



TITLE 9. HEALTH SERVICES

CHAPTER 17. DEPARTMENT OF HEALTH SERVICES - MEDICAL MARIJUANA PROGRAM

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Sections, Parts, Exhibits, Tables or Appendices codified in this supplement. The list provided contains quick links to the updated rules.

This Chapter contains rule Sections that were filed to be codified in the *Arizona Administrative Code* between the dates of April 1, 2020 through June 30, 2020.

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The release of this Chapter in Supp. 20-2 replaces Supp. 19-3, 1-31 pages

Please note that the Chapter you are about to replace may have rules still in effect after the publication date of this supplement. Therefore, all superseded material should be retained in a separate binder and archived for future reference.

PREFACE

Under Arizona law, the Department of State, Office of the Secretary of State (Office), accepts state agency rule filings and is the publisher of Arizona rules. The Office of the Secretary of State does not interpret or enforce rules in the *Administrative Code*. Questions about rules should be directed to the state agency responsible for the promulgation of the rule.

Scott Cancelosi, Director
ADMINISTRATIVE RULES DIVISION

RULES

The definition for a rule is provided for under A.R.S. § 41-1001. “‘Rule’ means an agency statement of general applicability that implements, interprets, or prescribes law or policy, or describes the procedures or practice requirements of an agency.”

THE ADMINISTRATIVE CODE

The *Arizona Administrative Code* is where the official rules of the state of Arizona are published. The *Code* is the official codification of rules that govern state agencies, boards, and commissions.

The *Code* is separated by subject into titles. Titles are divided into chapters. A chapter includes state agency rules. Rules in chapters are divided into Articles, then Sections. The “R” stands for “rule” with a sequential numbering and lettering outline separated into subsections.

Rules are codified quarterly in the *Code*. Supplement release dates are printed on the footers of each chapter.

First Quarter: January 1 - March 31

Second Quarter: April 1 - June 30

Third Quarter: July 1 - September 30

Fourth Quarter: October 1 - December 31

For example, the first supplement for the first quarter of 2019 is cited as Supp. 19-1.

Please note: The Office publishes by chapter, not by individual rule section. Therefore there might be only a few sections codified in each chapter released in a supplement. Historical notes at the end of a section provide an effective date and information when a rule was last updated.

AUTHENTICATION OF PDF CODE CHAPTERS

The Office began to authenticate chapters of the *Administrative Code* in Supp. 18-1 to comply with A.R.S. § 41-1012(B) and A.R.S. § 5302(1), (2)(d) through (e), and (3)(d) through (e).

A certification verifies the authenticity of each *Code* chapter posted as it is released by the Office of the Secretary of State. The authenticated pdf of the *Code* includes an integrity mark with a certificate ID. Users should check the validity of the signature, especially if the pdf has been downloaded. If the digital signature is invalid it means the document’s content has been compromised.

HOW TO USE THE CODE

Rules may be in effect before a supplement is released by the Office. Therefore, the user should refer to issues of the *Arizona Administrative Register* for recent updates to rule Sections.

ARIZONA REVISED STATUTE REFERENCES

The Arizona Revised Statutes (A.R.S.) are available online at the Legislature’s website, www.azleg.gov. An agency’s authority

note to make rules is often included at the beginning of a chapter. Other Arizona statutes may be referenced in rule under the A.R.S. acronym.

SESSION LAW REFERENCES

Arizona Session Law references in a chapter can be found at the Secretary of State’s website, under Services-> Legislative Filings.

EXEMPTIONS FROM THE APA

It is not uncommon for an agency to be exempt from the steps outlined in the rulemaking process as specified in the Arizona Administrative Procedures Act, also known as the APA (Arizona Revised Statutes, Title 41, Chapter 6, Articles 1 through 10). Other agencies may be given an exemption to certain provisions of the Act.

An agency’s exemption is written in law by the Arizona State Legislature or under a referendum or initiative passed into law by Arizona voters.

When an agency files an exempt rulemaking package with our Office it specifies the law exemption in what is called the preamble of rulemaking. The preamble is published in the *Register* online at www.azsos.gov/rules, click on the *Administrative Register* link.

Editor’s notes at the beginning of a chapter provide information about rulemaking sections made by exempt rulemaking. Exempt rulemaking notes are also included in the historical note at the end of a rulemaking Section.

The Office makes a distinction to certain exemptions because some rules are made without receiving input from stakeholders or the public. Other exemptions may require an agency to propose exempt rules at a public hearing.

EXEMPTIONS AND PAPER COLOR

At one time the office published exempt rules on either blue or green paper. Blue meant the authority of the exemption was given by the Legislature; green meant the authority was determined by a court order. In 2001 the Office discontinued publishing rules using these paper colors.

PERSONAL USE/COMMERCIAL USE

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Rhonda Paschal, managing rules editor, assisted with the editing of this chapter.



Administrative Rules Division
The Arizona Secretary of State electronically publishes each A.A.C. Chapter with a digital certificate. The certificate-based signature displays the date and time the document was signed and can be validated in Adobe Acrobat Reader.

TITLE 9. HEALTH SERVICES

CHAPTER 17. DEPARTMENT OF HEALTH SERVICES - MEDICAL MARIJUANA PROGRAM

Authority: A.R.S. § 36-2803

Editor's Note: This Chapter was adopted under a one-year exemption from the Arizona Administrative Procedure Act (A.R.S. Title 41, Chapter 6) pursuant to Proposition 203 passed by the voters in November 2010. Although exempt from certain provisions of the rulemaking process, Section 6 of the Proposition required the Department to provide the public with an opportunity to comment on these rules before publishing the exempted rules. The Department posted proposed rules for comment on its web site, conducted statewide public meetings and also posted public comments received on its web site. (Supp. 11-2).

Editor's Note: 9 A.A.C. 17, formerly contained the rules of the Department of Health Services - Pure Food Control. This Chapter expired under A.R.S. § 41-1056(E) at 13 A.A.R. 3531, effective August 31, 2007 (Supp. 07-3).

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Article 1, consisting of Sections R9-17-101 through R9-17-109, made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2).

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ARTICLE 1. GENERAL

R9-17-101. Definitions

In addition to the definitions in A.R.S. § 36-2801, the following definitions apply in this Chapter unless otherwise stated:

1. "Accreditation" means being deemed as technically competent under ISO 17025 by the:
 - a. American Association of Laboratory Accreditation,
 - b. Perry Johnson Laboratory Accreditation,
 - c. ANSI National Accreditation Board, or
 - d. International Accreditation Services.
2. "Accuracy testing" means a mechanism in which a laboratory performs testing on samples with known characteristics, prepared by the laboratory, to determine a laboratory agent's ability to analyze samples within specific acceptance criteria.
3. "Acquire" means to obtain through any type of transaction and from any source.
4. "Activities of daily living" means ambulating, bathing, dressing, grooming, eating, toileting, and getting in and out of bed.
5. "Amend" means adding or deleting information on an individual's registry identification card that affects the individual's ability to perform or delegate a specific act or function.
6. "Analyte" means a specific substance for which testing is performed by a laboratory.
7. "Applicant" means:
 - a. An individual submitting an application for a registry identification card or to amend, change, or replace a registry identification card for a qualifying patient, designated caregiver, dispensary agent, or laboratory agent; or
 - b. An individual or entity submitting an application for a dispensary registration certificate, approval to operate a dispensary, laboratory registration certificate, approval to test, or approval to change parameters.
8. "Batch" means:
 - a. When referring to cultivated medical marijuana, a specific lot of medical marijuana grown from one or more seeds or cuttings that are planted and harvested at the same time;
 - b. When referring to marijuana products, a specific amount of a marijuana product infused, manufactured, or prepared for sale from the same set of ingredients at the same time; and
 - c. When referring to testing of medical marijuana or a marijuana product, a specific set of samples prepared and tested during the same run using the same equipment.
9. "Batch number" means a unique numeric or alphanumeric identifier assigned to a batch by a dispensary when:
 - a. The batch of medical marijuana is planted, or
 - b. The batch of a marijuana product is infused, manufactured, or prepared for sale.
10. "Calendar day" means each day, not including the day of the act, event, or default from which a designated period of time begins to run, but including the last day of the period unless it is a Saturday, Sunday, statewide furlough day, or legal holiday, in which case the period runs until the end of the next day that is not a Saturday, Sunday, statewide furlough day, or legal holiday.
11. "CHAA" means a Community Health Analysis Area, a geographic area based on population, established by the Department for use by public health programs.
12. "Change" means:
 - a. When used in relation to a registry identification card, adding or deleting information on an individual's registry identification card that does not substantively affect the individual's ability to perform or delegate a specific act or function;
 - b. When used in relation to a place, moving to a different location;
 - c. When used in relation to an individual, selecting a different individual to perform specific actions;
 - d. When used in relation to parameters, revising a laboratory's standard operating procedures or quality assurance plan, required in R9-17-404.06, due to:
 - i. Adding or removing a parameter,
 - ii. Altering a testing method, or
 - iii. Using a different instrument for performing a test; and
 - e. When used in relation to testing results, altering the testing results in any way and for any reason.
13. "Commercial device" means the same as in A.R.S. § 41-2051.
14. "Contaminant" means matter, pollutant, hazardous substance, or other substance that is not intended to be part of dispensed medical marijuana or a marijuana product.
15. "Cultivation site" means the one additional location where marijuana may be cultivated, infused, or prepared for sale by and for a dispensary.
16. "Current photograph" means an image of an individual, taken no more than 60 calendar days before the submission of the individual's application, in a Department-approved electronic format capable of producing an image that:
 - a. Has a resolution of at least 600 x 600 pixels but not more than 1200 x 1200 pixels;
 - b. Is 2 inches by 2 inches in size;
 - c. Is in natural color;
 - d. Is a front view of the individual's full face, without a hat or headgear that obscures the hair or hairline;
 - e. Has a plain white or off-white background; and
 - f. Has between 1 and 1 3/8 inches from the bottom of the chin to the top of the head.
17. "Denial" means the Department's final decision not to issue a registry identification card, a dispensary registration certificate, a laboratory registration certificate, or an approval of a change of dispensary or a dispensary's cultivation site location, to an applicant because the applicant or the application does not comply with the applicable requirements in A.R.S. Title 36, Chapter 28.1 or this Chapter.
18. "Dispensary" means the same as "nonprofit medical marijuana dispensary" as defined in A.R.S. § 36-2801.
19. "Dispensary agent" means the same as "nonprofit medical marijuana dispensary agent" as defined in A.R.S. § 36-2801.
20. "Edible food product" means a substance, beverage, or ingredient used or intended for use or for sale in whole or in part for human oral consumption.
21. "Enclosed area" when used in conjunction with "enclosed, locked facility" means outdoor space surrounded by solid, 10-foot walls, constructed of metal, concrete, or stone that prevent any viewing of the marijuana plants, and a 1-inch thick metal gate.
22. "Entity" means a "person" as defined in A.R.S. § 1-215.
23. "Generally accepted accounting principles" means the set of financial reporting standards established by the Financial Accounting Standards Board, the Governmental

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- Accounting Standards Board, or another specialized body dealing with accounting and auditing matters.
24. "In-state financial institution" means the same as in A.R.S. § 6-101.
25. "Inhalable" means intended for use through intake into the lungs of an individual.
26. "Laboratory" means the same as "independent third-party laboratory" as defined in A.R.S. § 36-2801.
27. "Laboratory agent" means the same as "independent third-party laboratory agent" as defined in A.R.S. § 36-2801.
28. "Legal guardian" means an adult who is responsible for a minor:
- Through acceptance of guardianship of the minor through a testamentary appointment or an appointment by a court pursuant to A.R.S. Title 14, Chapter 5, Article 2; or
 - As a "custodian" as defined in A.R.S. § 8-201.
29. "Medical record" means the same as:
- "Adequate records" as defined in A.R.S. § 32-1401,
 - "Adequate medical records" as defined in A.R.S. § 32-1501,
 - "Adequate records" as defined in A.R.S. § 32-1800, or
 - "Adequate records" as defined in A.R.S. § 32-2901.
30. "Out-of-state financial institution" means the same as in A.R.S. § 6-101.
31. "Parameter" means the combination of a particular type of sample with a specific instrument or equipment by which the sample will be tested for a specific analyte or characteristic.
32. "Proficiency testing" means a mechanism in which samples with known characteristics are submitted to a laboratory for analysis to determine a laboratory agent's ability to analyze samples within specific acceptance criteria.
33. "Proficiency testing service" means an independent company or other person acceptable to the Department, based on ISO/IEC 17043:2010 certification, that:
- Is the source for samples with known characteristics for proficiency testing, and
 - Assesses the acceptability of a laboratory agent's results from the samples with known characteristics during proficiency testing.
34. "Private school" means the same as in A.R.S. § 15-101.
35. "Public place" means:
- Any location, facility, or venue that is not intended for the regular exclusive use of an individual or a specific group of individuals;
 - Includes, but not is limited to:
 - Airports;
 - Banks;
 - Bars;
 - Child care facilities;
 - Child care group homes during hours of operation;
 - Common areas of apartment buildings, condominiums, or other multifamily housing facilities;
 - Educational facilities;
 - Entertainment facilities or venues;
 - Health care institutions, except as provided in subsection (24)(c);
 - Hotel and motel common areas;
 - Laundromats;
 - Libraries;
 - Office buildings;
- Parking lots;
 - Parks;
 - Public transportation facilities;
 - Reception areas;
 - Restaurants;
 - Retail food production or marketing establishments;
 - Retail service establishments;
 - Retail stores;
 - Shopping malls;
 - Sidewalks;
 - Sports facilities;
 - Theaters; and
 - Waiting rooms; and
- c. Does not include:
- Nursing care institutions as defined in A.R.S. § 36-401,
 - Hospices as defined in A.R.S. § 36-401,
 - Assisted living centers as defined in A.R.S. § 36-401,
 - Assisted living homes as defined in A.R.S. § 36-401,
 - Adult day health care facilities as defined in A.R.S. § 36-401,
 - Adult foster care homes as defined in A.R.S. § 36-401, or
 - Private residences.
36. "Public school" means the same as "school" as defined in A.R.S. § 15-101.
37. "Registry identification number" means the random 20-digit alphanumeric identifier generated by the Department, containing at least four numbers and four letters, issued by the Department to a qualifying patient, designated caregiver, dispensary, dispensary agent, laboratory, or laboratory agent.
38. "Revocation" means the Department's final decision that an individual's registry identification card, a dispensary registration certificate, or a laboratory registration certificate is rescinded because the individual, the dispensary, or the laboratory does not comply with the applicable requirements in A.R.S. Title 36, Chapter 28.1 or this Chapter.
39. "Sample" means:
- A representative portion of a larger quantity of medical marijuana or a marijuana product,
 - A specific quantity of a substance or set of substances to be used for testing purposes, or
 - To collect the representative portion in subsection (39)(a).
40. "Working day" means a Monday, Tuesday, Wednesday, Thursday, or Friday that is not a state holiday or a statewide furlough day.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by final rulemaking at 18 A.A.R. 3354, with an immediate effective date of December 5, 2012 (Supp. 12-4). Amended by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3). Amended by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020 (Supp. 20-2).

R9-17-103. Application Submission

- A. An applicant submitting an application for a registry identification card or to amend, change, or replace a registry identification card for a qualifying patient, designated caregiver,

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dispensary agent, or laboratory agent, shall submit the application electronically in a Department-provided format.

- B. A residence address or mailing address submitted for a qualifying patient or designated caregiver as part of an application for a registry identification card is located in Arizona.
- C. A mailing address submitted for a principal officer or board member as part of a dispensary certificate registration application or as part of an application for a dispensary agent registration identification card is located in Arizona.
- D. A mailing address submitted for an owner as a part of a laboratory registration certificate application or as part of an application for a laboratory agent registration identification card is located in Arizona.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by final rulemaking at 18 A.A.R. 3354, with an immediate effective date of December 5, 2012 (Supp. 12-4). Amended by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3).

R9-17-104. Changing Information on a Registry Identification Card

Except as provided in R9-17-203(B) and (C), to make a change to a cardholder's name or address on the cardholder's registry identification card, the cardholder shall submit to the Department, within 10 working days after the change, a request for the change that includes:

1. The cardholder's name and the registry identification number on the cardholder's current registry identification card;
2. The cardholder's new name or address, as applicable;
3. For a change in the cardholder's name, one of the following with the cardholder's new name:
 - a. An Arizona driver's license,
 - b. An Arizona identification card, or
 - c. The photograph page in the cardholder's U.S. passport;
4. For a change in address, the county where the new address is located;
5. The effective date of the cardholder's new name or address; and
6. The applicable fee in R9-17-102 for changing a registry identification card.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2).

R9-17-105. Requesting a Replacement Registry Identification Card

To request a replacement card for a cardholder's registry identification card that has been lost, stolen, or destroyed, the cardholder shall submit to the Department, within 10 working days after the cardholder's registry identification card was lost, stolen, or destroyed, a request for a replacement card that includes:

1. The cardholder's name and date of birth;
2. If known, the registry identification number on the cardholder's lost, stolen, or destroyed registry identification card;
3. If the cardholder cannot provide the registry identification number on the cardholder's lost, stolen, or destroyed registry identification card, a copy of one of the following documents that the cardholder submitted when the cardholder obtained the registry identification card:
 - a. Arizona driver's license,
 - b. Arizona identification card,

- c. Arizona registry identification card, or
 - d. Photograph page in the cardholder's U.S. passport; and
4. The applicable fee in R9-17-102 for requesting a replacement registry identification card.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2).

R9-17-106. Adding a Debilitating Medical Condition

- A. An entity may request the addition of a medical condition to the list of debilitating medical conditions in R9-17-201 by submitting to the Department, at the times specified in subsection (C), the following in writing:
 1. The entity's name;
 2. The entity's mailing address, name of contact individual, telephone number, and, if applicable, e-mail address;
 3. The name of the medical condition the entity is requesting be added;
 4. A description of the symptoms and other physiological effects experienced by an individual suffering from the medical condition or a treatment of the medical condition that may impair the ability of the individual to accomplish activities of daily living;
 5. The availability of conventional medical treatments to provide therapeutic or palliative benefit for the medical condition or a treatment of the medical condition;
 6. A summary of the evidence that the use of marijuana will provide therapeutic or palliative benefit for the medical condition or a treatment of the medical condition; and
 7. Articles, published in peer-reviewed scientific journals, reporting the results of research on the effects of marijuana on the medical condition or a treatment of the medical condition supporting why the medical condition should be added.
- B. The Department shall:
 1. Acknowledge in writing the Department's receipt of a request for the addition of a medical condition to the list of debilitating medical conditions listed in R9-17-201 within 30 calendar days after receiving the request;
 2. Review the request to determine if the requester has provided evidence that:
 - a. The specified medical condition or treatment of the medical condition impairs the ability of the individual to accomplish activities of daily living, and
 - b. Marijuana usage provides a therapeutic or palliative benefit to an individual suffering from the medical condition or treatment of the medical condition;
 3. Within 90 calendar days after receiving the request, notify the requester that the Department has determined that the information provided by the requester:
 - a. Meets the requirements in subsection (B)(2) and the date the Department will conduct a public hearing to discuss the request; or
 - b. Does not meet the requirements in subsection (B)(2), the specific reason for the determination, and the process for requesting judicial review of the Department's determination pursuant to A.R.S. Title 12, Chapter 7, Article 6;
 4. If applicable:
 - a. Schedule a public hearing to discuss the request;
 - b. Provide public notice of the public hearing by submitting a Notice of Public Information to the Office of the Secretary of State, for publication in the *Arizona Administrative Register* at least 30 calendar days before the date of the public hearing;

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- c. Post a copy of the request on the Department's web site for public comment at least 30 calendar days before the date of the public hearing; and
 - d. Hold the public hearing no more than 150 calendar days after receiving the request; and
 - 5. Within 180 calendar days after receiving the request:
 - a. Add the medical condition to the list of debilitating medical conditions, or
 - b. Provide written notice to the requester of the Department's decision to deny the request that includes:
 - i. The specific reasons for the Department's decision; and
 - ii. The process for requesting judicial review of the Department's decision pursuant to A.R.S. Title 12, Chapter 7, Article 6.
 - C. The Department shall accept requests for the addition of a medical condition to the list of debilitating medical conditions in R9-17-201 in January and July of each calendar year starting in January 2012.
- Historical Note**
- New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2).
- R9-17-107. Time-frames**
- A. Within the administrative completeness review time-frame for each type of approval in Table 1.1, the Department shall:
 - 1. Issue a registry identification card, a dispensary registration certificate, an approval to operate a dispensary, a laboratory registration certificate, an approval for testing, or an approval to add a parameter;
 - 2. Provide a notice of administrative completeness to an applicant; or
 - 3. Provide a notice of deficiencies to an applicant, including a list of the information or documents needed to complete the application.
 - B. An application for approval to operate a dispensary is not complete until the date the applicant states on a written notice provided to the Department according to R9-17-305 that the dispensary is ready for an inspection by the Department.
 - C. A laboratory's application for approval for testing is not complete until the date the applicant states on a written notice provided to the Department according to R9-17-402.01 that the laboratory is ready for an inspection by the Department.
 - D. If the Department provides a notice of deficiencies to an applicant:
 - 1. The administrative completeness review time-frame and the overall time-frame are suspended from the date of the notice of deficiencies until the date the Department receives the missing information or documents from the applicant;
 - 2. The Department shall consider the application withdrawn if the applicant does not submit the missing information or documents to the Department within the time-frame in Table 1.1; and
 - 3. If the applicant submits the missing information or documents to the Department within the time-frame in Table 1.1, the substantive review time-frame begins on the date the Department receives the missing information or documents.
 - E. Within the substantive review time-frame for each type of approval in Table 1.1, the Department:
 - 1. According to subsection (H), shall issue or deny:
 - a. A registry identification card, dispensary registration certificate, or laboratory registration certificate; or
 - b. Approval to operate a dispensary, approval for testing, or approval to add a parameter;
 - 2. May complete an inspection that may require more than one visit to a dispensary and, if applicable, the dispensary's cultivation site;
 - 3. May complete an inspection that may require more than one visit to a laboratory; and
 - 4. May make one written comprehensive request for more information, unless the Department and the applicant agree in writing to allow the Department to submit supplemental requests for information.
 - F. If the Department issues a written comprehensive request or a supplemental request for information:
 - 1. The substantive review time-frame and the overall time-frame are suspended from the date of the written comprehensive request or the supplemental request for information until the date the Department receives all of the information requested, and
 - 2. The applicant shall submit to the Department all of the information and documents listed in the written comprehensive request or supplemental request for information within 10 working days after the date of the comprehensive written request or supplemental request for information.
 - G. If an applicant for an initial dispensary registration certificate is allocated a dispensary registration certificate as provided in R9-17-303, the Department shall provide a written notice to the applicant of the allocation of the dispensary registration certificate that contains the dispensary's registry identification number.
 - 1. After the applicant receives the written notice of the allocation, the applicant shall submit to the Department for each principal officer or board member for whom fingerprints were submitted according to R9-17-304(C)(3)(b):
 - a. An application for a dispensary agent registry identification card that includes:
 - i. The principal officer's or board member's first name; middle initial, if applicable; last name; and suffix, if applicable;
 - ii. The principal officer's or board member's residence address and mailing address;
 - iii. The county where the principal officer or board member resides;
 - iv. The principal officer's or board member's date of birth;
 - v. The identifying number on the applicable card or document in subsection (G)(1)(b)(i) through (v);
 - vi. The name and registry identification number of the dispensary;
 - vii. One of the following:
 - (1) A statement that the principal officer or board member does not currently hold a valid registry identification card, or
 - (2) The assigned registry identification number for each valid registry identification card currently held by the principal officer or board member;
 - viii. A statement signed by the principal officer or board member pledging not to divert marijuana to any individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
 - ix. An attestation that the information provided in and with the application is true and correct; and

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- x. The signature of the principal officer or board member and the date the principal officer or board member signed;
 - b. A copy the principal officer's or board member's:
 - i. Arizona driver's license issued on or after October 1, 1996;
 - ii. Arizona identification card issued on or after October 1, 1996;
 - iii. Arizona registry identification card;
 - iv. Photograph page in the principal officer's or board member's U.S. passport; or
 - v. Arizona driver's license or identification card issued before October 1, 1996 and one of the following for the principal officer or board member:
 - (1) Birth certificate verifying U.S. citizenship,
 - (2) U.S. Certificate of Naturalization, or
 - (3) U.S. Certificate of Citizenship;
 - c. A current photograph of the principal officer or board member; and
 - d. The applicable fee in R9-17-102 for applying for a dispensary agent registry identification card.
2. After receipt of the information and documents in subsection (G)(1), the Department shall review the information and documents.
- a. If the information and documents for at least one of the principal officers or board members complies with the A.R.S. Title 36, Chapter 28.1 and this Chapter, the Department shall issue:
 - i. A dispensary agent registry identification card to any principal officer or board member whose dispensary agent registry identification card application complies with A.R.S. Title 36, Chapter 28.1 and this Chapter; and
 - ii. The dispensary registration certificate.
 - b. If the information and documents for a dispensary agent registry identification card application for any principal officer or board member does not comply with A.R.S. Title 36, Chapter 28.1 and this Chapter, the Department shall deny the dispensary agent registry identification card application and provide notice to the principal officer or board member and to the dispensary that includes:
 - i. The specific reasons for the denial; and
 - ii. The process for requesting a judicial review of the Department's decision pursuant to A.R.S. Title 12, Chapter 7, Article 6.
- H. The Department shall issue:
- 1. A registry identification card, renewal of a dispensary registration certificate, an approval to operate a dispensary, a laboratory registration certificate, an approval for testing, or an approval to add a parameter, as applicable, if the Department determines that the applicant complies with A.R.S. Title 36, Chapter 28.1 and this Chapter:
- 2. For an applicant for a registry identification card, a denial that includes the reason for the denial and the process for requesting judicial review if:
 - a. The Department determines that the applicant does not comply with A.R.S. Title 36, Chapter 28.1 and this Chapter; or
 - b. The applicant does not submit all of the information and documents listed in the written comprehensive request or supplemental request for information within 10 working days after the date of the comprehensive written request or supplemental request for information;
 - 3. For an applicant for an initial dispensary registration certificate, if the Department determines that the dispensary registration certificate application complies with A.R.S. Title 36, Chapter 28.1 and this Chapter:
 - a. A dispensary registration certificate, if not all available dispensary registration certificates have been allocated according to the criteria and processes in R9-17-303; or
 - b. Written notice that:
 - i. The dispensary registration certificate application complies with A.R.S. Title 36, Chapter 28.1 and this Chapter;
 - ii. The applicant was not allocated a dispensary registration certificate according to the criteria and processes in R9-17-303 because all available dispensary registration certificates have been allocated according to the criteria and processes in R9-17-303; and
 - iii. The written notice is not a denial and is not considered a final decision of the Department subject to administrative review; or
 - 4. For an applicant for a dispensary registration certificate, an approval to operate, a laboratory registration certificate, an approval for testing, or an approval to add a parameter, a denial that includes the reason for the denial and the process for administrative review if:
 - a. The Department determines that the applicant does not comply with A.R.S. Title 36, Chapter 28.1 or this Chapter; or
 - b. The applicant does not submit all of the information and documents listed in the written comprehensive request or supplemental request for information within 10 working days after the date of the comprehensive written request or supplemental request for information.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by final rulemaking at 18 A.A.R. 3354, with an immediate effective date of December 5, 2012 (Supp. 12-4). Amended by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3). Amended by exempt rulemaking at 26 A.A.R. 968, effective April 20, 2020 (Supp. 20-2).

Table 1.1 Time-frames

Type of approval	Authority (A.R.S. § or A.A.C.)	Overall Time-frame (in working days)	Time-frame for applicant to complete application (in working days)	Administrative Completeness Time-frame (in working days)	Substantive Review Time-frame (in working days)
Changing a registry identification card	§ 36-2808	10	10	5	5

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Type of approval	Authority (A.R.S. § or A.A.C.)	Overall Time-frame (in working days)	Time-frame for applicant to complete application (in working days)	Administrative Completeness Time-frame (in working days)	Substantive Review Time-frame (in working days)
Requesting a replacement registry identification card	§ 36-2804.06	5	5	2	3
Applying for a registry identification card for a qualifying patient or a designated caregiver	§ 36-2804.02(A)	15	30	5	10
Amending a registry identification card for a qualifying patient or a designated caregiver	§ 36-2808	10	10	5	5
Renewing a qualifying patient's or designated caregiver's registry identification card	§§ 36-2804.02(A) and 36-2804.06	15	15	5	10
Applying for a dispensary registration certificate	§ 36-2804	30	10	5	25
Applying for approval to operate a dispensary	R9-17-305	45	-	15	30
Changing a dispensary location or adding or changing a dispensary's cultivation site location	§ 36-2804 and R9-17-307	90	90	30	60
Renewing a dispensary registration certificate	§ 36-2804.06	15	15	5	10
Applying for a dispensary agent registry identification card	§§ 36-2804.01 and 36-2804.03	15	30	5	10
Renewing a dispensary agent's registry identification card	§ 36-2804.06	15	15	5	10
Applying for a laboratory registration certificate	§ 36-2804.07	90	90	30	60
Applying for approval for testing	R9-17-402.01	90	90	30	60
Renewing a laboratory registration certificate	§ 36-2804.06	15	15	5	10
Applying to add a parameter	R9-17-404.07	90	90	30	60
Applying for a laboratory agent registry identification card	§ 36-2804.01	15	30	5	10
Renewing a laboratory agent's registry identification card	§ 36-2804.06	15	15	5	10

Historical Note

New Table 1.1 made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Table 1.1 amended by emergency rulemaking at 18 A.A.R. 1010, effective April 11, 2012 for 180 days (Supp. 12-2). Emergency expired; Table 1.1 amended by final rulemaking at 18 A.A.R. 3354, with an immediate effective date of December 5, 2012 (Supp. 12-4). Section symbols added to A.R.S. citations (Supp. 17-2). Amended by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3). Amended by exempt rulemaking at 26 A.A.R. 968, effective April 20, 2020 (Supp. 20-2).

