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ABOUT THIS PUBLICATION
The authenticated pdf of the Administrative Register (A.A.R.) posted on the Arizona Secretary of State's website is the official published version for rulemaking activity in the state of Arizona.

Rulemaking is defined in Arizona Revised Statutes known as the Arizona Administrative Procedure Act (APA), A.R.S. Title 41, Chapter 6, Articles 1 through 10.

The Register is cited by volume and page number. Volumes are published by calendar year with issues published weekly. Page numbering continues in each weekly issue.

In addition, the Register contains notices of rules terminated by the agency and rules that have expired.

ABOUT RULES
Rules can be: made (all new text); amended (rules on file, changing text); repealed (removing text); or renumbered (moving rules to a different Section number). Rulemaking activity published in the Register includes: proposed, final, emergency, expedited, and exempt rules as defined in the APA, and other state statutes.

New rules in this publication (whether proposed or made) are denoted with underlining; repealed text is stricken.

WHERE IS A “CLEAN” COPY OF THE FINAL OR EXEMPT RULE PUBLISHED IN THE REGISTER?
The Arizona Administrative Code (A.A.C) contains the codified text of rules. The A.A.C. contains rules promulgated and filed by state agencies that have been approved by the Attorney General or the Governor’s Regulatory Review Council. The Code also contains rules exempt from the rulemaking process.

The authenticated pdf of Code chapters posted on the Arizona Secretary of State’s website are the official published version of rules in the A.A.C. The Code is posted online for free.

LEGAL CITATIONS AND FILING NUMBERS
On the cover: Each agency is assigned a Chapter in the Arizona Administrative Code under a specific Title. Titles represent broad subject areas. The Title number is listed first; with the acronym A.A.C., which stands for the Arizona Administrative Code; following the Chapter number and Agency name, then program name. For example, the Secretary of State has rules on rulemaking in Title 1, Chapter 1 of the Arizona Administrative Code. The citation for this chapter is 1 A.A.C. 1, Secretary of State, Rules and Rulemaking

Every document filed in the office is assigned a file number. This number, enclosed in brackets, is located at the top right of the published documents in the Register. The original filed document is available for 10 cents a page.
Participate in the Process

Look for the Agency Notice

Review (inspect) notices published in the Arizona Administrative Register. Many agencies maintain stakeholder lists and would be glad to inform you when they proposed changes to rules. Check an agency’s website and its newsletters for news about notices and meetings.

Feel like a change should be made to a rule and an agency has not proposed changes? You can petition an agency to make, amend, or repeal a rule. The agency must respond to the petition. (See A.R.S. § 41-1033)

Attend a public hearing/meeting

Attend a public meeting that is being conducted by the agency on a Notice of Proposed Rulemaking. Public meetings may be listed in the Preamble of a Notice of Proposed Rulemaking or they may be published separately in the Register. Be prepared to speak, attend the meeting, and make an oral comment.

An agency may not have a public meeting scheduled on the Notice of Proposed Rulemaking. If not, you may request that the agency schedule a proceeding. This request must be put in writing within 30 days after the published Notice of Proposed Rulemaking.

Write the agency

Put your comments in writing to the agency. In order for the agency to consider your comments, the agency must receive them by the close of record. The comment must be received within the 30-day comment timeframe following the Register publication of the Notice of Proposed Rulemaking.

You can also submit to the Governor’s Regulatory Review Council written comments that are relevant to the Council’s power to review a given rule (A.R.S. § 41-1052). The Council reviews the rule at the end of the rulemaking process and before the rules are filed with the Secretary of State.

Arizona Regular Rulemaking Process

START HERE
APA, statute or ballot proposition is passed. It gives an agency authority to make rules. It may give an agency an exemption to the process or portions thereof.

Agency opens a docket. Agency files a Notice of Rulemaking Docket Opening; it is published in the Register. Often an agency will file the docket with the proposed rulemaking.

Agency drafts proposed rule and Economic Impact Statement (EIS); informal public review/comment.

Agency files Notice of Proposed Rulemaking. Notice is published in the Register. Notice of meetings may be published in Register or included in Preamble of Proposed Rulemaking. Agency opens comment period.

Oral proceeding and close of record. Comment period must last at least 30 days after publication of notice. Oral proceeding (hearing) is held no sooner than 30 days after publication of notice of hearing

Substantial change?
If no change then

Rule must be submitted for review or terminated within 120 days after the close of the record.

A final rulemaking package is submitted to G.R.R.C. or A.G. for review. Contains final preamble, rules, and Economic Impact Statement.

G.R.R.C. has 90 days to review and approve or return the rule package, in whole or in part; A.G. has 60 days.

After approval by G.R.R.C. or A.G., the rule becomes effective 60 days after filing with the Secretary of State (unless otherwise indicated).

Final rule is published in the Register and the quarterly Code Supplement.
Definitions


**Arizona Administrative Register (A.A.R.):** The official publication that includes filed documents pertaining to Arizona rulemaking. Available online at www.azsos.gov.

**Administrative Procedure Act (APA):** A.R.S. Title 41, Chapter 6, Articles 1 through 10. Available online at www.azleg.gov.

**Arizona Revised Statutes (A.R.S.):** The statutes are made by the Arizona State Legislature during a legislative session. They are compiled by Legislative Council, with the official publication codified by Thomson West. Citations to statutes include Titles which represent broad subject areas. The Title number is followed by the Section number. For example, A.R.S. § 41-1001 is the definitions Section of Title 41 of the Arizona Administrative Procedures Act. The “§” symbol simply means “section.” Available online at www.azleg.gov.

**Chapter:** A division in the codification of the Code designating a state agency or, for a large agency, a major program.

**Close of Record:** The close of the public record for a proposed rulemaking is the date an agency chooses as the last date it will accept public comments, either written or oral.


**Docket:** A public file for each rulemaking containing materials related to the proceedings of that rulemaking. The docket file is established and maintained by an agency from the time it begins to consider making a rule until the rulemaking is finished. The agency provides public notice of the docket by filing a Notice of Rulemaking Docket Opening with the Office for publication in the Register.

**Economic, Small Business, and Consumer Impact Statement (EIS):** The EIS identifies the impact of the rule on private and public employment, on small businesses, and on consumers. It includes an analysis of the probable costs and benefits of the rule. An agency includes a brief summary of the EIS in its preamble. The EIS is not published in the Register but is available from the agency promulgating the rule. The EIS is also filed with the rulemaking package.

**Governor’s Regulatory Review (G.R.R.C.):** Reviews and approves rules to ensure that they are necessary and to avoid unnecessary duplication and adverse impact on the public. G.R.R.C. also assesses whether the rules are clear, concise, understandable, legal, consistent with legislative intent, and whether the benefits of a rule outweigh the cost.

**Incorporated by Reference:** An agency may incorporate by reference standards or other publications. These standards are available from the state agency with references on where to order the standard or review it online.

**Federal Register (FR):** The Federal Register is a legal newspaper published every business day by the National Archives and Records Administration (NARA). It contains federal agency regulations; proposed rules and notices; and executive orders, proclamations, and other presidential documents.

**Session Laws or “Laws”:** When an agency references a law that has not yet been codified into the Arizona Revised Statutes, use the word “Laws” is followed by the year the law was passed by the Legislature, followed by the Chapter number using the abbreviation “Ch.”, and the specific Section number using the Section symbol (§). For example, Laws 1995, Ch. 6, § 2. Session laws are available at www.azleg.gov.

**United States Code (U.S.C.):** The Code is a consolidation and codification by subject matter of the general and permanent laws of the United States. The Code does not include regulations issued by executive branch agencies, decisions of the federal courts, treaties, or laws enacted by state or local governments.

**Acronyms**

A.A.C. – Arizona Administrative Code

A.A.R. – Arizona Administrative Register

APA – Administrative Procedure Act

A.R.S. – Arizona Revised Statutes

CFR – Code of Federal Regulations

EIS – Economic, Small Business, and Consumer Impact Statement

FR – Federal Register

G.R.R.C. – Governor’s Regulatory Review Council


**About Preambles**

The Preamble is the part of a rulemaking package that contains information about the rulemaking and provides agency justification and regulatory intent.

It includes reference to the specific statutes authorizing the agency to make the rule, an explanation of the rule, reasons for proposing the rule, and the preliminary Economic Impact Statement.

The information in the Preamble differs between rulemaking notices used and the stage of the rulemaking.
NOTICES OF PROPOSED RULEMAKING
This section of the Arizona Administrative Register contains Notices of Proposed Rulemaking.
A proposed rulemaking is filed by an agency upon completion and submittal of a Notice of Rulemaking Docket Opening. Often these two documents are filed at the same time and published in the same Register issue.
When an agency files a Notice of Proposed Rulemaking under the Administrative Procedure Act (APA), the notice is published in the Register within three weeks of filing. See the publication schedule in the back of each issue of the Register for more information.

NOTICE OF PROPOSED RULEMAKING
TITLE 9. HEALTH SERVICES
CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM (AHCCCS) ADMINISTRATION

[R21-216]

PREAMBLE

1. **Article, Part, or Section Affected (as applicable)**  
   R9-22-701  
   R9-22-712.08  
   **Rulemaking Action**  
   Amend  
   New Section

2. **Citations to the agency’s statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):**  
   Authorizing statute: A.R.S. § 36-2907.06  
   Implementing statute: A.R.S. § 36-2907.06

3. **Citations to all related notices published in the Register as specified in R1-1-409(A) that pertain to the record of the proposed rule:**  
   Notice of Rulemaking Docket Opening: 27 A.A.R. 2823, December 3, 2021 (in this issue)

4. **The agency’s contact person who can answer questions about the rulemaking:**  
   **Name:** Nicole Fries  
   **Address:** AHCCCS  
   Office of Administrative Legal Services  
   801 E. Jefferson, Mail Drop 6200  
   Phoenix, AZ 85034  
   **Telephone:** (602) 417-4232  
   **Fax:** (602) 253-9115  
   **Email:** AHCCCSRules@azahcccs.gov  
   **Website:** www.azahcccs.gov

5. **An agency’s justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:**  
   Currently, Graduate Medical Education (GME) funding is distributed to hospitals that provide training and education for medical school graduates. The GME fund is authorized pursuant to A.R.S. 36-2903.01(G). Under A.R.S. § 36-2903.01(G)(9), certain public entities are permitted to transfer funds to the AHCCCS Administration to support these distributions. The Centers for Medicare and Medicaid Services (CMS) require the Administration to annually update the amount allocated to each hospital in the State Plan. Before the Administration may make GME payments, a State Plan Amendment (SPA) must be submitted and approved by CMS. Therefore, no payments under this rulemaking may be made until AHCCCS has received approval for the SPA corresponding to this rulemaking.

   Laws 2021, Chapter 81, requires that by March 1, 2022, the Administration establish a separate GME program to reimburse qualifying CHCs and RHCs which have an approved primary care GME program. Through this rulemaking, the Administration proposes to create a separate program for GME for CHCs and RHCs, notwithstanding the existing GME programs found in R9-22-712.05 and R9-22-712.06. The AHCCCS Administration worked with the Arizona Alliance for Community Health Centers and a workgroup consisting of CHCs and RHCs to develop the methodology for distributing these payments, subject to CMS approval. Technical and conforming changes will also be considered as part of the rulemaking.
6. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

No study was relied upon.

7. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

As a result of information from the Arizona Alliance of Community Health Centers and a workgroup consisting of CHCs and RHCs, AHCCCS has determined that payments through this rulemaking are critical to support and incentivize primary care GME programs in Arizona. Although the state budget does not currently appropriate any monies for this program, the Laws 2021, Chapter 81 allows RHCs and CHCs to partner with local, county, and tribal governments and any universities under the jurisdiction of the Arizona Board of Regents to provide funds for a state contribution and receive federally matched funds, subject to approval by CMS. Thus, the proposed rulemaking would be funded from intergovernmental agreements with political subdivisions throughout the state.

9. The agency's contact person who can answer questions about the economic, small business and consumer impact statement:

Name: Nicole Fries
Address: AHCCCS
Office of Administrative Legal Services
801 E. Jefferson, Mail Drop 6200
Phoenix, AZ 85034
Telephone: (602) 417-4232
Fax: (602) 253-9115
Email: AHCCCSSRules@azahcccs.gov
Website: www.azahcccs.gov

10. The time, place, and nature of the proceedings to make, amend, repeal, or renumber the rule, or if no proceeding is scheduled, where, when, and how person may request an oral proceeding on the proposed rule:

Proposed rule language will be available on the AHCCCS website. Please send comments to the above address by the close of the comment period, 5:00 p.m., January 3, 2022.

Date: January 3, 2022
Time: 2:00 p.m.
Location: https://meet.google.com/vks-przq-uzh
Or dial: (US) + 1 941-216-5406
PIN: 640 245 818#
Nature: Public Hearing

11. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

No other matters have been prescribed.

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

   Not applicable

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

   Not applicable

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

   No analysis was submitted.

12. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:

   None

13. The full text of the rules follows:

   TITLE 9. HEALTH SERVICES
   CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM (AHCCCS)
   ADMINISTRATION

   ARTICLE 7. STANDARDS FOR PAYMENTS
R9-22-701. Standard for Payments Related Definitions

In addition to definitions contained in A.R.S. § 36-2901, the words and phrases in this Article have the following meanings unless the context explicitly requires another meaning:

“Accommodation” means room and board services provided to a patient during an inpatient hospital stay and includes all staffing, supplies, and equipment. The accommodation is semi-private except when the member must be isolated for medical reasons. Types of accommodation include hospital routine medical/surgical units, intensive care units, and any other specialty care unit in which room and board are provided.

“Aggregate” means the combined amount of hospital payments for covered services provided within and outside the GSA.

“AHCCCS inpatient hospital day or days of care” means each day of an inpatient stay for a member beginning with the day of admission and including the day of death, if applicable, but excluding the day of discharge, provided that all eligibility, medical necessity, and medical review requirements are met.

“Ancillary service” means all hospital services for patient care other than room and board and nursing services, including but not limited to, laboratory, radiology, drugs, delivery room (including maternity labor room), operating room (including postanesthesia and postoperative recovery rooms), and therapy services (physical, speech, and occupational).

“APC” means the Ambulatory Payment Classification system under 42 CFR 419.31 used by Medicare for grouping clinically and resource-similar procedures and services.

“Billed charges” means charges for services provided to a member that a hospital includes on a claim consistent with the rates and charges filed by the hospital with Arizona Department of Health Services (ADHS).

“Business agent” means a company such as a billing service or accounting firm that renders billing statements and receives payment in the name of a provider.

“Capital costs” means costs as reported by the hospital to CMS as required by 42 CFR 413.20.

“Copayment” means a monetary amount, specified by the Director, that a member pays directly to a contractor or provider at the time covered services are rendered.

“Cost-to-charge ratio” (CCR) means a hospital’s costs for providing covered services divided by the hospital’s charges for the same services. The CCR is the percentage derived from the cost and charge data for each revenue code provided to AHCCCS by each hospital.

“Covered charges” means billed charges that represent medically necessary, reasonable, and customary items of expense for covered services that meet medical review criteria of AHCCCS or a contractor.

“CHC” means a Community Health Center, which includes both Federally Qualified Health Centers and Rural Health Clinics.

“CPT” means Current Procedural Terminology, published, and updated by the American Medical Association. CPT is a nationally-accepted listing of descriptive terms and identifying codes for reporting medical services and procedures performed by physicians that provide a uniform language to accurately designate medical, surgical, and diagnostic services.

“Critical Access Hospital” is a hospital certified by Medicare under 42 CFR 485 Subpart F and 42 CFR 440.170(g).

“Direct graduate medical education costs” or “direct program costs” means the costs that are incurred by a hospital for the education activities of an approved graduate medical education program that are the proximate result of training medical residents in the hospital, including resident salaries and fringe benefits, the portion of teaching physician salaries and fringe benefits that are related to the time spent in teaching and supervision of residents, and other related GME overhead costs.

“DRI inflation factor” means Global Insights Prospective Hospital Market Basket.

“Eligibility posting” means the date a member’s eligibility information is entered into the AHCCCS Pre-paid Medical Management Information System (PMMIS).

“Encounter” means a record of a medically-related service rendered by an AHCCCS-registered provider to a member enrolled with a contractor on the date of service.

“Existing outpatient service” means a service provided by a hospital before the hospital files an increase in its charge master as defined in R9-22-712(G), regardless of whether the service was explicitly described in the hospital charge master before filing the increase or how the service was described in the charge master before filing the increase.

“Expansion funds” means funds appropriated to support GME program expansions as described under A.R.S. § 36-2903.01(G)(9)(b) and (c)(i).

“Factor” means a person or an organization, such as a collection agency or service bureau, that advances money to a provider for accounts receivable that the provider has assigned, sold, or transferred to the organization for an added fee or a deduction of a portion of the accounts receivable. Factor does not include a business agent.

“Fiscal intermediary” means an organization authorized by CMS to make determinations and payments for Part A and Part B provider services for a given region.

“Freestanding Children’s Hospital” means a separately standing hospital with at least 120 pediatric beds that is dedicated to providing the majority of the hospital’s services to children.

“GME program approved by the Administration” or “approved GME program” means a graduate medical education program that has been approved by a national organization as described in 42 CFR 415.152.
“Graduate medical education (GME) program or fellowship” means an approved residency program that prepares a physician for independent practice of medicine by providing didactic and clinical education in a medical environment to a medical student who has completed a recognized undergraduate medical education program.

“ICAC” means a health care acquired condition described under 42 CFR 447.26 but does not include Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE) as related to total knee replacement or hip replacement surgery in pediatric and obstetric patients.

