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MEMORANDUM

July 28, 2011

TO: Water Resources Review Committee
FROM: David Beaujon, Senior Analyst, 303-866-4781
SUBJECT: Regulation of Pharmaceutical Disposal

This memorandum summarizes federal and Colorado regulations concerning pharmaceutical waste disposal and describes a voluntary pharmaceutical collection program in Colorado. It also summarizes recent Illinois legislation concerning the collection of pharmaceutical waste.

Pharmaceutical Waste and Impacts on Water Quality

Pharmaceutical waste disposal. While the majority of prescribed drugs are fully consumed, a significant percentage go unused, expire, and become waste. According to the Colorado Department of Public Health and Environment (CDPHE), pharmaceutical waste primarily comes from pharmaceuticals that expire or otherwise become unuseable while on the pharmacy shelf and from unused pharmaceuticals that are distributed to patients. Most pharmaceuticals that are disposed by medical facilities are sent to a reverse distributor where an estimated 99 percent of the returned pharmaceuticals are destroyed in hazardous waste or solid waste incinerators. The Pharmaceutical Research and Manufacturers of America estimates that on an annual basis, 4.3 million pounds of prescribed medications go unused by consumers in U.S. households and by patients in long-term care facilities. Based on population, this equates to approximately 70,000 pounds of unused medications that are produced annually in Colorado. In a 2009 survey of Colorado residents conducted by the CDPHE, 36.5 percent of respondents said that they disposed of their expired or unused medications in the trash; 12.1 percent flushed the medication down the toilet; 10.1 percent took the medication to a medicine collection point; and 11.8 said that they used another, unspecified means of disposal. The remaining respondents said that they did not recall how they disposed of unused medications (6.5 percent) or they did not take medications (23 percent).

Water quality impacts from pharmaceuticals. The CDPHE estimates that most of the pharmaceuticals in wastewater come from human and animal waste. Current sewage treatment technologies are incapable of removing many types of pharmaceuticals from wastewater. The department estimates that modifying sewage treatment plants to remove these substances would be costly. According to the CDPHE, adverse human health effects related to pharmaceuticals in wastewater have not been proven. However, concern has been heightened by observed reproductive abnormalities in fish living in streams containing small concentrations of endocrine disrupting

compounds. These compounds are found in many medications and other household and personal care products. In Colorado, such effects have been observed in Boulder Creek.¹ Because of the lack of scientific information needed to support specific standards, Colorado and other states have not adopted water quality standards for pharmaceuticals.

Federal and State Regulations Concerning the Disposal of Pharmaceuticals

Federal regulation of the disposal of controlled substances. The federal Drug Enforcement Agency (DEA) enforces the Controlled Substances Act.² The goal of the act is to provide a closed distribution system for controlled substances including narcotics, opiates, and stimulants. As part of this closed distribution system, the DEA prohibits the return of controlled substances from patients to any DEA registrant (provider), or transfer to anyone other than a law-enforcement agent. Disposal of controlled substances by DEA registrants is regulated to ensure that the substance is destroyed or rendered unrecoverable. One acceptable method of destruction is flushing controlled substances into the wastewater. In 2010, the President signed the Secure and Responsible Drug Disposal Act of 2010 into law.³ This law allows patients who lawfully obtain controlled substances to transfer them to a government or private entity for disposal. It also allows persons lawfully entitled to dispose of a decedent's property to deliver that decedent's controlled substances to authorized persons for disposal. Under the provisions of the new law, the U.S. Attorney General must issue regulations governing the transfer of controlled substances for disposal to prevent diversion. Long-term care facilities will also be permitted to dispose of controlled substances on behalf of their patients or former patients. The Attorney General is prohibited by the 2010 act from requiring any entity to establish a pharmaceutical disposal program. Until the regulations are adopted, the DEA is coordinating a national take-back program for the collection of unused medications, including controlled substances. During the first two of these events held in Colorado, local law enforcement agencies collected a total of 23,327 pounds of medications. According to the CDPHE, these events are expected to occur every six months and cease upon adoption of the new regulations.

State regulation of uncontrolled pharmaceutical waste. Uncontrolled drugs that are hazardous waste must be disposed of at a permitted disposal facility. Drugs are hazardous if they exhibit one or more hazardous waste characteristics (ignitable, reactive, corrosive, or toxic) or they are specifically identified as hazardous in the Colorado Hazardous Waste Regulations.⁴ Uncontrolled drugs that are not hazardous may be sent to a medical waste incinerator, disposed in

¹Alan M. Vajda, Larry B. Barber, et al. "Reproductive Disruption in Fish Downstream from an Estrogenic Wastewater Effluent." *Environmental Science and Technology*. March 25, 2008.