R9-17-108. Expiration of a Registry Identification Card, Dispensary Registration Certificate, or Laboratory Registration Certificate

- A.** Except as provided in subsection (B), a registry identification card issued to a qualifying patient, designated caregiver, dispensary agent, or laboratory agent is valid for two years after the date of issuance.
- B.** If the Department issues a registry identification card to a qualifying patient, designated caregiver, dispensary agent, or laboratory agent based on a request for a replacement registry identification card or an application to change or amend a registry identification card, the replacement, changed, or

amended registry identification card shall have the same expiration date as the registry identification card being replaced, changed, or amended.

- C.** Except as provided in subsection (D), a dispensary registration certificate is valid for two years after the date of issuance.
- D.** If the Department issues an amended dispensary registration certificate based on a change of location or an addition of a cultivation site, the dispensary registration certificate shall have the same expiration date as the dispensary registration certificate previously held by the dispensary.

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- E. An approval to operate a dispensary shall have the same expiration date as the dispensary registration certificate associated with the approval to operate the dispensary.
- F. A laboratory registration certificate is valid for two years after the original date of issuance.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3).

R9-17-109. Notifications and Void Registry Identification Cards

- A. The Department shall provide written notice that a cardholder's registry identification card is void and no longer valid under A.R.S. Title 36, Chapter 28.1 and this Chapter to a:
1. Qualifying patient when the Department receives notification from:
 - a. The qualifying patient that the qualifying patient no longer has a debilitating medical condition, or
 - b. The physician who provided the qualifying patient's written certification that the:
 - i. Qualifying patient no longer has a debilitating medical condition,
 - ii. Physician no longer believes that the qualifying patient would receive therapeutic or palliative benefit from the medical use of marijuana, or
 - iii. Physician believes that the qualifying patient is not using the medical marijuana as recommended;
 2. Designated caregiver when:
 - a. The Department receives notification from the designated caregiver's qualifying patient that the designated caregiver no longer assists the qualifying patient with the medical use of marijuana, or
 - b. The registry identification card for the qualifying patient that is listed on the designated caregiver's registry identification card is no longer valid;
 3. Dispensary agent when:
 - a. The Department receives the written notification, required in R9-17-310(A)(9), that the dispensary agent:
 - i. No longer serves as a principal officer, board member, or medical director for the dispensary;
 - ii. Is no longer employed by the dispensary; or
 - iii. No longer provides volunteer service at or on behalf of the dispensary; or
 - b. The registration certificate for the dispensary that is listed on the dispensary agent's registry identification card is no longer valid; or
 4. Laboratory agent when:
 - a. The Department receives the written notification, required in R9-17-404(10), that the laboratory agent no longer:
 - i. Serves as an owner for the laboratory,
 - ii. Is employed by the laboratory, or
 - iii. Provides volunteer service at or on behalf of the laboratory; or
 - b. The registration certificate for the laboratory that is listed on the laboratory agent's registration identification card is no longer valid.
- B. The Department shall void a qualifying patient's registry identification card:
1. When the Department receives notification that the qualifying patient is deceased; or

2. For a qualifying patient under 18 years of age, when the qualifying patient's designated caregiver's registry identification card is revoked.

- C. The written notice required in subsection (A) that a registry identification card is void is not a revocation and is not considered a final decision of the Department subject to judicial review.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by final rulemaking at 18 A.A.R. 3354, with an immediate effective date of December 5, 2012 (Supp. 12-4). Amended by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3).

ARTICLE 2. QUALIFYING PATIENTS AND DESIGNATED CAREGIVERS**R9-17-201. Debilitating Medical Conditions**

An individual applying for a qualifying patient registry identification card shall have a diagnosis from a physician of at least one of the following debilitating medical conditions:

1. Cancer;
2. Glaucoma;
3. Human immunodeficiency virus;
4. Acquired immune deficiency syndrome;
5. Hepatitis C;
6. Amyotrophic lateral sclerosis;
7. Crohn's disease;
8. Agitation of Alzheimer's disease;
9. A chronic or debilitating disease or medical condition or the treatment for a chronic or debilitating disease or medical condition that produces cachexia or wasting syndrome;
10. A chronic or debilitating disease or medical condition or the treatment for a chronic or debilitating disease or medical condition that produces severe and chronic pain;
11. A chronic or debilitating disease or medical condition or the treatment for a chronic or debilitating disease or medical condition that produces severe nausea;
12. A chronic or debilitating disease or medical condition or the treatment for a chronic or debilitating disease or medical condition that produces severe seizures, including those characteristic of epilepsy;
13. A chronic or debilitating disease or medical condition or the treatment for a chronic or debilitating disease or medical condition that produces severe or persistent muscle spasms, including those characteristic of multiple sclerosis; or
14. A debilitating medical condition approved by the Department under A.R.S. § 36-2801.01 and R9-17-106.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2).

R9-17-202. Applying for a Registry Identification Card for a Qualifying Patient or a Designated Caregiver

- A. Except for a qualifying patient who is under 18 years of age, a qualifying patient is not required to have a designated caregiver.
- B. A qualifying patient may have only one designated caregiver at any given time.
- C. Except for a qualifying patient who is under 18 years of age, if the information submitted for a qualifying patient complies with A.R.S. Title 36, Chapter 28.1 and this Chapter but the information for the qualifying patient's designated caregiver does not comply with A.R.S. Title 36, Chapter 28.1 and this

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Chapter, the Department shall issue the registry identification card for the qualifying patient separate from issuing a registry identification card for the qualifying patient's designated caregiver.

- D.** If the Department issues a registry identification card to a qualifying patient under subsection (C), the Department shall continue the process for issuing or denying the qualifying patient's designated caregiver's registry identification card.
- E.** The Department shall not issue a designated caregiver's registry identification card before the Department issues the designated caregiver's qualifying patient's registry identification card.
- F.** Except as provided in subsection (G), to apply for a registry identification card, a qualifying patient shall submit to the Department the following:
1. An application in a Department-provided format that includes:
 - a. The qualifying patient's:
 - i. First name; middle initial, if applicable; last name; and suffix, if applicable;
 - ii. Date of birth; and
 - iii. Gender;
 - b. Except as provided in subsection (F)(1)(i), the qualifying patient's residence address and mailing address;
 - c. The county where the qualifying patient resides;
 - d. The qualifying patient's e-mail address;
 - e. The identifying number on the applicable card or document in subsection (F)(2)(a) through (e);
 - f. The name, address, and telephone number of the physician providing the written certification for medical marijuana for the qualifying patient;
 - g. Whether the qualifying patient is requesting authorization for cultivating marijuana plants for the qualifying patient's medical use because the qualifying patient believes that the qualifying patient resides at least 25 miles from the nearest operating dispensary;
 - h. If the qualifying patient is requesting authorization for cultivating marijuana plants, whether the qualifying patient is designating the qualifying patient's designated caregiver to cultivate marijuana plants for the qualifying patient's medical use;
 - i. If the qualifying patient is homeless, an address where the qualifying patient can receive mail;
 - j. Whether the qualifying patient would like notification of any clinical studies needing human subjects for research on the medical use of marijuana;
 - k. An attestation that the information provided in the application is true and correct; and
 - l. The signature of the qualifying patient and date the qualifying patient signed;
 2. A copy of the qualifying patient's:
 - a. Arizona driver's license issued on or after October 1, 1996;
 - b. Arizona identification card issued on or after October 1, 1996;
 - c. Arizona registry identification card;
 - d. Photograph page in the qualifying patient's U.S. passport; or
 - e. Arizona driver's license or identification card issued before October 1, 1996 and one of the following for the qualifying patient:
 - i. Birth certificate verifying U.S. citizenship,
 - ii. U.S. Certificate of Naturalization, or
 - iii. U.S. Certificate of Citizenship;
 3. A current photograph of the qualifying patient;
 4. A statement in a Department-provided format signed by the qualifying patient pledging not to divert marijuana to any individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
 5. A physician's written certification in a Department-provided format dated within 90 calendar days before the submission of the qualifying patient's application that includes:
 - a. The physician's:
 - i. Name,
 - ii. License number including an identification of the physician license type,
 - iii. Office address on file with the physician's licensing board,
 - iv. Telephone number on file with the physician's licensing board, and
 - v. E-mail address;
 - b. The qualifying patient's name and date of birth;
 - c. A statement that the physician has made or confirmed a diagnosis of a debilitating medical condition as defined in A.R.S. § 36-2801 for the qualifying patient;
 - d. An identification, initialed by the physician, of one or more of the debilitating medical conditions in R9-17-201 as the qualifying patient's specific debilitating medical condition;
 - e. If the debilitating medical condition identified in subsection (F)(5)(d) is a condition in:
 - i. R9-17-201(9) through (13), the underlying chronic or debilitating disease or medical condition; or
 - ii. R9-17-201(14), the debilitating medical condition;
 - f. A statement, initialed by the physician, that the physician:
 - i. Has established a medical record for the qualifying patient, and
 - ii. Is maintaining the qualifying patient's medical record as required in A.R.S. § 12-2297;
 - g. A statement, initialed by the physician, that the physician has conducted an in-person physical examination of the qualifying patient within the previous 90 calendar days appropriate to the qualifying patient's presenting symptoms and the qualifying patient's debilitating medical condition diagnosed or confirmed by the physician;
 - h. The date the physician conducted the in-person physical examination of the qualifying patient;
 - i. A statement, initialed by the physician, that the physician reviewed the qualifying patient's:
 - i. Medical records including medical records from other treating physicians from the previous 12 months,
 - ii. Response to conventional medications and medical therapies, and
 - iii. Profile on the Arizona Board of Pharmacy Controlled Substances Prescription Monitoring Program database;
 - j. A statement, initialed by the physician, that the physician has explained the potential risks and benefits of the medical use of marijuana to the qualifying patient;
 - k. A statement, initialed by the physician, that in the physician's professional opinion, the qualifying patient is likely to receive therapeutic or palliative benefit from the qualifying patient's medical use of

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- marijuana to treat or alleviate the qualifying patient's debilitating medical condition;
- l. A statement, initialed by the physician, that if the physician has referred the qualifying patient to a dispensary, the physician has disclosed to the qualifying patient any personal or professional relationship the physician has with the dispensary;
 - m. A statement, initialed by the physician, that the physician has provided information to the qualifying patient, if the qualifying patient is female, that warns about:
 - i. The potential dangers to a fetus caused by smoking or ingesting marijuana while pregnant or to an infant while breastfeeding, and
 - ii. The risk of being reported to the Department of Child Safety during pregnancy or at the birth of the child by persons who are required to report;
 - n. An attestation that the information provided in the written certification is true and correct; and
 - o. The physician's signature and the date the physician signed;
6. If the qualifying patient is designating a caregiver, the following in a Department-provided format:
- a. The designated caregiver's first name; middle initial, if applicable; last name; and suffix, if applicable;
 - b. The designated caregiver's date of birth;
 - c. The designated caregiver's residence address and mailing address;
 - d. The county where the designated caregiver resides;
 - e. The identifying number on the applicable card or document in subsection (F)(6)(i)(i) through (v);
 - f. One of the following:
 - i. A statement that the designated caregiver does not currently hold a valid registry identification card, or
 - ii. The assigned registry identification number for the designated caregiver for each valid registry identification card currently held by the designated caregiver;
 - g. An attestation signed and dated by the designated caregiver that the designated caregiver has not been convicted of an excluded felony offense as defined in A.R.S. § 36-2801;
 - h. A statement signed by the designated caregiver:
 - i. Agreeing to assist the qualifying patient with the medical use of marijuana; and
 - ii. Pledging not to divert marijuana to any individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
 - i. A copy of the designated caregiver's:
 - i. Arizona driver's license issued on or after October 1, 1996;
 - ii. Arizona identification card issued on or after October 1, 1996;
 - iii. Arizona registry identification card;
 - iv. Photograph page in the designated caregiver's U.S. passport; or
 - v. Arizona driver's license or identification card issued before October 1, 1996 and one of the following for the designated caregiver:
 - (1) Birth certificate verifying U.S. citizenship,
 - (2) U.S. Certificate of Naturalization, or
 - (3) U.S. Certificate of Citizenship;
 - j. A current photograph of the designated caregiver; and
- k. For the Department's criminal records check authorized in A.R.S. § 36-2804.05:
 - i. The designated caregiver's fingerprints on a fingerprint card that includes:
 - (1) The designated caregiver's first name; middle initial, if applicable; and last name;
 - (2) The designated caregiver's signature;
 - (3) If different from the designated caregiver, the signature of the individual physically rolling the designated caregiver's fingerprints;
 - (4) The designated caregiver's address;
 - (5) If applicable, the designated caregiver's surname before marriage and any names previously used by the designated caregiver;
 - (6) The designated caregiver's date of birth;
 - (7) The designated caregiver's Social Security number;
 - (8) The designated caregiver's citizenship status;
 - (9) The designated caregiver's gender;
 - (10) The designated caregiver's race;
 - (11) The designated caregiver's height;
 - (12) The designated caregiver's weight;
 - (13) The designated caregiver's hair color;
 - (14) The designated caregiver's eye color; and
 - (15) The designated caregiver's place of birth;
 - or
 - ii. If the designated caregiver's fingerprints and information required in subsection (F)(6)(k)(i) were submitted to the Department as part of an application for a designated caregiver or a dispensary agent registry identification card within the previous six months, the registry identification number on the registry identification card issued to the designated caregiver as a result of the application; and
7. The applicable fees in R9-17-102 for applying for:
- a. A qualifying patient registry identification card; and
 - b. If applicable, a designated caregiver registry identification card.
- G.** To apply for a registry identification card for a qualifying patient who is under 18 years of age, the qualifying patient's custodial parent or legal guardian responsible for health care decisions for the qualifying patient shall submit to the Department the following:
1. An application in a Department-provided format that includes:
 - a. The qualifying patient's:
 - i. First name; middle initial, if applicable; last name; and suffix, if applicable;
 - ii. Date of birth; and
 - iii. Gender;
 - b. The qualifying patient's residence address and mailing address;
 - c. The county where the qualifying patient resides;
 - d. The qualifying patient's custodial parent's or legal guardian's first name; middle initial, if applicable; last name; and suffix, if applicable;
 - e. The identifying number on the applicable card or document in subsection (G)(5)(a) through (e);
 - f. The qualifying patient's custodial parent's or legal guardian's residence address and mailing address;
 - g. The county where the qualifying patient's custodial parent or legal guardian resides;

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- h. The qualifying patient's custodial parent's or legal guardian's e-mail address;
 - i. The name, address, and telephone number of a physician who has a physician-patient relationship with the qualifying patient and is providing the written certification for medical marijuana for the qualifying patient;
 - j. The name, address, and telephone number of a second physician who has conducted a comprehensive review of the patient's medical record maintained by other treating physicians, and is providing a written certification for medical marijuana for the qualifying patient;
 - k. The qualifying patient's custodial parent's or legal guardian's date of birth;
 - l. Whether the qualifying patient's custodial parent or legal guardian is requesting authorization for cultivating medical marijuana plants for the qualifying patient's medical use because the qualifying patient's custodial parent or legal guardian believes that the qualifying patient resides at least 25 miles from the nearest operating dispensary;
 - m. Whether the qualifying patient's custodial parent or legal guardian would like notification of any clinical studies needing human subjects for research on the medical use of marijuana;
 - n. Whether the individual submitting the application on behalf of the qualifying patient under 18 years of age is the qualifying patient's custodial parent or legal guardian;
 - o. One of the following:
 - i. A statement that the qualifying patient's custodial parent or legal guardian does not currently hold a valid registry identification card, or
 - ii. The assigned registry identification number for the qualifying patient's custodial parent or legal guardian for each valid registry identification card currently held by the qualifying patient's custodial parent or legal guardian;
 - p. An attestation that the information provided in the application is true and correct; and
 - q. The signature of the qualifying patient's custodial parent or legal guardian and the date the qualifying patient's custodial parent or legal guardian signed;
2. A current photograph of the:
 - a. Qualifying patient, and
 - b. Qualifying patient's custodial parent or legal guardian serving as the qualifying patient's designated caregiver;
 3. An attestation in a Department-provided format signed and dated by the qualifying patient's custodial parent or legal guardian that the qualifying patient's custodial parent or legal guardian has not been convicted of an excluded felony offense as defined in A.R.S. § 36-2801;
 4. A statement in a Department-provided format signed by the qualifying patient's custodial parent or legal guardian who is serving as the qualifying patient's designated caregiver:
 - a. Allowing the qualifying patient's medical use of marijuana;
 - b. Agreeing to assist the qualifying patient with the medical use of marijuana; and
 - c. Pledging not to divert marijuana to any individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
 5. A copy of one of the following for the qualifying patient's custodial parent or legal guardian:
 - a. Arizona driver's license issued on or after October 1, 1996;
 - b. Arizona identification card issued on or after October 1, 1996;
 - c. Arizona registry identification card;
 - d. Photograph page in the qualifying patient's custodial parent or legal guardian U.S. passport; or
 - e. Arizona driver's license or identification card issued before October 1, 1996 and one of the following for the qualifying patient's custodial parent or legal guardian:
 - i. Birth certificate verifying U.S. citizenship,
 - ii. U. S. Certificate of Naturalization, or
 - iii. U. S. Certificate of Citizenship;
 6. If the individual submitting the application on behalf of a qualifying patient is the qualifying patient's legal guardian, a copy of documentation establishing the individual as the qualifying patient's legal guardian;
 7. For the Department's criminal records check authorized in A.R.S. § 36-2804.05:
 - a. The qualifying patient's custodial parent or legal guardian's fingerprints on a fingerprint card that includes:
 - i. The qualifying patient's custodial parent or legal guardian's first name; middle initial, if applicable; and last name;
 - ii. The qualifying patient's custodial parent or legal guardian's signature;
 - iii. If different from the qualifying patient's custodial parent or legal guardian, the signature of the individual physically rolling the qualifying patient's custodial parent's or legal guardian's fingerprints;
 - iv. The qualifying patient's custodial parent's or legal guardian's address;
 - v. If applicable, the qualifying patient's custodial parent's or legal guardian's surname before marriage and any names previously used by the qualifying patient's custodial parent or legal guardian;
 - vi. The qualifying patient's custodial parent's or legal guardian's date of birth;
 - vii. The qualifying patient's custodial parent's or legal guardian's Social Security number;
 - viii. The qualifying patient's custodial parent's or legal guardian's citizenship status;
 - ix. The qualifying patient's custodial parent's or legal guardian's gender;
 - x. The qualifying patient's custodial parent's or legal guardian's race;
 - xi. The qualifying patient's custodial parent's or legal guardian's height;
 - xii. The qualifying patient's custodial parent's or legal guardian's weight;
 - xiii. The qualifying patient's custodial parent's or legal guardian's hair color;
 - xiv. The qualifying patient's custodial parent's or legal guardian's eye color; and
 - xv. The qualifying patient's custodial parent's or legal guardian's place of birth; or
 - b. If the qualifying patient's custodial parent's or legal guardian's fingerprints and information required in subsection (G)(7)(a) were submitted to the Department as part of an application for a designated care-

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- giver or a dispensary agent registry identification card within the previous six months, the registry identification number on the registry identification card issued to the qualifying patient's custodial parent or legal guardian as a result of the application;
8. A written certification from the physician in subsection (G)(1)(i) and a separate written certification from the physician in (G)(1)(j) in a Department-provided format dated within 90 calendar days before the submission of the qualifying patient's application that includes:
- a. The physician's:
 - i. Name,
 - ii. License number including an identification of the physician license type,
 - iii. Office address on file with the physician's licensing board,
 - iv. Telephone number on file with the physician's licensing board, and
 - v. E-mail address;
 - b. The qualifying patient's name and date of birth;
 - c. An identification of one or more of the debilitating medical conditions in R9-17-201 as the qualifying patient's specific debilitating medical condition;
 - d. If the debilitating medical condition identified in subsection (G)(9)(c) is a condition in:
 - i. R9-17-201(9) through (13), the underlying chronic or debilitating disease or medical condition; or
 - ii. R9-17-201(14), the debilitating medical condition;
 - e. For the physician listed in subsection (G)(1)(i):
 - i. A statement that the physician has made or confirmed a diagnosis of a debilitating medical condition as defined in A.R.S. § 36-2801 for the qualifying patient;
 - ii. A statement, initialed by the physician, that the physician:
 - (1) Has established a medical record for the qualifying patient, and
 - (2) Is maintaining the qualifying patient's medical record as required in A.R.S. § 12-2297;
 - iii. A statement, initialed by the physician, that the physician has conducted an in-person physical examination of the qualifying patient within the previous 90 calendar days appropriate to the qualifying patient's presenting symptoms and the qualifying patient's debilitating medical condition diagnosed or confirmed by the physician;
 - iv. The date the physician conducted the in-person physical examination of the qualifying patient;
 - v. A statement, initialed by the physician, that the physician reviewed the qualifying patient's:
 - (1) Medical records, including medical records from other treating physicians from the previous 12 months,
 - (2) Response to conventional medications and medical therapies, and
 - (3) Profile on the Arizona Board of Pharmacy Controlled Substances Prescription Monitoring Program database;
 - vi. A statement, initialed by the physician, that the physician has explained the potential risks and benefits of the use of medical marijuana to the qualifying patient's custodial parent or legal guardian responsible for health care decisions for the qualifying patient; and
 - vii. A statement, initialed by the physician, that the physician has provided information to the qualifying patient's custodial parent or legal guardian responsible for health care decisions for the qualifying patient, if the qualifying patient is female, that warns about:
 - (1) The potential dangers to a fetus caused by smoking or ingesting marijuana while pregnant or to an infant while breastfeeding, and
 - (2) The risk of being reported to the Department of Child Safety during pregnancy or at the birth of the child by persons who are required to report;
 - f. For the physician listed in subsection (G)(1)(j), a statement, initialed by the physician, that the physician conducted a comprehensive review of the qualifying patient's medical records from other treating physicians;
 - g. A statement, initialed by the physician, that, in the physician's professional opinion, the qualifying patient is likely to receive therapeutic or palliative benefit from the qualifying patient's medical use of marijuana to treat or alleviate the qualifying patient's debilitating medical condition;
 - h. A statement, initialed by the physician, that if the physician has referred the qualifying patient's custodial parent or legal guardian to a dispensary, the physician has disclosed to the qualifying patient any personal or professional relationship the physician has with the dispensary;
 - i. An attestation that the information provided in the written certification is true and correct; and
 - j. The physician's signature and the date the physician signed; and
 9. The applicable fees in R9-17-102 for applying for a:
 - a. Qualifying patient registry identification card, and
 - b. Designated caregiver registry identification card.
- H.** For purposes of this Article, "25 miles" includes the area contained within a circle that extends for 25 miles in all directions from a specific location.
- I.** For purposes of this Article, "residence address" when used in conjunction with a qualifying patient means:
1. The street address including town or city and zip code assigned by a local jurisdiction; or
 2. For property that does not have a street address assigned by a local jurisdiction, the legal description of the property on the title documents recorded by the assessor of the county in which the property is located.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by final rulemaking at 18 A.A.R. 3354, with an immediate effective date of December 5, 2012 (Supp. 12-4). Amended by final rulemaking 23 A.A.R. 970, effective June 6, 2017 (Supp. 17-2).

R9-17-203. Amending a Qualifying Patient's or Designated Caregiver's Registry Identification Card

- A.** To add a designated caregiver or to request a change of a qualifying patient's designated caregiver, the qualifying patient shall submit to the Department, within 10 working days after the addition or the change, the following:

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1. An application in a Department-provided format that includes:
 - a. The qualifying patient's name and the registry identification number on the qualifying patient's current registry identification card;
 - b. If applicable, the name of the qualifying patient's current designated caregiver and the date the designated caregiver last provided or will last provide assistance to the qualifying patient;
 - c. The name of the individual that the qualifying patient is designating as caregiver; and
 - d. The signature of the qualifying patient and date the qualifying patient signed;
 2. For the caregiver the qualifying patient is designating:
 - a. The designated caregiver's first name; middle initial, if applicable; last name; and suffix, if applicable;
 - b. The designated caregiver's date of birth;
 - c. The designated caregiver's residence address and mailing address;
 - d. The county where the designated caregiver resides;
 - e. The identifying number on the applicable card or document in subsection (A)(2)(i)(i) through (v);
 - f. One of the following:
 - i. A statement that the designated caregiver does not currently hold a valid registry identification card, or
 - ii. The assigned registry identification number for the designated caregiver for each valid registry identification card currently held by the designated caregiver;
 - g. An attestation in a Department-provided format signed and dated by the designated caregiver that the designated caregiver has not been convicted of an excluded felony offense as defined in A.R.S. § 36-2801;
 - h. A statement in a Department-provided format signed by the designated caregiver:
 - i. Agreeing to assist the qualifying patient with the medical use of marijuana; and
 - ii. Pledging not to divert marijuana to any individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
 - i. A copy the designated caregiver's:
 - i. Arizona driver's license issued on or after October 1, 1996;
 - ii. Arizona identification card issued on or after October 1, 1996;
 - iii. Arizona registry identification card;
 - iv. Photograph page in the designated caregiver's U.S. passport; or
 - v. Arizona driver's license or identification card issued before October 1, 1996 and one of the following for the designated caregiver:
 - (1) Birth certificate verifying U.S. citizenship,
 - (2) U. S. Certificate of Naturalization, or
 - (3) U. S. Certificate of Citizenship;
 - j. A current photograph of the designated caregiver; and
 - k. For the Department's criminal records check authorized in A.R.S. § 36-2804.05:
 - i. The designated caregiver's fingerprints on a fingerprint card that includes:
 - (1) The designated caregiver's first name; middle initial, if applicable; and last name;
 - (2) The designated caregiver's signature;
 - (3) If different from the designated caregiver, the signature of the individual physically rolling the designated caregiver's fingerprints;
 - (4) The designated caregiver's address;
 - (5) If applicable, the designated caregiver's surname before marriage and any names previously used by the designated caregiver;
 - (6) The designated caregiver's date of birth;
 - (7) The designated caregiver's Social Security number;
 - (8) The designated caregiver's citizenship status;
 - (9) The designated caregiver's gender;
 - (10) The designated caregiver's race;
 - (11) The designated caregiver's height;
 - (12) The designated caregiver's weight;
 - (13) The designated caregiver's hair color;
 - (14) The designated caregiver's eye color; and
 - (15) The designated caregiver's place of birth; or
 - ii. If the designated caregiver's fingerprints and information required in subsection (A)(2)(k)(i) were submitted to the Department as part of an application for a designated caregiver or a dispensary agent within the previous six months, the registry identification number on the registry identification card issued to the designated caregiver as a result of the application; and
 3. The applicable fee in R9-17-102 for applying for a designated caregiver registry identification card.
- B.** To amend a qualifying patient's address on the qualifying patient's registry identification card when the qualifying patient or the qualifying patient's designated caregiver is authorized to cultivate marijuana, the qualifying patient shall submit to the Department, within 10 working days after the change in address, the following:
1. The qualifying patient's name and the registry identification number on the qualifying patient's current registry identification card;
 2. The qualifying patient's new address;
 3. The county where the new address is located;
 4. The name of the qualifying patient's designated caregiver, if applicable;
 5. Whether the qualifying patient is requesting authorization for cultivating marijuana plants for the qualifying patient's medical use because the qualifying patient believes that the qualifying patient resides at least 25 miles from the nearest operating dispensary;
 6. If the qualifying patient is requesting authorization for cultivating marijuana plants, whether the qualifying patient is designating the qualifying patient's designated caregiver to cultivate marijuana plants for the qualifying patient's medical use;
 7. The effective date of the qualifying patient's new address; and
 8. The applicable fee in R9-17-102 for applying to:
 - a. Amend a qualifying patient's registry identification card; and
 - b. If the qualifying patient is designating a designated caregiver for cultivation authorization, amend a designated caregiver's registry identification card.
- C.** To request authorization to cultivate marijuana based on a qualifying patient's current address or a new address, the qualifying patient shall submit to the Department, if applicable

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within 10 working days after the change in address, the following:

1. The qualifying patient's name and the registry identification number on the qualifying patient's current registry identification card;
2. If the qualifying patient's address is a new address, the qualifying patient's:
 - a. Current address,
 - b. New address,
 - c. The county where the new address is located, and
 - d. The effective date of the qualifying patient's new address;
3. The name of the qualifying patient's designated caregiver, if applicable;
4. Whether the qualifying patient is requesting authorization for cultivating marijuana plants for the qualifying patient's medical use because the qualifying patient believes that the qualifying patient resides at least 25 miles from the nearest operating dispensary;
5. If the qualifying patient is requesting authorization for cultivating marijuana plants, whether the qualifying patient is designating the qualifying patient's designated caregiver to cultivate marijuana plants for the qualifying patient's medical use; and
6. The applicable fee in R9-17-102 for applying to:
 - a. Amend a qualifying patient's registry identification card; and
 - b. If the qualifying patient is designating a designated caregiver for cultivation authorization, amend a designated caregiver's registry identification card.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by final rulemaking at 18 A.A.R. 3354, with an immediate effective date of December 5, 2012 (Supp. 12-4). The Department made a clerical error to R19-17-203(A)(1)(c) when promulgating rules in Supp. 12-4. Remediate or clarity "that" has been moved after "individual" at the request of the Department at file number R19-242 (Supp. 19-3).

