

Pharmaceutical Disposal Advisory Group Meeting #4

Date: April 22, 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, Tom Harrigan, Daniel Ingersoll, Clyde Bohmfalk. Additional TCEQ Staff: Danny Siebeneicher, HHW Coordinator.

Today's Powerpoint presentations will be available on the Pharmaceutical Disposal Advisory Group webpage by May 13th:

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

Total Attendees: A total of approximately 51 people attended in person (including TCEQ staff) and 29 people attended via LiveMeeting and/or teleconference for a total of 80 participants.

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

Time (am) Event

8:55 Meeting called to order by Jessica Huybregts (hereby JH).

8:56 Opening remarks and welcome by JH. JH presented a slide with the agenda for today's meeting.

8:57 Introductions were made by each participant, both onsite, LiveMeeting, and on teleconference.

9:05 JH clarified pharmacy regulations from State Board of Pharmacies regarding taking back pharmaceuticals from consumers. Pharmacies may take back pharmaceuticals for the purpose of disposal but not for resale and cannot take back controlled substances even for disposal. She emphasized that those rules did not include TCEQ regulations. JH also explained that the Drug Enforcement Administration (DEA) provided clarification on their position in writing to TCEQ regarding the rules about accepting controlled substances knowingly or not knowingly.

9:06 JH introduced further discussion of household hazardous waste (HHW) rules and the need for HHW managers to have clarification about how the TCEQ rules apply to them and their facilities. She introduced Danny Siebeneicher, the HHW coordinator at TCEQ, to answer questions from the audience regarding HHW rules, collections and how it relates to pharmaceuticals.

9:24 Dan Siebeneicher (hereby DS) gave a brief presentation about what can be taken regarding pharmaceuticals in HHW Collection programs. He explained that HHW collection events can take back pharmaceuticals regardless of whether they are hazardous or not, provided they are listed on the required operational plan. Pharmaceuticals do not become hazardous just because they are taken at an HHW collection event. DS clarified that HHW program rules are separate from Municipal Solid Waste rules and controlled substance rules. Non-hazardous pharmaceuticals do not fall under the HHW program because they do not meet the definition in Chapter 40 – Code of Federal Regulations (CFR) regarding hazardous waste. He cautioned managers that if they take pharmaceuticals that meet the definition in 40 CFR for hazardous waste, then they must meet the HHW rules requirements. He gave the following example of hazardous waste from a household. In a fire house with a bunk house upstairs and fire garage downstairs would have two classifications for items like Lye; upstairs the lye would be considered HHW, and is exempt from Federal hazardous waste rules. The lye downstairs would be considered hazardous waste because it is not located in a household. Only items that meet the federal definition of hazardous waste must be shipped as hazardous waste.

Jeannie Jaramillo (hereby JJ, Texas Tech Pharmacy Dept) asked if cough syrup that comes from a household, with over 24% alcohol, was considered hazardous.

DS clarified that because it comes from a household, it is not considered hazardous. If it was hazardous, it would not be allowed to be disposed of in a municipal solid waste landfill; it would require hazardous waste handling, which is expensive and not an option for most home owners.

JJ asked if an organization has a medication take back program and accepts P-listed and U-listed drugs, do these items need to be separated out? DS explained that if they meet the HHW requirements and list those items on their operational plan as accepted items and advertise those items, then they can accept those items from households.

Kelly Freeman (CAPCOG) asked if a collection is not taking typical HHW, only pharmaceutical take back, do they need to separate out HHW pharmaceuticals. DS said if a take back program has not complied with HHW regulations then they cannot take items from a household that would normally be considered hazardous. If an event has submitted the required documentation for an HHW

collection, then they can take the items that would otherwise be considered hazardous (if they were from a business setting). DS cautioned people about paying attention to other regulations that might apply to events they may hold.

{Stakeholder in audience} asked a question about a previous presentation that stated that the only way to do household take back program was under the HHW collection process. DS confirmed that if you plan to accept hazardous pharmaceuticals then you must comply with the HHW program.

