UTAH STATE BULLETIN

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Nancy L. Lancaster, Managing Editor

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Inquiries concerning the substance or applicability of an administrative rule that appears in the *Bulletin* should be addressed to the contact person for the rule. Questions about the *Bulletin* or the rulemaking process may be addressed to: Office of Administrative Rules, PO Box 141007, Salt Lake City, Utah 84114-1007, telephone 801-957-7110. Additional rulemaking information and electronic versions of all administrative rule publications are available at https://rules.utah.gov/.

The information in this *Bulletin* is summarized in the *Utah State Digest (Digest)* of the same volume and issue number. The *Digest* is available by e-mail subscription or online. Visit https://rules.utah.gov/ for additional information.

Office of Administrative Rules, Salt Lake City 84114

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TABLE OF CONTENTS

NOTICES OF PROPOSED RULES	1
AGRICULTURE AND FOOD	
Medical Cannabis and Industrial Hemp	
R66-3. Quality Assurance Testing on Cannabis	2
Plant Industry	
R68-29. Quality Assurance Testing on Cannabis	9
HEALTH AND HUMAN SERVICES	
Population Health, Emergency Medical Services	
R426-10. Air Ambulance Licensure and Operations	16
Data, Systems and Evaluation, Vital Records and Statistics	
R436-16. Violation of Rules	34
JUDICIAL PERFORMANCE EVALUATION COMMISSION	
Administration	
R597-7. General Provisions	36
LABOR COMMISSION	
Boiler, Elevator and Coal Mine Safety	
R616-2-3. Safety Codes and Rules for Boilers and Pressure Vessels	38
LIEUTENANT GOVERNOR	
Administration	
R622-3. Use of the Great Seal of the State of Utah	41
NOTICES OF 120-DAY (EMERGENCY) RULES	45
HEALTH AND HUMAN SERVICES	
Integrated Healthcare	
R414-60-7. Reimbursement	45
FIVE-YEAR NOTICES OF REVIEW AND STATEMENTS OF CONTINUATION	49
AGRICULTURE AND FOOD	
Conservation Commission	
R64-3. Utah Environmental Stewardship Certification Program	
(UESCP), a.k.a. Agriculture Certificate of Environmental	
Stewardship (ACES)	49
ENVIRONMENTAL QUALITY	
Water Quality	
R317-401. Graywater Systems	50

i

TABLE OF CONTENTS

HEALTH AND HUMAN SERVICES	
Integrated Healthcare	
R414-14A. Hospice Care	51
Health Care Facility Licensing	
R432-13. Freestanding Ambulatory Surgical Center Construction Rule	51
R432-14. Birthing Center Construction Rule	52
R432-32. Licensing Exemption for Non-Profit Volunteer End-of-Life Care	53
CULTURAL AND COMMUNITY ENGAGEMENT	
History	
R455-11. Historic Preservation Tax Credit	53
R455-14. Procedures for Electronic Meetings	54
R455-15. Procedures for Emergency Meetings	54
Public Safety	
Fire Marshal	
R710-12. Hazardous Materials Training and Certification	55
NOTICES OF RULE EFFECTIVE DATES	57

NOTICES OF PROPOSED RULES

A state agency may file a **Proposed Rule** when it determines the need for a substantive change to an existing rule. With a **Notice of Proposed Rule**, an agency may create a new rule, amend an existing rule, repeal an existing rule, or repeal an existing rule and reenact a new rule. Filings received between <u>March 16, 2024, 12:00 a.m.</u>, and <u>April 01, 2024, 11:59 p.m.</u> are included in this, the <u>April 15, 2024</u>, issue of the *Utah State Bulletin*.

In this publication, each **Proposed Rule** is preceded by a **Rule Analysis**. This analysis provides summary information about the **Proposed Rule** including the name of a contact person, anticipated cost impact of the rule, and legal cross-references.

Following the RULE ANALYSIS, the text of the PROPOSED RULE is usually printed. New rules or additions made to existing rules are underlined (example). Deletions made to existing rules are struck out with brackets surrounding them ([example]). Rules being repealed are completely struck out. A row of dots in the text between paragraphs (.....) indicates that unaffected text from within a section was removed to conserve space. Unaffected sections are not usually printed. If a PROPOSED RULE is too long to print, the Office of Administrative Rules may include only the RULE ANALYSIS. A copy of each rule that is too long to print is available from the filing agency or from the Office of Administrative Rules.

The law requires that an agency accept public comment on **PROPOSED RULES** published in this issue of the *Utah State Bulletin* until at least May 15, 2024. The agency may accept comment beyond this date and will indicate the last day the agency will accept comment in the **RULE ANALYSIS**. The agency may also hold public hearings. Additionally, citizens or organizations may request the agency hold a hearing on a specific **PROPOSED RULE**. Section 63G-3-302 requires that a hearing request be received by the agency proposing the rule "in writing not more than 15 days after the publication date of the proposed rule."

From the end of the public comment period through <u>August 13, 2024</u>, the agency may notify the Office of Administrative Rules that it wants to make the **Proposed Rule** effective. The agency sets the effective date. The date may be no fewer than seven calendar days after the close of the public comment period nor more than 120 days after the publication date of this issue of the *Utah State Bulletin*. Alternatively, the agency may file a **Change in Proposed Rule** in response to comments received. If the Office of Administrative Rules does not receive a **Notice of Effective Date** or a **Change in Proposed Rule**, the **Proposed Rule** lapses.

The public, interest groups, and governmental agencies are invited to review and comment on **Proposed Rules**. Comment may be directed to the contact person identified on the **Rule Analysis** for each rule.

PROPOSED RULES are governed by Section 63G-3-301, Rule R15-2, and Sections R15-4-3, R15-4-4, R15-4-5a, R15-4-9, and R15-4-10.

The Proposed Rules Begin on the Following Page

NOTICE OF PROPOSED RULE		
TYPE OF FILING: New		
Rule or Section R66-3 Filing ID: 56367		

Agency Information

-g,		
1. Department:	Agriculture and Food	
Agency:	Medical Cannabis and Industrial Hemp	
Building:	TSOB South Bldg, Floor 2	
Street address:	4315 S 2700 W	
City, state and zip:	Taylorsville, UT 84129	
Mailing address:	PO Box 146500	
City, state and zip:	Salt Lake City, UT 84114-6500	

Contact persons:

Name:	Phone:	Email:	
Amber Brown	385- 245- 5222	ambermbrown@utah.gov	
Brandon Forsyth	801- 710- 9945	bforsyth@utah.gov	
Kelly Pehrson	385- 977- 2147	kwpehrson@utah.gov	

Please address questions regarding information on this notice to the persons listed above.

General Information

2. Rule or section catchline:

R66-3. Quality Assurance Testing on Cannabis

3. Purpose of the new rule or reason for the change:

This rule originally existed as Rule R68-29.

However, a repeal has been filed on Rule R68-29 so it can be reenacted under a new title specific to medical cannabis and industrial hemp, Title R66.

An additional small change is needed to allow tiny amounts of THC O Acetate (THC-OAc) to be present in samples without them failing quality assurance testing. This clarification is needed to allow safe products to stay in the market despite the unintentional presence of a small amount of artificially derived cannabinoid.

4. Summary of the new rule or change:

This new rule is substantively the same as Rule R68-29, which is being repealed and simultaneously reenacted as Rule R66-3 under the new Title R66.

One change has been made to previous Subsection R68-29-7(2) which would allow for small amounts of THC-OAc to be present in samples without failing quality assurance testing.

(EDITOR'S NOTE: The proposed repeal of Rule R68-29 is under ID No. 56366 in this issue, April 15, 2024, of the Bulletin.)

Fiscal Information

5. Provide an estimate and written explanation of the aggregate anticipated cost or savings to:

A) State budget:

This proposed new rule does not have a fiscal impact to the state because the rule text is not changing between the repeal and the new rule.

It is just being repealed to be reenacted under new Rule R66-3.

The new language in Section R66-3-7 will not have a fiscal impact because the Department of Agriculture and Food (Department) laboratory was already testing for THC-OAc and will continue to do so.

B) Local governments:

Local governments will not be impacted because they do not participate in the medical cannabis program.

C) Small businesses ("small business" means a business employing 1-49 persons):

This change does not have a fiscal impact to small businesses because this rule is not changing, it is just being repealed to be reenacted under Rule R66-3.

The new language in Section R66-3-7 will impact small businesses in a positive way because it will allow cannabis licensees to continue to sell their products. The impact cannot be quantified at this time because the Department does not know how many of each licensee's products may have THC-OAc, nor does the Department have access to information regarding what portion of each licensee's revenue would be put in jeopardy without the ability to sell these products or whether that would impact the viability of their business overall.

The changes will not have a negative fiscal impact because the Department has not yet acted on a licensee based on the presence of THC-OAc.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

This change does not have a fiscal impact to non-small businesses because the rule is not changing, it is just being repealed to be reenacted under Rule R66-3.

The new language in Section R66-3-7 will impact nonsmall businesses in a positive way because it will allow cannabis licensees to continue to sell their products. The impact cannot be quantified at this time because the Department does not know how many of each licensee's products may have THC-OAc, nor does the Department have access to information regarding what portion of each licensee's revenue would be put in jeopardy without the ability to sell these products or whether that would impact the viability of their business overall.

The changes will not have a negative fiscal impact because the Department has not yet acted on a licensee based on the presence of THC-OAc.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

This change does not have a fiscal impact to other persons because this rule is not changing, it is just being repealed to be reenacted under Rule R66-3.

The change to Section R68-29-7 will not impact other persons because they are not cannabis licensees.

F) Compliance costs for affected persons (How much will it cost an impacted entity to adhere to this rule or its changes?):

Compliance costs are not impacted because the substance of this rule is not changing with this filing.

The change in Section R68-29-7 does not change the cost of participating in the program.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table Fiscal Cost FY2024 FY2025 FY2026 State \$0 \$0 \$0 Government Local \$0 \$0 Governments Small \$0 \$0 \$0 Businesses Non-Small \$0 \$0 \$0 Businesses Other SO. \$0 \$0 Persons Total Fiscal \$0 \$0 Cost **Fiscal** FY2024 FY2025 FY2026 **Benefits** \$0 State \$0 \$0

Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Benefits	\$0	\$0	\$0
Net Fiscal Benefits	\$0	\$0	\$0

H) Department head comments on fiscal impact and approval of regulatory impact analysis:

The Commissioner of the Department of Agriculture and Food, Craig W. Buttars, has reviewed and approved this regulatory impact analysis.

Citation Information

6. Provide citations to the statutory authority for the rule. If there is also a federal requirement for the rule, provide a citation to that requirement:

I.*	•	
Subsection		
4-2-103(1)(i)		

Public Notice Information

8. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. See Section 63G-3-302 and Rule R15-1 for more information.)

A)	Comments	will	be	accepted	05/15/2024
unti	il:				

9. This rule change MAY 05/22/2024 become effective on:

NOTE: The date above is the date the agency anticipates making the rule or its changes effective. It is NOT the effective date.

Agency Authorization Information

or designee	Craig W. Buttars, Commissioner	Date:	03/11/2024
and title:			

R66. Agriculture and Food, Medical Cannabis and Industrial Hemp.

R66-3. Quality Assurance Testing on Cannabis.

R66-3-1. Authority and Purpose.

Pursuant to Subsection 4-41a-701(3), this rule establishes the standards for cannabis and cannabis product potency testing and sets limits for water activity, foreign matter, microbial life, pesticides, residual solvents, heavy metals, and mycotoxins.

Government

R66-3-2. Definitions.

- (1) "Adulterant" means any poisonous or deleterious substance in a quantity that may be injurious to health, including:
 - (a) pesticides;
 - (b) heavy metals;
 - (c) solvents;
 - (d) microbial life;
 - (e) toxins; or
 - (f) foreign matter; or
 - (g) artificially derived cannabinoids.
- (2) "Analyte" means a substance or chemical component that is undergoing analysis.
- (3)(a) "Artificially derived cannabinoid" means a chemical substance that is created by a chemical reaction that changes the molecular structure of any chemical substance derived from the cannabis plant.
 - (b) "Artificially derived cannabinoid" does not include:
- (i) a naturally occurring chemical substance that is separated from the cannabis plant by a chemical or mechanical extraction process; or
- (ii) a cannabinoid that is produced by decarboxylation from a naturally occurring cannabinoid acid without the use of a chemical catalyst.
 - (4) "Batch" means a quantity of:
- (a) cannabis concentrate produced on a particular date and time, following clean up until the next clean up during which the same lots of cannabis are used;
- (b) cannabis product produced on a particular date and time, following clean up until the next clean up during which cannabis concentrate is used; or
- (c) cannabis flower from a single strain and growing cycle packaged on a particular date and time, following clean up until the next clean up during which lots of cannabis are being used.
 - (5) "Cannabinoid" means any:
- (a) naturally occurring derivative of cannabigerolic acid (CAS 25555-57-1); or
- (b) any chemical compound that is both structurally and chemically similar to a derivative of cannabigerolic acid.
 - (6) "Cannabis" means any part of the marijuana plant.
 - (7) "Cannabinoid concentrate" means:
- (a) the product of any chemical or physical process applied to naturally occurring biomass that concentrates or isolates the cannabinoids contained in the biomass; or
- (b) any amount of a natural or artificially derived cannabinoid.
 - (8) "Cannabis cultivation facility" means a person that:
 - (a) possesses cannabis;
 - (b) grows or intends to grow cannabis; and
- (c) sells or intends to sell cannabis to a cannabis cultivation facility or a cannabis processing facility.
- (9) "Cannabis cultivation byproduct" means any portion of a cannabis plant that is not intended to be sold as a cannabis plant product.
- (10) "Cannabis derivative product" means a cannabis product made using cannabis concentrate.
- (11) "Cannabinoid isolate" means a concentrated form of cannabinoid with less than a 0.3% combined concentration of THC or any THC analog that is intended for use as an ingredient in a cannabinoid product but is not grown by a Utah licensed cannabis cultivation facility.

- (12) "Cannabis plant product" means any portion of a cannabis plant intended to be sold in a form that is recognizable as a portion of a cannabis plant.
 - (13) "Cannabis processing facility" means a person that:
- (a) acquires or intends to acquire cannabis from a cannabis production establishment;
- (b) possesses cannabis with the intent to manufacture a cannabis product;
- (c) manufactures or intends to manufacture a cannabis product from unprocessed cannabis or cannabis concentrate; and
- (d) sells or intends to sell a cannabis product to a medical cannabis pharmacy.
 - (14) "Cannabis product" means a product that:
 - (a) is intended for human use; and
 - (b) contains cannabis or delta 9-tetrahydrocannabinol.
 - (15) "CBD" means cannabidiol (CAS 13956-29-1).
- (16) "CBDA" means cannabidiolic acid, (CAS 1244-58-2).
- (17) "Certificate of analysis" (COA) means a document produced by a testing laboratory listing the quantities of the various analytes for the performed testing.
- (18) "Delta-9-tetrahydrocannabinol" or "delta-9-THC" means the cannabinoid identified as CAS #1972-08-03, the primary psychotropic cannabinoid in cannabis.
- (19) "Department" means the Utah Department of Agriculture and Food.
- (20) "Final product" means a reasonably homogenous cannabis product in its final packaged form created using the same standard operating procedures and the same formulation.
 - (21) "Foreign matter" means:
- (a) any matter that is present in a cannabis lot that is not a part of the cannabis plant; or
- (b) any matter that is present in a cannabis or cannabinoid product that is not listed as an ingredient, including seeds.
- (22) "Industrial hemp" means a cannabis plant that contains less than 0.3% total THC by dry weight.
 - (23) "Lot" means the quantity of:
- (a) flower from a single strain of cannabis and growing cycle produced on a particular date and time, following clean up until the next clean up during which the same materials are used; or
- (b) trim, leaves, or other plant matter from cannabis plants produced on a particular date and time, following clean up until the next clean up.
 - (24) "Pest" means:
 - (a) any insect, rodent, nematode, fungus, weed; or
- (b) any other form of terrestrial or aquatic plant or animal life, virus, bacteria, or other microorganisms that are injurious to health or to the environment or that the department declares to be a pest.
 - (25) "Pesticide" means any:
- (a) substance or mixture of substances, including a living organism, that is intended to prevent, destroy, control, repel, attract, or mitigate any insect, rodent, nematode, snail, slug, fungus, weed, or other forms of plant or animal life that are normally considered to be a pest or that the commissioner declares to be a pest;
- (b) any substance or mixture of substances intended to be used as a plant regulator, defoliant, or desiccant; and
- (c) any spray adjuvant, such as a wetting agent, spreading agent, deposit builder, adhesive, or emulsifying agent with deflocculating properties of its own, used with a pesticide to aid in the application or effect of a pesticide.

- (26) "Sampling technician" means a person tasked with collecting a representative sample of a cannabis plant product, cannabis concentrate, or cannabis product from a cannabis production establishment who is:
 - (a) an employee of the department;
- (b) an employee of an independent cannabis laboratory that is licensed by the department to perform sampling; or
- (c) a person authorized by the department to perform sampling.
- (27) "Standard operating procedure" (SOP) means a document providing detailed instruction for the performance of a task.
- (28) "THC" means delta-9-tetrahydrocannabinol (CAS 1972-08-3).
- (29) "THCA" means delta-9-tetrahydrocannabinolic acid (CAS 23978-85-0).
- (30) "THC analog" means the same as the term is defined in Subsection 4-41-102(23).
- (31) "Total CBD" means the sum of the determined amounts of CBD and CBDA.
- (32) "Total THC" means the sum of the determined amounts of delta-9-THC and delta-9-THCA, according to the formula: Total THC = delta-9-THC + (delta-9-THCA x 0.877).
- (33) "Unit" means each individual portion of an individually packaged product.
- (34) "Unknown Cannabinoid" means any component of a cannabis plant product, cannabis concentrate, or cannabis product that a laboratory determines is likely to be a cannabinoid by comparison of physical properties, including molecular weight, retention time, and absorption spectra but is not included in Table 2 or Table 3.
- (35) "Water activity" is a dimensionless measure of the water present in a substance that is available to microorganisms; calculated as the partial vapor pressure of water in the substance divided by the standard state partial vapor pressure of pure water at the same temperature.

R66-3-3. Required Cannabis, Cannabis Product, and Cannabinoid Isolate Tests.

- (1) Before the transfer of cannabis biomass from a cannabis cultivation facility to a cannabis processing facility, the cultivation facility shall make a declaration to the department that the biomass to be transferred is either a cannabis plant product or a cannabis cultivation byproduct.
- (2) A representative sample of each batch or lot of cannabis plant product shall be tested by an independent cannabis testing laboratory to determine:
 - (a) the water activity of the sample;
- (b) the amount of total THC, total CBD, and any THC analog know to be present in the sample; and
- (c) the presence of adulterants in the sample, as specified in Table 1.
 - (3) Required testing shall be performed either:
- (a) before the transfer of the cannabis plant product to a cannabis processing facility; or
- (b) following the transfer of the cannabis plant product to a cannabis processing facility.
- (4) If cannabis plant product is tested before being transferred to a cannabis processing facility, the cannabis plant product shall be tested for microbial contaminants and foreign matter a second time following the transfer.
 - (5) Cannabis cultivation byproduct shall either be:

- (a) chemically or physically processed to produce a cannabis concentrate for incorporation into cannabis derivative product; or
 - (b) destroyed pursuant to Section 4-41a-405.
- (6) Cannabis concentrate shall be tested by an independent cannabis testing laboratory before it is incorporated into a cannabis derivative product to determine:
 - (a) the cannabinoid profile; and
- (b) the presence of adulterants in the sample, as specified in Table 1.
- (7) A medical cannabis processor shall isolate any artificially derived cannabinoids present in the cannabis concentrate to a purity of greater than 95%, with a 5% margin of error, as determined by an independent cannabis testing laboratory using liquid chromatography-mass spectroscopy or an equivalent method.
- (8) Before the transfer of a cannabis product to a medical cannabis pharmacy an independent cannabis testing laboratory shall test a representative sample of the product to determine:
- (a) the water activity of the sample, as determined applicable by the department;
- (b) the quantity of any cannabinoid or terpene to be listed on the product label; and
- (c) the presence of adulterants in the sample, as specified in Table 1.
- (9) Testing results for cannabis concentrate may be applied to cannabis product derived therefrom, provided that the processing steps used to produce the product are unlikely to change the results of the test, as determined by the department.
- (10) The department may require mycotoxin testing of a cannabis plant product or cannabis product if they have reason to believe that mycotoxins may be present.
- (11) Mycotoxin testing shall be required for cannabis concentrate.
- (12) A cannabis processing facility may remediate a cannabis plant product, cannabis concentrate, or cannabis product that fails any of the required adulterant testing standards after submitting and gaining approval for a remediation plan from the department.
- (13) A remediation plan shall be submitted to the department within 15 days of the receipt of a failed testing result.
- (14) A remediation plan shall be carried out and the cannabis plant product or cannabis concentrate shall be prepared for resampling within 60 days of department approval of the remediation plan.
- (15) Resampling or retesting of a cannabis lot or batch that fails any of the required testing standards is not allowed until the lot or batch has been remediated.
- (16) A cannabis lot or cannabis product batch that is not or cannot be remediated in the specified time shall be destroyed pursuant to Section 4-41a-405.
- (17) If test results cannot be retained in the Inventory Control System, the laboratory shall:
 - (a) keep a record of test results;
 - (b) issue a COA for required tests; and
 - (c) keep a copy of the COA on the laboratory premises.
 - (18) Cannabinoid isolate shall be tested for:
 - (a) solvents;
 - (b) pesticides;
 - (c) microbials;
 - (d) heavy metals; and
 - (e) mycotoxins.

- (19) Cannabinoid isolate shall be accompanied by a COA that complies with the standards included in Section R68-29-5 through Section R68-29-12.
- (20) Cannabinoid isolate shall receive cannabinoid testing from an independent cannabis testing laboratory before being used to create a cannabis derivative product.

	<u>TABLE 1</u>			
	Required Test by	Sample Type		
Test	Cannabis Plant	Cannabis	Cannabis	
	Product	Concentrate	Product	
Moisture	Required	X	X	
Content				
Water	Required	X	X	
Activity	_			
Foreign	Required	Required	Required	
<u>Matter</u>				
Potency	Required	Required	Required	
Microbial	Required	Required	Required	
Pesticides	Required	Required	Required	
Residual	X	Required	Required	
Solvents				
<u>Heavy</u>	Required	Required	Required	
Metals				

R68-29-4. Sampling Cannabis and Cannabis Products.

- (1) The entity that requests testing of a cannabis plant product lot, cannabis concentrate batch, or cannabis product batch shall make the entirety of the lot or batch available to the sampling technician.
- (2) The lot or batch being sampled shall be contained in a single location and physically separated from other lots or batches.
- (3) The sample shall be collected by a sampling technician who is unaffiliated with the entity that requested testing of the cannabis lot or cannabis product batch unless an exception is granted by the department.
- (4) The owner of the cannabis lot or cannabis product batch and any of their employees may not assist in the selection of the sample.
- (5) The sampling technician shall collect the representative sample in a manner set forth in a SOP, that is ISO 17025 compliant, maintained by the laboratory that will perform the testing.
- (6) When collecting the representative sample, the sampling technician shall:
- (a) use sterile gloves, instruments, and a glass or plastic container to collect the sample;
 - (b) place tamper proof tape on the container; and
- (c) appropriately label the sample pursuant to Section R68-30-6.
- (7) For cannabis plant product lots, the sampling technician shall take a minimum representative sample according to the following schedule:
- (a) 10 subunits with an average weight of one gram each for lots weighing 5 kilograms or less;
- (b) 16 subunits with an average weight of one gram each for lots weighing 5.01-9 kilograms;
- (c) 22 subunits with an average weight of one gram each for lots weighing 9.01-14 kilograms;
- (d) 28 subunits with an average weight of one gram each for lots weighing 14.01-18 kilograms;
- (e) 32 subunits with an average weight of one gram each for lots weighing 18.01-23 kilograms.

- (8) For cannabis concentrate, the sampling technician shall take a minimum representative sample according to the following schedule:
- (a) 10 mL or grams for batches of one liter or kilogram or less; or
- (b) 20 mL or grams for batches of four liters or kilograms or less.
- (9) For cannabis products in their final product form, the sampling technician shall take the following minimum number of sample units, the combined total weight of which must be at least 10 grams, not including packaging materials:
- (a) four units for a sample product batch with 5-500 products;
- (b) six units for a sample product batch with 501-1000 products;
- (c) eight units for a sample product batch with 1,001-5,000 products; and
- (d) ten units for a sample product batch with 5,001-10,000 products.
- (10) Additional material may be included in the representative sample if the material is necessary to perform the required testing.

R66-3-5. Moisture Content Testing and Water Activity Standards.

- (1) The moisture content of a sample and related lot of cannabis shall be reported on the COA as a mass over mass percentage.
- (2) A sample and related lot of cannabis fail quality assurance testing if the water activity of the representative sample is found to be greater than 0.65.
- (3) A sample and related cannabis or cannabinoid product batch intended for human consumption fail quality assurance testing if the water activity of the representative sample is greater than 0.65, unless water is a component of the product formulation and is listed as an ingredient.

R66-3-6. Foreign Matter Standards.

- A sample and related lot or batch of cannabis, cannabis product, or cannabinoid product fail quality assurance testing if:
- (1) the sample contains foreign matter visible to the unaided human eye;
- (2) the sample is found to contain microscopic foreign matter considered to be harmful or estimated to comprise greater than 3% of the mass of the representative sample as determined by the testing laboratory; or
- (3) foreign matter is found that is suspected of having been intentionally added to the sample to increase its visual appeal or market value; or
- (4) for a cannabis plant product, the total number of seeds found is greater than the net weight of the sample collected divided by 1.75.