R9-17-204. Renewing a Qualifying Patient's or Designated Caregiver's Registry Identification Card

- A.** Except for a qualifying patient who is under 18 years of age, to renew a qualifying patient's registry identification card, the qualifying patient shall submit the following to the Department at least 30 calendar days before the expiration date of the qualifying patient's registry identification card:
1. An application in a Department-provided format that includes:
 - a. The qualifying patient's first name; middle initial, if applicable; last name; and suffix, if applicable;
 - b. The qualifying patient's date of birth;
 - c. Except as provided in subsection (A)(1)(j), the qualifying patient's residence address and mailing address;
 - d. The county where the qualifying patient resides;
 - e. The qualifying patient's e-mail address;
 - f. The registry identification number on the qualifying patient's current registry identification card;
 - g. The name, address, and telephone number of the physician providing the written certification for medical marijuana for the qualifying patient;
 - h. Whether the qualifying patient is requesting authorization for cultivating marijuana plants for the qualifying patient's medical use because the qualifying

- patient believes that the qualifying patient resides at least 25 miles from the nearest operating dispensary;
- i. If the qualifying patient is requesting authorization for cultivating marijuana plants, whether the qualifying patient is designating the qualifying patient's designated caregiver to cultivate marijuana plants for the qualifying patient's medical use;
 - j. If the qualifying patient is homeless, an address where the qualifying patient can receive mail;
 - k. Whether the qualifying patient would like notification of any clinical studies needing human subjects for research on the medical use of marijuana;
 - l. An attestation that the information provided in the application is true and correct; and
 - m. The signature of the qualifying patient and the date the qualifying patient signed;
2. If the qualifying patient's name in subsection (A)(1)(a) is not the same name as on the qualifying patient's current registry identification card, one of the following with the qualifying patient's new name:
 - a. An Arizona driver's license,
 - b. An Arizona identification card, or
 - c. The photograph page in the qualifying patient's U.S. passport;
 3. A current photograph of the qualifying patient;
 4. A statement in a Department-provided format signed by the qualifying patient pledging not to divert marijuana to any individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
 5. A physician's written certification in a Department-provided format dated within 90 calendar days before the submission of the qualifying patient's renewal application that includes:
 - a. The physician's:
 - i. Name,
 - ii. License number including an identification of the physician license type,
 - iii. Office address on file with the physician's licensing board,
 - iv. Telephone number on file with the physician's licensing board, and
 - v. E-mail address;
 - b. The qualifying patient's name and date of birth;
 - c. A statement that the physician has made or confirmed a diagnosis of a debilitating medical condition as defined in A.R.S. § 36-2801 for the qualifying patient;
 - d. An identification of one or more of the debilitating medical conditions in R9-17-201 as the qualifying patient's specific debilitating medical condition;
 - e. If the debilitating medical condition identified in subsection (A)(5)(d) is a condition in:
 - i. R9-17-201(9) through (13), the underlying chronic or debilitating disease or medical condition; or
 - ii. R9-17-201(14), the debilitating medical condition;
 - f. A statement, initialed by the physician, that the physician:
 - i. Has established a medical record for the qualifying patient, and
 - ii. Is maintaining the qualifying patient's medical record as required in A.R.S. § 12-2297;
 - g. A statement, initialed by the physician, that the physician has conducted an in-person physical examination of the qualifying patient within the previous 90

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- calendar days appropriate to the qualifying patient's presenting symptoms and the qualifying patient's debilitating medical condition diagnosed or confirmed by the physician;
- h. The date the physician conducted the in-person physical examination of the qualifying patient;
 - i. A statement, initialed by the physician, that the physician reviewed the qualifying patient's:
 - i. Medical records including medical records from other treating physicians from the previous 12 months,
 - ii. Response to conventional medications and medical therapies, and
 - iii. Profile on the Arizona Board of Pharmacy Controlled Substances Prescription Monitoring Program database;
 - j. A statement, initialed by the physician, that the physician has explained the potential risks and benefits of the medical use of marijuana to the qualifying patient;
 - k. A statement, initialed by the physician, that in the physician's professional opinion, the qualifying patient is likely to receive therapeutic or palliative benefit from the qualifying patient's medical use of marijuana to treat or alleviate the qualifying patient's debilitating medical condition;
 - l. A statement, initialed by the physician, that if the physician has referred the qualifying patient to a dispensary, the physician has disclosed to the qualifying patient any personal or professional relationship the physician has with the dispensary;
 - m. A statement, initialed by the physician, that the physician has provided information to the qualifying patient, if the qualifying patient is female, that warns about:
 - i. The potential dangers to a fetus caused by smoking or ingesting marijuana while pregnant or to an infant while breastfeeding, and
 - ii. The risk of being reported to the Department of Child Safety during pregnancy or at the birth of the child by persons who are required to report;
 - n. An attestation that the information provided in the written certification is true and correct; and
 - o. The physician's signature and the date the physician signed;
6. If the qualifying patient is designating a caregiver or if the qualifying patient's designated caregiver's registry identification card has the same expiration date as the qualifying patient's registry identification card, the following in a Department-provided format:
 - a. The designated caregiver's first name; middle initial, if applicable; last name; and suffix, if applicable;
 - b. The designated caregiver's date of birth;
 - c. The designated caregiver's residence address and mailing address;
 - d. The county where the designated caregiver resides;
 - e. If the qualifying patient is renewing the designated caregiver's registry identification card, the registry identification number on the designated caregiver's registry identification card associated with the qualifying patient;
 - f. If the qualifying patient is designating an individual not previously designated as the qualifying patient's designated caregiver, the identification number on and a copy of the designated caregiver's:
 - i. Arizona driver's license issued on or after October 1, 1996;
 - ii. Arizona identification card issued on or after October 1, 1996;
 - iii. Arizona registry identification card;
 - iv. Photograph page in the designated caregiver's U. S. passport; or
 - v. Arizona driver's license or identification card issued before October 1, 1996 and one of the following for the designated caregiver:
 - (1) Birth certificate verifying U.S. citizenship,
 - (2) U. S. Certificate of Naturalization, or
 - (3) U. S. Certificate of Citizenship;
 - g. If the qualifying patient is designating an individual not previously designated as the qualifying patient's designated caregiver, one of the following:
 - i. A statement that the designated caregiver does not currently hold a valid registry identification card, or
 - ii. The assigned registry identification number for the designated caregiver for each valid registry identification card currently held by the designated caregiver;
 - h. A current photograph of the designated caregiver;
 - i. An attestation signed and dated by the designated caregiver that the designated caregiver has not been convicted of an excluded felony offense as defined in A.R.S. § 36-2801;
 - j. A statement in a Department-provided format signed by the designated caregiver:
 - i. Agreeing to assist the qualifying patient with the medical use of marijuana; and
 - ii. Pledging not to divert marijuana to any individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1; and
 - k. For the Department's criminal records check authorized in A.R.S. § 36-2804.05:
 - i. The designated caregiver's fingerprints on a fingerprint card that includes:
 - (1) The designated caregiver's first name; middle initial, if applicable; and last name;
 - (2) The designated caregiver's signature;
 - (3) If different from the designated caregiver, the signature of the individual physically rolling the designated caregiver's fingerprints;
 - (4) The designated caregiver's address;
 - (5) If applicable, the designated caregiver's surname before marriage and any names previously used by the designated caregiver;
 - (6) The designated caregiver's date of birth;
 - (7) The designated caregiver's Social Security number;
 - (8) The designated caregiver's citizenship status;
 - (9) The designated caregiver's gender;
 - (10) The designated caregiver's race;
 - (11) The designated caregiver's height;
 - (12) The designated caregiver's weight;
 - (13) The designated caregiver's hair color;
 - (14) The designated caregiver's eye color; and
 - (15) The designated caregiver's place of birth;

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- ii. If the designated caregiver's fingerprints and information required in subsection (A)(6)(k)(i) were submitted to the Department as part of an application for a designated caregiver or a dispensary agent registry identification card within the previous six months, the registry identification number on the registry identification card issued to the designated caregiver as a result of the application;
- 7. If the qualifying patient's designated caregiver's registry identification card has the same expiration date as the qualifying patient's registry identification card and the designated caregiver's name in subsection (A)(6)(a) is not the same name as on the designated caregiver's current registry identification card, one of the following with the designated caregiver's new name:
 - a. An Arizona driver's license,
 - b. An Arizona identification card, or
 - c. The photograph page in the designated caregiver's U.S. passport; and
- 8. The applicable fees in R9-17-102 for applying to:
 - a. Renew a qualifying patient's registry identification card; and
 - b. If applicable, issue or renew a designated caregiver's registry identification card.
- B.** To renew a registry identification card for a qualifying patient who is under 18 years of age, the qualifying patient's custodial parent or legal guardian responsible for health care decisions for the qualifying patient shall submit to the Department the following:
 - 1. An application in a Department-provided format that includes:
 - a. The qualifying patient's:
 - i. First name; middle initial, if applicable; last name; and suffix, if applicable; and
 - ii. Date of birth;
 - b. The qualifying patient's residence address and mailing address;
 - c. The county where the qualifying patient resides;
 - d. The registry identification number on the qualifying patient's current registry identification card;
 - e. The qualifying patient's custodial parent's or legal guardian's first name; middle initial, if applicable; last name; and suffix, if applicable;
 - f. The qualifying patient's custodial parent's or legal guardian's residence address and mailing address;
 - g. The county where the qualifying patient's custodial parent or legal guardian resides;
 - h. The qualifying patient's custodial parent's or legal guardian's e-mail address;
 - i. The registry identification number on the qualifying patient's custodial parent's or legal guardian's current registry identification card;
 - j. The name, address, and telephone number of a physician who has a physician-patient relationship with the qualifying patient and is providing the written certification for medical marijuana for the qualifying patient;
 - k. The name, address, and telephone number of a second physician who has conducted a comprehensive review of the qualifying patient's medical record maintained by other treating physicians, and is providing a written certification for medical marijuana for the qualifying patient;
 - l. Whether the qualifying patient's custodial parent or legal guardian is requesting approval for cultivating marijuana plants for the qualifying patient's medical use because the qualifying patient's custodial parent or legal guardian believes that the qualifying patient resides at least 25 miles from the nearest operating dispensary;
 - m. Whether the qualifying patient's custodial parent or legal guardian would like notification of any clinical studies needing human subjects for research on the medical use of marijuana;
 - n. A statement in a Department-provided format signed by the qualifying patient's custodial parent or legal guardian who is serving as the qualifying patient's designated caregiver:
 - i. Allowing the qualifying patient's medical use of marijuana;
 - ii. Agreeing to assist the qualifying patient with the medical use of marijuana; and
 - iii. Pledging not to divert marijuana to any individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
 - o. An attestation that the information provided in the application is true and correct; and
 - p. The signature of the qualifying patient's custodial parent or legal guardian and the date the qualifying patient's custodial parent or legal guardian signed;
 - 2. If the qualifying patient's custodial parent's or legal guardian's name in subsection (B)(1)(e) is not the same name as on the qualifying patient's custodial parent's or legal guardian's current registry identification card, one of the following with the custodial parent's or legal guardian's new name:
 - a. An Arizona driver's license,
 - b. An Arizona identification card, or
 - c. The photograph page in the qualifying patient's custodial parent's or legal guardian's U.S. passport;
 - 3. A current photograph of the qualifying patient;
 - 4. A written certification from the physician in subsection (B)(1)(j) and a separate written certification from the physician in subsection (B)(1)(k) in a Department-provided format dated within 90 calendar days before the submission of the qualifying patient's renewal application that includes:
 - a. The physician's:
 - i. Name,
 - ii. License number including an identification of the physician license type,
 - iii. Office address on file with the physician's licensing board,
 - iv. Telephone number on file with the physician's licensing board, and
 - v. E-mail address;
 - b. The qualifying patient's name and date of birth;
 - c. An identification of one or more of the debilitating medical conditions in R9-17-201 as the qualifying patient's specific debilitating medical condition;
 - d. If the debilitating medical condition identified in subsection (B)(4)(c) is a condition in:
 - i. R9-17-201(9) through (13), the underlying chronic or debilitating disease or medical condition; or
 - ii. R9-17-201(14), the debilitating medical condition;
 - e. For the physician listed in subsection (B)(1)(j):
 - i. A statement that the physician has made or confirmed a diagnosis of a debilitating medical

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- condition as defined in A.R.S. § 36-2801 for the qualifying patient;
- ii. A statement, initialed by the physician, that the physician:
 - (1) Has established a medical record for the qualifying patient, and
 - (2) Is maintaining the qualifying patient's medical record as required in A.R.S. § 12-2297;
 - iii. A statement, initialed by the physician, that the physician has conducted an in-person physical examination of the qualifying patient within the previous 90 calendar days appropriate to the qualifying patient's presenting symptoms and the qualifying patient's debilitating medical condition diagnosed or confirmed by the physician;
 - iv. The date the physician conducted the in-person physical examination of the qualifying patient;
 - v. A statement, initialed by the physician, that the physician reviewed the qualifying patient's:
 - (1) Medical records including medical records from other treating physicians from the previous 12 months,
 - (2) Response to conventional medications and medical therapies, and
 - (3) Profile on the Arizona Board of Pharmacy Controlled Substances Prescription Monitoring Program database;
 - vi. A statement, initialed by the physician, that the physician has explained the potential risks and benefits of the use of medical marijuana to the qualifying patient's custodial parent or legal guardian responsible for health care decisions for the qualifying patient; and
 - vii. A statement, initialed by the physician, that the physician has provided information to the qualifying patient's custodial parent or legal guardian responsible for health care decisions for the qualifying patient, if the qualifying patient is female, that warns about:
 - (1) The potential dangers to a fetus caused by smoking or ingesting marijuana while pregnant or to an infant while breastfeeding, and
 - (2) The risk of being reported to the Department of Child Safety during pregnancy or at the birth of the child by persons who are required to report;
 - f. For the physician listed in subsection (B)(1)(k), a statement, initialed by the physician, that the physician conducted a comprehensive review of the qualifying patient's medical records from other treating physicians;
 - g. A statement, initialed by the physician, that in the physician's professional opinion the qualifying patient is likely to receive therapeutic or palliative benefit from the qualifying patient's medical use of marijuana to treat or alleviate the qualifying patient's debilitating medical condition;
 - h. A statement, initialed by the physician, that if the physician has referred the qualifying patient's custodial parent or legal guardian to a dispensary, the physician has disclosed to the qualifying patient's custodial parent or legal guardian any personal or professional relationship the physician has with the dispensary;
 - i. An attestation that the information provided in the written certification is true and correct; and
 - j. The physician's signature and the date the physician signed; and
5. A current photograph of the qualifying patient's custodial parent or legal guardian;
 6. For the Department's criminal records check authorized in A.R.S. § 36-2804.05:
 - a. The qualifying patient's custodial parent's or legal guardian's fingerprints on a fingerprint card that includes:
 - i. The qualifying patient's custodial parent's or legal guardian's first name; middle initial, if applicable; and last name;
 - ii. The qualifying patient's custodial parent's or legal guardian's signature;
 - iii. If different from the qualifying patient's custodial parent or legal guardian, the signature of the individual physically rolling the qualifying patient's custodial parent's or legal guardian's fingerprints;
 - iv. The qualifying patient's custodial parent's or legal guardian's address;
 - v. If applicable, the qualifying patient's custodial parent's or legal guardian's surname before marriage and any names previously used by the qualifying patient's custodial parent or legal guardian;
 - vi. The qualifying patient's custodial parent's or legal guardian's date of birth;
 - vii. The qualifying patient's custodial parent's or legal guardian's Social Security number;
 - viii. The qualifying patient's custodial parent's or legal guardian's citizenship status;
 - ix. The qualifying patient's custodial parent's or legal guardian's gender;
 - x. The qualifying patient's custodial parent's or legal guardian's race;
 - xi. The qualifying patient's custodial parent's or legal guardian's height;
 - xii. The qualifying patient's custodial parent's or legal guardian's weight;
 - xiii. The qualifying patient's custodial parent's or legal guardian's hair color;
 - xiv. The qualifying patient's custodial parent's or legal guardian's eye color; and
 - xv. The qualifying patient's custodial parent's or legal guardian's place of birth; or
 - b. If the qualifying patient's custodial parent's or legal guardian's fingerprints and information required in subsection (B)(6)(a) were submitted as part of an application for a designated caregiver or a dispensary agent registry identification card to the Department within the previous six months, the registry identification number on the registry identification card issued to the patient's custodial parent or legal guardian serving as the qualifying patient's designated caregiver as a result of the application; and
 7. The applicable fees in R9-17-102 for applying to renew a:
 - a. Qualifying patient's registry identification card, and
 - b. Designated caregiver's registry identification card.
- C. Except as provided in subsection (A)(6), to renew a qualifying patient's designated caregiver's registry identification card, the qualifying patient shall submit to the Department, at least 30

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calendar days before the expiration date of the designated caregiver's registry identification card, the following:

1. An application in a Department-provided format that includes:
 - a. The qualifying patient's first name; middle initial, if applicable; last name; and suffix, if applicable;
 - b. The registry identification number on the qualifying patient's current registry identification card;
 - c. The designated caregiver's first name; middle initial, if applicable; last name; and suffix, if applicable;
 - d. The designated caregiver's date of birth;
 - e. The designated caregiver's residence address and mailing address;
 - f. The county where the designated caregiver resides;
 - g. The registry identification number on the designated caregiver's current registry identification card;
2. If the designated caregiver's name in subsection (C)(1)(a) is not the same name as on the designated caregiver's current registry identification card, one of the following with the designated caregiver's new name:
 - a. An Arizona driver's license,
 - b. An Arizona identification card, or
 - c. The photograph page in the designated caregiver's U.S. passport;
3. A current photograph of the designated caregiver;
4. A statement in a Department-provided format signed by the designated caregiver:
 - a. Agreeing to assist the qualifying patient with the medical use of marijuana; and
 - b. Pledging not to divert marijuana to any individual or person who is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1; and
5. For the Department's criminal records check authorized in A.R.S. § 36-2804.05:
 - a. The designated caregiver's fingerprints on a fingerprint card that includes:
 - i. The designated caregiver's first name; middle initial, if applicable; and last name;
 - ii. The designated caregiver's signature;
 - iii. If different from the designated caregiver, the signature of the individual physically rolling the designated caregiver's fingerprints;
 - iv. The designated caregiver's address;
 - v. If applicable, the designated caregiver's surname before marriage and any names previously used by the designated caregiver;
 - vi. The designated caregiver's date of birth;
 - vii. The designated caregiver's Social Security number;
 - viii. The designated caregiver's citizenship status;
 - ix. The designated caregiver's gender;
 - x. The designated caregiver's race;
 - xi. The designated caregiver's height;
 - xii. The designated caregiver's weight;
 - xiii. The designated caregiver's hair color;
 - xiv. The designated caregiver's eye color; and
 - xv. The designated caregiver's place of birth; or
 - b. If the designated caregiver's fingerprints and information required in subsection (C)(1)(j)(i) were submitted as part of an application for a designated caregiver or a dispensary agent registry identification card to the Department within the previous six months, the registry identification number on the registry identification card issued to the designated caregiver as a result of the application; and

6. The applicable fee in R9-17-102 for renewing a designated caregiver's registry identification card.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by final rulemaking at 23 A.A.R. 970, effective June 6, 2017 (Supp. 17-2).

R9-17-205. Denial or Revocation of a Qualifying Patient's or Designated Caregiver's Registry Identification Card

- A. The Department shall deny a qualifying patient's application for or renewal of the qualifying patient's registry identification card if the qualifying patient does not have a debilitating medical condition.
- B. The Department shall deny a designated caregiver's application for or renewal of the designated caregiver's registry identification card if the designated caregiver does not meet the definition of "designated caregiver" in A.R.S. § 36-2801.
- C. The Department may deny a qualifying patient's or designated caregiver's application for or renewal of the qualifying patient's or designated caregiver's registry identification card if the qualifying patient or designated caregiver:
 1. Previously had a registry identification card revoked for not complying with A.R.S. Title 36, Chapter 28.1 or this Chapter; or
 2. Provides false or misleading information to the Department.
- D. The Department shall revoke a qualifying patient's or designated caregiver's registry identification card if the qualifying patient or designated caregiver diverts medical marijuana to an individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1.
- E. The Department shall revoke a designated caregiver's registry identification card if the designated caregiver has been convicted of an excluded felony offense.
- F. The Department may revoke a qualifying patient's or designated caregiver's registry identification card if the qualifying patient or designated caregiver knowingly violates A.R.S. Title 36, Chapter 28.1 or this Chapter.
- G. If the Department denies or revokes a qualifying patient's registry identification card, the Department shall provide written notice to the qualifying patient that includes:
 1. The specific reason or reasons for the denial or revocation; and
 2. The process for requesting a judicial review of the Department's decision pursuant to A.R.S. Title 12, Chapter 7, Article 6.
- H. If the Department denies or revokes a qualifying patient's designated caregiver's registry identification card, the Department shall provide written notice to the qualifying patient and the designated caregiver that includes:
 1. The specific reason or reasons for the denial or revocation; and
 2. The process for requesting a judicial review of the Department's decision pursuant to A.R.S. Title 12, Chapter 7, Article 6.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3).

ARTICLE 3. DISPENSARIES AND DISPENSARY AGENTS**R9-17-301. Principal Officers and Board Members**

- A. For the purposes of this Chapter, in addition to the individual or individuals identified in the dispensary's by-laws as princi-

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pal officers of the dispensary, the following individuals are considered principal officers:

1. If an individual is applying for a dispensary registration certificate, the individual;
 2. If a corporation is applying for a dispensary registration certificate, two individuals who are officers of the corporation;
 3. If a partnership is applying for a dispensary registration certificate, two of the individuals who are partners;
 4. If a limited liability company is applying for a dispensary registration certificate, a manager or, if the limited liability company does not have a manager, an individual who is a member of the limited liability company;
 5. If an association or cooperative is applying for a dispensary registration certificate, two individuals who are members of the governing board of the association or cooperative;
 6. If a joint venture is applying for a dispensary registration certificate, two of the individuals who signed the joint venture agreement; and
 7. If a business organization type other than those described in subsections (A)(2) through (6) is applying for a dispensary registration certificate, two individuals who are members of the business organization.
- B.** For purposes of this Chapter, in addition to the individual or individuals identified in the dispensary's by-laws as board members of the dispensary, the following individuals are considered board members:
1. If a corporation is applying for a dispensary registration certificate, the officers of the corporation;
 2. If a partnership is applying for a dispensary registration certificate, the partners;
 3. If a limited liability company is applying for a dispensary registration certificate, the members of the limited liability company;
 4. If an association or cooperative is applying for a dispensary registration certificate, the members of the association or cooperative;
 5. If a joint venture is applying for a dispensary registration certificate, the individuals who signed the joint venture agreement; and
 6. If a business organization type other than the types of business organizations in subsections (B)(1) through (5), the members of the business organization.
- C.** When a dispensary is required by this Chapter to provide information, sign documents, or ensure actions are taken, the individual or individuals in subsection (A) shall comply with the requirement on behalf of the dispensary.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2).

R9-17-302. Repealed**Historical Note**

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by emergency rulemaking at 18 A.A.R. 1010, effective April 11, 2012 for 180 days (Supp. 12-2). Repealed by final rulemaking at 18 A.A.R. 3354, with an immediate effective date of December 5, 2012 (Supp. 12-4).

R9-17-303. Dispensary Registration Certificate Allocation Process

- A.** Each calendar year beginning in 2013, the Department shall review current valid dispensary registration certificates to

determine if the Department may issue additional dispensary registration certificates pursuant to A.R.S. § 36-2804(C).

1. If the Department determines that the Department may issue additional dispensary registration certificates, the Department shall post, on the Department's web site, the information that the Department is accepting dispensary registration certificate applications, including the deadline for accepting dispensary registration certificate applications.
 - a. The Department shall post the information in subsection (A)(1) at least 30 calendar days before the date the Department begins accepting applications.
 - b. The deadline for submission of dispensary registration certificate applications is 10 working days after the date the Department begins accepting applications.
 - c. Sixty working days after the date the Department begins accepting applications, the Department shall determine if the Department received more dispensary registration certificate applications that are complete and in compliance with A.R.S. Title 36, Chapter 28.1 and this Chapter to participate in the allocation process than the Department is allowed to issue.
 - i. If the Department received more dispensary registration certificate applications than the Department is allowed to issue, the Department shall allocate any available dispensary registration certificates according to the priorities established in subsection (B).
 - ii. If the Department is allowed to issue a dispensary registration certificate for each dispensary registration certificate application the Department received, the Department shall allocate the dispensary registration certificates to those applicants.
 2. If the Department determines that the Department is not allowed to issue additional dispensary registration certificates, the Department shall, on the Department's web site:
 - a. Post the information that the Department is not accepting dispensary registration certificate applications, and
 - b. Maintain the information until the next review.
- B.** Beginning in 2013, if the Department receives, by 60 working days after the date the Department begins accepting applications, more dispensary registration certificate applications that are complete and are in compliance with A.R.S. Title 36, Chapter 28.1 and this Chapter to participate in the allocation process than the Department is allowed to issue, the Department shall allocate the dispensary registration certificates according to the following criteria:
1. If dispensary registration certificate applications are received for a county that does not contain a dispensary:
 - a. If only one dispensary registration certificate application for a dispensary located in the county is received, the Department shall allocate the dispensary registration certificate to that applicant; or
 - b. If more than one dispensary registration certificate application for a dispensary located in the county is received, the Department shall prioritize and allocate a dispensary registration certificate to an applicant whose proposed dispensary location will provide dispensary services to the most qualifying patients based on:

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- i. The number of registry identification cards issued to qualifying patients who reside within 10 miles of the applicant's proposed dispensary location, and
 - ii. The number of dispensaries operating within 10 miles of the applicant's proposed dispensary location;
2. If there are additional dispensary registration certificates available after dispensary registration certificates are allocated according to subsection (B)(1), the Department shall allocate the dispensary registration certificates as follows:
 - a. The Department shall prioritize and assign a dispensary registration certificate allocation to a CHAA based on which CHAA has the most registry identification cards issued to qualifying patients who reside within the CHAA;
 - b. If the Department receives only one dispensary registration certificate application for a dispensary located in a CHAA assigned a dispensary registration certificate allocation under this subsection, the Department shall allocate the dispensary registration certificate to that applicant;
 - c. If the Department receives more than one dispensary registration certificate application for a dispensary located in a CHAA assigned a dispensary registration certificate allocation under this subsection, the Department shall prioritize and allocate dispensary registration certificates to an applicant whose proposed dispensary location will provide dispensary services to the most qualifying patients based on:
 - i. The number of registry identification cards issued to qualifying patients who reside within 10 miles of the applicant's proposed dispensary location, and
 - ii. The number of dispensaries operating within 10 miles of the applicant's proposed dispensary location;
 3. If there are additional dispensary registration certificates available after dispensary registration certificates are allocated according to subsections (B)(1) and (2), for all dispensary registration certificate applications not allocated a dispensary registration certificate pursuant to subsections (B)(1) and (2) and any other dispensary registration certificate applications received, the Department shall prioritize and allocate a dispensary registration certificate to an applicant whose proposed dispensary location will provide dispensary services to the most qualifying patients based on:
 - a. The number of registry identification cards issued to qualifying patients who reside within 10 miles of the applicant's proposed dispensary location, and
 - b. The number of dispensaries operating within 10 miles of the applicant's proposed dispensary location; and
 4. If there is a tie or a margin of 0.1% or less in the scores generated by applying the criteria in subsection (B), the Department shall randomly select one dispensary registration certificate application and allocate a dispensary registration certificate to that applicant.
- C. For purposes of subsection (B), "10 miles" includes the area contained within a circle that extends for 10 miles in all directions from a specific location.
- D. If the Department does not allocate a dispensary registration certificate to an applicant that had submitted a dispensary registration certificate application that the Department determined was complete and in compliance with A.R.S. Title 36, Chapter 28.1 and this Chapter to participate in the allocation process, the Department shall:
1. Provide a written notice to the applicant that states that, although the applicant's dispensary registration certificate application was complete and complied with A.R.S. Title 36, Chapter 28.1 and this Chapter, the Department did not allocate the applicant a dispensary registration certificate under the processes in this Section; and
 2. Return \$1,000 of the application fee to the applicant.
- E. If the Department receives a dispensary registration certificate application at a time other than the time stated in subsection (B), the Department shall return the dispensary registration certificate application, including the application fee, to the entity that submitted the dispensary registration certificate application.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by emergency rulemaking at 18 A.A.R. 1010, effective April 11, 2012 for 180 days (Supp. 12-2). Emergency expired (Supp. 12-4). Amended by final rulemaking at 18 A.A.R. 3354, with an immediate effective date of December 5, 2012 (Supp. 12-4).

