

NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* 1st as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Arizona Administrative Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 4. COMMERCE, PROFESSIONS, AND OCCUPATIONS

CHAPTER 16. BOARD OF MEDICAL EXAMINERS

PREAMBLE

1. Sections Affected
R4-16-104
R4-16-105
Table 1.
- Rulemaking Action
New Section
New Section
New Table
2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):
Authorizing statute: A.R.S. § 32-1404(D)
Implementing statute: A.R.S. §§ 32-1422, 32-1426, 32-1428, 32-1429, 32-1432.01, 32-1432.02, 32-1432.03; and 41-1072 through 41-1078
3. The effective date of the rules:
January 20, 1998
4. A list of all previous notices appearing in the Register, addressing the final rule:
Notice of Docket Opening: 3 A.A.R. 52, January 3, 1997
Notice of Docket Opening: 3 A.A.R. 327, January 31, 1997
Notice of Proposed Rulemaking: 3 A.A.R. 1120, April 25, 1997
Notice of Docket Opening: 3 A.A.R. 1349, May 23, 1997
Notice of Public Information: 3 A.A.R. 1360, May 23, 1997
5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:
Name: Elaine Hugunin, Deputy Director
Address: Board of Medical Examiners
1651 East Morten, Suite 210
Phoenix, AZ 85020
Telephone: (602) 255-3751
6. An explanation of the rule, including the agency's reasons for initiating the rule:
A.R.S. §§ 41-1072 through 41-1078 were added during the 1996 regular Legislative session and require that all administrative agencies, boards and commissions which are subject to the Administrative Procedures Act to establish, by rule, time-frames for any licensing activities. An overall time-frame for each licensing process must be established. That time-frame must then be split into 2 parts, the administrative completeness phase and the substantive review phase. Finally, these rules must be in place no later than December 31, 1998. The proposed rules establish for physicians the necessary licensing time-frames for initial licensing by examination and endorsement, renewal of license, temporary license, locum tenens and pro bono registration, teaching license, educational teaching permit, training permit, one-year training permit, and registration for dispensing controlled substances, drugs, and devices.
7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:
Not applicable.
8. The summary of the economic, small business and consumer impact:
There is no anticipated additional cost to private industry, small businesses, or consumers. There will be a small additional cost to the Board to formally implement the notice of deficiency in the administrative completeness portion of the licensing process as well as the one comprehensive written request for additional information in the substantive review portion of the licensing process. There is also the remote possibility that the Board may be required to return a licensing or registration fee for failure to

meet the time-frames established in these rules as well as pay a penalty to the general fund as required by A.R.S. § 41-1077. These costs would be expected to be minimal, if any. Otherwise, this is merely the codification of the time-frames and processes currently observed in carrying out the various licensing activities of the Board of Medical Examiners.

However, it is recognized that under the existing licensing process, which is being codified by these rules, there is a cost to the physician applicant for licensing which is incurred while awaiting the Board's licensing decision. That cost is the income which might otherwise have been earned as a physician during that time period.

9. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

There are a number of changes between the rules as proposed and as finally submitted to GRRC based almost entirely upon comments received from GRRC staff in the course of its review. However, the changes are more to form rather than substance. The multiple time-frame rules were consolidated into 2 sections with a table showing the pertinent time-frames. Essentially, R4-16-104 was rewritten to be generally applicable, setting time-frames for administrative completeness review, substantive review, and overall, by referencing a newly created table setting forth the time-frames for each of the licenses, registrations, and permits issued by the Board. R4-16-107 was renumbered to R4-16-105 and retained because the license renewal time-frame did not readily conform to the general procedure. All other proposed sections were stricken.

The rules were changed so that when an applicant fails to respond to information requests either during the administrative completeness time-frame or the substantive review time-frame, the application will now be deemed withdrawn rather than denied. In addition, 5 days were added to those administrative completeness time-frames and substantive review time-frames which were under 30 days, while the 180 day time-frames for administrative completeness and substantive review of applications for licensure by examination and endorsement were reduced to 120 days. Finally, there were a number of minor wording and sentence structure changes which were recommended by GRRC staff and implemented in this final submission.

10. A summary of the principal comments and the agency response to them:

No comments were received, either written or oral.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable.

12. Incorporations by reference and their location in the rules:

Not applicable.

13. Was this rule previously adopted as an emergency rule?

Not applicable.

14. The full text of the rules follows:

TITLE 4. COMMERCE, PROFESSIONS, AND OCCUPATIONS

CHAPTER 16. BOARD OF MEDICAL EXAMINERS

ARTICLE 1. GENERAL PROVISIONS

Section

R4-16-104. Time-Frames for License, Permit, or Registration

R4-16-105. Time-Frames for License Renewal

Table 1. Time-Frames

ARTICLE 1. GENERAL PROVISIONS

R4-16-104. Time Frames for Licenses, Permits and Registrations

A. For each type of license, permit, or registration issued by the Board, the overall time-frame described in A.R.S. § 41-1072(2) is listed in Table 1.

B. For each type of license, permit, or registration issued by the Board, the administrative completeness review time-frame described in A.R.S. §41-1072(1) is listed in Table 1 and begins on the date the Board receives an application and all required documents and information.

1. If the required application is not administratively complete, the Board shall send to the applicant, a deficiency notice.

a. The notice shall state each deficiency and the information needed to complete the application and documents.

b. Within the time provided in Table 1 for response to a deficiency notice, beginning on the date of mail-

ing of a deficiency notice, an applicant shall submit to the Board the missing documents and information specified in the notice. The time-frame for the Board to finish the administrative completeness review is suspended from the date the Board mails the deficiency notice to the applicant until the date the Board receives the missing documentation and information.

c. Under A.R.S. § 32-1427(E), an applicant for an initial license by examination or endorsement who disagrees with the deficiency notice may request a hearing before the Board at its next regular meeting if there is time at that meeting to hear the matter. The board shall not delay a requested hearing beyond 1 regularly scheduled meeting. At any hearing granted under this subsection, the applicant shall have the burden of proof to demonstrate that the alleged deficiencies do not exist.

d. Under A.R.S. § 32-1427(F), if an applicant for initial license by examination or endorsement does not submit the missing documents and information indicated in the deficiency notice within the time frame specified in subsection (B)(1)(b), the Board shall deem the application withdrawn.