R66-3-7. Potency Testing.

- (1) A lot or batch of cannabis plant product, cannabis concentrate, or cannabis product shall have its cannabinoid profile determined and listed on a COA as total THC, total CBD, and the total concentration of any THC analog known to be present.
- (2) A lot or batch of cannabis plant product, cannabis concentrate, or cannabis product fail quality assurance testing for cannabinoid content if:

- (a) it is not analyzed for each of the analytes listed in Table
- 2: (b) the determined amount of any analyte exceeds its action level given in Table 2:
- (c) any tetrahydrocannabinol acetate (THC-OAc) is found in a cannabis concentrate with a relative peak area greater than 1% of the total cannabinoid peak area or in a cannabis product with a relative peak area greater than 0.5% of the total cannabinoid peak area as determined by high-performance liquid chromatography with a diode array detector;
- (d) any of the artificially derived cannabinoids listed in Table 3 are found to have a peak area greater than 1% of total cannabinoid peak area as determined by high-performance liquid chromatography with a diode array detector (HPLC-DAD); or
- (e) greater than 10% of the total cannabinoid peak area is comprised of unknown cannabinoids after peaks smaller than 1% of the total peak area have been excluded as determined by high-performance liquid chromatography with a diode array detector (HPLC-DAD).

TABLE 2 Cannabinoid Components and Action Levels			
Analyte	Chemical Abstract Service	Action Level	
<u>Δ9-Tetrahydrocannabidiol</u> (<u>Δ9-THC</u>)	<u>1972-08-03</u>	No Limit	
<u>Δ8-Tetrahydrocannabidiol</u> (<u>Δ8-THC</u>)	<u>5957-75-5</u>	No Limit	
Δ9-Tetrahydrocannabinolic acid (THCA)	23978-85-0	No Limit	
Δ9-Tetrahydrocannabivarin (THCV)	31262-37-0	No Limit	
Cannabidiol (CBD)	13956-29-1	No Limit	
Cannabidiolic acid (CBDA)	1244-58-2	No Limit	
Cannabidivarin (CBDV)	24274-48-4	No Limit	
Cannabinol (CBN)	<u>521-35-7</u>	No Limit	
Cannabigerol (CBG)	<u>25654-31-3</u>	No Limit	
Cannabichromene (CBC)	20675-51-8	No Limit	
Cannabigerolic acid (CBGA)	<u>25555-57-1</u>	No Limit	
Cannabichromenic acid (CBCA)	20408-52-0	No Limit	
9R-Δ6a,10a-Tetrahydrocannabidiol (Δ3-THC)	95720-01-7	1%1	
9S-Δ6a,10a-Tetrahydrocannabidiol (Δ3-THC)	95720-02-8	1%1	
(6aR,9R)-Δ10- Tetrahydrocannabidiol	95543-62-7	<u>1%¹</u>	
(6aR,9S)-Δ10-Tetrahydrocannabidiol	<u>95588-87-7</u>	<u>1%¹</u>	
Cannabicitran (CBTC)	31508-71-1	2%	

¹If the laboratory performing the testing cannot chromatographically separate 9(R+S)- $\Delta 6a$, 10a-Tetrahydrocannabidiol or (6aR, 9(R+S))- $\Delta 10$ -Tetrahydrocannabidiol, then the action level for the combined isomers will be 1.5%.

TABLE 3 Artificially Derived Cannabinoids		
Analyte	Chemical Abstract Service	
Hexahydrocannabinol (HHC)	<u>36403-90-4,</u> <u>36403-91-5</u>	
3-Heptyl-delta(1)-tetrahydrocannabinol (THCP)	54763-99-4, 51768-60-6	

R66-3-8. Microbial Standards.

- (1) A sample and related lot or batch of cannabis plant product, cannabis concentrate, or cannabis product fail quality assurance testing for microbiological contaminants if the results exceed the limits as set forth in Table 4.
- (2) Each sample and related lot or batch of cannabis plant product, cannabis concentrate, or cannabis product shall be tested for total aerobic microbial count and total combined yeast and mold. The specific pathogens listed in Table 4 may be tested for at the discretion of the department.

	TABLE 4			
Microbi	al Analytes and Action Levels			
<u>Material</u>	Microbial Limit Requirement (cfu/g or			
	cfu/ml)			
Cannabis Plant	Total Aerobic Microbial Count			
Product	<u><100,000</u>			
	Absence of E. Coli and Salmonella spp.			
	Absence of Aspergillus fumigatus,			
	Aspergillus flavus, Aspergillus niger,			
	and Aspergillus terreus			
Cannabinoid	Total Aerobic Microbial Count ≤10,000			
Concentrate	Total Combined Yeast and Mold Count			
	<u>≤1,000</u>			
	Absence of STEC			
	Absence of Pseudomonas			
	Absence of Staph			
Orally Consumable	Total Aerobic Microbial Count ≤10,000			
Products	Total Combined Yeast and Mold Count			
	<u>≤1,000</u>			
	Absence of E. Coli and Salmonella spp.			
	Absence of Staph			
Transdermal	Total Aerobic Microbial Count ≤250			
<u>Products</u>	Total Yeast and Mold Count ≤250			
	Absence of Pseudomonas			
	Absence of Staph			

R66-3-9. Pesticide Standards.

- (1) Only pesticides allowed by the department may be used in the cultivation of cannabis.
- (2) If an independent cannabis laboratory identifies a pesticide that is not allowed under Subsection R68-29-5(1) and is above the action levels provided in Subsection R68-29-5(3) that lot or batch from which the sample was taken has failed quality assurance testing.
- (3) A sample and related lot or batch of cannabis, cannabis product, or cannabinoid product fail quality assurance testing for pesticides if the results exceed the limits as set forth in Table 5.

TABLE 5 Pesticide Analytes and Action Levels				
Analyte Pesticide Ana	Chemical Abstract	Action		
Allalyte	Service	<u>Level</u>		
	(CAS) Registry			
	number	<u>ppm</u>		
Abamectin	71751-41-2	0.5		
Acephate	30560-19-1	0.4		
Acequinocyl	57960-19-7	2		
<u>Acetamiprid</u>	135410-20-7	0.2		
Aldicarb	116-06-3	0.4		
Azoxystrobin	131860-33-8	0.2		
Bifenazate	<u>149877-41-8</u>	0.2		
Bifenthrin	82657-04-3	0.2		
Boscalid	188425-85-6	0.4		
Carbaryl	63-25-2	0.2		
Carbofuran	1563-66-2	0.2		
<u>Chlorantraniliprole</u>	500008-45-7	0.2		
<u>Chlorfenapyr</u>	122453-73-0	1		
<u>Chlorpyrifos</u>	<u>2921-88-2</u>	0.2		
Clofentezine	74115-24-5	0.2		
Cypermethrin	52315-07-8	1		
Daminozide	1596-84-5	1		
DDVP (Dichlorvos)	62-73-7	0.1		
Diazinon	333-41-5	0.2		
Dimethoate	60-51-5	0.2		
<u>Ethoprophos</u>	13194-48-4	0.2		
<u>Etofenprox</u>	80844-07-1	0.4		
Etoxazole	153233-91-1	0.2		
Fenoxycarb	72490-01-8	0.2		
Fenpyroximate	134098-61-6	0.4		
Fipronil	120068-37-3	0.4		
Flonicamid	158062-67-0	1		
Fludioxonil	131341-86-1	0.4		
Hexythiazox	78587-05-0	1		
Imazalil	35554-44-0	0.2		
<u>Imidacloprid</u>	138261-41-3	0.4		
Kresoxim-methyl	143390-89-0	0.4		
Malathion	143390-89-0	0.2		
Metalaxyl	57837-19-1	0.2		
Methiocarb	<u>2032-65-7</u>	0.2		
Methomyl	16752-77-5	0.4		
Methyl parathion	298-00-0	0.2		
MGK-264	<u>113-48-4</u>	0.2		
Myclobutanil	88671-89-0	0.2		
Naled	300-76-5	0.5		
Oxamyl	23135-22-0	1		
Paclobutrazol	<u>76738-62-0</u>	0.4		
Permethrins	<u>52645-53-1</u>	0.2		
Phosmet	732-11-6	0.2		
Piperonyl butoxide	<u>51-03-6</u>	2		
Prallethrin	23031-36-9	0.2		
Propiconazole	<u>60207-90-1</u>	0.4		
<u>Propoxur</u>	114-26-1	0.2		
Pyrethrins	8003-34-7	<u>0.2</u> <u>1</u>		
Pyridaben	96489-71-3	0.2		
Spinosad Spinosad	168316-95-8	0.2		
Spiromesifen	<u>283594-90-1</u>	0.2		
<u>Spirotetramat</u>	<u>203313-25-1</u>	0.2		
Spiroxamine Spiroxamine	<u>118134-30-8</u>	0.2		
<u>Tebuconazole</u>	80443-41-0	0.4		
Thiacloprid	<u>111988-49-9</u>	0.4		
<u>Thiamethoxam</u>	153719-23-4	0.2		
1 III GII CAI CAI III	100111-40-T	<u>0.4</u>		

<u>Trifloxystrobin</u>	<u>141517-21-7</u>	0.2

- (4) Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8).
- (5) Pyrethrins should be measured as the cumulative residues of pyrethrin I (CAS 121-21-1), pyrethrin II (CAS 121-29-9), cinerin 1 (CAS 25402-06-6), and jasmolin 1 (CAS 4466-14-2).
- (6) Abamectin is a composite of the amounts of avermectin B1a and avermectin B1b.

R66-3-10. Residual Solvent Standards.

- (1) A sample and related lot or batch of cannabis plant product, cannabis concentrate, or cannabis product fails quality assurance testing for residual solvents if the results exceed the limits provided in Table 6 unless the solvent is:
 - (a) a component of the product formulation;
 - (b) listed as an ingredient; and
- (c) generally considered to be safe for the intended form of use.

TABLE 6					
List of Solvents	s and Action Levels	<u>s</u>			
Solvent Chemical Action					
	Abstract	<u>ppm</u>			
	Service				
	(CAS)				
	Registry				
	<u>number</u>				
1,2 Dimethoxyethane	<u>110-71-4</u>	<u>100</u>			
1,4 Dioxane	<u>123-9</u>	<u>380</u>			
1-Butanol	71-36-3	5,000			
1-Pentanol	71-41-0	5,000			
1-Propanol	71-23-8	5,000			
2-Butanol	78-92-2	5,000			
2-Butanone	78-93-3	5,000			
2-Ethoxyethanol	110-80-5	160			
2-methylbutane	78-78-4	5,000			
2-Propanol (IPA)	67-63-0	5,000			
Acetone	67-64-1	5,000			
Acetonitrile	75-05-8	410			
Benzene	71-43-2	2			
Butane	106-97-8	5,000			
Cumene	98-82-8	<u>70</u>			
Cyclohexane	110-82-7	3,880			
Dichloromethane	<u>75-09-2</u>	<u>600</u>			
2,2-dimethylbutane	75-83-2	290			
2,3-dimethylbutane	79-29-8	290			
1,2-dimethylbenzene	95-47-6	See Xylenes			
1,3-dimethylbenzene	108-38-3	See Xylenes			
1,4-dimethylbenzene	106-42-3	See Xylenes			
Dimethyl sulfoxide	67-68-5	5,000			
Ethanol	64-17-5	5,000			
Ethyl acetate	141-78-6	5,000			
Ethylbenzene	100-41-4	See Xylenes			
Ethyl ether	60-29-7	5,000			
Ethylene glycol	107-21-1	620			
Ethylene Oxide	75-21-8	50			
Heptane	142-82-5	5,000			
n-Hexane	110-54-3	290			
Isopropyl acetate	290	5,000			
<u>Methanol</u>	67-56-1	3,000			
Methylpropane	<u>75-28-5</u>	<u>5,000</u>			

2-Methylpentane	107-83-5	<u>290</u>
3-Methylpentane	<u>96-14-0</u>	<u>290</u>
N,N-dimethylacetamide	<u>127-19-5</u>	1,090
N,N-dimethylformamide	<u>68-12-2</u>	<u>880</u>
Pentane	109-66-0	5,000
<u>Propane</u>	<u>74-98-6</u>	<u>5,000</u>
<u>Pyridine</u>	<u>110-86-1</u>	<u>100</u>
Sulfolane	126-33-0	<u>160</u>
<u>Tetrahydrofuran</u>	109-99-9	<u>720</u>
<u>Toluene</u>	108-88-3	890
<u>Xylenes</u>	<u>1330-20-7</u>	<u>2,170</u>

(2)) X	ylenes	is a	comb	ination	of	the	follo	owing	:

- (a) 1,2-dimethylbenzene;
- (b) 1,3-dimethylbenzene;
 - (c) 1,4-dimethylbenzene; and
- (d) ethyl benzene.

R66-3-11. Heavy Metal Standards.

A sample and related lot or batch of cannabis plant product, cannabis concentrate, cannabis product, or vaporizer cartridges fail quality assurance testing for heavy metals if the results exceed the limits provided in Table 7.

<u>TABLE 7</u> Heavy Metals				
Metals	Natural Health Products Acceptable limits in parts per million			
Arsenic	<u><2</u>			
<u>Cadmium</u>	<0.82			
Lead	<1.2			
<u>Mercury</u>	<u><0.4</u>			

R66-3-12. Mycotoxin Standards.

A sample and related lot or batch of cannabis plant product, cannabis concentrate, or cannabis product fail quality assurance testing for mycotoxin if the results exceed the limits provided in Table 8.

TABLE 8 Mycotoxin				
<u>Test</u>	Specification			
The Total of				
Aflatoxin B1,				
Aflatoxin B2,				
Aflatoxin G1, and				
Aflatoxin G2	<20 ppb of substance			
Ochratoxin A.	< 20 ppb of substance			

KEY: cannabis testing, quality assurance, cannabis laboratory Date of Last Change: 2024

Authorizing, and Implemented or Interpreted Law: 4-41a-701(3)

NOTICE OF PROPOSED RULE				
TYPE OF FILING: Repeal				
Rule or Section R68-29 Filing ID: 56366				

Agency Information

agonoy information			
1. Department:	Agriculture and Food		
Agency:	Plant Industry		
Building:	TSOB South Bldg, Floor 2		
Street address:	4315 S 2700 W		
City, state and zip:	Taylorsville, UT 84129		
Mailing address:	PO Box 146500		
City, state and zip:	Salt Lake City, UT 84114-6500		

Contact persons:

Name:	Phone:	Email:
Amber Brown	385- 245- 5222	ambermbrown@utah.gov
Brandon Forsyth	801- 710- 9945	bforsyth@utah.gov
Kelly Pehrson	385- 977- 2147	kwpehrson@utah.gov

Please address questions regarding information on this notice to the persons listed above.

General Information

2. Rule or section catchline:

R68-29. Quality Assurance Testing on Cannabis

3. Purpose of the new rule or reason for the change:

The rule is being repealed so it can be simultaneously reenacted under a new title specific to medical cannabis and industrial hemp, Title R66.

4. Summary of the new rule or change:

This rule is repealed in its entirety so it can be reenacted under a new title specific to medical cannabis and industrial hemp.

The substantive content will remain the same under new Rule R66-3.

(EDITOR'S NOTE: The proposed new Rule R66-3 is under ID No. 56367 in this issue, April 15, 2024, of the Bulletin.)

Fiscal Information

5. Provide an estimate and written explanation of the aggregate anticipated cost or savings to:

A) State budget:

This proposed repeal does not have a fiscal impact to the state because the rule text is not changing between the repeal and the new rule.

It is reenacted as new Rule R66-3.

B) Local governments:

Local governments will not be impacted because they do not participate in the medical cannabis program.

C) Small businesses ("small business" means a business employing 1-49 persons):

This proposed repeal does not have a fiscal impact to small businesses because the rule text is not changing between the repeal and the new rule.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

This proposed repeal does not have a fiscal impact to nonsmall businesses because the rule text is not changing between the repeal and the new rule.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

This proposed repeal does not have a fiscal impact to other persons because the rule text is not changing between the repeal and the new rule.

F) Compliance costs for affected persons (How much will it cost an impacted entity to adhere to this rule or its changes?):

Compliance costs are not impacted because the substance of the rule is not changing with this filing.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table

Fiscal Cost	FY2024	FY2025	FY2026
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0

Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Cost	\$0	\$0	\$0
Fiscal Benefits	FY2024	FY2025	FY2026
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Benefits	\$0	\$0	\$0
Net Fiscal Benefits	\$0	\$0	\$0

H) Department head comments on fiscal impact and approval of regulatory impact analysis:

The Commissioner of the Department of Agriculture and Food, Craig W. Buttars, has reviewed and approved this regulatory impact analysis.

Citation Information

6. Provide citations to the statutory authority for the rule. If there is also a federal requirement for the rule, provide a citation to that requirement:

provide a common to man requirement.		
Subsection 4-2-103(1)(i)		

Public Notice Information

- **8.** The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. See Section 63G-3-302 and Rule R15-1 for more information.)
- A) Comments will be accepted 05/15/2024 until:

9. This rule change MAY 05/22/2024 become effective on:

NOTE: The date above is the date the agency anticipates making the rule or its changes effective. It is NOT the effective date.

Agency Authorization Information

Agency head or designee	Craig W. Buttars, Commissioner	Date:	03/11/2024
and title:			

R68. Agriculture and Food, Plant Industry. [R68-29. Quality Assurance Testing on Cannabis. R68-29-1. Authority and Purpose.

Pursuant to Subsection 4-41a-701(3), this rule establishes the standards for cannabis and cannabis product potency testing and sets limits for water activity, foreign matter, microbial life, pesticides, residual solvents, heavy metals, and mycotoxins.

- R68-29-2. Definitions. (1) "Adulterant" means any poisonous or deleterious substance in a quantity that may be injurious to health, including: (a) pesticides; (b) heavy metals; (c) solvents; (d) microbial life; (e) toxins; or (f) foreign matter; or (g) artificially derived cannabinoids. (2) "Analyte" means a substance or chemical component that is undergoing analysis. (3)(a) "Artificially derived cannabinoid" means a chemical substance that is created by a chemical reaction that changes the molecular structure of any chemical substance derived from the cannabis plant.
 - (b) "Artificially derived cannabinoid" does not include:

 (i) a naturally occurring chemical substance that
- (i) a naturally occurring chemical substance that is separated from the cannabis plant by a chemical or mechanical extraction process; or
- (ii) a cannabinoid that is produced by decarboxylation from a naturally occurring cannabinoid acid without the use of a chemical catalyst.
- (4) "Batch" means a quantity of:
- (a) cannabis concentrate produced on a particular date and time, following clean up until the next clean up during which the same lots of cannabis are used;
- (b) cannabis product produced on a particular date and time, following clean up until the next clean up during which cannabis concentrate is used; or
- (c) cannabis flower from a single strain and growing cycle packaged on a particular date and time, following clean up until the next clean up during which lots of cannabis are being used.
 - (5) "Cannabinoid" means any:
- (a) naturally occurring derivative of cannabigerolic acid (CAS 25555-57-1); or
- (b) any chemical compound that is both structurally and chemically similar to a derivative of cannabigerolic acid.
 - (6) "Cannabis" means any part of the marijuana plant.
- (7) "Cannabinoid concentrate" means:
- (a) the product of any chemical or physical process applied to naturally occurring biomass that concentrates or isolates the cannabinoids contained in the biomass; or
- (b) any amount of a natural or artificially derived cannabinoid.
- (8) "Cannabis cultivation facility" means a person that:
- (a) possesses cannabis;
- (b) grows or intends to grow cannabis; and

- (c) sells or intends to sell cannabis to a cannabis cultivation facility or a cannabis processing facility.
- (9) "Cannabis cultivation byproduct" means any portion of a cannabis plant that is not intended to be sold as a cannabis plant product.
- (10) "Cannabis derivative product" means a cannabis product made using cannabis concentrate.
- (11) "Cannabinoid isolate" means a concentrated form of cannabinoid with less than a 0.3% combined concentration of THC or any THC analog that is intended for use as an ingredient in a cannabinoid product but is not grown by a Utah licensed cannabis cultivation facility.
- (12) "Cannabis plant product" means any portion of a cannabis plant intended to be sold in a form that is recognizable as a portion of a cannabis plant.
 - (13) "Cannabis processing facility" means a person that:
- (a) acquires or intends to acquire cannabis from a cannabis production establishment;
- (b) possesses cannabis with the intent to manufacture a cannabis product;
- (c) manufactures or intends to manufacture a cannabis product from unprocessed cannabis or cannabis concentrate; and
- - (14) "Cannabis product" means a product that:
 - (a) is intended for human use; and
 - (b) contains cannabis or delta 9-tetrahydrocannabinol.
 - (15) "CBD" means cannabidiol (CAS 13956-29-1).
- (16) "CBDA" means cannabidiolic acid, (CAS 1244-58-2).
- (17) "Certificate of analysis" (COA) means a document produced by a testing laboratory listing the quantities of the various analytes for the performed testing.
- (18) "Delta 9 tetrahydrocannabinol" or "delta 9 THC" means the cannabinoid identified as CAS #1972-08-03, the primary psychotropic cannabinoid in cannabis.
- (19) "Department" means the Utah Department of Agriculture and Food.
- (20) "Final product" means a reasonably homogenous cannabis product in its final packaged form created using the same standard operating procedures and the same formulation.
 - (21) "Foreign matter" means:
- (a) any matter that is present in a cannabis lot that is not a part of the cannabis plant; or
- (b) any matter that is present in a cannabis or cannabinoid product that is not listed as an ingredient, including seeds.
- (22) "Industrial hemp" means a cannabis plant that contains less than 0.3% total THC by dry weight.
 - (23) "Lot" means the quantity of:
- (a) flower from a single strain of cannabis and growing eyele produced on a particular date and time, following clean up until the next clean up during which the same materials are used; or
- (b) trim, leaves, or other plant matter from cannabis plants produced on a particular date and time, following clean up until the next clean up.
 - (24) "Pest" means:
 - (a) any insect, rodent, nematode, fungus, weed; or
- (b) any other form of terrestrial or aquatic plant or animal life, virus, bacteria, or other microorganisms that are injurious to health or to the environment or that the department declares to be a pest.
 - (25) "Pesticide" means any:

- (a) substance or mixture of substances, including a living organism, that is intended to prevent, destroy, control, repel, attract, or mitigate any insect, rodent, nematode, snail, slug, fungus, weed, or other forms of plant or animal life that are normally considered to be a pest or that the commissioner declares to be a pest;
- (b) any substance or mixture of substances intended to be used as a plant regulator, defoliant, or desiceant; and
- (e) any spray adjuvant, such as a wetting agent, spreading agent, deposit builder, adhesive, or emulsifying agent with deflocculating properties of its own, used with a pesticide to aid in the application or effect of a pesticide.
- (26) "Sampling technician" means a person tasked with collecting a representative sample of a cannabis plant product, cannabis concentrate, or cannabis product from a cannabis production establishment who is:
- (a) an employee of the department;
- (b) an employee of an independent cannabis laboratory that is licensed by the department to perform sampling; or
- (c) a person authorized by the department to perform sampling.
- (27) "Standard operating procedure" (SOP) means a document providing detailed instruction for the performance of a task.
- (28) "THC" means delta 9 tetrahydrocannabinol (CAS 1972-08-3).
- (29) "THCA" means delta 9 tetrahydrocannabinolic acid (CAS 23978-85-0).
- (30)(a) "THC analog" means the same as the term is defined in Subsection 4-41-102(23).
- (31) "Total CBD" means the sum of the determined amounts of CBD and CBDA.
- (32) "Total THC" means the sum of the determined amounts of delta 9 THC and delta 9 THCA, according to the formula: Total THC = delta 9 THC + (delta 9 THCA x 0.877).
- (33) "Unit" means each individual portion of an individually packaged product.
- (34) "Unknown Cannabinoid" means any component of a cannabis plant product, cannabis concentrate, or cannabis product that a laboratory determines is likely to be a cannabinoid by comparison of physical properties, including molecular weight, retention time, and absorption spectra but is not included in Table 2 or Table 3.
- (35) "Water activity" is a dimensionless measure of the water present in a substance that is available to microorganisms; calculated as the partial vapor pressure of water in the substance divided by the standard state partial vapor pressure of pure water at the same temperature.

R68-29-3. Required Cannabis, Cannabis Product, and Cannabinoid Isolate Tests.

