

A Primer on Conducting Medication Take Back Programs With Emphasis on Texas

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Agencies considered:

- Texas Commission on Environmental Quality (TCEQ)
- Texas State Board of Pharmacy (TSBP)
- Drug Enforcement Administration (DEA)
- Local Law Enforcement
- Environmental Protection Agency (EPA)

Laws/Regulations Considered:

- Federal Controlled Substances Act (CSA)
- Texas Dangerous Drug Act
 - Texas Health and Safety Code [Title 6, Subtitle C, Chapter 483, Subchapter A]
- Resource Conservation & Recovery Act (RCRA)
- Texas Administrative Code (TAC)

This document has been created to assist those who are considering or planning a medication take back event with specific guidance for programs to be conducted in Texas. It is intended to share information regarding the conduction of events to the best of the author's knowledge, but may not be inclusive of all regulations or rules in existence. The information collected and compiled is based on the author's experience in development and implementation of Medication Cleanout™, one of the first medication take-back programs to be conducted in Texas. The author's views are not necessarily those of Texas Tech University Health Sciences Center, the School of Pharmacy, or the Texas Panhandle Poison Center.

Program Rationale:

Poisonings are currently second only to motor vehicle accidents as a cause of unintentional injury death.¹ Additionally, 68.9% of emergency department visits for unintentional pediatric poisonings are due to medication overdoses; that's twice the amount of poisonings than those that occur from exposure to household products.² Of those, 82.2% resulted from children accessing medications on their own.² Nearly 2.5 million human exposure cases were reported to poison centers in the United States in 2008 with two of the top five most frequent exposures consisting of medications (analgesics and sedative/hypnotic/antipsychotics). Just these two medication classes were the offending agent in 20% (500,000) of all reported cases³.

Abuse of both prescription and non-prescription medications is also a growing problem. There are now more people aged 12 and up who use psychotherapeutic drugs for non-medical reasons than those who abuse cocaine, heroin, and methamphetamine combined. Prescription drug abuse is second only to marijuana⁴ in most states and has surpassed marijuana in some areas. Each day 2,500 teens use a prescription medication for the first time for a non-medical reason⁵ and 58% of surveyed teens reported that they obtained prescription drugs from their own family's medicine cabinet.⁶

Misuse of medications is also not an infrequent problem. In a study by Bedell et al., three-fourths of adults were found to misuse the medications that had been prescribed for them or that they had purchased over the counter.⁷ As the population ages, the use of medications increases creating a situation in which the misuse of medications will continue to grow. Misuse can lead to antibiotic resistance, inappropriate treatment, and delay to treatment; all situations that can be dangerous. Sharing of medications amongst family members and friends is also not uncommon and can be dangerous.

Environmental contamination can result when medications are improperly disposed of by flushing or by pouring down the drain. An investigation by the Associated Press showed that "a vast array of pharmaceuticals including antibiotics, anticonvulsants, mood stabilizers and sex hormones have been found in the drinking water supplies of at least 41 million Americans."⁸ Although the effects of such concentrations on humans is unknown, small amounts over a lifetime can become significant.

Providing residents with a mechanism for the safe and convenient disposal of medications can prevent poisonings, misuse, and abuse as well as protecting the environment from potential contamination. The development of medication take back programs by professionals of diverse disciplines is warranted. Environmental-related agencies, drug abuse and prevention organizations, school systems and healthcare providers, amongst others, all have vested interests in the development of these important programs.

Planning:

1. Law enforcement participation: Cooperation of a local law enforcement agency or agencies is essential for the conduction of legal and successful take back programs. The Federal Controlled Substances Act (FCSA) prohibits persons from having controlled substances in their possession unless these substances are prescribed for that individual. The Drug Enforcement Agency (DEA) has "recently granted temporary permission to law enforcement agencies who have requested authorization to accept for disposal controlled substances that have been dispensed to ultimate users."⁹

In theory, a take back event could be conducted in which the public is told that only non-controlled substances will be accepted. However, laypeople generally do not have knowledge of what constitutes a controlled substance or what does not and it is likely unwise to attempt to educate individuals in this respect for the following reason.