R9-17-304. Applying for a Dispensary Registration Certificate

- A. An individual shall not be an applicant, principal officer, or board member on:
1. More than one dispensary registration certificate application for a location in a single CHAA, or
 2. More than five dispensary registration certificate applications for locations in different CHAAs.
- B. If the Department determines that an individual is an applicant, principal officer, or board member on more than one dispensary registration certificate application for a CHAA or more than five dispensary registration certificate applications, the Department shall review the applications and provide the applicant on each of the dispensary registration certificate applications with a written comprehensive request for more information that includes the specific requirements in A.R.S. Title 36, Chapter 28.1 and this Chapter that the dispensary registration certificate application does not comply with.
1. If an applicant withdraws an application to comply with this Chapter and submits information demonstrating compliance with A.R.S. Title 36, Chapter 28.1 and this Chapter, the Department shall process the applicant's remaining dispensary registration certificate applications according to this Chapter.
 2. If an applicant does not withdraw an application or submit information demonstrating compliance with A.R.S. Title 36, Chapter 28.1 and this Chapter, the Department shall issue a denial to the applicant according to R9-17-322.
 3. An application fee submitted with a dispensary registration certificate application in subsection (B) that is withdrawn is not refunded.
- C. To apply for a dispensary registration certificate, an entity shall submit to the Department the following:
1. An application in a Department-provided format that includes:
 - a. The legal name of the dispensary;
 - b. The physical address of the proposed dispensary;

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- c. The following information for the entity applying:
 - i. Name,
 - ii. Type of business organization,
 - iii. Mailing address,
 - iv. Telephone number, and
 - v. E-mail address;
 - d. The name of the individual designated to submit dispensary agent registry identification card applications on behalf of the dispensary;
 - e. The name and license number of the dispensary's medical director;
 - f. The name, residence address, and date of birth of each:
 - i. Principal officer, and
 - ii. Board member;
 - g. For each principal officer or board member, whether the principal officer or board member:
 - i. Has served as a principal officer or board member for a dispensary that had the dispensary registration certificate revoked;
 - ii. Is a physician currently providing written certifications for qualifying patients;
 - iii. Is a law enforcement officer; or
 - iv. Is employed by or a contractor of the Department;
 - h. Whether the entity agrees to allow the Department to submit supplemental requests for information;
 - i. A statement that, if the dispensary is issued a dispensary registration certificate, the dispensary will not operate until the dispensary is inspected and obtains an approval to operate from the Department;
 - j. An attestation that the information provided to the Department to apply for a dispensary registration certificate is true and correct; and
 - k. The signatures of the principal officers of the dispensary according to R9-17-301(A) and the date the principal officers signed;
2. If the entity applying is one of the business organizations in R9-17-301(A)(2) through (7), a copy of the business organization's articles of incorporation, articles of organization, or partnership or joint venture documents that include:
 - a. The name of the business organization,
 - b. The type of business organization, and
 - c. The names and titles of the individuals in R9-17-301(A) and (B);
 3. For each principal officer and board member:
 - a. An attestation signed and dated by the principal officer or board member that the principal officer or board member has not been convicted of an excluded felony offense as defined in A.R.S. § 36-2801; and
 - b. For the Department's criminal records check authorized in A.R.S. § 36-2804.05:
 - i. The principal officer's or board member's fingerprints on a fingerprint card that includes:
 - (1) The principal officer's or board member's first name; middle initial, if applicable; and last name;
 - (2) The principal officer's or board member's signature;
 - (3) If different from the principal officer or board member, the signature of the individual physically rolling the principal officer's or board member's fingerprints;
 - (4) The principal officer's or board member's residence address;
 - ii. If the fingerprints and information required in subsection (C)(3)(b)(i) were submitted to the Department as part of an application for a designated caregiver or a dispensary agent registry identification card within the previous six months, the registry identification number on the registry identification card issued to the principal officer or board member as a result of the application;
4. Policies and procedures that comply with the requirements in this Chapter for:
 - a. Inventory control,
 - b. Qualifying patient recordkeeping,
 - c. Security, and
 - d. Patient education and support;
 5. As required in A.R.S. § 36-2804(B)(1)(d), a sworn statement signed and dated by the individual or individuals in R9-17-301(A) certifying that the dispensary is in compliance with any local zoning restrictions;
 6. Documentation from the local jurisdiction where the dispensary's proposed physical address is located that:
 - a. There are no local zoning restrictions for the dispensary's location, or
 - b. The dispensary's location is in compliance with any local zoning restrictions;
 7. Documentation of:
 - a. Ownership of the physical address of the proposed dispensary, or
 - b. Permission from the owner of the physical address of the proposed dispensary for the entity applying for a dispensary registration certificate to operate a dispensary at the physical address;
 8. The dispensary's by-laws including:
 - a. The names and titles of individuals designated as principal officers and board members of the dispensary;
 - b. Whether the dispensary plans to:
 - i. Cultivate marijuana;
 - ii. Acquire marijuana from qualifying patients, designated caregivers, or other dispensaries;
 - iii. Sell or provide marijuana to other dispensaries;

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- iv. Transport marijuana;
 - v. Prepare, sell, or dispense marijuana-infused edible food products;
 - vi. Prepare, sell, or dispense marijuana-infused non-edible products;
 - vii. Sell or provide marijuana paraphernalia or other supplies related to the administration of marijuana to qualifying patients and designated caregivers;
 - viii. Deliver medical marijuana to qualifying patients; or
 - ix. Provide patient support and related services to qualifying patients;
 - c. Provisions for the disposition of revenues and receipts to ensure that the dispensary operates on a not-for-profit basis; and
 - d. Provisions for amending the dispensary's by-laws;
9. A business plan demonstrating the on-going viability of the dispensary on a not-for-profit basis that includes:
- a. A description and total dollar amount of expenditures already incurred to establish the dispensary or to secure a dispensary registration certificate by the individual or business organization applying for the dispensary registration certificate,
 - b. A description and total dollar amount of monies or tangible assets received for operating the dispensary from entities other than the individual applying for the dispensary registration certificate or a principal officer or board member associated with the dispensary including the entity's name and the interest in the dispensary or the benefit the entity obtained,
 - c. Projected expenditures expected before the dispensary is operational,
 - d. Projected expenditures after the dispensary is operational, and
 - e. Projected revenue; and
10. The applicable fee in R9-17-102 for applying for a dispensary registration certificate.
- D.** Before an entity with a dispensary registration certificate begins operating a dispensary, the entity shall apply for and obtain an approval to operate a dispensary from the Department.
- Historical Note**
- New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by emergency rulemaking at 18 A.A.R. 1010, effective April 11, 2012 for 180 days (Supp. 12-2). Emergency expired (Supp. 12-4). Amended by final rulemaking at 18 A.A.R. 3354, with an immediate effective date of December 5, 2012 (Supp. 12-4).
- R9-17-305. Applying for Approval to Operate a Dispensary**
- A.** To apply for approval to operate a dispensary, a person holding a dispensary registration certificate shall submit to the Department, at least 60 calendar days before the expiration of the dispensary registration certificate, the following:
- 1. An application in a Department-provided format that includes:
 - a. The name and registry identification number of the dispensary;
 - b. The physical address of the dispensary;
 - c. The name, address, and date of birth of each dispensary agent;
 - d. The name and license number of the dispensary's medical director;
 - e. If applicable, the physical address of the dispensary's cultivation site;
 - f. The dispensary's Transaction Privilege Tax Number issued by the Arizona Department of Revenue;
 - g. The dispensary's proposed hours of operation during which the dispensary plans to be available to dispense medical marijuana to qualifying patients and designated caregivers;
 - h. Whether the dispensary agrees to allow the Department to submit supplemental requests for information;
 - i. Whether the dispensary and, if applicable, the dispensary's cultivation site are ready for an inspection by the Department;
 - j. If the dispensary and, if applicable, the dispensary's cultivation site are not ready for an inspection by the Department, the date the dispensary and, if applicable, the dispensary's cultivation site will be ready for an inspection by the Department;
 - k. An attestation that the information provided to the Department to apply for approval to operate a dispensary is true and correct; and
 - l. The signatures of the principal officers of the dispensary according to R9-17-301(A) and the date the principal officers signed;
 - 2. A copy of documentation issued by the local jurisdiction to the dispensary authorizing occupancy of the building as a dispensary and, if applicable, as the dispensary's cultivation site, such as a certificate of occupancy, a special use permit, or a conditional use permit;
 - 3. A sworn statement signed and dated by the individual or individuals in R9-17-301(A) certifying that the dispensary is in compliance with local zoning restrictions;
 - 4. The distance to the closest private school or public school from:
 - a. The dispensary; and
 - b. If applicable, the dispensary's cultivation site;
 - 5. A site plan drawn to scale of the dispensary location showing streets, property lines, buildings, parking areas, outdoor areas if applicable, fences, security features, fire hydrants if applicable, and access to water mains;
 - 6. A floor plan drawn to scale of the building where the dispensary is located showing the:
 - a. Layout and dimensions of each room,
 - b. Name and function of each room,
 - c. Location of each hand washing sink,
 - d. Location of each toilet room,
 - e. Means of egress,
 - f. Location of each video camera,
 - g. Location of each panic button, and
 - h. Location of natural and artificial lighting sources;
 - 7. If applicable, a site plan drawn to scale of the dispensary's cultivation site showing streets, property lines, buildings, parking areas, outdoor areas if applicable, fences, security features, fire hydrants if applicable, and access to water mains; and
 - 8. If applicable, a floor plan drawn to scale of each building at the dispensary's cultivation site showing the:
 - a. Layout and dimensions of each room,
 - b. Name and function of each room,
 - c. Location of each hand washing sink,
 - d. Location of each toilet room,
 - e. Means of egress,
 - f. Location of each video camera,
 - g. Location of each panic button, and
 - h. Location of natural and artificial lighting sources.

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- B. A dispensary's cultivation site may be located anywhere in the state where a cultivation site is allowed by the local jurisdiction.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2).

R9-17-306. Changes to a Dispensary Registration Certificate

- A. A dispensary may not transfer or assign the dispensary registration certificate.
- B. A dispensary may change the location of the:
1. Dispensary:
 - a. Within the first three years after the Department issues the dispensary's registration certificate, to another location in the CHAA where the dispensary is located; or
 - b. After the first three years after the Department issues a dispensary registration certificate to the dispensary, to another location in the state; or
 2. Dispensary's cultivation site to another location in the state.
- C. A dispensary or the dispensary's cultivation site shall not cultivate, manufacture, distribute, dispense, or sell medical marijuana at a new location until the dispensary submits an application for a change in a dispensary location or a change or addition of a cultivation site in R9-17-307 and the Department issues an amended dispensary registration certificate or an approval for the dispensary's cultivation site's new location to the dispensary.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2).

R9-17-307. Applying to Change a Dispensary's Location or Change or Add a Dispensary's Cultivation Site

- A. To change the location of a dispensary or the dispensary's cultivation site or to add a cultivation site, the dispensary shall submit an application to the Department that includes:
1. The following information in a Department-provided format:
 - a. The legal name of the dispensary;
 - b. The registry identification number for the dispensary;
 - c. Whether the request is for:
 - i. A change of location for the dispensary,
 - ii. A change of location for the dispensary's cultivation site, or
 - iii. An addition of a cultivation site;
 - d. The current physical address of the dispensary or the dispensary's cultivation site;
 - e. The physical address of the proposed location for the dispensary or the dispensary's cultivation site;
 - f. The distance to the closest public or private school from:
 - i. The proposed location for the dispensary, or
 - ii. The proposed location for the dispensary's cultivation site;
 - g. The name of the entity applying;
 - h. If applicable, the anticipated date of the change of location;
 - i. Whether the proposed dispensary or the dispensary's proposed cultivation site is ready for an inspection by the Department;
 - j. If the proposed dispensary or the dispensary's proposed cultivation site is not ready for an inspection by the Department, the date the dispensary or the

dispensary's cultivation site will be ready for an inspection by the Department;

- k. An attestation that the information provided to the Department to apply for a change in location is true and correct; and
 1. The signature of the individual or individuals in R9-17-301(A) and the date the individual or individuals signed;
 2. A copy of documentation issued by the local jurisdiction to the dispensary authorizing occupancy of the proposed building as a dispensary or the dispensary's cultivation site such as a certificate of occupancy, a special use permit, or a conditional use permit;
 3. A sworn statement signed by the individual or individuals in R9-17-301(A) certifying that the building where the proposed dispensary or the dispensary's proposed cultivation site will be located is in compliance with local zoning restrictions;
 4. If the change in location is for the dispensary:
 - a. A site plan drawn to scale of the proposed dispensary location showing streets, property lines, buildings, parking areas, outdoor areas if applicable, fences, security features, fire hydrants if applicable, and access to water mains; and
 - b. A floor plan drawn to scale of the building where the proposed dispensary is located showing the:
 - i. Layout and dimensions of each room,
 - ii. Name and function of each room,
 - iii. Location of each hand washing sink,
 - iv. Location of each toilet room,
 - v. Means of egress,
 - vi. Location of each video camera,
 - vii. Location of each panic button, and
 - viii. Location of natural and artificial lighting sources;
 5. If the change in location is for the dispensary's cultivation site or if adding a cultivation site:
 - a. A site plan drawn to scale of the dispensary's proposed cultivation site showing streets, property lines, buildings, parking areas, outdoor areas if applicable, fences, security features, fire hydrants if applicable, and access to water mains; and
 - b. If applicable, a floor plan drawn to scale of each building used by the dispensary's proposed cultivation site showing the:
 - i. Layout and dimensions of each room,
 - ii. Name and function of each room,
 - iii. Location of each hand washing sink,
 - iv. Location of each toilet room,
 - v. Means of egress,
 - vi. Location of each video camera,
 - vii. Location of each panic button, and
 - viii. Location of natural and artificial lighting sources; and
 6. The applicable fee in R9-17-102 for applying for a change in location or adding a cultivation site.
- B. If the information and documents submitted by the dispensary comply with A.R.S. Title 36, Chapter 28.1 and this Chapter, the Department shall issue an amended dispensary registration certificate that includes the new address of the new location and retains the expiration date of the previously issued dispensary registration certificate.
- C. An application for a change in location of a dispensary or a dispensary's cultivation site or the addition of a cultivation site may not be combined with an application for renewing a dispensary registration certificate. The Department shall process

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each application separately according to the applicable time-frame established in R9-17-107.

- D. A dispensary shall submit written notification to the Department when the dispensary no longer uses a previously approved cultivation site.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2).

R9-17-308. Renewing a Dispensary Registration Certificate

- A. An entity with a dispensary registration certificate that has not submitted an application for approval to operate a dispensary to the Department at least 60 calendar days before the expiration date of the dispensary registration certificate or has not obtained an approval to operate a dispensary issued by the Department is prohibited from renewing the dispensary registration certificate.
- B. To renew a dispensary registration certificate, a dispensary that has an approval to operate a dispensary issued by the Department, shall submit to the Department, at least 30 calendar days before the expiration date of the dispensary's current dispensary registration certificate, the following:
1. An application in a Department-provided format that includes:
 - a. The legal name of the dispensary;
 - b. The registry identification number for the dispensary;
 - c. The physical address of the dispensary;
 - d. The name of the entity applying;
 - e. The name of the individual designated to submit dispensary agent registry identification card applications on behalf of the dispensary;
 - f. The name and license number of the dispensary's medical director;
 - g. The dispensary's hours of operation during which the dispensary is available to dispense medical marijuana to qualifying patients and designated caregivers;
 - h. The name, address, date of birth, and registry identification number of each:
 - i. Principal officer,
 - ii. Board member, and
 - iii. Dispensary agent;
 - i. For each principal officer or board member, whether the principal officer or board member:
 - i. Has served as a principal officer or board member for a dispensary that had the dispensary registration certificate revoked,
 - ii. Is a physician currently providing written certifications for qualifying patients,
 - iii. Is a law enforcement officer, or
 - iv. Is employed by or a contractor of the Department;
 - j. The dispensary's Transaction Privilege Tax Number issued by the Arizona Department of Revenue;
 - k. Whether the dispensary agrees to allow the Department to submit supplemental requests for information;
 - l. An attestation that the information provided to the Department to renew the dispensary registration certificate is true and correct; and
 - m. The signature of the individual or individuals in R9-17-301(A) and the date the individual or individuals signed;
 2. If the application is for renewing a dispensary registration certificate that was initially issued within the previous 12

months, a copy of the dispensary's approval to operate a dispensary issued by the Department;

3. A copy of an annual financial statement for the previous two years, or for the portion of the previous two years the dispensary was operational, prepared according to generally accepted accounting principles;
4. A report of an audit by an independent certified public accountant of the annual financial statement required in subsection (B)(3); and
5. The applicable fee in R9-17-102 for applying to renew a dispensary registration certificate.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by emergency rulemaking at 18 A.A.R. 1010, effective April 11, 2012 for 180 days (Supp. 12-2). Emergency expired (Supp. 12-4). Amended by final rulemaking at 18 A.A.R. 3354, with an immediate effective date of December 5, 2012 (Supp. 12-4). Amended by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3).

R9-17-309. Inspections

- A. Submission of an application for a dispensary registration certificate constitutes permission for entry to and inspection of the dispensary and, if applicable, the dispensary's cultivation site.
- B. Except as provided in subsection (D), an onsite inspection of a dispensary or the dispensary's cultivation site shall occur at a date and time agreed to by the dispensary and the Department that is no later than five working days after the date the Department submits a written request to the dispensary to schedule the certification or compliance inspection, unless the Department agrees to a later date and time.
- C. The Department shall not accept allegations of a dispensary's noncompliance with A.R.S. Title 36, Chapter 28.1 or this Chapter from an anonymous source.
- D. If the Department receives an allegation of a dispensary's or a dispensary's cultivation site's noncompliance with A.R.S. Title 36, Chapter 28.1 or this Chapter, the Department may conduct an unannounced inspection of the dispensary or the dispensary's cultivation site.
- E. If the Department identifies a violation of A.R.S. Title 36, Chapter 28.1 or this Chapter during an inspection of a dispensary or the dispensary's cultivation site:
 1. The Department shall provide the dispensary with a written notice that includes the specific rule or statute that was violated; and
 2. The dispensary shall notify the Department in writing, with a postmark date within 20 working days after the date of the notice of violations, identifying the corrective actions taken and the date of the correction.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by final rulemaking at 18 A.A.R. 3354, with an immediate effective date of December 5, 2012 (Supp. 12-4).

R9-17-310. Administration

- A. A dispensary shall:
 1. Ensure that the dispensary is operating and available to dispense medical marijuana to qualifying patients and designated caregivers:
 - a. At least 30 hours weekly between the hours of 7:00 a.m. and 10:00 p.m.; and
 - b. For a dispensary with a dispensary registration certificate issued on or after April 1, 2020, within 18

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- months after receiving the dispensary registration certificate;
2. Develop, document, and implement policies and procedures regarding:
 - a. Job descriptions and employment contracts, including:
 - i. Personnel duties, authority, responsibilities, and qualifications;
 - ii. Personnel supervision;
 - iii. Training in and adherence to confidentiality requirements;
 - iv. Periodic performance evaluations; and
 - v. Disciplinary actions;
 - b. Business records, such as manual or computerized records of assets and liabilities, monetary transactions, journals, ledgers, and supporting documents, including agreements, checks, invoices, and vouchers;
 - c. Inventory control, including:
 - i. Tracking;
 - ii. Packaging;
 - iii. Accepting marijuana from qualifying patients and designated caregivers;
 - iv. Acquiring marijuana or marijuana products from other dispensaries;
 - v. Providing marijuana or marijuana products to another dispensary; and
 - vi. Either:
 - (1) Providing samples of marijuana or marijuana products to a laboratory for testing, or
 - (2) Allowing a laboratory agent access to medical marijuana or marijuana product to collect samples;
 - d. Laboratory testing, including:
 - i. The analytes, including possible contaminants, to be tested for;
 - ii. The process for separating a batch of marijuana or of a marijuana product until laboratory testing has been completed and testing results received by the dispensary;
 - iii. The process for collecting samples of medical marijuana or a marijuana product for laboratory testing, including:
 - (1) The amount to be collected from each batch,
 - (2) The method for ensuring that a sample collected is representative of the batch,
 - (3) The packaging of the sample,
 - (4) The method for documenting chain of custody for the sample, and
 - (5) Methods to deter tampering with the sample and to determine whether tampering has occurred;
 - iv. The process for submitting a sample of medical marijuana or a marijuana product to a laboratory agent or laboratory for testing;
 - v. The process for requesting retesting of the remaining portion of a sample of medical marijuana or a marijuana product; and
 - vi. Actions to be taken on the basis of laboratory testing results;
 - e. Remediation, including:
 - i. Criteria for when a batch of medical marijuana or marijuana product can be remediated;
 - ii. The process by which each type of medical marijuana or marijuana product is remediated, including the methods for remediation and subsequent retesting; and
 - iii. Documentation of the remediation process;
 - f. Disposal of medical marijuana or a marijuana product, including:
 - i. Destroying a batch of marijuana or a marijuana product that does not meet the requirements in Table 3.1 and documenting the destruction,
 - ii. Submitting marijuana that is not usable marijuana to a local law enforcement agency and documenting the submission, or
 - iii. Otherwise disposing of marijuana or a marijuana product and documenting the method of disposal, the laboratory agent overseeing the disposal, and the date of disposal;
 - g. Qualifying patient records, including purchases, denials of sale, any delivery options, confidentiality, and retention; and
 - h. Patient education and support, including the development and distribution of materials on:
 - i. Availability of different strains of marijuana and the purported effects of the different strains;
 - ii. Information about the purported effectiveness of various methods, forms, and routes of medical marijuana administration;
 - iii. Information about laboratory testing, the analytes for which the dispensary receives testing results, the right to receive a copy of the final report of testing specified in R9-17-404.06 upon request, and how to read and understand the final report of testing;
 - iv. Methods of tracking the effects on a qualifying patient of different strains and forms of marijuana; and
 - v. Prohibition on the smoking of medical marijuana in public places;
 3. Maintain copies of the policies and procedures at the dispensary and provide copies to the Department for review upon request;
 4. Review dispensary policies and procedures at least once every 12 months from the issue date of the dispensary registration certificate and update as needed;
 5. Employ or contract with a medical director;
 6. Ensure that each dispensary agent has the dispensary agent's registry identification card in the dispensary agent's immediate possession when the dispensary agent is:
 - a. Working or providing volunteer services at the dispensary or the dispensary's cultivation site, or
 - b. Transporting marijuana for the dispensary;
 7. Ensure that a dispensary agent accompanies any individual other than another dispensary agent associated with the dispensary when the individual is present in the enclosed, locked facility where marijuana is cultivated by the dispensary;
 8. Not allow an individual who does not possess a dispensary agent registry identification card issued under the dispensary registration certificate to:
 - a. Serve as a principal officer or board member for the dispensary,
 - b. Serve as the medical director for the dispensary,
 - c. Be employed by the dispensary, or

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- d. Provide volunteer services at or on behalf of the dispensary;
- 9. Provide written notice to the Department, including the date of the event, within 10 working days after the date, when a dispensary agent no longer:
 - a. Serves as a principal officer or board member for the dispensary,
 - b. Serves as the medical director for the dispensary,
 - c. Is employed by the dispensary, or
 - d. Provides volunteer services at or on behalf of the dispensary;
- 10. Document and report any loss or theft of marijuana from the dispensary to the appropriate law enforcement agency;
- 11. Maintain copies of any documentation required in this Chapter for at least 12 months after the date on the documentation and provide copies of the documentation to the Department for review upon request;
- 12. Post the following information in a place that can be viewed by individuals entering the dispensary:
 - a. If applicable, the dispensary's approval to operate;
 - b. The dispensary's registration certificate;
 - c. The name of the dispensary's medical director and the medical director's professional license number on a sign at least 20 centimeters by 30 centimeters;
 - d. The hours of operation during which the dispensary will dispense medical marijuana to a qualifying patient or a designated caregiver; and
 - e. A sign in a Department-provided format that contains the following language:
 - i. "WARNING: There may be potential dangers to fetuses caused by smoking or ingesting marijuana while pregnant or to infants while breastfeeding," and
 - ii. "WARNING: Use of marijuana during pregnancy may result in a risk of being reported to the Department of Child Safety during pregnancy or at the birth of the child by persons who are required to report;"
- 13. Not lend any part of the dispensary's income or property without receiving adequate security and a reasonable rate of interest;
- 14. Not purchase property for more than adequate consideration in money or cash equivalent;
- 15. Not pay compensation for salaries or other compensation for personal services that is in excess of a reasonable allowance;
- 16. Not sell any part of the dispensary's property or equipment for less than adequate consideration in money or cash equivalent; and
- 17. Not engage in any other transaction that results in a substantial diversion of the dispensary's income or property.
- B.** If a dispensary cultivates marijuana, the dispensary shall cultivate the marijuana in an enclosed, locked facility.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by final rulemaking at 18 A.A.R. 3354, with an immediate effective date of December 5, 2012 (Supp. 12-4). Amended by final rulemaking at 23 A.A.R. 970, effective June 6, 2017 (Supp. 17-2). Amended by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3). Amended by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020 (Supp.

20-2).

R9-17-311. Submitting an Application for a Dispensary Agent Registry Identification Card

Except as provided in R9-17-107(F), to obtain a dispensary agent registry identification card for an individual serving as a principal officer or board member for the dispensary, employed by the dispensary, or providing volunteer services at or on behalf of the dispensary, the dispensary shall submit to the Department the following for each dispensary agent:

1. An application in a Department-provided format that includes:
 - a. The dispensary agent's first name; middle initial, if applicable; last name; and suffix, if applicable;
 - b. The dispensary agent's residence address and mailing address;
 - c. The county where the dispensary agent resides;
 - d. The dispensary agent's date of birth;
 - e. The identifying number on the applicable card or document in subsection (5)(a) through (e);
 - f. The name and registry identification number of the dispensary; and
 - g. The signature of the individual in R9-17-304(C)(1)(d) or R9-17-308(B)(1)(e), as applicable, designated to submit dispensary agent applications on the dispensary's behalf and the date the individual signed;
2. An attestation signed and dated by the dispensary agent that the dispensary agent has not been convicted of an excluded felony offense as defined in A.R.S. § 36-2801;
3. One of the following:
 - a. A statement that the dispensary agent does not currently hold a valid registry identification card, or
 - b. The assigned registry identification number for the dispensary agent for each valid registry identification card currently held by the dispensary agent;
4. A statement in a Department-provided format signed by the dispensary agent pledging not to divert marijuana to any individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
5. A copy of the dispensary agent's:
 - a. Arizona driver's license issued on or after October 1, 1996;
 - b. Arizona identification card issued on or after October 1, 1996;
 - c. Arizona registry identification card;
 - d. Photograph page in the dispensary agent's U.S. passport; or
 - e. Arizona driver's license or identification card issued before October 1, 1996 and one of the following for the dispensary agent:
 - i. Birth certificate verifying U.S. citizenship,
 - ii. U.S. Certificate of Naturalization, or
 - iii. U.S. Certificate of Citizenship;
6. A current photograph of the dispensary agent;
7. For the Department's criminal records check authorized in A.R.S. § 36-2804.05:
 - a. The dispensary agent's fingerprints on a fingerprint card that includes:
 - i. The dispensary agent's first name; middle initial, if applicable; and last name;
 - ii. The dispensary agent's signature;
 - iii. If different from the dispensary agent, the signature of the individual physically rolling the dispensary agent's fingerprints;
 - iv. The dispensary agent's address;

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- v. If applicable, the dispensary agent's surname before marriage and any names previously used by the dispensary agent;
 - vi. The dispensary agent's date of birth;
 - vii. The dispensary agent's Social Security number;
 - viii. The dispensary agent's citizenship status;
 - ix. The dispensary agent's gender;
 - x. The dispensary agent's race;
 - xi. The dispensary agent's height;
 - xii. The dispensary agent's weight;
 - xiii. The dispensary agent's hair color;
 - xiv. The dispensary agent's eye color; and
 - xv. The dispensary agent's place of birth; or
 - b. If the dispensary agent's fingerprints and information required in subsection (7)(a) were submitted to the Department within the previous six months as part of an application for a designated caregiver registry identification card or a dispensary agent registry identification card for another dispensary, the registry identification number on the registry identification card issued to the dispensary agent as a result of the application; and
8. The applicable fee in R9-17-102 for applying for a dispensary agent registry identification card.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by emergency rulemaking at 18 A.A.R. 1010, effective April 11, 2012 for 180 days (Supp. 12-2). Emergency expired (Supp. 12-4). Amended by final rulemaking at 18 A.A.R. 3354, with an immediate effective date of December 5, 2012 (Supp. 12-4).