Shannon Herriott (TCEQ) stated that unless you have sent in the required notifications for an HHW collection program, you may not accept HHW. You cannot accept household hazardous waste unless you comply with the HHW regulations.

{Stakeholder in audience} wanted to know what TCEQ would do for those events that are scheduled but that are not registered with TCEQ prior to the event occurrence.

Eric Beller (hereby EB, TCEQ, Municipal Solid Waste) responded that while there was no mechanism or rule in 30 TAC Chapter 330 that authorizes a non-hazardous collection event. Recently, TCEQ provided an interim and temporary policy to such an event as a "citizen's collection station." *[30 TAC Chapter 330, Rule 330.3(20) Citizens' collection station--A facility established for the convenience and exclusive use of residents (not commercial or industrial users or collection vehicles), except that in small communities where regular collections are not available, small quantities of commercial waste may be deposited by the generator of the waste. The facility may consist of one or more storage containers, bins, or trailers.]* There still is not an official mechanism for these events, but the TCEQ requires authorization from MSW to hold a collection event. Until a definitive decision is made, all registrations will be assessed on a case-by-case basis. He clarified that this is a new procedure because we have never been approached with this situation before.

{Stakeholder in audience} asked a follow-up question about how drugs are considered a special waste and then become a hazardous waste.

DS clarified that if it comes from a house and is hazardous by law, it is not considered a hazardous waste. EB confirmed that drugs are considered a special waste, but clarified that he believed a household would not generate a special waste.

{Stakeholder in audience} concluded that if it is generated from a household it is by law never considered a hazardous waste.

Jack Ranney asked if it has alcohol levels over hazardous levels, is it not a hazardous waste? DS stated that by law, households are exempt from hazardous waste requirements.

{POST MEETING CLARIFICATION: Though households are exempt from hazardous waste regulation, if you collect waste from a household that would otherwise be considered hazardous in a business setting (that is, collect HHW) then you would need to dispose of the waste as though it were hazardous.}

Victoria Hodge (City of Denton) asked about notifications required for take back programs, whether or not they should be an HHW notification or a citizen collection station registration.

DS and EB agreed that they would need to do both in many cases. If an organization wants to *not* collect HHW pharmaceuticals, they can do the citizen collection station authorization (notification). If they want to collect HHW pharmaceuticals, they would need to go through the HHW program. DS noted that take back programs can take only what they list on their notification and operational plan.

Victoria Hodge asked what notification pharmacies have to give the TCEQ to take back drugs.

DS answered that because the pharmacy sells the product they are taking back, no HHW notification is required; they are exempt from HHW notifications. EB stated that any time you collect someone else's waste, it takes authorization from TCEQ. Even though they have authorization from State Board of Pharmacy to take it, they do not have authority from TCEQ to accept the Special Waste for disposal.

Bill Petty (Fort Bend County HHW) asked about the notification timeline for pharmaceutical take back events.

EB answered that the citizen collection event has a 90-day notification required, but to stay in line with the HHW regulations and not be more stringent than them, the 45-day deadline is currently being applied.

Cheri Huddleston (Texas Pharmacy Association Academy of Compounding Pharmacists & Texas Pharmacy Business Council) asked about pharmacies not being able to take back drugs because of no authorization from TCEQ, even though the State Board allows it and the TCEQ does not have any involvement with other pharmacy activities. She asked who the rule applies to specifically.

EB answered that there might be rule conflicts or possibly a memorandum of understanding, but commented that this is uncharted territory with a lot of gray areas that need to be confirmed before any solid information can be disseminated. He further quoted the rule 30 TAC 331.1(a) stating that it applies

to “any person involved in managing MSW waste.” How it applies varies, but it will apply somehow, even if a facility or person is exempt. Notifying TCEQ MSW Section is necessary to determine what level of authority would be required.