Arizona Administrative Register
Notices of Final Rulemaking

2. If the application is administratively complete, the Board shall send a written notice of administrative completeness to the applicant.
 3. If the application and submitted documents and information do not contain all of the components required by statute and rule, the Board shall send a written notice to the applicant informing the applicant that the application is deemed withdrawn.
- C. For each type of license, permit, or registration issued by the Board, the substantive review time-frame described in A.R.S. § 41-1072(3) is listed at Table 1 and begins on the date the Board sends written notice of administrative completeness to the applicant.
1. During the substantive review time-frame, the Board may make 1 comprehensive written request for additional information. The applicant shall submit to the Board the additional information identified by the comprehensive written request within the time provided in Table 1, beginning on the date of mailing of the comprehensive written request for additional information. The time-frame for the Board to finish the substantive review is suspended from the date the Board mails the comprehensive written request for additional information to the applicant until the Board receives the additional information.
 2. The Board shall issue a written notice of denial of license, permit, or registration if the Board determines that the applicant does not meet all of the substantive criteria required by statute and rule for a license, permit, or registration.
 3. The Board shall issue a written notice informing the applicant that the application is deemed withdrawn if the applicant does not submit the requested additional information within the time-frame in Table 1.
 4. If the applicant meets all of the substantive criteria required by statute and rule for license, permit, or registration, the Board shall issue a license, permit, or registration to the applicant.
- R4-16-105. Time Frames for License Renewal**
- A. For renewal of licensure, the overall time-frame described in A.R.S. § 41-1072(2) is 90 calendar days.
 - B. For renewal of licensure, the administrative completeness review time-frame described in A.R.S. § 41-1072(1) is 90 calendar days and begins on the date the Board receives the renewal application.
 1. If the required application is not administratively complete, the Board shall send to the applicant a deficiency notice. The notice shall state each deficiency and the documents and information needed to complete the renewal application.
 2. The 90-day time-frame for the Board to finish the administrative completeness review is suspended from the date the Board mails the deficiency notice to the applicant until the date the Board receives the needed documents and information.
 3. If an applicant does not submit a complete renewal application before May 1, the applicant's license expires, except that the license of a physician who does not renew the license and who has been advised in writing that an investigation is pending at the time the license is due to expire does not expire until the investigation is resolved. The license of a physician for whom an investigation is pending is suspended on the date it would otherwise expire and the physician shall not practice in this state until the investigation is resolved.
 4. If the submitted application is administratively complete, the Board shall send a written notice of renewal to the applicant.

Table 1. Time Frames (in calendar days)

<u>Type of License</u>	<u>Overall Time Frame</u>	<u>Administrative Review Time Frame</u>	<u>Time to Respond to Deficiency Notice</u>	<u>Substantive Review Time Frame</u>	<u>Time to Respond to Request for Additional Information</u>
<u>Initial License by Examination</u>	240	120	365	120	90
<u>Initial License by Endorsement</u>	240	120	365	120	90
<u>Locum Tenens or Pro Bono Registration</u>	120	60	30	60	30
<u>Temporary License</u>	60	30	30	30	30
<u>Teaching License</u>	40	20	30	20	30
<u>Educational Teaching Permit</u>	20	10	10	10	10
<u>Training Permit</u>	40	20	30	20	30
<u>Short Term Training Permit</u>	40	20	30	20	30
<u>One-year Training Permit</u>	40	20	30	20	30
<u>Registration to Dispense Controlled Substances and Prescription-only Drugs and Devices</u>	150	45	30	105	30

Arizona Administrative Register
Notices of Final Rulemaking

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

1. Sections Affected
R4-23-110
R4-23-692
R4-23-693
- Rulemaking Action
Amend
New Section
New Section
2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):
Authorizing Statutes: A.R.S. § 32-1904(A)(1)
Implementing Statutes: A.R.S. §§ 32-1901(8) through (11), 32-1929, and 32-1930(A)
3. The effective date of the rules:
January 12, 1998
4. A list of all previous notices appearing in the Register addressing the final rule:
Notice of Rulemaking Docket Opening: 1 A.A.R. 891, June 30, 1995
Notice of Rulemaking Docket Opening: 3 A.A.R. 248, January 24, 1997
Notice of Rulemaking Docket Opening: 3 A.A.R. 1934, July 18, 1997
Notice of Proposed Rulemaking: 3 A.A.R. 2722, October 10, 1997
5. The name and address of agency personnel with whom persons may communicate regarding the rule:
Name: Dean Wright, Compliance Officer
Address: Board of Pharmacy
5060 North 19th Avenue, Suite 101
Phoenix, Arizona 85015
Telephone: (602) 255-5125, Ext. 131
Fax: (602) 255-5740
6. An explanation of the rule, including the agency's reason for initiating the rule:

The rule establishes the requirements for the Compressed Medical Gas Distributor and Compressed Medical Gas Supplier permits created by the Forty-second legislative session in H.B. 2009. Although compressed medical gases have always been listed as prescription-only drugs by the federal act, there has never been anything specific in state statute. This change allows the Board to issue permits and conduct inspections. The only thing missing from the bill was a fee for the permits. The compressed medical gas rule implements this legislation.

To clarify terminology used in the new sections, the rule adds new definitions for "container", "current good manufacturing practice", "FDA", and "transfill" and amends the definition of "supplying". The rule adds new sections: R4-23-692 Compressed Medical Gas Distributor and R4-23-693 Compressed Medical Gas Supplier.

Section R4-23-692 establishes the permit, records, and inspection requirements for compressed medical gas distributors and incorporates by reference the current good manufacturing practice requirements of 21 CFR 210 through 211 of the federal act. The FDA already requires that compressed medical gas distributors comply with the federal current good manufacturing practice act. Instead of rewriting the federal act, the rule makes compliance with the federal current good manufacturing practice act a state requirement for an Arizona compressed medical gas distributor. A compressed medical gas distributor may manufacture, wholesale distribute, and supply direct to the consumer pursuant to a compressed medical gas order from a medical practitioner.

Section R4-23-693 establishes the permit, records, and inspection requirements for compressed medical gas suppliers. The FDA does not regulate compressed medical gas suppliers, so the rule establishes standards for this previously unregulated segment of the industry. A compressed medical gas supplier sells directly to the consumer or patient or their agent in the manufacturer's or distributor's original container pursuant to a compressed medical gas order from a medical practitioner.

The rule addresses grammar, format, and style changes necessary under the current administrative procedures act and other necessary language changes to provide a clear, concise, and understandable document.

The Board believes that adoption of these rules will benefit the public by establishing standards for the manufacture and distribution of compressed medical gases in Arizona.
7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:
Not applicable.

Arizona Administrative Register
Notices of Final Rulemaking

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

This economic, small business and consumer impact statement for the compressed medical gas rule analyzes the costs, savings, and benefits that accrue to the Board of Pharmacy, Secretary of State, permittees, and the public.

