New York State Department of Environmental Conservation
Division of Solid & Hazardous Materials
Office of the Director
625 Broadway, 9th Floor, Albany, New York 12233-7250
Phone: (518) 402-8651 • **Fax:** (518) 402-9024
Website: www.dec.ny.gov

JUN 04 2010

Alexander B. Grannis
Commissioner

Dear Program or Facility Administrator:

This letter is intended to introduce a New York State Department of Environmental Conservation (Department) initiative to reduce the presence of pharmaceuticals in New York State's waters. This letter also provides information on the Department's regulations that may be applicable to the management of pharmaceutical waste generated by your program or facility.

As you may be aware, trace amounts of pharmaceuticals, including antibiotics, have been detected in aquatic life and in the drinking water supplies of at least 41 million Americans. Data shows that the concentrations of pharmaceuticals in drinking water are extremely far below typical medical doses; however, recent studies have identified impacts on aquatic life. The United States Environmental Protection Agency (USEPA) has acknowledged that the issue is an emerging concern.

It is critical that all New Yorkers do their part to protect our State's water resources. Reducing the amount of pharmaceuticals that make their way into New York State's waters is a complicated task that requires collaboration among state and federal agencies, institutions, drug manufacturers, pharmacies, and individuals. The Department is working with all stakeholders to prevent discarded pharmaceuticals from entering the State's water resources and to ensure that pharmaceuticals are disposed of in a safe, legal and environmentally sound manner.

As a first step, in August 2008, the Department launched an initiative to help households reduce the growing presence of pharmaceuticals in water bodies. The "Don't Flush Your Drugs" campaign (www.dontflushyourdrugs.net) is designed to eliminate flushing of pharmaceuticals in household settings by raising public awareness about this issue and providing information about how to properly dispose of household pharmaceuticals. The Department is expanding this campaign by making a similar recommendation to health care providers and facilities that generate pharmaceutical waste.

Pharmaceutical waste that may be routinely generated by a program or facility like yours may be categorized under the Department's regulations as non-hazardous solid waste, hazardous waste, regulated medical waste, and under Department of Health (DOH) regulations as a controlled substance. The Department estimates that only about five percent of this pharmaceutical waste stream is regulated as a hazardous waste, and only about five percent may also be regulated as a controlled substance. The regulatory structures for managing these wastes may be different, as each waste category has specific regulations and procedures that apply to its management and disposal. The Department recognizes that regulatory compliance can be complex and is providing the following explanation of regulatory programs to assist you when deciding how to properly manage waste generated by your programs or facilities.

Pharmaceutical Wastes that are Controlled Substances

The DOH Part 80 Rules and Regulations on Controlled Substances in New York State set forth requirements for disposal of controlled substances by those entities registered by the Federal Drug Enforcement Administration (DEA), as well as those licensed by DOH. Section 80.51 of Part 80 requires that DOH approve the manner and detail of all such disposal pursuant to a written request. Controlled substances must be rendered totally unrecoverable and beyond reclamation when disposed.

DOH has been working aggressively to examine the issue of controlled substance disposal with various stakeholders and is currently engaged in a number of targeted efforts to ensure proper medication disposal with respect to public health, diversion prevention and the environment. A letter framing the current controlled substance disposal challenges facing programs and facilities licensed by DOH as Class 3A Institutional Dispensers Limited, and presenting the current status of DOH's efforts in this regard will be forthcoming from the DOH's Bureau of Narcotics Enforcement (BNE).

Pharmaceutical Wastes that are Hazardous Wastes

Providers and facilities are responsible for determining whether the wastes they generate are regulated hazardous wastes.

Hazardous pharmaceutical wastes may be generated as a result of a provider's or facility's central management of pharmaceuticals. Certain frequently used pharmaceuticals, such as physostigmine and warfarin, are identified and listed in 6 NYCRR Part 371 as hazardous waste and must be managed and disposed of as such. The pharmaceutical chloral hydrate is one example of a pharmaceutical that is both a hazardous waste and controlled substance. These hazardous pharmaceutical wastes are subject to hazardous waste generator regulations when the pharmaceuticals are under the control of a provider or facility.

Pharmaceutical wastes that are under the control of a patient or resident are excluded from regulation as hazardous wastes when discarded. They can be managed as non-hazardous solid waste as described below. Hazardous wastes generated by a resident are excluded from hazardous waste regulation because they are considered to be derived from a household.

It is important to be aware that *all* hazardous wastes generated throughout a program or facility, not just the hazardous pharmaceutical wastes, must be counted when determining the applicable hazardous waste management requirements.

Available Resources

The Department's "Environmental Self-assessment for Health Care Facilities: A Quick and Easy Checklist of Pollution Prevention Measures for Health Care Facilities" (www.dec.ny.gov/docs/permits_ej_operations_pdf/esahcf.pdf) provides information and a checklist of pollution prevention measures.

