

Medical Waste Management Act Consensus Statements

Overview of Proposal

- Limit the number of consumer products that are being incinerated by:
 - Excluding cosmetics, personal care products, and homeopathic remedies from the Medical Waste Management Act (“MWMA”)
 - Clarifying that supplements are not “drugs” subject to MWMA
- For remaining products regulated under MWMA (upon discard), provide options for incineration so that retailers can incarnate pharmaceutical waste without having to maintain two separate programs (medical waste and hazardous waste)
- Revise MWMA to effect legislative intent of previously enacted legislation (AB1442) to allow pharmaceuticals to be sent to a reverse distributor for credit
- **Excluding Cosmetics, Personal Care Products, and Homeopathic Remedies from MWMA**
 - The MWMA requires the incineration of any “pharmaceutical,” including “over-the counter [“OTC”] human or veterinary drug, including, but not limited to, a drug as defined in Section 109925 of the Federal Food, Drug, and Cosmetic Act” (“FDCA”). Section 117747 Health and Safety Code.
 - Some regulators and prosecutors have interpreted the MWMA to be applicable to retailers and OTC pharmaceuticals sold at retail locations. Moreover, some consumer products are labeled with “Drug Facts” even if they may not be considered a “drug” under the FDCA, creating regulatory uncertainty. As a result, homeopathic remedies as well as cosmetics and other personal care products that are labeled with Drug Facts, including sunscreen, lip balm, and saline solution, when discarded, are being incinerated to comply with the MWMA instead of being discarded in accordance with the Hazardous Waste Control Law (“HWCL”) (if hazardous upon discard), which would require disposal in a Subtitle C landfill, which are constructed with a double liner, double leachate collection system, groundwater monitoring, and are subject to ongoing inspections and post-closure care obligations.
 - **Proposal:** To avoid unnecessary incineration, pass legislation to exclude cosmetics and other personal care products like shampoos, sunscreens, toothpaste, lip balm, antiperspirants, and saline solution as well as homeopathic remedies from the MWMA. Instead, these products would be managed under the HWCL upon discard when hazardous (either RCRA or California-hazardous), and under California’s solid waste disposal rules when non-hazardous.
- **Clarify MWMA Does Not Apply to Dietary Supplements**
 - Dietary supplements are regulated under the Dietary Supplement Health and Education Act of 1994 (DSHEA), which defines dietary supplements as food and not drugs. Nevertheless, there is some confusion and concern within the regulated

community that some dietary supplements could be considered a “pharmaceutical,” and therefore, a medical waste regulated under the MWMA. As a result, some retailers are managing dietary supplements as pharmaceutical waste that must be incinerated out of an abundance of caution.

- **Proposal:** To avoid unnecessary incineration, issue written guidance clarifying that vitamins and other dietary supplements that are regulated under DSHEA are not subject to the MWMA and instructing generators to manage these products under the HWCL upon discard when hazardous (either RCRA or California-hazardous), and under California’s solid waste disposal rules when non-hazardous.
- **Provide Options for Incineration of Pharmaceutical Waste**
 - Pharmaceutical wastes that are hazardous, as defined under the federal Resource Conservation and Recovery Act (“RCRA”) are excluded from the MWMA. As currently drafted, the MWMA requires non-RCRA pharmaceutical waste to be managed as medical waste, which could be read to require retailers to maintain two separate waste management programs: (1) RCRA waste and (2) medical waste (a combination of California hazardous and non-hazardous pharmaceutical waste).
 - There is a legal presumption under RCRA and California’s HWCL that a waste is regulated by RCRA unless a generator determines that it is non-RCRA. See, e.g., Health and Safety Code section 25117.9. As recently as 2015, in the proposed Generator Improvements Rule, EPA acknowledged and endorsed the practice of self-declaring waste as RCRA hazardous, stating that “The Agency also realizes that generators, whether inadvertently or intentionally, often make a hazardous waste determination when the material is actually a non-hazardous solid waste. ... The generator is always free to manage its solid waste as a hazardous waste if it so desires.” 80 Fed. Reg. 57945, col. 2 (Sept. 25, 2015).
 - From retailers’ perspective, maintaining two separate waste management programs is overly complex, creating additional unnecessary regulatory burden without an attendant environmental benefit. Nevertheless, some stakeholders have expressed concern with the disposal of pharmaceutical waste in landfills, highlighting the potential for collected leachate to be discharged to publicly owned treatment works that were not designed to address complex chemicals.
 - **Proposal:** To reduce regulatory burden of complying with two management programs while avoiding disposal of pharmaceutical waste in landfills, issue joint guidance or pass legislation to ensure that generators have options for how to incinerate pharmaceutical waste, including as (1) medical waste, (2) California-hazardous waste subject to a land disposal ban (requiring incineration), or (3) if non-hazardous, for energy recovery.
- **Reverse Distribution of Medical Waste**
 - Under the MWMA, pharmaceuticals sent to a reverse distributor that is licensed as a wholesaler of dangerous drugs by the California Board of Pharmacy are