With the adoption of the proposed rule, the impact on established Board of Pharmacy procedures, Board staff time, Compliance Officer time, and other administrative and inspection related costs is substantial. The benefits to the Board and its compliance and office staff are non-quantifiable. The estimated additional cost to the Secretary of State's office is minimal. This additional cost stems from Secretary of State's staff time publishing the rules.

The Board bears the substantial costs of issuing permits to existing and future compressed medical gas distributors and suppliers and inspecting these permittees. The Board proposes to inspect each distributor and supplier once every two years. Based on the number of permits issued to date, there will be 39 distributor and 41 supplier inspections each year for a total annual cost of inspection of \$28,295.87. This figure will change as new outlets open or exiting outlets close. Under a contract with the FDA, for the period 9/30/95 to 9/29/96, the Board received revenue to cover the cost of inspecting 25 compressed medical gas distributors. Under a contract with the FDA, for the period 9/30/96 to 3/29/98, the Board will receive revenue to cover the cost of inspecting 37 compressed medical gas distributors. Total revenue to the Board for the two periods is \$32,512.86 which breaks down into an average annual revenue of \$13,005.12. There is no guarantee of future contracts with the FDA. The cost of continuing biennial inspections of compressed medical gas distributors and suppliers is borne by the Board. The rule imposes no additional financial impact unless the Board fails to meet the permit time frame limits. But even then there is no impact because the legislature did not establish a permit fee in the bill that created the compressed medical gas distributor and supplier permit. The Board does not foresee noncompliance with the time-frames.

The benefits provided by the proposed rules are non-quantifiable. Regulation by a state agency benefits the regulated public by increasing accessibility. The public and permittees will benefit from timely review and enforcement of compressed medical gas standards.

9. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

There were some formatting errors made by the Secretary of State's office during publishing of the proposed rulemaking. Section R4-23-692(C) in the published proposed rulemaking had subsections (a) and (b). The correct subsections as contained in this final rule are R4-23-692(C)(1) and (2). Section R4-23-693(B) in the published proposed rulemaking had subsections (a), (b), (c), and (d). The correct subsections as contained in this final rule are R4-23-693(B)(1), (2), (3), and (4). The errors were in numbering only not in rule content. There are no other changes between the proposed rules and the final rules.

10. A summary of the principal comments and the agency response to them:

There was 1 comment received via telephone in support of the proposed rule. A representative of the Board of Respiratory Care Examiners attended the public hearing and spoke in favor of the rule but had a concern that some distributors or suppliers of compressed medical gases might obtain a Board of Pharmacy permit and then not comply with Board of Respiratory Care Examiners statutes and rules concerning the administration of medical oxygen. The Board staff explained that the proposed rule deals with the manufacture and distribution of medical oxygen and not the administration. The Board feels that language could be written to ensure compressed medical gas distributor and supplier permittees comply with Board of Respiratory Care Examiners statutes and rules. After working on the proposed rule for over 2 years, the Board does not want to further delay passage of the rule. It is the Board's intent to proceed with the proposed rule as published. After the rule is approved by the Governor's Regulatory Review Council and filed with the Secretary of State, the Board staff will address this comment by opening a docket and drafting rule language in cooperation with the Board of Respiratory Care Examiners.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable.

12. Incorporations by reference and their location in the rules:

21 CFR 210 through 211, April 1, 1996, (and no future amendments or editions) located at A.A.C. R4-23-692(B).

13. Was this rule previously adopted as an emergency rule?

No.

14. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section

R4-23-110. Definitions

ARTICLE 6. PHARMACIST LICENSURE

R4-23-692. Compressed Medical Gas Distributor

R4-23-693. Compressed Medical Gas Supplier

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

"Active ingredient" means any component which is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body of man or other animals. The term shall include those components which may undergo chemical change in the manufacture of the drug and be present in the finished drug products

Arizona Administrative Register
Notices of Final Rulemaking

- in a modified form intended to furnish the specified activity or effect.
- “Authentication of product history” means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.
- “AZPLEX” means Arizona pharmacy law examination.
- “Batch” means a specific quantity of drug that has uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.
- “Beyond use date” means a date determined by a pharmacist and placed on a prescription label at the time of dispensing intended to indicate a time beyond which the contents of the prescription are not recommended to be used.
- “Biological safety cabinet” means a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel and environment, consistent with National Sanitation Foundation (NSF) standards, published in the National Sanitation Foundation Standard 49, Class II (Laminar Flow) Biohazard Cabinetry, Revised June 1987 edition, incorporated herein by reference and on file with the Office of the Secretary of State.
- “Class 100 environment” means an atmospheric environment in compliance with the Federal Standard 209 Clean Room and Work Station Requirements: Controlled Environment, publication FED-STD-209D, June 15, 1988 edition which includes January 28, 1991 changes, incorporated herein by reference and on file with the Office of the Secretary of State.
- “Community pharmacy” means any place under the direct supervision of a pharmacist where the practice of pharmacy occurs or where prescription orders are compounded and dispensed other than a hospital pharmacy or a limited service pharmacy.
- “Component” means any ingredient intended for use in compounding or manufacturing drugs in dosage form, including an ingredient that may not appear in the finished product.
- “Container” means
A receptacle, as described in the official compendium or the federal act, that is used in manufacturing or compounding a drug or in distributing, supplying, or dispensing the finished dosage form of a drug; or
A metal receptacle that is designed to contain liquefied or vaporized compressed medical gas and that is used in manufacturing, transfilling, distributing, supplying, or dispensing a compressed medical gas.
- “Correctional facility” has the same meaning as set forth in A.R.S. §§ 13-2501 and 31-341.
- “Current good compounding practices” means the minimum standards for methods used in, and facilities or controls used for, compounding a drug to ensure that the drug has the identity and strength and meets the quality and purity characteristics it purports or is represented to possess.
- “Current good manufacturing practice” means the minimum standard for methods to be used in, and facilities or controls to be used for manufacturing, processing, packing, or holding a drug to ensure that the drug meets the requirements of the federal act as to safety, and has the identity and strength and meets the quality and purity characteristics it purports or is represented to possess.
- “Cytotoxic” means a pharmaceutical that has the capability of killing living cells.
- “Drug sample” means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.
- “Extreme emergency” means the occurrence of a fire, water leak, electrical failure, public disaster or other catastrophe constituting an imminent threat of physical harm to pharmacy personnel or patrons.
- “FDA” means the Food and Drug Administration, a federal agency within the United States Department of Health and Human Services, established to set safety and quality standards for foods, drugs, cosmetics, and other consumer products.
- “First aid stations” means units within a business or industrial organization which are limited to, as the name implies, first aid treatment or injuries incurred in association with the business function.
- “Inactive ingredient” means any component other than an “active ingredient” present in a drug.
- “Industrial medical stations” means units where drugs are stored, established within businesses and industrial organizations.
- “Internal test assessment” means, but is not limited to, performing quality assurance procedures necessary to ensure the integrity of the test.
- “Limited-service correctional pharmacy” means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current permit issued by the Board pursuant to A.R.S. § 32-1931, is located in a correctional facility, and engages in the compounding, production, dispensing, and distribution of drugs.
- “Limited-service mail-order pharmacy” means a limited-service pharmacy, as defined in A.R.S. § 32-1931, that holds a current permit issued by the Board pursuant to A.R.S. § 32-1931, and dispenses a majority of its prescription medication or prescription-only devices by mailing or delivering the prescription medication or prescription-only device to an individual by the United States mail, a common or contract carrier, or a delivery service.
- “Limited-service nuclear pharmacy” means a limited service pharmacy, as defined in A.R.S. § 32-1901, that holds a current permit issued by the Board under A.R.S. § 32-1931, and provides radiopharmaceutical services.
- “Limited-service pharmacy permittee” means a person who has applied for and obtained a limited-service pharmacy permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and A.A.C. R4-23-606.
- “Long term care consultant pharmacist” means a pharmacist providing consulting services to a long term care facility.
- “Lot” means a batch or any portion of a batch of a drug or in the case of a drug produced by a continuous process, an amount of drug produced in a unit of time or quantity in a manner that assures it uniformity, and in either case which is identified by a distinctive lot number and has uniform character and quality with specified limits.
- “Lot number” or “control number” means any distinctive combination of letters or numbers, or both, from which the complete history of the compounding or manufacturing, control, packaging, and distribution of a batch or lot of a drug can be determined.
- “Materials approval unit” means any organizational element having the authority and responsibility to approve or reject components, in-process materials, packaging components and final products.
- “Mediated instruction” means learning transmitted via intermediate mechanisms such as audio and/or visual tape telephone transmission, etc.
- “NABPLEX” means National Association of Boards of Pharmacy Licensure Examination.