“HCPCS” means the Health Care Procedure Coding System, published, and updated by Center for Medicare and Medicaid Services (CMS). HCPCS is a listing of codes and descriptive terminology used for reporting the provision of physician services, other health care services, and substances, equipment, supplies, or other items used in health care services.

“HIPAA” means the Health Insurance Portability and Accountability Act of 1996, as specified under 45 CFR 162, that establishes standards and requirements for the electronic transmission of certain health information by defining code sets used for encoding data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes.

“ICU” means the intensive care unit of a hospital.

“Indirect program costs” means the marginal increase in operating costs that a hospital provider experiences as a result of having an approved graduate medical education program and that is not accounted for by the hospital’s direct program costs.

“Intern and Resident Information System” means a software program used by teaching hospital providers and the provider community for collecting and reporting information on resident training in hospital and non-hospital settings.

“Medical education costs” means direct hospital costs for intern and resident salaries, fringe benefits, program costs, nursing school education, and paramedical education, as described in the Medicare Provider Reimbursement Manual.

“Medical review” means a clinical evaluation of documentation conducted by AHCCCS or a contractor for purposes of prior authorization, concurrent review, post-payment review, or determining medical necessity. The criteria for medical review are established by AHCCCS or a contractor based on medical practice standards that are updated periodically to reflect changes in medical care.

“Medicare Urban or Rural Cost-to-Charge Ratio (CCR)” means statewide average capital cost-to-charge ratio published annually by CMS added to the urban or rural statewide average operating cost-to-charge ratio published annually by CMS.

“National Standard code sets” means codes that are accepted nationally in accordance with federal requirements under 45 CFR 160 and 45 CFR 164.

“New hospital” means a hospital for which Medicare Cost Report claim and encounter data are not available for the fiscal year used for initial rate setting or rebasing.

“NICU” means the neonatal intensive care unit of a hospital that is classified as a Level II or Level III perinatal center by the Arizona Perinatal Trust.

“Non-IHS Acute Hospital” means a hospital that is not run by Indian Health Services, is not a free-standing psychiatric hospital, such as an IMD, and is paid under ADHS rates.

“Observation day” means a physician-ordered evaluation period of less than 24 hours to determine whether a person needs treatment or needs to be admitted as an inpatient. Each observation day consists of a period of 24 hours or less.

“Operating costs” means AHCCCS-allowable accommodation costs and ancillary department hospital costs excluding capital and medical education costs.

“OPPC” means an Other Provider Preventable Condition that is: (1) a surgical or other invasive procedure performed on a patient, (2) a surgical or other invasive procedure performed on the wrong body part, or (3) a surgical or other invasive procedure performed on the wrong patient.

“Organized health care delivery system” means a public or private organization that delivers health services. It includes, but is not limited to, a clinic, a group practice prepaid capitation plan, and a health maintenance organization.

“Outlier” means a hospital claim or encounter in which the operating costs per day for an AHCCCS inpatient hospital stay meet the criteria described under this Article and A.R.S. § 36- 2903.01(G).

“Outpatient hospital service” means a service provided in an outpatient hospital setting that does not result in an admission.

“Ownership change” means a change in a hospital’s owner, lessor, or operator under 42 CFR 489.18(a).

“Participating institution” means an institution at which portions of a graduate medical education program are regularly conducted and to which residents rotate for an educational experience for at least one month.

“Peer group” means hospitals that share a common, stable, and independently definable characteristic or feature that significantly influences the cost of providing hospital services, including specialty hospitals that limit the provision of services to specific patient populations, such as rehabilitative patients or children.

“PPC” means prior period coverage. PPC is the period of time, prior to the member’s enrollment, during which a member is eligible for covered services. The time-frame is the first day of the month of application or the first eligible month, whichever is later, until the day a member is enrolled with a contractor.

“PPS bed” means Medicare-approved Prospective Payment beds for inpatient services as reported in the Medicare cost reports for the most recent fiscal year for which the Administration has a complete set of Medicare cost reports for every rural hospital as determined as of the first of February of each year.

“Primary care GME program” means a graduate medical education program that prepares a physician for the practice of internal medicine, family medicine, pediatrics, obstetrics, geriatrics, or psychiatry.

“Procedure code” means the numeric or alphanumeric code listed in the CPT or HCPCS manual by which a procedure or service is identified.
“Prospective rates” means inpatient or outpatient hospital rates set by AHCCCS in advance of a payment period and representing full payment for covered services excluding any quickpay discounts, slow-pay penalties, and first-and third-party payments regardless of billed charges or individual hospital costs.

“Public hospital” means a hospital that is owned and operated by county, state, or hospital health care district.

“Qualifying health information exchange organization” means a non-profit health information organization as defined in A.R.S. § 36-3801 that provides the statewide exchange of patient health information among disparate health care organizations and providers not owned, operated, or controlled by the health information exchange. A qualifying health information exchange organization must include representation by the administration on its board of directors, and have a significant number of health care participants, including hospitals, laboratories, payers, community physicians and Federally Qualified Health Centers.

“Rebase” means the process by which the most currently available and complete Medicare Cost Report data for a year and AHCCCS claim and encounter data for the same year are collected and analyzed to reset the Inpatient Hospital Tiered per diem rates, or the Outpatient Hospital Capped Fee-For-Service Schedule.

“Reinsurance” means a risk-sharing program provided by AHCCCS to contractors for the reimbursement of specified contract service costs incurred by a member beyond a certain monetary threshold.

“Remittance advice” means an electronic or paper document submitted to an AHCCCS-registered provider by AHCCCS to explain the disposition of a claim.

“Resident” means a physician engaged in postdoctoral training in an accredited graduate medical education program, including an intern and a physician who has completed the requirements for the physician’s eligibility for board certification.

“Revenue code” means a numeric code, that identifies a specific accommodation, ancillary service, or billing calculation, as defined by the National Uniform Billing committee for UB04 forms.

“Sub-acute services” means inpatient care for a patient with an acute illness, injury, or exacerbation of a disease process when the patient does not require acute inpatient hospitalization. Sub-acute care is rendered immediately after, or instead of, acute inpatient hospitalization.

“Specialty facility” means a facility where the service provided is limited to a specific population, such as rehabilitative services for children.

“Sponsoring institution” means the institution or entity that is recognized by the GME accrediting organization and designated as having ultimate responsibility for the assurance of academic quality and compliance with the terms of accreditation.

“Tier” means a grouping of inpatient hospital services into levels of care based on diagnosis, procedure, or revenue codes, peer group, NICU classification level, or any combination of these items.

“Tiered per diem” means an AHCCCS capped fee schedule in which payment is made on a per-day basis depending upon the tier (or tiers) into which an AHCCCS inpatient hospital day of care is assigned.

“Trip” means a one-way transport each time a taxi is called. If the taxi waits for the member, then the transport continues to be part of the one-way trip. If the taxi leaves and is called to pick up the member, that is considered a new one-way trip.

R9-22-712.08.  Reserved

Federal Qualified Health Center and Rural Health Clinic Graduate Medical Education Program

A. Subject to available funds and approval by CMS, the Administration shall annually distribute monies appropriated for primary care GME programs approved by the Administration to Federally Qualified Health Centers (FQHC) and Rural Health Clinics (RHC) for direct and indirect program costs eligible for funding under A.R.S. § 36-2907.06(1).

1. A GME program is deemed to be established as of the date of its original accreditation. All determinations that are necessary to make distributions described by this subsection shall be made using information possessed by the Administration as of the date of reporting under subsection (D).

2. For purposes of this subsection, the term “FQHC” includes Federally Qualified Health Center Look-Alikes.

B. Eligible health care facilities. A health care facility is eligible for a distribution under subsection (G) if all of the following apply:

1. It is an FQHC or RHC in Arizona that is the sponsoring institution of, or a full member of a consortium that is the sponsoring institution of, or a participating institution in, one or more approved primary care GME programs in Arizona;

2. It incurs direct or indirect costs for the training of residents in Arizona in approved primary care GME programs;

3. The GME program is not eligible for funding under R9-22-712.05; and

4. The GME program is not fully funded by the federal government.

C. Eligible residents and resident positions. For purposes of determining program allocation amounts under subsections (E) and (F) the following residents and resident positions are eligible for consideration, to the extent that the resident training takes place in Arizona and not at a health care facility made ineligible under subsection (B):

1. All filled resident positions in approved primary care GME programs; or

2. For approved primary care GME programs established for less than one year as of the date of annual reporting under subsection (D) and that have not yet filled their first-year resident positions, all prospective residents reasonably expected by the program to be enrolled as a result of the most recently completed annual resident match.

D. Annual reporting. By April 1st of each year, an FQHC or RHC seeking a distribution under this subsection shall:

1. Provide to the Administration the following information about each approved primary care GME program:

   a. The program name and number assigned by the accrediting organization;

   b. The original date of accreditation of the program;

   c. The names of the sponsoring institution and all participating institutions current as of the date of reporting;
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Arizona Administrative Register

d. The number of approved resident positions and the number of filled resident positions current as of the date of reporting;
e. The academic year rotation schedule on file with the program current as of the date of reporting; and
f. For programs described under subsection (C)(2), the number of residents expected to be enrolled as a result of the most recently completed annual resident match.

2. Provide to the Administration the most recent Medicare Cost Report for the FQHC or RHC seeking the distribution, and

3. For an FQHC or RHC that is a full member of a consortium that is the sponsoring institution of an approved primary care GME program, provide to the Administration a signed letter attesting to the responsibility of the full member FQHC or RHC for direct or indirect costs of training residents in the program.

E. Allocation of funds for direct graduate medical education costs. Annually the Administration shall allocate available funds for direct graduate medical education costs to each eligible FQHC or RHC in the following manner:

1. A Medicaid utilization percent for each FQHC or RHC seeking a distribution shall be calculated using the Medicare Cost Report submitted under subsection (D)(2), dividing the Title XIX visit count by the whole number of visits reported and rounding the result up to the nearest multiple of 5 percent.

2. A total number of residents eligible for funding in each program shall be calculated using the information submitted under subsection (D)(1), dividing the number of resident rotations in the year that take place in Arizona and not at a health care facility made ineligible under subsection (B) by the total number of resident rotations in the program for that year, multiplying the result by the total number of filled resident positions in the program and rounding to two digits after the decimal.

3. The allocation for direct graduate medical education costs for each eligible FQHC or RHC shall be calculated by multiplying the number of residents determined under subsection (E)(2) by the statewide average per-resident amount determined under this subsection and multiplying the result by the Medicaid utilization percent calculated for the FQHC or RHC under subsection (E)(1). The statewide average per-resident amount for the academic year ending June 30, 2022 is $170,090. Annually thereafter, a statewide average per-resident amount shall be calculated by applying the Federally Qualified Health Center PPS Market Basket Update less Productivity Adjustment published by CMS for the calendar year in which the GME academic year begins.

F. Allocation of funds for indirect program costs. Annually the Administration shall allocate available funds for indirect program costs to each eligible FQHC or RHC in the following manner:

1. By multiplying the number of residents determined under subsection (E)(2) by the statewide average per-resident amount determined under this subsection and multiplying the result by the Medicaid utilization percent calculated for the FQHC or RHC under subsection (E)(1). The statewide average per-resident amount for the academic year ending June 30, 2022 is $167,330; and

2. Annually thereafter, a statewide average per-resident amount shall be calculated by applying the Federally Qualified Health Center PPS Market Basket Update less Productivity Adjustment published by CMS for the calendar year in which the GME academic year begins.

G. Distribution of funds. On an annual basis subject to available funds, the Administration shall distribute to each eligible FQHC and RHC the sum of all amounts calculated for the FQHC or RHC under subsections (E)(3) and (F).

H. The Administration may enter into intergovernmental agreements with local, county, and tribal governments and any university under the jurisdiction of the Arizona Board of Regents wherein such entities may transfer funds or certify public expenditures to the Administration. Such funds or certification, subject to approval by CMS, will contribute to the state funding to qualify for federal matching funds. Those funds will be used for the purposes of reimbursing FQHCs and RHCs that are eligible under this rule and designated by the local, county, or tribal governments for receipt of the contributed funds. The Administration shall allocate available funds in accordance with subsections (E) and (F).
## NOTICES OF FINAL RULEMAKING

This section of the Arizona Administrative Register contains Notices of Final Rulemaking. Final rules have been through the regular rulemaking process as defined in the Administrative Procedures Act. These rules were either approved by the Governor’s Regulatory Review Council or the Attorney General’s Office. Certificates of Approval are on file with the Office.

The final published notice includes a preamble and text of the rules as filed by the agency. Economic Impact Statements are not published but are filed by the agency with their final notice.

The Office of the Secretary of State is the filing office and publisher of these rules. Questions about the interpretation of the final rules should be addressed to the agency that promulgated them. Refer to item #5 to contact the person charged with the rulemaking.

The codified version of these rules will be published in the Arizona Administrative Code.

### NOTICE OF FINAL RULEMAKING

**TITLE 4. PROFESSIONS AND OCCUPATIONS**

**CHAPTER 36. DEPARTMENT OF FORESTRY AND FIRE MANAGEMENT**

[R21-217]

**PREAMBLE**

1. **Article, Part, or Section Affected (as applicable)** | **Rulemaking Action**
   - R4-36-201
   - R4-36-301
   - R4-36-302
   - Exhibit A
   - R4-36-303
   - R4-36-304
   - R4-36-305
   - R4-36-306
   - R4-36-307
   - R4-36-308
   - R4-36-309
   - Amend
   - Amend
   - Amend
   - Amend
   - Amend
   - Amend
   - Repeal
   - Repeal
   - Repeal
   - Repeal

2. **Citations to the agency’s statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):**
   - Authorizing statute: A.R.S. § 37-1302(A)(2)
   - Implementing statute: A.R.S. § 37-1383(A)(2)

3. **The effective date of the rule**
   - January 7, 2022

4. **Citations to all related notices published in the Register as specified in R1-1-409(A) that pertain to the record of the proposed rules:**
   - Notice of Rulemaking Docket Opening: 27 A.A.R. 850, June 4, 2021
   - Notice of Proposed Rulemaking: 27 A.A.R. 845, June 4, 2021

5. **The agency’s contact person who can answer questions about the rulemaking:**
   - Name: Cassie Peters, Assistant Director
   - Address: Department of Forestry and Fire Management
   - 1110 W. Washington St., Suite 100
   - Phoenix, AZ 85007
   - Telephone: (602) 364-1015
   - Fax: (602) 771-1421
   - Email: cpeters@dffm.az.gov
   - Website: dffm.az.gov

6. **An agency’s justification and reason why a rule should be made, amended, repealed, or renumbered, to include an explanation about the rulemaking:**
   - The Department needs to amend and repeal some rules consistent with its five-year review report that was approved by the Governor’s Regulatory Review Council in January 2020. The Department proposed to amend its rules to adopt the 2018 edition of the International Fire Code (IFC 2018) as the minimum State Fire Code in order to better regulate fire hazards in Arizona and be more consistent with minimum national standards. The Department also needs to repeal some of its rules which are not necessary because it is adopting the IFC 2018 in its entirety.
   - In order to ensure that Arizona meets national standards for fire protection and prevention, the Department adopts the entirety of the International Fire Code (IFC), incorporated by reference. The IFC 2012 is incorporated by reference in R4-36-201 and needs to
be replaced with the IFC 2018. In addition to the safety measures addressed in the IFC 2012, the IFC 2018 addresses several additional items of concern, such as battery storage facilities and facilities that produce cannabis products. Adopting the IFC 2018 will allow the state to enforce life safety protections relating to such additional items of concern.

Adopting the IFC 2018 will establish minimum requirements consistent with nationally recognized good practice for providing a reasonable level of life safety and property protection. Additionally, it will ensure a reasonable level of safety for fire fighters and emergency responders during emergency operations.

7. A reference to any study relevant to the rules that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rules, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

Underlying each study, and any analysis of each study and other supporting material:

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

All costs associated with the changes will not have a broad economic impact. Rather, the economic impact of the changes will be based on individual compliance with current and updated safety requirements, meaning the range of economic impact could be minor to significant.

Chapter 1: There were nine permits added as part of additions to the code. No significant economic impact.

Chapter 2: Many new definitions are given to coincide with new chapters. In addition, occupation type definitions have been redefined to coincide with the State Health Department’s standards.

Chapter 3 319.1 Mobile Food Preparation Vehicles that are equipped with appliances that produce smoke or grease-laden vapors shall comply with this section, but these requirements have been in place since the IFC 2015 Edition.

Chapter 4 Lockdown plans require the approval of the fire code official

Chapter 9 901.6.2.2 High-rise buildings: Requires integrated testing of high-rise buildings to conform to NFPA 4. The test performance every 10 years or what is required by the design documents. This test is in addition to other required tests such as those required by NFPA 25 for water-based fire protection systems and NFPA 72 for fire alarm systems. There may be a marginal cost for high-rise building owners for vendors to test or assist in testing systems.

903.2.2 Ambulatory care facilities: Requires fire sprinklers in the entire building rather than just the entire floor and all floors below leading to exit discharge. Not believed to be a significant financial impact because most buildings will already have fire sprinklers throughout the entire building already.

Chapter 11 1103.9 Carbon monoxide alarms: The new code requires CO alarms based on use (Dwelling units, Sleeping units) and gives sole battery options.

1105.9 Group I-2 automatic sprinkler system: Adds fire sprinkler requirement to areas below the level of exit discharge in Group I-2 occupancies. Similar to 903.2.2, most buildings will already have this in place. However, if it does require installation, the cost could be significant to the individual owner.

