

Pharmaceutical Disposal Advisory Group Meeting #3

Date: March 24, 2010

Time: 9:00am – 12:30pm

Location: TCEQ Austin, Bldg E, RM 201S

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.

Today's Powerpoint presentations will be available on the Pharmaceutical Disposal Advisory Group webpage by April 7:

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

Total Attendees: A total of approximately 49 people attended in person (including TCEQ staff) and 33 people attended via LiveMeeting for a total of 82 participants.

See list of attendees (in person and LiveMeeting participants) is located on the webpage listed above.

Time (am) Event

9:02 Meeting called to order by Elston Johnson (hereby EJ).

9:03 Opening remarks and welcome by EJ. EJ presented slides with meeting information for those present and for LiveMeeting participants. EJ presented a slide with the agenda for today's meeting.

9:06 Introductions were made by each participant, both onsite and LiveMeeting.

9:12 Jessica Huybregts (hereby JH) presented a slide with SB1757 objectives. JH then presented slides about terminology used including pharmaceuticals, drugs, dangerous drugs, active pharmaceutical ingredients (API), controlled substances, hazardous waste, unwanted/unneeded, waste, disposal, processing, wastewater treatment plants (WWTPs) and publicly owned treatment works (POTW). JH asked the participants for any other terms that need to be included. No other terms were discussed.

9:20 JH began discussion of current methods of disposing of unused pharmaceuticals. Slides were presented to introduce possible topics such as

long-term care (LTC) facilities, reverse distribution, differences in rural vs urban areas, autoclave use, rules, changes, success measures, concerns, drug distribution, data availability, education strategies, labeling/sorting and costs.

9:24 Rodney Bias (Inmar – Reverse Logistics) gave a presentation regarding reverse distribution in health care and at pharmacies. Reverse distributors (RDs) typically act as an agent for the manufacturer or as agent for pharmacies. The unused drugs can go from one agent to another agent if they are permitted. If one RD doesn't represent a specific manufacturer, they may transfer the unused drugs to another RD that does represent that manufacturer. They will either take pharmaceuticals to manufacturing location, or take them for disposal (incineration or hazardous waste incineration). Inmar does not handle unused drugs in LTC facilities, but each RD is different. RDs are not waste handlers, but are generators, so only take products that have return value; they don't take wastes. Pharmacies generally have unused/unprescribed pharmaceuticals. Inmar processes approximately 20 million unused pharmaceutical products per year, mostly from pharmacies (not hospitals).

Selin Hoboy (Stericycle, Inc.) commented that they are seeing more reverse distribution as a disposal option. Waste should be identified as such (for disposal or for reverse distribution). Identifying what is waste for disposal or a returnable good is a time intensive process. Reverse distributors must have a permit to accept waste if taking anything other than returnables. Major carriers such as UPS and FedEx won't carry hazardous wastes.

Rodney Bias said that Minnesota defines all expired products as waste and Florida defines pharmaceuticals as universal waste with reduced burden.

{Stakeholder in audience} asked a question about who pays for reverse distribution.

Rodney Bias answered that retailer or manufacturer pay for the services that they receive.

JH asked what pharmacies think about reverse distribution, what kinds of drugs would actually be able to be returned (aside from expired drugs), and what manufacturers do with returned pharmaceuticals.

Rodney Bias commented that the main types of returned drugs are short dated, expired, recalled and contaminated pharmaceuticals.

Leslie Wood (Pharmaceutical Research and Manufacturers of America - PHRMA) commented that state laws are strict about what reverse distributors can do; once dispensed, pharmaceuticals can't be taken back by a reverse distributor. Reverse distributors can't have a roll in consumer waste. Suggest looking at state laws in Texas to help guide the process.

9:36 JH asked for comments regarding LTC facilities in Texas.

Kim Roberson (Texas Pharmacy Association) commented that LTC facilities formerly used bio-hazard waste collection for everything, including pharmaceuticals, but now many separate drugs, package them and send them to a waste management company for disposal by incineration. Bio-hazardous materials are then handled separately. Nursing staff and consulting pharmacist put the drugs in the box for disposal.