Daniel Ingersoll (hereby DI, TCEQ) added that we are in the process of dealing with “theory vs reality”. He addressed pharmacies accepting pharmaceuticals and said in theory it is accepting another person’s MSW and that how the TCEQ is planning to handle that issue is unclear. We received an application for conducting a take-back event, forcing us to say what sort of minimal requirements are necessary for these programs. For take-back, the best option appears to be notification, letting us know when you’re doing it, who you are, and where disposal will happen. This process is somewhat related to Chapter 328 rules on recycling, although technically recycling is not disposing of a waste. In the past facilities have used that recycling regulation to run an illegal dump and we are working to avoid that happening with take back programs who collect a truckful of waste with no disposal destination. He stated that he would prefer that the organizer of an event provide details of a landfill or incinerator where the waste is going and certification that the destination can accept that waste. He asked about whether pharmaceutical was a Special Waste if it comes from a household.

EB confirmed that the Special Waste classification for collection of household waste is unclear at this moment. Although it was not special waste in a household, once it’s collected, different rules kick in.

DI stated that the current situation does not have a concrete answer for pharmacies taking customer’s pharmaceuticals. He further stated that the notification for a take-back program currently is very mild in requirements compared to HHW collection notifications.

JH asked for any additional questions.

Jeanie Jaramillo asked where Texas was in terms of adopting the universal waste rule for pharmaceuticals. Her concern is related to the difficulty of meeting the HHW requirements to be able to accept HHW pharmaceutical, and the hope that under the pharmaceutical universal waste rule, that HHW requirement would not be necessary.

DI replied that the federal government has not updated the Federal Universal Waste Rule (UWR) yet in a final rule and the State would be required to adopt rules only if the Federal rules were more stringent than TCEQ’s rules. The current pharmaceutical UWR proposal is going to make things less stringent. If it has been adopted federally, as a result, we have made no move to adopt it yet.

09:39 JH introduced Charlotte Smith (hereby CS, PharmEcology), who presented educational information on proposed and/or adopted national and other State’s

legislation in relation to pharmaceuticals and pharmaceutical disposal. CS then took questions.

{POST MEETING ADDITION: Holli Hill (Daiichi Sankyo, Inc.) provided additional legislative information by email: "Legislation on stewardship, House File 1217, has been signed by the Governor. A competing bill, House File 2407, is scheduled for a hearing on April 27th. House File 1372/Senate File 1323, the Infectious Waste Control Act, has not passed. It was scheduled to be heard on Monday and contains an agreed upon amendment that calls for companies that sell or distribute sharps or manufacturers of products that generate sharps to post on their websites a plan that promotes the safe collection and disposal of sharps. There is opposition to this bill that calls for sharps disposal systems to be supplied to retailers at no cost, paid for by manufacturers.}

09:58 DI asked if CS was discussing the DEA rule "Advanced Notice of Proposed Rulemaking" as a clarification.

CS replied that yes, that was what she was referencing. She further elaborated that they put that notice out there then took it back with the statement that they were looking for information and will now use that information they collected to generate the regulation when legislation does get passed.

CS asked for questions from LiveMeeting and phone and got none. JH said that Charlotte's presentation showed that there are a lot of issues regarding pharmaceuticals coming to the fore in the form of legislation across the country.

DI asked how take-back programs will handle controlled substances.

CS said that DEA says they have to use a Sheriff to take possession and then escort to an incinerator for destruction. She is not confident that is what is always happening.

EB asked if DEA would consider alternative destruction methods to incineration.

CS replied that the DEA has not clarified what they mean by 'non-recoverable' to allow for non-incineration disposal methods. She stated that this is an issue that needs to be addressed and a solution is necessary.

Selin Hoboy (Stericycle Inc.) clarified that the non-recoverable issue is an important one to understand in terms of following regulations and laws. She forwarded a letter to TCEQ that Stericycle received from DEA with guidance on this stating that individuals cannot determine non-recoverable status independently and currently they prefer incineration or flushing. They say companies can provide samples of drugs rendered non-recoverable to the DEA for testing and approval by the Assistant Director of the DEA, which makes it a

time consuming and onerous process, but is available. She cautioned companies to make the determination themselves without consulting the DEA.

