ADEQ Arizona Department of Environmental Quality

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FACT SHEET

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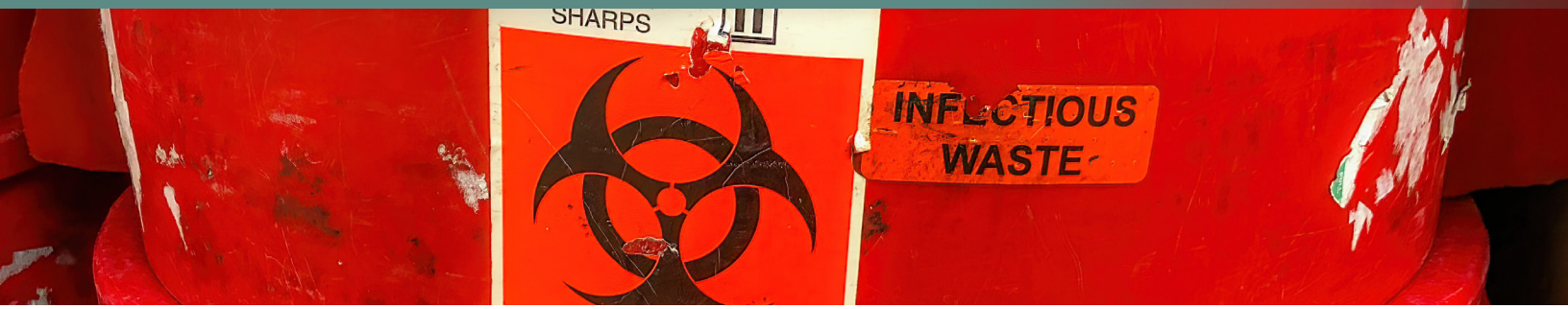
BIOHAZARDOUS MEDICAL WASTE AND DISCARDED DRUG RULE UPDATES



Overview

The Arizona Department of Environmental Quality (ADEQ) strives to protect and enhance public health and the environment. As part of that mission, the ADEQ has adopted changes to 18 AAC 13, Article 14 - Biohazardous Medical Waste (BMW) and Discarded Drugs rules within the Solid Waste area. The ADEQ, through consultation with various stakeholder groups, made amendments to current rules in an effort to improve clarity, bring the standards up to date, address stakeholder concerns, correct references and citations, and ensure adequate protection of human health and the environment. This fact sheet is provided to give an overview of the changes to 18 AAC 13, Article 14 (effective January 4, 2022), and the potential economic, small business, and consumer impacts of these rule changes.

Background

Arizona's BMW rules were first promulgated in 1999 after more than six years of stakeholder feedback and modifications. BMW generators and transporters communicated to ADEQ over the years that updates were necessary to make the process of handling and transporting BMW more clear and protective of human health and the environment. The COVID-19 epidemic further highlighted the need to make these changes. Technical changes were also made to fulfill a commitment to the Governor's Regulatory Review Council.

Legal Authority and Affected Statutes

ADEQ has changed, adopted, or repealed rules from the Administrative Code, Title 18, Chapter 13, Article 14, Sections 1 through 20. ADEQ has statutory authority to promulgate these rules under A.R.S. §§ 41-1003, 49-104, and 49-761(D). A full copy of the 18 AAC 13, Article 14 can be found here: apps.azsos.gov/public_services/Title_18/18-13.pdf or can be accessed by scanning the QR code to the right with a smart phone.

Persons Affected

These rule changes will affect County agencies (acting as regulatory authorities per delegation agreements), Exempt businesses, Licensed BMW transporters, regulated small businesses, and community members living near transporter's places of business (residential areas).

For More Information:

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Economic, Small Business, and Consumer Impact

In the development of the Biohazardous Medical Waste (BMW) rule changes, the ADEQ considered the economic, small-business, and consumer impacts of any rule change for the following topics: BMW Transport, Transporter Registration, Drug Sewering, US DOT Integration, and Mail-back Record Retention. Cost Savings, Conduct & Frequency, and Estimated Changes were assessed for each topic.

BMW Transport:

Changes to Biohazardous Medical Waste Transport grant additional unrefrigerated holding time for BMW and permit carrying multiple US Department of Transportation (DOT)- compatible containers. These changes allow transporters to carry larger amounts of waste unrefrigerated to maximize collection space, minimize inefficiency, improve customer relationships by collecting waste at one convenient time, and consolidate multiple trips.

Cost-Savings

Arizona Biohazardous Medical Waste (BMW) Transporters reported average estimated savings of $1872.31 per month for each transport vehicle due to changes in unrefrigerated storage times for BMW, and allowing DOT-compatible wastes to be transported in the same vehicle as BMW. *

Transporter Registration:

Changes to BMW Transporter Registration and hygiene standards were adopted to eliminate loopholes, eliminate confusion and frustration, allow for even and fair application of the requirements, and avoid counting the number of consecutive days, which can be an administrative burden and an additional expense for businesses.