Beth Skelton (Department of Aging and Disability Services) commented that they regulate LTC facilities but are not involved in day to day operations. Assisted living (AL) facilities are different from LTC. Assisted living facilities may have some difficulties with regulations. Unused/unwanted drugs must be disposed of by a pharmacist, but ALs are not required to have a pharmacist as a consultant. It is difficult to get one to come in for that purpose. Most use waste management service or render unusable and dispose of pharmaceuticals in the trash. Nursing facilities are required to have a consulting pharmacist so drug destruction can be done, but controlled substances are a problem, and they tend to collect on site since handling is a problem. Waste management companies won't take the controlled substances because they have already been dispensed to consumers.

Selin Hoboy commented that until pending federal legislation moves, disposal will be a problem for LTC facilities since no one can take dispensed controlled substances. They are watching this issue in Washington DC.

Jeff Jacoby (Texas Campaign for the Environment - telephone) asked why pharmaceutical take back is a problem.

Selin Hoboy answered that it is because of the controlled substance issues.

William Anderson (Curbside - telephone) commented that home generated waste can be collected if they take only non-controlled substances; controlled are not supposed to be collected at these drop box facilities. Curbside collects unused drugs in a locked box and destroy drugs on site. They advertise that they can not accept controlled substances and provide a list of controlled substances at the drop box. However it is possible that controlled substances may be included but Curbside isn't knowingly in possession of controlled substances. Even if they are collected they are destroyed on site and then disposed of.

9:45 JH asked for comments regarding rural vs. urban issues.

Dr. John Carlo (Texas Medical Association - telephone) commented that for health care providers it is more a factor of size and type of practice than rural or urban.

Tony Bennett (AECOM) commented that the previous speaker's controlled substances collection procedures sounds like doing something that you can't do and he would like clarification on that.

JH commented that the controlled substances act says that you can't knowingly possess controlled substances that were prescribed to someone else. The collection events are advertised as for non-controlled substances and include a list of controlled substances on the box.

William Anderson commented that there is no way to determine if controlled substances are in the box as no one goes through the collected pharmaceuticals before they are ground up on site, and they then go to a hazardous waste incinerator for disposal. The key is to not knowingly be in possession of controlled substances. The DEA generally says that if you try to prevent collection of controlled substances (that is, if you advertise the list of controlled substances and you advertise that you can't accept them), that is all you can do at this point.

Tony Bennett commented that this seems to be a plausible deniability stance and asked if there is an AG opinion in Texas regarding this.

William Anderson commented that it would be good to have that and it depends on which DEA office is consulted.

JH commented that we will talk more about this subject in future meetings and will attempt to contact DEA and the AG on this topic.

Selin Hoboy commented that if talking to the state DEA, be sure to have them talk to Federal DEA also since there have been issues with different opinions from the various DEA offices.

JH asked for comments regarding autoclave practices, which use pressure and heat to disinfect.

Keith McLeroy (Texas Engineering Extension Service) commented that for rural areas, the problem is a lack of information among consumers. It is common to flush pharmaceuticals, or take them back to the only pharmacy in town.

Keith McLeroy commented that autoclaving is not a good practice since it does not destroy pharmaceuticals.

JH commented that the advantage of autoclaving is that waste does not have to be sorted.

Kristina Mena (UT Public Health – telephone) commented that it is difficult to retrieve treated waste after autoclaving. Many compounds are not affected by autoclaving. Technologies are being developed to treat medical waste on site.

Selin Hoboy commented that autoclaving is not a preferred method for destruction of pharmaceuticals, and is really for bio-hazardous waste. There is a move towards separation of pharmaceuticals for disposal by incineration. More education is needed for separation of pharmaceuticals from medical waste. The old way of combining these wastes is convenient and health care providers are busy. Autoclave temperatures are too low to work well for many pharmaceuticals.

JH asked about keeping non-hazardous pharmaceuticals with medical waste and using the autoclave, then to landfill for disposal. Is this any different than sending non-hazardous pharmaceuticals directly to the landfill?

Selin Hoboy answered that there will still be potential issues in the environment with treatment of non-hazardous waste in an autoclave. Autoclaving is a wet process so there will be a wastewater discharge as a result. So autoclaves will do nothing to the pharmaceuticals except transfer some of the product into the wastewater. Most facilities send their waste to a landfill, then there may be potential landfill leachate issues.

10:00 JH asked for comment regarding rules, changes and what is considered a successful approach to disposing of unused pharmaceuticals.