A second publication which may be useful in characterizing and counting hazardous wastes generated by providers or facilities is the Department's "Environmental Compliance and Pollution Prevention Guide for Small Quantity Generators" (www.dec.ny.gov/docs/permits_ej_operations_pdf/ecppsqg.pdf). This document also explains the storage and transportation requirements for small quantity hazardous waste generators.

A third publication that can be used to help properly manage pharmaceutical wastes properly is "Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities In the United States, Revised August, 2008" (www.hercenter.org/hazmat/tenstepblueprint.pdf). This document describes the identification of, and best management practices and regulatory requirements for, many frequently used pharmaceuticals that are regulated as hazardous wastes. Please note that New York's interpretation of the hazardous waste regulations may be different from those provided by this document. For example, New York State has not adopted USEPA's "Epinephrine Syringe Interpretation Extended to Other P and U-Listed Drugs" (page 17), but is currently considering whether or not to do so. Also, New York would consider a used nicotine patch to have been "used for its intended purpose" and, therefore, no longer a hazardous waste (page 16). For questions on hazardous pharmaceutical waste in New York State, please contact the Department's Hazardous Waste Determination and Analysis Section, at (518) 402-8633, or by e-mail at sqginfo@gw.state.ny.us.

Drain Disposal Restrictions:

The Federal Clean Water Act General Pretreatment Regulations (40 CFR 403.12(p)) place additional requirements on the drain disposal or flushing of hazardous waste. The "Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities In the United States" guidance document provides the state and federal definitions of certain wastes as either "P-listed," "U-listed," or "characteristic" hazardous waste. Drain disposal of 15 kg (about 33 pounds) or greater of U-listed or characteristic hazardous waste in a calendar month, or any amount of P-listed hazardous waste, requires notification to the local publicly owned treatment works (POTW), the Department's Director of the Division of Solid and Hazardous Materials, and USEPA's Region 2 Director of the Division of Environmental Planning and Protection. In addition, in the case of P-listed waste, the notification must include a certification that a program is in place to reduce the volume and toxicity of hazardous waste generated to a degree determined to be economically practicable.

Pharmaceutical Wastes that are Non-Hazardous Solid Waste

The Department estimates that most pharmaceutical waste generated by health care providers or facilities will be classified as non-hazardous solid waste. Although options for such disposal in a landfill are legally available for non-hazardous, non-controlled pharmaceutical waste generated by health care providers and facilities, the Department is recommending that this disposal practice be avoided. It is recommended that providers and facilities arrange for this waste to be destroyed by incineration. The Department maintains a listing of solid waste combustors in New York State that can accept this waste. However, the Department cannot arrange the transaction or disposal contract for this waste. In all cases, reasonable attempts should be made to secure the pharmaceutical waste from loss or other diversion during collection, storage and transportation. The following options are suggested for the disposal of non-hazardous, non-controlled pharmaceuticals, listed in priority order:

1. Contract with a company that characterizes, segregates, transports and disposes of this type of waste by thermal destruction (incineration);

2. Dispose of non-hazardous pharmaceutical waste with other non-hazardous regulated medical waste generated by the provider or facility. This waste must be packaged and labeled "for incineration only." Note, however, that there are currently no commercial facilities in New York State that can incinerate medical waste;

3. Dispose of non-hazardous pharmaceutical waste with other solid waste generated by the provider or facility at a thermal destruction facility authorized to accept and destroy this specific waste stream; and

4. Dispose of non-hazardous pharmaceutical waste with other solid waste generated by the provider or facility at a solid waste landfill.

For questions on non-hazardous pharmaceutical waste disposal in New York State, please contact the Bureau of Solid Waste, Reduction & Recycling at (518) 402-8706.

Pharmaceutical Wastes that are Regulated Medical Wastes

Pharmaceutical wastes that are regulated medical wastes include discarded prescription drugs that are biological; including serums, vaccines, antigens and antitoxins made with living organisms and their products, associated injectables (i.e., medicine vials and their contents) and the hypodermic or intravenous syringes to which a needle (used or unused) or other sharp is attached that is used to administer such injectable.

Unless the above pharmaceutical waste is regulated as a hazardous waste or a controlled substance, regulated medical wastes must be managed and disposed of as a regulated medical waste. The Department's Guidance for Regulated Medical Waste Treatment, Storage, Containment, Transport and Disposal can be found at www.dec.ny.gov/regulations/8752.html. For additional information on disposal of regulated medical waste, please contact the Bureau of Solid Waste, Reduction, and Recycling at (518) 402-8706.

The Department appreciates all steps providers and facilities can take to reduce the presence of pharmaceuticals in our State's water resources. The Department encourages health care providers and facilities to use the information in this letter to develop and implement a comprehensive pharmaceutical waste management program that combines regulatory compliance and best management practices in order to safeguard human health and the environment.

Sincerely,

Edwin E. Dassatti, P.E.
Director
Division of Solid & Hazardous Materials