Conduct & Frequency

Previously, transporters were only subject to management and hygiene standards for a vehicle that was used to transport BMW for more than 30 consecutive days. However, some businesses exploited that loophole by rotating vehicles every 29 days and avoiding regulation that was intended to apply to BMW transporters in order to protect human health and the environment. ADEQ rule changes have closed that loophole and eliminated the frustration and confusion. *

Drug Sewering Ban:

ADEQ adopted additional restrictions on disposal of non-hazardous waste pharmaceuticals to better align with Hazardous Waste (HW) Pharmaceutical rule changes (effective November 3, 2020) that prohibit disposing of such substances in sewers. The modifications, which align with EPA recommendations for non-HW pharmaceuticals and stakeholder requests, streamline disposal and eliminate sorting and training time needed for the different types of pharmaceuticals.

US Department of Transportation Integration:

The ADEQ sought better integration with the US DOT, reducing the burden that required transporters to comply with overlapping regulations for BMW from both USDOT and ADEQ, thus improving cost- and time-savings for businesses.

Estimated Change

The changes mirrored USDOT requirements in the ADEQ rules, eliminating the additional administrative time and confusion required to comply with two different requirements. Arizona transporters reported that the rule changes would save between 1.23 and 6.46 hours of administrative time per month. *

Mail-back Records Retention:

The ADEQ adopted rule changes for medical sharps mail-back programs to provide clear retention schedules, and clarify document retention requirements already in place by the United States Postal Services (USPS).

**Arizona Administrative Registrar (AAR), Notice of Final Rulemaking (NFR), Vol. 27, Issue 49, pg. 2801. Published by the Arizona Secretary of State, December 3, 2021*

Section	Changes	Issued Addressed
R18-13-1401. Definitions	Removed definitions for: • "Administrative consent order" and "Free flowing" Added definitions for: • "Emergency situations" and "USDOT" Amended definitions for: • "Biohazardous medical waste: including: "Human blood and blood products" & "Human pathological wastes" • "Chemotherapy waste" • "Dedicated vehicle" • "Multi-purpose vehicle" • "Medical sharps container" • "Multi-purpose vehicle" • "Transporter"	Removed definitions that are unclear or correspond to removed provisions. Added definitions to clarify conditions and new language. Amendment of unclear definitions to provide clarity, conformity with present-day practices, and avoid over-regulation.
R18-13-1402. Applicability	Amended applicability of materials placed out of state or in Indian Country as well as at Department-approved facilities in state	Amendment clarifies that there is no restriction on interstate commerce.
R18-13-1403. Exemptions; Partial Exemptions	Amended language to clarify exemptions from Article 14	Clarified language on exemptions to ameliorate confusion or duplication.
R18-13-1404. Transition and Compliance Dates	Repealed	This section was meant as a transitional bridge, so most provisions are no longer applicable. Those provisions that are still applicable were transferred to the appropriate sections to eliminate confusion.
R18-13-1406. Biohazardous Medical Waste Transported Off Site for Treatment	Amended: • Integrated citations to applicable rules • Replaced one- (1) year retention with DOT requirements for retention	Amendment to include applicable section references to make compliance easier for stakeholders. Replacement of one- (1) year retention with the DOT timeframes as necessary to avoid duplicative regulation under A.R.S. 41-1002 (stakeholders are currently subject to both).

Section	Changes	Issued Addressed
R18-13-1407. Non-Sharps Packaging	Amended: • Clarified packaging to not include sharps	Amendment clarifies requirements to avoid confusion and inappropriate application of the rule.
R18-13-1408. Storage	Amended: • Clarified "trace chemotherapy waste" requirement • Clarified refrigeration and storage time frames of putrescible (72 hours room temperature, 90 days refrigerated) vs. non-putrescible waste (90 days room temperature)	Amendment requested by stakeholders to differentiate types of chemotherapy waste through the labeling requirement. Amendment clarifies that non-putrescible waste may be kept unrefrigerated, as requested by stakeholders. Also clarifies that refrigeration should occur at 72 hours (versus 7 days) to provide uniformity with other time frames and assure adequate protection for human health and the environment during generation of COVID-19 waste.
R18-13-1409. Transportation; Transporter License; Annual Fee	Removed: • "licensing year" definition • old subsections (C)-(E) Added: • Subsection (B) to lay out transporter license requirements • Internal Cross-references Amended: • Old subsection (B) to new (C) which clarifies requirements and costs • Citation to appeal process to accurate citation • Internal language for consistency • Changed "30 consecutive days" to "at least once weekly for a month" • 1 year retention to DOT retention requirements • Refrigeration and storage time frames of putrescible (72 hours room temperature, 90 days refrigerated) vs. non-putrescible waste (90 days room temperature)	Removed the "licensing year" definition as it reduced clarity. The new structure more clearly explains requirements. Removed old subsections (C)-(E) and replaced with the new subsection (B) which more clearly lays out transporter license requirements. Amendments included tables and restructuring provisions to make licensing more transparent and understandable. Appropriate citation to the appellate process was updated per promise to GRRC. All terms are now consistent internally with definitions. Transporter vehicle use changed due to stakeholder requests to clarify and close loopholes. Replaced the 1 year retention requirements with the DOT timeframes as necessary to avoid duplicative regulation under A.R.S. 41-1002 (stakeholders are currently subject to both). ADEQ also clarified refrigeration and storage timeframes to allow small businesses more flexibility and time (previously 24 hours, now 72); the 72 hour timeframe is in line with practices by a greater number of states, so this makes Arizona transporters more competitive with other southwestern states as well.