R9-17-312. Submitting an Application to Renew a Dispensary Agent's Registry Identification Card

To renew a dispensary agent's registry identification card for an individual serving as a principal officer or board member for the dispensary, employed by the dispensary, or providing volunteer services at or on behalf of the dispensary, the dispensary shall submit to the Department, at least 30 calendar days before the expiration of the dispensary agent's registry identification card, the following:

1. An application in a Department-provided format that includes:
 - a. The dispensary agent's first name; middle initial, if applicable; last name; and suffix, if applicable;
 - b. The dispensary agent's residence address and mailing address;
 - c. The county where the dispensary agent resides;
 - d. The dispensary agent's date of birth;
 - e. The registry identification number on the dispensary agent's current registry identification card;
 - f. The name and registry identification number of the dispensary; and
 - g. The signature of the individual in R9-17-304(C)(1)(d) or R9-17-308(B)(1)(e) designated to submit dispensary agent applications on the dispensary's behalf and the date the individual signed;
2. If the dispensary agent's name in subsection (1)(a) is not the same name as on the dispensary agent's current registry identification card, one of the following with the dispensary agent's new name:
 - a. An Arizona driver's license,
 - b. An Arizona identification card, or
 - c. The photograph page in the dispensary agent's U.S. passport;

3. A statement in a Department-provided format signed by the dispensary agent pledging not to divert marijuana to any individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
4. A current photograph of the dispensary agent;
5. For the Department's criminal records check authorized in A.R.S. § 36-2804.05:
 - a. The dispensary agent's fingerprints on a fingerprint card that includes:
 - i. The dispensary agent's first name; middle initial, if applicable; and last name;
 - ii. The dispensary agent's signature;
 - iii. If different from the dispensary agent, the signature of the individual physically rolling the dispensary agent's fingerprints;
 - iv. The dispensary agent's address;
 - v. If applicable, the dispensary agent's surname before marriage and any names previously used by the dispensary agent;
 - vi. The dispensary agent's date of birth;
 - vii. The dispensary agent's Social Security number;
 - viii. The dispensary agent's citizenship status;
 - ix. The dispensary agent's gender;
 - x. The dispensary agent's race;
 - xi. The dispensary agent's height;
 - xii. The dispensary agent's weight;
 - xiii. The dispensary agent's hair color;
 - xiv. The dispensary agent's eye color; and
 - xv. The dispensary agent's place of birth; or
 - b. If the dispensary agent's fingerprints and information required in subsection (5)(a) were submitted to the Department within the previous six months as part of an application for a designated caregiver registry identification card or a dispensary agent registry identification card for another dispensary, the registry identification number on the registry identification card issued to the dispensary agent as a result of the application; and
6. The applicable fee in R9-17-102 for applying to renew a dispensary agent's registry identification card.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by emergency rulemaking at 18 A.A.R. 1010, effective April 11, 2012 for 180 days (Supp. 12-2). Emergency expired (Supp. 12-4). Amended by final rulemaking at 18 A.A.R. 3354, with an immediate effective date of December 5, 2012 (Supp. 12-4).

R9-17-313. Medical Director

- A. A dispensary shall appoint an individual who is a physician to function as a medical director.
- B. During a dispensary's hours of operation, a medical director or an individual who is a physician and is designated by the medical director to serve as medical director in the medical director's absence is:
 1. Onsite; or
 2. Able to be contacted by any means possible, such as by telephone or pager.
- C. A medical director shall:
 1. Develop and provide training to the dispensary's dispensary agents at least once every 12 months from the initial date of the dispensary's registration certificate on the following subjects:

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- a. Guidelines for providing information to qualifying patients related to risks, benefits, and side effects associated with medical marijuana;
 - b. Guidelines for providing support to qualifying patients related to the qualifying patient's self-assessment of the qualifying patient's symptoms, including a rating scale for pain, cachexia or wasting syndrome, nausea, seizures, muscle spasms, and agitation;
 - c. Recognizing signs and symptoms of substance abuse; and
 - d. Guidelines for refusing to provide medical marijuana to an individual who appears to be impaired or abusing medical marijuana; and
2. Assist in the development and implementation of review and improvement processes for patient education and support provided by the dispensary.
- D.** A medical director shall provide oversight for the development and dissemination of:
1. Educational materials for qualifying patients and designated caregivers that include:
 - a. Alternative medical options for the qualifying patient's debilitating medical condition;
 - b. Information about possible side effects of and contraindications for medical marijuana including possible impairment with use and operation of a motor vehicle or heavy machinery, when caring for children, or of job performance;
 - c. Guidelines for notifying the physician who provided the written certification for medical marijuana if side effects or contraindications occur;
 - d. A description of the potential for differing strengths of medical marijuana strains and products;
 - e. Information about potential drug-to-drug interactions, including interactions with alcohol, prescription drugs, non-prescription drugs, and supplements;
 - f. Techniques for the use of medical marijuana and marijuana paraphernalia;
 - g. Information about different methods, forms, and routes of medical marijuana administration;
 - h. Signs and symptoms of substance abuse, including tolerance, dependency, and withdrawal; and
 - i. A listing of substance abuse programs and referral information;
 2. A system for a qualifying patient or the qualifying patient's designated caregiver to document the qualifying patient's pain, cachexia or wasting syndrome, nausea, seizures, muscle spasms, or agitation that includes:
 - a. A log book, maintained by the qualifying patient and or the qualifying patient's designated caregiver, in which the qualifying patient or the qualifying patient's designated caregiver may track the use and effects of specific medical marijuana strains and products;
 - b. A rating scale for pain, cachexia or wasting syndrome, nausea, seizures, muscles spasms, and agitation;
 - c. Guidelines for the qualifying patient's self-assessment or, if applicable, assessment of the qualifying patient by the qualifying patient's designated caregiver; and
 - d. Guidelines for reporting usage and symptoms to the physician providing the written certification for medical marijuana and any other treating physicians; and
3. Policies and procedures for refusing to provide medical marijuana to an individual who appears to be impaired or abusing medical marijuana.
- E.** A medical director for a dispensary shall not provide a written certification for medical marijuana for any qualifying patient.
- Historical Note**
New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2).
- R9-17-314. Dispensing Medical Marijuana**
Before a dispensary agent dispenses medical marijuana to a qualifying patient or a designated caregiver, the dispensary agent shall:
1. Verify the qualifying patient's or the designated caregiver's identity,
 2. Offer any appropriate patient education or support materials,
 3. Enter the qualifying patient's or designated caregiver's registry identification number on the qualifying patient's or designated caregiver's registry identification card into the medical marijuana electronic verification system,
 4. Verify the validity of the qualifying patient's or designated caregiver's registry identification card,
 5. Verify that the amount of medical marijuana the qualifying patient or designated caregiver is requesting would not cause the qualifying patient to exceed the limit on obtaining no more than two and one-half ounces of medical marijuana during any 14-calendar-day period, and
 6. Enter the following information into the medical marijuana electronic verification system for the qualifying patient or designated caregiver:
 - a. The amount of medical marijuana dispensed,
 - b. Whether the medical marijuana was dispensed to the qualifying patient or to the qualifying patient's designated caregiver,
 - c. The date and time the medical marijuana was dispensed,
 - d. The dispensary agent's registry identification number, and
 - e. The dispensary's registry identification number.
- Historical Note**
New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2).
- R9-17-315. Qualifying Patient Records**
- A.** A dispensary shall ensure that:
1. A qualifying patient record is established and maintained for each qualifying patient who obtains medical marijuana from the dispensary;
 2. An entry in a qualifying patient record:
 - a. Is recorded only by a dispensary agent authorized by dispensary policies and procedures to make an entry,
 - b. Is dated and signed by the dispensary agent,
 - c. Includes the dispensary agent's registry identification number, and
 - d. Is not changed to make the initial entry illegible;
 3. If an electronic signature is used to sign an entry, the dispensary agent whose signature the electronic code represents is accountable for the use of the electronic signature;
 4. A qualifying patient record is only accessed by a dispensary agent authorized by dispensary policies and procedures to access the qualifying patient record;
 5. A qualifying patient record is provided to the Department for review upon request;
 6. A qualifying patient record is protected from loss, damage, or unauthorized use; and

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7. A qualifying patient record is maintained for five years from the date of the qualifying patient's or, if applicable, the qualifying patient's designated caregiver's last request for medical marijuana from the dispensary.
- B.** If a dispensary maintains qualifying patient records electronically, the dispensary shall ensure that:
- There are safeguards to prevent unauthorized access, and
 - The date and time of an entry in a qualifying patient record is recorded electronically by an internal clock.
- C.** A dispensary shall ensure that the qualifying patient record for a qualifying patient who requests or whose designated caregiver on behalf of the qualifying patient requests medical marijuana from the dispensary contains:
- Qualifying patient information that includes:
 - The qualifying patient's name;
 - The qualifying patient's date of birth; and
 - The name of the qualifying patient's designated caregiver, if applicable;
 - Documentation of any patient education and support materials provided to the qualifying patient or the qualifying patient's designated caregiver, including a description of the materials and the date the materials were provided;
 - For each time the qualifying patient requests and does not obtain medical marijuana or, if applicable, the designated caregiver requests on behalf of the qualifying patient and does not obtain medical marijuana from the dispensary, the following:
 - The date,
 - The name and registry identification number of the individual who requested the medical marijuana, and
 - The dispensary's reason for refusing to provide the medical marijuana.
- Historical Note**
- New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2).
- R9-17-316. Inventory Control System**
- A.** A dispensary shall designate in writing a dispensary agent who has oversight of the dispensary's medical marijuana inventory control system.
- B.** A dispensary shall only acquire marijuana from:
- The dispensary's cultivation site,
 - Another dispensary or another dispensary's cultivation site,
 - A qualifying patient authorized by the Department to cultivate marijuana, or
 - A designated caregiver authorized by the Department to cultivate marijuana.
- C.** A dispensary shall establish and implement an inventory control system for the dispensary's medical marijuana that documents:
- Each day's beginning inventory, acquisitions, harvests, sales, disbursements, submissions to a laboratory agent or laboratory for testing, testing results received, disposal of unusable marijuana, and ending inventory;
 - For acquiring medical marijuana from a qualifying patient or designated caregiver:
 - A description of the medical marijuana acquired including the amount and strain,
 - The name and registry identification number of the qualifying patient or designated caregiver who provided the medical marijuana,
 - The name and registry identification number of the dispensary agent receiving the medical marijuana on behalf of the dispensary, and
 - The date of acquisition;
- 3.** For acquiring medical marijuana from another dispensary:
- A description of the medical marijuana acquired including the amount, strain, and batch number;
 - The name and registry identification number of the dispensary providing the medical marijuana;
 - The name and registry identification number of the dispensary agent providing the medical marijuana;
 - The name and registry identification number of the dispensary agent receiving the medical marijuana on behalf of the dispensary; and
 - The date of acquisition;
- 4.** For each batch of marijuana cultivated:
- The batch number;
 - Whether the batch originated from marijuana seeds or marijuana cuttings;
 - The origin and strain of the marijuana seeds or marijuana cuttings planted;
 - The number of marijuana seeds or marijuana cuttings planted;
 - The date the marijuana seeds or cuttings were planted;
 - A list of all chemical additives, including nonorganic pesticides, herbicides, and fertilizers used in the cultivation;
 - The number of plants grown to maturity;
 - Harvest information including:
 - Date of harvest,
 - Final processed usable marijuana yield weight, and
 - Name and registry identification number of the dispensary agent responsible for the harvest, and
 - The disposal of medical marijuana that is not usable marijuana including the:
 - Description of and reason for the marijuana being disposed of including, if applicable, the number of failed or other unusable plants;
 - Date of disposal;
 - Method of disposal; and
 - Name and registry identification number of the dispensary agent responsible for the disposal;
- 5.** For providing medical marijuana to another dispensary:
- The amount, strain, and batch number of medical marijuana provided;
 - The name and registry identification number of the other dispensary;
 - The name and registry identification number of the dispensary agent who received the medical marijuana on behalf of the other dispensary; and
 - The date the medical marijuana was provided;
- 6.** For receiving edible food products infused with medical marijuana from another dispensary:
- A description of the edible food products received from the dispensary including total weight of each edible food product and estimated amount and batch number of the medical marijuana infused in each edible food product;
 - Total estimated amount and batch number of medical marijuana infused in the edible food products;
 - The name and registry identification number of the:

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- i. Dispensary and the dispensary agent providing the edible food products to the receiving dispensary, and
 - ii. Dispensary agent receiving the edible food products on behalf of the receiving dispensary; and
 - d. The date the edible food products were provided to the dispensary; and
7. For submitting marijuana or marijuana products to a laboratory agent or laboratory for testing:
- a. The amount, strain, and batch number of the marijuana or marijuana products submitted;
 - b. The name and registry identification number of the laboratory;
 - c. The name and registry identification number of the laboratory agent who received the marijuana or marijuana products on behalf of the laboratory; and
 - d. The date the marijuana or marijuana products were submitted to the laboratory.
- D.** The individual designated in subsection (A) shall conduct and document an audit of the dispensary's inventory that is accounted for according to generally accepted accounting principles at least once every 30 calendar days.
- 1. If the audit identifies a reduction in the amount of medical marijuana in the dispensary's inventory not due to documented causes, the dispensary shall determine where the loss has occurred and take and document corrective action.
 - 2. If the reduction in the amount of medical marijuana in the dispensary's inventory is due to suspected criminal activity by a dispensary agent, the dispensary shall report the dispensary agent to the Department and to the local law enforcement authorities.
- E.** A dispensary shall:
- 1. Maintain the documentation required in subsections (C) and (D) at the dispensary for at least five years after the date on the document, and
 - 2. Provide the documentation required in subsections (C) and (D) to the Department for review upon request.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3).

R9-17-317. Product Labeling

- A.** A dispensary shall ensure that medical marijuana or a marijuana product provided by the dispensary to a qualifying patient or a designated caregiver is labeled with:
- 1. The dispensary's registry identification number;
 - 2. The amount, strain, and batch number of the medical marijuana or marijuana product;
 - 3. The form of the medical marijuana or marijuana product;
 - 4. As applicable, the weight of the medical marijuana or marijuana product;
 - 5. Beginning November 1, 2020, and in compliance with Table 3.1, the potency of the medical marijuana or marijuana product, based on laboratory testing results, including the percentage of:
 - a. Total tetrahydrocannabinol, reported according to R9-17-404.03(S)(2)(a);
 - b. Total cannabidiol, reported according to R9-17-404.03(S)(2)(b); and
 - c. Any other cannabinoid for which the dispensary is making a claim related to the effect of the cannabinoid on the human body;

- 6. The following statement: "ARIZONA DEPARTMENT OF HEALTH SERVICES' WARNING: Marijuana use can be addictive and can impair an individual's ability to drive a motor vehicle or operate heavy machinery. Marijuana smoke contains carcinogens and can lead to an increased risk for cancer, tachycardia, hypertension, heart attack, and lung infection. KEEP OUT OF REACH OF CHILDREN";
 - 7. If not cultivated by the dispensary, whether the medical marijuana was obtained from a qualifying patient, a designated caregiver, or another dispensary;
 - 8. If not infused or prepared for sale by the dispensary, whether the marijuana product was obtained from another dispensary;
 - 9. For a marijuana product, the ingredients in order of abundance;
 - 10. The date of manufacture, harvest, or sale; and
 - 11. The registry identification number of the qualifying patient.
- B.** If a dispensary provides medical marijuana cultivated, or a marijuana product infused or prepared for sale, by the dispensary to another dispensary, the dispensary shall ensure that:
- 1. The medical marijuana or marijuana product is labeled with:
 - a. The dispensary's registry identification number;
 - b. The amount, strain, and batch number of the medical marijuana or marijuana product; and
 - c. The date of harvest or sale; and
 - 2. A copy of laboratory testing results for the medical marijuana or marijuana product is provided to the receiving dispensary.
- C.** Until November 1, 2020, a dispensary shall ensure that medical marijuana or a marijuana product provided by the dispensary to a qualifying patient or designated caregiver either:
- 1. Is labeled with a list of all chemical additives, including nonorganic pesticides, herbicides, and fertilizers, used in the cultivation and production of the medical marijuana; or
 - 2. Complies with requirements in R9-17-317.01.
- D.** Until November 1, 2020, if a dispensary provides medical marijuana cultivated by the dispensary to another dispensary, the dispensary shall ensure that the medical marijuana is labeled with a list of all chemical additives, including nonorganic pesticides, herbicides, and fertilizers, used in the cultivation of the medical marijuana.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020; amended by exempt rulemaking at 26 A.A.R. 968, effective April 20, 2020 (Supp. 20-2).

R9-17-317.01. Analysis of Medical Marijuana or a Marijuana Product

- A.** Beginning on November 1, 2020, before offering a batch of medical marijuana or of a marijuana product for sale or dispensing to a qualifying patient or designated caregiver, a dispensary shall ensure that each batch of medical marijuana or marijuana product is tested in compliance with requirements in R9-17-404.03, R9-17-404.04, and Table 3.1.
- B.** A dispensary shall ensure that:
- 1. Until laboratory testing has been completed and testing results received by the dispensary that comply with requirements in R9-17-404.03, R9-17-404.04, and Table 3.1, a batch of marijuana or of a marijuana product is

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- stored in a location away from medical marijuana and marijuana products offered for dispensing;
2. Only one sample of each batch of medical marijuana or marijuana product is collected according to ANSI/ASQ Standard Z1.4 (2018), General Inspection Level II, incorporated by reference, including no future editions, and available at <https://asq.org/quality-resources/z14-z19>, including:
 - a. Use, as applicable, of one of the following sampling methods:
 - i. Top, middle, and bottom sampling using a sample thief, a device consisting of two nested tubes with one or more aligned slots through which a sample may be collected and then sealed into the inner tube by rotating the outer tube;
 - ii. Star pattern sampling from the top, middle, and bottom of each storage container;
 - iii. Collecting discrete incremental units of a batch, such as every tenth unit or every twentieth drop; or
 - iv. Quartering until the sample reaches the size specified in subsection (B)(3); and
 - b. For sampling methods specified in subsections (B)(2)(a)(i) through (iii), quartering the volume of the aggregated portions collected to obtain the sample size specified in subsection (B)(3);
 3. The minimum size of the sample provided to a laboratory for testing is 16 grams;
 4. Each sample in subsection (B)(3) is packaged in a container made of the same material that would be used for dispensing;
 5. Each packaged sample is labeled with the:
 - a. The dispensary's registry identification number;
 - b. The amount, strain, and batch number of the medical marijuana or marijuana product;
 - c. The storage temperature for the medical marijuana or marijuana product; and
 - d. The date of sampling;
 6. A packaged sample in subsection (B)(4) is submitted to a laboratory that:
 - a. Has a laboratory registration certificate issued by the Department, and
 - b. Is approved by the Department to test for the analyte for which testing is being requested;
 7. Except as specified in subsections (C)(1) or (3)(b), as applicable, the samples in subsection (B)(4) are tested for each analyte specified in Table 3.1;
 8. Only batches of marijuana or marijuana products for which laboratory testing results in subsection (B)(7) are in compliance with the requirements in R9-17-404.03, R9-17-404.04, and Table 3.1 are offered for sale or dispensing; and
 9. Except as provided in subsection (C), any batch of marijuana or marijuana product that does not comply with the requirements in R9-17-404.03, R9-17-404.04, and Table 3.1 is remediated, if applicable, or destroyed according to policies and procedures.
- C. If a dispensary receives a final report of testing, specified in R9-17-404.06(B)(3), from a laboratory that indicates that a batch of marijuana or marijuana product does not comply with the requirements in R9-17-404.03, R9-17-404.04, and Table 3.1, the dispensary:
1. Within seven days after receiving the final report of testing, may request retesting by a second, independent laboratory of the remaining portion of the sample in subsection (B)(4) for all analytes that do not comply with the requirements in R9-17-404.03, R9-17-404.04, and Table 3.1;
 2. If the final report of testing from the second laboratory indicates that any analyte tested for according to subsection (C)(1) does not comply with the requirements in R9-17-404.03, R9-17-404.04, and Table 3.1, shall remediate, if applicable, or destroy the batch of marijuana or marijuana product according to policies and procedures;
 3. If the final report of testing from the second laboratory indicates that all analytes tested for according to subsection (C)(1) comply with the requirements in R9-17-404.03, R9-17-404.04, and Table 3.1:
 - a. Shall ensure that the batch of medical marijuana or marijuana product is not offered for sale or dispensing; and
 - b. May request retesting by a third, independent laboratory of the remaining portion of the sample in subsection (B)(4) for the analytes that do not comply with the requirements in R9-17-404.03, R9-17-404.04, and Table 3.1; and
 4. If the dispensary requested retesting of the remaining portion of the sample in subsection (B)(4) for an analyte by a third, independent laboratory according to subsection (C)(3)(b):
 - a. If the final report of testing from the third laboratory indicates that the analyte tested for according to subsection (C)(3) complies with the requirements in R9-17-404.03, R9-17-404.04, and Table 3.1, may offer the batch of medical marijuana or marijuana product for sale or dispensing; and
 - b. If the final report of testing from the third laboratory indicates that an analyte tested for according to subsection (C)(3) does not comply with the requirements in R9-17-404.03, R9-17-404.04, and Table 3.1, shall remediate, if applicable, or destroy the batch of medical marijuana or marijuana product according to policies and procedures.
- D. A dispensary shall ensure that remediation of a batch of marijuana or of a marijuana product that has undergone laboratory testing and does not comply with the requirements in R9-17-404.03, R9-17-404.04, and Table 3.1:
1. Is performed according to policies and procedures,
 2. Uses a method that is appropriate to address an analyte not in compliance with Table 3.1, and
 3. Does not introduce or produce a substance in a concentration that is known to be harmful to humans.
- E. If a batch of medical marijuana or a marijuana product is remediated, a dispensary shall submit samples from the remediated batch for laboratory testing according to subsection (B).
- F. A dispensary shall provide to the Department upon request a sample of the dispensary's inventory of medical marijuana or a marijuana product of sufficient quantity to enable the Department to conduct an analysis of the medical marijuana or marijuana product.

Historical Note

New Section made by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020 (Supp. 20-2).

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Table 3.1. Analytes

Key:

CAS Number = Chemical Abstract Services Registry number

CFU = Colony-forming unit, a method to estimate the number of viable bacteria or fungal cells in a sample

A. Microbial Contaminants			
Analyte	Maximum Allowable Contaminants		Required Action
<i>Escherichia coli</i>	100 CFU/g		Remediate and retest, or Destroy
<i>Salmonella</i> spp.	Detectable in 1 gram		Destroy
<i>Aspergillus flavus</i> <i>Aspergillus fumigatus</i> <i>Aspergillus niger</i> <i>Aspergillus terreus</i>	Inhalable: Detectable in 1 gram		Remediate and retest, Remediate and use for preparing an extract or a concentrate, or Destroy
Mycotoxins: Aflatoxin B1, B2, G1, and G2 Ochratoxin A	Marijuana product prepared from an extract or concentrate of medical marijuana: 20 µg/kg (ppb) of total aflatoxins 20 µg/kg (ppb) of ochratoxin		Destroy
B. Heavy Metals			
Analyte	Maximum Allowable Contaminants		Required Action
Arsenic	0.4 ppm		Remediate and retest, or Destroy
Cadmium	0.4 ppm		
Lead	1.0 ppm		
Mercury	1.2 ppm		
C. Residual Solvents			
Analyte	CAS Number	Maximum Allowable Concentration	Required Action
Acetone	67-64-1	1,000 ppm	Remediate and retest, or Destroy
Acetonitrile	75-05-8	410 ppm	
Benzene	71-43-2	2 ppm	
Butanes (measured as the cumulative residue of n-butane and iso-butane)	106-97-8 and 75-28-5, respectively	5,000 ppm	
Chloroform	67-66-3	60 ppm	
Dichloromethane	75-09-2	600 ppm	
Ethanol	64-17-5	5,000 ppm	
Ethyl Acetate	141-78-6	5,000 ppm	
Ethyl Ether	60-29-7	5,000 ppm	
Heptane	142-82-5	5,000 ppm	
Hexanes (measured as the cumulative residue of n-hexane, 2-methylpentane, 3-methylpentane, 2,2-dimethylbutane, and 2,3-dimethylbutane)	110-54-3, 107-83-5, 96-14-0, 75-83-2, and 79-29-8, respectively	290 ppm	
Isopropyl Acetate	108-21-4	5,000 ppm	
Methanol	67-56-1	3,000 ppm	
Pentanes (measured as the cumulative residue of n-pentane, iso-pentane, and neo-pentane)	109-66-0, 78-78-4, and 463-82-1, respectively	5,000 ppm	
2-Propanol (IPA)	67-63-0	5,000 ppm	
Propane	74-98-6	5,000 ppm	
Toluene	108-88-3	890 ppm	
Xylenes (measured as the cumulative residue of 1,2-dimethylbenzene, 1,3-dimethylbenzene, and 1,4-dimethylbenzene, and the non-xylene, ethyl benzene)	1330-20-7 (95-47-6, 108-38-3, and 106-42-3, respectively, and 100-41-4)	2,170 ppm	

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D. Pesticides, Fungicides, Herbicides, Growth Regulators			
Analyte	CAS Number	Maximum Allowable Concentration	Required Action
Abamectin	71751-41-2	0.5 ppm	Remediate and retest, or Destroy
Acephate	30560-19-1	0.4 ppm	
Acequinocyl	57960-19-7	2.0 ppm	
Acetamiprid	135410-20-7	0.2 ppm	
Aldicarb	116-06-3	0.4 ppm	
Azoxystrobin	131860-33-8	0.2 ppm	
Bifenazate	149877-41-8	0.2 ppm	
Bifenthrin	82657-04-3	0.2 ppm	
Boscalid	188425-85-6	0.4 ppm	
Carbaryl	63-25-2	0.2 ppm	
Carbofuran	1563-66-2	0.2 ppm	
Chlorantraniliprole	500008-45-7	0.2 ppm	
Chlorfenapyr	122453-73-0	1.0 ppm	
Chlorpyrifos	2921-88-2	0.2 ppm	
Clofentezine	74115-24-5	0.2 ppm	
Cyfluthrin	68359-37-5	1.0 ppm	
Cypermethrin	52315-07-8	1.0 ppm	
Daminozide	1596-84-5	1.0 ppm	
DDVP (Dichlorvos)	62-73-7	0.1 ppm	
Diazinon	333-41-5	0.2 ppm	
Dimethoate	60-51-5	0.2 ppm	
Ethoprophos	13194-48-4	0.2 ppm	
Etofenprox	80844-07-1	0.4 ppm	
Etoxazole	153233-91-1	0.2 ppm	
Fenoxycarb	72490-01-8	0.2 ppm	
Fenpyroximate	134098-61-6	0.4 ppm	
Fipronil	120068-37-3	0.4 ppm	
Flonicamid	158062-67-0	1.0 ppm	
Fludioxonil	131341-86-1	0.4 ppm	
Hexythiazox	78587-05-0	1.0 ppm	
Imazalil	35554-44-0	0.2 ppm	
Imidacloprid	138261-41-3	0.4 ppm	
Kresoxim-methyl	143390-89-0	0.4 ppm	
Malathion	121-75-5	0.2 ppm	
Metalaxyl	57837-19-1	0.2 ppm	
Methiocarb	2032-65-7	0.2 ppm	
Methomyl	16752-77-5	0.4 ppm	
Methyl parathion	298-00-0	0.2 ppm	
MGK-264	113-48-4	0.2 ppm	
Myclobutanil	88671-89-0	0.2 ppm	
Naled	300-76-5	0.5 ppm	
Oxamyl	23135-22-0	1.0 ppm	
Paclobutrazol	76738-62-0	0.4 ppm	

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Permethrins (measured as the cumulative residue of cis- and trans- isomers)	52645-53-1 (54774-45-7 and 51877-74-8)	0.2 ppm
Phosmet	732-11-6	0.2 ppm
Piperonyl_butoxide	51-03-6	2.0 ppm
Prallethrin	23031-36-9	0.2 ppm
Propiconazole	60207-90-1	0.4 ppm
Propoxur	114-26-1	0.2 ppm
Pyrethrins (measured as the cumulative residue of pyrethrin 1, cinerin 1 and jasmolin 1)	8003-34-7 (121-21-1, 25402-06-6, and 4466-14-2)	1.0 ppm
Pyridaben	96489-71-3	0.2 ppm
Spinosad	168316-95-8	0.2 ppm
Spiromesifen	283594-90-1	0.2 ppm
Spirotetramat	203313-25-1	0.2 ppm
Spiroxamine	118134-30-8	0.4 ppm
Tebuconazole	107534-96-3	0.4 ppm
Thiacloprid	111988-49-9	0.2 ppm
Thiamethoxam	153719-23-4	0.2 ppm
Trifloxystrobin	141517-21-7	0.2 ppm

E. Potency		
Analyte	Labelling	Required Action
Tetrahydrocannabinolic acid (THC-A)	Label claim is not within +/- 20% of tested value	Revise label as necessary
Delta-9-tetrahydrocannabinol (Δ9-THC)		
Cannabidiolic acid (CBD-A)		
Cannabidiol (CBD)		

Historical Note

New Table 3.1 made by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020 (Supp. 20-2).