- (1) Before the transfer of cannabis biomass from a cannabis cultivation facility to a cannabis processing facility, the cultivation facility shall make a declaration to the department that the biomass to be transferred is either a cannabis plant product or a cannabis cultivation byproduct.
- (2) A representative sample of each batch or lot of eannabis plant product shall be tested by an independent cannabis testing laboratory to determine:
- (a) the water activity of the sample;
- (b) the amount of total THC, total CBD, and any THC analog know to be present in the sample; and

- (c) the presence of adulterants in the sample, as specified in Table 1.
- (3) Required testing shall be performed either:
- (a) before the transfer of the cannabis plant product to a cannabis processing facility; or
- (b) following the transfer of the cannabis plant product to a cannabis processing facility.
- (4) If cannabis plant product is tested before being transferred to a cannabis processing facility, the cannabis plant product shall be tested for microbial contaminants and foreign matter a second time following the transfer.
 - (5) Cannabis cultivation byproduct shall either be:
- (a) chemically or physically processed to produce a cannabis concentrate for incorporation into cannabis derivative product; or
 - (b) destroyed pursuant to Section 4-41a-405.
- (6) Cannabis concentrate shall be tested by an independent cannabis testing laboratory before it is incorporated into a cannabis derivative product to determine:
 - (a) the cannabinoid profile; and
- (b) the presence of adulterants in the sample, as specified in Table 1.
- (7) A medical cannabis processor shall isolate any artificially derived cannabinoids present in the cannabis concentrate to a purity of greater than 95%, with a 5% margin of error, as determined by an independent cannabis testing laboratory using liquid chromatography mass spectroscopy or an equivalent method.
- (8) Before the transfer of a cannabis product to a medical cannabis pharmacy an independent cannabis testing laboratory shall test a representative sample of the product to determine:
- (a) the water activity of the sample, as determined applicable by the department;
- (b) the quantity of any cannabinoid or terpene to be listed on the product label; and
- (c) the presence of adulterants in the sample, as specified in Table 1.
- (9) Testing results for cannabis concentrate may be applied to cannabis product derived therefrom, provided that the processing steps used to produce the product are unlikely to change the results of the test, as determined by the department.
- (10) The department may require mycotoxin testing of a cannabis plant product or cannabis product if they have reason to believe that mycotoxins may be present.
- (11) Mycotoxin testing shall be required for cannabis concentrate.
- (12) A cannabis processing facility may remediate a cannabis plant product, cannabis concentrate, or cannabis product that fails any of the required adulterant testing standards after submitting and gaining approval for a remediation plan from the department.
- (13) A remediation plan shall be submitted to the department within 15 days of the receipt of a failed testing result.
- (14) A remediation plan shall be carried out and the cannabis plant product or cannabis concentrate shall be prepared for resampling within 60 days of department approval of the remediation plan.
- (15) Resampling or retesting of a cannabis lot or batch that fails any of the required testing standards is not allowed until the lot or batch has been remediated.
- (16) A cannabis lot or cannabis product batch that is not or cannot be remediated in the specified time shall be destroyed pursuant to Section 4-41a-405.

- (17) If test results cannot be retained in the Inventory Control System, the laboratory shall:
 - (a) keep a record of test results;
 - (b) issue a COA for required tests; and
- (c) keep a copy of the COA on the laboratory premises.
 - (18) Cannabinoid isolate shall be tested for:
 - (a) solvents:
 - (b) pesticides;
- (c) microbials:
 - (d) heavy metals; and
- (e) mycotoxins.
- (19) Cannabinoid isolate shall be accompanied by a COA that complies—with the standards included in Section R68-29-5 through Section R68-29-12.
- (20) Cannabinoid isolate shall receive cannabinoid testing from an independent cannabis testing laboratory before being used to create a cannabis derivative product.

TABLE 1				
	Required Test by Sample Type			
Test	Cannabis Plant	Cannabis	Cannabis	
	Product	Concentrate	Product	
Moisture	Required	X	X	
Content				
Water	Required	X	X	
Activity				
Foreign	Required	Required	Required	
Matter				
Potency	Required	Required	Required	
Microbial	Required	Required	Required	
Pesticides	Required	Required	Required	
Residual	X	Required	Required	
Solvents				
Heavy	Required	Required	Required	
Metals				

R68-29-4. Sampling Cannabis and Cannabis Products.

- (1) The entity that requests testing of a cannabis plant product lot, cannabis concentrate batch, or cannabis product batch shall make the entirety of the lot or batch available to the sampling technician.
- (2) The lot or batch being sampled shall be contained in a single location and physically separated from other lots or batches.
- (3) The sample shall be collected by a sampling technician who is unaffiliated with the entity that requested testing of the cannabis lot or cannabis product batch unless an exception is granted by the department.
- (4) The owner of the cannabis lot or cannabis product batch and any of their employees may not assist in the selection of the sample.
- (5) The sampling technician shall collect the representative sample in a manner set forth in a SOP, that is ISO 17025 compliant, maintained by the laboratory that will perform the testing.
- (6) When collecting the representative sample, the sampling technician shall:
- (a) use sterile gloves, instruments, and a glass or plastic container to collect the sample;
- (b) place tamper proof tape on the container; and
- (c) appropriately label the sample pursuant to Section R68-30-6.
- (7) For cannabis plant product lots, the sampling technician shall take a minimum representative sample according to the following schedule:

- (a) 10 subunits with an average weight of one gram each for lots weighing 5 kilograms or less;
- (b) 16 subunits with an average weight of one gram each for lots weighing 5.01-9 kilograms;
- (c) 22 subunits with an average weight of one gram each for lots weighing 9.01-14 kilograms;
- (d) 28 subunits with an average weight of one gram each for lots weighing 14.01-18 kilograms;
- (e) 32 subunits with an average weight of one gram each for lots weighing 18.01-23 kilograms.
- (8) For cannabis concentrate, the sampling technician shall take a minimum representative sample according to the following schedule:
- (a) 10 mL or grams for batches of one liter or kilogram or less; or
- (b) 20 mL or grams for batches of four liters or kilograms or less.
- (9) For cannabis products in their final product form, the sampling technician shall take the following minimum number of sample units, the combined total weight of which must be at least 10 grams, not including packaging materials:
- (a) four units for a sample product batch with 5-500 products;
- (b) six units for a sample product batch with 501-1000 products;
- (e) eight units for a sample product batch with 1,001-5,000 products; and
- (d) ten units for a sample product batch with 5,001-10,000 products.
- (10) Additional material may be included in the representative sample if the material is necessary to perform the required testing.

R68-29-5. Moisture Content Testing and Water Activity Standards.

- (1) The moisture content of a sample and related lot of cannabis shall be reported on the COA as a mass over mass percentage.
- (2) A sample and related lot of cannabis fail quality assurance testing if the water activity of the representative sample is found to be greater than 0.65.
- (3) A sample and related cannabis or cannabinoid product batch intended for human consumption fail quality assurance testing if the water activity of the representative sample is greater than 0.65, unless water is a component of the product formulation and is listed as an ingredient.

R68-29-6. Foreign Matter Standards.

- (1) A sample and related lot or batch of cannabis, cannabis product, or cannabinoid product fail quality assurance testing if:
- (a) the sample contains foreign matter visible to the unaided human eye;
- (b) the sample is found to contain microscopic foreign matter considered to be harmful or estimated to comprise greater than 3% of the mass of the representative sample as determined by the testing laboratory; or
- (c) foreign matter is found that is suspected of having been intentionally added to the sample to increase its visual appeal or market value; or
- (d) for a cannabis plant product, the total number of seeds found is greater than the net weight of the sample collected divided by 1.75.

R68-29-7. Potency Testing.

- (1) A lot or batch of cannabis plant product, cannabis concentrate, or cannabis product shall have its cannabinoid profile determined and listed on a COA as total THC, total CBD, and the total concentration of any THC analog known to be present.
- (2) A lot or batch of cannabis plant product, cannabis concentrate, or cannabis product fail quality assurance testing for cannabinoid content if:
- (a) it is not analyzed for each of the analytes listed in Table 2:
- (b) the determined amount of any analyte exceeds its action level given in Table 2;
- (c) it is found to contain a detectable amount of any of the artificially derived cannabinoids listed in Table 3 as determined by liquid chromatography-mass spectroscopy; or
- (d) greater than 10% of the total cannabinoid peak area is comprised of unknown cannabinoids after peaks smaller than 1% of the total peak area have been excluded as determined by high-performance liquid chromatography with a diode array detector (HPLC-DAD).

TABLE 2 Cannabinoid Components and Action Levels		
Cumuomera compensario	Chemical	
Analyte	Abstract Service	Action Level
Δ9 Tetrahydrocannabidiol		
<u>(Д9 ТНС)</u>	1972 08 03	No Limit
Δ8 Tetrahydrocannabidiol -(Δ8 THC)	5957-75-5	No Limit
Δ9-Tetrahydrocannabinolic acid (THCA)	23978-85-0	No Limit
A9-Tetrahydrocannabivarin (THCV)	31262-37-0	No Limit
Cannabidiol (CBD)	13956-29-1	No Limit
Cannabidiolic acid (CBDA)	1244-58-2	No Limit
Cannabidivarin (CBDV)	24274-48-4	No Limit
Cannabinol (CBN)	521-35-7	No Limit
Cannabigerol (CBG)	25654-31-3	No Limit
Cannabichromene (CBC)	20675-51-8	No Limit
Cannabigerolic acid (CBGA)	25555-57-1	No Limit
Cannabichromenic acid (CBCA)	20408-52-0	No Limit
9R Δ6a,10a Tetrahydrocannabidiol (Δ3 THC)	95720 01 7	1% ¹
9S A6a,10a Tetrahydrocannabidiol (A3 THC)	95720 02 8	1% ¹
(6aR,9R) Δ10- Tetrahydrocannabidiol	95543 62 7	1% [↓]
(6aR,9S)-Δ10-Tetrahydrocannabidiol	95588-87-7	1% ¹
Cannabicitran (CBTC)	31508-71-1	2%

¹If the laboratory performing the testing cannot chromatographically separate 9(R+S) Δ6a,10a Tetrahydrocannabidiol or (6aR,9(R+S)) Δ10 Tetrahydrocannabidiol, then the action level for the combined isomers will be 1.5%.

TABLE 3 Artificially Derived Cannabinoids		
Analyte Chemical Abstract Service		
Hexahydrocannabinol (HHC)	36403 90 4, 36403 91 5	
Tetrahydrocannabinol acetate (THC-OAe)	23132-17-4	
3-Heptyl-delta(1)-tetrahydrocannabinol (THCP)	54763-99-4, 51768-60-6	

R68-29-8. Microbial Standards.

- (1) A sample and related lot or batch of cannabis plant product, cannabis concentrate, or cannabis product fail quality assurance testing for microbiological contaminants if the results exceed the limits as set forth in Table 4.
- (2) Each sample and related lot or batch of cannabis plant product, cannabis concentrate, or cannabis product shall be tested for total aerobic microbial count and total combined yeast and mold. The specific pathogens listed in Table 4 may be tested for at the discretion of the department.

	TABLE 4
Microbial Analytes and Action Levels	
Material	Microbial Limit Requirement (cfu/g or
	cfu/ml)
Cannabis Plant	Total Aerobie Microbial Count
Product	<u>≤100,000</u>
	Absence of E. Coli and Salmonella spp.
	Absence of Aspergillus fumigatus,
	Aspergillus flavus, Aspergillus niger,
	and Aspergillus terreus
Cannabinoid	Total Aerobie Microbial Count ≤10,000
Concentrate	Total Combined Yeast and Mold Count
	≤1,000
	Absence of STEC
	Absence of Pseudomonas
	Absence of Staph
Orally Consumable	Total Aerobic Microbial Count ≤10,000
Products	Total Combined Yeast and Mold Count
	<u>≤1,000</u>
	Absence of E. Coli and Salmonella spp.
	Absence of Staph
Transdermal	Total Aerobic Microbial Count ≤250
Products	Total Yeast and Mold Count ≤250
	Absence of Pseudomonas
	Absence of Staph

R68-29-9. Pesticide Standards.

- (1) Only pesticides allowed by the department may be used in the cultivation of cannabis.
- (2) If an independent cannabis laboratory identifies a pesticide that is not allowed under Subsection R68-29-5(1) and is above the action levels provided in Subsection R68-29-5(3) that lot or batch from which the sample was taken has failed quality assurance testing.
- (3) A sample and related lot or batch of cannabis, cannabis product, or cannabinoid product fail quality assurance testing for pesticides if the results exceed the limits as set forth in Table 5.

	analytes and Action Levels	
Analyte	Chemical Abstract	Action
	Service	Level
	(CAS) Registry	ppm
4.1	number 71751 41 2	0.5
Abamectin	71751 41 2	0.5
Acephate	30560-19-1	0.4
Acequinocyl	57960 19 7	2
Acetamiprid	135410 20 7	0.2
Aldiearb	116-06-3	0.4
Azoxystrobin	131860 33 8	0.2
Bifenazate Bifenazate	149877-41-8	0.2
Bifenthrin	82657 04 3	0.2
Boscalid	188425 85 6	0.4
Carbaryl	63-25-2	0.2
Carbofuran	1563 66 2	0.2
Chlorantraniliprole	500008 45 7	0.2
Chlorfenapyr	122453-73-0	1
Chlorpyrifos	2921 88 2	0.2
Clofentezine	74115-24-5	0.2
Cypermethrin	52315-07-8	1
Daminozide	1596 84 5	1
DDVP (Dichlorvos)	62-73-7	0.1
Diazinon	333 41 5	0.2
Dimethoate	60-51-5	0.2
Ethoprophos	13194 48 4	0.2
Etofenprox	80844-07-1	0.4
Etoxazole	153233 91 1	0.2
Fenoxycarb	72490 01 8	0.2
Fenpyroximate	134098-61-6	0.4
Fipronil	120068 37 3	0.4
Flonicamid	158062 67 0	1
Fludioxonil	131341 86 1	0.4
Hexythiazox	78587 05 0	1
Imazalil	35554-44-0	0.2
Imidacloprid	138261 41 3	0.4
Kresoxim methyl	143390 89 0	0.4
Malathion	143390-89-0	0.2
Metalaxyl	57837 19 1	0.2 0.2
Methiocarb	2032-65-7	0.2
Methomyl	16752 77 5	0.4
Methyl parathion	298 00 0	0.2
MGK-264	113-48-4	0.2
Myclobutanil	88671 89 0	0.2
Naled	300-76-5	0.5
Oxamyl	23135-22-0	1
Paclobutrazol	76738 62 0	0.4
Permethrins	52645-53-1	0.2
Phosmet	732 11 6	0.2
Piperonyl butoxide	51-03-6	2
Prallethrin	23031 36 9	0.2
Propiconazole	60207-90-1	0.4
Propoxur	114-26-1	0.2
Pyrethrins	8003-34-7	1
Pyridaben	96489-71-3	0.2
Spinosad	96489-71-3 168316-95-8	0.2
_1	168316-93-8 283594-90-1	0.2
Spiromesifen Spirotetromet		_
Spirotetramat Communication	203313-25-1 118134-30-8	0.2
Spiroxamine Talassassassassassassassassassassassassas		0.4
This stands	80443-41-0	0.4
Thiacloprid	111988 49 9	0.2

Trifloxystrobin	141517 21 7	0.2

- (4) Permethrins should be measured as cumulative residue of cis—and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8).
- (5) Pyrethrins should be measured as the cumulative residues of pyrethrin I (CAS 121-21-1), pyrethrin II (CAS 121-29-9), cinerin I (CAS 25402-06-6), and jasmolin I (CAS 4466-14-2).
- (6) Abameetin is a composite of the amounts of avermeetin B1a and avermeetin B1b.

R68-29-10. Residual Solvent Standards.

- (1) A sample and related lot or batch of cannabis plant product, cannabis concentrate, or cannabis product fails quality assurance testing for residual solvents if the results exceed the limits provided in Table 6 unless the solvent is:
 - (a) a component of the product formulation;
 - (b) listed as an ingredient; and
- (c) generally considered to be safe for the intended form of use.

TABLE 6		
List of Solvents	and Action Levels	}
Solvent	Chemical	Action level
	Abstract	ppm
	Service	11
	(CAS)	
	Registry	
	number	
1,2 Dimethoxyethane	110-71-4	100
1,4 Dioxane	123 9	380
1-Butanol	71-36-3	5,000
1 Pentanol	71 41 0	5,000
1 Propanol	71 23 8	5,000
2 Butanol	78 92 2	5,000
2 Butanone	78 93 3	5,000
2-Ethoxyethanol	110-80-5	160
2 methylbutane	78 78 4	5,000
2-Propanol (IPA)	67-63-0	5,000
Acetone	67-64-1	5.000
Acetonitrile	75 05 8	410
Benzene	71-43-2	2
Butane	106 97 8	5,000
Cumene	98-82-8	70
Cyclohexane	110 82 7	3,880
Dichloromethane	75 09 2	600
2,2-dimethylbutane	75-83-2	-290
2,3 dimethylbutane	79 29 8	290
1,2 dimethylbenzene	95 47 6	See Xylenes
1,3-dimethylbenzene	108-38-3	See Xylenes
1,4 dimethylbenzene	106-42-3	See Xylenes
Dimethyl sulfoxide	67-68-5	5,000
Ethanol	64 17 5	5,000
Ethyl acetate	141 78 6	5,000
Ethylbenzene	100-41-4	See Xylenes
Ethyl ether	60 29 7	5,000
Ethylene glycol	107-21-1	620
Ethylene Oxide	75 21 8	50
Heptane	142 82 5	5,000
n-Hexane	110-54-3	290
Isopropyl acetate	290	5,000
Methanol	67-56-1	3,000
Methylpropane	75 28 5	5,000

2 Methylpentane	107-83-5	290
3 Methylpentane	96-14-0	290
N,N dimethylacetamide	127 19 5	1,090
N,N dimethylformamide	68-12-2	880
Pentane	109-66-0	5,000
Propane	74 98 6	5,000
Pyridine	110 86 1	100
Sulfolane	126-33-0	160
Tetrahydrofuran	109 99 9	720
Toluene	108-88-3	890
Xylenes	1330 20 7	2,170

(2) Xylenes is a combination of the following:

(a) 1,2-dimethylbenzene;

(b) 1,3-dimethylbenzene;

(c) 1,4-dimethylbenzene; and

(d) ethyl benzene.

R68-29-11. Heavy Metal Standards.

A sample and related lot or batch of cannabis plant product, cannabis concentrate, cannabis product, or vaporizer cartridges fail quality assurance testing for heavy metals if the results exceed the limits provided in Table 7.

TABLE 7		
Heavy Heavy	Metals	
Metals	Natural Health Products Acceptable limits in parts per million	
Arsenic	<2	
Cadmium	<0.82	
Lead	<1.2	
Mercury	<0.4	

R68-29-12. Mycotoxin Standards.

A sample and related lot or batch of cannabis plant product, cannabis concentrate, or cannabis product fail quality assurance testing for mycotoxin if the results exceed the limits provided in Table 8.

TABLE 8			
Mycotoxin			
Test	Specification		
The Total of			
Aflatoxin B1,			
Aflatoxin B2,			
Aflatoxin G1, and			
Aflatoxin G2 <20 ppb of substance			
Ochratoxin A.	<20 ppb of substance		

KEY: cannabis testing, quality assurance, cannabis laboratory Date of Last Change: February 5, 2024

Authorizing, and Implemented or Interpreted Law: 4-41a-701(3)

NOTICE OF PROPOSED RULE			
TYPE OF FILING: Repeal and Reenact			
Rule or Section Number:	R426-10	Filing ID: 56397	

Agency Information

1. Department:	Health and Human Services
Agency:	Population Health, Emergency Medical Services
Building:	Cannon Health Building
Street address:	288 N 1460 W
City, state and zip:	Salt Lake City, UT 84116
Mailing address:	PO Box 142004
City, state and zip:	Salt Lake City, UT 84114-2004

Contact persons:

Name:	Phone:	Email:
Dean Penovich	801- 913- 2621	dpenovich@utah.gov
Mariah Noble	385- 214- 1150	mariahnoble@utah.gov

Please address questions regarding information on this notice to the persons listed above.

General Information

2. Rule or section catchline:

R426-10. Air Ambulance Licensure and Operations

3. Purpose of the new rule or reason for the change:

The Department of Health and Human Services (Department) is amending this rule to clarify requirements for accreditation for licensed air ambulance providers.

These rule amendments are being made at the request of the Air Ambulance Committee and affected stakeholders.

Additionally, upon review of this rule, the Department determined that the rule's original language should be restructured with significant updates to style and formatting to improve clarity and consistency with the Rulewriting Manual for Utah.

4. Summary of the new rule or change:

The filing clarifies the responsibilities for accreditation and licensed providers.

Additionally, this filing updates definitions and makes updates to style and formatting throughout this rule to improve clarity and consistency with the Rulewriting Manual for Utah.

Fiscal Information

- 5. Provide an estimate and written explanation of the aggregate anticipated cost or savings to:
- A) State budget:

There is no anticipated fiscal impact to the state budget with this proposed rule, as these updates to provider reporting requirements clarify responsibilities already in practice for the state and any other updates to this rule make style and formatting changes to improve clarity and consistency with the Rulewriting Manual for Utah.

B) Local governments:

There is no anticipated fiscal impact to local governments with this proposed rule, as these updates to provider reporting requirements clarify responsibilities and any other updates make style and formatting changes to improve clarity and consistency with the Rulewriting Manual for Utah.

Additionally, local governments do not own or operate licensed air ambulance services and do not have a role in the licensing, accreditation, or associated reporting for the provision of services.

C) Small businesses ("small business" means a business employing 1-49 persons):

There is an inestimable fiscal impact to small businesses with this proposed rule, as this rule change aligns state requirements for an air ambulance accreditation service with national model standards.

The additional criteria of training requirements for personnel and the inclusion of a board of directors required by this rule change could add a cost to small businesses offering air ambulance accreditation services that have not previously implemented those practices.

This amount is inestimable because small businesses may already have staff that meet some or all of the additional training requirements and may already have access to a board of directors. Compensation to a board of directors is in no way required by this rule and is solely left to the discretion of a small business.

It is not anticipated that this change will result in any savings for small businesses. Any other updates make style and formatting changes to improve clarity and consistency with the Rulewriting Manual for Utah.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

There is an inestimable fiscal impact to non-small businesses with this proposed rule, as this rule change aligns state requirements for an air ambulance accreditation service with national model standards.

The additional criteria of training requirements for personnel and the inclusion of a board of directors required by this rule change could add a cost to non-small businesses offering air ambulance accreditation services that have not previously implemented those practices.

This amount is inestimable because non-small businesses may already have staff that meet some or all of the additional training requirements and may already have access to a board of directors. Compensation to a board of directors is in no way required by this rule and is solely left to the discretion of a non-small business.

It is not anticipated that this change will result in any savings for non-small businesses. Any other updates make style and formatting changes to improve clarity and consistency with the Rulewriting Manual for Utah.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

There is no anticipated fiscal impact to other persons with this proposed rule, as these updates to provider reporting requirements clarify responsibilities and any other updates make style and formatting changes to improve clarity and consistency with the Rulewriting Manual for Utah.

Additionally, other persons do not own or operate licensed air ambulance services and do not have a role in the licensing, accreditation, or associated reporting for the provision of services.

F) Compliance costs for affected persons (How much will it cost an impacted entity to adhere to this rule or its changes?):

As there are no affected persons, there are no anticipated compliance costs.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table

Fiscal Cost	FY2024	FY2025	FY2026
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Cost	\$0	\$0	\$0

Fiscal Benefits	FY2024	FY2025	FY2026
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Benefits	\$0	\$0	\$0
Net Fiscal Benefits	\$0	\$0	\$0

H) Department head comments on fiscal impact and approval of regulatory impact analysis:

The Executive Director of the Department of Health and Human Services, Tracy S. Gruber, has reviewed and approved this regulatory impact analysis.

Citation Information

6. Provide citations to the statutory authority for the rule. If there is also a federal requirement for the rule, provide a citation to that requirement:

Section 26B-4-102

Public Notice Information

- 8. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. See Section 63G-3-302 and Rule R15-1 for more information.)
- A) Comments will be accepted 05/15/2024 until:

9. This rule change MAY 05/22/2024 become effective on:

NOTE: The date above is the date the agency anticipates making the rule or its changes effective. It is NOT the effective date.

Agency Authorization Information

	Tracy S. Gruber,	03/25/2024
or designee	Executive Director	
and title:		

[R426. Health and Human Services, Population Health Emergency Medical Services.

R426-10. Air Ambulance Licensure and Operations. R426-10-100. Authority and Purpose.

(1) Section 26B-4-102 authorizes this rule.

(2) This rule provides department requirements for air ambulance provider licensure and operations.

R426-10-200. Air Ambulance Service Application and Licensure.

- (1) No person, either as owner, agent or otherwise, shall furnish, operate, conduct, maintain, advertise or otherwise be engaged in the provision of emergency medical care using an air ambulance unless currently licensed by the State of Utah Department of Health and Human Services. The state retains the right to conduct air ambulance service investigations per state law.
- (2) The following shall be complied with to obtain a State of Utah air ambulance license:
- (a) A person from another state shall not provide emergency medical services aboard an air ambulance within the state unless that person complies with the requirements under this chapter. This requirement applies to any person that provides patient care within the State of Utah.
- (b) Applicants desiring to be licensed or to renew its license for an air ambulance service shall submit the applicable fees and application on department approved forms prior to being issued a license to operate.
- (e) Applicants shall submit a copy of air ambulance service license(s) concurrently issued and on file with other states.
- (d) Applicants shall provide information about individual aircraft that will be used while providing medical care licensed under this Chapter to the state for physical inspection of medical compliance.
- (e) Applicants shall provide results to the department from the prior 10 years of any investigations, disciplinary actions, or exclusions with the potential to impact the quality of medical care provided to patients. Such investigations, disciplinary actions, or exclusions that shall be reported apply to all current and prior legal names of the entity and all other names used by the entity to provide health—care—services—(see—R426-10-600,—Change—of Ownership/Management) and any person or entity who had direct or indirect ownership of at least 50% interest in the air ambulance service within the prior 10-year period.
- (f) Applicants shall identify an air ambulance service medical director pursuant to requirements found in R426-5-2400. The medical director shall be responsible for medical direction and oversight regarding credentialing air medical providers, clinical practice, and all patient care issues. Personnel changes in medical director shall be reported to the department within 30 days.
- (g) Applicants shall submit all required fees, when applicable.
- (h) When the name or ownership of the air ambulance service changes, an air ambulance service license application shall be submitted to the department at least 30 days prior to the effective date of the change.
- (i) Air ambulance services shall provide emergency information about the service to the department. This information shall be used by the department to provide effective communications and resource management, in the event of a statewide or localized disaster or emergency situation. The information is included in the initial and renewal application for certification of air ambulance services.
- (j) Air ambulance permits and licenses are not transferable.

 (k) Duplicate air ambulance permits and licenses can be obtained by submitting a written request to the department. The request shall include a letter signed by the licensee certifying that the original permit and license has been lost, destroyed or rendered unusable.