DI asked for Charlotte's middle ground on protections for controlled substances compared to limited allowed disposal options.

CS opinion is that take back programs with a "track and trace" process would be reasonable to provide diversion from waste water stream, but there is a lot of concern from DEA about security of that. She stated that she thought it was a workable idea and would provide an outlet for controlled substances to be accepted by registrants of the DEA for destruction.

10:20 JH announced a break.

10:40 DI resumed meeting with a reminder to mute phones and a disclaimer that even though representatives of Waste Management were presenting, their views did not reflect TCEQ views or the agency's regulated standpoint. They are presenting as part of the spirit of the bill to accept stakeholder input and the TCEQ welcomes comments and concerns from anyone present today to be included on the recording.

10:45 CS presented a second educational presentation discussing healthcare pharmaceutical disposal and the alternative options they may have. She then took questions.

11:02 JH introduced Eric Beller to discuss the definition of Special Waste. She clarified that the presentations would be loaded on the Web Site.

Eric Beller discussed Special Wastes narrowed down to non-households and limited it to non-hazardous pharmaceuticals. He explained that the definition of Special Waste found in 30 TAC 330.3(148) identifies the items that are considered special waste and one item is drugs, but does not include hazardous drugs. Given this definition, he said that a pharmacy could send non-hazardous pharmaceuticals to a landfill as a special waste. The rule on 30 TAC 330.171 requires some special waste to have prior written authorization from the executive director before disposal; one of those Special Wastes groups that requires approval is drugs. Two separate approval options for drugs as special waste are offered by the MSW permit group. He further talked about Conditionally Exempt Small Quality Generators (CESQGs) and suggested that a pharmacy might fall in that category and send their waste (less than 220 of hazardous waste a month) to a municipal landfill. His perception is that this may be the simplest route for handling another person's pharmaceuticals.

11:04 Rebecca Zinnante (Carl R. Darnall Army Medical Center, Fort Hood) asked if the approval to manage special waste involved a change in the waste management permit.

EB responded no, but cautioned that the landfill had to be authorized to receive it. All Type 1 Municipal Solid Waste landfills can, but some choose not to. The authorization he discussed is granted to the generator of the waste; i.e. the coordinator of the take-back program or pharmacy who accepts the waste.

Rebecca followed up with a question asking if the approval requires a detailed inventory or could pharmaceuticals be mixed.

EB replied that you do not have to provide a detailed list of individual drugs disposed of as Special Waste. However, part of the authorization form is a certification that the waste collected is not hazardous and is coming from a municipal generator.

DI asked if a CESQG must have an inventory of their wastes.

EB confirmed that a CESQG could send its hazardous waste as a Special Waste to a qualified landfill under the previously mentioned authorization.

11:09 JH asked for any items for discussion related to pharmacies or hospitals methods of disposal.

Selin Hoboy (Stericycle) asked if TCEQ thought it was part of the study to look at the impact of Special Waste and pharmaceutical disposal in landfills given the presence of some chemicals in leachate from landfills.

EB answered that the study group has looked at the evidence from current studies and currently feel the landfill design is sufficient to manage pharmaceuticals and some hazardous waste disposal.

Selin Hoboy (Stericycle) asked if there were any landfills in Texas that do not fall under Subtitle D landfills.

EB replied that there is no waste disposal currently happening in any non-Subtitle D landfills, and that arid exempt landfills have some reduced requirements, but also are not able to accept Special Waste.

JH stated that this issue is a difficult one given the Maine study and current studies underway (USGS) that show parts per trillion concentrations in landfill leachate or groundwater downgradient of a landfill. The study group is open to looking at any other evidence available to understand the impact of disposal in landfills.