Section	Changes	Issued Addressed
R18-13-1411. Storage and Transfer Facilities; Design and Operation	Amended: • Internal language for consistency • Refrigeration and storage time frames of putrescible (72 hours room temperature, 90 days refrigerated) vs. non-putrescible waste (90 days room temperature) to clarify requirements • Cleaning provision to specify storage area separately from container provision	Amendments make all terms consistent internally with definitions. Clarify refrigeration and storage timeframes to allow small businesses more flexibility and time (previously 24 hours, now 72); the 72 hour timeframe makes Arizona transporters more competitive with other southwestern states. The cleaning provision for containers previously laid out in 1407 was criticized as worded strangely for application in 1411 to storage areas (referenced), so the requirements from 1407 were duplicated and rephrased from 1407 into 1411 to better reflect the size of space being cleaned. This avoids confusion and enhances clarity.
R18-13-1412. Treatment Facilities; Design and Operation	Amended: • Refrigeration and storage time frames of putrescible (72 hours room temperature, 90 days refrigerated) vs. non-putrescible waste (90 days room temperature) to clarify requirements and allow flexibility for small businesses • Subsection (A)(3)-(12) to go under subsection (B)(1)-(11) for clarity Added: • Subsection (C) to clarify that records shall be available upon request for inspection	Amendments clarify refrigeration and storage timeframes to allow small businesses more flexibility (previously 24 hours, now 72); the 72 hour timeframe makes Arizona transporters more competitive with other southwestern states. Moving provisions to (B) helps provide clarity and eliminate confusion. Records availability requirements mirror current practices, but has not been as clearly stated previously. This amendment provides clarity for compliance.
R18-13-1413. Changes to Approved Medical Waste Facility Plans	Amended: • Language for internal consistency of terms Added: • Type III changes provision from deleted 1404 to 1413, where it fits best	Amendment adds clarity by ensuring consistent use of terms throughout. Moving the Type III provision here makes the most sense after its removal from 1404 because 1413 discusses other Type I-IV changes. This rule organization change helps the clarity of the rule.
R18-13-1414. Alternative Medical Waste Treatment Methods: Registration and Equipment Specifications	Added: • Documentation provision regarding alternative medical waste treatment technology deleted from 1404 and added to 1414 since it makes sense here	Amended to move the documentation provision to this section on alternative treatment methods makes the most sense after that provision was removed from the now-deleted 1404. This rule organization change helps the clarity of the rule.

Section	Changes	Issued Addressed
R18-13-1417. Disposal Facilities: Design and Operation	Amended: • Title changed to reflect the "design" component	Amended to accurately reflect the section topic which includes both design and operation requirements.
R18-13-1418. Discarded Drugs	Amended: • The discarded drugs provision in subsection (A) to clarify the rule requirements Removed: • Provision allowing drug sewering in subsection (B)	Amended to make the provision more clear. Removed a provision that no longer reflects EPA suggested best practices and that stakeholders expressly wished to see removed as well.
R18-13-1419. Medical Sharps	Added: • Subsection (A) heading before language to delineate subsections • Subsection (B) to clarify what does not need to go in a sharps container • Subsection (C) which clarifies that even if a sharp is exempted from (B) it may still be biohazardous medical waste • Subsection (C) which clarifies that Sharpless syringes are not biohazardous medical waste if they do not contain items listed in the biohazardous medical waste definition. Amended: • Mail-back encapsulation requirement and replaced with a retention of proof of shipping Removed: • Treatment facility sharps in subsection (A)(3)	Added missing subsection header to help with rule clarity. Added provisions to clarify what is not a sharp, per stakeholder request, and that some exempted items may still be biohazardous medical waste and require treatment as such. This incorporated an ADEQ substantive policy statement into rule. Amendment to add clarity and document retention requirement suggested by stakeholders (mail back already generates a USPS document, which is required to be retained separately; this allows ADEQ to confirm compliance with mail-back requirements of our own provision with no extra work for those mailing back sharps). Removed provision that does not prove helpful for sharps.
R18-13-1420. Additional Handling Requirements for Certain Wastes	Amended: • Language reorganized to match DOT requirements • Addition of "trace" to chemotherapy waste	Amendment of language to comply with DOT requirements, thus avoiding having two different standards to comply with and provides clarity. Adding "trace" clarifies the type of chemotherapy waste that is biohazardous medical waste (rather than hazardous waste).