FACT SHEET

PROPOSED REVISIONS TO MARYLAND'S HAZARDOUS WASTE REGULATIONS

Purpose of this fact sheet: This document provides information about proposed amendments to the State's hazardous waste regulations that that were published for public comment on May 16, 2025.

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.

What are the federal requirements that MDE is proposing to adopt? MDE is proposing 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 is also proposing 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 is proposing 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. The alternate management standards proposed for aerosol cans, solvent-contaminated wipes, and recalled airbags are optional.

Why were the federal regulations on pharmaceuticals developed? The U.S. Environmental Protection Agency (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 by the pharmaceutical provisions?
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 for the pharmaceutical provisions?
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 pharmaceutical 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.

Where can I find the proposed regulations?
The Noice of Proposed Action (NPA) is available on the "Maryland Register Online" page of the Maryland Division of State Documents at <https://dsd.maryland.gov/Pages/MDRegister.aspx>. Click on the link to the May 16, 2025 issue (Volume 52, Issue 10). The NPA begins on page 478. The Notice of Proposed Action includes information on how to comment. Comments are being accepted through June 16, 2025.

How can I obtain additional information?
Information is posted on the MDE website at
<https://mde.maryland.gov/programs/land/HazardousWaste/Pages/index.aspx>

Questions may be directed to Edward Hammerberg of the Solid Waste Program at (410) 537-3356 or ed.hammerberg@maryland.gov .