- (l) Each licensed air ambulance provider shall obtain a new air ambulance inspection and subsequent permit or certification from the department prior to returning an air ambulance to service following a modification, change or any renovation that results in a change to the stretcher placement or seating in the air ambulance interior configuration to ensure the aircraft meets patient care requirements.
- (m) The licensed air ambulance service shall file an amended list of aircraft that are used to provide service within the state to the department within 30 days after an air ambulance is added or removed permanently from service.
- (n) The licensure period for all licensed air ambulance services shall be for 4 years.
- (o) Licensure authorizes the air ambulance provider only to provide emergency medical care using an air ambulance, and does not constitute authority to provide air transportation. Such authority shall be obtained from the Federal Aviation Administration and United States Department of Transportation.
- (p) The following regulations shall not relieve the licensed air ambulance provider from compliance with other statutes, rules, or regulations in effect for medical personnel and emergency medical services, involving licensing and authorizations, insurance, prescribed and proscribed acts and penalties.

R426-10-300. Exceptions to Air Ambulance Service Application and Licensure.

- (1) This rule does not apply to the following:
- (a) An air ambulance or air ambulance service operated by an agency of the United States government.
- (b) Services that provide rescue and evacuation equipment and aircraft owned and operated by a governmental entity whose primary role is not to transport patients by air ambulance, and who is not receiving payment for such services.
- (c) Evacuation and rescue equipment used and owned by the department of public safety in air, ground, or water evacuation.

R426-10-400. Air Ambulance Service Deemed Status.

- (1) The department may grant deemed status for state license to an air ambulance provider that has received accreditation from a department recognized accreditation service. An air ambulance provider who has deemed status may receive a license if they meet all of the requirements for application and licensure.
- (2) To be recognized by the department as an approved accreditation organization for the purposes of this section, the accrediting organization shall meet the following minimum standards:
- (a) Publish standards that are equivalent to or exceed the standards in this chapter.
- (b) Publish standards which address every component of a medical transport service that could potentially impact the quality of eare and patient safety with respect to communications centers, pilots, drivers, maintenance, patient care providers, and administrative support.
- (c) Provide evidence of timely reviews of applications from providers seeking accreditation.
- (d) Procedures for random site visits, audits, and other strategies utilized to ensure an accredited provider or a provider seeking accreditation is adhering to the accreditation standards.
 - (e) Publish policies for the
 - (i) initial accreditation requirements;
- (ii) the tenure of accreditation, not to exceed three (3) years;

- (iii) the requirements for reaccreditation; and
- (iv) the accreditation decision making process.
- (f) Uses trained accreditation personnel with experience in medical transport at the level of accreditation and license for the level of accreditation being sought.
- (g) A formal training program that educates accreditation auditors in consistent interpretation of standards and policies of the accreditation agency.
- (h) Publish the required qualifications for accreditation personnel who conduct site surveys. Such qualifications must demonstrate an extensive depth of experience with and knowledge of the air ambulance industry.
- (i) Policies and standards that recognize the special circumstances of medical transport services that serve rural areas.
- (j) Demonstrate that accreditation standards are updated on a regular basis to stay current with changes in healthcare and air medical transportation.
- (k) Provide definition of all sentinel events including near misses. The accrediting agency shall outline the processes for notifying the department of such events and the process for investigating and instituting corrective measures for such events.
- (l) Provide information about the Board of Directors. Members of the Board of Directors shall have experience in the air medical transport industry. The Board of Directors shall include broad representation by members of relevant national organizations that are engaged in the development, training, and oversight of critical care and air medical patient transportation.
- (m) Clearly outline the Conflict of Interest Policy that excludes Board members or other accreditation agency representatives from participating in accreditation decisions, site surveys, or other processes when a real or potential conflict of interest exists.
 - (n) Publish fees for providers seeking accreditation.
- (p) Explain the procedure for a corrective action plan when an audit uncovers areas that are out of compliance.
- (r) Maintain insurance (General liability, Medical Professional Liability, Directors and Officers and Travel) and be able to present their current certificates of insurance to the state licensing agency.
- (s) Comply with all applicable Health Insurance Portability and Accountability Act (HIPAA) regulations, including any necessary requirements of a Business Associate entity.
- (t) Allow a department representative to be present during site surveys, investigations, and any other on-site visit performed in the Utah.
- (u) Provide simultaneous notification to the department of an air ambulance provider's accreditation decisions, corrective action, any changes in accreditation status, and sentinel event reports; and
- (v) List the accrediting agency's involvement in research to improve the air medical transportation industry.
- (3) A current list of recognized accreditation organizations is available on the department's website.

R426-10-500. Air Ambulance Service Compliance with State Licensure Requirements.

- (1) Deemed status recognition is intended to streamline the licensure process for air ambulance services by preventing duplicative documentation.
- (2) The department reserves the right to verify and inspect all equipment and documentation at any time to ensure that the air ambulance service maintains full compliance with requirements related to the air ambulance service licensure.

R426-10-600. Licensed Air Ambulance Provider Change of Ownership and Management.

- (1) When a currently licensed air ambulance provider anticipates a change of ownership, the current licensed air ambulance provider shall notify the department within thirty (30) calendar days before a change of ownership. A licensed air ambulance provider who is seeking a new license, shall submit an application for change of ownership along with the requisite fees and documentation within thirty (30) calendar days.
- (2) The conversion of a licensed air ambulance provider's legal structure, or the legal structure of an entity that has a direct or indirect ownership interest in the licensed air ambulance provider is not a change of ownership unless the conversion also includes a transfer of at least 50 percent of the licensed air ambulance provider's direct or indirect ownership interest to one or more new owners. Specific instances of what does or does not constitute a change of ownership are set forth below in section (4).
- (3) The department shall consider the following criteria in determining whether there is a change of ownership of a licensed air ambulance provider that requires a new license:
- (a) Sole proprietors:
- (i) The transfer of at least 50 percent of the ownership interest in a licensed air ambulance provider from a sole proprietor to another individual, whether or not the transaction affects the title to real property, shall be considered a change of ownership.
- (ii) Change of ownership does not include forming a corporation from the sole proprietorship with the proprietor as the sole shareholder.
- (b) Partnerships:
- (i) Dissolution of the partnership and conversion into any other legal structure shall be considered a change of ownership if the conversion also includes a transfer of at least 50 percent of the direct or indirect ownership to one or more new owners.
- (ii) Change of ownership does not include dissolution of the partnership to form a corporation with the same persons retaining the same shares of ownership in the new corporation.
- (c) Corporations:
- (i) Consolidation of two or more corporations resulting in the creation of a new corporate entity shall be considered a change of ownership if the consolidation includes a transfer of at least 50 percent of the direct or indirect ownership to one or more new owners.
- (iii) The transfer, purchase, or sale of shares in the corporation such that at least 50 percent of the direct or indirect ownership of the corporation is shifted to one or more new owners shall be considered a change of ownership.
 - (d) Limited liability companies:

- (i) The transfer of at least 50 percent of the direct or indirect ownership interest in the company shall be considered a change of ownership.
- (ii) The termination or dissolution of the company and the conversion thereof into any other entity shall be considered a change of ownership if the conversion also includes a transfer of at least 50 percent of the direct or indirect ownership to one or more new owners.
- (iii) Change of ownership does not include transfers of ownership interest between existing members if the transaction does not involve the acquisition of ownership interest by a new member. For the purposes of this subsection, "member" means a person or entity with an ownership interest in the limited liability company.
- (4) Management contracts, leases or other operational arrangements:
- (a) If the owner of an air ambulance service enters into a lease arrangement or management agreement whereby the owner retains no authority or responsibility for the operation and management of the licensed air ambulance provider, the action shall be considered a change of ownership that requires a new license.
- (5) Each applicant for a change of ownership shall provide the following information:
- (a) The legal name of the entity and all other names used by it to provide health care services. The applicant has a continuing duty to notify the department of all name changes at least thirty (30) calendar day prior to the effective date of the change.
- (b) Contact information for the entity including mailing address, telephone and facsimile numbers, e-mail address and website address, as applicable.
- (c) The identity of all persons and business entities with a controlling interest in the licensed air ambulance provider, including administrators, directors, managers and management contractors.
- (i) A non-profit corporation shall list the governing body and officers.
- (ii) A for profit corporation shall list the names of the officers and stockholders who directly or indirectly own or control five percent or more of the shares of the corporation.
- (iii) A sole proprietor shall include proof of lawful presence in the United States in compliance with section 24-76.5-103(4), C.R.S.
- (d) The name, address and business telephone number of every person identified in R426-10-600 as ownership or management and the individual designated by the applicant as the chief executive officer of the entity. If the addresses and telephone numbers provided above are the same as the contact information for the entity itself, the applicant shall also provide an alternate address and telephone number for at least one individual for use in the event of an emergency or closure of the licensed air ambulance provider.
- (e) Proof of professional liability insurance obtained and held in the name of the license applicant. Such coverage shall be maintained for the duration of the license term and the department shall be notified of any change in the amount, type or provider of professional liability insurance coverage during the license term.
- (f) Articles of incorporation, articles of organization, partnership agreement, or other organizing documents required by the secretary of state to conduct business in Utah; and by laws or equivalent documents that govern the rights, duties and capital contributions of the business entity.
- (g) The address of the entity's physical location and the name(s) of the owner(s) of each structure on the campus where licensed services are provided if different from those identified in elsewhere in this section.

- (h) A copy of any management agreement pertaining to operation of the entity that sets forth the financial and administrative responsibilities of each party.
- (i) If an applicant leases one or more building(s) to operate as a licensed air ambulance service, a copy of the lease shall be filed with the license application and show clearly in its context which party to the agreement is to be held responsible for the physical condition of the property.
- (j) A statement signed and dated contemporaneously with the application stating whether, within the previous ten (10) years, any of the new owners have been the subject of, or a party to, one of more of the following events, regardless of whether action has been stayed in a judicial appeal or otherwise settled between the parties.
- (i) Been convicted of a felony or misdemeanor involving crimes as described in R426-5-3100 under the laws of any state of the United States.
- (ii) Had a state license or federal certification denied, revoked, or suspended by another jurisdiction.
- (iii) Had a civil judgment or a criminal conviction in a case brought by federal, state or local authorities that resulted from the operation, management, or ownership of a health facility or other entity related to substandard patient care or health care fraud.
- (iv) Certifies whether it is presently or has ever been debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in a Contract by any governmental department or agency, whether international, national, state, or local, and certifies it is in compliance with Utah Code Ann. Section 63G-6a-904 et seq. and OMB guidelines at 2 C.F.R. 180 which implement Executive Order Nos. 12549 and 12689. Notification to the department within thirty (30) days must occur if debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in any contract by any governmental entity during the tenure of the license.
- (k) Any statement regarding the information requested in this section of rule shall include the following, if applicable:
- (i) If the event is an action by federal, state or local authorities; the full name of the authority, its jurisdiction, the case name, and the docket, proceeding or case number by which the event is designated, and a copy of the consent decree, order or decision.
- (ii) If the event is a felony or misdemeanor conviction involving moral turpitude, the court, its jurisdiction, the case name, the case number, a description of the matter or a copy of the indictment or charges, and any plea or verdict entered by the court.
- (iii) If the event involves a civil action or arbitration proceeding, the court or arbiter, the jurisdiction, the case name, the case number, a description of the matter or a copy of the complaint, and a copy of the verdict, the court or arbitration decision.
- (6) The existing licensee shall be responsible for correcting all rule violations and deficiencies in any current plan of correction before the change of ownership becomes effective. In the event that such corrections cannot be accomplished in the time frame specified, the prospective licensee shall be responsible for all uncorrected rule violations and deficiencies including any current plan of correction submitted by the previous licensee unless the prospective licensee submits a revised plan of correction, approved by the department, before the change of ownership becomes effective.
- (7) If the department issues a license to the new owner, the previous owner shall return its license to the department within five (5) calendar days of the new owner's receipt of its license.

R426-10-700. Air Ambulance Service Insurance Requirements.

- (1) Applicants for licensure shall demonstrate liability coverage for injuries to persons and for loss or property damages resulting from negligence by the service or medical crew. A license holder shall immediately notify the department and cease operations if the coverage required by this section is cancelled or suspended.
- (2) The department shall not issue an air ambulance license to an air ambulance provider unless the applicant for a license or the licensee has evidence of medical professional liability insurance that requires the insurer to compensate for injuries to persons or unintentional damage to property.
- (a) Applicants shall provide a copy of the current certificates of insurance demonstrating coverage for each air ambulance medical crew member that demonstrates, at a minimum, aggregate limits of \$1,000,000 per claim made and a total of \$3,000,000 for all claims made against the provider during the policy year.
- (3) Worker's compensation coverage is required as defined by the State of Utah regulating bodies.

R426-10-800. Base Locations.

- (1) A base location is the physical address where the crew, medical equipment and supplies, and the air ambulance are located. This will be designated by where the licensee operates and maintains or makes readily available records of operations.
- (2) The department may conduct announced and unannounced inspections at any locations where a licensed air ambulance provider operates at any time, including nights or weekends to determine compliance with these rules and regulations.
- (3) Each base location shall have readily available at all times the following:
- (i) Security measures in place that protects medical supplies and equipment onboard the air ambulance from tampering and unauthorized access, including pharmaceuticals. This would include direct visual monitoring or closed circuit television or the air ambulance must be in a secured location with locked perimeter fencing or hangar.
- (ii) State license or certificate of operation prominently displayed within the building.
 - (iii) Evidence of medical professional liability insurance.
- (iv) Drug Enforcement Agency Registration shall be prominently displayed within those buildings that store controlled substances.
 - (v) Current Post-Accident Incident Plan.
- (vi) Documentation showing the professional certifications and licenses of all flight crew members.
- (4) The facility shall be clean and free of debris at all times and shall be compliant with all state and local building and fire codes.

R426-10-900. Number and Type of Air Ambulances.

(1) Air ambulance providers shall provide a list of all air ambulances to be licensed and inspected for medical compliance by the department, including tail number (N-Number) and designation of (rotor or fixed wing) capabilities.

R426-10-1000. Capabilities of Medical Communications.

(1) A licensed air ambulance provider shall have a communications network available consisting of reliable equipment designed to afford clear communications related to the number and condition of patients among all stakeholders within the system.

- (2) The communication center shall demonstrate and maintain voice communications linkage with the radios and other allowable communication devices used in the air ambulance for the declared service area.

 (3) Licensed air ambulance providers shall have two-way communications equipment available that allows for or has the following:
- (a) Real time patient tracking that shall be maintained and documented every 15 minutes including the time the air ambulance returns to service following transport.
- (b) Appropriate wireless communications capabilities with dispatch centers, local first responders, to include fire, EMS, and law enforcement.
- (c) Communications with medical referral and receiving facilities to exchange patient information and consult with medical control that shall be capable of communications exclusive of the air traffic control system.
- (4) The licensed air ambulance provider base station or communications network shall be manned during all phases of patient treatment and transport.
- (5) An emergency plan for communications during power outages and in disaster situations shall be established.
- (6) A policy for delineating methods for maintaining medical communications during power outages and in disaster situations.

R426-10-1100. Coordination of Medical Communications.

- (1) All licensed air ambulance providers shall have flights coordinated by designated medical dispatchers or communications specialists.
- (3) Communication specialists are required for processing requests, initiating responses, telecommunications, and assessing the capability for utilizing emergency medical dispatch protocols approved by the department.
- (4) Air ambulance communications specialists shall have training commensurate with the scope of responsibility given them by the particular licensed air ambulance provider.
- (5) The following requirements shall apply to all air ambulance communications centers:
- (a) Establish and maintain policies and procedures based on state or nationally accepted emergency medical dispatch standards and state or nationally accepted EMS clinical guidelines to aid in directing the daily operation of the air ambulance communications center.
- (b) Coordinate air ambulance deployment activities and communications with primary 911 PSAP call centers and appropriate medical facilities.
- (c) Require its communications specialists to satisfy performance standards that are based on state or nationally accepted emergency medical dispatch standards and state or nationally accepted EMS clinical guidelines.
- (6) At a minimum, the air ambulance communications center's performance standards shall measure a communication specialist's ability to:
- (a) Deploy the appropriate medical resources within the prescribed timeframe established by the communications center's standard operating procedures.
- (b) Provide pertinent information to the appropriate 911 PSAP call center and receive updated information about the incident from the responding units or medical facilities.

(e) Establish a quality assurance review process that is executed with consistency and objectivity in accordance with internal standards developed by the licensed air ambulance provider.

R426-10-1200. Communications Specialists Personnel Qualifications.

(1) Communication specialists shall have appropriate training pertaining to EMS and medical transportation communications related to the provision of health care and receive certification within (1) year.

R426-10-1300. Pre-arrival and Hand-Off Communications to Hospitals or Emergency Patient Receiving Facilities.

- (1) All licensed air ambulance providers shall have a plan in place to transmit significant clinical data to hospital or emergency patient receiving facility medical personnel prior to arrival.
- (2) Licensed air ambulance providers shall start the process for transferring responsibility of patient care during patient transport to reduce the communication load on patient arrival to the facility as early as possible. Transfer of care documentation shall be part of the EMS record.
- (3) Information transmitted to the hospital or the emergency patient receiving facility prior to arrival shall include:
 - (a) patient information;
- (b) chief complaint;
 - (c) brief patient history;
 - (d) condition of patient;
 - (e) treatment provided; and
 - (f) estimated time of arrival.
- (4) Information at the time of patient hand off shall include a copy of the patient care report to the hospital or emergency patient receiving facility within 24 hours after the end of the patient transport. If a completed patient care report cannot be left at the facility at the end of the patient transfer to the hospital or emergency patient receiving facility, an abbreviated patient encounter form containing information essential to continued patient care shall be provided.
 - (5) Abbreviated Patient Encounter form shall include:
 - (a) patient information;
 - (b) chief complaint;
 - (c) brief patient history;
 - (d) allergies (if known);
 - (e) time and date of onset of symptoms;
 - (f) pertinent physical findings;
 - (g) patient medications (if known);
 - (h) vital signs;
- (i) air medical treatment, including medications administered, IV fluids, procedures performed, and oxygen delivery; and
- (j) transfer of care (name of air medical crew member to the receiving healthcare professional legibly included in documentation).

R426-10-1400. Data Collection, Submission and Call Volume.

- (1) All licensed air ambulance providers shall have a system in place to collect, submit, monitor, and track all flight requests This information shall be submitted to the department.
 - (2) All licensed air ambulance providers shall:
- (a) Report the specified state minimum data set, as required by the department for every request that results in the dispatch of an air ambulance, whether emergency prehospital, inter-hospital transport, aborted flight, cancellation of requested service, death on

scene (non-transport), or refusal of care as requested by the department.

(b) Provide a yearly call volume report or EMS agency status report documenting the number of flights made within that calendar year. This report shall contain the number of flights organized by emergency prehospital, inter-hospital transport, aborted flight, cancellation of requested service, death on scene, non-transport, or refusal of care to assist efforts related to evaluating patient care and the improvement of the EMS system.

R426-10-1500. Temporary Air Ambulance Use.

- (1) A licensed air ambulance provider shall notify the department when it temporarily removes a permitted air ambulance from service, or replaces it with a substitute air ambulance.
- (2) Upon receipt of notification, the department may issue a temporary permit for the operation of said air ambulance, as required by the department.

R426-10-1600. Medical Operations Policies and Procedures.

- (1) A detailed manual of policies and procedures shall be available for reference in the flight coordination office and available for inspection by the department to assist with EMS system planning and resource coordination efforts.
- (2) Personnel shall be familiar and comply with policies contained within the manual, which shall include all of the following:

 (a) procedures for acceptance of requests, referrals, and/or denial of service for medically related reasons;
- (b) a written description of the geographical boundaries and features for the service area, and a copy of the service area map;
 - (c) scheduled hours of operation;
- (d) criteria for the medical conditions and indications or medical contraindications for flight;
- (e) medical communication procedures, including but not limited to medically related dispatch protocol, call verification, and advisories to the requesting party, to include procedures for informing requesting party of flight procedures, anticipated time of aircraft patient arrival, or cancellation of flight;
- (f) criteria regarding acceptable destinations based upon medical needs of the patient;
- (g) non-aviation safety procedures for medical crew assignments and notification, including rosters of medical personnel;
- (h) written policy that ensures that air medical personnel shall not be assigned or assume cockpit duties concurrent with patient care duties and responsibilities;
- (i) written policy that directs air ambulance personnel to honor a patient request for a specific service or destination when the circumstances will not jeopardize patient safety;
 - (j) medical communications procedures;
- (k) flight cancellation and referral procedures;
- (1) mutual aid procedures;
- (m) a written plan that addresses the actions to be taken in the event of an emergency, diversion, or patient crisis during transport operations;
- (n) patient tracking procedures that shall assure air/ground position reports at intervals not to exceed fifteen (15) minutes (inflight) and forty-five (45) minutes while landed on the ground;

(o) policy for delineating methods of maintaining medical

communications during power outages and in disaster situations; and

(p) written procedures governing the licensed air
ambulance provider's medical complaint resolution process and
protocols. At a minimum, the licensed air ambulance provider shall
designate personnel responsible for its dispute resolution process and

provide the protocols it shall follow when investigation, tracking, documenting, reviewing, and resolving the complaint. The licensed air ambulance provider's complaint resolution procedures shall emphasize resolution of complaints and problems within a specified period of time.

R426-10-1700. Medical Transport Plans.

- (1) To ensure proper patient care and the effective coordination of statewide emergency medical and trauma services, all licensed air ambulance providers shall have an integrated medical transport plan for each air ambulance permitted by the department that describes the following:
 - (a) base location;
 - (b) hours of operation;
- (c) emergency (dispatch) and non emergency (business) contact information;
- (d) description of primary and secondary service areas;
 - (e) medical criteria for utilization;
- (f) description of medical capabilities (including availability of specialized medical transport equipment);
- (g) communications capabilities including (but not limited to) radio frequencies and talk groups;
- (h) procedures for communicating with the air medical erew; and
- (i) mutual aid or backup procedures when the service is not available.

R426-10-1800. Coordination with Regional and State Disaster Preparedness Plans.

(1) To ensure coordinated response to local, regional, or statewide disaster, all licensed air ambulance providers shall participate in regional and state disaster preparedness advisory groups, including preparedness planning meetings and scheduled exercises.

R426-10-1900. Medically Related Dispatch Protocols.

(1) When air ambulance transport is indicated, requests shall be coordinated through the local Public Safety Answering Point (PSAP) or 911 call center as part of an integrated response, whenever possible in order for the PSAP to be able to coordinate communications among all entities involved in the response.

R426-10-2000. Ethical Practices and Conduct.

- (1) All licensed air ambulance providers shall have and follow a written code of conduct that demonstrates ethical practices including business, clinical operations, marketing and professional conduct.
- (2) Licensed air ambulance providers are subject to disciplinary action, or may be denied licensure for unethical practices or conduct which includes but shall not be limited to the following:
- (a) misrepresentation of the availability or level of medical or patient related services offered or provided; and
- (b) failing to take appropriate action in safeguarding the patient from incompetent or inappropriate health care practices of emergency medical services personnel.

R426-10-2100. Continuous Quality Improvement (QI) Program.

- (1) Licensed air ambulance providers shall establish a quality management team and a program implemented by this team to assess and improve the quality and appropriateness of patient care provided by the air ambulance services.
- (2) The program shall include:

(a) development of protocols, standing orders, training, service's scope of care. The licensed nurse also shall have three (3) policies and procedures; years critical care experience, which is no less than 4000 hours (b) approval of medications and techniques permitted for experience in an ICU or emergency department. (b) The paramedic shall have a FP-C or CCP-C within (2) field use by service personnel in accordance with regulations of the years of hire in addition to at least (3) years (minimum of 4000 hours) department; (c) direct observation, field instruction, in-service training, of advanced life support experience. or other means available to assess the quality of field performance; (c) The RRT shall have a minimum of 4000 hours of emergency department or ICU experience and appropriate specialty and (d) Participation in local and regional performance certification within two (2) years of hire. improvement activities. (3) Medical personnel shall have cognitive, affective, and psychomotor abilities sufficient to meet the clinical needs for the type (3) All licensed air ambulance providers shall have a written policy that outlines a process to identify, document, and of patient missions served. analyze sentinel events, adverse medical events, or potentially (4) A licensed air ambulance provider shall have a plan to adverse events with specific goals to improve patient medical safety assess and document the competency and proficiency of the and/or quality of patient care. personnel who provide medical services. (4) Policies shall include the following: R426-10-2400. (a) review of events should address the effectiveness and Air Ambulance Personnel Training efficiency of the organization, its support systems, as well as that of Requirements. (1) All licensed air ambulance providers shall have a individuals within the organization; (b) when a sentinel event is identified, a method of documented, structured educational program required for all air information gathering shall be developed, and shall include outcome ambulance personnel, including the medical director. studies, chart review, case discussion, or other methodology; (2) The educational program shall at a minimum contain (c) findings, conclusions, recommendations, and actions program orientation; initial and recurrent training which adheres to shall be made and recorded including follow-up which also shall be the services scope of care, patient population, mission statement and determined, recorded, and performed; and medical direction. (d) training and education needs, individual performance (3) Each medical crew member shall complete and evaluations, equipment or resource acquisition, patient medical document training in mission specific procedures related to patient safety and risk management issues shall be integrated with the care as established by the licensed air ambulance provider's medical continuous quality improvement process. director and such federal, state, or local agencies with authority to (5) All licensed air ambulance providers shall have a regulate licensed air ambulance providers. Documentation showing written policy outlining a utilization review process. completion of all initial and recurrent training may be required by the department for license renewal. R426-10-2200. Staffing and Medical Personnel Requirements. (4) Clinical experiences shall include but are not limited to (1) At a minimum a licensed air ambulance provider shall the following: have the following medical personnel: (a) experiences specific to the mission statement and scope (a) Medically qualified Utah licensed, or certified, of care of the medical transport service; individuals appropriate to the scope and mission of the licensed air (b) measurable objectives developed and documented for ambulance provider, or EMS personnel recognized under an each experience listed below reflecting hands-on experience versus interstate compact of which Utah is a member. Acceptable medical observation only: personnel include, but are not limited to physicians(MD/DO), care of patients in the air medical environment paramedics, registered nurses(RN), registered including the impact of altitude and other stressors; practitioners(RN-P), advanced practice nurses, physician (d) advanced airway management; assistants(PA), respiratory therapists(RRT), or other allied health (e) applicable medical device specific training (Automatic Implantable Cardioverter Defibrillator (AICD), Extracorporeal professionals. (b) One medical attendant who is a licensed PA, RN, or Membrane Oxygenation (ECMO), Intra-Aortic Balloon Pump MD/DO. This attendant shall be the primary medical attendant. The (IABP), Left Ventricular Assist Device (LVAD), medication pumps, second medical attendant shall be a paramedic, PA, Respiratory ventilators, etc.); (f) cardiology; Therapist, RN, or MD/DO. (g) mechanical ventilation and respiratory physiology for R426-10-2300. Air Ambulance Staffing and Personnel adult, pediatric, and neonatal patients as it relates to the mission Qualifications. statement and scope of care of the medical transport service specific (1) Each patient transport by a licensed air ambulance to the equipment;

provider requires a minimum of two (2) medically qualified staff who are licensed or certified according to Utah or providers recognized under an interstate compact, REPLICA, who provide direct patient

care, plus a vehicle operator.