Chapter 12: All elements of Chapter 6 related to energy systems with some additional requirements.

1204.2.1 Solar photovoltaic systems for Group R-3 buildings: It shall not apply to equipment associated with the generation, control, transformation, transmission, or distribution of energy installations that is under the exclusive control of an electric utility or lawfully designated agency.

Chapter 31 Title change: Adds safety requirements for outdoor assemblies including stages and other events. Comes as a result of injuries at an outdoor concert with a weather event. Conforms to mass gathering requirements of the health department.

Chapter 32: Two significant changes: First, increased fire access doors from 100 ft. to 125 ft. and commodities now align with NFPA 13 commodity classifications. This will save time and money for design professionals when designing fire suppression for high-piled storage. More importantly, it will reduce the risk of design deficiencies by decreasing commodity misclassification.

Chapter 38: Entirely new chapter on higher education laboratories. As a B Occupancy, places safety requirements primarily centered on hazardous material storage and handling.

Chapter 39 3901.1: Plant processing or extraction facilities shall comply with this chapter and the International Building Code. Due to recent voter approval for recreational use of cannabis in the State of Arizona, new and existing facilities may be impacted if they are engaging in plant processing and extracting operations.

Chapter 51: Cooking sprays have been classified and several regulations placed on storage.

10. A description of any changes between the proposed rulemaking, to include supplemental notices, and the final rulemaking:

There are no substantial changes between the proposed rules and final rules.

11. An agency’s summary of the public stakeholder comments made about the rulemaking and the agency response.

The Department held an Oral Proceeding on July 6, 2021. In addition to Department staff, two representatives from local fire districts and one representative from the International Code Council attended the Oral Proceeding. All three representatives expressed support for the rulemaking.
12. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:
   The Department issues specific permits for operations and construction. A general permit is not feasible because each permit must ensure that the applicant meets the specific requirements necessary for the applicant to operate safely in compliance with the IFC.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:
   The National Fire Protection Association (NFPA) Codes and Standards apply to these rules, but these rules are not more stringent than the NFPA.

c. Whether a person submitted an analysis to the agency that compares the rule’s impact of the competitiveness of business in this state to the impact on business in other states:
   No analysis was submitted.

13. A list of any incorporation by reference material as specified in A.R.S. § 41-1028 and its location in the rules:
   R4-36-201 incorporates by reference the IFC 2018.

14. Whether the rule was previously made, amended or repealed as an emergency rule. If so, cite the notice published in the Register as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages.
   The rules were not made as emergency rules.

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS
CHAPTER 36. DEPARTMENT OF FORESTRY AND FIRE MANAGEMENT

ARTICLE 2. ARIZONA STATE FIRE CODE

Section
R4-36-201. Incorporation by Reference of the International Fire Code

ARTICLE 3. INTERNATIONAL FIRE CODE MODIFICATIONS AND ACCEPTED PRACTICES

Section
R4-36-301. Definitions
R4-36-302. Appendices
Exhibit A. Incorporated Appendices
R4-36-303. Permits
R4-36-304. Inspections and Enforcement
R4-36-305. General Precautions Against Fire Repealed
R4-36-306. Emergency Planning and Preparedness Repealed
R4-36-307. Fire Service Features Repealed
R4-36-308. Building Services and Systems Repealed
R4-36-309. Fire Protection Systems Repealed

ARTICLE 2. ARIZONA STATE FIRE CODE

R4-36-201. Incorporation by Reference of the International Fire Code
   Unless otherwise provided by law, any person residing, doing business, or who is physically present within the state of Arizona shall comply with the provisions of the International Fire Code (2012-2018 Edition), including D102.1 and D107.1 of Appendix D and all provisions of Appendices B, C, E, F, G, H, I, and J, and N, which is published by the International Code Council, incorporated by reference as the State Fire Code, and modified by Article 3. The incorporated material does not include any later amendments or editions. Copies of the International Fire Code are available from the International Code Council, 4051 W. Flossmoor Road, Country Club Hills, IL 60478-5795 and a copy is available for inspection at the Office of the State Fire Marshal.

ARTICLE 3. INTERNATIONAL FIRE CODE MODIFICATIONS AND ACCEPTED PRACTICES

R4-36-301. Definitions
   The following terms as used in the International Fire Code, incorporated by reference at R4-36-201, apply to the State Fire Code established in this Chapter, unless the context otherwise requires:

1. “Department of fire prevention” means the State Fire Marshal or the State Fire Marshal’s designated representative.
2. “fire code official” as used in the International Fire Code, these terms include means the State Fire Marshal or the State Fire Marshal’s designated representative, unless the context otherwise requires.
3. “fire Fire department” or “department of fire prevention” as used in the International Fire Code, these terms include means the State Fire Marshal or the State Fire Marshal’s designated representative, unless the context otherwise requires.
Section 202, the definition of Occupancy Classification for R-3 within the Residential Group is modified to read: Residential

Section 108.1
Boarding houses (transient) with 10 or fewer occupants
Care facilities within a dwelling. Care facilities for five or fewer persons receiving care that are within a single-family
Section 105.1.1 is modified to read: Permits required. Any property owner or authorized agent that intends to conduct an operation or
Boarding houses (non-transient) with 16 or fewer occupants
Congregate living facilities (transient) with 10 or fewer occupants
Congregate living facilities (non-transient) with 16 or fewer occupants
Care facilities that provide accommodations for five or fewer persons receiving care
Congregate living facilities (non-transient) with 16 or fewer occupants
Building that do not contain more than four dwelling units
Care facilities for five or fewer persons receiving care that are within a single-family
dwelling are permitted to comply with the International Residential Code provided an automatic sprinkler system is
installed in accordance with Section 903.3.1.3 or Section P2904 of the International Residential Code.

R4-36-302. Appendices
The International Fire Code (2012 2018 Edition), which is incorporated by reference at R4-36-201, is modified as shown in Exhibit A.

EXHIBIT A. INCORPORATED APPENDICES
Incorporated Appendices
Section 101.2.1. The following appendices are adopted as part of this Code:
B. Fire-Flow Requirements for Buildings
C. Fire Hydrant Locations and Distribution
D102.1 or the minimum requirement of the local fire response agency
D107.1 or the minimum requirement of the local building or subdivision authority
E. Hazard Categories
F. Hazard Ranking
G. Cryogenic Fluids – Weight and Volume Equivalents
H. Hazardous Materials Management Plan (HMMP) and Hazardous Materials Inventory Statement (HMIS) Instructions
I. Fire Protection Systems – Noncompliant Conditions
J. Building Information Sign
N. Indoor Trade Shows and Exhibitions

R4-36-303. Permits
A. The following time-frames are established for permits issued under the State Fire Code:
1. The Office of the State Fire Marshal shall determine within five business days after receipt of a permit application and plan sub-
mission whether the permit application and plan are administratively complete and ready for review.
2. The Office of the State Fire Marshal shall either grant or deny the permit within 60 calendar days after the documents are deter-
dined to be administratively complete.
3. A permittee shall commence work within 180 days after the permit is issued or apply in writing for an extension from the State
Fire Marshal. Without an extension, the permit is valid only for 180 days from the date of issuance.
B. The holder of an operational or construction permit is entitled to inspections as prescribed in this Chapter. The Office of the State Fire
Marshal shall invoice a re-inspection caused by a violation or cancellation without 24-hours’ notice at a rate established in the fee
schedule and shall not conduct the re-inspection until the fee is paid.
C. Section 105.1.1 is modified to read: Permits required. Any property owner or authorized agent that intends to conduct an operation or
business, install or modify systems and equipment that are regulated by this code, or cause any such work to be done, shall first make
application to the fire code official and obtain the required permit. The fire code official is authorized to waive the require-
ment for any permit listed in sections 105.6.1 through 105.6.46 and 105.7.1 through 105.7.46.
D. Section 105.1.2 is modified to read: Types of permits. There shall be two types of permits as follows:
1. Operational permit. An operational permit allows the applicant to conduct an operation for which a permit is required by Section
105.6 for a period that does not exceed 180 days from the date of issuance.
2. Construction permit. A construction permit allows the applicant to install or modify systems and equipment for which a permit is
required by Section 105.7.
E. Section 105.2.4, the first sentence is modified to read: The fire code official shall examine or cause to be examined each application
for a permit or a permit amendment.
F. Section 105.3.1, the first sentence is modified to read: An operational permit shall remain in effect until reissued, renewed, or
revoked, or for 180 days.
G. Section 105.3.3 is modified to read: Occupancy prohibited before approval. The building or structure shall not be occupied prior to
the fire code official issuing a report indicating that applicable provisions of this code have been met.

R4-36-304. Inspections and Enforcement
A. Section 109.1 is modified to read: Board of appeals established. In order to hear and decide appeals of orders, decisions, or
other determinations made by the fire code official regarding application or interpretation of this code, the authority having jurisdic-
tion may establish a board of appeals. If established, the board of appeals shall be appointed by and hold office at the pleasure of the
governing body. The fire code official shall be an ex officio member of the board of appeals with no vote on any matter before
the board. The board of appeals shall adopt rules of procedure for conducting its business. The board of appeals shall provide a writ-
ten copy of the findings and decision in an appeal to the appellant and fire code official.
B. Section 109.1 is modified to read: Violation penalties. If a person violates a provision of this code or fails to comply with any of the
requirements of the code, the State Fire Marshal shall proceed in accordance with A.R.S. § 41-2196.
G. Section 111.2 is modified to read: Issuance. The State Fire Marshal shall issue a stop work order, referred to in statute as a cease and desist order, in accordance with A.R.S. § 41-2196.

D. Section 111.4 is modified to read: Failure to Comply. Any person who shall continue any work having been served with a stop work order, except such work as that person is directed to perform to remove a violation or unsafe condition, is subject to the provisions of A.R.S. § 41-2196.

R4-36-305. General Precautions Against FireRepealed

A. Section 307.2 is modified to read: Permit required. When required by the fire code official, a permit shall be obtained in accordance with Section 105.6 before kindling a fire for recognized silvicultural or range or wildlife management practices, prevention or control of disease or pests, or a bonfire. Application for the required permit shall only be made by and a permit issued to the owner of the land upon which the fire is to be kindled.

B. Section 311.1.1 is modified to read: Abandoned premises. Buildings, structures, and premises for which an owner cannot be identified or located by dispatch of a certificate of mailing to the last known or registered address, which persistently or repeatedly become unprotected or unsecured, which have been occupied by unauthorized persons or for illegal purposes, or which present a danger of structural collapse or fire spread to adjacent properties shall be considered abandoned, declared unsafe, and abated in accordance with state law.

R4-36-306. Emergency Planning and PreparednessRepealed

Section 401.1 is modified to read: Scope. Reporting of emergencies, coordination with the local authorized emergency response providers, emergency plans, and procedures for managing or responding to emergencies shall comply with the provisions of this Section.

R4-36-307. Fire Service FeaturesRepealed

A. Section 501.2 is modified to read: Permits. A permit shall be required as set forth in Sections 105.6 and 105.7 as modified by this Article.

B. Section 508.1.1 is modified to read: Location and access. The location and accessibility of the fire command center shall be approved by a local authorized emergency response provider.

R4-36-308. Building Services and SystemsRepealed

A. Section 606.2 is modified to read: Refrigerants. The use and purity of new, recovered, and reclaimed refrigerants shall be in accordance with state law.

B. Section 606.14 is modified to read: Notification of refrigerant discharges. The fire department shall be notified immediately when a discharge becomes reportable under state, federal, or local regulations in accordance with Section 5003.3.1.

C. Sections 5003.3.1 and 5003.3.1.1 replace “fire code official” with “fire department.”

R4-36-309. Fire Protection SystemsRepealed

Section 901.1 is modified to read: Scope. The provisions of this Chapter shall specify where fire protection systems are required and shall apply to the design, installation, inspection, operation, testing, and maintenance of all fire protection systems. Absent specific statutory authority to the contrary, these provisions provide the minimum protective standards relating to fire protection systems.
2. **Citations to the agency’s statutory rulemaking authority to include the authorizing statutes (general) and the implementing statutes (specific):**
   - Authorizing statute: A.R.S. §§ 41-1003 and 49-104
   - Implementing statute: A.R.S. § 49-761(D)

3. **The effective date of the rules:**
   January 4, 2022

4. **Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the proposed rules:**
   - Notice of Proposed Rulemaking: 27 A.A.R. 535, April 9, 2021

5. **The agency’s contact person who can answer questions about the rulemaking:**
   - Name: Terry Baer
   - Address: Arizona Department of Environmental Quality
   - Waste Programs Division
   - 1110 W. Washington St.
   - Phoenix, AZ 85007
   - Phone: (602) 771-4503, or (800) 234-5677, enter 771-4503 (Arizona only)
   - Fax: (602) 771-4272
   - Email: baer.terry@azdeq.gov

   - Name: Mark Lewandowski
   - Address: Arizona Department of Environmental Quality
   - Waste Programs Division
   - 1110 W. Washington St.
   - Phoenix, AZ 85007
   - Phone: (602) 771-2230, or (800) 234-5677, enter 771-2230 (Arizona only)
   - Fax: (602) 771-4272
   - Email: lewandowski.mark@azdeq.gov

6. **The agency’s justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:**
   **Summary.** The Arizona Department of Environmental Quality (ADEQ) has amended the state’s Biohazardous Medical Waste (BMW) rules within the Solid Waste (SW) area 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.

   **Background.** BMW is medical waste from regulated generators that is either soaked with blood or that has come into contact with infectious agents capable of transmitting disease to humans. Arizona’s BMW rules were promulgated in 1999 after more than 6 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 (GRRC). All of these changes increase the health and safety of the community without imposing undue burdens on the regulated community.

   **Background to this Notice of Final Rulemaking.** ADEQ’s rulemaking process contained significant stakeholder dialogue leading up to the formal final rule. From October 2020 to January 2021, ADEQ posted informational documents on its website and held two virtual public stakeholder meetings prior to producing a draft rule in February 2021. An additional stakeholder meeting occurred in February seeking feedback on the draft language. Stakeholders sent in comments throughout the October 2020 to February 2021 period. These meetings were well attended and answered many early stakeholder questions, particularly with regard to the potential application of any changes to their businesses. ADEQ also consulted with members of the Arizona Department of Health Services during the rulemaking process to ensure consistency.

   **Effective date of rule.** Contingent upon approval by the Governor's Regulatory Review Council (GRRC), these rules would be effective 60 days after the date they are filed with the Secretary of State.

   **Subsections not amended listed as “No change.”** ADEQ exercised the option in A.A.C. R1-1-502(B)(18)(f) to list most rule text subsections not amended by this rulemaking as “No change”, rather than showing long sections of text that were not changed. Occasionally, certain subsections of unchanged text were shown to provide context for nearby changes.

7. **A reference to any study relevant to the rules that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rules, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:**
   No such study was relied upon in this instance.

8. **A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:**
   There is no diminution of previous grants of authority under this rule.

9. **A summary of the economic, small business and consumer impact:**
   - **Identification of the rulemaking:** 18 A.A.C. 13, Article 14
Brief summary of Economic Impact Statement (EIS) rule information, by rule topic:

Transport

- Conduct & Frequency. The previous rule burden required transporters to deposit BMW at a licensed facility within 24 hours if it was unrefrigerated and did not allow carriage of multiple waste streams on the same vehicle. Nonputrescible waste was subject to the same 24-hour rule, even though it can be stored at room temperature safely for much longer.

- Estimated Change. One change included allowing 48 hours of additional unrefrigerated storage time and carrying multiple U.S. Department of Transportation (DOT)-compatible wastes on the same vehicle. 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. From the self-reported transporter data gathered by 2/24/21, the cost savings estimate ranged from $0 to $5,000, with a mean savings of $1,872.31 per month for each licensed transporter.

DOT Integration

- Conduct & Frequency. The previous burden required transporters to comply with overlapping regulations for BMW from both USDOT and ADEQ. For instance, USDOT requires a longer records-retention period than ADEQ (2 to 3 years versus 1 year). Therefore, transports expended administrative time keeping track of compliance with both timeframes.

- Estimated Change. The changes mirrored USDOT requirements in the ADEQ rules, thus eliminating the additional administrative time and confusion required to comply with two different requirements. From the self-reported transporter data gathered by 2/24/21, the time savings estimates ranged from 0 to 24 hours per month, with a mean low savings of 1.23 hours per month and a mean high savings of 6.46 hours per month.

- Cost Savings. The time savings amounted to administrative personnel cost savings. From the self-reported transporter data gathered by 2/24/21, 31% anticipated some cost savings, 15% were unsure of cost savings, and 54% did not see any cost savings in the record retention requirement. When responses were broken down by business size (1 to 3 versus 4 to 10 transport vehicles), 36.3% of the smallest transporters (1 to 3 vehicles) anticipated a cost savings, 45.5% of the smallest transporters anticipated no savings, and 18.2% of the smallest transporters were unsure of potential savings. The larger transporters (4 to 10 vehicles) reported no anticipated savings.

Registration

- 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. That provision also created frustration and confusion regarding compliance.

