but not successful. Take back or other programs for consumers need to be convenient, multiple options would be good.

Group 5: Pharmaceutical Manufacturers: Daniel Ingersoll, TCEQ

Pharmaceutical manufacturers could not speak to disposal methods since it is not within their area of expertise. Some manufacturers present do not have facilities in Texas. There may be some problems with online survey, some benefits to having written survey. The public information act should be considered in the survey.

Group 6: Ranchers/Farmers: Ben Weinheimer, Texas Cattle Feeders Association

Common types are prescription and over the counter pharmaceuticals, with small quantities remaining unused. Disposal methods are commercial waste services and local municipal landfills. These methods are convenient, acceptable and remove the waste from the end user. Constraints include not uniform requirements, need to red bag waste, cost of service and availability in rural areas. Take home comments are that the farm and ranch group has a small amount of unused pharmaceuticals, mostly dispensed in quantities as needed and/or by veterinarians. Products are usually fully used. Over the counter products are purchased in amounts needed due to cost considerations.

Group 7: End Users/Consumers: Angela Curry, TCEQ

Common disposal includes trash and sewerage. Advantages are easy, accessible, low cost, can maintain control over labels and information. Constraints are possible safety issues with availability in trash, impacts of flushing on environment. Take home comment is lack of information on recommended disposal practices with pharmaceuticals.

Group 8: In-Home Care Providers: Angela Curry, TCEQ

Two categories: hospice and in-home care.

Hospice: Common types are controlled substances, non-controlled and non-hazardous.

In-home: non-controlled, non-hazardous, controlled.

Advantages of current disposal:

Hospice: responsible for assisting with disposal

In home: not responsible for assisting with disposal, information is provided (FDA,EPA)

Disadvantages of current disposal:

Hospice: Must follow EPA and federal guidelines,

Rachel Hammon, Texas Association for Home Care & Hospice added:

In-home care providers: Provide information to the care recipients, but not responsible for disposal.

Take home comments:

System is fragmented, barriers faced when returning pharmaceuticals to pharmacies.

Group 9: Water and Wastewater Utilities: Carol Batterton, Water

Environment Association of Texas/Texas Association of Clean Water Agencies

Some utilities have conducted sampling of raw and treated water and wastewater, some share data and some are reluctant to share information. WW utilities with pretreatment program often have industrial discharger sampling data. Some utilities have web site info and public information flyers, but the message is not clear regarding disposal options. The group expressed concern regarding public education to convey the pharmaceutical disposal issue as safety/prevention of abuse issue instead of environmental/public health issue since that is not yet known. Two utilities have hosted collection events for pharmaceuticals (City of Arlington and SAWS), and they partnered with local law enforcement. Events were expensive and funding was an issue. The take home comments are that a simplified clearly defined process is needed, and a source of funding. Small utilities will have a difficult time having pharmaceutical collection events.

Group 10: Local Governments: Kelly Freeman, Capital Area Council of Governments

Pharmaceuticals are collected at HHW events by local governments, not advertised; and by seizures of pharmaceuticals at the Dept of Health. Most common types of unused pharmaceuticals are largely unknown, birth control, pain meds, unknown expensive drugs, biologics, cancer meds and unknowns. Most common disposal is by incineration, drums w/toxics, drums with bulk flammable materials and landfill. Advantages of these methods are low expense, easy and convenient. Disadvantage is that may not meet current state and federal rules or pharmacy rules, which are not always clear. Reasons for not collecting are legal issues not clear, who can manage materials, unclear guidance, lack of support from manufacturers. Benefits of collection are getting them out of the waste stream and the environment, diversion to those who can use them, public demand for disposal options, poison control, prevention of illegal distribution and safety. Perceived issues are unclear rules, difficult to serve a large population, need to engage law enforcement, burdensome and unclear documentation requirements, confidentiality of medical information, funding issues, need to train staff and volunteers, difficult to get support of elected

officials, need for interagency cooperation to resolve conflicting guidance, and lack of manufacturer support of collection efforts.

Group 11: Law Enforcement: Pat Johnson, Texas Department of Public Safety

The DPS has 13 crime labs and 12 incinerators. All DPS drug seizures are sent to a crime lab for ultimate disposal. The labs also receive drug evidence from cities, counties and other agencies, but they are returned to those agencies. The DPS handles relatively small quantities of pharmaceuticals compared to marijuana, cocaine and methamphetamines. DPS incinerators are dual chambered gas fired type and are permitted by the TCEQ for air permits. They burn all the seized marijuana and some cocaine, heroin and methamphetamines, but are not allowed to incinerate pharmaceuticals. DPS would like to be able to incinerate pharmaceuticals at its incinerators. Over the years the pharmaceuticals have been sewered by the DPS, but less is done now. Constraints include air permitting for incinerators. Not aware of any DPS pharmaceutical collection events.

Group 12: Research Institutions: George Maxey, University of North Texas

1: Regarding data gaps

Educators are interested in the activity of each group. Biggest problem are the laws regarding pharmaceutical disposal, not sure what they are. Are human and vet pharmaceutical interactions in the water a risk to aquatic life and human health? Will take back programs reduce risks? What is the data? Need clearinghouse for all of the available data. Would like to see GIS systems used for data analysis. Would like to look at modern and older methods of pharmaceutical detection. How can education programs be used in different areas?

2: Regarding the effects of disposal practices on public health

What metrics will be used to determine effects of take back programs? Need for more data. Would like data from stakeholder groups. Need to identify key pharmaceuticals and problems that must be addressed. What are the real issues? This requires more study. What are the effects on morbidity and mortality? Do they contribute to chronic diseases such as cancer, diabetes, heart disease, neurological diseases, birth defects?

3. Regarding the effects of disposal practices on the environment

What pharmaceuticals should be monitored? What biological indicators should be used in the field and lab? What are indicators within a watershed? What are effects on water quality and soils? What are the effects of plant uptake in the food chain on milk and meat for example? Need research programs and collaboration. Budget concerns are an issue. Can biodegradable pharmaceuticals be produced?

Added by Irina Cech, University of Texas School of Public Health:

Researchers have tools to use data without revealing the source and this is a common practice in the public health field. Need a public education component. Funds are needed for research.

12:30 EJ asked all attendees for any final questions or points of discussion they would like to offer. No questions/comments were received.

Jack Ranney, LCRA, asked about the timeline for the final questionnaires. JH answered that the TCEQ study team will edit the first draft and send out for a second review prior to finalizing the questionnaires. TCEQ requests comments on the first draft by March 5. Each group has multiple reviewers.

12:35 Closing Remarks.

EJ thanked all for their attendance. The next meeting is scheduled for March 24th at TCEQ offices. Agenda minutes will be posted on the web site by March 12.

12:36 Adjourn

*Minutes offered for review 3/2/2010 (changes due by 4.30pm 3/10/2010)
Minutes finalized 3/11/2010.*