"Occupational Medicine" or "Industrial Medicine" means the field of medicine dealing with the medical problems associated with persons employed in any occupation.

"Outpatient" or "Outpatient setting" means a person that receives medical treatment as result of not being a residential patient in a health care institution, or a location where medical treatment is provided to patients not required to be overnight residents of the facility.

"Patient profile" means a readily retrievable, centrally located information record which contains, but is not limited to: patient demographics, allergies, and medication profile.

"Pharmaceutical care" means the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes, related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process, by identifying potential and actual drug-related problems, resolving actual drug-related problems, and preventing potential drug-related problems.

"Pharmacy law continuing education" means a continuing education activity that addresses practice issues related to state or federal pharmacy statutes, rules or regulations, offered by an Approved Provider.

"Prepackaged drug" means a drug which is packaged, ordinarily in frequently prescribed quantities, labeled, in compliance with A.R.S. §§ 32-1967 and 32-1968, for storage and subsequent dispensing by a pharmacist, or pharmacy intern under the supervision of a pharmacist, who at that time verifies that it is properly labeled for the patient.

"Provider pharmacist" means the pharmacist who supplies medication to a long term care facility and maintains medication profiles.

"Radiopharmaceutical" means any drug that emits ionizing radiation and includes:

Any nonradioactive reagent kit, nuclide generator, or ancillary drug intended to be used in the preparation of any radiopharmaceutical but does not include drugs such as carbon-containing compounds or potassium-containing salts, that contain trace quantities of naturally occurring radionuclides; and

Any biological product that is labeled with a radionuclide or intended to be labeled with a radionuclide.

"Radiopharmaceutical quality assurance" means the performance of appropriate chemical, biological, and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine the suitability of the potential radiopharmaceuticals for use in humans and animals. Radiopharmaceutical quality assurance includes internal test assessment, authentication of product history, and the keeping of proper records.

"Radiopharmaceutical services" means, the procuring, storing, handling, compounding, preparing, labeling, quality assurance testing, dispensing, distributing, transferring, record-keeping, and disposing of radiochemicals, radiopharmaceuticals, and ancillary drugs, and includes quality assurance procedures, radiological health and safety procedures, consulting activities associated with the use of radiopharmaceuticals, and any other activities required for the provision of pharmaceutical care.

"Remodel" means to structurally alter the pharmacy area or location.

"Remote drug storage area" means an area that is outside the premises of the pharmacy, used for the storage of drugs, locked to deny access by unauthorized persons, and secured against the use of force.

"Resident" means a person admitted to and residing in a long term care facility.

"Sterile pharmaceutical product" means a dosage form free from living micro-organisms.

"Strength" means:

The concentration of the drug substance (for example, w/w, w/v, or unit dose/volume basis) and/or

The potency, that is, the therapeutic activity of the drug substance as indicated by bioavailability tests or by controlled clinical data (expressed, for example, in terms of unity by reference to a standard).

"Supervision" means the pharmacist shall be present, assume legal responsibility, and have personal oversight of activities relating to the acquisition, preparation, distribution, and sale of prescription medications by pharmacy interns or supportive personnel.

"Supplying" is means selling, transferring, or delivering to a patient or a patient's agent the issuing of 1 or more doses of: A nonprescription proprietary drug in the original container of a manufacturer for subsequent use by the patient, or A compressed medical gas in the original container of a manufacturer or compressed medical gas distributor for subsequent use by the patient.

"Supportive Personnel" means an individual trained to perform activities related to the preparation and distribution of prescription medications, under the supervision of a pharmacist and consistent with policy and procedures as required in R4-23-403.

"Transfill" means the manufacturing process by which one or more compressed medical gases are transferred from a bulk container or containers to a properly labeled container or containers for subsequent distribution or supply.

"Wholesale distribution" means distribution of drugs to persons other than a consumer or patient, but does not include:

The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this section, "emergency medical reasons" includes transfer of prescription drugs by a community or hospital pharmacy to another community or hospital pharmacy to alleviate a temporary shortage; The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

The sale, purchase, or trade of blood and blood components intended for transfusion.

"Wholesale distributor" means any one engaged in wholesale distribution of drugs, including, but not limited to manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions in the amount of at least five percent of gross sales.

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-692. Compressed Medical Gas Distributor

A. Permit:

1. A person shall not manufacture, process, transfill, package, or label a compressed medical gas before a compressed medical gas distributor permit is issued by the Board or its designee following a satisfactory final inspection by a Board compliance officer.