- Estimated Change. The requirement now requires a license for vehicles that transport BMW “at least once weekly for a month.” This revision captured those in the business of transporting BMW regularly while excluding those not intended for inclusion. This modification eliminated confusion and frustration, allowed for even and fair application of the requirements, and avoided counting the number of consecutive days, which can be an administrative burden. From the self-reported transporter data gathered by 2/24/21, 84.6% of transporters spent time tracking the operation days of vehicles, with 38.5% spending between 1 and 3 hours per month and 46.2% spending between 4 and 24 hours per month. Estimates of time expended to comply with the management and hygiene standard ranged from 15 to 30 minutes per vehicle (average of 22.5 minutes), at a rate of one to two times per week (average of 1.5 used); this weekly cleaning amount averaged 33.75 minutes per week per vehicle. For transporters with 1-3 vehicles, this amounted to 33.75 to 101.25 minutes, on average, of total cleaning time weekly. For transporters with 4 to 10 vehicles, this amounted to 135 to 337.5 minutes, on average, of total cleaning time weekly. Depending upon size, transporters spent from 60 to 1,440 minutes per month tracking (a general average of 750 minutes) versus 135 to1,350 minutes cleaning (a general average of 742.5 minutes), yielding a break-even or small time savings.

- Cost Savings. The modification in the rules ameliorated frustration and time needed to count the exact number of days a vehicle transported BMW and saved expenses involved in such tracking. From the self-reported transporter data gathered by 2/24/21, the tracking savings estimates ranged from $0 to $5,000, with a mean savings of $875.38 per month. From survey data, the chemical used to clean was typically diluted bleach or a similarly priced product. A typical 121-ounce jug of bleach ranges in price from $2.97 to $21.99 ($12.48 as a general average of these 2), depending on formulation, brand, and retailer, with the strongest concentration the CDC recommends (for bleach to water ratio) being 8 ounces of bleach to 1 gallon of water; this allows for 15.125 cleanings per 121-ounce jug of bleach, which is a material cost of around $0.83 per cleaning. Given the above data regarding time, the employee time expended was anticipated to be the same or slightly less. Given the price per cleaning and employee time factors, tracking costs likely break even with cleaning costs. However, some stakeholders who retained insurance apprised ADEQ that their insurer required cleaning after each pick up and required picture submissions and logging; typically, this resulted in trucks being cleaned one or twice per week. One stakeholder said they were “happy to clean the truck” because they got paid for it, through an insurance program called “Xactimate.” The amount of cost savings was not disclosed to ADEQ by the stakeholder, but is an additional factor in cost savings for the cleaning requirement.

Sewering

- Conduct & Frequency. Due to the Hazardous Waste (HW) Pharmaceutical rule changes (effective November 3, 2020) that prohibit disposing of such substances in sewers (sewering), non-HW pharmaceuticals were subject to different requirements than HW pharmaceuticals, which caused increased compliance costs incurred through training and sorting.
- Estimated Change. The removal of the provisions that allowed for non-HW pharmaceutical sewer ing matched EPA recommendations for non-HW pharmaceuticals and stakeholder requests for such removal. The removal also streamlined disposal and eliminated sorting and training time needed for the different types of pharmaceuticals.
- Cost Savings. The modification in the rules equated to fewer hours spent sorting and training at the generator level. Although there was not a precise measure localized to Arizona generators for non-hazardous waste pharmaceuticals available, training for the hazardous waste pharmaceuticals sewer ing ban had already been conducted as necessitated by the incorporation of the sewer ing ban into the hazardous waste rules. Therefore, no additional training is likely to be necessary and any time previously spent differentiating the types of pharmaceuticals for sewer ing purposes can be used more productively.

Mail-back Records Retention
- Conduct & Frequency. The previous rules did not provide clear records retention requirements for mail-back sharps and created confusion and concern about compliance.
- Estimated Change. The change clarified that the requirement is to retain documentation that is already required under United States Postal Service mailing guidelines. There is no increase in burden other than filing.
- Cost Savings. This change minimizes discussions about basic compliance requirements during inspections and maximizes efficiency. There are no cost savings, nor any added cost.

2. Identification of persons who will be directly affected by, bear the costs of, or directly benefit from the rules:

Parties Affected:
- Arizona Department of Environmental Quality (ADEQ)
- County agencies acting as regulatory authorities
- Exempt businesses
- Licensed BMW Transporters
- BMW Generators
- Small businesses regulated
- Community members living near transporter’s places of business (residential areas)

3. Cost/Benefit Analysis:
   a. Part I - Cost/Benefit Stakeholder Matrix

<table>
<thead>
<tr>
<th>Description of Affected Groups</th>
<th>Description of Effect</th>
<th>Increased Cost/Decreased Revenue</th>
<th>Decreased Cost/Increased Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. State and Local Government Agencies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADEQ</td>
<td>Clarity of the new rule</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>County agencies acting as regulatory authorities</td>
<td>Clarity of the new rule</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>B. Privately Owned Businesses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exempt businesses</td>
<td>Clarity of the new rule</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Licensed BMW transporters</td>
<td>Clarity of the new rule</td>
<td>Minimal to Moderate</td>
<td>Minimal to Moderate</td>
</tr>
</tbody>
</table>
b. **Part II - Individual Stakeholder Summaries/Calculations**

**ADEQ**
1. Staffing levels will not change. No new employees need to be hired or laid off. Current staff will update their inspection procedures to meet the new rules. Minimal time is needed for these small updates.
2. Cash flow will not change as a result of the rules. There will be no delay in receipts or increase in expenses. There are no fee increases or decreases impacting ADEQ.
3. Barriers to industry entry will not be affected; this is an existing regulatory program so there are no startup costs for ADEQ. Business start-up costs already in existence for the regulated community will remain the same, and no additional burden is created on ADEQ for processing.

**County agencies acting as regulatory authorities**
1. Staffing levels will not change. No new employees need to be hired or laid off. Current staff will update their inspection procedures to meet the new rules. Minimal time is needed for these small updates.
2. Cash flow will not change as a result of the rules. There will be no delay in receipts or increase in expenses. There are no fee increases or decreases impacting the agency either way.
3. Barriers to industry entry will not be affected; this is an existing regulatory program so there are no startup costs for county agencies. Business start-up costs already in existence for the regulated community will remain the same, thus no additional burden is created on county agencies for processing.

**Exempt businesses**
1. Staffing levels of both small and large businesses exempt from the provisions in these rules will not change, as they are not affected. In this rulemaking, there are no additional obligations or costs for those who are exempt, nor should there be any staffing changes as a result of these rules.
2. Cash flow for exempt businesses will not be impacted, as there are no changes to these rules for exempt businesses. There would be no expected delay in receipts or increased expenses as a result of this rulemaking for businesses exempt from these rules.
3. Barriers to industry entry would not be increased for businesses exempt from these rules, as there is no change that affects those businesses under these rules. Start-up costs for exempt businesses would not change based on this rulemaking.

**Licensed BMW Transporters**
1. Staffing levels could vary slightly for larger businesses but are not expected to change for small businesses. The only potential increase in staffing could come from cleaning requirements. This increase would not have an impact on those small businesses with fewer vehicles as the time required to clean appears not to require additional staff. Larger transporters who do not now comply but begin complying will need to budget some additional time, although it is unlikely there will be a need to hire people for this task. It is unlikely anyone will need to be laid off.
2. Cash flow change could occur if a transporter adds a vehicle via License Modification due to the update in R18-13-1409(J). A vehicle is required to be included on a license if used at least once each week for a month under the amended rule as opposed to...
the previous requirement for licensing occurring after 30 consecutive days of use. Small transporters in particular commented that they wished to see such a modification in order to level the playing field competitively. Those with additional vehicles used for transport will need to comply with proper licensing and cleaning protocols, which will allow smaller transporters with properly licensed vehicles and cleaning procedures to compete. The additional cost that could be incurred for these vehicles will vary according to R18-13-1409(D), with a license modification application fee of $100 and fees up to $5,000 based upon a formula in the rule that considers the number of vehicles and the actual hours spent by ADEQ. There should be no delay in receipts, however.

3. Barriers to industry entry should not change with these rule updates, and no additional business start-up costs will be imposed. No new fees are being added, and current fees are not being increased.

**BMW Generators**

1. Staffing levels will likely not be impacted for generators of various sizes under these rules. It is unlikely there would be a need for either additional employees or a reduction in employees, as responsibilities are largely remaining the same.

2. Cash flow is unlikely to be altered for generators of all sizes under these rules. Nothing in these rules should delay receipts or increase expenses. The practices in place for these generators will remain largely the same.

3. Barriers to industry entry will not increase. The requirements are largely the same under this rulemaking as under the previous rules for generators, so no increase in start-up costs is anticipated due to these rules.

**Small businesses regulated**

1. Staffing levels for small businesses regulated under these rules will be largely the same both before and after the updated rules go into effect. As examined in the previous industry-specific sections, it is unlikely small businesses will need to hire or lay off staff due to this rulemaking.

2. Cash flow for small businesses regulated under these rules should not delay receipts or increase expenses. Although some requirements, such as cleaning, will take a small amount of additional staff time, other requirements, such as increase in storage times, should result in less staff time expended. The net effect would be no change.

3. Barriers to industry entry are unlikely to increase under these rules. Regardless of business size, no additional start-up costs are imposed on businesses in this rulemaking.

4. **Probable Impact on Employment:** There is likely no impact on employment, as noted in the above sections with industry-specific discussions. There is the potential for increased hours or hiring should a stakeholder decide to expand their business to address additional COVID-19 waste. There will be no change to state employment as a result of this rule.

5. **Probable Impact on Small Businesses:** A.R.S. § 41-1035 requires agencies to consider reducing the rule’s impact on small businesses. ADEQ has considered the feasibility of A.R.S. § 41-1035 methods (1)-(5) along with ADEQ’s statutory mandate and has weighed the benefits of each against the need to protect human health and the environment. ADEQ is already allowing the regulated community to use the least stringent requirements necessary to maintain the appropriate levels of human safety and environmental protection. Due to the statutory mandate, the nature of these regulations, and the potential impact to the community if businesses generating or transporting BMW are not regulated, it is not possible to exempt small businesses from these requirements. However, ADEQ has employed less stringent standards when doing so would not compromise human health and safety, such as increasing putrescible waste non-refrigeration time frames up to 72 hours. This extension allows small businesses more time to gather waste and deposit the waste in an appropriate facility, thus reducing trips and associated costs. ADEQ has also simplified record-keeping requirements to align with federal requirements so there is a unified retention schedule and documentation required. These simplified requirements should reduce training time and administrative burden.

a. Identification of Small Businesses subject to the rules: Directly affected small businesses include transporters and generators of BMW, like dentists, doctors, and veterinarians. Sharps provisions apply to tattoo shops. Individuals in their own homes will not be affected by these regulations.

b. Compliance Costs: Additional administrative costs required for compliance with the rules are not necessary, as no provision is anticipated to increase personnel hours or outside expenses. Additional compliance costs are likely to be minor, such as the time to clean vehicles, mentioned above; since many are already providing this cleaning to comply with insurance policies, little change is anticipated, if any. Since rule provisions have been redrafted for clarity, these rules should be easier to follow than in their previous form, particularly when it comes to the licensing requirements, which have not changed. It is not anticipated that counsel will be required, although all parties are encouraged to consult with an attorney if they wish.

c. Methods to Reduce Impact: In the beginning of the “Probable Impact on Small Businesses” section, ADEQ elaborates on its work to reduce the impact on small businesses. The rules have the least burden on business while accomplishing the regulatory objective provided in statute. ADEQ’s robust stakeholder process has allowed for unique insights into the challenges and opinions of our business community. These insights have demonstrated opportunities where ADEQ could lessen regulations while remaining appropriately protective of human health and environment. This effort also highlighted areas where the small business owners felt strongly that regulations were necessary. ADEQ thanks its stakeholders for their collaboration and honesty.

d. Cost/Benefit Analysis to Private Persons: ADEQ is conscious of the variation in business sizes and interests involved in this rulemaking and has worked to build consensus among stakeholders such that the rules provide a balanced benefit to all. ADEQ believes the rules may increase costs minimally, while decreasing costs elsewhere. The regulations are appropriately protective of human health and the environment while allowing for discretion. This will advance the goal of keeping Arizona an enjoyable place to live and work. Please see the above sections for additional details on costs. Various business sizes are analyzed above, as well as farther up in the EIS where impacts from specific changes are discussed.

6. **Effect on Revenues to State Agencies.** There will be no additional or reduced costs to ADEQ or other state agencies, nor will there be any change in state tax revenues, resulting from changes to these rules. No fee changes and no increase in business costs or decrease in business revenues are expected; therefore, no reduction in business activity that could lower state tax revenues should result from these rule changes. However, should the volume of transporters increase proportionate to COVID-19 waste volumes, the state would expect increased tax revenues due to increased business activity. In that scenario, businesses would also be increasing revenues and, incrementally, costs as they expand. However, these changes are not due to rule changes, but supply and demand in the market.
7. **Less Intrusive/Costly Alternatives:** ADEQ has examined as many potentially less intrusive or less costly alternatives as possible, but concludes most of these measures are untenable due to unique Arizona factors. For example, increasing unrefrigerated storage time frames for putrescible waste beyond 72 hours is not recommended in Arizona despite being utilized in other states, primarily because recommendations for safety indicate that the Arizona heat, especially in the summer months, could speed up decomposition of the putrescible waste more rapidly, thus creating potential disease vectors or nuisance odors. Additionally, the fee structure has been examined for available reduction; however, the current fees are as low as possible to account for program operational costs. The fees have been in place since 2012 without increase, despite increasing staff wages. These fees were also developed with extensive stakeholder feedback. So, while ADEQ is not able to lower fees, ADEQ also will not increase fees. Thus, the burden on stakeholders will not increase. ADEQ has allowed maximum flexibility for storage times for non-putrescible waste (90 days), in order to allow transporters and generators to make the determinations for wastes that take refrigeration space versus those that may be safely stored elsewhere. ADEQ is balancing the least intrusive and most cost-effective approach with the need to protect the public and environment from potential disease vectors.

8. **Data Basis:** Searches on Lexis were conducted to compare various states’ medical waste rules for comparison, including storage timeframes. State regulations from that database were used for comparison and modeling. All relevant information was summarized for stakeholders and opened for discussion prior to rule drafting, so all rules incorporate the stakeholder-preferred provisions and language. Data for impact on stakeholders was gathered via a simple anonymous online survey of transporters, wherein the link was available prior to and during the final stakeholder meeting. Participants were assured their data would be anonymous. Additional data was collected from transporters as to cleaning costs through program staff outreach to better understand current industry practices. This data comes directly from stakeholder responses targeted to specific areas and captures a small amount of their daily practices in an anonymous way so that trade secrets are not publicly shared. ADEQ thanks our stakeholders for their participation, feedback, and involvement in this rulemaking.

10. **A description of any changes between the proposed rulemaking, including supplemental notices, and the final rulemaking:**

The proper Code of Federal Regulations (CFR) effective date and the corrected citation for 49 CFR 177.848 (instead of 49 CFR 176.83(b)) were omitted in the proposed rule and have been inserted into the final rule. This insertion does not change the impact of the rules and was done for administrative reasons. Additionally, stakeholder comments indicated areas where the rule conflicted with federal regulations. ADEQ addressed these conflicts through removal of contradictory language regarding a “controlled substance” being regulated under these rules, appropriate cap security for medical sharps containers (“securely closed” instead of “locking”), and elimination of the phrase “transportation management plan” when used in a manner that was inaccurate. Further, ADEQ was able to remove a redundant sentence, thanks to stakeholder input. A previous addition to the definition of biohazardous medical waste in R18-13-1401(4) that required an interpretation of what was “sufficient virulence” was removed in favor of relying on specific examples of biohazardous medical waste. A clarification was made to the medical sharp section R18-13-1419 that states sharp-less syringes are not biohazardous medical waste if they are not composed of items listed in the biohazardous medical waste definition. Finally, ADEQ clarified that only biohazardous medical waste is regulated under these rules, so biohazardous medical items that were not yet waste would not be covered by these regulations.

11. **Agency’s summary of the public or stakeholder comments or objections made about the rulemaking and the agency response to the comments:**

ADEQ thanks all commenters for their input. Although ADEQ in the rulemaking process is unable to address criticisms regarding how enforcement is carried out, these concerns have been shared with the appropriate staff. Additionally, ADEQ heard stakeholder concerns about landfill non-acceptance of certain wastes. ADEQ cannot require landfills to accept specific wastes; waste acceptance decisions are made at the discretion of the landfill operator. No comments were received on the following rules: R18-13-1403, R18-13-1404, R18-13-1413, R18-13-1414, R18-13-1415, R18-13-1417, R18-13-1419, R18-13-1419, R18-13-1420.

