FACT SHEET

FORTHCOMING REGULATIONS

MANAGEMENT STANDARDS FOR HAZARDOUS WASTE PHARMACEUTICALS

Purpose of this fact sheet: This document provides advance notice that the Maryland Department of the Environment (MDE) will be proposing significant amendments to the State's hazardous waste regulations.

Why are the regulations being amended? MDE is required to periodically revise the State's hazardous waste regulations to maintain consistency with current federal regulations promulgated by the U.S. Environmental Protection Agency (EPA).

What federal requirements will MDE be proposing to adopt? MDE will propose regulations equivalent to those that appear in the Code of Federal Regulations (CFR) as Subpart P of 40 CFR Part 266 (Hazardous Waste Pharmaceuticals). MDE will also propose regulations equivalent to EPA's simplified management standards for hazardous waste aerosol cans, solvent-contaminated wipes, and automotive airbags that are covered by recall programs, and will propose technical revisions to the definition of ignitability.

What do the federal regulations require? The federal regulations established management standards that healthcare facilities have to follow in managing waste pharmaceuticals that meet the definition of hazardous waste. Once MDE adopts these regulations, these pharmaceutical-specific management standards will need to be followed instead of the management standards that apply to general hazardous waste. Some of the key provisions are highlighted later in this fact sheet.

Why were the federal regulations developed? The EPA determined that the regular hazardous waste regulations were not always well-adapted to the healthcare setting and the nature of waste pharmaceuticals. To eliminate some confusion and facilitate compliance without compromising protectiveness, EPA developed regulations that were tailored to the management of hazardous waste pharmaceuticals in the healthcare sector.

What will be the general impact on the regulated community of the forthcoming regulations? Hazardous waste pharmaceuticals and entities in the healthcare sector that generate them are currently subject to Maryland's hazardous waste regulations. The revisions will not expand the universe of regulated wastes or affect previously unregulated entities. Alternate management standards will have to be implemented, but these standards will be better adapted to the nature of these wastes and the settings in which they are generated. The regulations will also provide for some new flexibilities and burden reductions without compromising protectiveness.

What is a "pharmaceutical" for the purposes of the regulation? A material would be covered by the regulation if it meets the definition of hazardous waste and falls into one of the following categories:

- A drug or dietary supplement for use by humans or animals;
- An electronic nicotine delivery system, such as an electronic cigarette or vaping pen; and
- Liquid nicotine-containing products packaged for retail sale for use in electronic nicotine delivery systems

Some specific examples of pharmaceuticals include prescription drugs, over-the-counter drugs, homeopathic drugs, compounded drugs, investigational new drugs, a pharmaceutical remaining in a container that does not meet specified criteria to be considered empty, personal protective equipment contaminated with a pharmaceutical, and clean-up material from the spill of a pharmaceutical.

Who is potentially affected?
Consistent with the corresponding federal regulations, "healthcare facility" will mean any person or entity that is legally authorized to:

- Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care with respect to the physical or mental condition, or functional status, of a human or animal;
- Act as a provider of counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of a human or; or
- Distribute, sell, or dispense pharmaceuticals, including over-the counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals.

Examples of "healthcare facilities" for the purposes of the regulations include wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, and ambulatory surgical centers, health clinics and physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies (general, long term-care, mail-order), retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals.

Will there be a small quantity exclusion?
In a given calendar month, a facility will not be subject to most of the new requirements If the total amount of hazardous waste generated by the facility (hazardous waste pharmaceuticals plus non-pharmaceutical hazardous waste) is, in that calendar month, 1 kilogram or less of acute hazardous waste, and 100 kilograms or less of nonacute hazardous waste. Also, a long-term care facility with 20 or fewer beds will be presumed to be excluded from most of the requirements unless it is demonstrated that the facility is generating hazardous waste in quantities in excess of the monthly limit specified above.

What will be some of the key provisions of the regulations?
Among the highlights: the regulations will: allow accumulation of hazardous waste pharmaceuticals for up to 1 year, clarify the meaning of "empty" for various types of pharmaceutical containers, accommodate existing management procedures for pharmaceuticals returned for manufacturers' credits, require facilities to provide a notification that they are managing hazardous waste pharmaceuticals, require some records to be kept, and specify container management standards.

When will proposed regulations be published for public comment?
MDE hopes to publish a Notice of Proposed Action in the Maryland Register by May 16, 2025.

How can I obtain additional information?
Information on the federal regulations on which the Maryland regulations will be based is available at <https://www.epa.gov/hwgenerators/management-hazardous-waste-pharmaceuticals>

Once a publication date has been established, information will be posted on the MDE website at <https://mde.maryland.gov/programs/land/HazardousWaste/Pages/index.aspx>

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