11:15 Kelly Freeman (hereby KF, CAPCOG) asked if a citizen collection station authorization would be prevented from accepting CESQG waste, as HHW

collections are, because a small pharmacy or other CESQG may be able to co-mingle collected waste to be more cost effective.

EB responded that CESQG and municipal waste collections are completely separate entities. He stated that a pharmacy is not likely to take their waste to a collection event, so it would probably not be an issue.

KF responded that if the pharmacy acts as a consolidation point and takes possession of the household waste, they would become the generator and it would possibly become CESQG waste, which they might not be authorized to manage.

EB answered that a pharmacy should not co-mingle their waste with a collection event waste to maintain their status and manage the collected waste as Special Waste.

11:20 JH moved the meeting from discussion of hazardous waste rules and special waste to a presentation by Jeff Gloyd, a subject matter expert, in consumer collection, management and disposal.

Jeff Gloyd (hereby JG, WM Healthcare Solutions) presented on consumer pharmaceutical management, collection and disposal. Throughout the presentation JG proposed the question (for each of the 4 take-back program styles) if it would be feasible in Texas. He first asked the question of whether the group thought community pharmaceutical collection events would “work” in Texas.

JH replied with a request for what he means by “work”. She pointed out that he mentioned legal, cost effective, safety issues, and ways to refine the way collections are held. She asked what the ultimate goal of the collection was; for example to reduce impact on wastewater, to get the drugs from households, what is the definition by which you determine if they “work”. She asked should that be the main measure of success and the other factors the measure of feasibility.

KF asked about partnerships she has seen between groups who held collections; and asked what options are possible to receive funding through the municipal solid waste grants program, administered through the COGs; they are not currently providing funding for these collections, but if the collections are authorized as citizen collection stations, they are authorized events and should receive funding.

JG replied that there are some states that provide grant funding for these events, and with TCEQs decisions it might be possible here.

JH added that the Utah environmental agency added take-back events to their State Revolving Fund activities, as an example of ways other state agencies have helped fund collection events with EPA funds.

Claude Dance (Sharps Compliance) a number of states (IA, Dakotas) have provided take-backs through community pharmacies.

JG commented that the success of irregular community collection events is unclear. Studies show landfills are safe, but consumers prefer not to throw it in the trash and a collection event is an alternative for consumers and can prevent poisonings or other safety concerns with keeping unused drugs in the house.

Jeanie Jaramillo mentioned that in their take-back event in September 2009 they surveyed each participant and one question is what they would do with the drug if they didn't bring it to event. 55% said they would have kept the pharmaceuticals in their home if they didn't bring it to collection, 9% would have flushed drugs and 16% would have put them in the trash. She mentioned that this is probably not going to make a difference in water quality but can make a difference for public health if events can cause people to get the unused drugs out of the house.

11:35 JG continued his presentation on consumer disposal including permanent collections facilities. JG asked the other stakeholders if there was a possibility of drop boxes and/or kiosks as an option in Texas.

Kathy Barber (Texas Federation of Drug Stores) stated that one issue with kiosks is that they are prohibited from being stationed outside a pharmacy or other building, and there were additional questions about putting one in the pharmacy.

JG agreed that he had reservations about putting the kiosks outside.

Bill Petty (Fort Bend County HHW) asked who was going to pay for it and stated that the county was unable to do that.

JH added that the King Co, WA program pilot project found that the pharmacy is providing a community service and could pull customers into the store for the service and they then may purchase additional items. The pharmacy paid for the kiosk since they saw it as a business/marketing choice.

Bill Anderson (Curbside) stated that they are working with Colorado to coordinate kiosks in a chain of pharmacies. The survey included with each kiosk shows that nearly 70% of the drop off customers are not regular customers of the pharmacy, indicating a motivation for pharmacy business. This is not typically true of smaller pharmacies, i.e. inside doctor's offices.

11:40 JG continued his presentation with additional points.

