



Reducing Pharmaceutical Waste March 26, 2009

Prescription medications are critical to maintaining health and improving the quality of life for millions of Americans. Not all medications dispensed to patients, however, are consumed. Prescribed medications may go unused for a variety of reasons, including: a patient's medical condition has been resolved before the medication is totally consumed; the patient has an adverse effect from the medication and must stop therapy; the medication is not effective and the physician changes the patient to a different medication; the patient fails to adhere to the prescribed therapy; or the person dies and leaves behind a supply of medications.

In the last several years, the topic of pharmaceutical waste has become a public health issue of increasing urgency, as evidenced by numerous Associated Press articles and nationwide pharmaceutical waste initiatives that generally have focused on household waste. Little has been done to deal with institutional pharmaceutical waste and the lack of any comprehensive, coordinated action by the Drug Enforcement Administration (DEA), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) has allowed this problem to fester. Major reasons to address unused drug disposal include preventing the illegal diversion of controlled substances, protecting the environment and reducing the costs for patients and payers by eliminating waste.

Preventing the Illegal Diversion of Controlled Substances

There are no federal regulations for the proper disposal of controlled substances or prescription medications by consumers but there are suggested guidelines by the Office of National Drug Control Policy (ONDCP) (www.whitehousedrugpolicy.gov/drugfact/factsht/proper_disposal.html). They include taking unused, unneeded, or expired prescription drugs out of their original containers; mixing them with an undesirable substance, such as used coffee grounds or kitty litter; putting them in impermeable, non-descript containers or sealable bags; and discarding the concoction in the trash. Flushing prescription drugs down the toilet is advised *only* if the label or accompanying patient information specifically instructs doing so. The ONDCP guidelines also suggest taking advantage of community pharmaceutical take-back programs that allow the public to bring unused drugs to a central location for proper disposal. However, there are very few take-back programs because very little funding is available for such programs, and there is no federal coordination or clearinghouse of information about these programs that is readily available to the public.

While there are no federal requirements for the disposal of non-controlled prescription medicines by pharmacists, the disposal and return of controlled substances by pharmacists is governed by the Controlled Substances Act (CSA), its implementing regulations and DEA's interpretations. Under the CSA, only DEA registrants can handle or transfer controlled substances. Thus, patients and long-term care facilities that possess unused or expired controlled substances cannot return them to pharmacies or reverse distributors. DEA's current policy is that long-term care facilities that are not DEA registrants must dispose of controlled substances directly, which frequently means flushing them down the toilet.

Protecting the Environment

A certain amount of water pollution from medications is inevitable. When consumed, some medications are excreted from the body in active form, or as active metabolites of the original medication. These waste products enter the sewage system. Another source of pollution, however, is the disposal of leftover medications that are not consumed.

The disposal of household medications by flushing them down the toilet (which goes to a sewage system or septic tank), throwing them into the household trash (which usually goes to a landfill), or incinerating them (consumers would have to participate in “take-back” programs in order for their medications to end up being incinerated) can cause environmental problems.

Of these three disposal methods, throwing medications into the toilet or pouring liquid medications down the drain are the most significant contributors to water pollution. Medications and personal care products (such as antimicrobial soaps) may go directly into streams or rivers, or may be delivered to water treatment plants, where current technology is inefficient in removing these contaminants from water. The result is that small concentrations of a variety of pharmaceuticals and personal care products can end up in drinking water. Medications delivered to landfills may also leach into groundwater and eventually end up polluting streams or rivers or getting into the drinking water. Generally, however, putting medications into the trash results in less adverse environmental effects than putting them directly into the water supply. Sealing the medications in containers, such as a plastic sealable bag, is helpful in reducing the amount of pharmaceuticals that leaches into the groundwater. Incineration may pose a slight negative impact on the environment, but it is the most environmentally friendly option that is currently available and the preferred method of disposal.