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excluded from the definition of “pharmaceutical waste” that must be incinerated. This language was added by AB1442 and was intended to allow pharmaceuticals to be sent back to reverse distributors for credit determinations, even if expired or otherwise unsellable.

- For example, AB1442 Assembly Floor Analysis comments indicated that “Under existing law, pharmaceutical drugs can be sent to health care facilities through standard common carriers, or standard shipping means. Unused drugs can sometimes be returned to the manufacturer for credit, via a common carrier. Expired and non-dispensable drugs must be shipped as ‘Medical Waste,’ requiring expensive hazardous waste shipping, instead of common carrier. This is unnecessarily expensive for pharmacies, hospitals, and other health care facilities, who are simply returning the exact same drug that was shipped to them by common carrier.”
- In practice, this exclusion has not been implemented as intended, as a result of intervening legislation (AB333), which moved this language to Section 117690. As currently drafted, some regulators and prosecutors have interpreted this language to exclude such pharmaceuticals from the MMWA entirely, and thus subject to the Hazardous Waste Control Law (“HWCL”) (if hazardous), which currently does not provide a similar allowance.
- **Proposal:** To the extent that the HWCL is not amended to allow consumer products to be sent back to reverse distributors for credit determinations, even if expired or otherwise unsellable, the MWMA should be further amended to give effect to the intent of previously enacted legislation (AB1442).

Questions and Answers

Question: How can we be sure that excluding cosmetics, personal care products, and homeopathic remedies from the MWMA is protective of human health and the environment?

Answer: Excluding these products from the MWMA would not mean they will no longer be subject to regulatory standards upon disposal. Instead, if they exhibit a hazardous characteristic under RCRA or California’s stringent hazardous waste standards (including the aquatic toxicity test), the HWCL would require them to be disposed of in a Subtitle C landfill, with a double liner, double leachate collection system, groundwater monitoring, ongoing inspections, and post-closure care requirements. Many personal care products, cosmetics, and homeopathic remedies meet the RCRA or California-hazardous standards and would need to be managed as hazardous waste upon discard.

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Question: How do retailers address differences in brands, where one's product formulation may be benign while another's formula for the same type product contains a hazardous or toxic substance that would require management as a hazardous waste upon discard? Examples can include personal care and cleaning products and disposal criteria could differ.

Answer: Most retailers make waste characterizations at the universal product code (UPC) level, which differs by manufacturer and therefore accounts for differences in formulation between brands even if in the same item category. As a result, differences in formulation will be accounted for upon discard, and those products with hazardous characteristics will be disposed of in Subtitle C landfills.

Subtitle C Landfill Requirements

<https://www.epa.gov/hwpermitting/hazardous-waste-management-facilities-and-units#landfills>

Landfills regulated under Subtitle C of RCRA are excavated or engineered sites where nonliquid hazardous waste is deposited for final disposal and covered. These units are selected and designed to minimize the chance of release of hazardous waste into the environment. Design standards for hazardous waste landfills require:

- Double liner
- Double leachate collection and removal systems
- Leak detection system
- Run on, runoff, and wind dispersal controls
- Construction quality assurance program

Operators must also comply with inspection, monitoring, and release response requirements. Since landfills are permanent disposal sites and are closed with waste in place, they are subject to closure and post-closure care requirements including:

- Installing and maintaining a final cover
- Continuing operation of the leachate collection and removal system until leachate is no longer detected
- Maintaining and monitoring the leak detection system
- Maintaining ground water monitoring
- Preventing storm water run on and runoff
- Installing and protecting surveyed benchmarks