(2) The composition of the medical team may be amended

for specialty missions upon approval and credentialing by the licensed air ambulance provider's medical director:

(a) The licensed nurse shall have appropriate specialty certification within two (2) years of hire and must have pre-hire experience in the medications and interventions necessary for the

UTAH STATE BULLETIN, April 15, 2024, Vol. 2024, No. 08

(i) basic care for pediatrics, neonatal and obstetrics;

(k) hazardous materials recognition and response;

(m) infection control and prevention; and

(n) ethical and legal issues.

(1) management of disaster and mass casualty events;

(j) emergency/critical care for all patient populations to

(h) high risk obstetric emergencies;

include special needs population;

R426-10-2500. Medical Staff and Patient Safety Welfare.

- (1) Medical personnel scheduling and individual work schedules shall demonstrate strategies to minimize duty time fatigue, length of shift, number of shifts per week, and day-to-night rotation.
- (2) On site scheduled shifts for a period to exceed twenty-four (24) hours are not acceptable under most circumstances.
- (3) The following criteria shall be met for shifts scheduled more than twelve (12) hours:
- (a) medical personnel are not required to routinely perform any duties beyond those associated with the transport services:
- (b) medical personnel are provided with access to and permission for uninterrupted rest after daily medical personnel duties are met;
- (c) the physical base of operations includes an appropriate place for uninterrupted rest;
- (d) medical personnel shall have the right to call "time out" and be granted a reasonable rest period if the team member (or fellow team member) determines that he or she is unfit or unsafe to continue duty, no matter the shift length;
- (e) there shall be no adverse personnel action or undue pressure to continue in a "time-out" circumstance;
- (f) licensed air ambulance management shall monitor transport volumes and personnel's use of a "time out" policy;
- (g) licensed air ambulance providers shall utilize a fatigue risk management tool that is widely recognized in the industry; and
- (h) shifts extended over several days may be scheduled to address long commutes at programs with low volumes.
- (4) The licensed air ambulance provider shall clearly demonstrate and document it meets this above criteria for shifts over twelve (12) hours.
- (5) Provide at least (10) hours of rest in each twenty-four (24) hour period.
- (6) If the location of the base is remote and one-way commutes are more than two (2) hours, transportation time shall be considered.
- (7) Licensed air ambulance providers shall utilize a fatigue risk management tool that is widely recognized in the industry.
- (8) Scheduling of on call shifts shall be evaluated to address fatigue in a written policy based on monitoring of duty times by managers, quality management tracking, and fatigue risk management.
- (9) The license air ambulance provider shall establish safety and infection control protocol that comply with the Occupational Safety and Health Administration (OSHA) Standards.
- (10) The licensed air ambulance provider shall have an appropriate dress code that addresses mission specific hazards as well as jewelry, hair, and other personal items that may possibly be used by medical personnel that may interfere with patient care.

R426-10-2600. Air Ambulance Service Medical Director Qualifications.

- (1) A licensed air ambulance provider's medical director who oversees the practice of the emergency medical services during patient transport shall be familiar with Utah state medical standards practices, and licensing requirements.
- (2) A licensed air ambulance provider's medical director shall be a Utah licensed physician in good standing to supervise the medical care provided in an air medical environment.
- (3) The medical director shall also:
- (a) be board certified or board-eligible in EMS, emergency medicine, or other appropriate critical care specialty that services the patient population involved;

- (b) have experience in the care of patients consistent with the licensing and mission profile of the air ambulance provider's service:
- (e) designate other medical physician specialists for direction outside medical director's area of practice as appropriate to the licensed air ambulance provider's service mission profile;
- (d) have access to medical specialists for consultation regarding patients whose illness and care needs are outside the medical director's area of practice;
 - (e) have a current DEA registration; and
- (f) have current credentials achieved through active participation in patient care and continuing medical education activities appropriate for the role of a licensed air ambulance provider's medical director.
- (4) The licensed air ambulance provider's medical director shall have familiarity in the following areas:
- (a) care of patients in the air medical environment, including the impact of altitude and other patient stressors, in flight assessment and care, monitoring capabilities, and limitations of the flight environment;
- (b) hazardous materials recognition and response;
 - (c) management of disaster and mass casualty events;
- (d) infection control and prevention;
- (e) advanced resuscitation and care of adult, pediatric and neonatal patients with both traumatic and non-traumatic diagnoses;
 - (f) quality improvement theories and applications;
- (g) principles of adult learning;
 - (h) capabilities and limitations of care in air ambulance;
- (i) applicable federal, state, and local law, rules and protocols related to air ambulance providers and state trauma rule guidelines;
- (j) air ambulance dispatch and communications; and
 - (k) ethical and legal issues related to air medical transport.
- (5) The licensed air ambulance provider's medical director roles and responsibilities shall include:
- (a) oversight of medical care provided by the air medical service provider;
- (b) ensure competency and currency of all medical personnel;
- (c) active engagement in the evaluation credentialing, initial training, and continuing education of all personnel who provide patient care;
- (d) development and approval of written patient care guidelines, policies and protocols, including, but not limited to, those addressing the adverse impact of altitude on patient physiology and stressors of transport; and
- (e) active engagement in quality management, utilization review, and safety reviews.

R426-10-2700. Patient Compartment General Standards.

- (1) A licensed air ambulance provider shall ensure that a permitted air ambulance has the following:
- (a) a climate control system to prevent temperature variations that would adversely affect patient care;
- (b) the air ambulance shall have an adequate interior lighting system so that patient care can be given and the patient's status monitored;
- (c) for each place where a patient may be positioned, at least one electrical power outlet or other power source that is capable of operating all electrically powered medical equipment without compromising the operation of any electrical air ambulance equipment;

- (e) a back-up source of electrical power or batteries capable of operating all electrically powered life support equipment for at least one hour;
- (f) an appropriate power source which is sufficient to meet the requirements of the complete specialized equipment package without compromising the operation of any electrical air ambulance equipment;
- (g) an entry that allows for patient loading and unloading without excessive maneuvering and without compromising the operation of monitoring systems, intravenous lines, or manual or mechanical ventilation;
- (h) If an isolette is used during patient transport, the operator shall ensure that the isolette is able to be opened from its secured in-flight position in order to provide full access to the patient;
- (i) adequate access and necessary space to maintain the patient's airway and to provide adequate ventilatory support by an attendant from the secured, seat-belted position within the air ambulance:
- (j) a configuration that allows for rapid exit of personnel and patients that will not allow obstruction from stretchers and medical equipment;
- (k) an interior of the air ambulance that is sanitary and in good working order during use;
- (l) secure positioning of cardiac monitors, defibrillators, and external pacers so that displays are visible to medical personnel; and
- (m) provision for medications that maintains temperatures within manufacturer recommendations. Glass containers shall not be used unless required by medication specifications and be properly vented.
- (2) Each air ambulance operator shall ensure that all medical equipment is appropriate to the air medical service's scope and mission and maintained in working order according to the manufacturer's recommendations.
- (3) All permitted air ambulances shall be equipped to provide patient care according to approved medical protocols.]
- R426. Health and Human Services, Population Health, Emergency Medical Services.

R426-10. Air Ambulance Licensure and Operations.

R426-10-1. Authority and Purpose.

- (1) Section 26B-4-102 authorizes this rule.
- (2) This rule provides department requirements for air ambulance provider licensure and operations.

R426-10-2. Definitions.

- For the purposes of this rule:
- (1) "Air ambulance provider" means a state-licensed entity providing air ambulance services.
- (2) "Base location" means the physical address where the crew, medical equipment, supplies, and the air ambulance are located.
- (3) "Deemed status" means an air ambulance provider has received accreditation from a department-approved accreditation service.
- (4) "Department" means the Department of Health and Human Services.
- (5) "PSAP" means the public safety answering point for 911 calls.

R426-10-3. Air Ambulance Provider Requirements.

(1) A person in any capacity, including as an owner or agent, may furnish, operate, conduct, maintain, advertise, or

- otherwise be engaged in providing emergency medical care using an air ambulance only when licensed by the department.
- (2) The department may conduct air ambulance provider investigations.
- (3) A person from another state may only provide emergency medical services (EMS), including patient care, aboard an air ambulance within the state if that person complies with the requirements under this rule.
- (4)(a) An air ambulance provider shall have a medical director who shall be responsible for medical direction and oversight regarding credentialing air medical providers, clinical practice, and patient care.
- (b) An air ambulance provider shall report a personnel change in the medical director position to the department within 30 days.
- (5) An air ambulance provider shall get a deemed status or receive state certification by state-approved auditors of the required criteria to meet national standards for patient safety and quality of
- (6) Air ambulance permits and licenses are not transferable.
- (7) An air ambulance provider may get a replacement air ambulance permit or license by submitting a written request to the department certifying that the original permit or license has been lost, destroyed, or made unusable.
- (8) Each air ambulance provider shall get a new air ambulance inspection and subsequent permit from the department before returning an air ambulance to service following a modification, change, or any renovation that results in a change to the stretcher placement or seating in the air ambulance interior configuration.
- (9) An air ambulance provider shall file an amended list of aircraft that are used to provide service within the state to the department within 30 days after an air ambulance is added to or removed permanently from service.
- (10) The licensure period for an air ambulance provider shall be four years.
- (11) An air ambulance provider may only use an air ambulance to provide emergency medical care. State licensure does not constitute authority to provide non-medical air transportation.
- (12) An air ambulance provider shall comply with other statutes, rules, or regulations in effect for medical personnel and EMS, involving:
 - (a) licensing and authorizations;
 - (b) insurance;
 - (c) prescribed and proscribed acts; and
 - (d) penalties.
- (13) The department may verify and inspect equipment and documentation to ensure compliance.
- (14) An air ambulance provider seeking deemed status shall allow a department representative to be present during a site visit conducted by an accreditation organization.

R426-10-4. Air Ambulance Provider Licensure Application.

- (1) An applicant for an air ambulance license desiring to get or to renew a license shall submit the following to the department:
- (a) the applicable fees and application on the department-approved forms;
- (b) a copy of the air ambulance service licenses concurrently issued and on file with other states;

- (c) information about individual aircraft that will be used while providing medical care for physical inspection of medical compliance, as referenced in Section R426-10-10;
- (d) results from the prior ten years of any investigations, disciplinary actions, or exclusions with the potential to impact the quality of medical care provided to patients. Such investigations, disciplinary actions, or exclusions apply to:
 - (i) current and prior legal names of the entity;
- (ii) other names used by the entity to provide health care services; and
- (iii) any person or entity who had direct or indirect ownership of at least 50% interest in the air ambulance service within the prior 10-year period;
- (e) the name of the air ambulance service medical director pursuant to requirements found in Sections R426-5-2500 and R426-5-2600;
- (f) proof of deemed status or state certification by state-approved auditors;
- (g) emergency contact information, which the department may use to provide effective communications and resource management in the event of a statewide or localized disaster or emergency situation;
- (h) a roster of medical personnel including level of certification or licensure to ensure there is sufficient trained and certified staff that meets the requirements in Section R426-10-22;
- (i) the air ambulance provider's policies and procedures based on state or nationally accepted emergency medical dispatch standards and state or nationally accepted EMS clinical guidelines to aid in directing the daily operation of the air ambulance communications center as referenced in Section R426-10-12;
- (j) a copy of the air ambulance provider's plan to send significant clinical data to hospital or emergency patient receiving facility medical personnel before arrival;
- (k) a copy of the air ambulance provider's quality improvement program that assesses and improves patient care provided by the air ambulance services, as referenced in Section R426-10-21;
- (1) an integrated medical transport plan, as established in Section R426-10-17; and
- (m) the air ambulance provider's insurance requirements as referenced in Section R426-10-8.

R426-10-5. Exceptions to Air Ambulance Provider Licensure.

- This rule does not apply to the following:
- (1) an entity providing air ambulance services operated by an agency of the United States Government;
- (2) services that provide rescue and evacuation equipment and aircraft owned and operated by a governmental entity other than one that includes transporting patients by air ambulance in its primary role and receives payment for such services; and
- (3) evacuation and rescue equipment used and owned by the Department of Public Safety in air, ground, or water evacuation.

R426-10-6. Department-Approved Accreditation Service.

- To be recognized as a department-approved accreditation service, a service must meet the following criteria:
- (1) provide evidence of timely reviews of applications from air ambulance providers seeking accreditation;
- (2) publish standards that address the components of medical transport impacting quality of patient care and provider safety;

- (3) outline procedures for random site visits, audits, and other strategies utilized to ensure an accredited provider or a provider seeking accreditation is adhering to accreditation standards;
- (4) publish policies for the initial accreditation requirements, including:
 - (a) the tenure of accreditation, not to exceed three years;
 - (b) the requirements for reaccreditation; and
 - (c) the accreditation decision-making process;
- (5) use trained personnel, including site surveyors, with experience in medical transport at the level of accreditation and licensure;
- (6) utilize a formal training program that educates accreditation personnel, including site surveyors, in consistent interpretation of standards and policies of the accreditation provider;
- (7) publish the required qualifications for accreditation personnel who conduct site surveys that demonstrate experience with and knowledge of the air ambulance industry;
- (8) demonstrate that accreditation standards are updated to comply with national standards in healthcare and air medical transportation;
- (9) have a multi-disciplinary board of directors representing medical transport organizations;
- (10) clearly outline and enforce a conflict of interest policy that excludes board members or other accreditation agency representatives from participating in accreditation decisions, site surveys, or other processes when a real or potential conflict of interest exists;
 - (11) publish fees for providers seeking accreditation;
- (12) utilize and provide documentation of an open process that encourages and accepts comments on changes to its accreditation standards:
- (13) explain the procedure for a corrective action plan, which assures that air ambulance providers will implement corrective actions for any identified deficiencies;
- that reviews the application process, site surveys, accreditation decisions, and accreditation standards;
- (15) maintain and be able to present current certificates of insurance to include:
 - (a) general liability; and
 - (b) medical professional liability; and
- (16) allow a department representative to be present during site surveys, investigations, and any other on-site visit.

R426-10-7. Air Ambulance Provider Change of Ownership and Management.

- (1) When an air ambulance provider anticipates a change of ownership, the air ambulance provider shall notify the department 30 calendar days before the change of ownership.
- (2) The conversion of an air ambulance provider's legal structure, or the legal structure of an entity that has a direct or indirect ownership interest in the air ambulance provider, is a change of ownership if the conversion includes a transfer of at least 50% of the air ambulance provider's direct or indirect ownership interest to any new owner.
- (3) A change of ownership of a licensed air ambulance provider requires a new license if:
- (a) the change of ownership's transfer is for at least 50% of the ownership interest from a sole proprietor to another individual, regardless of whether the transaction affects the title to real property;

- (b) the dissolution of a partnership and conversion into any other legal structure includes a transfer of at least 50% of the direct or indirect ownership from a partnership to any new owner;
- (c) the consolidation of two or more corporations resulting in the creation of a new corporate entity includes a transfer of at least 50% of the direct or indirect ownership to any new owner;
- (d) the formation of a corporation from a partnership, a sole proprietorship, or a limited liability company includes a transfer of at least 50% of the direct or indirect ownership to any new owner;
- (e) the transfer, purchase, or sale of shares in a corporation result in a shift of at least 50% of the direct or indirect ownership of the corporation to any new owner;
- (f) there is a transfer of at least 50% of the direct and indirect ownership interest in a limited liability company;
- (g) the termination or dissolution of a limited liability company and the conversion into any other entity includes a transfer of at least 50% of the direct or indirect ownership to any new owner;
- (h) any transfer of ownership interest between an existing person or entity in a limited liability company involves the acquisition of ownership interest by a new person or entity with an ownership interest; or
- (i) the air ambulance provider enters into a lease arrangement or management agreement whereby the air ambulance provider keeps no authority or responsibility for the operation and management of service.
 - (4) A change of ownership may not result from:
- (a) forming a corporation from a sole proprietorship with the proprietor as the sole shareholder; or
- (b) the dissolution of a partnership to form a corporation with the same persons keeping the same shares of ownership in the new corporation.
- (5) To report a change of ownership, each applicant shall provide:
- (a) the legal name of the entity and any other names used by it to provide health care services;
- (b) contact information for the entity including mailing address, telephone and fax numbers, email address, and website address, as applicable;
- (c) the identity of each person and business with a controlling interest in the air ambulance provider, including:
- (i) a list of the governing body and officers for a non-profit corporation;
- (ii) a list of the names of the officers and stockholders who directly or indirectly own or control 5% or more of the shares of a for-profit corporation; and
- (iii) proof of lawful presence in the United States in compliance with Subsection 41-1a-202(1)(b) for a sole proprietor;
- (d) the name, address, and business telephone number of every person identified in this section as ownership or management and the individual designated by the applicant as the chief executive officer of the entity;
- (e) an alternate address and telephone number for at least one individual for use in the event of an emergency or closure of the air ambulance provider if the addresses and telephone numbers provided are the same as the contact information for the entity itself;
- (f) proof of professional liability insurance held in the name of the applicant;
- (g) by-laws or equivalent documents that govern the rights, duties, and capital contributions of the business entity;
- (h) the address of the entity's physical location and the name of the owner of each structure on the campus where licensed services are provided;

- (i) a copy of any management agreement pertaining to operation of the entity that sets forth the financial and administrative responsibilities of each party;
- (j) a statement signed and dated at the same time as the application stating whether any of the new owners have been the subject of, or a party to, any of the following events within the previous ten years, regardless of whether action has been stayed in a judicial appeal or otherwise settled between the parties:
- (i) a felony or misdemeanor conviction involving crimes as described in Section R426-5-3200;
- (ii) a state license or federal certification denial, revocation, or suspension by another jurisdiction; or
- (iii) a civil judgment or a criminal conviction in a case brought by federal, state, or local authorities that resulted from the operation, management, or ownership of a health facility or other entity related to substandard patient care or health care fraud; and
- (k) a statement signed and dated at the same time as the application that:
- (i) states whether any new owner has ever been or is the subject of, or a party to debarment, suspension, a proposal for debarment, a declaration of ineligibility, or voluntarily exclusion from participation in a contract by any governmental department or agency, whether international, national, state, or local, regardless of whether action has been stayed in a judicial appeal or otherwise settled between the parties; and
- (ii) certifies the applicant is compliant with Section 63G-6a-904 and OMB guidelines at 2 C.F.R. 180 (October 23, 2023) which implement Executive Order Nos. 12549 and 12689.
- (6) Any statement regarding information requested in Subsection R426-10-7(5)(j) shall, if applicable, include:
- (a) whether the event is the result of action by federal, state, or local authorities and, if so, the full name of the authority; its jurisdiction; the case name; the docket, proceeding, or case number by which the event is designated; and a copy of the consent decree, order, or decision;
- (b) whether the event is a felony or misdemeanor conviction involving moral turpitude and, if so, the court, its jurisdiction, the case name, the case number, a description of the matter or a copy of the indictment or charges, and any plea or verdict entered by the court; and
- (c) whether the event involves a civil action or arbitration proceeding and, if so, the court or arbiter, the jurisdiction, the case name, the case number, a description of the matter or a copy of the complaint, and a copy of the verdict, court or arbitration decision.
- (7) If an applicant leases one or more buildings to operate as an air ambulance provider, the applicant shall also provide a copy of the lease that clearly shows which party in the agreement is to be held responsible for the physical condition of the property.
- (8) The applicant shall keep any article of incorporation, article of organization, partnership agreement, or other organizing document required by the secretary of state to conduct business.
- (9) The existing applicant shall be responsible for correcting rule violations and deficiencies in any current plan of correction before the change of ownership becomes effective. If the applicant cannot accomplish such corrections in the time frame specified, the prospective applicant shall be responsible for uncorrected rule violations and deficiencies including any current plan of correction submitted by the previous licensee unless the prospective licensee submits a revised plan of correction, approved by the department, before the change of ownership becomes effective.

- (10) If the department issues a license to the new owner, the previous owner shall return its license to the department within five calendar days of the new owner's receipt of its license.
- (11) The applicant shall maintain professional liability insurance during the license term and shall notify the department of any change in the amount, type, or provider of professional liability insurance coverage during the license term.
- (12) An air ambulance provider shall notify the department within 30 days if debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in any contract by any governmental entity during the tenure of a license.

R426-10-8. Air Ambulance Provider Insurance Requirements.

- (1) An air ambulance provider applicant shall demonstrate liability coverage for injuries to persons and for loss or property damages resulting from negligence by the service or medical crew.
- (2) An air ambulance provider shall immediately notify the department and stop operations if the coverage required by this section is canceled or suspended.
- (3) The department may not issue an air ambulance license to an applicant unless the applicant has evidence of medical professional liability insurance that requires the insurer to compensate for injuries to persons or unintentional damage to property.
- (4) An air ambulance provider applicant shall provide a copy of the current certificate of insurance demonstrating coverage for each air ambulance medical crew member that states, at a minimum, aggregate limits of \$1,000,000 per claim made and a total of \$3,000,000 for claims made against the provider during the policy year.
- (5) An applicant shall provide proof of worker's compensation coverage as required by law.

R426-10-9. Base Locations.

- (1) The air ambulance provider shall provide the base location to the department.
- (2) The department may conduct announced and unannounced inspections at any location where an air ambulance provider operates. An inspection may occur at any time, including nights or weekends, to determine compliance.
- (3) Each base location shall have and maintain security measures that protect medical supplies, pharmaceuticals, and equipment onboard the air ambulance from tampering and unauthorized access, including direct visual monitoring or closed-circuit television
- (4) A base location shall provide a secured location with locked perimeter fencing or hangar for each air ambulance.
- (5) The base location shall prominently display the following within the building:
 - (a) the state license or certificate of operation;
- (b) Drug Enforcement Agency registration within base locations that store controlled substances;
 - (c) current Post-Accident Incident Plan; and
- (d) documentation showing the professional certifications and licenses of flight crew members.
- (6) The air ambulance provider shall ensure the facility is clean and free of debris and compliance with state and local building and fire codes.
- (7) The base location shall maintain evidence of medical professional liability insurance.

R426-10-10. Number and Type of Air Ambulances.

An air ambulance provider shall provide a list of each air ambulance to be licensed and inspected for medical compliance by the department, including tail number, the N-Number, and designation of rotor or fixed wing capabilities.

R426-10-11. Capabilities of Medical Communications.

- (1) An air ambulance provider shall have a communications network available consisting of reliable equipment designed for clear communications related to the number and condition of patients among each stakeholder within the system.
- (2) The communication center shall demonstrate and maintain voice communications linkage with the radios and other allowable communication devices used in the air ambulance for the declared service area.
- (3) Air ambulance providers shall have two-way communications equipment available that allows for or has the following:
- (a) real-time patient tracking that shall be maintained and documented every 15 minutes including the time the air ambulance returns to service following transport;
- (b) appropriate wireless communications capabilities with dispatch centers and local first responders to include fire, EMS, and law enforcement;
- (c) communications with medical referral and receiving facilities to exchange patient information and consult with medical control that shall be capable of communications exclusive to the air traffic control system; and
- (d) a dedicated telephone number for the air ambulance service dispatch center.
- (4) The air ambulance provider base station shall use a communications network during each phase of patient treatment and transport.
- (5) The air ambulance provider shall establish an emergency plan for communications during power outages and in disaster situations.
- (6) The air ambulance provider shall establish a policy for delineating methods for maintaining medical communications during power outages and in disaster situations.

R426-10-12. Coordination of Medical Communications.

- (1) An air ambulance provider shall have flights coordinated by designated medical dispatchers or communications specialists.
- (2) Communication specialists are required for processing requests, initiating responses, telecommunications, and assessing the capability for utilizing emergency medical dispatch protocols approved by the department.
 - (3) Communication specialists shall have:
 - (a) certification;
- (b) appropriate training pertaining to EMS and medical transportation communications related to health care; and
- (c) training commensurate with the scope of responsibility given to them by the particular air ambulance provider.
 - (4) Air ambulance communications centers shall:
- (a) establish and maintain policies and procedures based on state or nationally accepted emergency medical dispatch standards and state or nationally accepted EMS clinical guidelines to aid in directing the daily operation of the air ambulance communications center;

- (b) coordinate air ambulance deployment activities and communications with primary 911 PSAP call centers and appropriate medical facilities; and
- (c) require its communications specialists to satisfy performance standards that are based on state or nationally accepted emergency medical dispatch standards and state or nationally accepted EMS clinical guidelines.
- (5) At a minimum, the air ambulance communications center's performance standards shall measure a communication specialist's ability to:
- (a) deploy the appropriate medical resources within the prescribed timeframe established by the communications center's standard operating procedures; and
- (b) provide pertinent information to the appropriate 911 PSAP call center and receive updated information about the incident from the responding units or medical facilities.
- (6) An air ambulance provider's communications center shall establish a quality assurance review process that is executed with consistency and objectivity in accordance with internal standards developed by the air ambulance provider.