<table>
<thead>
<tr>
<th>Rule</th>
<th>Comments</th>
<th>Agency Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>R18-13-1401(3)</td>
<td>Stericycle: The description of autoclaving is incorrect. Autoclaving is a process that relies on steam at high temperature and pressure to kill pathogens and render materials non-infectious. Autoclaving is not intended to achieve sterile conditions, nor are sterile conditions required for disposal of BMW.</td>
<td>The definition of “sterile” in Merriam-Webster includes “failing to bear or incapable of producing fruit or spores... [or] off-spring...” Killing pathogens and avoiding pathogen reproductivity is consistent with the intent. Merriam-Webster defines “autoclave (verb)” as “to treat in an autoclave. Autoclave (noun) is defined as “especially: an apparatus (as for sterilizing) using steam under high pressure.” The current definition for “autoclave” in the rules is consistent with the dictionary meanings of these words.</td>
</tr>
<tr>
<td>R18-13-1401(4)(c)</td>
<td>Stericycle: Cerebrospinal, synovial, pleural, peritoneal, pericardial and amniotic fluid are not typically characterized as pathological wastes. To maximize protection of human health and the environment, ADEQ should also require that such human pathological wastes be incinerated. Human pathological wastes pose unique challenges compared to other BMW. For instance, autoclave treatment does not usually change the physical appearance of most pathological wastes, which often raises concerns with landfills. In addition, some generators of pathological wastes keep the material frozen or at very low temperatures, which can affect applicable treatment standards / methods. For these and other reasons, many states currently require that pathological waste be segregated from other BMW and treated by incineration. This is also a practice followed by Stericycle’s customers per the company’s waste acceptance policy.</td>
<td>ADEQ shared several state definitions with stakeholders for pathological wastes and feedback was received. Among them was South Carolina’s definition that includes the mentioned “body fluids”, which “may be infectious due to bloodborne pathogens.” A stakeholder provided the following information during one of the stakeholder meetings: “OSHA from BBP Standard: Regulated Waste means liquid or semi-liquid blood or other potentially infectious materials … and pathological and microbiological wastes containing blood or other potentially infectious materials.” Another stakeholder provided: “pathological means disease-related”. A third stated, “any and all bodily fluids and substances are [are] Biohazardous”. In light of the comments received by our stakeholders, ADEQ integrated fluids into the pathological waste definition. The rules do not specify the method of destruction in order to allow for flexibility. There is nothing in these rules that prevents compliance with other regulations or company policies.</td>
</tr>
</tbody>
</table>
R18-13-1401(14)(1)

Stericycle: The proposed definition is too broad. Tattoo parlors and ear piercing operations likely generate multiple waste streams, but only those that contain human blood or blood products should be regulated as BMW. Similarly, “waste generated during the course of physically altering a human being … where a foreign object is used to cut or pierce the skin…” is too broad, and unnecessarily captures activities that are already covered by other sections of the BMW definition. For clarity, Stericycle recommends limiting the definition to tattoo and ear piercing-related wastes that contain human blood.

R18-13-1401(18)

Stericycle: The regulations at 49 CFR Part 176 govern the carriage of hazardous materials by vessel and are inapplicable to motor vehicle transportation.

R18-13-1401(11)

Sharps Compliance: "Discarded drug": The definition is confusing as in the initial sentence you state that controlled substances are included as a "discarded drug", then in the second sentence you state that controlled substances regulated by the DEA are exempt. Additionally, you exclude “hazardous waste” however this definition is specific to discarded drugs so should say “hazardous waste pharmaceuticals”.

R18-13-1401(18)

Sharps Compliance: "Medical sharps container": this definition is too general, and given the definitions are for regulated entities, we feel a more specific definition is required.

R18-13-1401(18)

Stericycle: USDOT requires that a sharps container be:
- "securely closed"
- "registered under the Medical Device Regulations of FDA"
- "made of puncture resistant plastic" See 49 C.F.R. §173.134

Similarly, OSHA requires that a sharps container be "puncture resistant" "leakproof" and "closed." See 29 C.F.R. § 1910.1030.

A “locking cap” is not required by USDOT. OSHA or any other state where Stericycle currently operates. Stericycle operates nationwide, and its ability to efficiently serve its customers is compromised if it is required to design and use a specific sharps container only for customers in Arizona.

In addition, requiring a “locking cap” is contrary to ADEQ’s stated goal of protecting human health. For example, OSHA requires that sharps containers be “easily accessible to personnel.” See 29 C.F.R. § 1910.1030(d)(4)(ii)(A)(2)(i). A locking cap can render a sharps container difficult to access, which is inconsistent with OSHA’s standard and may cause additional sharps-related injuries for generators.

State and local regulations concerning the transportation of hazardous materials must be “substantively the same” as the USDOT requirements. The “locking cap” rule does not meet that standard and is unduly burdensome.
For clarity, this language [in R18-13-1402(B)] should be removed from ADEQ’s BMW regulations. First, it is inaccurate. Several provisions within the BMW regulations do impose requirements on how a generator is to collect and handle BMW. See, e.g., R18-13-1406(A), R18-13-1408 and R18-13-1419. Second, to maximize protection of human health and the environment, it is important that all parties involved with handling BMW (including generators, transporters, treaters and disposers) are familiar with and follow applicable requirements related to proper classification, separation, labeling and storage. A generator that does not follow ADEQ’s regulations puts both its and Stericycle’s employees at risk.

The reference is nonsensical. The regulations at 49 C.F.R. § 172.200 – 172.205 contain the requirements for shipping papers (or “tracking documents”). The regulations at 49 C.F.R §§ 172.300 – 172.338 relate to marking requirements. The shipping papers do not cross-reference or otherwise incorporate the marking requirements. As such, under USDOT regulations, a tracking document prepared per 49 CFR 172.201 would not contain an identification number specified by 172.300. State and local regulations concerning the transportation of hazardous materials must be “substantively the same” as the USDOT requirements. The proposed identification number rule does not meet that standard.

For consistency and clarity, the tracking document should refer to the packaged waste in some manner to allow for identification. Under 49 CFR §172.201(a)(4), the regulations provide permissive authority to include additional information: “A shipping paper may contain additional information concerning the material provided the information is not inconsistent with the required description. Unless otherwise permitted or required by this subpart, additional information must be placed after the basic description required by § 172.202(a).” Additionally, it is required under 49 CFR §172.300(b) that packaging be appropriately marked: “When assigned the function by this subpart, each carrier that transports a hazardous material shall mark each package, freight container, and transport vehicle containing the hazardous material in the manner required by this subpart.” ADEQ is linking this information in order to provide quicker comprehension for those reviewing shipping papers while also complying with USDOT regulations.

R18-13-1407

Kenneth Bauer

This is focused on non-sharps packaging. What about waste that contains sharps containers? Not loose sharps but containerized ones that are generally processed with the waste and sealed in red bags?

Medical sharps are addressed directly in R18-13-1419 rather than in R18-13-1407.

R18-13-1408

Sharps Compliance

Most RMW generators, except for large generators, do not have the ability to refrigerate their waste. A 72-hour limit for storage places an undue burden and expense on small to medium waste generators to have to get rid of their waste basically immediately upon full. This would be one of the strictest storage time limits of all 50 states. The majority have 30-day limit.

The previous rule included a 7-day accumulation limit for both putrescible and nonputrescible waste. However, putrescible waste was subject to refrigeration at any point if it would “create a nuisance.” ADEQ sought to clarify expectations for this vague provision on putrescible waste refrigeration by creating clear timelines for refrigeration (72 hours). The International Committee of the Red Cross recommends unrefrigerated storage for putrescible waste for up to 72 hours and refrigerated storage at 37-46 degrees Fahrenheit for up to one week for putrescible waste, depending on ambient temperatures. Due to Arizona’s high temperatures, longer limits may be unsafe for putrescible waste due to the more rapid decomposition and creation of dangerous conditions.

The revised regulations make compliance simpler for non-putrescible waste since the potential for harm while unrefrigerated is much less. These revised regulations clarify that non-putrescible waste may be kept unrefrigerated for up to 90 days, an increase of 83 days from the previous 7-day maximum.

Although some states, such as Florida, may allow for 30 days of storage, during that time the biohazardous medical waste must be kept in a “sanitary condition”. Dictionary definitions of “sanitary” indicate the meaning is synonymous with “aseptic, germ-free, hygienic, sterile.” In this sense, ADEQ has clarified something that Florida left vague: guidelines for proper sanitation for putrescible waste. ADEQ’s rules allow a timeline triple that of Florida (90 days) for nonputrescible waste, while providing appropriate clarity for storage of putrescible waste (as indicated above). Texas, for instance, requires that such wastes are “not to create nuisances” and indicates the facility should “Maintain at a temperature of 45 degrees Fahrenheit or less any putrescible or untreated medical waste stored for longer than 72 hours after collection”.

Utah allows up to 7 days unrefrigerated for infectious waste, with a maximum on-site storage of 60 days. Comparisons of the most populous areas in Utah and Arizona indicate that Arizona is, on average, at least 12 degrees warmer than Utah, with an average of 2.5 hours per day more sunlight. In these conditions, it is reasonable to estimate that putrescible waste will decay faster in Arizona, thus making the 7-day period of Utah too long to be appropriate.

R18-13-1412(A)(2)(a) directly addresses permitted treatment facilities and storage times. This requirement has not been changed.

Just clarifying. Since the portion for the processor always referenced this section for storage requirements, does this mean that processors now have 90 days to process materials also?

ADEQ understands that the provision could cause confusion and has provided qualification to clarify that an item must first become waste before it is subject to the biohazardous medical waste regulations. Prior to becoming waste, such an item is not considered a biohazardous medical waste under these rules.

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Kenneth Bauer: If these changes go into effect, everyone will have to update their plans. Will that require everyone to pay for an amendment? The changes in R18-13-1409 are a reorganization of current provisions to improve clarity. Additional changes were meant to add flexibility (such as allowing electronic submittal and explicitly allowing for the use of trailers). The expansion from 24 hours to 72 hours aims to provide small businesses additional time and reduce unnecessary burden. ADEQ is aware that some updates may be needed where changes have been made to the “30 consecutive days” rule. However, these changes will only affect those who were exploiting the provisions in a manner not intended by the rules in order to avoid compliance. An amendment to address such changes will cost $100 for the application to add these vehicles onto the license. ADEQ has received no other comments that licenses or facility plans may need to be updated, so it appears that only a small number of stakeholders may need to pay for an amendment.

Stericycle: The requirement to submit a transportation management plan in a “department-approved format” should be removed. Stericycle is already required to prepare a transportation management plan per USDOT regulations. The obligation to prepare a similar but separate plan for ADEQ is duplicative and unnecessary. State and local regulations concerning the transportation of hazardous materials must be “substantively the same” as the USDOT requirements. The transportation management plan requirement does not meet that standard. Subsection (G) states that the transporter must have a transportation management plan, but leaves the requirements open such that a transporter may easily comply with both ADEQ and USDOT regulations using the same document. The commenter misstates the requirement regarding “department-approved format.” The term “department-approved format” does not appear in regard to transportation management plans. The phrase “department-approved format” appears only in regard to a transporter license, in R18-13-1409(B). While an application for a transporter license is required to be submitted in a “department-approved format” in (B)(1), there is no similar requirement for a transportation management plan.

In reviewing the document for transportation management plan information, ADEQ noted a few areas that needed to be clarified. First, 1409(D) has been corrected to clarify that adding vehicles to the license via amendment will incur a fee, rather than adding a transportation management plan. Second, ADEQ noticed the redundancy in R18-13-1409(G)(1) and (2), given that both components (1) and (2) are already accounted for in the definition of “transportation management plan” at R18-13-1401(33). Therefore, ADEQ eliminated (1) and (2) from 1409(G) to remove the redundancy.

Stericycle: The requirement to submit all transportation vehicles for inspection by ADEQ should be removed. Stericycle is already required to submit its vehicles for annual inspection by USDOT. See 49 C.F.R. Part 396. The obligation to undergo a similar but separate inspection by ADEQ is duplicative and unnecessary. State and local regulations concerning the transportation of hazardous materials must be “substantively the same” as the USDOT requirements. The inspection requirement does not meet that standard. Under 49 CFR Part 396, the Federal Motor Carrier Safety Administration (FMCSA) has clarified in guidance on §396.17 (Periodic inspection) that: “If the State requires all vehicles registered in the State to be inspected through its mandatory program, then the motor carrier must use the State program to satisfy the Federal requirements.” Under 49 CFR §396.3 (Inspection, repair, and maintenance), there is no specified inspection interval “because such intervals are fleet specific and, in some instances, vehicle specific” and “[t]he requirements of §396.11, 396.13, and §396.17 are in addition to the systematic inspection, repair, and maintenance required by §396.3.” FMCSA language clarifies that state inspections are allowed and, if state inspections are mandated, the transporter “must use the State program to satisfy the Federal requirements.” Therefore, it is evident that USDOT did not preempt state inspections, and in fact contemplated them as the appropriate means to meet federal requirements.

ADEQ also notes that the purpose of the respective USDOT regulations and ADEQ regulations differ, so state inspections may account for this to ensure compliance with ADEQ rules.

Stericycle: A transporter is not prohibited from delivering BMW to a medical waste storage, transfer, treatment or disposal facility located outside of Arizona, in which case such facility would not be “Department-approved.” ADEQ has no authority to regulate or otherwise approve facilities that are not located in Arizona.

ADEQ explicitly provides in R18-13-1402(C): “Provisions in this Article requiring placement in Department-approved facilities do not restrict the right to place materials in facilities that are out of state or in Indian Country.” ADEQ does not purport to regulate or approve facilities located outside of Arizona, nor does ADEQ prohibit delivering BMW to an out of state facility. Rather, ADEQ regulates in-state facilities by requiring they be approved by the department.

Stericycle: Stericycle is a transporter of BMW in Arizona and operates transfer facilities in Arizona. To clarify, Stericycle requests that the Proposed Rule be revised to indicate that a storage or transfer facility operator need not sign the tracking document if that operator is also the transporter. To indicate the appropriate custodial record and responsibility for the waste, ADEQ requires that each party accepting the waste indicate their acceptance by signing. If ADEQ were to make an exception, the records could appear incomplete such that there is not appropriate documentation of the acceptance of waste by the treating facility. Although Stericycle contends that its role as both transporter and operator indicates the need for only one signature on behalf of Stericycle, this proposal does not provide for a complete record. Under the commenter’s proposed circumstance, the individual transporter signing on behalf of Stericycle and the individual operator signing on behalf of Stericycle would not both sign, therefore the record would only show transmittal to the transporter with no indication of receipt at the operating facility. Both signatures attesting to acceptance by the transporter and acceptance at the facility are necessary to show appropriate waste chain of custody.
### R18-13-1411(B)(8)

The requirement to clean storage areas daily is unduly burdensome and should be removed. Other requirements throughout the BMW regulations, including the obligation to use containers that are leakproof, help ensure that spills are rare. In the absence of a spill, the cleaning procedures described in the Proposed Rule, including applying disinfectant and removing visible particles, are unnecessary. Such extreme cleaning procedures are only appropriate in the event of a spill. Reasonable housekeeping practices as necessary to protect the public health and employee health and safety should otherwise be sufficient for a BMW storage area.

### R18-13-1412(A)(1)(e)

Stericycle: An autoclave may have many potential applications and an autoclave manufacturer is not typically aware of, and does not have the design or build according to, particular treatment standards. Operators perform efficacy testing and are often in a better position than manufacturers to certify that the equipment can meet the required treatment standards. The regulations should therefore offer the option for operators to test that the equipment can achieve the treatment standards.

As discussed above, an autoclave may have many potential applications and an autoclave manufacturer may not have specifications that are relevant to BMW treatment operations. The text should therefore be revised to clarify that only applicable manufacturer specifications need be consulted.

### R18-13-1412(B)(10)

Kenneth Bauer: You have changed the verbage from red bag to container. The way it is worded would mean that we would have to take our reusable barrels and put them in the autoclave. That might be a tad expensive. Please identify what containers you mean. What is the purpose of the change from Red Bag to container?

### R18-13-1418

**Sharps Compliance:**

We believe there needs to be a stronger statement about medication disposal that should not include on-site destruction given the dangers improperly disposed medications pose to both humans and the environment. As of August 2019, hazardous waste pharmaceuticals can no longer be flushed. As of 2014, DEA has stated that flushing controlled substances does not meet their non-retrieval requirement. Drug degradation/decomposition products utilizing carbon or charcoal-based formulas (typically pouches or bottles) cannot be placed into the trash by RMW generators. Use of drug degradation products increase medication disposal costs since generators pay for both the products themselves as well as hazardous waste pickup fees, since the resulting concoction of medications cannot be profiled as non-hazardous. The degradation pouches have not been proven to meet the DEA’s non-retrievable standard. The environmental dangers posed by the improper disposal of any medication, not just hazardous or controlled medications, have been well-documented and give further cause to ensure all medications are disposed of in a regulated manner.

### R18-13-1418

Stericycle: ADEQ specifies “according to the manufacturer’s specifications for the unit” in order to ensure uniformity and conformity with appropriately tested uses for autoclaves. Although an operator may certainly have more specified knowledge in their field than a manufacturer of an autoclave, the manufacturer has conducted strict testing to ensure the device complies with appropriate safety standards, as set by the FDA or other appropriate governmental entities. It is ADEQ’s goal to avoid risks to the public health, which necessarily involves ensuring that autoclaves are not operated in a way inappropriate to their specifications so as to avoid explosions and dispersion of infectious materials.

### R18-13-1418

Stakeholders pointed out in ADEQ’s stakeholder meetings that red bags are not the only type of container that may be utilized, and therefore the word “container” seeks to be more inclusive of RMW storage. ADEQ states that they are not operated in a way inappropriate to their specifications so as to avoid explosions and dispersion of infectious materials.

<table>
<thead>
<tr>
<th>12. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:</strong></td>
</tr>
<tr>
<td>A.R.S. § 41-1037(A)(3), “The issuance of a general permit is not technically feasible or would not meet the applicable statutory requirements,” applies in this case. This rulemaking amends two existing rules that require a license or permit, R18-13-1409 and 1410. ADEQ cannot use a general permit in R18-13-1409 because transporters meet the requirements for licensing through criteria and information specific to their vehicles. Therefore, individual processing is required in order to issue licenses and conduct inspections. The transporters pay fees according to that processing, capped at a maximum fee. The vehicle-dependent nature of this license makes it impossible to use a general permit. Regarding the R18-13-1410 license, A.R.S. §49-762(A)(3) requires individual solid waste facility plans for medical waste facilities. Therefore, it is not possible to utilize a general permit for a license under R18-13-1410 either.</td>
</tr>
<tr>
<td><strong>b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal:</strong></td>
</tr>
<tr>
<td>The rules do not specify the method of destruction in order to allow for flexibility.</td>
</tr>
</tbody>
</table>
There are no federal laws that are applicable specifically to biohazardous medical waste, therefore the rule is not more stringent than federal law. A.R.S § 49-761(D) provides authorization for ADEQ to “regulate biohazardous medical waste and medical sharps” and ADEQ has considered specific areas where United States Department of Transportation (USDOT) rules may intersect with ADEQ regulations and harmonized as much as possible.

c. Whether a person submitted an analysis to the agency regarding the rule’s impact on the competitiveness of businesses in this state as compared to the competitiveness of businesses in other states:
No person has submitted a competitiveness analysis under A.R.S. § 41-1055(I).

