Safe Medication Disposal and Related Considerations
A white position paper
Pennsylvania Pharmacists Association

Background and Situation Analysis:
Consumers are rightly confused about what to do with their unwanted medications because they've received conflicting messages from government and environmental sources. Federal guidelines direct consumers which medications to flush and how to properly put others in the trash. But, landfills can leak, potentially causing medications to leach into the soil, and flushing can contaminate waterways. There have been many recent environmental reports of chemical compounds found in our natural water supplies, including trace amounts of medications. All of this has lead to a growing concern about the impact of medication disposal and its effect on the quality of our water supply, aquatic life and, ultimately, human life.

Most medications enter our waterways and water systems in two ways: when they are flushed down the toilet or when people pass the substances through their system. Many medications are only partially metabolized in the human system; the rest are excreted from the body through urine and fecal matter. While wastewater is treated before it is reintroduced to rivers and streams, most treatments do not remove all chemical residues. Many treatment systems have not been updated to include contemporary chemical additives. The Associated Press in March 2008 reported the results of a five-month investigation, which found that the drinking water in 24 major metropolitan areas contained a variety of prescription medicines in minute concentrations. The medications included sex hormones, antibiotics, mood stabilizers, anti-convulsants and many others. In a 2004 joint evaluation of a drinking-water-treatment (DWT) facility by the US Geological Survey and the Centers for Disease Control and Prevention, it was found that pharmaceuticals compounds— including anti-convulsants and nicotine byproducts— can survive typical DWT processes and occur in drinking-water supplies [Stackelberg et al 2004]. Most recently, in their January 2014 report evaluating effluent samples of 50 large wastewater treatment plants, the Environmental Protection Agency (EPA) found concentrations of blood pressure medication in all samples tested and levels of anti-convulsants in up to 90% of samples [Kostich et al 2014]. The effect on humans remains unknown at this time.

Pharmaceuticals and other chemicals also enter the waterways from farms and animal excrement, landfill leaching, manufacturing, and medical waste. Drug disposal and medication waste from hospitals is also a major concern. Factor in the additional medication destruction generated by long term care facilities, clinics, and the like and the problem becomes even broader in scope. Healthcare systems spend thousands of dollars a year trying to safely manage their waste and protect waterways.

Unfortunately, at this point there does not seem to be an easy answer to a problem that impacts everyone. A broad-based solution must be found that addresses the problem from all fronts and takes a multitude of factors into consideration, only some of which will be discussed below.

Current Practices:

Patients, families, and caregivers often have shelves or medicine cabinets filled with old, outdated, and potentially dangerous medications. If they choose to dispose these medications, they often do so by simply throwing them in the trash or flushing them down the toilet. Throwing them in the trash opens up opportunities for misuse, causes harm to landfills, and creates the potential for poisoning of children, pets, and wild animals. Flushing them down toilets or drains harms our waterways. Some people will take these medications to their pharmacy and ask the pharmacist to dispose of them. When possible, a pharmacist may agree to do so in order to ease a patient's burden or prevent a potentially dangerous situation for a patient's family (i.e. the presence of small children in the home, or an elderly patient who is easily confused). They then typically dispose of them according to the recommendations outlined below. Despite warnings to the contrary, many people consider it appropriate to give their medications to another person. This is an extremely dangerous proposition for a variety of reasons: lack of verification of proper storage, medications "switched" into another prescription container, and most importantly, no professional oversight that the medications being shared are even safe and relevant to the recipient's current health condition.

Resources

The U.S. Food and Drug Administration (FDA) encourages responsible disposal of unwanted medications from homes and has been advising people to throw away their extra medications in the trash and to mix them with non-desirable substances such as coffee grounds or kitty litter to avoid drug diversion. Additionally, they warn that certain medications with a high incident of abuse and overdose, need special precautions to avoid diversion and supports Take Back programs as well as flushing of these medications. A copy of their recommendations as well as a number of resources on this topic may be found at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/default.htm and http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm

The U.S. Department of Justice, Drug Enforcement Administration (DEA) has been sponsoring regular Take Back programs nationwide in conjunction with local law enforcement for the last four years. Typically, there had been two of these annually in April and September. In September 2014, the last national Take Back Day was held. Recent changes in their laws will allow for greater flexibility in return of controlled substances, which was the main reason that DEA held the programs. The program was successful and underlines the magnitude of the problem. Since the first National Take Back Day in September of 2010, the DEA collected more than 4.1 million pounds (over 2,100 tons) of prescription drugs throughout all 50 states, the District of Columbia, and several U.S. territories. The DEA remains concerned, particularly with the diversion aspect of unwanted medications, and maintains a website of other helpful resources on the topic. http://www.deadiversion.usdoj.gov/drug_disposal/index.html

Although Pennsylvania pharmacies cannot participate, there are a number of community, company, and pharmacy sponsored programs available, locally, regionally, and nationally. The National Community Pharmacists Association sponsors a DisposeMyMeds program through their Foundation in partnership with a number of companies, which provides helpful information and a pharmacy locator, where individuals can search by zip code to find pharmacies that are accepting medications and safely disposing of them. http://disposemymeds.org/

The Department of Drug and Alcohol Programs, in conjunction with local law enforcement, has established a number of sites with Take Back boxes across the state to return unneeded or unwanted medications on an ongoing basis. The website, http://www.ddap.pa.gov/portal/server.pt?open=514&objID=1666644&mode=2, provides a listing by county of participating locations, most of which are in police stations. However, not all police departments and locations are participating so it is important to check the above website.

Additionally, some Pennsylvania pharmacies have applied for and received approval to be locations to take back many medications. Through the PA Department of Environmental protection, approved pharmacies may take back medications, with the exception of controlled substances, if they arrange to have the medications removed by a hazardous waste hauler. Application and information on the program is available at http://www.elibrary.dep.state.pa.us/dsweb/View/Collection-10770

The concern and interest in disposal programs is increasing as the debate on best practices continues. There does not appear to be a single answer to this growing problem of safe medication disposal and it is important to consider several key points, discussed below, when formulating any policy in this area.

Consideration – Disposing of Controlled Substances

One significant area of concern regarding the safe disposal of unused prescription medications is the risk of drug diversion and abuse. Drug diversion can occur in a variety of ways. Medications may easily be diverted and misused if simply discarded in trash receptacles with household waste. For a variety of reasons, this method of drug disposal is clearly not appropriate, especially for controlled substances. The potential for children, waste management employees, passersby, or other individuals to obtain access to the medications in a the trash can is simply too great.

Controlled substance pharmaceutical waste is simply unwanted medications comprising of the Drug Enforcement Agency identified scheduled medications. With this class of medications, alternative disposal methods need to be carefully evaluated for their potential to allow drug diversion. Pharmacies do have a method of returning their own expired medications; but this comes with a price-tag and may not eliminate drug diversion concerns. Consumers cannot simply bring medications back to the pharmacy for disposal as there are regulatory implications as well as drug diversion risks. The established supply chain for prescription medications was designed, in part, to avoid the risk of drug diversion.

The DEA allows limited options for disposal of controlled substances by persons not registered. One option is for patients and consumers to take unwanted controlled substances to a public controlled substance disposal location. Locations can be identified by searching https://www.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s5. There are also take back programs that are offered several times a year in various communities that allow for safe disposal of controlled substances. In some localities, local law enforcement has been granted permission to take controlled substances back from community members. As an

alternative, patients and consumers can also contact their local DEA agency for direction on disposal.

Despite these options, most hospitals and pharmacies are not collection or destruction sites. However, patients that may be admitted to a healthcare facility may be able to transfer controlled substances to the organization for disposal, during their care.

Consideration – Method and Cost
In order to prevent an adverse impact on the environment, the most appropriate methods of drug disposal must be utilized. Pharmaceutical waste can contaminate the environment through improper incineration or landfill placement. Healthcare facilities are regulated by the EPA via the Resource Conservation and Recovery Act which provides guidance on disposal of solid waste. Up to 5% of all pharmaceutical agents are deemed to be hazardous waste or RCRA waste.

One way to dispose of medications permanently is to correctly incinerate them, although appropriate facilities and extremely high temperatures are needed. There is a relatively high cost to this. Incineration also causes harm to the environment by fouling air quality.