R426-10-13. Pre-arrival and Hand-Off Communications to Hospitals or Emergency Patient Receiving Facilities.

- (1) An air ambulance provider shall have a plan in place to send significant clinical data to hospital or emergency patient receiving facility medical personnel before arrival.
- (2) An air ambulance provider shall start the process for transferring responsibility of patient care during patient transport to reduce the communication load on patient arrival to the facility as early as possible. Transfer of care documentation shall be part of the EMS record.
- (3) Information sent to the hospital or the emergency patient receiving facility before arrival shall include:
 - (a) patient information;
 - (b) chief complaint;
 - (c) brief patient history;
 - (d) condition of the patient;
 - (e) treatment provided; and
 - (f) estimated time of arrival.
- (4) Information provided to the hospital or emergency patient receiving facility during patient hand-off shall include either:
 - (a) a copy of the full patient care report; or
- (b) an abbreviated patient encounter form containing information essential to continued patient care, including:
 - (i) patient information;
 - (ii) chief complaint;
 - (iii) brief patient history;
 - (iv) allergies, if known;
 - (v) time and date of onset of symptoms;
 - (vi) pertinent physical findings;
 - (vii) patient medications, if known;
 - (viii) vital signs;
- (ix) air medical treatment, including medications administered, IV fluids, procedures performed, and oxygen delivery; and
- (x) transfer of care documentation, including the legibly written name of the air medical crew member.
- (5) An air ambulance provider shall provide a copy of the full patient care report to the hospital or emergency patient receiving facility within 24 hours after the end of the patient transport.

R426-10-14. Data Collection, Submission, and Call Volume.

- (1) An air ambulance provider shall have a system in place to collect, submit, monitor, and track flight requests. The provider shall submit this information to the department.
 - (2) An air ambulance provider shall:
- (a) report the specified state minimum data set, as required by the department, for every request that results in the dispatch of an air ambulance, whether emergency prehospital, inter-hospital transport, aborted flight, cancelation of requested service, death on scene, or refusal of care as requested by the department; and
- (b) provide a yearly call volume report or EMS agency status report documenting the number of flights made within that calendar year.
- (3) The yearly call volume report or EMS agency status report identified in Subsection (2)(b) shall contain the following totals:
 - (a) flights organized by emergency prehospital;
 - (b) inter-hospital transports;
 - (c) aborted flights;
 - (d) cancelation of requested services;
 - (e) death on scene;
 - (f) non-transport; and
- (g) the refusal of care to assist efforts related to evaluating patient care and the improvement of the EMS system.

R426-10-15. Temporary Air Ambulance Use.

- (1) An air ambulance provider shall notify the department when a permitted air ambulance is removed from service or is replaced with a substitute air ambulance.
- (2) Upon receipt of notification, the department may issue a temporary permit for the operation of the air ambulance.

R426-10-16. Medical Operations Policies and Procedures.

- (1) An air ambulance provider shall have a detailed manual of policies and procedures available for reference in the flight coordination office and available for department inspection to assist with EMS system planning and resource coordination efforts.
- (2) An air ambulance provider's personnel shall be familiar and comply with policies contained within the manual, which shall include:
- (a) procedures for acceptance of requests, referrals, and denial of service for medically related reasons;
- (b) a written description of the geographical boundaries and features for the service area;
 - (c) a copy of the service area map;
 - (d) scheduled hours of operation;
- (e) criteria for the medical conditions and indications or medical contraindications for flight;
 - (f) medical communication procedures, including:
 - (i) medically related dispatch protocol;
 - (ii) call verification; and
- (iii) advisories to the requesting entity to include procedures for informing the requesting entity of flight procedures, anticipated time of aircraft patient arrival, or cancelation of flight;
- (g) criteria regarding acceptable destinations based upon medical needs of the patient;
- (h) non-aviation safety procedures for medical crew assignments and notification, including rosters of medical personnel;
- (i) written policy that ensures air medical personnel may not be assigned or assume cockpit duties concurrent with patient care duties and responsibilities;

- (j) written policy that directs air ambulance personnel to honor a patient request for a specific service or destination when the circumstances will not jeopardize patient safety;
 - (k) medical communications procedures;
 - (l) flight cancelation and referral procedures;
 - (m) mutual aid procedures;
- (n) a written plan that addresses the actions to be taken in the event of an emergency, diversion, or patient crisis during transport operations;
- (o) patient tracking procedures that shall ensure air and ground position reports at intervals not to exceed 15 minutes in-flight and 45 minutes after landing;
- (p) policy for delineating methods of maintaining medical communications during power outages and in disaster situations; and
- (q) written procedures governing the air ambulance provider's medical complaint resolution process and protocols.
- (3)(a) At a minimum, the air ambulance provider shall designate personnel responsible for its dispute resolution process and provide protocols it shall follow when investigating, tracking, documenting, reviewing, and resolving the complaint.
- (b) The air ambulance provider's complaint resolution procedures shall emphasize resolution of complaints and problems within a specified period.

R426-10-17. Medical Transport Plans.

- To ensure proper patient care and the effective coordination of statewide emergency medical and trauma services, an air ambulance provider shall have an integrated medical transport plan for each air ambulance permitted by the department that describes:
 - (1) base location;
 - (2) hours of operation;
 - (3) emergency dispatch contact information;
 - (4) non-emergency business contact information;
 - (5) description of primary and secondary service areas;
 - (6) medical criteria for utilization;
- (7) description of medical capabilities, including availability of specialized medical transport equipment;
- (8) communications capabilities including radio frequencies and talk groups;
- (9) procedures for communicating with the air medical crew; and
- (10) mutual aid or backup procedures when the service is not available.

R426-10-18. Coordination with Regional and State Disaster Preparedness Plans.

To ensure coordinated response to local, regional, or statewide disaster, an air ambulance provider shall participate in regional and state disaster preparedness advisory groups, including preparedness planning meetings and scheduled exercises.

R426-10-19. Medically Related Dispatch Protocols.

When air ambulance transport is indicated, requests shall be coordinated through the local PSAP or 911 call center as part of an integrated response, when possible, for the PSAP to be able to coordinate communications among entities involved in the response.

R426-10-20. Ethical Practices and Conduct.

(1) An air ambulance provider shall have and follow a written code of conduct that demonstrates ethical practices including business, clinical operations, marketing, and professional conduct.

- (2) An air ambulance provider is subject to disciplinary action and may be denied licensure for unethical practices or conduct which includes:
- (a) misrepresentation of the availability or level of medical or patient related services offered or provided; and
- (b) failing to take appropriate action in safeguarding the patient from incompetent or inappropriate health care practices of EMS personnel.

R426-10-21. Continuous Quality Improvement Program.

- (1) An air ambulance provider shall establish a quality management team and a program that shall assess and improve patient care provided by the air ambulance provider.
 - (2) The quality management program shall include:
- (a) a development of protocols, standing orders, training, policies, and procedures;
- (b) approval of medications and techniques for field use by service personnel;
- (c) direct observation, field instruction, in-service training, or other means available to assess the quality of field performance; and
- (d) participation in local and regional performance improvement activities.
- (3) An air ambulance provider shall have a written policy that outlines a process to identify, document, and analyze sentinel events, adverse medical events, or potentially adverse events with specific goals to improve patient medical safety and the quality of patient care.
 - (4) Policies and procedures shall include:
- (a) a review of events for the effectiveness and efficiency of the organization, its support systems, and individuals within the organization;
- (b) a method of information gathering developed for when a sentinel event is identified, including outcome studies, chart review, case discussion, or other methodology;
 - (c) a utilization review process;
- (d) findings, conclusions, recommendations, actions, and follow-up made and recorded; and
- (e) training and education needs, individual performance evaluations, equipment or resource acquisition, patient medical safety, and risk management issues.
- (5) An air ambulance provider shall notify the department within 72 hours of the identification of any sentinel event, a change in accreditation status, an incident, an accident, or an outside investigation for patient care, patient safety, or provider safety.

R426-10-22. Staffing and Medical Personnel Requirements.

- (1) Acceptable medical personnel include:
- (a) physicians (MD/DO);
- (b) paramedics;
- (c) registered nurses (RN);
 - (d) registered nurse practitioners;
- (e) advanced practice nurses;
 - (f) physician assistants (PA);
 - (g) respiratory therapists (RRT); or
 - (h) other allied health professionals;
- (2) At a minimum, an air ambulance provider shall have the following medical personnel:
- (a) one primary medical attendant who is a licensed PA, RN, or MD/DO;

- (b) a second medical attendant who is a paramedic, PA, respiratory therapist, RN, or MD/DO; and
- (c) medically qualified Utah licensed or certified individuals appropriate to the scope and mission of the air ambulance provider, or EMS personnel recognized under an interstate compact of which Utah is a member.

R426-10-23. Air Ambulance Staffing and Personnel Qualifications.

- (1) The air ambulance provider may modify composition of the medical team for specialty missions upon credentialing and approval by the air ambulance provider's medical director.
- (2) The licensed nurse shall have appropriate specialty certification within two years of hire and must have pre-hire experience in the medications and interventions necessary for the air ambulance provider's scope of care. The licensed nurse also shall have three years critical care experience, which is no less than 4,000 hours experience in an ICU or emergency department.
- (3) The paramedic shall have a FP-C or CCP-C within two years of hire in addition to at least three years, a minimum of 4,000 hours, of advanced life support experience.
- (4) The RRT shall have a minimum of 4,000 hours of emergency department or ICU experience and appropriate specialty certification within two years of hire.
- (5) Medical personnel shall have cognitive, affective, and psychomotor abilities sufficient to meet the clinical needs for the type of patient missions served.
- (6) An air ambulance provider shall have a plan to assess and document the competency and proficiency of the personnel who provide medical services.

R426-10-24. Air Ambulance Personnel Training Requirements.

- (1) An air ambulance provider shall have a documented, structured educational program which is required for air ambulance personnel, including the medical director.
- (2) The educational program under Subsection (1) shall at a minimum contain program orientation and initial and recurrent training that adheres to the services scope of care, patient population, mission statement and medical direction.
- (3) Each medical crew member shall complete and document training in mission specific procedures related to patient care as established by the air ambulance provider's medical director and such federal, state, or local agencies with authority to regulate air ambulance providers. For license renewal, the department may require documentation showing completion of initial and recurrent training.
 - (4) Clinical experiences shall include:
- (a) experiences specific to the mission statement and scope of care of the medical transport service;
- (b) measurable objectives developed and documented reflecting hands-on experience versus observation only;
- (c) care of patients in the air medical environment including the impact of altitude and other stressors;
 - (d) advanced airway management;
- (e) applicable medical device specific training, this includes:
 - (i) Automatic Implantable Cardioverter Defibrillator;
 - (ii) Extracorporeal Membrane Oxygenation;
 - (iii) Intra-Aortic Balloon Pump;
 - (iv) Left Ventricular Assist Device;

- (v) medication pumps; and
- (vi) ventilators;
- (f) cardiology;
- (g) mechanical ventilation and respiratory physiology for adult, pediatric, and neonatal patients as it relates to the mission statement and scope of care of the medical transport service specific to the equipment;
 - (h) high risk obstetric emergencies;
 - (i) basic care for pediatrics, neonatal, and obstetrics;
- (j) emergency and critical care for patient populations to include special needs population;
 - (k) hazardous materials recognition and response;
 - (1) management of disaster and mass casualty events;
 - (m) infection control and prevention; and
 - (n) ethical and legal issues.

R426-10-25. Medical Staff and Patient Safety Welfare.

- (1) Medical personnel scheduling and individual work schedules shall demonstrate strategies to minimize duty-time fatigue, length of shift, number of shifts per week, and day-to-night rotation.
- (2) On-site scheduled shifts for a period to exceed 24 hours are not acceptable under most circumstances.
- (3) The following criteria shall be met for shifts scheduled more than 12 hours:
- (a) medical personnel are not required to routinely perform any duties beyond those associated with the transport services;
- (b) medical personnel are provided with access to and permission for uninterrupted rest after daily medical personnel duties are met;
- (c) the physical base of operations includes an appropriate place for uninterrupted rest;
- (d) medical personnel shall have the right to call "time out" and be granted a reasonable rest period if the team member, or fellow team member, determines that the team member is unfit or unsafe to continue duty, no matter the shift length;
- (e) there shall be no adverse personnel action or undue pressure to continue in a "time out" circumstance;
- (f) licensed air ambulance management shall monitor transport volumes and personnel's use of a "time out" policy; and
- (g) shifts extended over several days may be scheduled to address long commutes at programs with low volumes.
- (4) An air ambulance provider shall clearly demonstrate and document it meets criteria listed in Subsection R426-10-26(3) for shifts over 12 hours.
- (5) An air ambulance provider shall ensure medical staff have at least ten hours of rest in each 24-hour period.
- (6) If the base location is remote and one-way commutes are more than two hours, transportation time shall be considered.
- (7) An air ambulance provider shall utilize a fatigue risk management tool that is widely recognized in the industry.
- (8) An air ambulance provider shall evaluate the scheduling of on-call shifts to address fatigue in a written policy based on monitoring of duty times by managers, quality management tracking, and fatigue risk management.
- (9) An air ambulance provider shall establish safety and infection control protocols that comply with the Occupational Safety and Health Administration (OSHA).
- (10) An air ambulance provider shall have an appropriate dress code that addresses mission specific hazards as well as jewelry, hair, and other personal items that medical personnel may possibly use that may interfere with patient care.

R426-10-26. Air Ambulance Provider Medical Director Qualifications.

- (1) An air ambulance provider's medical director who oversees the practice of the EMS during patient transport shall be familiar with Utah medical practices and licensing requirements.
- (2) An air ambulance provider's medical director shall be a Utah licensed physician in good standing to supervise the medical care provided in an air medical environment.
 - (3) A medical director shall:
- (a) be board certified or board-eligible in EMS, emergency medicine, or other appropriate critical care specialty that services the patient population involved;
- (b) have experience in the care of patients consistent with the licensing and mission profile of the air ambulance provider's service:
- (c) designate other medical physician specialists for direction outside medical director's area of practice as appropriate to the air ambulance provider's service mission profile;
- (d) have access to medical specialists for consultation regarding patients whose illness and care needs are outside the medical director's area of practice;
 - (e) have a current DEA registration; and
- (f) have current credentials achieved through active participation in patient care and continuing medical education activities appropriate for the role of an air ambulance provider's medical director.
- (4) An air ambulance provider's medical director shall have familiarity in the following areas:
- (a) care of patients in the air medical environment, including the impact of altitude and other patient stressors, in-flight assessment and care, monitoring capabilities, and limitations of the flight environment;
 - (b) hazardous materials recognition and response;
 - (c) management of disaster and mass casualty events;
 - (d) infection control and prevention;
- (e) advanced resuscitation and care of adult, pediatric, and neonatal patients with both traumatic and non-traumatic diagnoses;
 - (f) quality improvement theories and applications;
 - (g) principles of adult learning;
 - (h) capabilities and limitations of care in air ambulance;
- (i) applicable federal, state, and local law, rules, and protocols related to air ambulance providers and state trauma rule guidelines;
 - (j) air ambulance dispatch and communications; and
 - (k) ethical and legal issues related to air medical transport.
- (5) An air ambulance provider's medical director roles and responsibilities shall include:
- (a) oversight of medical care provided by the air medical service provider;
 - (b) ensure competency and currency of medical personnel;
- (c) active engagement in the evaluation credentialing, initial training, and continuing education of personnel who provide patient care;
- (d) development and approval of written patient care guidelines, policies and protocols, including those addressing the adverse impact of altitude on patient physiology and stressors of transport; and
- (e) active engagement in quality management, utilization review, and safety reviews.

R426-10-27. Patient Compartment General Standards.

- (1) An air ambulance provider shall ensure that a permitted air ambulance has the following:
- (a) a climate control system to prevent temperature variations that would adversely affect patient care;
- (b) the air ambulance shall have an adequate interior lighting system so that patient care can be given and the patient's status monitored;
- (c) for each place where a patient may be positioned, at least one electrical power outlet or other power source that is capable of operating electrically powered medical equipment without compromising the operation of any electrical air ambulance equipment;
- (d) a back-up source of electrical power or batteries capable of operating electrically powered life support equipment for at least one hour;
- (e) an appropriate power source which is sufficient to meet the requirements of the complete specialized equipment package without compromising the operation of any electrical air ambulance equipment;
- (f) an entry that allows for patient loading and unloading without excessive maneuvering and without compromising the operation of monitoring systems, intravenous lines, or manual or mechanical ventilation;
- (g) if an isolette is used during patient transport, the operator shall ensure that the isolette can be opened from its secured in-flight position to provide full access to the patient;
- (h) adequate access and necessary space to maintain the patient's airway and to provide adequate ventilatory support by an attendant from the secured, seat-belted position within the air ambulance:
- (i) a configuration that allows for rapid exit of personnel and patients that will not allow obstruction from stretchers and medical equipment;
- (j) an interior of the air ambulance that is sanitary and in good working order during use;
- (k) secure positioning of cardiac monitors, defibrillators, and external pacers so that displays are visible to medical personnel; and
- (l) procedures for medications to maintain temperatures within manufacturer recommendations.
- (2) An air ambulance provider may not use glass containers unless required by medication specifications and be properly vented.
- (3) Each air ambulance operator shall ensure that medical equipment is appropriate to the air medical service's scope and mission and maintained in working order according to the manufacturer's recommendations.
- (4) Each permitted air ambulance shall be equipped to provide patient care according to approved medical protocols.

KEY: emergency medical services, air

Date of Last Change: <u>2024</u>[November 8, 2023] Notice of Continuation: September 27, 2023

Authorizing, and Implemented or Interpreted Law: [26B,-

Chapter 4, Part 1]26B-4-102

NOTICE OF PROPOSED RULE				
TYPE OF FILING: Repeal				
Rule or Section R436-16 Filing ID: 56393				

Agency Information

<u> </u>			
1. Department:	Health and Human Services		
Agency:	Data, Systems and Evaluation, Vital Records and Statistics		
Building:	Cannon Health Building		
Street address:	288 N 1460 W		
City, state and zip:	Salt Lake City, UT 84116		
Mailing address:	PO Box 141012		
City, state and zip:	Salt Lake City, UT 84114-1012		

Contact persons:

Name:	Phone:	Email:
Linda S. Wininger	801- 538- 6262	lindaw@utah.gov
Mariah Noble	385- 214- 1150	mariahnoble@utah.gov

Please address questions regarding information on this notice to the persons listed above.

General Information

2. Rule or section catchline:

R436-16. Violation of Rules

3. Purpose of the new rule or reason for the change:

Following a five-year review of this rule, the Department of Health and Human Services (Department) has determined that this rule is no longer necessary and that the provisions established in Sections 26B-1-221 through 26B-1-226 setting forth the penalties for violations of public health laws and rules would be included into subsequent amendments to the applicable Title R436 rules.

Subsection 63G-3-201(5)(a) requires rules to enumerate any penalty authorized by statute that may result from their violation.

The process of adding language regarding penalties to applicable Title R436 rules has been completed, and therefore, this repeal is now appropriate.

4. Summary of the new rule or change:

The substance of this rule has been incorporated into each rule that requires a penalty if violated, so this rule is repealed entirely.

Fiscal Information

5. Provide an estimate and written explanation of the aggregate anticipated cost or savings to:

A) State budget:

There is no anticipated cost or savings to the state budget, as this rule change is clerical in nature.

The provisions of this rule are incorporated into the applicable Title R436 rules.

B) Local governments:

The change in this rule is not expected to impact local governments, as this rule change is clerical in nature.

The provisions of this rule are incorporated into the applicable Title R436 rules.

C) Small businesses ("small business" means a business employing 1-49 persons):

The change in this rule is not expected to impact small businesses, as this rule change is clerical in nature.

The provisions of this rule are incorporated into the applicable Title R436 rules.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

The change in this rule is not expected to impact non-small businesses, as this rule change is clerical in nature.

The provisions of this rule are incorporated into the applicable Title R436 rules.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

The change in this rule is not expected to impact persons other than small businesses, non-small businesses, state, or local government entities, as this rule change is clerical in nature.

The provisions of this rule are incorporated into the applicable Title R436 rules.

F) Compliance costs for affected persons (How much will it cost an impacted entity to adhere to this rule or its changes?):

Compliance costs for affected persons will not change because the Department is incorporating the provisions of this rule into the applicable Title R436 rules.

This rule change is clerical in nature.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table				
Fiscal Cost	FY2024	FY2025	FY2026	
State Government	\$0	\$0	\$0	
Local Governments	\$0	\$0	\$0	
Small Businesses	\$0	\$0	\$0	
Non-Small Businesses	\$0	\$0	\$0	
Other Persons	\$0	\$0	\$0	
Total Fiscal Cost	\$0	\$0	\$0	
Fiscal Benefits	FY2024	FY2025	FY2026	
State Government	\$0	\$0	\$0	
Local Governments	\$0	\$0	\$0	
Small Businesses	\$0	\$0	\$0	
Non-Small Businesses	\$0	\$0	\$0	
Other Persons	\$0	\$0	\$0	
Total Fiscal Benefits	\$0	\$0	\$0	
Net Fiscal Benefits	\$0	\$0	\$0	

H) Department head comments on fiscal impact and approval of regulatory impact analysis:

The Executive Director of the Department of Health and Human Services, Tracy S. Gruber, has reviewed and approved this regulatory impact analysis.

Citation Information

6. Provide citations to the statutory authority for the rule. If there is also a federal requirement for the rule, provide a citation to that requirement:

Section 26B-1-202

Public Notice Information

8. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. See Section 63G-3-302 and Rule R15-1 for more information.)

A)	Comments	will	be	accepted	05/15/2024
unti	l:				

9. This rule change MAY 05/22/2024 become effective on:

NOTE: The date above is the date the agency anticipates making the rule or its changes effective. It is NOT the effective date.

Agency Authorization Information

Agency head or designee	Tracy S. Gruber, Executive Director	 03/20/2024
and title:		

R436. Health, Center for Health Data, Vital Records and Statistics.

[R436-16. Violation of Rules.

R436-16-1. Purpose and Authority.

(1) This rule sets forth the penalties for violating vital records rules.

(2) Authority for this rule is found in Sections 26-1-5.

R436-16-2. Penalties.

The penalties for violation of rules R436-1 through R436-19 are provided in Sections 26-23-3 through 26-23-8.

KEY: vital statistics, penalties

Date of Last Change: January 21, 2022

Notice of Continuation: July 19, 2023

Authorizing, and Implemented or Interpreted Law: 26-23-3 through 26-23-8

NOTICE OF PROPOSED RULE				
TYPE OF FILING: New				
Rule or Section Number:				

Agency Information

Agency information	J11					
1. Department:	Judicial Performance Evaluation Commission					
Agency:	Adminis	tration				
Room number:	Suite 33	0				
Building:	Senate I	Senate Building				
Street address:	350 State Street					
City, state and zip:	Salt Lake City, UT 84114					
Contact persons:						
Name:	Phone:	Email:				
Mary-Margaret Pingree	385- 910- 2097	mmpingree@utah.gov				
Madison Klein	801-	mklein@utah.gov				

Please address questions regarding information on this notice to the persons listed above.

538-1146

General Information

2. Rule or section catchline:

R597-7. General Provisions

3. Purpose of the new rule or reason for the change:

Rule R597-1 expired on 02/06/2024. This new rule replaces the expired rule.

4. Summary of the new rule or change:

This rule outlined the authorization and purpose of the Judicial Performance Evaluation Commission and provides definitions.

It replaces an expired rule and does not introduce any new information.

Fiscal Information

5. Provide an estimate and written explanation of the aggregate anticipated cost or savings to:

A) State budget:

This new rule requires no additional state funds.

This new rule replaces a rule that recently expired. As the substance of the rule remains the same, there is no fiscal impact to this new rule filing.

B) Local governments:

This new rule will have no fiscal impact on local governments.

Judicial performance evaluations are performed at the state level and do not require funding from local governments.

C) Small businesses ("small business" means a business employing 1-49 persons):

This new rule will have no fiscal impact on small businesses.

It replaces a recently expired rule, and the substance of this rule is essentially the same.

Additionally, it outlines general provisions including purpose and definitions which do not have fiscal impact.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

This new rule will have no fiscal impact on non-small businesses.

It replaces a recently expired rule, and the substance of this rule is unchanged.

Additionally, it outlines general provisions including purpose and definitions which do not have fiscal impact.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

This new rule does not introduce any additional costs to individuals or organizations.

This new rule will have no fiscal impact on non-small businesses.

It replaces a recently expired rule, and the substance of this rule is unchanged.

Additionally, it outlines general provisions including purpose and definitions which do not have fiscal impact.

F) Compliance costs for affected persons (How much will it cost an impacted entity to adhere to this rule or its changes?):

There are no compliance costs for this new rule.

It replaces a rule that recently expired.

Additionally, it outlines general provisions including purpose and definitions which do not have compliance costs.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table

Fiscal Cost	FY2024	FY2025	FY2026
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Cost	\$0	\$0	\$0
Fiscal Benefits	FY2024	FY2025	FY2026
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0

Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Benefits	\$0	\$0	\$0
Net Fiscal Benefits	\$0	\$0	\$0

H) Department head comments on fiscal impact and approval of regulatory impact analysis:

The Executive Director of the Judicial Performance Evaluation Commission, Mary-Margaret Pingree, has reviewed and approved this analysis.