Arizona Administrative Register
Notices of Final Rulemaking

2. Before operating as a compressed medical gas distributor, a person shall register with the FDA as a medical gas manufacturer and comply with the drug listing requirements of the federal act.
 3. To obtain a compressed medical gas distributor permit a person shall submit a completed application, on a form furnished by the Board, to the Board's office.
 4. A compressed medical gas distributor permittee shall distribute a compressed medical gas only:
 - a. Pursuant to a compressed medical gas order; and
 - b. If the compressed medical gas is listed on the distributor's permit application. To receive approval to distribute an additional compressed medical gas, the permittee shall request that the permit application be amended.
 - i. The permittee shall send a written request to amend the permit application to the Board office.
 - ii. The request shall include documentation that the FDA has approved manufacture of the additional compressed medical gas not listed on the original permit application.
 - iii. If a request to amend an original permit application includes the documentation referenced in subsection (A)(4)(b)(ii) and if the Board or its designee determines that the amendment is in the interest of public health and safety, the Board or its designee shall approve the request to amend within 30 days of receipt.
 5. A compressed medical gas distributor permit is subject to denial, suspension, or revocation under A.R.S. § 32-1932.
- B. Current Good Manufacturing Practice:** A compressed medical gas distributor permittee shall comply with the current good manufacturing practice requirements of 21 CFR 210 through 211, published April 1, 1996, (and no future amendments or editions), incorporated by reference and on file with the Board and the office of the Secretary of State.
- C. Records:** A compressed medical gas distributor permittee shall establish and implement written procedures for maintaining records pertaining to production, transfilling, process control, labeling, packaging, quality control, distribution, complaints, and any information required by federal or state law.
1. A permittee shall retain the records required by this Article and 21 CFR 210 through 211 for at least 2 years after distribution of the compressed medical gas or 1 year after the expiration date of the compressed medical gas, whichever is longer.
2. A permittee shall make the records required by this Article and 21 CFR 210 through 211 available within 48 hours for review by the Board, its compliance officers, or the FDA.
- D. Inspections:** A permittee shall make the compressed medical gas distributor's facility available for inspection by the Board or its compliance officers under A.R.S. § 32-1904.
- R4-23-693. Compressed Medical Gas Supplier**
- A. Permit:**
1. A person shall not supply a compressed medical gas before a compressed medical gas supplier permit is issued by the Board or its designee following a satisfactory final inspection by a Board compliance officer.
 2. To obtain a compressed medical gas supplier permit a person shall submit a completed application, on a form furnished by the Board, to the Board's office.
 3. A compressed medical gas supplier permittee shall supply a compressed medical gas only:
 - a. Pursuant to a compressed medical gas order, and
 - b. To the consumer, patient, or agent of the consumer or patient for whom the compressed medical gas order is written.
 4. A compressed medical gas supplier permittee shall not manufacture, process, transfill, package, or label a compressed medical gas, except as set forth in subsection (B)(2)
- B. Records:** A compressed medical gas supplier permittee shall establish and implement written procedures for maintaining records pertaining to acquisition and distribution of, and complaints related to, compressed medical gases.
1. A permittee shall ensure that a compressed medical gas order is obtained and filed for each compressed medical gas container supplied by the permittee.
 2. A permittee shall ensure that each compressed medical gas container supplied by the permittee contains a label bearing the name and address of the compressed medical gas supplier.
 3. A permittee shall retain the records required by this Article for at least 2 years after supplying the compressed medical gas or 1 year after the expiration date of the compressed medical gas, whichever is longer.
 4. A permittee shall make the records required by this Article available within 48 hours for review by the Board or its compliance officers.
- C. Inspections:** A permittee shall make the compressed medical gas supplier's facility available for inspection by the Board or its compliance officers under A.R.S. § 32-1904.

NOTICE OF FINAL RULEMAKING

TITLE 15. REVENUE

CHAPTER 10. DEPARTMENT OF REVENUE - GENERAL ADMINISTRATION

PREAMBLE

1. Sections Affected

Article 1
R15-10-101
R15-10-102
R15-10-102
R15-10-105
R15-10-107

Rulemaking Action

Amend
Amend
Repeal
New Section
Amend
Amend

Arizona Administrative Register

Notices of Final Rulemaking

R15-10-109	Amend
R15-10-117	Amend
R15-10-121	Amend
R15-10-130	Amend
R15-10-131	Amend
R15-10-132	Amend
R15-10-201	Amend

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes:A.R.S. §§ 42-105, 41-1003

Implementing statutes:A.R.S. §§ 41-1092.01, 41-1092.02, 42-122, 42-123, 42-124

3. The effective date of the rules:

January 20, 1998

4. A list of all previous notices appearing in the Register addressing the final rule:

Notice of Rulemaking Docket Opening:1 A.A.R. 2707, December 15, 1995

Notice of Rulemaking Docket Opening: 3 A.A.R.1222, May 2, 1997

Notice of Proposed Rulemaking: 3 A.A.R. 2359, August 29, 1997

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Ernest Powell, Tax Analyst

Address: Tax Research and Analysis Section
Arizona Department of Revenue
1600 West Monroe
Phoenix, Arizona 85007

Telephone: (602) 542-4672

Fax: (602) 542-4680

6. An explanation of the rule, including the agency's reasons for initiating the rule:

The rules provide taxpayers with the procedures to follow when appealing a decision of the department regarding taxes administered under A.R.S. § 42-111. The rules were initiated as a result of the department's 5-year review of Chapter 10 and subsequent legislative changes. The rules are adopted as repealed, added and amended to make them more clear, concise and understandable, to conform to current rulemaking guidelines and to incorporate legislative changes.

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

Not applicable.

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

Identification of the Rulemaking:

The department has adopted the rules as repealed, added and amended to make them more clear, concise and understandable and to conform to current rulemaking guidelines.

In addition, Laws 1995, Chapter 251 added a requirement that all administrative hearings regarding contested cases, other than income tax, withholding tax, estate tax, or any issue associated with income tax, withholding tax or estate tax shall be conducted by the newly created Office of Administrative Hearings. Laws 1996, Chapter 102 added a requirement for the Office of Administrative Hearings to conduct hearings regarding "Appealable agency actions." Laws 1996, Chapter 128 added a provision which allows taxpayers to appeal directly to tax court in certain circumstances. The department has adopted the rules as repealed, added and amended to incorporate the legislative changes.