Controlled substances are some of the most highly abused of prescription medications. So, by detailing what these medications are, promotion of drug abuse might actually result.

Additionally, because controlled substances are some of the most highly abused of prescription medications and because they can be highly toxic, it is most desirable to remove these items from homes and therefore, exclusion would be counterproductive to the goals of most programs.

Therefore, participation of law enforcement is essential and would wisely be placed as the highest priority in program planning.

2. Funding: While programs may be conducted with minimal funds, the degree of success of programs is generally proportional to the amount of funding that is available. Aggressive marketing through cost-free channels (school districts, churches, community organizations, etc.) may also be effective. Funds are necessary for printing of materials, marketing, and supplies, services of law enforcement and/or pharmacists, space rental, and medication disposal (incineration) expenses. In-kind services may be obtained due to the public service nature of the event.

Medication Cleanout™ was started with \$15,000 and resulted in collection of 863 pounds of medications at the first event.

3. Location: Securing a location is also an important step when planning an event. A centrally-located building that is well-recognized by the community is ideal. School cafeterias or gyms usually provide a large indoor space that can be used for processing and are often close to parking lots that are conducive to a drive through format for take back events. Additionally, these locations may also be secured at no cost for such a community event.

The use of schools should be avoided if students will be present in close proximity at the time of the event (i.e. if students are using the cafeteria, this may be a poor site for event conduction).

While grocery stores or malls have high visibility with the public, the ability to secure a processing area that is not accessible by the public is limited and therefore, the author does not recommend these as potential event sites.

Conducting the event as a drive through is well-received by the public and promotes the use of a safe and secure processing area. It is recommended that the processing area be indoors due both to possible weather-related issues and due to safety and security concerns.

4. Partnerships: While this item is listed as #4 in terms of planning, it could easily be deemed as or more important than items #1-3. As previously discussed, law enforcement is an essential partnership. With buy-in from local law enforcement, officer time at the event may be obtained at a reduced cost or at no cost as take back events have goals that often overlap those of law enforcement (prevention of abuse & related criminal activity).

School districts and drug free organizations are also ideal partnerships for take back events. With participation of a school district, print shop services are often available at minimal cost or may be provided in kind. These services are needed for the printing of flyers, push cards, and similar promotional items. Additionally, school district personnel or programs can effectively market the event to all families of students through distribution of flyers and or newsletters or emails.

A partnership with a hospital or healthcare facility that utilizes waste management services is also ideal as such a service is needed for appropriate disposal of collected items. These organizations generally have contracts in place for waste management and therefore, economies of scale may be gained. Without such a partnership, event organizers must negotiate their own contract and may be required to enter into a multiple-year agreement.

A partnership with a university or college that provides education for health sciences such as medicine, pharmacy, nursing, etc. can be mutually beneficial as it can provide a source for volunteers as well as valuable learning and community service opportunities for students.

Partnerships with environmental groups are also encouraged and can be a source of supplemental funding.

Laws, Rules, and Regulations:

Conduction of medication take back events must be done in compliance with Federal, state, and local laws, rules, and regulations related both to waste collection and disposal as well as handling and destruction of medications. The need to consider both environmental-related regulations and drug handling and management regulations has lead to considerable delay in the development of responsible programs. While environmental professionals have a strong knowledge base regarding environmental rules and regulations, they generally do not have knowledge of medication management and disposal regulations. Vice versa is true of medical professionals. Therefore, a collaborative group that includes both of these disciplines is ideal when researching and planning a take back event. National guidance for events, while possible, would have to be extensively researched, prepared, and documented in order to include pertinent laws, rules, and regulations that vary from state to state. Additional local requirements would be even more difficult to include.

Federal law regarding the management of controlled substances: To be in compliance with the Federal Controlled Substances Act, staff and volunteers must not take possession of controlled substances that were prescribed for others. This law was discussed previously under the “Planning” section. By including law enforcement officers and having them take possession of these items, a compliant program can be conducted.