R9-17-318. Security

- A. Except as provided in R9-17-310(A)(7), a dispensary shall ensure that access to the enclosed, locked facility where marijuana is cultivated is limited to the dispensary’s principal officers, board members, and authorized dispensary agents.
- B. A dispensary agent may transport marijuana, marijuana plants, and marijuana paraphernalia between the dispensary and:
 - 1. The dispensary’s cultivation site,
 - 2. A qualifying patient,
 - 3. Another dispensary, and
 - 4. A laboratory agent or laboratory for testing.
- C. Before transportation, a dispensary agent shall:
 - 1. Complete a trip plan that includes:
 - a. The name of the dispensary agent in charge of transporting the marijuana;
 - b. The date and start time of the trip;
 - c. A description of the marijuana, marijuana plants, or marijuana paraphernalia being transported; and
 - d. The anticipated route of transportation; and
 - 2. Provide a copy of the trip plan in subsection (C)(1) to the dispensary.
- D. During transportation, a dispensary agent shall:
 - 1. Carry a copy of the trip plan in subsection (C)(1) with the dispensary agent for the duration of the trip;
 - 2. Use a vehicle without any medical marijuana identification;
 - 3. Have a means of communication with the dispensary; and
- 4. Ensure that the marijuana, marijuana plants, or marijuana paraphernalia are not visible.
- E. After transportation, a dispensary agent shall enter the end time of the trip and any changes to the trip plan on the trip plan required in subsection (C)(1).
- F. A dispensary shall:
 - 1. Maintain the documents required in subsection (C)(2) and (E), and
 - 2. Provide a copy of the documents required in subsection (C)(2) and (E) to the Department for review upon request.
- G. To prevent unauthorized access to medical marijuana at the dispensary and, if applicable, the dispensary’s cultivation site, the dispensary shall have the following:
 - 1. Security equipment to deter and prevent unauthorized entrance into limited access areas that include:
 - a. Devices or a series of devices to detect unauthorized intrusion, which may include a signal system interconnected with a radio frequency method, such as cellular, private radio signals, or other mechanical or electronic device;
 - b. Exterior lighting to facilitate surveillance;
 - c. Electronic monitoring including:
 - i. At least one 19-inch or greater call-up monitor,
 - ii. A video printer capable of immediately producing a clear still photo from any video camera image,
 - iii. Video cameras:
 - (1) Providing coverage of all entrances to and

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- exits from limited access areas and all entrances to and exits from the building, capable of identifying any activity occurring in or adjacent to the building; and
- (2) Having a recording resolution of at least 704 x 480 or the equivalent;
 - iv. A video camera at each point of sale location allowing for the identification of any qualifying patient or designated caregiver purchasing medical marijuana,
 - v. A video camera in each grow room capable of identifying any activity occurring within the grow room in low light conditions,
 - vi. Storage of video recordings from the video cameras for at least 30 calendar days,
 - vii. A failure notification system that provides an audible and visual notification of any failure in the electronic monitoring system, and
 - viii. Sufficient battery backup for video cameras and recording equipment to support at least five minutes of recording in the event of a power outage; and
- d. Panic buttons in the interior of each building; and
2. Policies and procedures:
 - a. That restrict access to the areas of the dispensary that contain marijuana and if applicable, the dispensary's cultivation site to authorized individuals only;
 - b. That provide for the identification of authorized individuals;
 - c. That prevent loitering;
 - d. For conducting electronic monitoring; and
 - e. For the use of a panic button.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3).

R9-17-319. Edible Food Products

- A. A dispensary that prepares, sells, or dispenses marijuana-infused edible food products shall:
 1. Before preparing, selling, or dispensing marijuana-infused edible food product obtain written authorization from the Department to prepare, sell, or dispense marijuana-infused edible food products;
 2. If the dispensary prepares the marijuana-infused edible food products, ensure that the marijuana-infused edible food products are prepared according to the applicable requirements in 9 A.A.C. 8, Article 1;
 3. If the marijuana-infused edible food products are not prepared at the dispensary, obtain and maintain at the dispensary a copy of the current written authorization to prepare marijuana-infused edible food products from the dispensary that prepares the marijuana-infused edible products; and
 4. If a dispensary sells or dispenses marijuana-infused edible food products, ensure that the marijuana-infused edible food products are sold or dispensed according to applicable requirements in 9 A.A.C. 8, Article 1.
- B. A dispensary is responsible for the content and quality of any edible food product sold or dispensed by the dispensary.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2).

R9-17-320. Cleaning and Sanitation

- A. A dispensary shall ensure that any building or equipment used by a dispensary for the cultivation, harvest, preparation, packaging, storage, infusion, or sale of medical marijuana is maintained in a clean and sanitary condition.
 1. Medical marijuana in the process of production, preparation, manufacture, packing, storage, sale, distribution, or transportation is protected from flies, dust, dirt, and all other contamination.
 2. Refuse or waste products incident to the manufacture, preparation, packing, selling, distributing, or transportation of medical marijuana are removed from the building used as a dispensary and, if applicable, a building at the dispensary's cultivation site at least once every 24 hours or more often as necessary to maintain a clean condition.
 3. All trucks, trays, buckets, other receptacles, platforms, racks, tables, shelves, knives, saws, cleavers, other utensils, or the machinery used in moving, handling, cutting, chopping, mixing, canning, packaging, or other processes are cleaned daily.
 4. All stored edible food products are securely covered.
- B. A dispensary shall ensure that a dispensary agent at the dispensary or the dispensary's cultivation site:
 1. Cleans the dispensary agent's hands and exposed portions of the dispensary agent's arms in a hand washing sink:
 - a. Before preparing medical marijuana including working with food, equipment, and utensils;
 - b. During preparation, as often as necessary to remove soil and contamination and to prevent cross-contamination when changing tasks;
 - c. After handling soiled equipment or utensils;
 - d. After touching bare human body parts other than the dispensary agent's clean hands and exposed portions of arms; and
 - e. After using the toilet room;
 2. If working directly with the preparation of medical marijuana or the infusion of marijuana into non-edible products:
 - a. Keeps the dispensary agent's fingernails trimmed, filed, and maintained so that the edges and surfaces are cleanable;
 - b. Unless wearing intact gloves in good repair, does not have fingernail polish or artificial fingernails on the dispensary agent's fingernails; and
 - c. Wears protective apparel such as coats, aprons, gowns, or gloves to prevent contamination;
 3. Wears clean clothing appropriate to assigned tasks;
 4. Reports to the medical director any health condition experienced by the dispensary agent that may adversely affect the safety or quality of any medical marijuana with which the dispensary agent may come into contact; and
 5. If the medical director determines that a dispensary agent has a health condition that may adversely affect the safety or quality of the medical marijuana, is prohibited from direct contact with any medical marijuana or equipment or materials for processing medical marijuana until the medical director determines that the dispensary agent's health condition will not adversely affect the medical marijuana.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2).

R9-17-321. Physical Plant

- A. A dispensary or a dispensary's cultivation site shall be located at least 500 feet from a private school or a public school that

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- existed before the date the dispensary submitted the initial dispensary registration certificate application.
- B.** A dispensary shall provide onsite parking or parking adjacent to the building used as the dispensary.
- C.** A building used as a dispensary or the location used as a dispensary's cultivation site shall have:
1. At least one toilet room;
 2. Each toilet room shall contain:
 - a. A flushable toilet;
 - b. Mounted toilet tissue;
 - c. A sink with running water;
 - d. Soap contained in a dispenser; and
 - e. Disposable, single-use paper towels in a mounted dispenser or a mechanical air hand dryer;
 3. At least one hand washing sink not located in a toilet room;
 4. Designated storage areas for medical marijuana or materials used in direct contact with medical marijuana separate from storage areas for toxic or flammable materials; and
 5. If preparation or packaging of medical marijuana is done in the building, a designated area for the preparation or packaging that:
 - a. Includes work space that can be sanitized, and
 - b. Is only used for the preparation or packaging of medical marijuana.
- D.** For each commercial device used at a dispensary or the dispensary's cultivation site, the dispensary shall:
1. Ensure that the commercial device is licensed or certified pursuant to A.R.S. § 41-2091,
 2. Maintain documentation of the commercial device's license or certification, and
 3. Provide a copy of the commercial device's license or certification to the Department for review upon request.
- Historical Note**
- New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2).
- R9-17-322. Denial or Revocation of a Dispensary Registration Certificate**
- A.** The Department shall deny an application for a dispensary registration certificate or a renewal if:
1. For an application for a dispensary registration certificate, the physical address of the building or, if applicable, the physical address of the dispensary's cultivation site is within 500 feet of a private school or a public school that existed before the date the dispensary submitted the initial dispensary registration certificate application;
 2. A principal officer or board member:
 - a. Has been convicted of an excluded felony offense;
 - b. Has served as a principal officer or board member for a dispensary that:
 - i. Had the dispensary registration certificate revoked, or
 - ii. Did not obtain an approval to operate the dispensary within the first year after the dispensary registration certificate was issued;
 - c. Is under 21 years of age;
 - d. Is a physician currently providing written certifications for medical marijuana for qualifying patients;
 - e. Is a law enforcement officer; or
 - f. Is an employee or contractor of the Department; or
 3. The application or the dispensary does not comply with the requirements in A.R.S. Title 36, Chapter 28.1 and this Chapter.
- B.** The Department may deny an application for a dispensary registration certificate if a principal officer or board member of the dispensary provides false or misleading information to the Department.
- C.** The Department shall revoke a dispensary's registration certificate if:
1. The dispensary:
 - a. Operates before obtaining approval to operate a dispensary from the Department;
 - b. Diverts marijuana to an entity other than another dispensary with a valid dispensary registration certificate issued by the Department, a laboratory with a valid laboratory registration certificate issued by the Department, a qualifying patient with a valid registry identification card issued by the Department, a designated caregiver with a valid registry identification card issued by the Department, or a laboratory agent with a valid registry identification card issued by the Department; or
 - c. Acquires usable marijuana or mature marijuana plants from any entity other than another dispensary with a valid dispensary registration certificate issued by the Department, a qualifying patient with a valid registry identification card, or a designated caregiver with a valid registry identification card; or
 2. A principal officer or board member has been convicted of an excluded felony offense.
- D.** The Department may revoke a dispensary registration certificate if the dispensary does not:
1. Comply with the requirements in A.R.S. Title 36, Chapter 28.1 and this Chapter; or
 2. Implement the policies and procedures or comply with the statements provided to the Department with the dispensary's application.
- E.** If the Department denies a dispensary registration certificate application, the Department shall provide notice to the applicant that includes:
1. The specific reason or reasons for the denial, and
 2. All other information required by A.R.S. § 41-1076.
- F.** If the Department revokes a dispensary registration certificate, the Department shall provide notice to the dispensary that includes:
1. The specific reason or reasons for the revocation; and
 2. The process for requesting a judicial review of the Department's decision pursuant to A.R.S. Title 12, Chapter 7, Article 6.
- Historical Note**
- New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by emergency rulemaking at 18 A.A.R. 1010, effective April 11, 2012 for 180 days (Supp. 12-2). Emergency expired (Supp. 12-4). Amended by final rulemaking at 18 A.A.R. 3354, with an immediate effective date of December 5, 2012 (Supp. 12-4). Amended by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3).
- R9-17-323. Denial or Revocation of a Dispensary Agent's Registry Identification Card**
- A.** The Department shall deny a dispensary agent's application for or renewal of the dispensary agent's registry identification card if the dispensary agent:
1. Does not meet the definition "nonprofit medical marijuana dispensary agent" in A.R.S. § 36-2801; or
 2. Previously had a registry identification card revoked for not complying with A.R.S. Title 36, Chapter 28.1 or this Chapter.

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- B.** The Department may deny a dispensary agent's application for or renewal of the dispensary agent's registry identification card if the dispensary agent provides false or misleading information to the Department.
- C.** The Department shall revoke a dispensary agent's registry identification card if the dispensary agent:
1. Uses medical marijuana, if the dispensary agent does not have a qualifying patient registry identification card;
 2. Diverts medical marijuana to an entity other than another dispensary with a valid dispensary registration certificate issued by the Department, a laboratory with a valid laboratory registration certificate issued by the Department, a qualifying patient with a valid registry identification card issued by the Department, a designated caregiver with a valid registry identification card issued by the Department, or a laboratory agent with a valid registry identification card issued by the Department; or
 3. Has been convicted of an excluded felony offense.
- D.** The Department may revoke a dispensary agent's registry identification card if the dispensary agent knowingly violates A.R.S. Title 36, Chapter 28.1 or this Chapter.
- E.** If the Department denies or revokes a dispensary agent's registry identification card, the Department shall provide notice to the dispensary agent and the dispensary agent's dispensary that includes:
1. The specific reason or reasons for the denial or revocation; and
 2. The process for requesting a judicial review of the Department's decision pursuant to A.R.S. Title 12, Chapter 7, Article 6.

Historical Note

New Section made by exempt rulemaking at 17 A.A.R. 734, effective April 14, 2011 (Supp. 11-2). Amended by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3).

ARTICLE 4. LABORATORIES AND LABORATORY AGENTS**R9-17-401. Owner**

- A.** For the purposes of this Chapter the following individuals are considered owners:
1. If an individual is applying for a laboratory registration certificate, the individual;
 2. If a corporation is applying for a laboratory registration certificate, two individuals who are officers of the corporation;
 3. If a partnership is applying for a laboratory registration certificate, two of the individuals who are partners;
 4. If a limited liability company is applying for a laboratory registration certificate, a manager or, if the limited liability company does not have a manager, an individual who is a member of the limited liability company;
 5. If an association or cooperative is applying for a laboratory registration certificate, two individuals who are members of the governing board of the association or cooperative;
 6. If a joint venture is applying for a laboratory registration certificate, two of the individuals who signed the joint venture agreement; and
 7. If a business organization type other than those described in subsections (A)(2) through (6) is applying for a laboratory registration certificate, two individuals who are members of the business organization.
- B.** When a laboratory is required by this Chapter to provide information, sign documents, or ensure actions are taken, the indi-

vidual or individuals in subsection (A) shall comply with the requirement on behalf of the laboratory.

Historical Note

New Section made by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3).

R9-17-402. Applying for a Laboratory Registration Certificate

- A.** To apply for a laboratory registration certificate, an applicant shall submit to the Department the following:
1. An application in a Department-provided format that includes:
 - a. The physical address of the laboratory;
 - b. The distance to the closest private school or public school from the laboratory;
 - c. The following information for the laboratory applying:
 - i. The legal name of the laboratory,
 - ii. Type of business organization,
 - iii. Mailing address,
 - iv. Telephone number, and
 - v. E-mail address;
 - d. The name of the owner designated to submit laboratory agent registry identification card applications on behalf of the laboratory;
 - e. The name, residence address, and date of birth of each owner;
 - f. The identifying number on the applicable card or document in subsection (A)(4)(d)(i) through (v);
 - g. The name, residence address, and date of birth of the technical laboratory director designated according to R9-17-404(3);
 - h. The name, residence address, and date of birth of each laboratory agent other than an owner or the technical laboratory director, if applicable;
 - i. Whether the laboratory agrees to allow the Department to submit supplemental requests for information;
 - j. An attestation that the information provided to the Department to apply for a laboratory registration certificate is true and correct; and
 - k. The signatures of the owner of the laboratory, according to R9-17-401(A), and the technical laboratory director and the date each signed;
 2. Policies and procedures that comply with the requirements in this Chapter that contain:
 - a. A quality assurance program and standards;
 - b. Inventory control;
 - c. A chain of custody and sample requirement process;
 - d. A records retention process;
 - e. A secure method to transfer the portion of a sample remaining after testing to another laboratory at the request of a dispensary according to R9-17-317.01(C);
 - f. Security;
 - g. A process to ensure marijuana or marijuana products testing results are accurate, precise, and scientifically valid before reporting the results; and
 - h. A process for disposal of marijuana or marijuana products that are submitted to the laboratory for testing;
 3. If the applicant is one of the business organizations in R9-17-401(A)(2) through (7), a copy of the business organization's articles of incorporation, articles of organization, or partnership or joint venture documents that include:
 - a. The name of the business organization,
 - b. The type of business organization, and

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- c. The names and titles of the individuals in R9-17-401(A);
4. For each owner:
- a. An attestation signed and dated by the owner that the owner has not been convicted of an excluded felony offense as defined in A.R.S. § 36-2801;
 - b. An attestation signed and dated by the owner that the owner does not have a direct or indirect familial or financial relationship with or interest in a dispensary, related medical marijuana business entity, or management company;
 - c. An attestation signed and dated by the owner that the laboratory will not test marijuana or marijuana products for a designated caregiver who the owner has a direct or indirect familial or financial relationship with;
 - d. An attestation signed and dated by the owner pledging not to divert marijuana to any individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
 - e. A copy the owner's:
 - i. Arizona driver's license issued on or after October 1, 1996;
 - ii. Arizona identification card issued on or after October 1, 1996;
 - iii. Arizona registry identification card;
 - iv. Photograph page in the owner's U.S. passport; or
 - v. Arizona driver's license or identification card issued before October 1, 1996 and one of the following for the owner:
 - (1) Birth certificate verifying U.S. citizenship,
 - (2) U.S. Certificate of Naturalization, or
 - (3) U.S. Certificate of Citizenship; and
 - f. For the Department's criminal records check authorized in A.R.S. §§ 36-2804.01 and 36-2804.07:
 - i. The owner's fingerprints on a fingerprint card that includes:
 - (1) The owner's first name; middle initial, if applicable; and last name;
 - (2) The owner's signature;
 - (3) If different from the owner, the signature of the individual physically rolling the owner's fingerprints;
 - (4) The owner's residence address;
 - (5) If applicable, the owner's surname before marriage and any names previously used by the owner;
 - (6) The owner's date of birth;
 - (7) The owner's Social Security number;
 - (8) The owner's citizenship status;
 - (9) The owner's gender;
 - (10) The owner's race;
 - (11) The owner's height;
 - (12) The owner's weight;
 - (13) The owner's hair color;
 - (14) The owner's eye color; and
 - (15) The owner's place of birth; or
 - ii. If the fingerprints and information required in subsection (A)(4)(f)(i) were submitted to the Department as part of an application for a designated caregiver registry identification card, dispensary agent registry identification card, or laboratory agent registry identification card within the previous six months, the registry identification number on the registry identification card issued to the owner as a result of the application;
5. If zoning restrictions have been enacted, a sworn statement signed and dated by the individual or individuals in R9-17-401(A) certifying that the laboratory is in compliance with any local zoning restrictions;
6. A copy of documentation issued by the local jurisdiction to the laboratory authorizing occupancy of the building as a laboratory, such as a certificate of occupancy, a special use permit, or a conditional use permit;
7. A site plan drawn to scale of the laboratory location showing streets, property lines of the contiguous premises, buildings, parking areas, outdoor areas if applicable, fences, security features, fire hydrants if applicable, and access to water mains;
8. A building plan drawn to scale of the building where the laboratory is located showing the:
 - a. Layout and dimensions of each room;
 - b. Name and function of each room;
 - c. Fire ratings of the materials used for ceilings, walls, doors, and floors of rooms used to store flammable substances;
 - d. Location of each fire protection device;
 - e. Layout of heating, air conditioning, exhaust, and ventilation systems;
 - f. Location and layout of refrigerated rooms or freezer rooms;
 - g. Location of each sink, safety shower, other water supply, or plumbing fixture;
 - h. Location of fixed or movable equipment and instruments that require dedicated electrical, water, vacuum, gas, or other building systems;
 - i. Location of security measures or equipment to protect from diversion of marijuana or marijuana products; and
 - j. Means of egress;
9. Documentation of accreditation;
10. The laboratory's Transaction Privilege Tax Number issued by the Arizona Department of Revenue, if applicable; and
11. The applicable fee in R9-17-102 for applying for a laboratory registration certificate.
- B.** Within 72 hours after an owner receives a laboratory registration certificate pursuant to an application submitted according to subsection (A), the owner shall apply for a laboratory agent registry identification card, according to R9-17-405, for each laboratory agent, including an owner or a technical laboratory director.
- C.** A change in location of the laboratory's physical address or ownership requires a new application to be submitted according to subsection (A).
- D.** A separate laboratory registration certificate is required for each noncontiguous portion of a laboratory.

Historical Note

New Section made by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3). Amended by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020; amended by exempt rulemaking at 26 A.A.R. 968, effective April 20, 2020 (Supp. 20-2).

R9-17-402.01. Applying for Approval for Testing

To apply for approval for testing, an applicant shall submit to the Department, at least 60 calendar days before the expiration of the initial laboratory registration certificate for the laboratory, the following:

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1. An application in a Department-provided format that includes:
 - a. The name and registry identification number of the laboratory;
 - b. The physical address of the laboratory;
 - c. The name of the applicant;
 - d. The name of the technical laboratory director designated according to R9-17-404(3);
 - e. The name, address, and date of birth of or the laboratory agent registry identification card number for each laboratory agent;
 - f. For each parameter for which approval for testing is being requested:
 - i. The analyte to be tested for,
 - ii. The instruments and equipment to be used for testing, and
 - iii. The software to be used at the laboratory for instrument control and data reduction interpretation;
 - g. The laboratory's proposed hours of operation;
 - h. Whether the laboratory agrees to allow the Department to submit supplemental requests for information;
 - i. Whether the laboratory is ready for an inspection by the Department;
 - j. If the laboratory is not ready for an inspection by the Department, the date the laboratory will be ready for an inspection by the Department;
 - k. An attestation that the information provided to the Department to apply for approval to operate the laboratory is true and correct; and
 - l. The signatures of the owner of the laboratory, according to R9-17-401(A), and the technical laboratory director and the date each signed;
 2. For each parameter listed according to subsection (1)(f):
 - a. The limit of quantitation;
 - b. A copy of current accreditation;
 - c. A copy of a proficiency testing report, if applicable, or accuracy testing documentation; and
 - d. A copy of the standard operating procedure; and
 3. If different from the building plan submitted according to R9-17-402(A)(8), a building plan drawn to scale of the building where the laboratory is located showing the:
 - a. Layout and dimensions of each room;
 - b. Name and function of each room;
 - c. Fire ratings of the materials used for ceilings, walls, doors, and floors of rooms used to store flammable substances;
 - d. Location of each fire protection device;
 - e. Layout of heating, air conditioning, exhaust, and ventilation systems;
 - f. Location and layout of refrigerated rooms or freezer rooms;
 - g. Location of each sink, safety shower, other water supply, or plumbing fixture;
 - h. Location of fixed or movable equipment and instruments that require dedicated electrical, water, vacuum, gas, or other building systems;
 - i. Location of security equipment to protect from diversion of marijuana or marijuana products; and
 - j. Means of egress.
- Historical Note**
- New Section made by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020;
- amended by exempt rulemaking at 26 A.A.R. 968, effective April 20, 2020 (Supp. 20-2).
- R9-17-403. Renewing a Laboratory Registration Certificate**
- To renew a laboratory registration certificate, an applicant shall submit to the Department, at least 30 calendar days before the expiration date of the current laboratory registration certificate, but no more than 90 days before the expiration date of the current laboratory registration certificate, the following:
1. An application in a Department-provided format that includes:
 - a. The physical address of the laboratory;
 - b. The following information for the laboratory:
 - i. The legal name of the laboratory,
 - ii. The registry identification number for the laboratory,
 - iii. Type of business organization,
 - iv. Mailing address,
 - v. Telephone number, and
 - vi. E-mail address;
 - c. The name of the owner designated to submit laboratory agent registry identification card applications on behalf of the laboratory;
 - d. The name, residence address, and date of birth of each owner;
 - e. The name, residence address, and date of birth of the technical laboratory director designated according to R9-17-404(3);
 - f. The name, residence address, and date of birth of each laboratory agent, if applicable;
 - g. Whether the laboratory agrees to allow the Department to submit supplemental requests for information;
 - h. An attestation that the information provided to the Department to renew the laboratory registration certificate is true and correct; and
 - i. The signatures of the owner of the laboratory, according to R9-17-401(A), and the technical laboratory director and the date each signed;
 2. For each owner:
 - a. An attestation signed and dated by the owner that the owner has not been convicted of an excluded felony offense as defined in A.R.S. § 36-2801; and
 - b. An attestation signed and dated by the owner that the laboratory will not test medical marijuana and medical marijuana products for:
 - i. A dispensary, related medical marijuana business entity, or management company that the owner has a direct or indirect familial or financial relationship with or interest in; or
 - ii. A designated caregiver who the owner has a direct or indirect familial or financial relationship with;
 3. For each new or current parameter, documentation of current accreditation;
 4. If a change has been made to the standard operating procedure for a current parameter, a copy of the revised standard operating procedure;
 5. If a change has been made in the quality assurance plan for a current parameter required in R9-17-404.03 or R9-17-404.04, a copy of the revised quality assurance plan; and
 6. The applicable fee in R9-17-102 for applying to renew a laboratory registration certificate.

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Historical Note

New Section made by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3). Amended by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020; amended by exempt rulemaking at 26 A.A.R. 968, effective April 20, 2020 (Supp. 20-2).

R9-17-404. Administration

An owner of a laboratory with a laboratory registration certificate shall:

1. Comply with the:
 - a. Quality assurance requirements in R9-17-404.05,
 - b. Operation requirements in R9-17-404.06, and
 - c. Laboratory records and reports requirements in R9-17-404;
2. Maintain accreditation for each approved parameter;
3. Designate in writing a technical laboratory director who:
 - a. Has knowledge and experience in overseeing a laboratory as documented by:
 - i. A doctoral degree in chemistry, biochemistry, microbiology, or a similar laboratory science;
 - ii. A master's degree in chemistry, biochemistry, microbiology, or a similar laboratory science and at least two years of experience working in a laboratory and providing laboratory testing; or
 - iii. A bachelor's degree in chemistry, biochemistry, microbiology, or a similar laboratory science and at least four years of experience working in a laboratory and providing laboratory testing; and
 - b. Is responsible for:
 - i. Ensuring that all services and tests provided by the laboratory are performed in compliance with the requirements in this Article;
 - ii. Directing and supervising services and tests provided by the laboratory;
 - iii. Overseeing the work of all personnel in the laboratory;
 - iv. Providing ongoing training to laboratory agents, as applicable to the functions performed by a laboratory agent; and
 - v. Ensuring safety and hazardous substance control in the laboratory;
4. Notify the Department in writing within 20 working days after any change in the technical laboratory director, providing the name and contact information for the new technical laboratory director;
5. Develop, document, and implement policies and procedures regarding:
 - a. Job descriptions and employment contracts, including:
 - i. Personnel duties, authority, responsibilities, and qualifications;
 - ii. Personnel supervision;
 - iii. Ongoing training, applicable to the functions performed by a laboratory agent;
 - iv. Training in and adherence to confidentiality requirements;
 - v. Periodic performance evaluations, including proficiency testing or accuracy testing, as applicable, on a rotating basis among all laboratory agents performing similar functions; and
 - v. Disciplinary actions;
 - b. Business records, such as manual or computerized records of assets and liabilities, monetary transactions, journals, ledgers, and supporting documents, including agreements, checks, invoices, and vouchers;
- c. Inventory control, including:
 - i. Tracking;
 - ii. Accepting medical marijuana or marijuana products for testing;
 - iii. Testing medical marijuana and marijuana products;
 - iv. Providing the remaining sample of tested medical marijuana or a marijuana product to another laboratory at the request of a dispensary according to R9-17-317.01(C);
 - v. Retaining the residual portion of a sample accepted for testing from a dispensary for at least 14 days after sending the final report of testing required in R9-17-404.06(B)(3) to the dispensary; and
 - vi. Disposing of medical marijuana or a marijuana product and documenting:
 - (1) The method of disposal;
 - (2) Whether the medical marijuana or marijuana product was tested;
 - (3) If not tested, the reason for not testing;
 - (4) The laboratory agent overseeing the disposal; and
 - (5) The date of disposal;
- d. Standard operating procedures, including:
 - i. The review and updating of standard operating procedures;
 - ii. Requirements for a laboratory agent to review current, new, or updated standard operating procedures applicable to the functions performed by the laboratory agent; and
 - iii. Documenting the review of standard operating procedures by applicable laboratory agents;
- e. Laboratory records, including:
 - i. Maintenance and monitoring of instruments and equipment;
 - ii. Acceptance of medical marijuana and marijuana products for testing;
 - iii. The chain of custody for a sample accepted by the laboratory for testing;
 - iv. The storage of a submitted sample prior to testing to maintain the integrity of the sample and analyte;
 - v. The process for selecting a portion of a submitted sample for testing;
 - vi. Ensuring testing results are accurate, precise, and scientifically valid before reporting the results;
 - vii. Reporting of testing results;
 - viii. If applicable, transfer of the portion of a sample remaining after testing to another laboratory at the request of a dispensary according to R9-17-317.01(C), including:
 - (1) The name and registry identification number of the dispensary,
 - (2) The name and registry identification number of the dispensary agent requesting the transfer on behalf of the dispensary,
 - (3) The date of the request,
 - (4) The amount of sample being transferred,
 - (5) The name and registry identification number of the other laboratory, and
 - (6) The name and registry identification number

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- ber of the laboratory agent receiving the marijuana or marijuana products on behalf of the other laboratory;
- ix. Confidentiality; and
 - x. Retention;
 - f. A quality assurance program and standards;
 - g. A records retention process; and
 - h. Security;
6. Review and document the review of laboratory policies and procedures at least once every 12 months after the issue date of the laboratory registration certificate and update as needed;
 7. Ensure that each laboratory agent has the laboratory agent's registry identification card in the laboratory agent's immediate possession when the laboratory agent is working or providing volunteer services related to marijuana or marijuana products testing at the laboratory;
 8. Ensure that a laboratory agent accompanies any individual other than another laboratory agent associated with the laboratory when the individual is present in the area of the laboratory where marijuana or marijuana products are being tested or stored for testing;
 9. Not allow an individual who does not possess a laboratory agent registry identification card issued under the laboratory registration certificate to:
 - a. Serve as an owner for the laboratory,
 - b. Be employed by the laboratory, or
 - c. Provide volunteer services at or on behalf of the laboratory;
 10. Provide written notice to the Department, including the date of the event, within 10 working days after the date, when a laboratory agent no longer:
 - a. Serves as an owner for the laboratory,
 - b. Is employed by the laboratory, or
 - c. Provides volunteer services at or on behalf of the laboratory; and
 11. Unless otherwise specified, maintain copies of any documentation required in this Chapter for at least 12 months after the date on the documentation and provide copies of the documentation to the Department for review upon request.
- F.** If the Department determines that a laboratory is not in compliance with the requirements of A.R.S. Title 36, Chapter 28.1, or this Chapter, the Department:
1. Shall provide the owner, according to R9-17-401(A), and technical laboratory director with a written notice that includes the specific rule or statute that was violated; and
 2. May:
 - a. Take an enforcement action as described in R9-17-410; or
 - b. Require that the technical laboratory director submit to the Department, within 30 calendar days after written notice from the Department, a corrective action plan to address issues of compliance that do not directly affect the health or safety of a qualifying patient or laboratory agent that:
 - i. Describes how each identified instance of non-compliance will be corrected and reoccurrence prevented, and
 - ii. Includes a date for correcting each instance of noncompliance that is appropriate to the actions necessary to correct the instance of noncompliance.
- G.** Under A.R.S. § 41-1009(G) and (I), the Department's decision regarding whether a technical laboratory director may submit a corrective action plan on behalf of a laboratory or whether a deficiency has been corrected or has been corrected within a reasonable period of time is not an appealable agency action as defined by A.R.S. § 41-1092.