Summary of Information in the Economic, Small Business, and Consumer Impact Statement:

It is expected that the benefits of the rules will be greater than the costs. The repeal, addition and amendment of these rules will benefit taxpayers by making the rules more clear, concise and understandable. In addition, the repeal, addition and amendment of the rules will benefit the taxpayers by making the rules conform with current statutes. The department will incur the costs associated with the rulemaking process. Taxpayers are not expected to incur any expense in the repeal, addition and amendment of these rules.

9. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

The Notice of Proposed Rulemaking submitted to the Secretary of State's Office showed strike-outs through the word "an" and underlining of the words "a" and "proposed" in R15-10-101(8). However, due to a publishing error, the strike-outs and underlining were not shown when it was published in the *Arizona Administrative Register*. The strike-outs and underlining are included in the rule as adopted.

Arizona Administrative Register
Notices of Final Rulemaking

The word "one" in R15-10-131(D) was changed to the numeric "1" when the Notice of Proposed Rulemaking was published in the *Arizona Administrative Register*. The word "one" is used in the rule as adopted.

The Notice of Proposed Rulemaking submitted to the Secretary of State's Office showed strike-outs through the language "which sets forth the reasons for the decision" in R15-10-131(I). However, due to a publishing error, the strike-outs were printed as underlining when it was published in the *Arizona Administrative Register*. The strike-outs are included in the rule as adopted.

In R15-10-131(D)(1) the word "are" is used rather than the word "is" after the underlined word "decision" and also after the stricken word "decision."

In addition, based on the review performed by staff to the Governor's Regulatory Review Council, the department corrected minor grammatical errors.

10. **A summary of the principal comments and the agency response to them:**
The department did not receive any written or oral comments on the rule action after the publication of the rulemaking in the Notice of Proposed Rulemaking.
11. **Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:**
None.
12. **Incorporations by reference and their location in the rules:**
None.
13. **Was the rule previously adopted as an emergency rule?**
No.
14. **The full text of the rules follows:**

TITLE 15. REVENUE

CHAPTER 10. DEPARTMENT OF REVENUE - GENERAL ADMINISTRATION

ARTICLE 1. APPEAL HEARING PROCEDURES

Section

- R15-10-101. Definitions
R15-10-102. ~~Scope of Article 1 Matters Subject to the Hearing Procedure Rules~~
R15-10-105. Petition
R15-10-107. Timeliness of Petition
R15-10-109. Memoranda
R15-10-117. Evidence
R15-10-121. Subpoena by Petitioner
R15-10-130. Decisions and Orders
R15-10-131. Review of Decision of the Hearing Officer or ALJ
R15-10-132. Appeal of the Final Order of the Department of Revenue to State Board of Tax Appeals, Division Two

denial, or any other action taken or proposed to be taken that is subject to appeal as a contested case or an appealable agency action under A.R.S. Title 41, Chapter 6 as issued by the Department.

- ~~4.~~ 5. "Petition" means a written request for hearing, correction, or redetermination ~~of a tax assessment or of a refund denial~~, including all applicable attachments.
- ~~5.~~ 6. "Petitioner" means the taxpayer or the representative of the taxpayer who files a petition.
- ~~7.~~ 7. "Refund denial" means a taxpayer's claim for a refund of tax, penalty, interest, or refundable credit that has been denied by the department.
- ~~8.~~ 6. "Tax assessment" means any tax issue whether associated with ~~a an~~ proposed amount due or the application of penalties and interest.
- ~~7.~~ 7. "Tax liability" means an amount due including the application of penalties and interest.

ARTICLE 2. ADMINISTRATION

Section

- R15-10-201. Closing agreements relating to tax liability

ARTICLE 1. APPEAL HEARING PROCEDURES

R15-10-101. Definitions

For purposes of the hearing procedure rules in this Article:

- ~~1.~~ 1. "ALJ" means an administrative law judge who issues decisions on behalf of the Office of Administrative Hearings established by A.R.S. § 41-1092.01.
- ~~2.~~ 2. "Day" means a calendar day. If the last day for filing a document under the provisions of this Article falls on a Saturday, Sunday, or legal holiday, the document ~~is~~ shall be considered timely if filed on the following business day.
- ~~3.~~ 2. "Department" means the Arizona Department of Revenue as represented by personnel of the applicable section or area.
- ~~4.~~ 3. "Notice" means ~~a the~~ written notification, determination issued by the Department, of a tax assessment, refund

R15-10-102. Scope of Article 1 Matters Subject to the Hearing Procedure Rules

A Department hearing officer shall conduct all hearings regarding taxes administered by the Department under A.R.S. § 42-111, unless A.R.S. § 41-1092.02 requires that an ALJ hear the matter. All matters assigned by the Director to the Hearing Office shall be handled under the hearing procedure rules unless otherwise provided.

R15-10-105. Petition

- A. The petitioner shall mail the petition ~~shall be directed to the applicable section at the Department of Revenue headquarters in Phoenix, Arizona or hand-deliver the petition to the License and Registration Section in any Department of Revenue office. A petitioner that hand-delivers a petition shall clearly mark the envelope to indicate that it is a petition. The License and Registration Section shall provide a receipt to a petitioner that hand delivers a petition. The Department shall not charge a No fee is charged for filing a petition or any supporting documents.~~

Arizona Administrative Register
Notices of Final Rulemaking

1. ~~A petition shall be filed by and in the name of the taxpayer as named on the notice or by and in the full name of the fiduciary or other person authorized to institute the proceedings. The petitioner shall sign the petition.~~
 2. ~~The petitioner A petition shall file the original and one copy of the petition be filed in duplicate.~~
- B. A petition regarding a tax assessment or a refund denial shall include the following:
1. ~~The taxpayer's Taxpayer's name, address, federal identification number, and all applicable state identification numbers number. If there is a difference-variance between the taxpayer's name set forth in the notice and the taxpayer's name in the petition of the petitioner, the petition shall contain an explanation of explanatory statement regarding the difference variance. A petition that concerns a married-filing-joint return shall include the last known name and address of both individuals;~~
 2. ~~A copy of the notice or a statement that which references the tax type and the tax period involved and contains includes the amount of the tax assessment liability or refund claimed including tax, penalties, interest and refundable credits denial, the tax period, and the amount in-controversy if different from the tax assessment;~~
 3. ~~A statement of the amount of the tax assessment or refund denial that is protested;~~
 4. ~~A statement Statement of errors alleged to have been committed by the Department in the determination of the tax assessment liability or refund denial that is protested;~~
 5. ~~A statement Statement of facts and legal arguments upon which the taxpayer relies to support the statement assignment of errors alleged to have been committed by the Department;~~
 6. ~~The relief Relief sought; and~~
 7. ~~Whether an oral hearing is requested; and~~
 8. ~~The payment for all unprotested amounts of tax, interest and penalties.~~
- C. A petition regarding matters other than a tax assessment or a refund denial shall include the following:
1. ~~The taxpayer's name, address, federal identification number, and all applicable state identification numbers. If there is a difference between the taxpayer's name in the notice and the taxpayer's name in the petition, the petition shall contain an explanation of the difference;~~
 2. ~~A copy of the notice or a statement describing the action, proposed action or determination for which a hearing is sought;~~
 3. ~~A statement of errors alleged to have been committed by the Department in its action;~~
 4. ~~A statement of facts and legal arguments upon which the taxpayer relies to support the statement of errors;~~
 5. ~~The relief sought; and~~
 6. ~~Whether an oral hearing is requested.~~