Texas law regarding the management of dangerous drugs: On the state level, event coordinators must consider the Texas Dangerous Drug Act. Dangerous drugs are defined as those medications that create a “danger” to the patient who chooses to self-medicate and are synonymous with prescription medications. The Texas Dangerous Drug Act is outlined in the Texas Health and Safety Code. According to Sec. 483.041 of this act, “A person commits an offense if the person possesses a dangerous drug unless the person obtains the drug from a pharmacist [pursuant to a valid prescription]...” While at first glance, this Act appears to be prohibitive of take back events, exceptions are listed. For instance, this subsection “does not apply to the possession of a dangerous drug in the usual course of business or practice or in the performance of official duties by ... (1) a pharmacy licensed by the board; (2) a practitioner; (3) a person who obtains a dangerous drug for lawful research, teaching, or testing, but not for resale;(5) an officer or employee of the federal, state, or local government...”¹⁰

Therefore, events in which data are collected as research efforts would be allowable and events in which local government officials (such as water treatment personnel, MSW, etc) would qualify for the exception.

Since medication take back events are conducted to collect unused medications, the authors consider the possession of dangerous drugs to be in the “usual course of business or practice...” While this is somewhat ambiguous, a written definition is not provided in the Act’s introduction and this exception may be open for interpretation.

The Texas State Board of Pharmacy has a rule within the Texas Administrative Code regarding the destruction of dangerous drugs and controlled substances by pharmacists.¹¹ This rule provides information on the destruction of drugs dispensed to patients in health care facilities or institutions and the destruction of drugs returned to a pharmacy, but provides no guidance for destruction of drugs at take back events not conducted at pharmacies.

If an event were to be conducted at a pharmacy, elements of the rule must be followed and include “(1) the dangerous drugs shall be destroyed in a manner to render the drugs unfit for human consumption and disposed of in compliance with all applicable state and federal requirements, (2) documentation shall be maintained that includes the following information: (A) name and address of the dispensing pharmacy; (B) unique identification number assigned to the prescription, if available; (C) name and strength of

the dangerous drug; and (D) signature of the pharmacist.” Interpreted literally, pharmacists would be responsible for destruction of collected medications and thus use of a waste management or disposal company appears to be implicitly prohibited.

Federal environmental regulation: In the context of medication take back programs, it is important to define hazardous waste. According to the EPA, “hazardous waste is defined as liquid, solid, contained gas, or sludge wastes that contain properties that are dangerous or potentially harmful to human health or the environment.”

The EPA lists wastes that are determined to be hazardous. This includes some pharmaceuticals that consist of ingredients that are categorized as P- or U-listed wastes. (These wastes include medications such as warfarin and nitroglycerin.) Unfortunately, these lists are outdated and many pharmaceuticals that have been developed or introduced following the formation of the lists are still hazardous, but do not appear on the lists. Therefore, when determining which pharmaceuticals are hazardous, one must consider whether the item includes a P-listed or U-listed component or if the product exhibits any of the following characteristics: ignitability, corrosivity, reactivity, and/or toxicity. These items are considered hazardous.

Hazardous items must be managed in compliance with the Federal Resource Conservation and Recovery Act (RCRA). RCRA was created, in part, as an effort to protect human health and the environment from waste disposal hazards as well as to make sure that waste management is performed in “an environmentally sound” manner. However, federal regulations exempt wastes generated from households from being hazardous.

As reiterated in an EPA Office of Solid Waste and Emergency Response (OSWER) Policy Directive, all household wastes are exempt by definition from the federal hazardous waste regulations. This applies even when these items are accumulated in large quantities. In fact, this Policy Directive goes on to state, “Section 261.4(b)(1) unconditionally exempts household wastes from being designated as hazardous even when accumulated in quantities that would otherwise be regulated or when transported, stored, treated, disposed, recovered, or reused. However, when household wastes are mixed with hazardous wastes from small quantity generators, this resulting mixture is subject to the small quantity generator rules... [and] sponsors of household hazardous waste collection programs should be careful to limit the participation in their programs to households to avoid the possibility of receiving regulated hazardous wastes from commercial or industrial sources.”¹²

At this point, pharmaceuticals from households would appear to not require the strict management dictated by RCRA. Event coordinators need to contact their state and local environmental authorities to determine if further regulations exist.

Texas environmental regulation: Although federal regulations exempt household-generated wastes from being classified as *hazardous waste*, under Texas laws and regulations, these *hazardous-yet-federally-exempt* items are classified as *household hazardous waste (HHW)* and thus, special handling, transportation, and management needs must be considered.