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rule:

<table>
<thead>
<tr>
<th>Incorporated Federal Citation</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>49 CFR 177.848</td>
<td>R18-13-1401(9)</td>
</tr>
<tr>
<td>49 CFR 172.201</td>
<td>R18-13-1406(B); R18-13-1409(K)</td>
</tr>
<tr>
<td>49 CFR 172.300-172.338</td>
<td>R18-13-1406(B)(3)</td>
</tr>
</tbody>
</table>

14. Whether the rule was previously made, amended, or repealed as an emergency rule. If so, cite the notice published in the Register as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:
The rule was not previously made, amended, or repealed as an emergency rule.

15. The full text of the rules follows:

**TITLE 18. ENVIRONMENTAL QUALITY**

**CHAPTER 13. DEPARTMENT OF ENVIRONMENTAL QUALITY**

**SOLID WASTE MANAGEMENT**

**ARTICLE 14. BIOHAZARDOUS MEDICAL WASTE AND DISCARDED DRUGS**

Section
R18-13-1401. Definitions
R18-13-1402. Applicability
R18-13-1403. Exemptions; Partial Exemptions
R18-13-1404. Transition and Compliance Dates Repealed
R18-13-1406. Biohazardous Medical Waste Transported Off Site for Treatment
R18-13-1407. Packaging
R18-13-1408. Storage
R18-13-1409. Transportation; Transpoter License; Annual Fee
R18-13-1411. Storage and Transfer Facilities; Design and Operation
R18-13-1412. Treatment Facilities; Design and Operation
R18-13-1413. Changes to Approved Medical Waste Facility Plans
R18-13-1415. Treatment Standards, Quantification of Microbial Inactivation and Efficacy Testing Protocols
R18-13-1418. Discarded Drugs
R18-13-1419. Medical Sharps
R18-13-1420. Additional Handling Requirements for Certain Wastes

**ARTICLE 14. BIOHAZARDOUS MEDICAL WASTE AND DISCARDED DRUGS**

R18-13-1401. Definitions
In addition to the definitions in A.R.S. § 49-701, the following definitions apply in this Article:

1. “Administrative consent order” means a bilateral agreement between the consenting party and the Department. A bilateral agreement is not subject to administrative appeal.

2. “Alternative treatment technology” means a treatment method other than autoclaving or incineration that achieves the treatment standards described in R18-13-1415.

3. “Approved medical waste facility plan” means the document that has been approved by the Department under A.R.S. § 49-762.04, and that authorizes the operator to accept biohazardous medical waste at its solid waste facility.

4. “Autoclaving,” means using a combination of heat, steam, pressure, and time to achieve sterile conditions.

5. “Biohazardous medical waste” is composed of one or more of the following:

   a. Cultures and stocks: Discarded cultures and stocks generated in the diagnosis, treatment or immunization of a human being or animal or in any research relating to that diagnosis, treatment or immunization, or in the production or testing of biologicals.

   b. Human blood and blood products: Discarded products and materials containing free-flowing blood or free-flowing blood components that are saturated and/or dripping with human blood or caked with dried human blood, including items that would release blood in a liquid or semi-liquid form if compressed or broken, and items that contain serum, plasma, and other blood components. An item would be considered caked if it could release flakes or particles when handled.
c. Human pathological wastes: Discarded organs, tissues, and body parts, including cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid and amniotic fluid, removed during surgery, or other medical procedures, including autopsies, obstetrics, or emergency care. Human pathological wastes do not include the head, or spinal column, hair, nails, or teeth.

d. Medical sharps: Discarded sharps that pose a stick hazard that have come into contact with blood, blood products, or pathological waste, used in animal or human patient care, medical research, or clinical laboratories. Examples include: This includes hypodermic needles; syringes; pipettes; scalpels; blood vials; and needles attached to tubing or syringes, broken and unbroken glassware; and slides and coverslips.

e. Research animal wastes: Animal carcasses, body parts, and bedding of animals that have been infected with agents that produce, or may produce, human infection.

f. Tattoo and body modification waste: any waste generated during the course of physically altering a human being, including tattooing, ear piercing, or any other process where a foreign object is used to cut or pierce the skin.

g. Trauma scene waste: any crime scene, accident, or trauma clean-up wastes generated by individuals or commercial entities hired to clean crime scenes or accidents, such as sharps and materials that contain human blood and blood products.

h. “Biologicals” means preparations made from living organisms or their products, including vaccines, cultures, or other biological products intended for use in diagnosing, immunizing, or treating humans or animals or in research pertaining to these activities.

i. “Biological indicator” means a representative microorganism used to evaluate treatment efficacy.

j. “Blood and blood products” means discarded human blood and any product derived from human blood, including but not limited to blood plasma, platelets, red or white blood corpuscles, and other derived products.


l. “Chemotherapy waste” means any discarded material that has come in contact with an agent that kills or prevents the reproduction of malignant cells.

m. Trace contaminated chemotherapy waste includes: masks, empty drug vials, gloves, gowns, IV tubing, empty IV bags/bottles, and spill clean-up materials.

n. Bulk chemotherapy waste, such as full expired vials of chemotherapy drugs, is not hazardous medical waste. Bulk chemotherapy waste may be considered hazardous wastes and must be handled according to the hazardous waste regulations if deemed a hazardous waste by the generator.

o. “Dedicated vehicle” means a motor vehicle or trailer that is pulled by a motor vehicle used by a transporter for the sole purpose of transporting biohazardous medical waste, in conjunction with other compatible waste according to the USDOT requirements, listed at 49 CFR 177.848, revised as of October 1, 2020, and no future editions or later amendments, is incorporated by reference in this rule and on file with ADEQ.

p. “Department-approved facility” means a storage, transfer, treatment, or disposal facility that has undergone plan approval as described in R18-13-1410.

q. “Discarded drug” means any prescription medicine, o over-the-counter medicine, or controlled substance, used in the diagnosis, treatment, or immunization of a human being or animal, that the generator intends to abandon. The term does not include hazardous waste or controlled substances regulated by the United States Drug Enforcement Agency.

r. “Disposal facility” means a municipal solid waste landfill that has been approved by the Department under A.R.S. § 49-762.04 to accept untreated biohazardous medical waste for disposal.

s. “Emergency situations” include those situations where following location restrictions may result in an imminent threat to human health and the environment.

1. “Facility plan” has the meaning given to it in A.R.S. § 49-701.

m. “Free flowing” means liquid that separates readily from any portion of a biohazardous medical waste under ambient temperature and pressure.

n. “Generator” means a person whose act or process produces biohazardous medical waste, or a discarded drug, or whose act first causes medical waste or a discarded drug to become subject to regulation.

o. “Hazardous waste” has the meaning prescribed in A.R.S. § 49-921.

p. “Health care worker” means, with respect to R18-13-1403(B)(5), a person who provides health care services at an off-site location that is none of the following: a residence, a facility where health care is normally provided, or a facility licensed by the Arizona Department of Health Services.

q. “Improper disposal of biohazardous medical waste” means the disposal by a person of untreated or inadequately treated biohazardous medical waste at any place that is not approved to accept untreated hazardous medical waste.

r. “Independent testing laboratory” means a testing laboratory independent of oversight activities by a provider of alternative treatment technology.

s. “Medical sharps container” means a vessel that is rigid, puncture resistant, leak proof, and equipped with a locking cap capable of being securely closed.

t. “Medical waste,” as defined in A.R.S. § 49-701, means “any solid waste which is generated in the diagnosis, treatment or immunization of a human being or animal or in any research relating to that diagnosis, treatment or immunization, or in the production or testing of biologicals, and includes discarded drugs but does not include hazardous waste as defined in A.R.S. § 49-921 other than conditionally exempt small quantity generator waste.”

u. “Medical waste treatment facility” or “treatment facility” means a solid waste facility approved by the Department under A.R.S. § 49-762.04 to accept and treat biohazardous medical waste from off-site generators.

v. “Multi-purpose vehicle” means any motor vehicle operated by a health care worker, in the course of providing health care services, where the general purpose is the non-commercial transporting of people and the hauling of goods and supplies, but not solid waste. A multi-purpose vehicle is limited to hauling biohazardous medical waste generated off-site by health workers in providing services. “Off-site” for purposes of this definition means a location other than a hospital or clinic, at a location other than a hospital or clinic.
“USDOT” means the United States Department of Transportation.

Provisions in this Article requiring placement in Department-approved facilities do not restrict the right to place materials in facilities

A person who returns unused medical sharps to the manufacturer.

C.

B.

The requirements for biohazardous medical waste set out for collection do not apply to the manner in which the generator collects,

A.

No change

R18-13-1403. Exemptions; Partial Exemptions

A.

The following persons are exempt from the requirements of this Article:

1. No change

R18-13-1402. Applicability

A.

No change

B.

The requirements for biohazardous medical waste set out for collection do not apply to the manner in which the generator collects or handles material prior to that material becoming biohazardous medical waste or radioactive material.

C.

Provisions in this Article requiring placement in Department-approved facilities do not restrict the right to place materials in facilities that are out of state or in Indian Country.
5. No change
6. No change
7. A person who sends used medical sharps via the United States Postal Service or private shipping agent to a treatment facility.

B. The following are conditionally exempt from the requirements of this Article:
1. A person who prepares human corpses, remains, and anatomical parts that are intended for interment or cremation. However, if medical sharps are generated during the preparation of the human remains, they must be disposed of as prescribed by this Article.
2. A person who operates an emergency rescue vehicle, an ambulance, or a blood service collection vehicle in the course of providing medical services if the biohazardous medical waste is returned to the home facility for disposal. This facility is considered to be the point of generation for packaging, treatment, and disposal.
3. A person who discharges discarded drugs and liquid and semi-liquid biohazardous medical wastes, excluding cultures and stocks, to the sanitary sewer system if the operator of the wastewater sewer system and treatment facility allows, permits, authorizes, or otherwise approves of the discharges.
5. A health care worker who uses a multi-purpose vehicle in the conduct of routine health care business other than transporting wastes, is exempt from the requirements of R18-13-1409 if the health care worker complies with all of the following:
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
6. No change
7. No change

C. No change
1. No change
2. No change

R18-13-1404. Transition and Compliance Dates

A. Unless otherwise specified in subsections (B) through (H), the date for compliance with this Article by generators, transporters, treaters, providers of alternative medical waste technology, and persons in possession of untreated biohazardous medical waste is the effective date of this Article.

B. A person who provides alternative medical waste treatment technology used by a generator before the effective date of this Article shall perform all of the following:
   1. Register the alternative medical waste technology with the Department as prescribed in R18-13-1414 within 90 days after the effective date of this Article.
   2. Not provide alternative technology 90 days after the effective date of this Article unless a Departmental registration certificate is received.
   3. After receipt of the Departmental registration certificate, provide to all generators using the alternative treatment technology a copy of the registration certificate and the alternative technology manufacturer's specifications.

C. A generator who utilizes alternative medical waste treatment technology before the effective date of this Article shall obtain, within 180 days after the effective date of this Article, the Departmental registration number and equipment specifications, described in R18-13-1414, from the technology provider. If documentation of Departmental registration is not on file with the generator, the Department shall classify biohazardous medical waste treated 180 days after the effective date of this Article using the unregistered alternative treatment technology as untreated biohazardous medical waste.

D. A generator who utilizes incineration or autoclaving for onsite treatment of biohazardous medical waste before the effective date of this Article may continue to do so after the effective date if the treatment requirements of R18-13-1415 and the onsite treatment requirements of R18-13-1405 are met.

E. A transporter of biohazardous medical waste in business on the effective date of this Article shall register, within 90 days after the effective date of this Article, as required in R18-13-1409(A).

F. An operator of a medical waste storage facility, who has obtained approval for a solid waste facility under A.R.S. § 49-762.04 on or before the effective date of this Article, may continue to store biohazardous medical waste if the facility complies in compliance with the design and operation standards prescribed in R18-13-1411. The addition of a refrigeration unit is a Type II change as described in R18-13-1411(A)(2).

G. An operator of a medical waste transfer facility shall obtain solid waste facility plan approval that meets the requirements of R18-13-1410 within 180 days after the effective date of this Article.

H. An operator of a medical waste treatment facility who has obtained Departmental plan approval to operate a medical waste treatment facility on or before the effective date of this Article may continue to operate under that plan approval if both of the following are met:
   1. The treater complies with the treatment standards of R18-13-1415 and the recordkeeping requirements of R18-13-1412, except as noted in the subsection below.
   2. If the treater determines that the waste is not being treated to the applicable treatment standards of R18-13-1415, the treater informs the Department within two working days after the date of the determination, and within 30 working days enters into an administrative consent order to bring the facility into compliance.

I. An operator of an existing municipal solid waste landfill who intends to accept untreated biohazardous medical waste shall submit a notice of a Type III change and an amended facility plan within 180 days after the effective date of this Article.

J. Notwithstanding subsection (H), if the Department determines that an updated solid waste facility plan is required, a treater shall submit an updated plan within 180 days after the date on the Department’s determination. The treater may continue to operate under the
conditions specified in subsection (H) of this Section while the Department reviews and determines whether to approve or deny the updated plan.

K. After the effective date of this Article, solid waste facility plan approval under A.R.S. § 49-762.04 is required for a new medical waste treatment or disposal facility before construction.

R18-13-1406. Biohazardous Medical Waste Transported Off Site for Treatment

A. A generator of biohazardous medical waste shall cause the waste to first be packaged as prescribed in this article R18-13-1407 before and shall subsequently either self-haul or before store the waste as provided under R18-13-1408 and setting the waste out for collection by a properly licensed transporter under R18-13-1409.

B. A generator shall obtain a copy of the tracking document signed by the transporter signifying acceptance of the biohazardous medical waste. A generator shall keep a copy of the tracking document for one year from the date of acceptance by the transporter. The tracking document shall contain all of the following information:
1. No change
2. No change
3. Identification number attached to bags or containers, as specified by the USDOT requirements, as listed in 49 CFR 172.300 - 172.338. 49 CFR 172.300 - 172.338, revised as of October 1, 2020, and no future editions or later amendments, is incorporated by reference in this rule and on file with ADEQ. The tracking document shall contain:
4. No change

C. No change

D. No change

R18-13-1407. Non-Sharps Packaging

A. A generator who sets biohazardous medical waste that does not include sharps out for collection for off-site treatment or disposal shall package the biohazardous medical waste in either of the following:

1. No change
   a. No change
   b. No change
   c. No change
   d. Sealed to prevent leakage during transport, and
   e. Puncture resistant for sharps, and
   f. Placed in a secondary container. This container shall be constructed of materials that will prevent breakage of the bag in storage and handling during collection and transportation and bear the universal biohazard symbol. The secondary container may be either disposable or reusable.

2. No change
   a. No change
   b. No change
   i. No change
   ii. No change
   iii. No change

B. No change

C. No change

D. No change

R18-13-1408. Storage

A. A generator may place a container of biohazardous medical waste alongside a container of solid waste if the biohazardous medical waste is identified and not allowed to co-mingle with the solid waste. The storage area shall not be used to store substances for human consumption or for medical supplies.

B. No change

1. No change
2. No change

C. Beginning at the time the waste is set out for collection, a generator who stores biohazardous medical waste shall comply with all of the following requirements:

1. Keep putrescible biohazardous medical waste may be kept unrefrigerated up to 72 hours if it does not create a nuisance. However, refrigerate putrescible biohazardous medical waste kept more than seven days would not otherwise cause odor detectable beyond the property line or attract vermin.
2. Refrigerate at 40° F. or less from hour 72 through day 90 putrescible biohazardous medical waste kept for up to 90 days.
3. Nonputrescible biohazardous medical waste may be kept unrefrigerated for up to 90 days.
4. Store biohazardous medical waste for 90 days or less unless the generator has obtained facility plan approval under A.R.S. § 49-762.04 and is in compliance with the design and operational requirements prescribed in R18-13-1412.
5. Keep the storage area free of visible contamination.
6. Protect biohazardous medical waste from contact with water, precipitation, wind, or animals. A generator shall ensure that the waste does not provide a breeding place or a food source for insects or rodents.
7. Handle spills by re-packaging the biohazardous medical waste, re-labeling the containers and cleaning any soiled surface as prescribed in R18-13-1407(A)(2)(b).
6.8. Notwithstanding subsections (C)(1) if odors become a problem, and (2), a generator shall minimize objectionable odors and the off-site migration of odors and the presence of vermin. If the Department determines that a generator has not acted or adequately addressed the problem, odors or vermin, the Department shall require the waste to be removed or refrigerated at 40°F or less.

D. Trace chemotherapy waste shall be clearly identified as such by its label.

R18-13-1409. Transporter License; Fees; Transportation; Transporter License; Annual Fee

A. A transporter shall obtain a transporter license from the Department as provided under subsections (B), and (C), and (D) below in addition to possessing a permit, license, or approval if required by a local health department, environmental agency, or other governmental agency with jurisdiction.