As this rule is a replacement of an expired rule, there is no fiscal impact.

Citation Information

6. Provide citations to the statutory authority for the rule. If there is also a federal requirement for the rule, provide a citation to that requirement:

Title 78A, Chapter-12		
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Public Notice Information

8. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. See Section 63G-3-302 and Rule R15-1 for more information.)

A)	Comments	will	be	accepted	05/15/2024
unti	il:				

9. This rule change MAY 05/22/2024 become effective on:

NOTE: The date above is the date the agency anticipates making the rule or its changes effective. It is NOT the effective date.

Agency Authorization Information

Agency head or designee	Gil Miller, JPEC Chairperson	Date:	03/20/2024
and title:			

R597. Judicial Performance Evaluation Commission, Administration.

R597-7. General Provisions.

R597-7-1. Authorization and Purpose.

- As authorized by Section 78A-12-101 et seq., this rule establishes procedures for:
 - (1) implementing judicial performance evaluations;
- (2) informing voters about judges standing for retention election; and
- (3) notifying judges of the standards by which they will be evaluated.

R597-7-2. Definitions.

- (1) "Controlling cycle" means the single retention election year which, when assigned to a judge, establishes the time frames for performance evaluation.
- (2) "Courtroom observation report" means the individual narrative report a courtroom observer authors after observing the judge.
- (3) "Courtroom observer" means a volunteer, recruited by commission staff through public outreach and advertising, who has the duties described in Subsection R597-6-3(6).
- (4) "Court staff" means employees of the judiciary, as identified in Subsection R597-6-2(9)(c), who have regular contact with the judge as the judge performs judicial duties. Court staff also includes those who are not employed by the judiciary but who have ongoing administrative duties in the courtroom.
- (5) For purposes of administering a survey to a juror, a case is "closed" when the verdict is rendered or the jury is dismissed.
- (6) "Disqualification," as used in Section R597-2-2, means the involuntary disqualification of a commissioner by other commissioners, in accordance with Subsections R597-2-2(6) and R597-2-2(7).
- (7) "Evaluation cycle" means a time period during which a judge is evaluated. Judges not on the supreme court are subject to two evaluation cycles over a six-year judicial term. Justices of the supreme court are subject to three evaluation cycles over a ten-year judicial term.
- (8) "Juvenile court professional" means an individual, as identified in Subsection R597-6-2(9)(d), whose professional duties place that individual in juvenile court on a regular and continuing basis.
- (9) "Observation instrument" means the form approved for use by courtroom observers to evaluate the judicial behavior observed in court.
- (10) "Procedural fairness" means the type of treatment judges should afford people in their courts and includes the principles and behavioral standards identified in Subsection R597-6-3(12).
- (11) "Recusal," as used in Section R597-2-2, means a voluntary self-disqualification by a commissioner.
- (12) "Survey" means the aggregate of questionnaires, each targeting a separate classification of survey respondents, which together are used to assess judicial performance.
- (13) "Survey respondent" means an individual, as identified in Subsection R597-6-2(9), eligible to author a survey response.
- (14) "Surveyor" means the organization or individual awarded a contract through procedures established by the state procurement code to survey respondents regarding judicial performance.

KEY: performance evaluations, judicial performance evaluations, judiciary, judges

Date of Last Change: 2024

Authorizing, and Implemented or Interpreted Law: 78A-12

NOTICE OF PROPOSED RULE		
TYPE OF FILING:	Amendment	
Rule or Section Number:	R616-2-3	Filing ID: 56396

Agency Information

1. Department:	Labor Commission
Agency:	Boiler, Elevator and Coal Mine Safety
Room number:	3rd Floor
Building:	Heber M Wells Bldg
Street address:	160 E 300 S
City, state and zip:	Salt Lake City, UT 84111
Mailing address:	PO Box 146600
City, state and zip:	Salt Lake City, UT 84114-6600

Contact persons:

Name:	Phone:	Email:
Rick Sturm	801- 530- 6850	rsturm@utah.gov
Chris Hill	801- 530- 6113	chill@utah.gov

Please address questions regarding information on this notice to the persons listed above.

General Information

2. Rule or section catchline:

R616-2-3. Safety Codes and Rules for Boilers and Pressure Vessels

3. Purpose of the new rule or reason for the change:

The purpose of this rule change is to adopt the 2023 edition of the national Board Inspection Code (NBIC, NB-23), Part 3-Repairs and Alterations and Part 4-Pressure Relief Devices.

This rule also adopts the 2023 editions of the American Society of Mechanical Engineers (ASME) Sections 1 (Rules for Construction of Power Boilers), Section IV (Rules for Construction of Heating Boilers) and Section VIII (Rules for Construction of Pressure Vessels).

It also removes ASME B31.1-2016 edition Power Piping.

4. Summary of the new rule or change:

This rule change adopts the 2023 editions of the ASME Sections 1, IV and VIII and the NBIC Parts. 3 and 4.

It also repeals the ASME B31.1-2015 edition.

The current editions make no significant changes, and what changes are being made apply to the manufacturing and repair of boilers and pressure vessels.

Repairs to existing boilers and pressure vessels can be to any appropriate NBIC Standard since original installation.

Fiscal Information

5. Provide an estimate and written explanation of the aggregate anticipated cost or savings to:

A) State budget:

There should be no cost or savings to the state budget because new codes books are provided to the state.

The changes in the 2023 editions are not significant changes. The ASME standards being adopted apply to the manufacturing of boilers and pressure vessels and the NBIC Standards being adopted apply to the repair of boilers and pressure vessels.

The Division of Boiler, Elevator and Coal Mine Safety (Division) inspects to the standard that applies to the date of manufacture and subsequent repair standards; therefore, there should be no cost or savings to the state budget due to the incorporation of these standards.

B) Local governments:

There should be no cost or savings to local governments because local governments do not need to obtain copies of the incorporated materials.

The changes in the 2023 editions are not significant changes. The ASME standards being adopted apply to the manufacturing of boilers and pressure vessels and the NBIC Standards being adopted apply to the repair of boilers and pressure vessels.

The Division inspects to the standard that applies to the date of manufacture and subsequent repair standards; therefore, there should be no cost or savings to the local governments due to the incorporation of these standards.

C) Small businesses ("small business" means a business employing 1-49 persons):

The only cost to small businesses is for those ASME/NB Code Stamp Certification holders (for construction and/or repairs to boilers/pressure vessels) that are required to purchase these codes for the associated Stamps held regardless of adoption.

The changes in the 2023 editions are not significant changes. The ASME standards being adopted apply to the manufacturing of boilers and pressure vessels and the NBIC Standards being adopted apply to the repair of boilers and pressure vessels.

The Division inspects to the standard that applies to the date of manufacture and subsequent repair standards; therefore, there should be no cost or savings to small businesses due to the incorporation of these standards

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

The only cost to non-small businesses is for those ASME/NB Code Stamp Certification holders (for

construction and/or repairs to boilers/pressure vessels) that are required to purchase these codes for the associated Stamps held regardless of adoption.

The changes in the 2023 editions are not significant changes. The ASME standards being adopted apply to the manufacturing of boilers and pressure vessels and the NBIC Standards being adopted apply to the repair of boilers and pressure vessels.

The Division inspects to the standard that applies to the date of manufacture and subsequent repair standards; therefore, there should be no cost or savings to non-small businesses due to the incorporation of these standards.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

The only cost to persons other than small businesses, nonsmall businesses, state or local government entities would be to those entities that are ASME/NB Code Stamp Certification holders, who are required to purchase the codes for their stamps.

The changes in the 2023 editions are not significant changes. The ASME standards being adopted apply to the manufacturing of boilers and pressure vessels and the NBIC Standards being adopted apply to the repair of boilers and pressure vessels.

The Division inspects to the standard that applies to the date of manufacture and subsequent repair standards; therefore, there should be no cost or savings to other persons due to the incorporation of these standards.

F) Compliance costs for affected persons (How much will it cost an impacted entity to adhere to this rule or its changes?):

The changes in the 2023 editions are not significant changes. The ASME standards being adopted apply to the manufacturing of boilers and pressure vessels and the NBIC Standards being adopted apply to the repair of boilers and pressure vessels.

The Division inspects to the standard that applies to the date of manufacture and subsequent repair standards; therefore, there should be no compliance costs for affected persons due to the incorporation of these standards.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory In	npact Table)	
Fiscal Cost	FY2024	FY2025	FY2026
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Cost	\$0	\$0	\$0
Fiscal Benefits	FY2024	FY2025	FY2026
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Benefits	\$0	\$0	\$0
Net Fiscal Benefits	\$0	\$0	\$0

H) Department head comments on fiscal impact and approval of regulatory impact analysis:

The Commissioner of the Utah Labor Commission, Jaceson R. Maughan, has reviewed and approved this regulatory impact analysis.

Citation Information

6. Provide citations to the statutory authority for the rule. If there is also a federal requirement for the rule, provide a citation to that requirement:

ļ.•	•	
Section		
34A-7-101 et seq.		

Incorporations by Reference Information

7. Incorporations by Reference:

A) This rule adds, updates, or removes the following title of materials incorporated by references:

art 3 Repairs and

Publisher	National Board Inspection Code
Issue or Version	2023

B) This rule adds, updates, or removes the following title of materials incorporated by references:

ture of materials meet perateur by references.	
Official Title of Materials Incorporated (from title page)	2023 NBIC Part 4 Pressure Relief Devices
Publisher	National Board Inspection Code
Issue or Version	2023

C) This rule adds, updates, or removes the following title of materials incorporated by references:

title of materials in	corporated by references:
Official Title of Materials Incorporated (from title page)	2023 ASME Boiler and Pressure Vessel Code Section 1
Publisher	American Society of Mechanical Engineers
Issue or Version	2023

D) This rule adds, updates, or removes the following title of materials incorporated by references:

Official Title of Materials Incorporated (from title page)	2023 ASME Boiler and Pressure Vessel Code Section IV
Publisher	American Society of Mechanical Engineers
Issue or Version	2023

E) This rule adds, updates, or removes the following title of materials incorporated by references:

Official Title of Materials Incorporated (from title page)	2023 ASME Boiler and Pressure Vessel Code Section VIII	
Publisher	American Society of Mechanical Engineers	
Issue or Version	2023	

Public Notice Information

8. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. See Section 63G-3-302 and Rule R15-1 for more information.)

A)	Comments	will	be	accepted	05/15/2024
unti	l:				

9. This rule change MAY 05/22/2024 become effective on:

NOTE: The date above is the date the agency anticipates making the rule or its changes effective. It is NOT the effective date.

Agency Authorization Information

Agency head	Jaceson	Date:	03/25/2024
or designee	Maughan,		
and title:	Commissioner		

R616. Labor Commission, Boiler, Elevator and Coal Mine Safety.

R616-2. Boiler and Pressure Vessel Rules.

R616-2-3. Safety Codes and Rules for Boilers and Pressure Vessels.

The following safety codes and rules shall apply to all boilers and pressure vessels in Utah, except those exempted pursuant to Section 34A-7-101, and are incorporated by reference in this rule.

- _A. ASME Boiler and Pressure Vessel Code -- 202[1]3.
- 1. Section I Rules for Construction of Power Boilers.
- 2. Section IV Rules for Construction of Heating Boilers.
- 3. Section VIII Rules for Construction of Pressure Vessels.

B. Power Piping ASME B31.1 -- 2016.

[G]B. Controls and Safety Devices for Automatically Fired Boilers, Applicable to boilers with fuel input ratings greater than or equal to 400,000 Btu/hr, ASME CSD-1-2015. Except:

1. Part CG-130(c).

 $[\underline{\mathcal{P}}]\underline{\mathbb{C}}$. National Board Inspection Code ANSI/NB-23 - $[\underline{2021 \text{ Part 3}}]2023 \text{ Parts and 4}$.

 $\cbar{\bf [E]\underline{D}}.$ NFPA 85 Boiler and Combustion Systems Hazard Code 2015.

[F]E. Pressure Vessel Inspection Code: Maintenance Inspection, Rating, Repair and Alteration API 510 Tenth Edition, 2014. Except:

- 1. Section-8, and
- 2. Appendix-A.

KEY: boilers, certification, safety

Date of Last Change: <u>2024[February 8, 2023]</u> Notice of Continuation: March 2, 2021

Authorizing, and Implemented or Interpreted Law: 34A-7-101

et seq.

NOTICE OF PROP	OSED RULE	
TYPE OF FILING:	New	
Rule or Section Number:	R622-3	Filing ID: 56403

Agency Information

1. Department:	Lieutenant Governor
Agency:	Administration
Room number:	Suite 220
Building:	Utah State Capitol
Street address:	350 N State Street

City, state and zip:	Salt Lake City, UT 84114
Mailing address:	PO Box 142325
City, state and zip:	Salt Lake City, UT 84114-2325

Contact persons:

Name:	Phone:	Email:
	801- 538- 1501	munderwood@utah.gov

Please address questions regarding information on this notice to the persons listed above.

General Information

2. Rule or section catchline:

R622-3. Use of the Great Seal of the State of Utah

3. Purpose of the new rule or reason for the change:

Section 67-1a-7 assigns custody of the Great Seal to the Lieutenant Governor's office.

The purpose of this rule is to set appropriate boundaries on the use of the Great Seal. Due to staff turnover, a five-year review was not filed on Rule R622-2, which resulted in its expiration. Rule R622-2 previously set the appropriate boundaries on the use of the Great Seal.

This new rule replaces the recently expired rule.

4. Summary of the new rule or change:

The rule establishes permitted uses of the Great Seal, identifies prohibited uses, describes an application process for use, and sets enforcement provisions.

Fiscal Information

5. Provide an estimate and written explanation of the aggregate anticipated cost or savings to:

A) State budget:

There is minimal cost to the state associated with processing applications and investigating alleged misuse of the Great Seal.

There is some small revenue to the state from an administrative filing fee associated with an application for use. The agency is unable to estimate an aggregate cost or savings as there is no way of knowing how many applications will be received or how many investigations will be undertaken.

B) Local governments:

Most local governments use of the Great Seal falls under the list of generally permitted uses under Section R622-3-4, which are exempted from application fee by Section R622-3-6. Any other use would require paying a \$5 application fee.

The agency has no way of knowing how many applications it would receive and so cannot estimate an aggregate cost.

C) Small businesses ("small business" means a business employing 1-49 persons):

There is no cost to small businesses. Small businesses may not use the seal.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

There is no cost to non-small businesses. Non-small businesses may not use the seal.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

Other persons who wish to use the seal may apply for use. The application fee is \$5.

The agency has no way of knowing how many applications it would receive and so cannot estimate an aggregate cost.

F) Compliance costs for affected persons (How much will it cost an impacted entity to adhere to this rule or its changes?):

Compliance costs for affected persons are limited to the \$5 application fee for use of the seal.

G) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table

Fiscal Cost	FY2024	FY2025	FY2026
State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Cost	\$0	\$0	\$0
Fiscal Benefits	FY2024	FY2025	FY2026

State Government	\$0	\$0	\$0
Local Governments	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Benefits	\$0	\$0	\$0
Net Fiscal Benefits	\$0	\$0	\$0

H) Department head comments on fiscal impact and approval of regulatory impact analysis:

The Lieutenant Governor, Deidre M. Henderson, has reviewed and approved this regulatory impact analysis.

Citation Information

6. Provide citations to the statutory authority for the rule. If there is also a federal requirement for the rule, provide a citation to that requirement:

Section 67-1a-2 Section 67-1a-7 Section 76-6-501

Public Notice Information

8. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. See Section 63G-3-302 and Rule R15-1 for more information.)

A)	Comments	will	be	accepted	05/15/2024
uı	ntil:				

9. This rule change MAY 05/22/2024 become effective on:

NOTE: The date above is the date the agency anticipates making the rule or its changes effective. It is NOT the effective date.

Agency Authorization Information

Agency head	Mallory	Date:	03/29/2024
or designee	Underwood,		
and title:	Office		
	Administrator		

R622. Lieutenant Governor, Administration.

R622-3. Use of the Great Seal of the State of Utah. R622-3-1. Purpose.

(1) The Great Seal of the State of Utah is a symbol of the sovereignty of this state, and its use denotes authenticity of official state government functions and authority. The Great Seal is a single mounted engraved plate, comprising form and content as described

- in Section 67-1a-8. The purpose of this rule is to define how the state will:
- (a) manage the use and application of the Great Seal (the seal); and
 - (b) define criteria for its authorized application.

R622-3-2. Primary Function of the Seal.

- (1) Since its conception, the seal has been employed for specific governmental applications within the state's executive, legislative, and judicial branches. The seal will be administered consistent with state law and policy, and its principal application shall be to authenticate or attest to:
- (a) official documents which are authorized or required by statute; and
- (b) other state documents having historic, civic, commemorative, or educational value or import.
- (2) The seal's impression on a legal document shall require the lieutenant governor's signature to appear on the same page as, and in proximity thereto.

R622-3-3. Custody and Use.

Pursuant to Subsections 67-1a-2(1)(d) through (f) the lieutenant governor is the custodian of the Great Seal.

R622-3-4. General Permitted Uses of the Seal.

- (1) The seal shall be permitted for use without the written authorization of the lieutenant governor, in the following circumstances:
- (a) printings of replicas of the seal on official state letterhead, business cards, and stationery for agencies, entities, or officers of the state; and
- (b) exhibition of permitted reproductions of the seal on state flags.
- (2) The seal shall be permitted for use in the following circumstances upon describing and submitting a list of intended uses with the lieutenant governor's office to assure uniformity and continuity of use:
- (a) application or display of replicas of the seal by state agencies and state political sub-divisions which delineate official state purposes, and by state elected officials in connection with their official state business;
- (b) for educational and academic uses by schools, colleges and universities to convey information about official state functions;
- (c) for use on a product or article offered to the public, for profit or without charge, through the Utah State Capitol gift shop; and
- (d) such uses may not try to endorse, authenticate, recognize or promote persons or roles, or be part of administrative or promotional functions.

R622-3-5. Prohibited Usage.

- (1) The seal, or replica, may not be committed for general use, including:
 - (a) for personal financial gain;
- (b) for, or in connection with, any advertising or promotion of any product, business, organization, service, or article whether offered for sale, for profit or without charge, except as provided in Subsection R622-3-4(2)(c);
- (c) in a political campaign, or in ways that may legitimize or assist to defeat another candidate for elective office; or

- (d) to function, or be construed to function in any way, as an endorsement of any business, organization, product, service, or article.
- (2) No symbol shall be used that imitates or appears similar to the seal in a way that intends to deceive, or is displayed in a manner that conveys improper use of the official Great Seal itself.
- (3) When the seal is used, no mark, insignia, letter, word, figure, design, picture, or drawing of any nature may be placed upon the seal, or any part of it.
- (4) A state agency, or an elected official, other than the lieutenant governor, may not authorize an individual or entity associated with a state agency or state elected official, to use the seal or replica for a commercial purpose whereby items will be distributed for sale, even though such purpose may include the providing of goods or services to the state.
- (5) The seal may not be displayed in a manner which lessens or detracts from its dignity or impact.

R622-3-6. Application for Use.

- (1) Persons or entities seeking permission to use the seal or replica, excepting uses outlined in Section R622-3-4, will complete and file a legible application with the lieutenant governor, on a form provided by that office, which shall include:
- (a) a specific description of the intended usage involving the Great Seal of the State of Utah, or replica of the seal;
- (b) the payment of a non-refundable administrative filing fee in the amount of \$5; and
- (c) a precise description and specification of the product or item to bear the seal, or replica, in the form of an architectural drawing, engineering draft-to-scale, brochure, or lucid photograph or computer-graphic.
- (2) The application and supporting documents shall become the property of the lieutenant governor's office.
- (3) Upon approval of a complete application, the applicant shall be issued a certificate bearing an identification number, by the lieutenant governor, which shall be kept by the applicant on file for four years following use of the seal. State agencies and entities which

- use the state seal or replica for official state functions have no application or fee requirement.
 - (4) An application may be denied for:
 - (a) failure to comply with relevant statutes or this rule;
 - (b) failure to include the required fee; or
- (c) if the intended use is found to be detrimental to the image of the state and not in its best interest.

R622-3-7. Revocation of Approved Applications.

The lieutenant governor may revoke any prior approved usage if it is determined that the seal is being used improperly, if the actual use differs from the intended use as described on the application, or if false or inaccurate information was used to gain approval.

R622-3-8. Enforcement.

- (1) Pursuant to Section 67-1a-7, except as otherwise provided by law, only the lieutenant governor, or the lieutenant governor's designee, may use or affix the seal to a document in pursuance of law. If any person illegally uses the seal, or such seal when defaced, the state may refer such criminal violations to an appropriate prosecuting authority.
- (2) Under the provisions of Section 76-6-501 the state may seek redress against a person, or persons, who impermissibly replicate the seal as a forgery. A person or entity employing the seal, or a replica, with the intent to defraud or imply that the presence of the seal or replica appeared by permission of the state, or whose presentation of the seal denigrates its ability to authenticate by proper state authority, may be referred to an appropriate prosecuting authority.

KEY: Great Seal

Date of Last Change: 2024

Authorizing, and Implemented or Interpreted Law: 67-1a-7; 67-1a-2; 76-6-501

End of the Notices of Proposed Rules Section

NOTICES OF 120-DAY (EMERGENCY) RULES

An agency may file a 120-DAY (EMERGENCY) RULE when it finds that regular rulemaking procedures would:

- (a) cause an imminent peril to the public health, safety, or welfare;
- (b) cause an imminent budget reduction because of budget restraints or federal requirements; or
- (c) place the agency in violation of federal or state law (Subsection 63G-3-304(1)).

As with a **Proposed Rule**, a **120-Day Rule** is preceded by a **Rule Analysis**. This analysis provides summary information about the **120-Day Rule** including the name of a contact person, justification for filing a **120-Day Rule**, anticipated cost impact of the rule, and legal cross-references.

Following the RULE ANALYSIS, the text of the 120-DAY RULE is printed. New text is underlined (<u>example</u>) and text to be deleted is struck out with brackets surrounding the deleted text ([example]). An emergency rule that is new is entirely underlined. Likewise, an emergency rule that repeals an existing rule shows the text completely struck out. A row of dots in the text (.....) indicates that unaffected text was removed to conserve space.

A **120-Day Rule** is effective when filed with the Office of Administrative Rules, or on a later date designated by the agency. A **120-Day Rule** is effective for 120 days or until it is superseded by a permanent rule. Because of its temporary nature, a **120-Day Rule** is not codified as part of the *Utah Administrative Code*.

The law does not require a public comment period for **120-DAY RULEs**. However, when an agency files a **120-DAY RULE**, it may file a **PROPOSED RULE** at the same time, to make the requirements permanent.

Emergency or 120-DAY RULES are governed by Section 63G-3-304, and Section R15-4-8.

NOTICE OF EMER	GENCY (120-DAY)	RULE
Rule or Section Number:	R414-60-7	Filing ID: 56395
Effective Date:	03/22/2024	

Agency Information

1. Department:	Health and Human Services		
Agency:	Integrated Healthcare		
Building:	Cannon Health Building		
Street address:	288 N 1460 W		
City, state and zip:	Salt Lake City, UT 84116		
Mailing address:	PO Box 143102		
	Salt Lake City, UT 84114-3102		
City, state and zip:	Salt Lake City, UT 84114-3102		
	,		
zip:	,		
zip: Contact persons:			

Please address questions regarding information on this notice to the persons listed above.

General Information

2. Rule or section catchline:

R414-60-7. Reimbursement

3. Purpose of the new rule or reason for the change:

This emergency amendment addresses a significant disruption to the pharmacy point of sale system affecting Medicaid users in the state.

The purpose of this change is to allow the Medicaid division director flexibility to waive the 24-day limit on pharmacy dispensing fees if there is a significant disruption to the pharmacy point of sale system.

4. Summary of the new rule or change:

This emergency filing allows the Medicaid division director flexibility to waive the 24-day limit on pharmacy dispensing fees due to the system interruption to the pharmacy point of sale system that resulted in extensive downtime and increased administrative workload for pharmacy providers.

It also updates the agency name within the rule title.

5A) The agency finds that regular rulemaking would:

- cause an imminent peril to the public health, safety, or welfare;
- □ cause an imminent budget reduction because of budget restraints or federal requirements; or
- □ place the agency in violation of federal or state law.

B) Specific reasons and justifications for this finding:

The Department of Health and Human Services (Department) needs the ability to waive the 24-day limit to pharmacy dispensing fees due to the Medicaid point of sale system currently experiencing a system interruption that results in extensive downtime and increased administrative workload for pharmacy providers.

The additional administrative burden for pharmacies that fill prescriptions for Medicaid members results in the disruption of a Medicaid member's access to medical care.

As a result, remaining without this emergency rule would cause imminent peril to public health, safety, and welfare.

An exception to the 24-day limit to pharmacy dispensing fees provides a pathway for pharmacies to fill medications for Medicaid members and be compensated for the additional workload during the system interruption that results in extended downtime until the Medicaid pharmacy claims can be submitted and processed for payment using usual pathways.

This emergency rule is intended to allow the Department to bolster pharmacies' ability to handle the increased administrative workload to fill prescriptions in a timely manner and avert the imminent peril threatening the public.

The Department must facilitate the pharmacy's ability to remain a viable business entity and remain in the network for member access to medically necessary services to avoid imminent peril to public health, as fewer in-network pharmacies would result in an additional burden on Medicaid members who need access to prescriptions.

Fiscal Information

6. Provide an estimate and written explanation of the aggregate anticipated cost or savings to:

A) State budget:

Due to the time constraints of the current emergency, the Department cannot accurately estimate potential fiscal impacts, as an estimation would require the agency to slow the process of filing this emergency rule and cause an imminent peril to the public health, safety, or welfare.