Notifications of Events:

Notification requirements are currently difficult to discern. However, the following organizations are frequently contacted by public health officials and by the public in general in an effort to plan or to locate take back event drop off opportunities.

1. Regional DEA Office: In Texas, there are multiple DEA regions. Event coordinators should contact their respective regional office to determine if notification is required. If notification is required, it generally consists of a letter from the participant law enforcement agency (on agency letterhead) and might include: date and location of the event, statement of participation by law enforcement agency, statement that chain of custody for controlled substances will be maintained by said law enforcement agency, and that controlled substances will be managed and disposed of in accordance with established agency policy. Inclusion of steps that will be taken by program personnel to prevent drug diversion, specifically the diversion of controlled substances, would be appropriate.

The requirement for notification of the DEA is currently at the discretion of each region's respective Special Agent in Charge (SAC)(personal correspondence with Lisa Sullivan, Diversion Program Manager, DEA Dallas Region). Should the SAC not require a letter, a simple letter of notification with an open invitation to the event as a professional courtesy is suggested.

2. Texas State Board of Pharmacy (TSBP): Although there are currently no requirements by the TSBP for notification of events, the author again suggests a simple letter of notification as a professional courtesy. Inclusion of an open invitation to attend the event seems appropriate. Additionally, in previous communications between the author and the TSBP, officials appreciate assurance of law enforcement participation.
3. Texas Commission on Environmental Quality (TCEQ): In an earlier version of this paper, the author mentioned that there were no requirements of notification of the TCEQ. After further investigation, however, it appears that certain types of collection events may need TCEQ authorization. This is because the act of collecting another individual's waste – even pharmaceutical waste – is an activity that falls within TCEQ jurisdiction.

Two possibilities currently exist in order for a program to comply with TCEQ regulations. The event director/operator should either 1) apply for a HHW permit, thus allowing the

program to collect both non-HHW pharmaceuticals and HHW pharmaceuticals, or 2) the Municipal Solid Waste division should be notified.

A program in which no more than 100 pounds of HHW-pharmaceuticals are collected per year is exempt from Subchapter N of TAC 30, Chapter 335 (Household Hazardous Wastes).

For those who wish to conduct a program in which both non-HHW and HHW pharmaceuticals may be collected, **procedure A** below should be followed. A take back event in which pharmaceuticals that include these items are being collected, must meet HHW program requirements (TAC 30, Part 1, Chapter 335, Subchapter N, Rule §335.403). These requirements are fairly stringent and include extensive training and administrative components.

For those who wish to conduct a program in which only non-HHW pharmaceuticals are collected (with screening and rejection of HHW pharmaceuticals at the collection site) OR for those who wish to collect non-HHW pharmaceuticals AND no more than 100 pounds of HHW-pharmaceuticals per year, **procedure B** below should be followed.

Procedure A (HHW + non-HHW program): The event director/operator should contact the TCEQ Pollution Prevention and Education Section (PPE) regarding a Household Hazardous Waste collection event. Although this respective notification process is more complex, the rules are more well-established (30 TAC 335, Subchapter N). More information on this process can be found at:

<http://www.tceq.state.tx.us/assistance/hhw/howto.html>

Further assistance and information is available from the Small Business and Local Government Assistance Section of TCEQ. They are available at: <http://www.tceq.state.tx.us/assistance/sblga/sblga.htm> and a confidential compliance hotline is available at 800-447-2827.

Procedure B (non-HHW program ONLY or non-HHW + less than 100 pounds per year HHW program): As mandated by recent Senate Bill 1757, TCEQ is currently in the process of developing recommendations for the state legislature regarding alternative disposal methods for pharmaceutical waste.

Until formal policies are implemented regarding pharmaceutical waste disposal, event directors can contact TCEQ's Municipal Solid Waste Permits Section to discuss, on a case-by-case basis, whether authorization is required for a specific event, and if so, what level of authorization is needed. Event directors should contact TCEQ at least 45 days before a collection event. Depending on the nature of the collection event, a simple notification under 30 TAC § 330.11 may be sufficient.