Rose Dunaway (Texas Association for Home Care and Hospice) commented that the cost to separate out pharmaceuticals from biohazard bag is a factor; it will take more labor and time.

William Anderson asked if pharmacies can handle waste from consumers in Texas.

Jeanie Jaramillo (Texas Panhandle Poison Center) answered that there are regulations in Texas within the Texas Administrative Code that pharmacies can take back pharmaceuticals, and must destroy on site, with record keeping, but they can't accept controlled substances in accordance with current Federal rules. Some pharmacists refuse to accept dispensed pharmaceuticals, some put in sharps container and some use reverse distributors.

JH presented a slide from the previous meeting regarding State Board of Pharmacy Rules.

Jeanie Jaramillo commented that pharmacies are not the best place to destroy medications. If a waste management company could take care of these items it would be a better option.

JH asked for any other comments.

Matt Wall (Texas Hospitals Association) commented that costs must be considered when making rules; both disposal costs and resources usage. Matt also commented that the problem in rural areas is access to resources, not lack of knowledge, when referring to pharmacists.

Kristina Mena (UT Health Science Center) commented that there is a safety concern for workers that handle waste, and that human behavior is an issue that should be considered.

Andrea McNair (University of Texas System) commented that drugs are a problem for employee safety. For example, used syringes with remaining drugs are stored in patient's rooms in a separate box and can be accessed by patients.

JH asked if the liquid gets separated from the IV bag or syringe.

Jeanie Jaramillo commented that take back program in Amarillo can't accept drugs from nursing home pharmacist, and some grind and dispose of them down the drain. She suggested grind and put in the trash.

Andrea McNair commented that a nurse can lose their license if drugs get in the wrong hands, so they are motivated to get rid of them.

Rebecca Zinnante (Carl R. Darnall Army Medical Center - Ft. Hood) commented that at their medical facilities, the policy is that drugs must be wasted by the individual administering the drug and a witness. Putting materials in the sharps container is not a secure disposal option. People do get into sharps containers and remove items. Materials must be wasted on gauze or wasted down the drain.

Carol Batterton (Water Environment Association of Texas/Texas Association of Clean Water Agencies) commented that utilities are willing to do collection events, but that rules are unfamiliar. A guidance document is needed to help with this. Many utilities interpret the rules differently.

Raj Bhattarai (City of Austin) commented that he would like to eliminate or minimize pharmaceuticals from entering waters. In addition, it does not make sense to put pharmaceuticals in an autoclave due to the liquid component that goes to the wastewater system.

Selin Hoboy commented that there are problems with wasting drugs remaining in syringes; squirting liquids into the sharps container is not a good practice, but is approved by some local DEA but not federal. Studies have shown that pharmaceuticals can be recovered from absorbent materials.

Rodney Bias commented that in rural areas, the distance to a collection event is an issue.

Pete Martinez (PhRMA) commented that the majority of studies show that pass-through (excretion) is the source of most pharmaceuticals in the environment. We need to educate the public on how to properly dispose of unused pharmaceuticals.

Leslie Wood (PhRMA) commented that it was common to flush pharmaceuticals in homes (healthcare providers traditionally advised this to avoid unintentional poisonings). Before PhRMA changed guidance to household trash disposal, scientists conducted research to ensure that household trash disposal would be protective of the environment. PhRMA's landfill study demonstrates that disposal in Subtitle D landfills is protective of the environment. PhRMA advocates household trash disposal. PhRMA advocates landfilling following SMARxT Disposal guidance (mix with medicine in a plastic bag with a small amount of liquid and add an undesirable substance). Landfilling avoids aggregation of pharmaceuticals in one place. Pharmaceuticals can be diverted from collection events. In response to a question about leachate: Leachate is collected in Subtitle D Landfills and is either recycled on an active cell or sent to water treatment.

Jeff Jacoby commented that landfills eventually leak and this does not solve the problem since still have liquid trash soup in the bottom of landfill. Pharmaceuticals are not mitigated at wastewater treatment plants. For consumers, if a disposal method is cheap (free) and convenient, it will be used. Putting pharmaceuticals in the trash may eventually result in them getting into the water supply. Texas Campaign for the Environment advocates a manufacturer take back or funding approach. Oregon has started a pilot program. For take back, there is an incentive to prescribe the correct dose of a drug. Overprescribing is the number one reason for unused medications. Texas Campaign for the Environment wants Texas to move towards a shared responsibility model with manufacturer involvement.