Patients and consumers challenged with disposal of noncontrolled pharmaceutical waste should first review the medication for any special disposal instructions. The medication should not be put into the sewer unless specifically instructed to do so. Community take back programs may be an alternative strategy that can be used by consumers at no cost. Lastly, if there are no other avenues for disposal, the de-identified medication can be disposed of in household trash after it's made unusable (FDA).

Consideration - Current Law and Public Perception
Section 5(a)(9)(xi) of the act (63 P. S. § 390-5(a)(9)(xi)) prohibits the return to stock of medication once it has left the premises of the pharmacy. Intuitively, this makes sense in the context of medication safety and integrity. Once a product is out of the control of the pharmacist, it is impossible to guarantee the conditions under which it was stored or if, in fact, it remained unadulterated. Unfortunately, should pharmacies become the primary collection point for medication disposal, the public might easily assume that the pharmacist's desire to profit from recycling previously dispensed medications will overtake their obligation to patient safety. At a minimum, this potential vacuum of trust creates the need for costly inventory, storage, and removal mechanisms that will likely have a devastating financial impact on pharmacies.

Consideration – Over-the-Counter (OTC) and Complementary and Alternative Medicine (CAM)
Many people initially think only of prescription medications when discussing safe medication disposal. Many OTC medications as well as CAMs are also contributing factors in waterway problems and must also be included in the solution. Also, not all medication, prescription or OTC, comes in a tablet or capsule form. There are liquids as well. Vitamins and mineral preparations may contain potential toxicity due to chromium, selenium and cadmium. It is best practice to treat these agents similar to pharmaceutical waste. *See section on Method and Cost.*

Consideration – Privacy
Under current HIPAA law, one must be careful with the handling of private health information. There would need to be careful consideration given to the disposal process, as this private health information is protected and must not be available for anyone to see. Conversely, simply allowing or encouraging the public to throw away prescription containers, with their personal identification on the label, is creating undue risk for an unsuspecting public.

Some Recommended Solutions
1) **Allocating Resources:** Nationwide, a commitment must be made to find resources to fund major initiatives to resolve this problem in a multitude of ways. All of the following items involve substantial investment to accomplish.

2) **Avoiding Over-prescribing:** Licensed prescribers must be educated and encouraged to re-examine prescribing practices so as to reasonably limit the amount of medication written for any given prescription. The quantity prescribed should satisfy the anticipated clinical needs of the patient – period. Quantities and refills should not be prescribed solely for the convenience of the practitioner, the financial gains of the third-party payor, or the unnecessary, perhaps uninformed, expectations of the patient.

3) **Medication Quantities**: Insurers need to reconsider processes that foster the dispensing of larger than necessary prescription medication quantities (e.g. mandatory 90 day mail order supplies). Stories abound of patients accumulating large quantities of unused medications secondary to a change in therapy, etc. This scenario only heightens the concern about medication safety and disposal.

4) **Waste Water Plants:** Waste water plants are encouraged to consult the 2013 Emerging Technologies report of the EPA which defines established and emerging processes to update their operations and begin processing the chemicals not currently removed from the water supply. Technologies such as nanofiltration plus reverse osmosis are innovative technologies that have been shown to remove pharmaceuticals from drinking water; approximately 2% of US treatment plants currently use them. [EPA March 2013]

5) **Agriculture and Other Chemical Contamination**: Other sources of chemical contamination need to be addressed: including but not limited to agricultural waste such as pesticides, fertilizers, livestock hormones and antibodies; industrial contaminates such as plasticizers, solvents, and propellants; and residues of water treatment such as byproducts of water disinfection. [EWG Tap Water Database 2009] It is short-sighted to think that human prescription medication waste is the sole source of concern.

6) **Community Disposal Programs:** Communities, through state mandates to the county level, could be called upon to set up collection and disposal systems. This might be accomplished through various collection points and/or specific days and dates in conjunction with law enforcement. Currently, there are programs for hazardous waste, needle collection, tires, and other items, which might be replicated in some way. Many of these programs look for funding from the producer of the product. Other issues include addressing the removal by

hazardous waste haulers to incinerators and the handling of controlled substances. Current locations such as police stations, could be a deterrent for some or inconvenient.