Event Structure Models:

Research model: If program coordinators wish to collect data as a research effort, they may choose to conduct either a partial or full inventory of items brought to the event. Such an undertaking requires abundant resources and may be well-suited for programs in which numerous volunteers are available.

Logging collected items can provide information that is needed as impetus for policy and legislative changes. Substantial “stockpiling” of unused medications by individuals is a growing problem that will only worsen as the population ages. Therefore, efforts to address the problem on the “front end” are greatly needed. A logical first step is to determine what medications “typically” are not used and therefore are brought to collection events. However, the logging process is very time- and resource-consuming and a collection program could quickly become overwhelmed by such an endeavor if not carefully and thoughtfully planned and coordinated.

Law enforcement logging requirement model: Depending on the policies and procedures of partnering law enforcement agencies, anything from a detailed, line-item inventory to no inventory at all may be required.

In the case of Medication Cleanout™, the partnering law enforcement agency requested a line item inventory of all collected controlled substances. These were the only items being turned over to the agency and this line-item inventory was necessary in order for the officers to check the collected items into their evidence room for storage until time of disposal.

Approximately 5-10% of collected items are generally controlled substances; therefore, logging of these items can usually be achieved with minimal personnel resources. The author suggests that the inventory be logged by event personnel leaving the law enforcement officer(s) free to observe activities in this area.

Law enforcement coordinated/minimal resources model: In some cases, the law enforcement agency is the actual coordinator of the event. If this agency chooses to accept all collected items, regardless of controlled or non-controlled substance status, an inventory may not be needed at all. In this case, an outcome measure would be the weight of the items collected.

For organizations who wish to coordinate events with minimal resources, the agreement of the participating law enforcement agency to accept all items without inventory requirements is ideal. In this case, no sorting is required and time and personnel resources are minimal.

Medication Cleanout™ Case Study:

Medication Cleanout™ was developed collaboratively by staff of the Texas Panhandle Poison Center (TPPC) of the Texas Tech University Health Sciences Center (TTUHSC) in Amarillo and the Safe Schools/ Healthy Students initiative of the Amarillo Independent School District.

Because the TPPC is affiliated with a health sciences center and staff of TPPC also serve as faculty at TTUHSC, recruitment of student volunteers was not difficult. Also, pharmacy students had curriculum requirements to obtain community service volunteer hours and thus, were in need of such an opportunity.

For the first event, 90 volunteers were recruited and split between two collection sites located on opposite ends of the City of Amarillo. A one-hour, mandatory training session was conducted to instruct volunteers and staff regarding operation of the event, safe handling of medications, a site safety plan, volunteer/staff roles, zero tolerance drug diversion policy & reporting of diversion, management of potential criminal confrontation (robbery at the event), purpose of inventory and navigating the computer database for logging collections, confidentiality agreement, liability waivers, and photo consent information. Volunteer manuals were also developed and provided to all volunteers containing this information. A diversion prevention plan was developed by Medication Cleanout™ coordinators.

The event was conducted as a drive through. A schematic of the event flow is provided as Appendix A. Law enforcement officers were assigned to the parking lot/drive through area and to the indoor processing area. As each vehicle approached, a volunteer stepped up to the vehicle, greeted the participant, and asked a set of survey questions. The final survey question assessed if the participant had brought any sharps (insulin syringes, lancets, etc.) to the event for disposal. If they did, the volunteer handed the participant a sharps container and instructed the participant to insert their own sharps into the container. Outcome data on sharps collection was not recorded outside of the survey question.

After the survey was completed, the volunteer accepted the items brought to the event. Disposable gloves were worn by all volunteers who handled medications or their packages including the surveyors. This collection was then transported to the secure, indoor processing area. (Only event staff/volunteers were permitted in this area.) The first step in processing was to remove patient information. Patient names, addresses, and prescription numbers were obliterated from the label utilizing black paint pens. Items were then moved to the sorting area.

In the sorting area, pharmacists, pharmacy technicians, and/or pharmacy students separated the controlled substances from the non-controls. The controlled substances were then transferred to the controlled substance inventory area for logging, while the non-controls were sent to the non-controlled substance inventory area for logging. Any items that had been removed from their original container or were otherwise non-identifiable were sent to the pill identification area for attempted identification.