10:22 JH presented slides about frequently asked questions including the source of pharmaceuticals in wastewater from excretion vs. flushing, and the magnitude of the problem in Texas. The study group is looking for peer reviewed literature on this subject.

Rodney Bias (Inmar) asked if it would be in our best interest to treat pharmaceuticals at the WWTP.

Carol Batterton answered that there is literature regarding removal at WWTPs, but that it is a work in progress. There is some removal, but not total, and reduction in the amounts received at WWTPs could have an impact on the WWTPs ability to treat them without extensive upgrades.

JH commented that there are still a lot of unknowns on that topic.

Vincent Nathan (Texas A&M Health Science Center) commented that there are two different waste streams, both wastewater and water treatment plants, that both handle pharmaceuticals. We must address drinking water and wastewater treatment, worker safety, and distribution of pharmaceuticals.

Keith McLeroy commented that it is cheaper to landfill pharmaceuticals than ask cities to upgrade plants with membranes or other technology. What is in our waters now? What are the impacts of that?

JH commented that for public water systems, water rates are an issue. Concentrations of pharmaceuticals found in Texas waters are in the parts per billion and parts per trillion range.

Tony Bennett (AECOM) commented that end results are unknown and information on the effects on humans and the environment is limited. With that, prevention programs are a good idea. Controlled substances are difficult to deal with. Cost to remove at plants is expensive, so more data are needed first, including cost comparisons on treatment/disposal options.

JH commented that impacts on public health/safety and the environment must be considered in this study.

Raj Bhattarai (City of Austin, Austin Water Utility) commented that we should try to prevent pharmaceuticals from entering water bodies.

Andrea McNair asked if there are data about the percent pharmaceuticals coming from hospitals.

JH answered that we don't have much data. A study done on emerging contaminants (including some pharmaceuticals) in the influent and effluent of a wastewater treatment plant in south-central Texas showed that a hospital contributed 12 emerging contaminants to the WWTP influent.

10:40 JH presented slides with additional frequently asked questions, including why consider reducing pharmaceuticals entering WWTPs if there are no known human health impacts, aquatic life impacts, and landfill issues.

{Stakeholder in audience} commented that Maine DEP study shows a correlation between landfill leachate and pharmaceuticals in groundwater.

Leslie Wood (PhRMA) commented that a PhRMA study shows that landfills disposal sufficiently contains pharmaceuticals disposed from households. JH mentioned the EPA came to similar conclusions.

Bill Petty (Fort Bend County Household Hazardous Waste Program) commented that old landfills are a problem since they can still leak and contaminate groundwater.

Vincent Nathan commented that old landfills not accepting new waste still have waste in them and can be a problem anyway.

JH commented that this study is about the current methods for disposal of unused pharmaceuticals and will not address old landfills.

Jeff Jacoby commented that old unlined landfills can be expanded with new cells.

JH commented that TCEQ will address what required by SB1757 and that there are also many peripheral issues.

Vincent Nathan asked about regulating companies that don't operate in Texas.

JH answered that this will be for Texas only.

JH presented slides with additional frequently asked questions, including landfill leachate issues.

Kelly Freeman (Capital Area Council of Governments) asked what the term "negligible" levels (in reference to the negligible effect of pharmaceutical in landfills on groundwater) means, since we don't know the levels that are harmful.

Leslie Wood (PhRMA) answered that pharmaceuticals have been detected in parts per trillion or nanogram per liter concentrations, that that 99.9% of pharmaceuticals that end up in the environment would be from human excretion if unused medicines were disposed of in landfills and that there is no demonstrable risk to human health from drinking water or consuming fish with low levels of pharmaceuticals. The science community generally agrees that most of the pharmaceuticals in the environment are from human use of prescription medicines.

JH commented that the PhRMA landfill study does not address the biosolids that can be disposed of in a landfill.

10:53 JH announced that there will be a break until 11:15.

11:12 Return from Break

JH reopened the discussion on current disposal methods.