²21 U.S.C. § 871(a); 28 C.F.R. § 0.100(b)

³S. 3397 [111th]

⁴6 CCR 1007-3, Section 261.3

a landfill along with other solid waste, or flushed down the drain unless specifically prohibited by the receiving treatment facility. CDPHE guidelines recommend that nonhazardous pharmaceutical waste be stabilized prior to landfill disposal, in part, by:

- taking the medications out of their original containers, crushing any pills and mixing the medications with undesirable substances, such as used coffee grounds or kitty litter;
- putting the mixture in a container with a tightly fitting lid or in a plastic zip-top bag or other tightly sealed plastic bag;
- removing or destroying all identifying personal information on the empty medicine container labels;
- wrapping the medication mixture and empty containers in newspaper to help conceal them;
- wrapping the medication mixture and empty containers in a trash bag; and
- placing the packaged waste in the trash.

Prescription drug recycling. Colorado law allows a pharmacist to *redispense* a returned medication that is prescribed to a patient or resident of a licensed facility if the medication was originally dispensed to another patient or resident of the facility. Licensed facilities include hospitals, community mental health centers, acute treatment units, hospices, nursing care facilities, assisted living residences, and licensed long-term care facilities. The pharmacist may also donate a returned medication to a nonprofit entity that has the legal authority to possess the medication.⁵ Another law creates the Colorado Cancer Drug Repository Program to accept donated unused cancer drugs and medical devices for use by uninsured and underinsured cancer patients. Specifically, cancer patients or their family may donate unused cancer drugs or medical devices to a health care facility, medical clinic, or pharmacy that elects to participate in the program. These facilities may distribute the cancer drug to another eligible health care facility, medical clinic, or pharmacy for use under the program. The law also allows a pharmacist to dispense cancer drugs and medical devices donated under the program to eligible patients if certain requirements are met.⁶

Recent Colorado legislation concerning pharmaceutical disposal. Senate Bill 08-190 would have required pharmacists, who are Medicaid providers, to accept unused medications from a licensed facility and to reimburse the state for the cost of the returned medication. This bill was postponed indefinitely in the House Committee on Health and Human Services.

Colorado Medication Take-Back Pilot Project. The CDPHE is coordinating the Colorado Medication Take-Back Pilot Project with funding and other support from the Pollution Prevention Advisory Board, King Soopers, City Market, the Tri-County Health Department, Denver Health, U.S. EPA Region 8, Denver Water, and other entities. The Colorado Medication Take-Back Pilot Project is a network of secure boxes for the collection of unused and unwanted household medications that are located near the pharmacies of participating grocery stores or at certain local health agency offices. There are eleven collection locations — nine on the Front Range and two in Summit County. The take-back program accepts prescription medications, over-the-counter

⁵Section 12-22-133, C.R.S.

⁶Section 25-35-103, C.R.S.

medications, medication samples, medications for pets, vitamins, medicated ointments/lotions, inhalers, and liquid medication in glass or leak-proof containers. It does not accept needles, thermometers, narcotics and other controlled substances, IV bags, bloody or infectious waste, personal care products, business waste, empty containers, hydrogen peroxide, aerosol cans, and plastic bags. When the collection box is full, the contractor and host each unlock separately keyed padlocks. The contents are then removed and taken to the contractor's vehicle where the collected medications are shredded. The waste is then transported to a transfer facility for final destruction in a hazardous waste incinerator. According to the CDPHE, the project has collected 11,500 pounds of unused and unwanted household medications, and has increased public awareness about the environmental and public health concerns related to improper disposal of medications.

According to the CDPHE, the project has not secured sufficient funding to continue the operation of all collection sites beyond 2011. CDPHE plans to work with its partners to identify future funding sources. It will also review proposed federal regulations to determine if the project may be operated in a manner that allows for the collection of controlled substances.

Recent State Legislative Efforts to Create Drug Take-Back Programs

Illinois legislation. In 2011, the Illinois Legislature enacted legislation that adds a \$20 fine to drug-related convictions in the State of Illinois.⁷ These moneys will be allocated by the Illinois Criminal Justice Information Authority as grants to local law enforcement agencies for the purpose of facilitating the collection, transportation, and incineration of pharmaceuticals from residential sources that are collected and transported by law enforcement agencies. The authority is governed by a 23-member board of state and local criminal justice officials. The act is currently awaiting the signature of the Governor. Another act passed in 2011 authorizes the installation of receptacles to collect used, expired, or unwanted pharmaceuticals in city halls and police departments.⁸ It also specifies security measures for these containers. This act is currently awaiting the signature of the Governor.

⁷Illinois House Bill 2056, 97th General Assembly

⁸Illinois House Bill 3090, 97th General Assembly