The Department cannot wait until data on claims and payment information, which is normally available in quarterly reports, is released.

As such, there is insufficient information to estimate the fiscal impact to the state budget.

B) Local governments:

Due to the time constraints of the current emergency, the Department cannot accurately estimate potential fiscal impacts, as an estimation would require the agency to slow the process of filing this emergency rule and cause an imminent peril to the public health, safety, or welfare.

The Department cannot wait until data on claims and payment information, which is normally available in quarterly reports, is released.

As such, there is insufficient information to estimate the fiscal impact to local governments.

C) Small businesses ("small business" means a business employing 1-49 persons):

Due to the time constraints of the current emergency, the Department cannot accurately estimate potential fiscal impacts, as an estimation would require the agency to slow the process of filing this emergency rule and cause an imminent peril to the public health, safety, or welfare.

The Department cannot wait until data on claims and payment information, which is normally available in quarterly reports, is released.

As such, there is insufficient information to estimate the fiscal impact to small businesses.

D) Persons other than small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an *agency*):

Due to the time constraints of the current emergency, the Department cannot accurately estimate potential fiscal impacts, as an estimation would require the agency to slow the process of filing this emergency rule and cause an imminent peril to the public health, safety, or welfare.

The Department cannot wait until data on claims and payment information, which is normally available in quarterly reports, is released.

As such, there is insufficient information to estimate the fiscal impact to other persons or entities.

E) Compliance costs for affected persons (How much will it cost an impacted entity to adhere to this rule or its changes?):

Due to the time constraints of the current emergency, the Department cannot accurately estimate potential fiscal impacts, as an estimation would require the agency to slow the process of filing this emergency rule and cause an imminent peril to the public health, safety, or welfare.

The Department cannot wait until data on claims and payment information, which is normally available in quarterly reports, is released.

As such, there is insufficient information to estimate compliance costs to a single person or entity.

F) Comments by the department head on the fiscal impact this rule may have on businesses (Include the name and title of the department head):

The Executive Director of the Department of Health and Human Services, Tracy S. Gruber, has reviewed and approved this fiscal analysis.

Due to the time constraints of the current emergency, the Department cannot accurately estimate potential fiscal impacts, as an estimation would require the agency to slow the process of filing this emergency rule and cause an imminent peril to the public health, safety, or welfare.

The Department cannot wait until data on claims and payment information, which is normally available in quarterly reports, is released.

As such, there is insufficient information to estimate the fiscal impact to businesses. -Tracy S. Gruber, Executive Director

Citation Information

7. Provide citations to the statutory authority for the rule. If there is also a federal requirement for the rule, provide a citation to that requirement:

Section 26B-1-213 Section 26B-3-108

Agency Authorization Information

Agency head	Tracy S. Gruber,	Date:	03/22/2024
or designee	Executive		
and title:	Director		

R414. Health and Human Services, [Health Care Financing, Coverage and Reimbursement Policy] Integrated Healthcare. R414-60. Medicaid Policy for Pharmacy Program. R414-60-7. Reimbursement.

(1) A pharmacy may not submit a charge to Medicaid that exceeds the pharmacy's usual and customary charge.

- (2) Covered outpatient drugs are reimbursed as outlined in Attachment 4.19-B of the [Utah] Medicaid State Plan.
- (3) A pharmacy that participates in the 340B program and uses medications obtained through the 340B program to bill Medicaid, must submit the acquisition cost of the medication on the claim
- (4) A pharmacy that participates in the federal supply schedule and uses medications obtained through the schedule to bill Medicaid, must submit the acquisition cost of the medication on the claim unless the claim is reimbursed as a bundled charge or all—inclusive rate
- (5) A pharmacy that obtains and uses medications at a nominal price must submit the acquisition cost of the medication on the claim.
- (6) Dispensing fees are outlined in Attachment 4.19-B of the [Utah-]Medicaid State Plan. Medicaid pays the lesser of the assigned dispensing fee or the submitted dispensing fee.
- (7) Medicaid pays a pharmacy only one dispensing fee every 24 days for each covered outpatient drug.
- (a) In the event the Medicaid point of sale system experiences a system interruption that results in extensive downtime and increased administrative workload for pharmacy providers, the Medicaid division director may waive the 24-day limit on dispensing fees.
- (8) Medicaid pays a provider that immunizes a Medicaid member who is 19 years of age or older, for the cost of the immunization plus a dispensing fee. Medicaid pays the lesser of the allowed or submitted charges.
- (9) A provider that immunizes a Medicaid member who is 18 years of age or younger, may only be eligible for a dispensing fee with no reimbursement for the immunization. Immunizations for Medicaid members who are 18 years of age or younger must be obtained through the Vaccines for Children program.
- (10) Diabetic supplies listed on the Utah Medicaid PDL are reimbursed at the lesser of the wholesale acquisition cost with no dispensing fee or the billed charges.
- (11) Pursuant to Section 58-17b-805, a dispensing medical practitioner may prescribe and dispense medication directly to a patient if providing outpatient cancer therapy. Details of reimbursement are found on the Medicaid website at http://health.utah.gov/medicaid/stplan/lookup/CoverageLookup.php

KEY: Medicaid

Date of Last Change: March 22, 2024 Notice of Continuation: March 11, 2022

Authorizing, and Implemented or Interpreted Law: 26B-1-213;

26B-3-108

End of the Notices of 120-Day (Emergency) Rules Section

FIVE-YEAR NOTICES OF REVIEW AND STATEMENTS OF CONTINUATION

Within five years of an administrative rule's original enactment or last five-year review, the agency is required to review the rule. This review is intended to help the agency determine, and to notify the public, that the administrative rule in force is still authorized by statute and necessary. Upon reviewing a rule, an agency may: repeal the rule by filing a **Proposed Rule**; continue the rule as it is by filing a **FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION (REVIEW)**; or amend the rule by filing a **PROPOSED RULE** and by filing a **REVIEW**. By filing a **REVIEW**, the agency indicates that the rule is still necessary.

A **Review** is not followed by the rule text. The rule text that is being continued may be found in the online edition of the *Utah Administrative Code* available at adminrules.utah.gov. The rule text may also be inspected at the agency or the Office of Administrative Rules. **Reviews** are effective upon filing.

REVIEWS are governed by Section 63G-3-305.

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION			
Rule Number:	R64-3	Filing ID: 50125	
Effective Date:	03/21/2024		

Agency Information

Department: Agriculture and Food		re and Food	
Agency:	Conservation Commission		
Building:	South Bldg		
Street address:	4315 S 2	4315 S 2700 W, Floor 2	
City, state and zip:	Taylorsville, UT 84129		
Mailing address:	PO Box	146500	
City, state and zip:	Salt Lake City, UT 84114-6500		
Contact persons:			
Name: Pho		Email:	
Amber Brown	385- 245- 5222	ambermbrown@utah.gov	
Jim Bowcutt	435- 232- 4017	jdbowcutt@utah.gov	
Kelly Pehrson	385- 977- 2147	kwpehrson@utah.gov	

Please address questions regarding information on this notice to the persons listed above.

General Information

2. Rule catchline:

R64-3. Utah Environmental Stewardship Certification Program (UESCP), a.k.a. Agriculture Certificate of Environmental Stewardship (ACES)

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Section 4-18-107, Utah Agricultural Certificate of Environmental Stewardship (ACES) Program, has been effective since 07/01/2017.

The Department of Agriculture and Food (Department), in 2020, implemented the Agriculture Voluntary Incentive Program (AGVIP) due to funding appropriated to the AGVIP each year and the lack of interest in the ACES program.

Since the statute requires and defines the ACES program, the Department would like to continue this rule until the 2025 General Session when possible legislation may repeal the program.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

Currently, the Department has not received any public comments about the ACES program or this rule and has not issued any statements about the program.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

At this time, the Department wants to keep this rule until possible legislation can repeal the program. After legislators pass the repeal of the program, the Department

plans to repeal this rule. Therefore, this rule should be continued.

Agency Authorization Information

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

CONTINUATION			
Rule Number:	R317-401	Filing ID: 52484	
Effective Date:	04/01/2024		

Agency Information

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1. Department:	Environmental Quality		
Agency:	Water Quality		
Room number:	DEQ 3rd Floor		
Building:	Multi Agency State Office Building (MASOB)		
Street address:	195 N 1950 W		
City, state and zip:	Salt Lake City, UT 84116		
Mailing address:	PO Box 144870		
City, state and zip:	Salt Lake City, UT 84114-4870		
Contact persons:	Contact persons:		
Name:	Phone: Email:		
Robert Beers	385- 501- 9580	rbeers@utah.gov	

Please address questions regarding information on this notice to the persons listed above.

General Information

2. Rule catchline:

R317-401. Graywater Systems

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

The Water Quality Board is authorized by Subsection 19-5-104(1)(A)(v) to make rules in order to protect the public health for the design, construction, operation, and maintenance of underground wastewater disposal systems.

The director is authorized by Section 19-5-105 to:

- 1) develop programs for the prevention, control, and abatement of new or existing pollution of the waters of the state;
- 2) enforce rules created by the Board;
- 3) require permits for the construction of treatment facilities:

- 4) review plans and specifications; and
- 5) adopt other measures to prevent, control, or abate pollution of waters of the state.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

This rule was first promulgated on 07/02/2004. This rule was revised in March 2020.

No written comments have been received since the last five-year review.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule was developed in response to a number of inquiries from the public and local health departments regarding the use, under certain conditions, of graywater originating from laundries, showers, tubs, and lavatories for subsurface irrigation.

This rule sets out the requirements for use of graywater and is required for adequate protection of the state's water resources. Therefore, this rule should be continued.

Agency Authorization Information

Agency head or designee and title:	John K. Mackey, Division Director	Date:	04/01/2024
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FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

Rule Number:	R414-14A	Filing ID: 55984
Effective Date:	03/25/2024	

Agency Information

1. Department:	Health and Human Services
Agency:	Integrated Healthcare
Building:	Cannon Health Building
Street address:	288 N 1460 W
City, state and zip:	Salt Lake City, UT 84116
Mailing address:	PO Box 143102
City, state and zip:	Salt Lake City, UT 84114-3102

Contact persons:		
Name:	Phone:	Email:
Craig Devashrayee	801- 538- 6641	cdevashrayee@utah.gov
Mariah Noble	385- 214- 1150	mariahnoble@utah.gov

Please address questions regarding information on this notice to the persons listed above.

General Information

2. Rule catchline:

R414-14A. Hospice Care

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Section 26B-3-108 requires the Department of Health and Human Services (Department) to implement Medicaid through administrative rules.

Section 26B-1-213 grants the Department the authority to adopt, amend, or rescind these rules.

Additionally, 42 CFR 418 sets forth provisions of hospice care services for Medicaid members.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

The Department did not receive any written comments regarding this rule since its last five-year review.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

The Department has determined this rule is necessary because it is required by statute and defines the scope of hospice care services available to Medicaid members. Therefore, this rule should be continued.

As the Department received no public comments, it did not respond to any comments.

Agency Authorization Information

Agency head	Tracy S. Gruber,	Date:	03/25/2024
or designee	Executive		
and title:	Director		

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION			
Rule Number:	R432-13	Filing ID: 55415	
Effective Date:	03/19/2024		

Agency Information

Agency Informatio	n	
1. Department:	Health and Human Services	
Agency:	Health Care Facility Licensing	
Building:	MASOB	
Street address:	195 N 19	950 W
City, state and zip:	Salt Lake City, UT 84116	
Contact persons:		
Name:	Phone:	Email:
Janice Weinman	385- 321- 5586	jweinman@utah.gov
Mariah Noble	385- 214- 1150	mariahnoble@utah.gov

Please address questions regarding information on this notice to the persons listed above.

General Information

2. Rule catchline:

R432-13. Freestanding Ambulatory Surgical Center Construction Rule

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Section 26B-2-202 authorizes the office to write and enforce rules to govern licensure of health care facilities in Utah.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

There have been no comments received since the last five-year review and no recommended substantive changes from the Health Care Facility Rule Committee since the most recent activation of this rule.

This five-year review filing is intended to ensure this rule remains in continual effect for statutory compliance.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

Aside from recodification and the Rulewriting Manual for Utah compliance edits, there have been no comments or recommendations for changes to this rule over the past five years.

Statute requires the Office of Licensing to write and enforce rules pertaining to the construction of freestanding ambulatory surgical centers. This rule is necessary to ensure there is no lapse in oversight of the construction requirements for freestanding ambulatory surgical centers. Therefore, this rule should be continued.

Agency Authorization Information

Agency head	Tracy S. Gruber,	Date:	03/19/2024
or designee	Executive		
and title:	Director		

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

Rule Number:	R432-14	Filing ID: 55945
Effective Date:	03/19/2024	

Agency Information

1. Department:	Health and Human Services
Agency:	Health Care Facility Licensing
Building:	MASOB
Street address:	195 N 1950 W
City, state and zip:	Salt Lake City, UT 84116
Contact paragraph	

Contact persons:

Name:	Phone:	Email:
Janice Weinman	385- 321- 5586	jweinman@utah.gov
Mariah Noble	385- 214- 1150	mariahnoble@utah.gov

Please address questions regarding information on this notice to the persons listed above.

General Information

2. Rule catchline:

R432-14. Birthing Center Construction Rule

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Section 26B-2-202 authorizes the office to write and enforce rules to govern licensure of health care facilities in Utah.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

There have been no comments received since the last five-year review and no recommended substantive changes from the Health Care Facility Rule Committee.

This five-year review filing is intended to ensure this rule remains in continual effect for statutory compliance.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

Aside from recodification and the Rulewriting Manual for Utah compliance edits, there have been no comments or recommendations for changes to this rule over the past five years.

Statute requires the Office of Licensing to write and enforce rules pertaining to the construction of birthing centers. This rule is necessary to ensure there is no lapse in oversight of the construction requirements for birthing centers. Therefore, this rule should be continued.

Agency Authorization Information

Agency head	Tracy S. Gruber,	Date:	03/19/2024
or designee	Executive		
and title:	Director		

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

Rule Number:	R432-32	Filing ID: 55940
Effective Date:	03/29/2024	

Agency Information

1. Department:	Health a	nd Human Services
Agency:	Health Care Facility Licensing	
Building:	MASOB	
Street address:	195 N 1950 W	
City, state and zip:	Salt Lake City, UT 84116	
Contact persons:		
Name:	Phone:	Email:
Janice Weinman	385- 321- 5586	jweinman@utah.gov
Mariah Noble	385- 214- 1150	mariahnoble@utah.gov

Please address questions regarding information on this notice to the persons listed above.

General Information

2. Rule catchline:

R432-32. Licensing Exemption for Non-Profit Volunteer End-of-Life Care

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Section 26B-2-205 authorizes the agency to write and enforce rules to govern exempt health care facilities in Utah.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

There have been no comments received since the last five-year review and no recommended substantive changes from the Health Care Facility Rule Committee.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

Aside from recodification and nonsubstantive updates to comply with the Rulewriting Manual for Utah, there have been no comments or recommendations for changes to this rule over the past five years.

Non-profit, volunteer end-of-life care providers are exempted from licensure in this rule.

This rule needs to remain in place to ensure the appropriate distinctions exist between these exempted providers and providers who are required to become licensed by the agency. Therefore, this rule should be continued.

Agency Authorization Information

Agency head	Tracy S. Gruber,	Date:	03/29/2024
or designee	Executive		
and title:	Director		

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

Rule Number:	R455-11	Filing ID: 54435
Effective Date:	03/25/2024	

Agency Information

1. Department:	Cultural and Community Engagement
Agency:	History
Building:	Highland Building

Street address:	3760 S I	Highland Dr
City, state and zip:		e City, UT 84106
Contact persons:		
Name:	Phone:	Emaile
itailie.	Phone.	Eman:

Please address questions regarding information on this notice to the persons listed above.

General Information

2. Rule catchline:

R455-11. Historic Preservation Tax Credit

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

To be eligible of the Historic Preservation Tax Credit, all rehabilitation work must be approved by the State Historic Preservation Office before project completion, ensuring it meets the Secretary of the Interior's Standards for Rehabilitation.

A tax credit is available for taxpayers (subject to Section 59-7-104) who incur qualified rehabilitation expenditures of more than \$10,000 on residential certified historic buildings. The credit is equal to 20% of these qualified expenditures.

This credit applies to all qualifying expenses exceeding \$10,000. This is enacted in Sections 59-7-609 and 59-10-1006.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

There were no comments received since the last five-year review of this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule provides a structured approval process with the State History Board and State Historic Preservation Office for the historic preservation tax credit. Therefore, this rule should be continued.

Agency Authorization Information

	Chris Merritt, Utah Historic	Date:	03/25/2024
and title:	Preservation Officer		

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

Rule Number: R455-14 Filing ID: 54436
Effective Date: 03/25/2024

Agency Information

1. Department:	Cultural and Community Engagement
Agency:	History
Street address:	3760 S Highland Dr
City, state and zip:	Salt Lake City, UT 84106

Contact persons:

Name:	Phone:	Email:
	801- 874- 7205	sophiariggs@utah.gov

Please address questions regarding information on this notice to the persons listed above.

General Information

2. Rule catchline:

R455-14. Procedures for Electronic Meetings

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

A public body may not hold an electronic meeting unless the public body has adopted a resolution, rule, or ordinance governing the use of electronic meetings. This rule is enacted under Section 52-4-207.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

No written comments were received since the last fiveyear review of this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

There are times when members of the Board of State History may need to meet electronically. This rule will allow electronic meetings with advanced notice, an anchor location and the ability for the public to attend. Therefore, this rule should be continued.

Agency Authorization Information

Agency head	,	Date:	03/25/2024
or designee	Director		
and title:			

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION

Rule Number:	R455-15	Filing ID: 54452
Effective Date:	03/25/2024	

Agency Information

1. Department:	Cultural and Community Engagement				
Agency:	History				
Street address:	3760 S Highland Dr				
City, state and zip:	Salt Lake City, UT 84106				
Contact persons:	Contact persons:				
Name:	Phone:	Email:			
Sophia Riggs	801- 874- 7205	sophiariggs@utah.gov			

Please address questions regarding information on this notice to the persons listed above.

General Information

2. Rule catchline:

R455-15. Procedures for Emergency Meetings

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

Emergency meetings do not require a 24-hour notice if unforeseen circumstances with an urgent nature a rise and the public body gives the best notice practicable.

There must also be an attempt to notify all public body members, with the majority approving the meeting. This is enacted in Subsection 52-4-202(5).

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

No comments have been received since the last five-year review of this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule allows the Board of State History to hold an emergency meeting when or if urgent matters come to fruition. Therefore, this rule should be continued.

Agency Authorization Information

Agency head	Jennifer Oritz,	Date:	03/25/20241
or designee	Director		
and title:			

FIVE-YEAR NOTICE OF REVIEW AND STATEMENT OF CONTINUATION Rule Number: R710-12 Filing ID: 51916 Effective Date: 03/28/2024

Agency Information

1. Department:	Public Safety		
Agency:	Fire Marshal		
Building:	Confere	nce Center at Miller Campus	
Street address:	410 W 9800 S, Suite 372		
City, state and zip:	Sandy, UT 84070		
Contact persons:			
Name:	Phone: Email:		
Kim Gibb	801- 556- 8198	kgibb@utah.gov	
Ted Black	801- 256-	tblack@utah.gov	

Please address questions regarding information on this notice to the persons listed above.

2390

General Information

2. Rule catchline:			
R710-12.	Hazardous Materials Training and Certification		

3. A concise explanation of the particular statutory provisions under which the rule is enacted and how these provisions authorize or require this rule:

This rule is authorized by Section 53-7-204, which requires that the Utah Fire Prevention Board make rules establishing ongoing training standards for hazardous materials emergency response agencies.

4. A summary of written comments received during and since the last five-year review of this rule from interested persons supporting or opposing this rule:

There have been no written comments received during or since the last five-year review of this rule.

5. A reasoned justification for continuation of this rule, including reasons why the agency disagrees with comments in opposition to this rule, if any:

This rule is required under Section 53-7-204 and is necessary to establish ongoing training standards for hazardous materials emergency response agencies. Therefore, this rule should be continued.

Agency Authorization Information

Agency head	Ted Black, State	Date:	03/28/2024
or designee	Fire Marshal		
and title:			

End of the Five-Year Notices of Review and Statements of Continuation Section

NOTICES OF **RULE EFFECTIVE DATES**

State law provides for agencies to make their administrative rules effective and enforceable after publication in the Utah State Bulletin. In the case of PROPOSED RULES or CHANGES IN PROPOSED RULES with a designated comment period, the law permits an agency to make a rule effective no fewer than seven calendar days after the close of the public comment period, nor more than 120 days after the publication date. In the case of CHANGES IN PROPOSED Rules with no designated comment period, the law permits an agency to make a rule effective on any date including or after the thirtieth day after the rule's publication date, but not more than 120 days after the publication date. If an agency fails to file a NOTICE OF EFFECTIVE DATE within 120 days from the publication of a PROPOSED RULE or a related CHANGE IN PROPOSED RULE the rule lapses.

Agencies have notified the Office of Administrative Rules that the rules listed below have been made effective.

Notices of Effective Date are governed by Subsection 63G-3-301(12), Section 63G-3-303, and Sections R15-4-5a and R15-4-5b.

Agriculture and Food

Marketing and Development

No. 56278 (Repeal and Reenact) R65-1: Utah Apple

Marketing Order Published: 02/01/2024 Effective: 03/26/2024

No. 56279 (Repeal and Reenact) R65-5: Utah Red Tart

and Sour Cherry Marketing Order

Published: 02/01/2024 Effective: 03/26/2024

Education

Administration

No. 56324 (Amendment) R277-308: New Educator

Induction and Mentoring Published: 03/01/2024 Effective: 04/09/2024

No. 56325 (Amendment) R277-328: Educational Equity in

Schools

Published: 03/01/2024 Effective: 04/09/2024

No. 56326 (Amendment) R277-471: School Construction

Oversight, Inspections, Training and Reporting

Published: 03/01/2024 Effective: 04/09/2024

No. 56327 (Amendment) R277-910: Underage Drinking

and Substance Abuse Prevention Program

Published: 03/01/2024 Effective: 04/09/2024

No. 56328 (Amendment) R277-912: Law Enforcement

Related Incident Reporting Published: 03/01/2024 Effective: 04/09/2024

Financial Institutions

Credit Unions

No. 56311 (Amendment) R337-5: Allowance for Loan and

Lease Losses - Credit Unions Published: 03/01/2024 Effective: 04/09/2024

Health and Human Services

Integrated Healthcare

No. 56258 (Amendment) R414-90: Diabetes Self-

Management Training Published: 01/15/2024 Effective: 03/25/2024

No. 56259 (Repeal) R414-310: Medicaid Primary Care

Network Demonstration Waiver

Published: 01/01/2024 Effective: 03/25/2024

No. 56260 (Amendment) R414-504: Nursing Facility

Payments

Published: 01/01/2024 Effective: 03/25/2024

Data, Systems and Evaluation, Vital Records and Statistics No. 56173 (Amendment) R436-9: Persons and Institutions Required to Keep Monthly Listings of Vital Statistics Events

Published: 12/01/2023 Effective: 03/25/2024

Lieutenant Governor

Elections

No. 56238 (New Rule) R623-11: Signature Verification

Standards

Published: 01/01/2024 Effective: 04/04/2024

NOTICES OF RULE EFFECTIVE DATES

Natural Resources

Outdoor Recreation No. 56280 (New Rule) R650-102: Adjudicatory

Proceedings

Published: 02/01/2024 Effective: 03/19/2024

State Parks

No. 56329 (Repeal) R651-301: State Recreation Fiscal

Assistance Program
Published: 03/01/2024
Effective: 04/08/2024

Pardons (Board of)

Administration

No. 56298 (Amendment) R671-201: Original Hearing

Schedule and Notice Published: 02/15/2024 Effective: 04/01/2024

No. 56299 (Amendment) R671-312a: Commutation Procedures Applicable to Persons Sentence to Death Before

April 26, 1992

Published: 02/15/2024 Effective: 04/01/2024

No. 56300 (Amendment) R671-312b: Commutation Procedures Applicable to Persons Sentenced to Death After

April 26, 1992

Published: 02/15/2024 Effective: 04/01/2024

No. 56301 (Amendment) R671-313: Commutation

Hearings (Non-Death Penalty Cases)

Published: 02/15/2024 Effective: 04/01/2024

No. 56302 (Amendment) R671-314: Compassionate

Release

Published: 02/15/2024 Effective: 04/01/2024

No. 56303 (Amendment) R671-509: Progress / Violation

Reports

Published: 02/15/2024 Effective: 04/01/2024 No. 56304 (Amendment) R671-510: Evidence for Issuance

of Warrants

Published: 02/15/2024 Effective: 04/01/2024

No. 56305 (Amendment) R671-514: Waiver and Pleas of

Guilt

Published: 02/15/2024 Effective: 04/01/2024

Public Service Commission

Administration

No. 56315 (Amendment) R746-312: Electrical

Interconnection

Published: 03/01/2024 Effective: 04/09/2024

No. 56316 (Amendment) R746-313: Electrical Service

Reliability

Published: 03/01/2024 Effective: 04/09/2024

Tax Commission

Auditing

No. 56307 (Amendment) R865-19S-33: Admissions and User Fees Pursuant to Utah Code Ann. Sections 59-12-102

and 59-12-103 Published: 02/15/2024 Effective: 03/28/2024

Transportation

Program Development

No. 56314 (Amendment) R926-13: Designated Scenic

Byways

Published: 03/01/2024 Effective: 04/08/2024

Workforce Services

Employment Development

No. 56310 (Amendment) R986-700: Child Care Assistance

Published: 02/15/2024 Effective: 04/01/2024

End of the Notices of Rule Effective Dates Section