R15-10-107. Timeliness of Petition

- A. A petition regarding taxes other than individual income tax is timely filed with the Department if it is filed as prescribed by R15-10-105(A) is received by the Department within 45 days after the taxpayer receives the tax assessment or refund denial from the Department.
- B. A petition for an individual income tax assessment or refund denial is timely filed with the Department if it is filed as prescribed by R15-10-105(A) is received by the Department within 90 days after the Department mails mailing of a notice to the taxpayer.

- C. A petition or an extension request filed by mail is considered filed on the date shown by its U.S. Postal Service postmark.
 - D. ~~A taxpayer or the taxpayer's representative may request that the Hearing Office grant an extension of time to file a petition. A petition not filed on or before the statutory due date is untimely unless a request for extension has been granted.~~
 1. ~~The taxpayer or the taxpayer's representative petitioner shall submit an extension request in writing before the expiration of the time allowed for filing the petition in subsection (A) or subsection (B). statutory due date The request shall be in writing and shall show showing good cause for the extension. The Department may grant additional Additional time not to exceed 60 days may be granted at the discretion of the Hearing Office Officer or on stipulation of the parties.~~
 2. ~~If the Hearing Office does not grant the request for an extension in writing, the petition is due on the date specified in subsection (A) or subsection (B).~~
- E. ~~2: The Hearing Office Officer shall dismiss a petition which the Hearing Office Officer determines is not timely filed.~~
- F. ~~If the taxpayer does not file a petition protesting a deficiency assessment within the time prescribed, the taxpayer may, after paying the tax assessment in full, apply for a refund pursuant to statutory provisions.~~

R15-10-109. Memoranda

- A. ~~Any party to the hearing A petitioner may file a written memorandum memoranda, which further explains explain the facts or the application of the law to the facts, at any time before the conclusion of the hearing.~~
- B. ~~Any party to the hearing Post-hearing memoranda may submit a post-hearing memorandum be submitted by any party to the hearing at the discretion of the Hearing Officer or at the request of the Hearing Officer.~~
- C. Post-hearing memoranda shall be submitted within a reasonable period of time, as agreed to by the parties or as determined by the Hearing Officer.

R15-10-117. Evidence

- A. Each party to a hearing may:
 1. ~~Call call and examine witnesses,~~
 2. ~~Introduce introduce exhibits,~~
 3. ~~Cross-examine cross-examine opposing witnesses on any matter relevant to the issues even though the matter was not covered in the direct examination,~~
 4. ~~Dispute dispute the testimony of any witness regardless of which party first called the witness to testify, and~~
 5. ~~Challenge challenge the evidence presented. The Hearing Officer may call any party at the hearing, or other person who is present, to testify.~~
- B. The Hearing Officer shall admit any relevant evidence. ~~The Hearing Officer shall be liberal in admitting evidence, but shall consider objections to the admission of and comments on the weakness of evidence will be considered in assigning weight to the evidence. The Hearing Officer may deny admission of evidence that the Hearing Officer considers which is considered irrelevant, immaterial, or unduly repetitious.~~
- C. A party may substitute an exact copy of an original exhibit.
- D. ~~The Hearing Officer may call anyone at the hearing to testify.~~

R15-10-121. Subpoena by Petitioner

- A. A petitioner requesting a subpoena shall apply make application, accompanied by the subpoena being requested, to the Hearing Officer submitting a proposed subpoena at least 10 days before the hearing.

- B. ~~The Hearing Office shall not issue issuance of a subpoena for shall not be used to obtain confidential or privileged information.~~

R15-10-130. Decisions and Orders

- A. The Hearing Officer shall issue a written decision, which sets forth the reasons for the decision, after reviewing the evidence submitted by the petitioner and the Department.
- B. A decision dismissing a petition as incomplete or not timely filed shall be based on the Hearing Officer's review of the petition, documents available, and any information officially noticed.
- C. ~~The Hearing Office shall mail the decision of the Hearing Officer, by certified mail, shall be mailed to the last known address of the taxpayer petitioner, return receipt requested. The Hearing Office shall immediately forward a copy of the decision shall be immediately forwarded to the applicable section in the Department of Revenue and to the Director.~~

R15-10-131. Review of Decision of the Hearing Officer or ALJ

- A. ~~The Except as provided in subsection (B), the decision of the Hearing Officer or ALJ is the final order of the Department of Revenue, as of the date the petitioner receives the decision which is mailed return receipt requested pursuant to R15-10-130(C) unless, within 30 days after the taxpayer petitioner receives the decision unless prior to that time:~~
1. The petitioner or the Department petitions the Director to review the decision, or
 2. The Director independently determines that the decision requires review.
- B. The Director may grant an extension of time for filing a petition for review on a showing of good cause, if the request for an extension is in writing and is filed with the Director before the expiration of the 30-day period prescribed in subsection (A).
- C. A petition or an extension request filed by mail is considered filed on the date shown by the U.S. Postal Service postmark.
- D. ~~The Director may grant a review of the A decision of the Hearing Officer or ALJ if one of the parties asserts that any of the following causes has materially affected the party's rights may be reviewed based on evidence that the finding is not supported by the facts or by the law. Any of the following causes may be deemed valid in granting a review of a decision by the Hearing Officer:~~
1. ~~The That the findings of fact, conclusions of law, order or decision are not supported by the evidence or the decision is are contrary to law;~~
 2. The party seeking review was deprived of a fair hearing due to irregularity in the proceedings, abuse of discretion, or misconduct of the prevailing party;
 3. Accident or surprise which could not have been prevented by ordinary prudence;
 4. Material evidence which has been newly discovered, which with reasonable diligence could not have been discovered and produced at the hearing;
 5. Error in admission or rejection of evidence or other errors of law occurring at the hearing or during the progress of the action; or
 6. That the decision is the result of bias or prejudice.
- E. The Director may independently determine to review a decision of the Hearing Officer or ALJ if it appears that any of the causes listed in subsection (D) may have materially affected a party's rights.
- F. ~~The petition for review of the Hearing Officer's or ALJ's decision shall be in writing, shall state the grounds upon~~

which the petition is based, and the Director may grant leave to amend the petition may be amended at any time before it is ruled upon by the Director. At the time of filing, the petitioning party shall also serve a copy of the petition on the other party.