Historical Note

New Section made by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020 (Supp. 20-2).

R9-17-404.02. Proficiency Testing; Accuracy Testing

- A.** At least once in each 12-month period, and more often if requested by the Department, a technical laboratory director shall have at least one laboratory agent, selected according to policies and procedures, participate in proficiency testing provided by the Department or a proficiency testing service that:
1. Includes at least one proficiency testing sample for each parameter for which the laboratory has been approved or is requesting approval and for which proficiency testing samples are available;
 2. Demonstrates the laboratory agent's competence in testing for the parameter; and
 3. If the laboratory has been approved or has requested approval to test an analyte by different methods, may use the same proficiency testing sample for each method.
- B.** If a proficiency testing sample is not available for a specific parameter, a technical laboratory director shall have at least one laboratory agent, selected according to policies and procedures, participate in accuracy testing for the parameter.
- C.** To demonstrate competence in testing for a parameter, test results reported for the parameter shall be within acceptance limits established by the Department, according to R9-17-404.03 or R9-17-404.04, or the proficiency testing service, as applicable.
- D.** A technical laboratory director shall ensure that:
1. Each sample for proficiency testing accepted at the laboratory is analyzed at the laboratory;
 2. Each sample for accuracy testing is analyzed at the laboratory;
 3. Each sample for proficiency testing or accuracy testing is tested according to R9-17-404.03 or R9-17-404.04, using the same procedures and techniques employed for routine sample testing;

Historical Note

New Section made by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3). Amended by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020 (Supp. 20-2).

R9-17-404.01. Compliance Monitoring

- A.** Submission of an application for a laboratory registration certificate constitutes permission for:
1. The Department's entry to and inspection of the laboratory, and
 2. The Department to conduct proficiency testing according to R9-17-404.02.
- B.** The Department shall conduct:
1. An initial laboratory inspection; and
 2. A follow-up laboratory inspection, at least annually.
- C.** The Department shall comply with A.R.S. § 41-1009 in conducting a laboratory inspection or investigation.
- D.** The Department shall not accept allegations of a laboratory's noncompliance with A.R.S. Title 36, Chapter 28.1 or this Chapter from an anonymous source.
- E.** If the Department receives an allegation of a laboratory's non-compliance with A.R.S. Title 36, Chapter 28.1 or this Chapter, the Department may conduct an unannounced inspection of the laboratory.

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4. A proficiency testing service provides the results for each proficiency testing sample directly to the laboratory and the Department;
 5. If proficiency testing is provided by the Department, the laboratory submits to the Department payment for the actual costs of the materials for proficiency testing; and
 6. If proficiency testing is not provided by the Department, the laboratory selects a proficiency testing service and contracts with and pays the proficiency testing service directly for proficiency testing.
- E. The Department may submit blind proficiency testing samples to a laboratory at any time during the certification period.

Historical Note

New Section made by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020 (Supp. 20-2).

R9-17-404.03. Method Criteria and References for Chemical Analyses

- A. In addition to the definitions in A.R.S. § 36-2801 and R9-17-101, the following definitions apply in this Section unless otherwise stated:
1. "Limit of quantitation" means the lowest concentration of an analyte that may be detected and the concentration of the analyte reliably and accurately determined.
 2. "Matrix" means the specific components of a sample, other than the analyte being tested for.
 3. "Mid-level standard" means a standard that is between the highest concentration and lowest concentration of standards containing the same substances that are used as a reference when testing for the concentration of an analyte.
 4. "Response factor" means the ratio between a signal produced by an analyte relative to a signal produced by an internal standard at a specific concentration.
 5. "Retention time" means the length of time taken by an analyte to pass through a chromatography column.
 6. "Standard" means a sample of known concentration and containing specific substances that is used as a reference when testing for the concentration of an analyte.
- B. To perform laboratory testing using chemical analytical methods for any of the analytes in Table 3.1, a laboratory may use:
1. An established national or international chemical method; or
 2. A laboratory-developed method that was validated according to:
 - a. AOAC - Appendix K: Guidelines for Dietary Supplements and Botanicals, 2013, which is incorporated by reference, includes no future editions or amendments, and is available at http://www.eoma.aoc.org/app_k.pdf;
 - b. USDA - Guidelines for the Validation of Chemical Methods for the FDA FVM Program, 2nd Edition, April 2015, which is incorporated by reference, includes no future editions or amendments, and is available at <https://www.fda.gov/media/81810/download>; or
 - c. ICH - Validation of Analytical Procedures: Text and Methodology Q2(R1) 2005, which is incorporated by reference, includes no future editions or amendments, and is available at https://database.ich.org/sites/default/files/Q2_R1_Guideline.pdf or <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q2-r1-validation-analytical-procedures-text-and-methodology>.
- C. A technical laboratory director shall ensure that all instruments and equipment used for testing medical marijuana or a marijuana product by chemical analytical methods are:
1. Set up, tuned, and calibrated according to:
 - a. Manufacturer's acceptance criteria, or
 - b. Criteria validated according to subsection (B), as applicable;
 2. Monitored and maintained according to AOAC - Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals, Appendix A: Equipment, August 2018, which is incorporated by reference, includes no future editions or amendments, and is available at <https://www.aoc.org/aoac-accreditation-guidelines-for-laboratories-alacc>; and
 3. Applicable for the analytes to be tested.
- D. A technical laboratory director shall ensure that for an initial demonstration of capability:
1. Before implementing a method, at least four replicate reference samples for each analyte are:
 - a. Spiked into a clean matrix with, as applicable, an amount at or near the maximum allowable concentration for the analyte in Table 3.1 or the mid-level standard for potency testing; and
 - b. Taken through the entire sample preparation and analysis process;
 2. Whenever a significant change to instrumentation or to a standard operating procedure occurs, the laboratory demonstrates, as specified in subsection (D)(1), that acceptable precision and bias can still be obtained by the changed conditions; and
 3. Whenever a new laboratory agent who will be performing testing on medical marijuana or marijuana products is being trained, the laboratory agent demonstrates, as specified in subsection (D)(1), acceptable precision and bias.
- E. For potency testing or testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents, a technical laboratory director shall ensure that:
1. For establishing the retention time for an analyte, the retention time is determined by three injections, over the course of a 72-hour period, of a standard at or near, as applicable:
 - a. The maximum allowable concentration in Table 3.1 for the analyte; or
 - b. The mid-level standard for potency testing; and
 2. The width of the retention time window for each analyte is defined as ± 3 times the standard deviation of the mean absolute retention time that was established during the 72-hour period or 0.1 minutes, whichever is greater.
- F. A technical laboratory director shall ensure that:
1. The laboratory complies with the following requirements related to calibration and standards:
 - a. Except as specified in subsection (F)(1)(c), a minimum of:
 - i. Five standards are used for an average response factor or for a linear model,
 - ii. Six standards are used for a quadratic model, and
 - iii. Seven standards are used for a cubic model;
 - b. An X-value of zero is not included as a calibration point;
 - c. A calibration curve for heavy metal testing includes a minimum of three standards and a calibration blank;
 - d. One standard is at or near the limit of quantitation;

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- e. Except as specified in subsection (F)(1)(f) and as applicable, one standard for each analyte is at or near the:
 - i. Maximum allowable concentration in Table 3.1 for the analyte, or
 - ii. Mid-level standard for potency testing; and
- f. For testing for residual solvents, either:
 - i. One standard for each analyte is at or near the maximum allowable concentration in Table 3.1 for the analyte; or
 - ii. A standard is created containing a concentration of specific analytes that is a dilution factor from the maximum allowable concentration in Table 3.1 for the analyte and is used when performing multiple runs on a sample, with or without dilution, to cover the range of maximum allowable concentrations in Table 3.1;
- g. One standard is above the maximum allowable concentration in Table 3.1 for an analyte;
- 2. The acceptance criteria for testing is one of the following, as applicable:
 - a. The maximum relative standard deviation for the average calibration factor, for an external calibration model, or the response factor, for an internal calibration model, is no more than 20%; and
 - b. For linear and non-linear calibration models, the coefficient of determination (r^2) is greater than or equal to 0.99;
- 3. For chromatographic testing methods using internal standards for calibration:
 - a. The relative retention time of each analyte to the internal calibration standard is within 0.06 units;
 - b. The areas of the peaks for the internal standards in any sample are between 50 and 200% of the area of the peak of the internal standard in subsection (F)(1)(e) used for calibration; and
 - c. The internal standards:
 - i. Have retention times similar to the analytes being tested for,
 - ii. Do not interfere with any of the analytes, and
 - iii. Have similar chemical properties as the analytes being tested for; and
- 4. For methods testing for heavy metals, the internal standards:
 - a. Are appropriate for the analyte, and
 - b. Do not interfere with any of the analytes.
- G. To obtain an acceptable calibration, a technical laboratory director:
 - 1. May use any of the following options:
 - a. Perform instrument maintenance to optimize analyte responses, as long as all resulting calibration models meet the acceptance criteria appropriate for the analyte;
 - b. If the problem appears to be associated with a single standard:
 - i. Reanalyze that one standard, at the time of calibration and before any samples are analyzed, to rule out problems due to random error: and
 - ii. Recalculate and reevaluate the standard against the acceptance criteria;
 - c. Narrow the calibration range by replacing one or more of the calibration standards at the upper or lower ends of the curve;
 - d. Narrow the calibration range by removing data points from either extreme end of the range and recalculating the calibration function; or
 - e. Perform a new initial calibration according to subsection (F); and
 - 2. May not:
 - a. Remove data points from within a calibration range while still retaining the extreme ends of the calibration range, or
 - b. Use non-linear calibrations to compensate for detector saturation or to avoid proper instrument maintenance.
- H. A technical laboratory director shall ensure that for initial calibration verification:
 - 1. Standards are prepared either from a different source or from a different lot of standards from the same source than the source from which the initial calibration standards specified in subsection (F)(1) were obtained and must be at or near, as applicable:
 - a. The maximum allowable concentrations for an analyte in Table 3.1,
 - b. According to subsection (F)(1)(f)(ii), or
 - c. The mid-level standard for potency testing; and
 - 2. The following acceptance criteria are used:
 - a. For potency testing, 80 to 120% recovery of true value;
 - b. For testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents, 70 to 130% recovery of the true value; and
 - c. For heavy metal testing, 90 to 110% recovery of the true value.
- I. A technical laboratory director shall ensure that for the limit of quantitation:
 - 1. The limit of quantitation is initially verified by the analysis of at least seven replicate samples, spiked at the limit of quantitation, and processed through all preparation and analysis steps of the method;
 - 2. The signal to noise ratio of the replicate samples in subsection (I)(1) is at least 5:1;
 - 3. The mean recovery of the replicate samples in subsection (I)(1) is:
 - a. For potency testing, $\pm 20\%$ of the true value;
 - b. For testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents, $\pm 50\%$ of the true value; and
 - c. For heavy metal testing, $\pm 35\%$ of the true value;
 - 4. The relative standard deviation of the replicate samples in subsection (I)(1) is less than 20%;
 - 5. The limit of quantitation is, as applicable, no greater than:
 - a. Half the maximum allowable concentrations for an analyte in Table 3.1, or
 - b. 1.0 mg/g for each analyte for potency testing;
 - 6. Any changes to specific sample amounts, dilutions, or volumes employed are reflected in the limit of quantitation stated on a sample report; and
 - 7. Documentation of the current limit of quantitation is maintained for each analyte for each instrument.
- J. Except as provided in subsection (P), a technical laboratory director shall ensure that for batch analysis:
 - 1. Continuing calibration verification standards:
 - a. Are prepared from the same calibration standard source used to prepare the standards specified in subsection (F)(1):
 - i. Initially, with a concentration at or near, as applicable, the maximum allowable concentration for an analyte in Table 3.1, according to subsection (F)(1)(f)(ii), or the mid-level standard for potency testing; and

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- ii. Subsequently, with a concentration at or between the highest concentration and lowest concentration of standards for the analytes in the batch;
- b. Have the following acceptance criteria:
 - i. For potency testing, 80 - 120% recovery of true value;
 - ii. For testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents, 70 - 130% recovery of the true value; and
 - iii. For heavy metal testing, 90 - 110% recovery of the true value;
- 2. If internal standards are used in continuing calibration verification, the acceptability criteria of the internal standards is determined as follows:
 - a. For testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents by mass spectrometry, if the area of the peak for an internal standard is different by a factor of two from the area of the respective standard in subsection (F)(1)(e), for the most recent initial calibration sequence, according to subsection (F):
 - i. The mass spectrometer is inspected for malfunctions and corrected, and
 - ii. Reanalysis of the continuing calibration verification meets acceptance criteria in subsection (J)(1)(b)(ii) before any samples are tested; and
 - b. For heavy metal testing:
 - i. The intensity of an internal standard is monitored for each analysis to ensure that the intensity does not vary by more than $\pm 30\%$, with respect to the intensity during the initial calibration in subsection (F); and
 - ii. If the intensity of an internal standard is outside the range also observed in the calibration blank required in subsection (F)(1)(c):
 - (1) Testing is stopped until the problem is corrected, the instrument is recalibrated, and the new calibration is verified;
 - (2) Reanalysis of the continuing calibration verification meets acceptance criteria in subsection (J)(1)(b)(iii) before any samples are tested; and
 - (3) The affected samples are retested; and
- 3. The frequency of continuing calibration verification is as follows:
 - a. For potency testing, heavy metal testing, or testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents by a method other than mass spectrometry:
 - i. At the beginning of the test;
 - ii. After every 20 samples, not counting a quality control sample, such as a sample required in subsection (K); and
 - iii. At the end of the test; and
 - b. For testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents by mass spectrometry:
 - i. At the beginning of the testing,
 - ii. After every 12 hours of running, and
 - iii. At the end of the run.
- K. Except as provided in subsection (P), a technical laboratory director shall ensure that for batch analysis:
 - 1. A method blank, with a matrix similar to each type of sample matrix to be tested within the batch:
 - a. Contains the same internal standards as the samples in the batch,
 - b. Is prepared and tested with each batch, and
 - c. Produces results below the limit of quantitation;
 - 2. Except as provided in subsection (R), a laboratory control sample and duplicate:
 - a. Are prepared at or near, as applicable:
 - i. The maximum allowable concentrations for an analyte in Table 3.1,
 - ii. According to subsection (F)(1)(f)(ii), or
 - iii. The mid-level standard for potency testing;
 - b. Are carried through all stages of sample preparation and included with each analytical batch of up to 20 samples; and
 - c. Have the following acceptance criteria:
 - i. For potency testing, 80 - 120% recovery of true value;
 - ii. For testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents, 70 - 130% recovery of the true value; and
 - iii. For heavy metal testing, 80 - 120% recovery of the true value;
 - 3. The relative percent difference for the laboratory control sample and duplicate, calculated on the basis of concentration or amount, is no more than 20%; and
 - 4. A matrix spike:
 - a. Is prepared at or near, as applicable, the maximum allowable concentrations for an analyte in Table 3.1 or the mid-level standard for potency testing;
 - b. Is carried through all stages of sample preparation and included with each analytical batch of up to 20 samples for each matrix type; and
 - c. Has either the following acceptance criteria or acceptance criteria within statistically derived limits developed by the laboratory:
 - i. For potency testing, 80 - 120% recovery of true value;
 - ii. For testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents, 70 - 130% recovery of the true value; and
 - iii. For heavy metal testing, 75 - 125% recovery of the true value.
- L. A technical laboratory director shall ensure that:
 - 1. Except as provided in subsection (P), for potency testing or testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents by mass spectrometry, the relative intensities of the characteristic ions agrees within 30% of the relative intensities of these ions in the reference spectrum; and
 - 2. For heavy metal testing, the intensity of each internal standard is monitored for each analysis to ensure that the intensity does not vary more than $\pm 30\%$, with respect to the intensity of the internal standard during the initial calibration specified in subsection (F).
- M. A technical laboratory director shall ensure that the resolution of chromatographic peaks in potency testing or testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents by a method other than mass spectrometry is maintained so that the height of the valley between the two chromatographic peaks is less than 50% of the average of the two peak heights.
- N. A technical laboratory director shall ensure that confirmation for testing for pesticides, fungicides, herbicides, growth regulators, or residual solvents by a method other than mass spectrometry:
 - 1. Is performed using:

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- a. A second column:
 - i. That has a stationary phase dissimilar to the stationary phase in the primary column, and
 - ii. From which the analyte is eluted in a different order than from the primary column;
 - b. A different instrument type, such as gas chromatography followed by mass spectrometry;
 - c. Gas chromatography with two different types of detectors; or
 - d. Other recognized confirmation techniques;
2. Meets the applicable criteria in subsections (D) through (M); and
 3. Includes as part of the confirmation of the analyte:
 - a. An evaluation of the agreement of the quantitative values of the results from both methods of testing; and
 - b. Determination of the relative percent difference between the values.
- O.** If the relative percent difference between the values obtained according to subsection (N) is more than 40%, a technical laboratory director shall ensure that:
1. The chromatograms are checked to see if an obviously overlapping peak is causing an erroneously high result, and the chromatographic conditions are reviewed; and
 2. Either:
 - a. If a problem is found with one of the tests, the result from the other test is reported; and
 - b. If there is no evidence of a chromatographic problem, the higher result is reported.
- P.** A technical laboratory director may release testing results that are scientifically valid and defensible, according to R9-17-404.06(B)(3), with the following data qualifier notations if:
1. The target analyte detected in the calibration blank required in subsection (F)(1)(c) or the method blank specified in subsection (K)(1) is at or above the limit of quantitation, but the sample result:
 - a. For potency testing, is below the limit of quantitation – B1; or
 - b. When testing for pesticides, fungicides, herbicides, growth regulators, heavy metals, or residual solvents, is below the maximum allowable concentration in Table 3.1 for the analyte – B2;
 2. The limit of quantitation and the sample results were adjusted to reflect sample dilution - D1;
 3. The relative intensity of a characteristic ion in a sample analyte exceeded the acceptance criteria in subsection (L)(1) with respect to the reference spectra, indicating interference – I1;
 4. When testing for pesticides, fungicides, herbicides, growth regulators, heavy metals, or residual solvents, the percent recovery of a laboratory control sample is greater than the acceptance limits in subsection (K)(2)(c), but the sample's target analytes were not detected above the maximum allowable concentrations in Table 3.1 for the analytes in the sample – L1;
 5. The recovery from the matrix spike in subsection (K)(4) was:
 - a. High, but the recovery from the laboratory control sample in subsection (K)(2) was within acceptance criteria – M1,
 - b. Low, but the recovery from the laboratory control sample in subsection (K)(2) was within acceptance criteria – M2, or
 - c. Unusable because the analyte concentration was disproportionate to the spike level, but the recovery from the laboratory control sample in subsection (K)(2) was within acceptance criteria – M3;
 6. The analysis of a spiked sample required a dilution such that the spike recovery calculation does not provide useful information, but the recovery from the associated laboratory control sample in subsection (K)(2) was within acceptance criteria – M4;
 7. The analyte concentration was determined by the method of standard addition, in which the standard is added directly to the aliquots of the analyzed sample – M5;
 8. A description of the variance is described in the final report of testing according to R9-17-404.06(B)(3)(d)(iii) – N1;
 9. The relative percent difference for the laboratory control sample and duplicate exceeded the limit in subsection (K)(3), but the recovery in subsection (K)(2) was within acceptance criteria – R1;
 10. The relative percent difference for a sample and duplicate exceeded the limit in subsection (O) – R2; or
 11. The recovery from continuing calibration verification standards exceeded the acceptance limits in subsection (J)(1)(b), but the sample's target analytes were not detected above the maximum allowable concentrations in Table 3.1 for the analytes in the sample – V1.
- Q.** A technical laboratory director shall include in the final report of testing, according to R9-17-404.06(B)(3)(d)(ii), the following data qualifier notations if:
1. Sample integrity was not maintained – Q1; or
 2. The sample is heterogeneous, and sample homogeneity could not be readily achieved using routine laboratory practices – Q2.
- R.** For batch analysis of samples to determine potency, a technical laboratory director may check precision by using either a duplicate laboratory control sample or a duplicate sample prepared from the medical marijuana or marijuana product being tested, according to requirements in subsections (K)(2) and (3).
- S.** A technical laboratory director shall ensure that the reporting units for:
1. Pesticides, fungicides, herbicides, growth regulators, heavy metals, or residual solvents is in parts per million (ppm); and
 2. Potency is in percent relative to the bulk plant material (w/w) and for:
 - a. Total tetrahydrocannabinol, the sum of tetrahydrocannabinolic acid (THC-A), multiplied by 0.877, and delta-9-tetrahydrocannabinol (Δ 9-THC); and
 - b. Total cannabidiol, the sum of cannabidiolic acid (CBD-A), multiplied by 0.877, and cannabidiol (CBD).

Historical Note

New Section made by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020 (Supp. 20-2).

R9-17-404.04. Method Criteria and References for Analyses for Microbial Contaminants

- A.** To perform laboratory testing for the microbial contaminants in Table 3.1, a laboratory shall use an applicable method:
1. Described in:
 - a. The Bacteriological Analytical Manual (BAM), 2019, which is incorporated by reference, includes no future editions or amendments, and is available at <https://www.fda.gov/food/laboratory-methods-food/bacteriological-analytical-manual-bam>; or

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- b. AOAC Official Methods of Analysis, 21st Edition, 2019, which is incorporated by reference, includes no future editions or amendments, and is available at <https://www.aoac.org/official-methods-of-analysis-21st-edition-2019>; and
- 2. Validated according to, as applicable:
 - a. AOAC - Appendix J: Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces, 2012, which is incorporated by reference, includes no future editions or amendments, and is available at http://www.eoma.aoac.org/app_j.pdf;
 - b. AOAC - Appendix K: Guidelines for Dietary Supplements and Botanicals, 2013, which is incorporated by reference, includes no future editions or amendments, and is available at http://www.eoma.aoac.org/app_k.pdf; or
 - c. ICH - Validation of Analytical Procedures: Text and Methodology Q2(R1) 2005, which is incorporated by reference, includes no future editions or amendments, and is available at https://database.ich.org/sites/default/files/Q2_R1_Guideline.pdf or <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q2-r1-validation-analytical-procedures-text-and-methodology>.
- B.** A technical laboratory director shall ensure that all instruments and equipment used for testing medical marijuana or a marijuana product for microbial contaminants are:
 - 1. Set up, calibrated, and verified according to:
 - a. Manufacturer's acceptance criteria; and
 - b. Requirements for the specific method, as specified in subsection (A)(1)(a) or (b), as applicable;
 - 2. Monitored and maintained according to AOAC - Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals, Appendix A: Equipment, August 2018, which is incorporated by reference, includes no future editions or amendments, and is available at <https://www.aoac.org/aoac-accreditation-guidelines-for-laboratories-alacc>; and
 - 3. Applicable for the analytes to be tested.
- C.** A technical laboratory director shall ensure that:
 - 1. The organisms required as controls are checked, as appropriate for their application:
 - a. To ensure there is no contamination with other organisms,
 - b. For verification of biochemical or other biological characteristics, and
 - c. To ascertain the number of organisms; and
 - 2. Documentation is maintained of the:
 - a. Checking required in subsection (C)(1), and
 - b. Traceability of the organisms in subsection (C)(1) from date of possession.
- D.** A technical laboratory director shall ensure that for an initial demonstration of capability:
 - 1. Before implementing a method, at least four replicate reference samples for each analyte are:
 - a. Spiked with control organisms at an amount allowing for quantitation, and
 - b. Taken through the entire sample preparation and analysis process;
 - 2. Whenever a significant change to instrumentation or to a standard operating procedure occurs, the laboratory demonstrates, as specified in subsection (D)(1), that acceptable precision and bias can still be obtained by the changed conditions; and
- 3. Whenever a new laboratory agent who will be performing testing on medical marijuana or marijuana products is being trained, the laboratory agent demonstrates, as specified in subsection (D)(1), acceptable precision and bias.
- E.** A technical laboratory director shall ensure that each batch of media or reagent:
 - 1. Is examined to ensure it is suitable for use;
 - 2. If externally prepared, has a certificate of meeting quality control standards, issued by the manufacturer;
 - 3. If internally prepared, has documentation of:
 - a. Instructions for preparation;
 - b. Traceability to dehydrated media or reagent concentrate;
 - c. Sterility, including, as applicable:
 - i. Autoclave records showing the date, run number, autoclave identifier, nature of the material being autoclaved, time at desired temperature, and name of the laboratory agent starting the autoclave; and
 - ii. For another sterilization method, records showing the date, type of sterilization method, nature of the material being sterilized, confirmation of the sterilization as applicable to the method, and name of the laboratory agent initiating the sterilization method;
 - d. Checking for the following, as applicable, including the name of the laboratory agent who performed the check and date of the check:
 - i. pH,
 - ii. Appearance,
 - iii. Fill volumes,
 - iv. Batch size, and
 - v. Quantity; and
 - 4. Undergoes quality control verification, as applicable, including the name of the laboratory agent who performed the verification and date of verification, for:
 - a. The ability of media to sustain growth of the organism for which the media will be used;
 - b. If applicable, the ability of media to select for specific organisms or characteristics of an organism;
 - c. The ability of a reagent to function as intended; and
 - d. Sterility of the media or reagent before use.
- F.** If test kits or other identification systems are used for laboratory testing, a technical laboratory director shall ensure that:
 - 1. Each lot of test kits or other identification systems undergoes quality control verification, including the name of the laboratory agent who performed the verification and date of verification, for:
 - a. Having a certificate of meeting quality control standards, issued by the manufacturer; and
 - b. Passing a visual inspection of physical characteristics; and
 - 2. If an identification system is intended to speciate organisms, the identification system is tested with at least one control organism appropriate for the identification system to confirm acceptability.
- G.** A technical laboratory director shall ensure that:
 - 1. For testing for *Aspergillus* with a plating method:
 - a. One of the following plating media is used:
 - i. Malt extract agar, BAM Media M182;
 - ii. Dichloran rose bengal chloramphenicol agar, BAM Media M183; or
 - iii. Potato dextrose agar with rose bengal and chloramphenicol; and

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- b. Petrifilm™, Simplate™, or another pre-made plate that is unsuitable for growing spreading molds is not used; and
- 2. For testing for mycotoxins by any method, at least a 0.5 g sample is tested.
- H. A technical laboratory director shall ensure that:
 - 1. The reporting units for *Escherichia coli* are colony forming units per gram (CFU/g);
 - 2. Reporting for *Salmonella* is “Detected” or “Not detected” in one gram;
 - 3. Reporting for *Aspergillus* is “Detected” or “Not detected” in one gram; and
 - 4. Reporting for mycotoxins includes:
 - a. Total aflatoxins in units of micrograms per kilogram (µg/kg), and
 - b. Ochratoxin A in units of micrograms per kilogram (µg/kg).
- 13. Assessment procedures for data acceptability, including appropriate procedures for manual integration of chromatograms and when manual integration is inappropriate;
- 14. Corrective action procedures to be taken when results from analytical quality control checks are unacceptable, including steps to demonstrate the presence of any interference if the precision, accuracy, or limit of quantitation of the reported testing result is affected by the interference; and
- 15. Procedures for chain-of-custody documentation, including procedures for the documentation and reporting of any deviation from the sample handling or preservation requirements.
- C. An owner holding a laboratory registration certificate or applicant shall ensure that a laboratory’s written quality assurance plan is a separate document available at the laboratory and includes all of the components required in subsection (B), but an owner or applicant may satisfy the components required in subsections (B)(3) through (15) through incorporating by reference provisions in separate documents, such as standard operating procedures.
- D. An owner holding a laboratory registration certificate or applicant shall:
 - 1. Have available at the laboratory all methods, equipment, reagents, and supplies necessary for the testing for which the owner or applicant is approved or is requesting approval;
 - 2. Use only reagents of a grade equal to or greater than that required by the method criteria in R9-17-404.03 or R9-17-404.04, and document the use of the reagents;
 - 3. Maintain and require each laboratory agent performing testing on medical marijuana or a marijuana product to comply with a complete and current standard operating procedure that meets the requirements for each method, as specified in R9-17-404.03 or R9-17-404.04, which shall include at least:
 - a. A description of all procedures to be followed when the method is performed;
 - b. A list of the concentrations for calibration standards, check standards, and spikes;
 - c. Requirements for instrumental conditions and set up;
 - d. A requirement for frequency of calibration;
 - e. The quantitative methods to be used to calculate the final concentration of an analyte in samples, including any factors used in the calculations and the calibration algorithm used; and
 - f. Requirements for preventative maintenance;
 - 4. Calibrate each instrument as required by the standard operating procedure, as specified in R9-17-404.03 or R9-17-404.04, for which the equipment is used;
 - 5. Maintain calibration documentation, including documentation that demonstrates the calculations performed using each calibration model;
 - 6. Develop, document, and maintain a current limit of quantitation, as specified in R9-17-404.03, for each compliance parameter for each instrument;
 - 7. For each parameter tested at the laboratory use the quality control acceptance criteria specified according to R9-17-404.03, R9-17-404.04, and Table 3.1;
 - 8. Discard or segregate all expired standards or reagents;
 - 9. Maintain a record showing the traceability of reagents; and
 - 10. Ensure that a calibration model is not used or changed to avoid necessary instrument maintenance.