At the controlled substance area, pills were counted and logged into the controlled substance inventory database. This area was closely observed by a dedicated law enforcement officer. Also logged were the original quantity of pills dispensed, quantity remaining, the prescription fill date, and the drug name and strength. Liquid volumes were estimated in milliliters or ounces. At the end of the event, the controlled substance inventory was printed and signed by

both an event coordinator and the law enforcement officer and each were provided a copy. Pills were returned to their containers and packed by law enforcement officers.

At the non-controlled substance area, pills were also counted and the same information was entered as that for the controlled substances. Liquid volumes were also estimated. Liquids were maintained in their containers and were packed in plastic containers as required by the utilized waste management company. Pills and other solid dosage forms were emptied into lined waste management disposal boxes. Filled disposal boxes were stored in a secure closet that was only accessible to University safety officers (#2) and University police officers until waste management pick up occurred. Empty bottles were then disposed of as ordinary garbage.

At the pill identification area, pill imprint codes were utilized to attempt to identify these substances. The Lexi-Comp® pill identification application and Identidex® applications were utilized for this purpose. Identa-drug® hard copy references were also available. If items were identified as controls or non-controls, they were marked and then processed accordingly as listed above. Any items that were unidentifiable, including liquids and pills without imprint codes, were assumed to be controlled substances, were labeled as “unknown” and were processed as controls.

An Access database was developed and utilized for logging of all items collected. This data was then exported to Excel for tabulation. Data will be submitted for publication.

296 vehicles participated with a resulting collection of 863 pounds of medications. Approximately 75 pounds of the collected items were controlled substances.

Marketing of the event included 21 mini-billboards across Amarillo (population ~180,000), newspaper ads, TV interviews, flyers and push-cards at pharmacies, flyers distributed by the school district through all elementary students, and various emails.

Lessons Learned:

Marketing efforts must stress to the public that items need to be kept in their original containers. Photos or videos should not include a mixture of pills outside of their containers – although this is visually appealing, it is thought that the public views these images and may follow suit by pouring all of their medications into one container or bag.

Well-meaning individuals at various organizations suggested using groups such as high school student council members to go door-to-door to promote collections. Due to abuse, diversion, poisoning, and liability concerns, no minors should be involved in collections. For liability reasons, it is also suggested that minors not be allowed to participate as volunteers.

Also suggested was requesting that parents send unused medications to school with their children to promote collection. This tactic is also not recommended due to the same risks listed above.

Partnerships were invaluable. We were able to capitalize on one another's strengths and minimize our weaknesses and networking opportunities were abundant.

Conduction of the event as a drive-through is very well received by the public and facilitates a safe, secure, limited access medication processing area.

Support of law enforcement officials can be sought directly or through city commission or city council meetings. Providing local statistics in support of a program is helpful although national statistics are also meaningful.

For events in which separation of controlled and non-controlled substances is required, the use of experienced retail pharmacists or pharmacy technicians for sorting significantly speeds up the process. These individuals can generally sort items based on practice-based experience versus other individuals who may be referring to numerous pages listing controlled substances (both brand and generic names).