B. A transporter license is valid for five years after issuance. To renew the license, the licensee shall submit an application under subsection (B)(1) no later than 60 days prior to the license’s expiration and shall pay the fee provided in subsections (B)(2). With each application submitted for approval, the applicant shall remit an initial transporter license application fee in accordance with the Fee Table in subsection (B)(2). This subsection also lists the maximum fees that the Department will bill the applicant. All fees paid shall be payable to the state of Arizona. The Department shall deposit the fees paid into the Solid Waste Fee Fund established pursuant to A.R.S. § 49-881, unless otherwise authorized or required by law.

1. To apply for or to renew a transporter license, an applicant shall submit all of the following in a Department-approved format:
   a. The name, address, and telephone number of the transportation company or entity.
   b. All owners’ names, addresses, and telephone numbers.
   c. All names, addresses, and telephone numbers of any agents authorized to act on behalf of the owner.
   d. A copy of either the certificate of disclosure required by A.R.S. § 49-109 or a written acknowledgment that this disclosure is not required.
   e. Photocopies or other evidence of the issuance of a permit, license, or approval if required by a local health department, environmental agency, or other governmental agency with jurisdiction.
   f. A copy of the transportation management plan as defined in R18-13-1401.
   g. A list identifying each dedicated vehicle.
   h. The initial transporter application license fee indicated in the Fee Table in (B)(2) for Transporter License Fees.

2. The new or renewal application license fee shall be calculated by multiplying the hourly rate of $122 by the number of personnel hours involved in inspecting each transporting vehicle, evaluating the application, and approving the license, which amount shall be subtracted from the initial application license fee on deposit. Any remaining surplus of the initial application license fee on deposit shall be returned to the applicant. Any cost that exceeds the initial application license fee on deposit shall be billed to the applicant, but shall not exceed the maximum.

Fee Table

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<thead>
<tr>
<th>Transporter License Fees</th>
<th>Initial</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Application</td>
<td>$2,000</td>
<td>$20,000</td>
</tr>
<tr>
<td>Renewal Application</td>
<td>$2,000</td>
<td>$20,000</td>
</tr>
<tr>
<td>Amendment Application</td>
<td>$100</td>
<td>$5,000</td>
</tr>
</tbody>
</table>

Frequency of Application for Transporter License

<table>
<thead>
<tr>
<th>Year</th>
<th>Type of Application</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>1, 2, 3, 4, 5, 6, 11, 16, etc.</td>
<td>New</td>
<td>Once</td>
</tr>
<tr>
<td>6, 11, 16, etc.</td>
<td>Renewal</td>
<td>Every 5th Year</td>
</tr>
</tbody>
</table>

3. The Department may only issue a transporter license, including a renewal, if all of the items in subsection (B)(1) have been received and determined to be correct and complete, and a Department inspection of each transporting vehicle shows that the vehicle is in compliance with this Article.

B.C. Beginning on July 1, 2012, a transporter Transporters shall pay by the invoice due date an annual fee of $750 for each calendar year according to the following schedule, except that no transporter shall pay more than one annual fee in any calendar year, following payment of the new or renewal application license fee and subsequent years in which a renewal application license fee is not charged and paid, such as in the Transporters Annual Fee table.

1. Transporters registered with the Department before July 1, 2012, shall apply for a license according to subsections (C) and (D) at no more than 60 days before their registration expires.
2. Transporters who have been issued a license or renewal of a license under this Section and have paid the licensing year fee as provided in subsection (D) shall pay the annual fee by December 31st of each year thereafter.
3. A transporter that has not been registered with the Department shall apply and obtain a license according to subsections (C) and (D) of this Section and pay an annual fee by December 31st of each year thereafter.

Fee Table

<table>
<thead>
<tr>
<th>Years</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>2, 3, 4, 5, 6, 7, 8, 9, 10, etc.</td>
<td>$750</td>
</tr>
</tbody>
</table>

G. To apply for or to renew a transporter license, an applicant shall submit all of the following on a form approved by the Department:

1. The name, address, and telephone number of the transportation company or entity.
2. All owners’ names, addresses, and telephone numbers.
3. All names, addresses, and telephone numbers of any agents authorized to act on behalf of the owner.
4. A copy of either the certificate of disclosure required by A.R.S. § 10-109 or a written acknowledgment that this disclosure is not required.
5. Photocopies or other evidence of the issuance of a permit, license, or approval if required by a local health department, environmental agency, or other governmental agency with jurisdiction.
6. A copy of the transportation management plan that meets the requirements in subsection (H).
7. A list identifying each dedicated vehicle.
8. An application fee of $2,000 which shall apply toward the licensing year fee in subsection (D)(3).

D. The Department may only issue a transporter license, including a renewal, after all of the following:
1. All of the items in subsection (C) have been received and determined to be correct and complete;
2. A Department inspection of each transporting vehicle shows that the vehicle is in compliance with this Article; and
3. The applicant has paid a licensing year fee consisting of:
   a. An amount based on the expenses associated with inspecting each transporting vehicle, evaluating the application, and approving the license, minus the application fee. The amount shall be calculated using a rate of $122 per hour, multiplied by the number of personnel hours used in these duties.
   b. The annual fee of $750 for the year as provided for in subsection (B).
   c. The maximum fee for both subsections (D)(3)(a) and (b) shall be $20,000.

E. A transporter license is valid for five years after issuance. To renew the license, the licensee shall submit an application under subsection (C) no later than 60 days before expiration. Renewals shall be issued after payment of a licensing year fee as provided in subsection (D)(3).

D(G). Amendments. After issuance, the licensee shall submit to the Department any change to the information listed in subsection (C) within 30 days of its occurrence. Vehicles may only be added to the license after a Department inspection shows that the vehicle is in compliance with this Article. Amendments to the transportation management plan or amendments adding vehicles to the license shall be processed after payment of inspection fees and other expenses at the rate listed in subsection (D)(2), except that the application fee shall be $100 and the maximum fee $5,000.

G. An applicant who disagrees with the final bill received from the Department for the amendment, issuance, renewal or denial of a transporter license or vehicle inspections may make a written request to the Director for a review of the bill and may pay the bill under protest. The request for review shall specify the matters in dispute and shall be received by the Department within 10 working days of the date of receipt of the final bill.

H. Unless the Department and applicant agree otherwise, the review shall take place within 30 days of receipt by the Department of the request. The Director shall make a final decision as to whether the time and costs billed are correct and reasonable. The final decision shall be mailed to the applicant within 10 working days after the date of the review and is subject to appeal pursuant to A.R.S. § 49-769.

I. A person who transports biohazardous medical waste shall maintain in each transporting vehicle at all times a transportation management plan consisting of both of the following:
1. Routine procedures used to minimize the exposure of employees and the general public to biohazardous medical waste throughout the process of collecting, transporting, and handling.
2. Emergency procedures used for handling spills or accidents.

J. A transporter who accepts biohazardous medical waste from a generator shall transmit electronically or leave a physical copy of the tracking document described in R18-13-1406(B) with the person from whom the waste is accepted. A transporter shall ensure that a copy of the tracking document accompanies the person who has physical possession of the biohazardous medical waste. Upon delivery to a Department-approved transfer, storage, treatment, or disposal facility, the transporter shall obtain a copy of the tracking document, signed by a person representing the receiving facility, signifying acceptance of the biohazardous medical waste.

K. A transporter who transports biohazardous medical waste in a dedicated vehicle dedicated to the transportation of biohazardous medical waste shall ensure that the cargo box, trailer, or compartment can be secured to limit access to authorized persons at all times except during loading and unloading. In addition, the cargo box, trailer, or compartment shall be constructed in compliance with one of the following:
1. Have a fully enclosed, leak-proof cargo compartment consisting of a floor, sides, and a roof that are made of a non-porous material impervious to biohazardous medical waste and physically separated from the driver’s compartment.
2. Haul a fully enclosed, leak-proof cargo box made of a non-porous material impervious to biohazardous medical waste.
3. Tow a fully enclosed leak-proof trailer made of a non-porous material impervious to biohazardous medical waste.

L. A person who transports biohazardous medical waste in a vehicle not dedicated to the transportation of biohazardous medical waste, but that is used longer than 30 consecutive days, at least once weekly for a month shall comply with the following:
1. Subsections (A) and (H)(G) through (M)(K).
2. Clean the vehicle as prescribed in R18-13-1407(A)(2)(b) before it is used for another purpose.

M. A person who transports biohazardous medical waste shall comply with all of the following:
1. Accept only biohazardous medical waste packaged as prescribed in R18-13-1407.
2. Accept biohazardous medical waste only after providing the generator with a signed tracking form as prescribed in R18-13-1406(B), and keep a copy of the tracking document for one year: the period required under the USDOT requirements, as listed in 49 CFR 172.201,
3. Deliver biohazardous medical waste to a Department-approved biohazardous medical waste storage, transfer, treatment, or disposal facility within 24 hours of collection or refrigerate the waste for not more than 90 days at 40°F or less until delivery; the following timeframes:
   a. 72 hours of collection, if putrefiable and unrefrigerated; or
   b. 90 days of collection, if putrefiable and refrigerated at 40°F or less from hour 72 through day 90; or
90 days of collection, if nonputrescible and unrefrigerated.
4. Not hold biohazardous medical waste longer than specified under subsection (K)(3) for 96 hours in a refrigerated vehicle unless the vehicle is parked at a Department-approved facility.
5. Not, except in emergency situations, not unload, reload, or transfer the biohazardous medical waste to another vehicle in any location other than a Department-approved facility, except in emergency situations. Combination vehicles or trailers may be uncoupled and coupled to another cargo vehicle or truck trailer as long as the biohazardous medical waste is not removed from the cargo compartment.

As used in this Section, “licensing year” means the calendar year in which the Department issues a license or a renewal of a license under this Section.

R18-13-1411. Storage and Transfer Facilities; Design and Operation
An operator of a storage facility or transfer facility shall comply with all of the following design and operation requirements:
1. No change
2. No change
3. No change
4. No change
5. Specify in the application for facility plan approval the maximum storage time that biohazardous medical waste will remain at the facility. If the putrescible biohazardous medical waste will be stored for more than 24 hours, 72 hours, the operator shall equip the facility with a refrigerator to refrigerate the putrescible biohazardous medical waste. The operator of the facility shall maintain the temperature in the refrigerator at 40° F. or less.
6. Accept biohazardous medical waste only if it is accompanied by the tracking form document. The operator shall sign the tracking form document and keep a copy of the acceptance documentation for one year, the period required under the USDOT requirements, as listed in 49 CFR 172.201.
7. Accept biohazardous medical waste if it is packaged as described in R18-13-1407. If a biohazardous medical waste container is damaged or leaking, improperly labeled, or otherwise unacceptable, a transfer facility operator shall do one of the following:
   a. Reject the waste and return it to the transporter or self-hauling generator.
   b. No change
8. Clean the storage area daily, as prescribed in R18-13-1407(A)(2). “Clean” means to remove visible particles combined with one of the following:
   a. Exposure to hot water at a temperature of at least 180 degrees Fahrenheit for a minimum of 15 seconds.
   b. Exposure to an EPA-approved chemical disinfectant used under established protocols and regulations.
   c. Any other method that the Department determines is acceptable, if the determination of acceptability is made in advance of the cleaning.

R18-13-1412. Treatment Facilities; Application Requirements; Design and Operation
A. An operator who applies for facility plan approval shall comply with all of the following subsections (1) and (2) as well as all of the requirements in subsection (B):
1. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
2. Submit to the Department and have readily available at the facility, an operations procedure manual describing how the waste will be handled from the time it is accepted by the treater through the treatment process and final disposition of the treated waste. The operations procedure manual shall include all of the following:
   a. Provisions for treating biohazardous medical waste within 24 hours of receipt or refrigerating immediately at 40° F. or less upon determination that treatment or disposal will not occur within 24 hours. Nonputrescible biohazardous medical waste that is not immediately treated may be stored for up to 90 days unrefrigerated.
   b. No change
   c. No change
3. Have on hand written procedures stating that biohazardous medical waste is to be accepted from a transporter only if the waste is accompanied by a tracking form, and written procedures that require compliance with both of the following:
   a. The treater or the treater’s authorized agent shall sign the tracking document and keep a copy of the acceptance documentation for one year.
   b. If a biohazardous medical waste container is damaged or leaking, improperly labeled, or otherwise unacceptable, a treater shall do one of the following:
      i. Reject the waste and return it to the transporter.
      ii. Accept the waste and transfer it directly from the transporting vehicle to the treatment processing unit.
      iii. If the waste will not be treated immediately, repackage the waste for storage.
4. Assure that the facility is designed to meet both of the following requirements:
   a. Any floor or wall surface in the processing area of the facility which may come into contact with biohazardous medical waste is constructed of a smooth, easily cleanable non-porous material that is impervious to liquids.
   b. The floor surface in the treatment and storage area either has a curb of sufficient height to contain spills or slopes to a drain that connects to an approved sanitary sewage system, septic tank system, or collection device.
5. Store biohazardous medical waste as required in R18-13-1408.
6. Comply with all of the following if the treatment method is incineration:
Reduce the incinerated medical waste, excluding metallic items, into carbonized or mineralized ash by incineration.

Determine whether the ash is hazardous waste as required under R18-8-262.

Conduct any autoclaving according to the manufacturer’s specifications for the unit.

Use only alternative medical waste treatment methods that achieve the treatment standards in R18-13-1415(A).

Treat animal waste, chemotherapy waste, and cultures and stocks as prescribed in R18-13-1420.

Treat medical sharps as prescribed in R18-13-1419.

Keep records of equipment maintenance and operational performance levels for three years. The records shall include the date and result of all equipment calibration and maintenance. Operational performance level records shall indicate the duration of time for each treatment cycle and:

- For steam treatment and microwaving treatment records, both the temperature and pressure maintained in the treatment unit during each cycle and the method used for confirmation of temperature and pressure.
- For chemical treatment, a description of the solution used.
- For incineration, the temperature maintained in the treatment unit during operation.
- Any other operating parameters in the manufacturer’s specifications.
- A description of the treatment method used and a copy of the maintenance test results.

Not open a sealed biohazardous medical waste container prior to treatment unless opening the container is required to treat the contents. Transfer of the entire contents, when performed as part of the treatment process, is permitted.

Keep records of equipment maintenance and operational performance levels for three years. The records shall include the date and result of all equipment calibration and maintenance. Operational performance level records shall indicate the duration of time for each treatment cycle and:

- For steam treatment and microwaving treatment records, both the temperature and pressure maintained in the treatment unit during each cycle and the method used for confirmation of temperature and pressure.
- For chemical treatment, a description of the solution used.
- For incineration, the temperature maintained in the treatment unit during operation.
- Any other operating parameters in the manufacturer’s specifications.
- A description of the treatment method used and a copy of the maintenance test results.

Determine whether the ash is hazardous waste as required under R18-8-262.

Use only alternative medical waste treatment methods that achieve the treatment standards in R18-13-1415(A).

If a biohazardous medical waste container is damaged or leaking, improperly labeled, or otherwise unacceptable, a treater shall do one of the following:

- Reject the waste and return it to the transporter or self-hauling generator.
- Accept the waste and transfer it directly from the transporting vehicle to the treatment processing unit.
- Store biohazardous medical waste as required in R18-13-1408.

Conduct any autoclaving according to the manufacturer’s specifications for the unit.

Treat medical sharps as prescribed in R18-13-1419.

R18-13-1413. Changes to Approved Medical Waste Facility Plans

A. As required by A.R.S. § 49-762.06, before making any change to an approved facility plan, a treatment facility owner or operator shall submit a notice to the Department stating which of the following categories type of change is requested, including but not limited to:

1. No change
2. No change
3. No change
   a. No change
   b. No change
   c. No change
4. No change
a. No change
b. No change
c. No change
d. No change

B. No change
1. No change
2. No change
3. No change

C. An owner or operator of an existing municipal solid waste landfill who intends to accept untreated biohazardous medical waste shall submit a notice of a Type III change and an amended facility plan.


A. No change
1. No change
2. No change
3. No change
4. No change
5. No change
6. No change
7. No change
8. No change
9. No change

B. No change

C. If documentation of Departmental registration is not on file with a generator utilizing alternative medical waste treatment technology, the Department shall classify biohazardous medical waste treated using the unregistered alternative treatment technology as untreated biohazardous medical waste.

R18-13-1415. Treatment Standards, Quantification of Microbial Inactivation and Efficacy Testing Protocols

A. No change
1. No change
2. A 4 log\textsubscript{10} inactivation in the concentration of \textit{Bacillus stearothermophilus} \textit{Bacillus stearothermophilus} or \textit{Bacillus subtilis} \textit{Bacillus subtilis} as is appropriate to the technology.

B. No change
1. No change
a. No change
b. No change

2. No change
a. No change
b. No change

C. No change
1. No change
2. No change
3. No change
a. No change
i. No change
ii. No change
iii. No change
iv. No change
v. No change
b. No change
i. No change
ii. No change
iii. No change
iv. No change
v. No change

D. No change


An operator of a municipal solid waste landfill that accepts untreated biohazardous medical waste shall comply with all of the following in design and operational requirements:
1. No change
2. No change
3. No change
4. No change
5. No change
6. No change

R18-13-1418. Discarded Drugs
A. A generator of discarded drugs that are not hazardous waste, not returned to the manufacturer, and not segregated and labeled on site for transport to a treatment facility shall destroy the drugs on site by any method that prevents the drugs’ use prior to placing the waste out for collection. A generator shall destroy the discarded drugs by any method that prevents the drug’s use. If federal or state law prescribes a specific method for destruction of discarded drugs, the generator shall comply with that law.