{Stakeholder in audience} asked in all events where there is co-mingling of waste, what is the final disposition of these.

JG answered that it varies by state. Most states follow RCRA rules for pharmaceuticals, i.e. HHW exemption. He clarified that there are a few states that treat it as hazardous, but many do not. He further stated that if it is a kiosk and they count the waste as hazardous it can make the collection prohibitive cost-wise.

He continued his presentation and ended with a question to the other stakeholders of whether an HHW collection center would work as a pharmaceutical collection station in Texas.

JH asked if collection of pharmaceuticals was something that HHW managers wanted to do or whether it was something that they are being ask to do by customers.

Bill Petty stated he has done HHW collections for 12 years and has always taken pharmaceuticals in the absence of guidance not to. He further stated that the main concern was related to DEA's regulations and requirements to have law enforcement present for controlled substances.

KF stated she works with HHW managers asking if there is funding available to do this, asking if they can do this because citizens are demanding the service and the result overall is that people want to accept pharmaceuticals at HHW centers.

Chris Geisler (Waste Management) provided information about Houston's permanent collection facility that does accept pharmaceutical drugs and suggested looking at it as a model on how the City does it.

11:55 JG continued with his presentation, covering mail back programs.

Claude Dance (Sharps Compliance) clarified that the NCPA program has very explicit instructions about what you can/cannot mail back. Only non-controlled pharmaceuticals are accepted and this is not related to the Kentucky program.

Bill Petty mentioned that a negative aspect of mail back would be the population served. Maine, as an example, has fewer people than Texas.

JH expressed her concern about who will bear the cost of a mail in program in Texas, and whether or not a mail-in program would achieve the same result (in terms of pounds of drugs collected) as two collection programs a year.

Matthew Mireles (Community Medical Foundation for Patient Safety) stated that it is important to look at the quality compared to the quantity of the drugs returned.

Mail back programs provide a bigger sense of anonymity and illegal drugs are more often received via mail-back than the other take-back options. He also stated that he believes that cost will be a major factor and that, based in part on his data, the federal levels are looking at mail back programs and the burden of funding appears to be directed to manufacturers.

Burt Kunik (Sharps Compliance) stated that there are many options for making programs financially sustainable.

Jack Ranney (LCRA) stated that no matter how it is funded or organized that the public awareness component is essential with good data to let people know that this is important.

JG stated that for the program to be successful it will include a number of options. He further continued his presentation, which included information on education and outreach as well as personal disposal kits that are available on the market.

{Stakeholder in audience} stated that any programs will have cost issues. All programs but the home disposal unit you describe will have to involve the homeowner to actively participate and take the medication from the house. He stated there is a leap for consumers regarding participation.

12:02 JH opened the floor for more questions and comments.

Burt Kunik expressed concerns about not paying enough attention to the end consumer and how it fits their perceptions and what they need. He wants to develop a program that will address all the issues. His suggestion was to bring someone from the pharmacy world and the consumer world to touch base on the needs of this group.

Victoria Hodge (City of Denton) stated that one concern was to make sure the collection scheduled was legal, including contacting sherriff and police department, and answering questions from a pharmacy with concerns that the collection was legal. An additional concern she raised was that while some collections know they need law enforcement involved, they did not know they needed authorization from the TCEQ.

JH responded that legal should be involved in the planning process as well as law enforcement to make sure all parties are aware of what compliance means and who must be included.

Kathy Barber stated that pharmacies do not just take back the drugs, they put their licenses at risk from the State Board of Pharmacy, TCEQ and DEA to name a few.

Jeanie Jaramillo recognized that many programs are being created in Texas and suggested guidance from TCEQ helping organizations conduct these in compliance with all state and federal regulations.

JH asked for additional comments or questions. She asked that if anyone was interested in speaking at the last two meetings to please contact her.

12:10 Adjourn

*Minutes offered for review 4/30/2010 through 5/7/2010.
Minutes finalized 5/11/2010.*