Jeff Gloyd (Waste Management Healthcare Solutions) commented that successful take back programs should be accessible, cost effective and legal, and that programs must meet federal rules also. Jeff said that he has heard a lot regarding a lack of information and he hopes that we don't move too quickly regarding treatment or requiring manufacturer take back programs because there are costs associated with both. Additional data are needed.

JH commented that education is a big factor for consumers and health care providers. Landfilling unused drugs is promoted at the federal level (e.g. Food and Drug Administration) and educational materials can be developed about how to do that correctly.

JH asked about the most common way to obtain pharmaceuticals in Texas (e.g. retail pharmacies, internet pharmacies or mail-order programs).

Kim Roberson answered that retail and mail order pharmacies are the largest sources, and internet is also used. Some operations in Texas are large and send pharmaceuticals to various U.S. states.

JH asked if pharmacies are required to use reverse distribution in Texas.

Kim Roberson answered that pharmacies are not required to have reverse distribution in Texas.

Cheri Huddleston commented that their members do not want laws requiring reverse distribution, although most pharmacies are doing reverse distribution now since have incentive in the form of credits.

JH asked about sorting and cost of disposal issues.

Jeanie Jaramillo commented that a take back event in Amarillo in September 2009 disposed of 900 pounds of pharmaceuticals for less than five hundred dollars. Rates for hazardous waste incineration are possibly eight dollars per pound and would make the collection event cost prohibitive.

Victoria Hodge (City of Denton Household Hazardous Waste Section) commented that the cost of WWTP and DWTP upgrade would be by residents and that grant funding or other assistance is needed. Consumer consumption (of drugs) is also an issue that needs to be considered in addition to producer responsibility.

Keith McLeroy commented about liability issues at HHW collection events where they can accept many wastes (why not pharmaceuticals also?).

Eric Beller (TCEQ) answered that HHW programs can take pharmaceuticals and that the rules require that all HHW be managed as hazardous, which increases costs compared to non-hazardous waste.

JH commented that there are also controlled substance issues at HHW collection facilities.

Jack Ranney (LCRA) commented that clarifying rules are needed for HHW events and pharmaceuticals. Controlled substances require a chain of custody process and costs are associated with that.

JH commented that it seems educational information needs to be developed.

11:32 JH introduced the final discussion regarding current disposal methods.

William Anderson commented that all incineration is not the same. Incineration at a permitted hazardous waste incinerator is not the same as burning in a barrel. Clarification is needed that all incineration must be at a regulated facility with air pollution controls.

JH asked if there are any other comments regarding current methods.

11:35 Eric Beller (TCEQ) noted that discussions about alternative methods implies alternative processes for handling in route to disposal. One method may not meet the needs of everyone and all categories of pharmaceuticals.

11:40 JH asked if the group wants to discuss alternative methods now or wait for the next meeting.

Eric Beller (TCEQ) asked if there are any more questions.

Tony Bennett asked if everything is open for discussion.

JH answered that yes, if we identify gaps in rules and needed changes, they can be included in the report.

Eric Beller commented that current rules inhibit pharmaceutical collection at HHW collection sites. For example, a permit is needed for collection of non-hazardous waste if it is not treated as hazardous.

Jack Ranney (LCRA) commented that HHW is exempt from RCRA hazardous waste classification, but it must be collected, packaged and managed as hazardous.

Tony Bennett asked what difference that makes if it must be managed as hazardous waste.

Kelly Freeman (CapCOG) commented that there are cost differences for RCRA classified hazardous waste disposal.

Eric Beller commented that costs will be an issue to consider.

Pete Martinez (PhRMA) commented that we should talk about costs in the next meeting.

Victoria Hodge asked if there will be a discussion about how to collect pharmaceuticals from consumers.

JH answered that collection alternatives for consumers and health care providers will be discussed in detail at the April meeting.

11:50 JH presented slides introducing alternate disposal methods.

Rebecca Zinnante asked if DEA can come to a meeting to talk about controlled substances.

JH answered that DEA deals with handling, not disposal, but that someone from the Houston office will be asked to attend the April meeting.

JH presented a slide regarding some information resources.

11:54 JH presented slides about future meetings and other closing information. Next meeting is April 22nd, 9am-12.30pm, TCEQ Austin Building E, Room E201S.

11:55 Adjourn

*Minutes offered for review 3/30/2010 (changes due by 4.30pm 4/6/2010)
Minutes finalized 4/6/2010.*