B. A generator of discarded drugs may flush them down a sanitary sewer if allowed by the wastewater treatment authority.

R18-13-1419. Medical Sharps
A. Medical sharps shall be handled as follows:
   1. A generator who treats biohazardous medical waste on site shall place medical sharps in a sharps container after rendering them incapable of creating a stick hazard by using an encapsulation agent or any other process that prevents a stick hazard. Medical sharps encapsulated or processed in this manner are considered to be solid waste.
   2. A generator who ships biohazardous medical waste off site for treatment shall either:
      a. Place medical sharps in a medical sharps container and follow the requirements of R18-13-1406, or
      b. Package and send medical sharps to a treatment facility via a mail-back system as prescribed by the instructions provided by the mail-back system operator. An Arizona treatment facility shall render medical sharps incapable of creating a stick hazard by using an encapsulation agent or any other process that prevents a stick hazard. The generator shall retain proof of shipping.
   3. A person operating a treatment facility who accepts medical sharps for treatment shall either:
      a. Encapsulate medical sharps to prevent stick hazard, or
      b. Use any other process that prevents a stick hazard.

B. Notwithstanding subsections (A)(1) and (A)(2), the following syringes do not have to be placed in a medical sharps container:
   1. Syringes that have never had a needle (sharp) attached.
   2. Syringes where a needle or sharp had been attached and has been separated from the syringe so that no stick or puncture hazard remains with the syringe.

C. Syringes that are exempted by subsection (B) from being placed in a medical sharps container are not biohazardous medical waste, and may be treated as a solid waste, if they are not composed of biohazardous items listed in R18-13-1401(4) and do not contain discarded drugs or another regulated substance.

R18-13-1420. Additional Handling Requirements for Certain Wastes
A. A person who treats the following biohazardous medical waste categories shall meet the following additional requirements:
   1. Cultures and stocks shall be incinerated, autoclaved, or treated by an alternative medical waste treatment method that meets the treatment standards set forth in R18-13-1415(A), and if cultures and stocks are shipped off site for treatment or disposal, they shall be packaged inside a watertight primary container with absorbent packing materials if shipped off site for treatment or disposal. The primary container shall be placed inside a watertight secondary inner container that is then placed inside an outer container with sufficient cushioning material to prevent shifting between the secondary inner container and the outer container. If federal or state law prescribes specific requirements for packaging and transporting this waste, the treater shall comply with that law.
   2. Chemotherapy: Trace chemotherapy waste shall be incinerated or disposed of in either an approved solid waste or hazardous waste disposal facility.
   3. No change
      a. No change
      b. No change
         i. No change
         ii. No change

B. No change
NOTICES OF RULEMAKING DOCKET OPENING

This section of the Arizona Administrative Register contains Notices of Rulemaking Docket Opening under A.R.S. § 41-1021.

A docket opening is the first part of the administrative rulemaking process. It is an “announcement” that an agency intends to work on its rules.

When an agency opens a rulemaking docket to consider rulemaking, the Administrative Procedure Act (APA) requires the publication of the Notice of Rulemaking Docket Opening.

Under the APA, effective January 1, 1995, agencies must submit a Notice of Rulemaking Docket Opening before beginning the formal rulemaking process. An agency may file the Notice of Rulemaking Docket Opening along with the Notice of Proposed Rulemaking.

The Office of the Secretary of State is the filing office and publisher of these notices. Questions about the interpretation of this information should be directed to the agency contact person listed in item #4 of this notice.

NOTICE OF RULEMAKING DOCKET OPENING

ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM (AHCCCS) ADMINISTRATION

[R21-218]

1. Title and its heading: 9. Health Services
   Chapter and its heading: 22, Arizona Health Care Cost Containment System - Administration
   Article and its heading: 7, Standards for Payments
   Section numbers: R9-22-701 and R9-22-712.08 (As part of this rulemaking, the Administration may add, delete, or modify Sections as necessary.)

2. The subject matter of the proposed rule:
   Currently, Graduate Medical Education (GME) funding is distributed to hospitals that provide training and education for medical school graduates. The GME fund is authorized pursuant to A.R.S. 36-2903.01(G). Under A.R.S. § 36-2903.01(G)(9), certain public entities are permitted to transfer funds to the AHCCCS Administration to support these distributions. The Centers for Medicare and Medicaid Services (CMS) require the Administration to annually update the amount allocated to each hospital in the State Plan. Before the Administration may make GME payments, a State Plan Amendment (SPA) must be submitted and approved by CMS. Therefore, no payments under this rulemaking may be made until AHCCCS has received approval for the SPA corresponding to this rulemaking.

   Laws 2021, Chapter 81, requires that by March 1, 2022, the Administration establish a separate GME program to reimburse qualifying CHCs and RHCs which have an approved primary care GME program. Through this rulemaking, the Administration proposes to create a separate program for GME for CHCs and RHCs, notwithstanding the existing GME programs found in R9-22-712.05 and R9-22-712.06. The AHCCCS Administration worked with the Arizona Alliance for Community Health Centers and a workgroup consisting of CHCs and RHCs to develop the methodology for distributing these payments, subject to CMS approval. Technical and conforming changes will also be considered as part of the rulemaking.

3. A citation to all published notices relating to the proceeding:
   Notice of Proposed Rulemaking: 27 A.A.R. 2791, December 3, 2021 (in this issue)

4. The name and address of agency personnel with whom persons may communicate regarding the rule:
   Name: Nicole Fries
   Address: AHCCCS
           Office of Administrative Legal Services
           701 E. Jefferson, Mail Drop 6200
           Phoenix, AZ 85034
   Telephone: (602) 417-4232
   Fax: (602) 253-9115
   Email: AHCCCSrules@azahcccs.gov

5. The time which the agency will accept written comments and the time and place where oral comments may be made:
   The Administration will accept written comments Monday through Friday, 8 a.m. to 5 p.m., at the address indicated in question #4. Public hearings will be scheduled later to provide a forum for interactive discussion with interested parties. Email comments will be accepted.

6. A timetable for agency decisions or other action on the proceeding, if known:
   The Administration has initiated this rulemaking within the 60-day time period as stated under A.R.S. § 41-1033. The Notice of Proposed Rulemaking is published along with this notice.
GOVERNOR EXECUTIVE ORDER

EXECUTIVE ORDER 2021-02
Moratorium on Rulemaking to Promote Job Creation and
Economic Development; Internal Review of Administrative Rules

WHEREAS, government regulations should be as limited as possible; and
WHEREAS, burdensome regulations inhibit job growth and economic development; and
WHEREAS, in 2015 the State of Arizona implemented a moratorium on all new regulatory rulemaking by State agencies through executive order, and renewed the moratorium in 2016, 2017, 2018, 2019 and 2020; and
WHEREAS, the State of Arizona eliminated or improved 462 burdensome regulations in 2020 and for a total of 2,751 needless regulations eliminated or improved since 2015; and
WHEREAS, estimates show these eliminations saved job creators $14.7 million in operating costs in 2020 and for a total of over $148.9 million in savings since 2015; and
WHEREAS, in 2020, for every one new necessary rule added to the Administrative Code, four have been repealed or improved; and
WHEREAS, COVID-19 has been hard on small businesses and the economy, and administrative barriers should be removed for their sake; and
WHEREAS, all government agencies of the State of Arizona should continue to promote customer service oriented principles for the people that it serves; and
WHEREAS, each State agency shall continue to conduct a critical and comprehensive review of its administrative rules and take action to reduce the regulatory burden, administrative delay and legal uncertainty associated with government regulation while protecting the health, peace and safety of residents; and
WHEREAS, each State agency should continue to evaluate its administrative rules using any available and reliable data and performance metrics; and
WHEREAS, Article 5, Section 4 of the Arizona Constitution and Title 41, Chapter 1, Article 1 of the Arizona Revised Statutes vests the executive power of the State of Arizona in the Governor.

NOW, THEREFORE, I, Douglas A. Ducey, by virtue of the authority vested in me by the Constitution and laws of the State of Arizona hereby declare the following:

1. A State agency subject to this Order shall not conduct any rulemaking, including regular, expedited, emergency and exempt, whether informal or formal, without the prior written approval of the Office of the Governor. In seeking approval, a State agency shall address one or more of the following as justifications for the rulemaking:
   a. To fulfill an objective related to job creation, economic development or economic expansion in this State.
   b. To reduce or ameliorate a regulatory burden on the public, while achieving the same regulatory objective.
   c. To prevent a significant threat to public health, peace or safety.
   d. To avoid violating a court order or federal law that would result in sanctions by a federal court for failure to conduct the rulemaking action.
   e. To comply with a federal statutory or regulatory requirement if such compliance is related to a condition for the receipt of federal funds or participation in any federal program.
   f. To comply with a new state statutory requirement.
   g. To fulfill an obligation related to fees or any other action necessary to implement the State budget that is certified by the Governor’s Office of Strategic Planning and Budgeting.
   h. To promulgate a rule or other item that is exempt from Title 41, Chapter 6, Arizona Revised Statutes, pursuant to section 41-1005, Arizona Revised Statutes.
   i. To address matters pertaining to the control, mitigation, or eradication of waste, fraud, or abuse within an agency or wasteful, fraudulent or abusive activities perpetrated against an agency.
   j. To eliminate rules which are antiquated, redundant or otherwise no longer necessary for the operation of state government.
2. After the public comment period and the close of the rulemaking record, a State agency subject to this Order shall not submit the proposed rules to the Governor’s Regulatory Review Council without a written final approval from the Office of the Governor.
Before considering the rules submitted by a State agency, the Governor’s Regulatory Review Council must obtain from the State agency the initial approval, referenced in Section 1, and the final approval from the Office of the Governor.

3. A State agency that submits a rulemaking request pursuant to this Order shall recommend for consideration by the Governor’s Office at least three existing rules to eliminate for every one additional rule requested by the agency.

4. All State agencies shall conduct a comprehensive review of any rules that were suspended during the Public Health State of Emergency for COVID-19 to determine if those rules should be permanently suspended and send a report on their findings no later than June 1, 2021.

5. A State agency subject to this Order shall not publicize any directives, policy statements, documents or forms on its website unless such are explicitly authorized by the Arizona Revised Statutes or Arizona Administrative Code. Any material that is not specifically authorized must be removed immediately.

6. A State agency that issues occupational or professional licenses shall prominently post on the agency’s website landing page all current state policies that ease licensing burdens and the exact steps applicants must complete to receive their license using these policies. State agencies should provide information that applies to all applicants, but have a designated area on the landing page that includes licensing information specifically for military spouses, active duty service members and veterans and all policies that make it easier for these applicant groups to receive their license. Examples of reduced licensing burdens include “universal recognition” of out-of-state licenses, availability of temporary licenses, fee waivers, exam exemptions and/or allowing an applicant to substitute military education or experience for licensing requirements. A landing page feature may link to an internal agency web page with more information, if necessary. All information must be easy to locate and written in clear and concise language.

7. A State agency that issues occupational or professional licenses must track veteran and military spouse status of applicants immediately and report that information to the Governor’s Office on an annual basis, starting July 1, 2021.

8. All State agencies that are required to issue occupational or professional licenses by “universal recognition” (established by A.R.S. § 32-4302) must track all applications received for this license type immediately and report that information to the Governor’s Office on an annual basis, starting July 1, 2021. Before any agency denies a professional or occupational license applied for under A.R.S. § 32-4302, the agency shall submit the application and justification for denial to the Office of the Governor for review before any official action is taken by the agency. The Governor’s Office should be notified of any required timeframes, whether in statute or rule, for approval or denial of the license by the agency.

9. For the purposes of this Order, the term “State agencies” includes, without limitation, all executive departments, agencies, offices, and all state boards and commissions, except for: (a) any State agency that is headed by a single elected State official; (b) the Corporation Commission; and (c) any board or commission established by ballot measure during or after the November 1998 general election. Those state agencies, boards and commissions excluded from this Order are strongly encouraged to voluntarily comply with this Order in the context of their own rulemaking processes.

10. This Order does not confer any legal rights upon any persons and shall not be used as a basis for legal challenges to rules, approvals, permits, licenses or other actions or to any inaction of a State agency. For the purposes of this Order, “person,” “rule” and “rulemaking” have the same meanings prescribed in section 41-1001, Arizona Revised Statutes.

11. This Executive Order supersedes Executive Order 2019-01 and Executive Order 2020-02.

IN WITNESS THEREOF, I have hereunto set my hand and caused to be affixed the Great Seal of the State of Arizona.

Douglas A. Ducey
GOVERNOR
DONE at the Capitol in Phoenix on this twelfth day of February in the Year Two Thousand and Twenty-One and of the Independence of the United States of America the Year Two Hundred and Forty-Fifth.

ATTEST:
Katie Hobbs
SECRETARY OF STATE
The Register is published by volume in a calendar year (See “General Information” in the front of each issue for more information).

Abbreviations for rulemaking activity in this Index include:

**PROPOSED RULEMAKING**
- PN = Proposed new Section
- PM = Proposed amended Section
- PR = Proposed repealed Section
- P# = Proposed renumbered Section

**SUPPLEMENTAL PROPOSED RULEMAKING**
- SPN = Supplemental proposed new Section
- SPM = Supplemental proposed amended Section
- SPR = Supplemental proposed repealed Section
- SP# = Supplemental proposed renumbered Section

**FINAL RULEMAKING**
- FN = Final new Section
- FM = Final amended Section
- FR = Final repealed Section
- F# = Final renumbered Section

**SUMMARY RULEMAKING**

**PROPOSED SUMMARY**
- PSMN = Proposed Summary new Section
- PSMM = Proposed Summary amended Section
- PSMR = Proposed Summary repealed Section
- PSM# = Proposed Summary renumbered Section

**FINAL SUMMARY**
- FSMN = Final Summary new Section
- FSMM = Final Summary amended Section
- FSMR = Final Summary repealed Section
- FSM# = Final Summary renumbered Section

**EXPIRED RULEMAKING**

**PROPOSED EXPEDITED**
- PEN = Proposed Expedited new Section
- PEM = Proposed Expedited amended Section
- PER = Proposed Expedited repealed Section
- PE# = Proposed Expedited renumbered Section

**SUPPLEMENTAL EXPEDITED**
- SPEN = Supplemental Proposed Expedited new Section
- SPEM = Supplemental Proposed Expedited amended Section
- SPER = Supplemental Proposed Expedited repealed Section
- SPE# = Supplemental Proposed Expedited renumbered Section

**FINAL EXPEDITED**
- FEN = Final Expedited new Section
- FEM = Final Expedited amended Section
- FER = Final Expedited repealed Section
- FE# = Final Expedited renumbered Section

**EXEMPT RULEMAKING**

**EXEMPT**
- XN = Exempt new Section
- XM = Exempt amended Section
- XR = Exempt repealed Section
- X# = Exempt renumbered Section

**EXEMPT PROPOSED**
- PXN = Proposed Exempt new Section
- PXM = Proposed Exempt amended Section
- PXR = Proposed Exempt repealed Section
- PX# = Proposed Exempt renumbered Section

**EXEMPT SUPPLEMENTAL PROPOSED**
- SPXN = Supplemental Proposed Exempt new Section
- SPXR = Supplemental Proposed Exempt repealed Section
- SPXM = Supplemental Proposed Exempt amended Section
- SPX# = Supplemental Proposed Exempt renumbered Section

**FINAL EXEMPT RULEMAKING**
- FXN = Final Exempt new Section
- FXM = Final Exempt amended Section
- FXR = Final Exempt repealed Section
- FX# = Final Exempt renumbered Section

**EMERGENCY RULEMAKING**
- EN = Emergency new Section
- EM = Emergency amended Section
- ER = Emergency repealed Section
- E# = Emergency renumbered Section
- EEXP = Emergency expired

**RECODIFICATION OF RULES**
- RC = Recodified

**REJECTION OF RULES**
- RJ = Rejected by the Attorney General

**TERMINATION OF RULES**
- TN = Terminated proposed new Sections
- TM = Terminated proposed amended Section
- TR = Terminated proposed repealed Section
- T# = Terminated proposed renumbered Section

**RULE EXPIRATIONS**
- EXP = Rules have expired

See also "emergency expired" under emergency rulemaking

**CORRECTIONS**
- C = Corrections to Published Rules
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The Secretary of State’s Office publishes the Register weekly. There is a three-week turnaround period between a deadline date and the publication date of the Register. The weekly deadline dates and issue dates are shown below. Council meetings and Register deadlines do not correlate. Also listed are the earliest dates on which an oral proceeding can be held on proposed rulemakings or proposed delegation agreements following publication of the notice in the Register.

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The following deadlines apply to all Five-Year Review Reports and any adopted rule submitted to the Governor's Regulatory Review Council. Council meetings and Register deadlines do not correlate. We publish these deadlines under A.R.S. § 41-1013(B)(15).

All rules and Five-Year Review Reports are due in the Council office by 5 p.m. of the deadline date. The Council's office is located at 100 N. 15th Ave., Suite 305, Phoenix, AZ 85007. For more information, call (602) 542-2058 or visit http://grrc.az.gov.

### GOVERNOR’S REGULATORY REVIEW COUNCIL DEADLINES FOR 2021/2022

*Meeting dates are subject to change*

<table>
<thead>
<tr>
<th>Deadline for Placement on Agenda*</th>
<th>Final Materials Submitted to Council</th>
<th>Date of Council Study Session</th>
<th>Date of Council Meeting</th>
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* Materials must be submitted by **5 PM** on dates listed as a deadline for placement on a particular agenda. Placement on a particular agenda is not guaranteed.