Historical Note

New Section made by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020 (Supp. 20-2).

R9-17-404.05. Quality Assurance

- A. An owner holding a laboratory registration certificate or applicant shall ensure that the analytical data produced at the owner’s or applicant’s laboratory are of known and acceptable precision and accuracy, as prescribed by the method criteria for each analyte in R9-17-404.03 or R9-17-404.04, and are scientifically valid and defensible.
- B. An owner holding a laboratory registration certificate or applicant shall establish, implement, and comply with a written quality assurance plan that contains the following and is available at the laboratory for Department review:
 - 1. A title page identifying the laboratory and date of review and including the technical laboratory director’s signature of approval;
 - 2. A table of contents;
 - 3. An organization chart or list of the laboratory personnel, including names, lines of authority, and identification of principal quality assurance personnel;
 - 4. A copy of the current laboratory registration certificate and a list of approved parameters;
 - 5. A statement of quality assurance objectives, including data quality objectives with precision and accuracy goals and the criteria for determining the acceptability of each testing;
 - 6. Specifications for:
 - a. Sample containers,
 - b. Preparation of sample containers, and
 - c. Preservation of samples;
 - 7. A procedure for documenting laboratory receipt of samples and tracking of samples during laboratory testing;
 - 8. A procedure for analytical instrument calibration, including frequency of calibration and complying with the requirements for calibration in subsection (D);
 - 9. A procedure for testing data reduction and validation and reporting of final results, including the identification and treatment of data outliers, the determination of the accuracy of data transcription, and all calculations;
 - 10. A statement of the frequency of all quality control checks;
 - 11. A statement of the acceptance criteria for all quality control checks;
 - 12. Preventive maintenance procedures and schedules;

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- E. Except as provided in subsection (F), an owner holding a laboratory registration certificate or applicant shall ensure that each laboratory standard operating procedure is a separate document available at the laboratory and includes all of the components required in subsection (D)(3).
- F. An owner holding a laboratory registration certificate or applicant may satisfy the components required in subsections (D)(3)(e) and (f) through incorporating by reference provisions in separate documents, such as other standard operating procedures.
 - g. Documentation of each laboratory agent's completion of initial demonstration of capability, as required in R9-17-404.03(D)(3) or R9-17-404.04(D)(3), for each approved method performed by the laboratory agent;
 - h. Documentation of each laboratory agent's performance of proficiency testing or accuracy testing, as applicable; and
 - i. Documentation of each laboratory agent's completion of training related to instrument calibration that includes:
 - i. Instruction on each calibration model that the laboratory agent will use or for which the laboratory agent will review data;
 - ii. For each calibration model in subsection (A)(7)(i), description of the specific aspects of the calibration model that might compromise the data quality, such as detector saturation, lack of detector sensitivity, the calibration model's not accurately reflecting the calibration points, inappropriate extension of the calibration range, weighting factors, and dropping of mid-level calibration points without justification; and
 - iii. Instruction that a calibration model shall not be used or changed to avoid necessary instrument maintenance.

Historical Note

New Section made by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020 (Supp. 20-2).

R9-17-404.06. Operations

- A. A technical laboratory director shall ensure that:
 - 1. A sample of medical marijuana or a marijuana product accepted at the technical laboratory director's laboratory is analyzed at the laboratory and as received;
 - 2. If an instrument or equipment used for testing medical marijuana or a marijuana product has a mechanism to track any changes made to testing results, the tracking mechanism is activated;
 - 3. The facility and utilities required to operate equipment and perform testing of medical marijuana or marijuana products are maintained;
 - 4. Environmental controls are maintained within the laboratory to ensure that laboratory environmental conditions do not affect analytical results beyond quality control limits established for the methods performed at the laboratory;
 - 5. Storage, handling, and disposal of hazardous materials at the laboratory are in accordance with all state and federal regulations;
 - 6. The laboratory complies with all applicable federal, state, and local occupational safety and health regulations; and
 - 7. The following information is maintained for all laboratory agents providing supervisory, quality assurance, or analytical functions related to testing of medical marijuana or a marijuana product:
 - a. A summary of each laboratory agent's education and professional experience;
 - b. Documentation of each laboratory agent's applicable certifications and specialized training;
 - c. Information related to the laboratory agent's registry identification card;
 - d. Documentation of each laboratory agent's review of the quality assurance plan required under R9-17-404.05(B) and the methods and laboratory standard operating procedures for all testing of marijuana or marijuana products performed by the laboratory agent or for which the laboratory agent has supervisory or quality assurance responsibility;
 - e. Documentation of each laboratory agent's completion of training on the use of equipment and of proper laboratory technique, including the name of the laboratory agent, the name of the instructor, the duration of the training, and the date of completion of the training;
 - f. Documentation of each laboratory agent's completion of training classes, continuing education courses, seminars, and conferences that relate to the testing procedures used by the laboratory agent for testing of marijuana or marijuana products;
- B. A technical laboratory director shall ensure that:
 - 1. A testing record for marijuana or marijuana products contains:
 - a. Sample information, including the following:
 - i. A unique sample identification assigned at the laboratory;
 - ii. A description of the marijuana or marijuana product from which the submitted sample was taken, including the amount, strain, and batch number;
 - iii. The sample collection date and time; and
 - iv. The type of testing to be performed;
 - b. A picture of the sample as submitted;
 - c. The name and registry identification number of the dispensary, qualifying patient, or designated caregiver submitting the sample to the laboratory;
 - d. If applicable, name and the registry identification number of the dispensary agent submitting the sample to the laboratory on behalf of a dispensary;
 - e. The date and time of receipt of the sample at the laboratory;
 - f. The name and registry identification number of the laboratory agent who received the sample at the laboratory;
 - g. The dates and times of testing, including the date and time of each critical step;
 - h. Whether testing results related to a sample were changed;
 - i. If testing results related to a sample were changed, what was changed, the name of the laboratory agent who changed the testing results, the time and date the data were changed, and why the testing results were changed;
 - j. If testing results were changed due to retesting:
 - i. What was used or done to the sample, and
 - ii. The original and changed testing results;
 - k. The actual results of testing, including all raw data, work sheets, and calculations performed;

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- l. The actual results of quality control data validating the test results, including the calibration and calculations performed;
 - m. The name of each laboratory agent who performed the testing; and
 - n. A copy of the final report;
 2. A testing result for medical marijuana or a marijuana product that is known to be inaccurate is not reported; and
 3. A final report of testing of marijuana or marijuana products contains:
 - a. The name, address, and telephone number of the laboratory;
 - b. The registry identification number assigned to the laboratory by the Department;
 - c. Actual scientifically valid and defensible results of testing of a sample of medical marijuana or a marijuana product in appropriate units of measure, obtained in accordance with R9-17-404.03, R9-17-404.04, and the quality assurance plan;
 - d. Either:
 - i. A statement that testing results were obtained according to requirements in the quality assurance plan in R9-17-404.05, in the applicable standard operating procedure, and in R9-17-404.03 or R9-17-404.04; or
 - ii. A description of any variances from the requirements in the quality assurance plan in R9-17-404.05, the applicable standard operating procedure, R9-17-404.03, or R9-17-404.04, and the reason for the variance;
 - e. A list of each method used to obtain the reported results;
 - f. Sample information, including the following:
 - i. The unique sample identification assigned at the laboratory;
 - ii. A picture of the sample as submitted;
 - iii. A description of the marijuana or marijuana product from which the submitted sample was taken, including the amount, strain and batch number;
 - iv. The sample collection date and time;
 - v. The name and registry identification number of the dispensary, qualifying patient, or designated caregiver submitting the sample to the laboratory; and
 - vi. If applicable, name and the registry identification number of the dispensary agent submitting the sample to the laboratory on behalf of a dispensary;
 - g. The date of testing for each parameter reported;
 - h. The date of the final report; and
 - i. The technical laboratory director's or designee's signature.
1. The following information in a Department-provided format:
 - a. The name, address, and telephone number of the applicant;
 - b. The name, address, and telephone number of the laboratory for which the change is requested;
 - c. If requesting the removal of a parameter, identification of the parameter to be removed; and
 - d. If requesting the addition of a parameter:
 - i. The analyte to be tested for;
 - ii. The instruments and equipment to be used for testing;
 - iii. The software to be used at the laboratory for instrument control and data reduction interpretation; and
 - iv. The limit of quantitation, if applicable;
 2. The following for each parameter requested to be added:
 - a. A copy of current accreditation;
 - b. A copy of a proficiency testing report, if applicable, or accuracy testing documentation; and
 - c. A copy of the standard operating procedure; and
 3. If applicable, any changes to the quality assurance plan in R9-17-404.05(B) made due to the addition or removal of the parameter.
- C.** The Department may conduct a laboratory inspection during the substantive review period for a request to have one or more parameters added to a laboratory registration certificate.
- D.** The Department shall process a request to have one or more parameters added to a laboratory registration certificate as provided in R9-17-107.

Historical Note

New Section made by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020 (Supp. 20-2).

R9-17-405. Submitting an Application for a Laboratory Agent Registry Identification Card

To obtain a laboratory agent registry identification card for an individual serving as an owner for the laboratory, employed by the laboratory, or providing volunteer services at or on behalf of the laboratory, the owner shall submit to the Department the following for each laboratory agent:

1. An application in a Department-provided format that includes:
 - a. The laboratory agent's first name; middle initial, if applicable; last name; and suffix, if applicable;
 - b. The laboratory agent's residence address and mailing address;
 - c. The county where the laboratory agent resides;
 - d. The laboratory agent's date of birth;
 - e. The identifying number on the applicable card or document in subsections (5)(a) through (e);
 - f. The name and registry identification number of the laboratory; and
 - g. The signature of the individual in R9-17-402(A)(1)(c) designated to submit laboratory agent applications on the laboratory's behalf and the date the individual signed;
2. An attestation signed and dated by the laboratory agent that the laboratory agent:
 - a. Has not been convicted of an excluded felony offense as defined in A.R.S. § 36-2801, and
 - b. Will not test medical marijuana and medical marijuana products for:
 - i. A dispensary, related medical marijuana business entity, or management company that the

Historical Note

New Section made by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020 (Supp. 20-2).

R9-17-404.07. Adding or Removing Parameters for Testing

- A.** During the term of a laboratory registration certificate, an owner may request to have one or more parameters:
1. Added to the laboratory registration certificate, or
 2. Removed from the laboratory registration certificate.
- B.** To request a change to one or more parameters, an applicant shall submit to the Department:

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- laboratory agent has a direct or indirect familial or financial relationship with or interest in; or
- ii. A designated caregiver who the laboratory has a direct or indirect familial or financial relationship with;
3. One of the following:
 - a. A statement that the laboratory agent does not currently hold a valid registry identification card, or
 - b. The assigned registry identification number for the laboratory agent for each valid registry identification card currently held by the laboratory agent;
 4. A statement in a Department-provided format, signed by the laboratory agent, pledging not to divert marijuana to any individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
 5. A copy of the laboratory agent's:
 - a. Arizona driver's license issued on or after October 1, 1996;
 - b. Arizona identification card issued on or after October 1, 1996;
 - c. Arizona registry identification card;
 - d. Photograph page in the laboratory agent's U.S. passport; or
 - e. Arizona driver's license or identification card issued before October 1, 1996 and one of the following for the laboratory agent:
 - i. Birth certificate verifying U.S. citizenship,
 - ii. U.S. Certificate of Naturalization, or
 - iii. U.S. Certificate of Citizenship;
 6. A current photograph of the laboratory agent;
 7. For the Department's criminal records check authorized in A.R.S. §§ 36-2804.01 and 36-2804.07:
 - a. The laboratory agent's fingerprints on a fingerprint card that includes:
 - i. The laboratory agent's first name; middle initial, if applicable; and last name;
 - ii. The laboratory agent's signature;
 - iii. If different from the laboratory agent, the signature of the individual physically rolling the laboratory agent's fingerprints;
 - iv. The laboratory agent's address;
 - v. If applicable, the laboratory agent's surname before marriage and any names previously used by the laboratory agent;
 - vi. The laboratory agent's date of birth;
 - vii. The laboratory agent's Social Security number;
 - viii. The laboratory agent's citizenship status;
 - ix. The laboratory agent's gender;
 - x. The laboratory agent's race;
 - xi. The laboratory agent's height;
 - xii. The laboratory agent's weight;
 - xiii. The laboratory agent's hair color;
 - xiv. The laboratory agent's eye color; and
 - xv. The laboratory agent's place of birth; or
 - b. If the laboratory agent's fingerprints and information required in subsection (7)(a) were submitted to the Department within the previous six months as part of an application for a designated caregiver registry identification card, a dispensary agent registry identification card, or a laboratory agent registry identification card, the registry identification number on the registry identification card issued to the laboratory agent as a result of the application; and
 8. The applicable fee in R9-17-102 for applying for a laboratory agent registry identification card.

Historical Note

New Section made by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3).

R9-17-406. Submitting an Application to Renew a Laboratory Agent's Registry Identification Card

To renew a laboratory agent's registry identification card for an individual serving as an owner for the laboratory, employed by the laboratory, or providing volunteer services at or on behalf of the laboratory, the laboratory shall submit to the Department, at least 30 calendar days before the expiration of the laboratory agent's registry identification card, but no more than 90 days before the expiration date of the laboratory's agent's registry identification card, the following:

1. An application in a Department-provided format that includes:
 - a. The laboratory agent's first name; middle initial, if applicable; last name; and suffix, if applicable;
 - b. The laboratory agent's residence address and mailing address;
 - c. The county where the laboratory agent resides;
 - d. The laboratory agent's date of birth;
 - e. The registry identification number on the laboratory agent's current registry identification card;
 - f. The identifying number on the applicable card or document in subsection (6)(a) through (e);
 - g. The name and registry identification number of the laboratory; and
 - h. The signature of the individual in R9-17-402(A)(1)(c) designated to submit laboratory agent applications on the laboratory's behalf and the date the individual signed;
2. If the laboratory agent's name in subsection (1)(a) is not the same name as on the laboratory agent's current registry identification card, one of the following with the laboratory agent's new name:
 - a. An Arizona driver's license,
 - b. An Arizona identification card, or
 - c. The photograph page in the laboratory agent's U.S. passport;
3. An attestation signed and dated by the laboratory agent that the laboratory agent:
 - a. Has not been convicted of an excluded felony offense as defined in A.R.S. § 36-2801; and
 - b. Will not test medical marijuana and medical marijuana products for:
 - i. A dispensary, related medical marijuana business entity or management company the laboratory agent has a direct or indirect familial or financial relationship with or interest in; or
 - ii. A designated caregiver the laboratory has a direct or indirect familial or financial relationship with;
4. One of the following:
 - a. A statement that the laboratory agent does not currently hold a valid registry identification card, or
 - b. The assigned registry identification number for the laboratory agent for each valid registry identification card currently held by the laboratory agent;
5. A statement in a Department-provided format signed by the laboratory agent pledging not to divert marijuana to any individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
6. A copy of the laboratory agent's:
 - a. Arizona driver's license issued on or after October 1, 1996;

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- b. Arizona identification card issued on or after October 1, 1996;
- c. Arizona registry identification card;
- d. Photograph page in the laboratory agent's U.S. passport; or
- e. Arizona driver's license or identification card issued before October 1, 1996 and one of the following for the laboratory agent:
 - i. Birth certificate verifying U.S. citizenship,
 - ii. U.S. Certificate of Naturalization, or
 - iii. U.S. Certificate of Citizenship;
7. A current photograph of the laboratory agent;
8. For the Department's criminal records check authorized in A.R.S. §§ 36-2804.01 and 36-2804.07:
 - a. The laboratory agent's fingerprints on a fingerprint card that includes:
 - i. The laboratory agent's first name; middle initial, if applicable; and last name;
 - ii. The laboratory agent's signature;
 - iii. If different from the laboratory agent, the signature of the individual physically rolling the laboratory agent's fingerprints;
 - iv. The laboratory agent's address;
 - v. If applicable, the laboratory agent's surname before marriage and any names previously used by the laboratory agent;
 - vi. The laboratory agent's date of birth;
 - vii. The laboratory agent's Social Security number;
 - viii. The laboratory agent's citizenship status;
 - ix. The laboratory agent's gender;
 - x. The laboratory agent's race;
 - xi. The laboratory agent's height;
 - xii. The laboratory agent's weight;
 - xiii. The laboratory agent's hair color;
 - xiv. The laboratory agent's eye color; and
 - xv. The laboratory agent's place of birth; or
 - b. If the laboratory agent's fingerprints and information required in subsection (8)(a) were submitted to the Department within the previous six months as part of an application for a designated caregiver registry identification card, a dispensary agent registry identification card, or a laboratory agent registry identification card, the registry identification number on the registry identification card issued to the laboratory agent as a result of the application; and
9. The applicable fee in R9-17-102 for applying to renew a laboratory agent's registry identification card.

Historical Note

New Section made by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3).

R9-17-407. Inventory Control System

- A. A laboratory shall not accept submissions of marijuana or marijuana products for testing from an individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1.
- B. A technical laboratory director laboratory shall designate in writing a laboratory agent who has oversight of the laboratory's marijuana inventory control system.
- C. A technical laboratory director shall establish and implement an inventory control system for the laboratory's medical marijuana and marijuana products that documents:
 1. Each day's beginning medical marijuana and marijuana products inventory, medical marijuana and marijuana products accepted for testing, medical marijuana and marijuana products transferred to another laboratory at

the request of a dispensary according to R9-17-3317.01(C), disposal of medical marijuana or marijuana products, and ending medical marijuana and marijuana products inventory;

2. The chain of custody for each sample of medical marijuana or a marijuana product submitted to the laboratory for testing;
3. Any damage to a sample's container or possible tampering; and
4. As applicable, for submissions of marijuana and marijuana products for testing:
 - a. A description of the submitted marijuana or marijuana products including the amount, strain and batch number;
 - b. The name and registry identification number of the dispensary that submitted the marijuana or marijuana products;
 - c. The name and registry identification number of the dispensary agent that submitted the marijuana or marijuana products;
 - d. The name and registry identification number of the qualifying patient that submitted the marijuana or marijuana products;
 - e. The name and registry identification number of the designated caregiver that submitted the marijuana or marijuana products;
 - f. The name and registry identification number of the laboratory agent receiving the marijuana or marijuana products on behalf of the laboratory;
 - g. The date of acquisition;
 - h. The date of each test; and
 - i. The test results.
- D. The individual designated in subsection (A) shall conduct and document an audit of the laboratory's inventory that is accounted for according to generally accepted accounting principles at least once every 30 calendar days.
 1. If the audit identifies a reduction in the amount of marijuana or marijuana products in the laboratory's inventory not due to documented causes, the technical laboratory director shall determine where the loss has occurred and take and document corrective action.
 2. If the reduction in the amount of marijuana or marijuana products in the laboratory's inventory is due to suspected criminal activity by a laboratory agent, the technical laboratory director shall report the laboratory agent to the Department and to the local law enforcement authorities and document the report.
- E. A laboratory shall:
 1. Maintain the documentation required in subsections (C) and (D) at the dispensary for at least five years after the date on the document, and
 2. Provide the documentation required in subsections (C) and (D) to the Department for review upon request.

Historical Note

New Section made by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3). Amended by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020; amended by exempt rulemaking at 26 A.A.R. 968, effective April 20, 2020 (Supp. 20-2).

R9-17-408. Security

- A. Except as provided in R9-17-404(8), a laboratory shall ensure that access to the area of the laboratory where marijuana or marijuana products are being tested or stored for testing is limited to a laboratory's owners and authorized laboratory agents.

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- B.** A laboratory agent may transport marijuana or marijuana products submitted for testing to a laboratory.
- C.** Before transportation to a laboratory, a laboratory agent shall:
1. Complete a trip plan that includes:
 - a. The name of the laboratory agent in charge of transporting the marijuana or marijuana products;
 - b. The date and start time of the trip;
 - c. A description of the marijuana or marijuana products being transported;
 - d. Any anticipated stops during the trip, including the locations of the stops; and
 - e. The anticipated route of transportation; and
 2. Provide a copy of the trip plan in subsection (C)(1) to the laboratory.
- D.** During transportation to the laboratory, a laboratory agent shall:
1. Carry a copy of the trip plan in subsection (C)(1) with the laboratory agent for the duration of the trip;
 2. Use a vehicle without any medical marijuana identification;
 3. Have a means of communication with the laboratory; and
 4. Ensure that the marijuana or marijuana products are not visible.
- E.** After transportation, a laboratory agent shall enter the end time of the trip and any changes to the trip plan on the trip plan required in subsection (C)(1).
- F.** If a dispensary agent transports medical marijuana or a marijuana product to a laboratory for testing, the laboratory shall require that a copy of the trip plan be provided by the dispensary before accepting the medical marijuana or marijuana product for testing.
- G.** A laboratory shall:
1. Maintain the documents required in subsections (C)(2), (E), and (F); and
 2. Provide a copy of the documents required in subsections (C)(2), (E), and (F) to the Department for review upon request.
- H.** To prevent unauthorized access to marijuana or marijuana products at the laboratory for testing, the laboratory shall have the following:
1. Security equipment to deter and prevent unauthorized entrance into limited access areas that include:
 - a. Devices or a series of devices to detect unauthorized intrusion, which may include a signal system interconnected with a radio frequency method, such as cellular, private radio signals, or other mechanical or electronic device;
 - b. Exterior lighting to facilitate surveillance;
 - c. Electronic monitoring including:
 - i. At least one 19-inch or greater call-up monitor;
 - ii. A video printer capable of immediately producing a clear still photo from any video camera image;
 - iii. Video cameras:
 - (1) Providing coverage of all entrances to and exits from limited access areas and all entrances to and exits from the building, capable of identifying any activity occurring in or adjacent to the building; and
 - (2) Having a recording resolution of at least 704 x 480 or the equivalent;
 - iv. A video camera in each area of the laboratory where marijuana or marijuana products are being tested or stored for testing capable of identifying any activity occurring within the area in low light conditions;
 2. Storage of video recordings from the video cameras for at least 30 calendar days;
 3. A failure notification system that provides an audible and visual notification of any failure in the electronic monitoring system; and
 4. Sufficient battery backup for video cameras and recording equipment to support at least five minutes of recording in the event of a power outage; and
 5. Panic buttons in the interior of each building; and
- 2.** Policies and procedures that:
- a. Restrict access to the areas of the laboratory that contain marijuana or marijuana products and, if applicable, to authorized individuals only;
 - b. Provide for the identification of authorized individuals; and
 - c. Prevent loitering.

Historical Note

New Section made by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3). Amended by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020 (Supp. 20-2).

R9-17-409. Physical Plant

- A.** A laboratory shall ensure that designated storage areas for marijuana or marijuana products or materials used in direct contact with marijuana or marijuana products are:
1. Separate from storage areas for toxic or flammable materials; and
 2. Maintained in a manner to prevent:
 - a. Microbial contamination and proliferation, and
 - b. Contamination or infestation by insects or rodents.
- B.** A laboratory shall ensure that a designated storage area for medical marijuana or a marijuana product is:
1. At an appropriate temperature for the medical marijuana or marijuana product, as specified on the packaged sample;
 2. Monitored to ensure that a:
 - a. Room temperature storage area is maintained between 20°C and 28°C,
 - b. Refrigerated storage area is maintained between 2°C and 8°C, and
 - c. Freezer storage area is maintained at less than -20°C; and
 3. Labelled to indicate the temperature range and types of medical marijuana or marijuana products to be stored in the storage area.
- C.** A laboratory shall ensure that a designated area for testing medical marijuana or a marijuana product for microbial contaminants is maintained in a manner to prevent exposure of the medical marijuana or marijuana product to external microbial contaminants.
- D.** A laboratory shall ensure that a designated area for testing medical marijuana or a marijuana product for pesticides, fungicides, herbicides, growth regulators, heavy metals, or residual solvents is maintained in a manner to prevent exposure of the medical marijuana or marijuana product to external contamination.

Historical Note

New Section made by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3). Amended by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020 (Supp. 20-2).

R9-17-410. Denial or Revocation of a Laboratory Registration Certificate

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- A. The Department shall deny an application for a laboratory registration certificate if:
1. The physical address of the laboratory is within 500 feet of a private school or a public school that existed before the date the laboratory submitted the initial laboratory registration certificate application;
 2. An owner:
 - a. Has been convicted of an excluded felony offense, or
 - b. Is under 21 years of age;
 3. The application or the laboratory does not comply with the requirements in A.R.S. Title 36, Chapter 28.1 and this Chapter;
 4. The laboratory acquires marijuana or marijuana products from an individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
 5. The laboratory diverts marijuana or marijuana products to an individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
 6. An owner has any direct or indirect familial or financial relationship with or interest in a dispensary or related medical marijuana business entity or management company, or any direct or indirect familial or financial relationship with a designated caregiver for whom the laboratory is testing marijuana and marijuana products for medical use in this state; or
 7. The laboratory fails to maintain accreditation.
- B. The Department may deny an application for a laboratory registration certificate if an owner of the laboratory provides false or misleading information to the Department.
- C. The Department shall revoke a laboratory's registration certificate if:
1. The laboratory acquires marijuana or marijuana products from an individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
 2. The laboratory diverts marijuana or marijuana products to an individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1;
 3. An owner has been convicted of an excluded felony offense;
 4. An owner has any direct or indirect familial or financial relationship with or interest in a dispensary or related medical marijuana business entity or management company, or any direct or indirect familial or financial relationship with a designated caregiver for whom the laboratory is testing marijuana and marijuana products for medical use in this state; or
 5. The laboratory fails to maintain accreditation.
- D. The Department may deny an application for a laboratory registration certificate or revoke a laboratory registration certificate if the laboratory does not:
1. Comply with:
 - a. The requirements in A.R.S. Title 36, Chapter 28.1 and this Chapter; or
 - b. The provisions in a corrective action plan submitted according to R9-17-404.01(E)(2)(b); or
 2. Implement the policies and procedures or comply with the statements provided to the Department with the laboratory's application.
- E. If the Department denies a laboratory registration certificate application, the Department shall provide notice to the applicant that includes:
1. The specific reason or reasons for the denial, and
 2. All other information required by A.R.S. § 41-1076.
- F. If the Department revokes a laboratory registration certificate, the Department shall provide notice to the laboratory that includes:
1. The specific reason or reasons for the revocation; and
 2. The process for requesting a judicial review of the Department's decision pursuant to A.R.S. Title 12, Chapter 7, Article 6.

Historical Note

New Section made by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3). Amended by exempt rulemaking at 26 A.A.R. 734, with an immediate effective date of April 2, 2020 (Supp. 20-2).

R9-17-411. Denial or Revocation of a Laboratory Agent's Registry Identification Card

- A. The Department shall deny an application for or renewal of a laboratory agent's registry identification card if the laboratory agent does not meet the requirements in A.R.S. § 36-2801.
- B. The Department may deny an application for or renewal of a laboratory agent's registry identification card if the laboratory agent provides false or misleading information to the Department.
- C. The Department shall revoke a laboratory agent's registry identification card if the laboratory agent:
1. Uses marijuana, if the laboratory agent does not have a qualifying patient registry identification card;
 2. Diverts marijuana or marijuana products to an individual who or entity that is not allowed to possess marijuana pursuant to A.R.S. Title 36, Chapter 28.1; or
 3. Has been convicted of an excluded felony offense.
- D. The Department may revoke a laboratory agent's registry identification card if the laboratory agent knowingly violates A.R.S. Title 36, Chapter 28.1 or this Chapter.
- E. If the Department denies or revokes a laboratory agent's registry identification card, the Department shall provide notice to the laboratory agent and the laboratory agent's laboratory that includes:
1. The specific reason or reasons for the denial or revocation; and
 2. The process for requesting a judicial review of the Department's decision pursuant to A.R.S. Title 12, Chapter 7, Article 6.

Historical Note

New Section made by exempt rulemaking at 25 A.A.R. 2421, effective August 27, 2019 (Supp. 19-3).