In a September 2008 article, the Associated Press estimated that U.S. hospitals and long-term care facilities annually generate at least 250 million pounds of waste that includes both pharmaceuticals and contaminated packaging. Experts say drugs may account for half of this waste with millions of pounds being flushed.

Nursing homes generate a significant amount of pharmaceutical waste including controlled substances for a variety of reasons. Unlike hospitals, most nursing facilities do not have on-site pharmacies. Long-term care pharmacies that service nursing facilities often rely on third party payors who are reluctant to pay multiple dispensing fees. Thus, these pharmacies often package and ship medications in 30 day supplies. Yet, medication orders change frequently in this population, leaving a significant quantity of dispensed, but unused medications.

The EPA believes that long-term care facilities flush most of their unused drugs but it has not developed any policies to curtail this practice. The EPA doesn't feel this is the best practice nor does it think using landfills is a permanent solution. The EPA is looking at setting a national standard for how much drug waste may be released into the waterways by the medical services industry, but the earliest this decision will be made is in 2009. On the other hand, DEA's current policy directs nursing facilities to flush unused controlled substances down the toilet.

As a result of the lack of a national policy to address pharmaceutical waste, nursing home operators face difficult choices. In Kentucky this past year, an emergency waiver that had been in place since 1996 that allowed long-term care facilities as non-DEA registrants to send back

unused controlled substances to reverse distributors for destruction was rescinded by the DEA with no notice. This led to stockpiling controlled substances in the 250 nursing facilities in the state, until a solution could be found. The DEA would not re-instate the waiver and all facilities now destroy controlled substances on site, leading to more pollution of the water supply.

Reducing Costs for Patients and Payers by Eliminating Waste

Someone paid for all consumer medications that end up being wasted. If the patient did not pay directly, the medication cost may have been covered by Medicaid, Medicare, commercial insurance, the Veterans Administration, or some other third party payer. Any medication that goes unused adds to the total costs of our health care system.

Strategies that focus on appropriate disposal of medications do not address the underlying problem that resulted in the waste in the first place. For that reason, strategies that reduce the amount of pharmaceutical waste may be more important and effective in the long run than changing the method used to dispose of unwanted medications. Understanding factors and policies that contribute to pharmaceutical waste is an important first step.

As noted above, one key factor is how pharmacies are paid to dispense medications. Over 90 percent of prescriptions dispensed by pharmacies are covered by a third party payer. The payment and coverage policies of these payers are a critical factor to address if pharmaceutical waste is to be reduced. In long-term care facilities, including nursing homes and assisted living, a monthly medication dispensing cycle has been the historic pattern. These medications are often provided in “bingo cards” or blister packs that contain tablets or capsules that can be punched out as each dose is due. However, payors only want to pay one dispensing fee a month – so cards usually contain a 30-day supply of medication. If long-term care pharmacies could dispense medications in shorter dispensing cycles, such as a seven day unit dose system, or a 3day/4day, daily or just-in-time by shift system, a great deal of medication waste could be avoided. Because these shorter dispensing cycles are more labor-intensive, or require more costly technology, however, pharmacies would need higher or more frequent dispensing fees to support the shorter dispensing cycles.

Recent advances in technology, including newer automated dispensing systems, greatly improve the feasibility of long-term care pharmacies adopting shorter dispensing cycles and medication systems that reduce or eliminate pharmaceutical waste. While the DEA has issued regulations to allow for the installation of Automated Dispensing System (ADS) at long-term care facilities—in some states, laws and regulations either prohibit ADS or restrict their use. Labeling requirements and whether controlled drugs can legally be dispensed in ADS may differ from state to state. The cost of this new technology may also be prohibitive for many facilities. The federal government could take the lead through Medicare and the Veterans Administration and sponsor pilot programs and fund research to identify payment methodologies for long-term care pharmacies to encourage both shorter dispensing cycles and new technologies to reduce waste.