7) **Pharmacies as Collection Sites:** Pharmacies may elect to be collection points as long as other additional methods are also identified and there is a plan for regular and safe collection from the pharmacy by the community. Across the country, some communities are providing large metal locked boxes for use at pharmacy collection points. With changes to DEA regulations, the possibilities for this have increased; but, continued awareness for safety and diversion is an ongoing concern. In Pennsylvania, pharmacies are limited in what they can do both in terms of what they can take back, (no controlled substances), and how they may do it, (must be approved through DEP program and use hazardous waste hauler). Changing this to allow other options could be considered to augment the law enforcement programs through state initiatives.

8) **Incineration Availability:** Incineration appears to be the most logical form for permanent removal. Additional points of incineration and increased efficiencies in this method may need to be developed.

9) **Consumer Options:** Medication disposal systems, such as carbon adsorbents, are becoming available as a way for consumers to directly inactivate medications and reduce harm to the environment. Available for on-line or retail outlet purchase, these proprietary systems allow consumers to dispose of unwanted medications, including liquids, tablets, capsules, and transdermal patches, by placing product in a disposal pouch or other container and discarding directly in the trash. The use of deactivating and binding agents renders the medication unusable and prevents both drug diversion and contamination of the environment. Disposal systems range in size and price beginning at $3.99 for a system that can accommodate up to 45 tablets/capsules, 6 ounces of liquid, or 6 transdermal patches.

(10) **Public Information, Education, and Awareness:** Public education regarding the problem of medication disposal and the various options to address it needs to happen. To date, efforts including Drug Take-Back Programs and the AWARxE campaigns have begun to raise awareness on medication disposal; however, a state-coordinated communication plan on disposal options is necessary. As solutions are developed they must be effectively communicated and promoted to the public. One avenue for this would be that plans for collection and return as well as disposal could potentially be distributed through pharmacies on a voluntary basis. Another solution may be notification of proper medication disposal as a service to providers and patients coordinated through the PA Department of Health and the Drug and Alcohol programs bureau.

Conclusion

The issues of medication disposal is a vast and complex one. There does not seem to be one easy answer and many organizations and federal and state agencies all have very different perspectives based on their framework of concern. It appears that the best thing that can be done at this time is to acknowledge the issue, engage in ongoing discussions among all stakeholders, work towards solutions while avoiding unintended consequences, and encourage public awareness. Any solution must be accessible, affordable, sustainable, replicable, and environmentally sound

Reference Table (updated January 2015)

Reference Information	Website
US FDA Recommendations on Safe Disposal of Unused Medications (Consumers)	http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/default.htm AND http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm
Safe Disposal of Controlled (Scheduled) Substances (Consumers)	http://www.deadiversion.usdoj.gov/drug_disposal/index.html
Listing of Pharmacies & Locations Participating in Drug Disposal-Take Back Program (Consumers)	http://disposemymeds.org/ http://www.ddap.pa.gov/portal/server.pt?open=514&objID=1666644&mode=2
Listing of Locations Participating in Drug Disposal-Controlled Substances (Consumers)	https://www.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1
Application for Take Back Locations (applicable for Pharmacies)	http://www.elibrary.dep.state.pa.us/dsweb/View/Collection-10770

References (in order of appearance in document)

- Kostich M, Batt A, Lazorchak J. Concentrations of prioritized pharmaceuticals in effluents from 50 large wastewater treatment plants in the US and implications for risk estimation. *Environmental Pollution*. January 2014;184:354-9.
- Stackelberg P, Furlong E, Meyer M, et al. Persistence of pharmaceutical compounds and other organic wasterwater contaminants in a conventional drinking-water-treatment plant. *Science of the Total Environment*. 2004. 329: 99-113.
- United States Environmental Protection Agency. Emerging Technologies for Wastewater Treatment and In-Plant Wet Weather Management. March 2013.
- National Drinking Water Database. Pollution Sources. Available at: http://www.ewg.org/tap-water/sourcesofwaterpollution.php. Accessed: January 20, 2015.
- Pennsylvania eHealth Partnership Authority. Available at: http://www.paehealth.org/index.php