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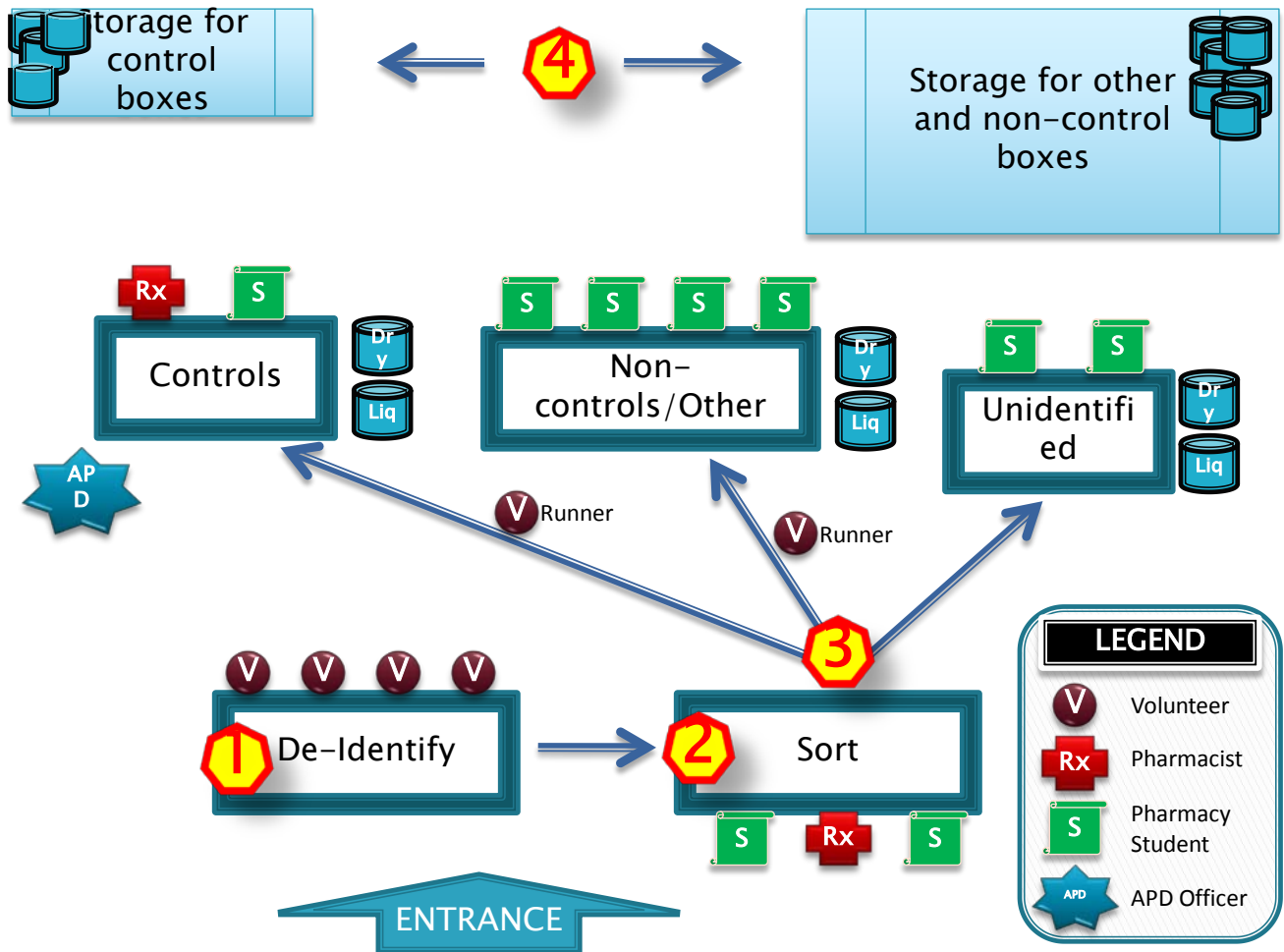
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Appendix A



- 1 State-Specific Unintentional-Injury Deaths – United States, 1999-2004. *MMWR*. 2007;56(43):1137-1140.
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- 6 2008 Partnership Attitude Tracking Study (PATS). The Partnership for a Drug-Free America. http://www.drugfree.org/Files/full_report_teens_2008 Accessed: 08/21/2009.
- 7 Bedell SE, Jabbour S, Goldberg R, et al. Discrepancies in the use of medications. *Arch Intern Med*. 2000;160:2129-2134.
- 8 AP investigation: Pharmaceuticals found in drinking water – Framingham, MA – The MetroWest Daily News. <http://www.metrowestdailynews.com/homepage/x1574803042> Accessed: 02/11/2010.
- 9 Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration. Department of Justice. Drug Enforcement Administration. 21 CFR Parts 1300, 1301, 1304, 1305, and 1307. Federal Register; Vol. 74, No. 12; January 21, 2009.
- 10 Texas Health and Safety Code. Title 6, Subtitle C, Chapter 483.
- 11 Texas Administrative Code. Title 22, Part 15, Chapter 303, Rule §303.2.

- 12 Office of Solid Waste and Emergency Response (OSWER) Policy Directive No. 9574.00-1.
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