Confusion About Disposal Requirements in Institutions

Institutions (nursing homes, hospitals, etc.) often face conflicting advice from authorities because there is no clear guidance on how to dispose of unused drugs. Not only are there conflicting federal policies, but there may be state policies as well that may be more restrictive. On the federal level, the DEA, the EPA and the FDA have uncoordinated policies that deal with

pharmaceutical waste disposal. On the state level, drug disposal laws and regulations may be under the purview of the Board of Pharmacy, the Department of Health and/or environmental agencies. Not only is there a myriad of agencies to contend with but also different categories of pharmaceutical waste including controlled substances, hazardous waste, and infectious waste that require different disposal procedures. The quantity of the waste may dictate different disposal requirements as well. The disposal requirement for one pill may differ from that of 25 other pills. Transdermal patches pose another disposal dilemma. Different disposal methods need to be followed depending on the medication content of these patches. The following recent questions from consultant pharmacists illustrate the need for a clear and consistent national policy on pharmaceutical waste disposal in facilities. One pharmacist writes:

Could someone please share their policies/procedure for destroying transdermal patches at the nursing home?...Many of the nurses told me that they have on gloves while they apply a new patch and when they de-glove they put the used patch in the glove and throw it away in the trash. I...suggested folding them in half so it sticks together and putting in the sharps container. Every article I read suggested folding the patches in half to stick together, but then many recommended flushing the patches. Considering the environmental concerns I did not think this was a good option, which is why I suggested the sharps container. Also for new patches that need to be destroyed I would recommend the same process, but I know many of our homes cut these up and put in sharps container. I was curious how other were handling this issue. Thanks.

Another pharmacist writes:

Does anyone have a "best practice" policy and procedure for proper destruction of controlled substances in community-based care facilities (AL, congregate care, adult foster care, etc., depending on the State's definition)? With the recent report that pharmaceuticals are now present in many sources of drinking water flushing is being revisited. Some mix the unused meds in coke and discard the resulting solution with the sharps and some pour it in the trash. What about opioid patches? Is putting them in the sharps container sufficient or do you add water? Any feedback would be appreciated!

Even the most conscientious personnel find all the different rules and regulations promulgated by numerous agencies confusing. They strive to follow these policies and want to be environmentally conscious. However, without a comprehensive, coordinated policy by the federal government that is safe, sensible and good for the environment, not only will the confusion continue but the improper disposal of pharmaceutical waste and the flushing will continue as well. It is critical that EPA and DEA work together to adopt standards to address the disposal of pharmaceutical waste, including controlled substances, faced by institutional providers.

Potential Solutions and Recommendations

Possible solutions to reduce pharmaceutical waste include:

1. Reduce the number of unused doses

The first priority should be to reduce the amount of pharmaceutical waste generated, rather than dealing with the pharmaceutical waste once it has been generated. Reducing the amount of pharmaceutical waste addresses the root cause of the problem as well as reducing overall

health care costs. The federal government should fund research and pilot programs to identify new payment methodologies for long-term care pharmacies to encourage shorter dispensing cycles and to explore the use of new technologies like Automated and Remote Dispensing Systems that reduce waste because medications are not dispensed until they are needed.

2. *Establish national guidelines through the coordinated efforts of federal agencies*

There is very little coordination between the EPA, the DEA and the FDA when it comes to the disposal of controlled substances and other medications. Currently, the DEA and EPA have their own individual efforts underway to address the disposal of medications—the DEA is accepting comments on proposed questions about the disposal of controlled substances by non-DEA registrants, while the EPA is finalizing a separate questionnaire that will be sent to health institutions about drug disposal. In order to have a comprehensive, coordinated program, these agencies need to work together to establish national guidelines.

3. *Educate the public and providers*

To begin to solve this problem, it's imperative that both the public and providers be informed of the importance of disposing of drugs properly and to provide information on safe, easy and environmentally friendly options that are available for them to utilize. The federal government should establish a national clearinghouse to collect and disseminate information about best practices, provide technical assistance to communities and providers and provide information to the public and health care providers about safe disposal practices.

4. *Offer convenient disposal options and implement take-back programs*

Take-back programs to collect leftover medications from consumer households have grown in popularity in recent years. Several approaches have been used for individual consumers and some of these might be modified and used for institutions. One common method is to schedule an appointed day and location where consumers can bring unwanted medications and turn them in to a sponsoring organization. Another strategy in use is to have a secure box located at the pharmacy where consumers can drop off unwanted medications. However, if the take back programs involve controlled substances, law enforcement must be involved. This can be an impediment because local law enforcement agencies are already "stretched" and don't have enough personnel to support this effort. Limited funds are available for take back programs. They are frequently pilot programs funded by federal government grants. Additional funding is needed to establish more take back programs and to enable them to become permanent programs. Government entities are looking for other funding sources including requiring pharmaceutical companies to pay for these programs, and levying other waste disposal taxes and fees.

The state of Maine has a pilot program in which consumers can mail unwanted medications including controlled drugs in prepaid envelopes to a central collection point. Legislation has been introduced in Maine to require pharmaceutical companies to pay for a permanent program. Oregon and Washington are also looking at similar funding proposals for their disposal programs.

In addition to take-back programs, 37 states have enacted legislation authorizing drug recycling programs. These programs allow unused medications to be donated to charitable clinics for redistribution. However, these programs have faced a number of implementation

obstacles including concerns about liability and lack of reimbursement to pharmacies, as well as questions regarding the cost effectiveness of recycling inexpensive generic drugs.

Because it is so easy for consumers to flush unwanted medications, or throw them in the trash, take-back programs must be convenient, voluntary and free for consumers who participate in them. Removing statutory and regulatory barriers so that disposal programs can flourish should be considered not only for consumers but for providers as well.

5. *Provide incentives for more environmentally friendly incinerators to be utilized*

Incineration has the advantage of destroying unwanted medications and preventing significant adverse environmental impact. It is necessary, however, for the incineration to be done with an incinerator that has been designed and approved for this purpose. Few of these are available in the United States, and the available options can be costly. Incomplete or inadequate incineration can contribute to air pollution and potential health problems through poor air quality. Providing incentives possibly through the tax code to expand the use of these incinerators should be examined.

6. *Authorize non-DEA registered institutions to dispose of controlled substances*

It is often not feasible for institutions to follow the consumer-focused guidelines provided thus far. So an even greater need exists for practical and cost-effective guidelines/policy to address disposal within/by institutions. As noted above, the DEA granted Kentucky an emergency waiver to allow non-DEA registered long-term care facilities to use reverse distributors to collect and incinerate unused controlled substances. While this was an isolated waiver, it was a safe and environmentally friendly solution. Amending the CSA to permit safe disposal practices, including allowing non-registrants (who are licensed health care providers or facilities) to deliver unused controlled drugs to a qualified reverse distributor for proper disposal is something that should be explored. An additional consideration is cost -- who will pay for this service and other solutions listed above remains a stumbling block.

Conclusion

The lack of consistent, workable guidelines has contributed to the growing problem of pharmaceutical waste polluting the environment and wasting precious health care resources. Numerous health care, environmental and consumer groups have been trying to address this problem and have generally focused on household waste. State and local governments also have laws and regulations that deal with medication disposal, and drug manufacturers may recommend disposal methods for specific medications or products in the package insert or product labeling. This patchwork approach has made some progress in reducing pharmaceutical waste but more cohesive national guidelines are needed. Establishing national guidelines for the disposal of pharmaceutical waste that are safe, practical and environmentally friendly for consumers and institutions would be a good first step to prevent the illegal diversion of controlled substances and to protect the environment. Developing and implementing strategies that reduce pharmaceutical waste, by promoting shorter dispensing cycles and use of advanced technology, should be a priority and a part of the solution.