- G. ~~If Notice that the Director has independently determined that the decision requires review, the Director shall send, by certified mail, notification of intent to review to the taxpayer, be mailed, return receipt requested, to the petitioner, and forwarded to the Department not more than within 30 days after of the taxpayer's petitioner's receipt of the Hearing Officer's or ALJ's decision which is mailed return receipt requested pursuant to R15-10-130(C).~~
- H. ~~On petition for review, or on the Director's independent review:~~
1. The Director may open the decision of the Hearing Officer ~~Office or ALJ~~, take additional evidence, amend findings of fact and conclusions of law, or make new findings and conclusions, and issue a new decision;
 2. The Director may issue a decision that summarily denying the petition for review in which case the Director's decision affirms the Hearing Officer's decision of the Hearing Officer or ALJ; or
 3. The Director may remand any matter to the Hearing Office, the Office of Administrative Hearings, or the appropriate section or area of the Department at the request of either party or at the Director's discretion.
- I. ~~The Director's decision, which sets forth the reasons for the decision, shall be sent by certified mail mailed to the taxpayer petitioner, at the taxpayer's last known address, return receipt requested, and forwarded to the Hearing Office and the Department.~~
- J. The taxpayer may appeal a Director's decision or a decision that is final pursuant to subsection (A) to the State Board of Tax Appeals or tax court under R15-10-132.

R15-10-132. Appeal of the Final Order of the Department of Revenue to State Board of Tax Appeals, Division Two

- A. Within 30 days of the date an order of the Department becomes final, a taxpayer disputing the final order of the Department of Revenue may:
1. File an An appeal may be filed with the State Board of Tax Appeals, Division Two, or
 2. Bring an action in tax court, unless the case involves an individual income tax dispute of less than \$5,000, by a taxpayer disputing the final order of the Department of Revenue. The appeal shall be submitted as provided by law and rules of the Board.
- B. If the Director is reviewing the Hearing Officer's or ALJ's decision under R15-10-131 a party to the hearing process has requested review by the Director, such review by the Director shall be completed before an appeal can be taken to the State Board of Tax Appeals, Division Two or an action can be brought in tax court.

ARTICLE 2. ADMINISTRATION

R15-10-201. Closing Agreements Relating to Tax Liability

- A. A closing agreement Closing agreements provided for in Section A.R.S. § 42-123 or A.R.S. § 42-139.06 may relate to any taxable period.
1. A closing agreement entered into With respect to for taxable periods ending prior to the date of the agreement, the matter agreed upon may relate to the total liability of the taxpayer or it may relate to 1 or more separate items affecting the liability of the taxpayer.

Notices of Final Rulemaking

- 2. ~~A closing agreement entered into~~ With respect to for taxable periods ending subsequent to the date of the agreement, ~~the matter agreed upon may shall only~~ relate to one or more separate items affecting the liability of the taxpayer.
- 3. ~~B. The Department and the taxpayer may enter into a closing agreement~~ Closing agreements may be executed even though under the agreement the taxpayer is not liable for any tax for the period to which the agreement relates.
- 4. There may be a series of closing agreements relating to the liability of a taxpayer for a single taxable period. ~~Any tax or deficiency determined pursuant to a closing agreement shall be assessed and collected and or any overpayment determined pursuant to a closing agreement shall be credited or refunded in accordance with the applicable provision of the Arizona Revised Statutes, Title 42, Chapter 1, Article 2.~~
- B. A closing agreement shall be in writing and shall state the conditions of the agreement.
- C. A closing agreement is not effective until it is signed by the taxpayer or an authorized representative of the taxpayer, and ~~by an authorized employee of the Department. The procedure for entering into closing agreements shall be as follows:~~
 - 1. ~~Either the taxpayer or the Department shall prepare a proposed form of the agreement in writing stating conditions of the agreement and the applicable sections of the law under which it has been made.~~
 - 2. ~~Agreements generated by the taxpayer shall be signed by the taxpayer and submitted to the Department in triplicate.~~
 - 3. ~~After an agreement generated by the taxpayer has been received by the Department, it shall be reviewed and if acceptable, signed by an authorized employee of the Department. One of the signed copies shall be returned to the taxpayer. If the terms of an agreement generated by the taxpayer are not acceptable to the Department, the taxpayer shall be notified in writing of the reasons thereof.~~
- D. Tax periods subject to a closing agreement shall be reopened when a change or correction in tax liability is made by the Internal Revenue Service or the taxpayer at the federal level. All closing agreements shall provide for such reopening.

NOTICE OF FINAL RULEMAKING

TITLE 19. ALCOHOL, HORSE AND DOG RACING, LOTTERY, AND GAMING

CHAPTER 2. ARIZONA RACING COMMISSION

PREAMBLE

- 1. Sections Affected

R19-2-103	<u>Rulemaking Action</u>
R19-2-106	Amend
R19-2-303	Amend
R19-2-306	Amend
- 2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):
 - Authorizing statute: §§ 5-104(A)(2) and 5-104(T)
 - Implementing statute: §§ 5-107 and 5-107.01, 5-107.02, 5-108, 5-108.01, and Title 41, Chapter 6, Article 7.1
- 3. The effective date of the rules:

January 6, 1998
- 4. A list of all previous notices appearing in the Register addressing the final rule:
 - Notice of Rulemaking Docket Opening: 3 A.A.R. 2033, August 1, 1997
 - Notice of Proposed Rulemaking: 3 A.A.R. 2548, September 19, 1997
- 5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:
 - Name: Paul Ryneveld
 - Address: Arizona Department of Racing
3877 North 7th Street, Suite 201
Phoenix, Arizona 85014
 - Telephone: (602) 277-1704
 - Fax: (602) 277-1165
- 6. An explanation of the rule, including the agency's reasons for initiating the rule:

The amendments to the rules will establish time-frames for the issuance of licenses and permits as required by A.R.S. § 41-1072 et seq.

Arizona Administrative Register

Notices of Final Rulemaking

- 7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state: Not applicable.
8. The summary of the economic, small business, and consumer impact: There will be no economic impact to small businesses or consumers.
9. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable): Several minor grammatical changes were made to the final text...
10. A summary of the principal comments and the agency response to them: None.
11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules: None.
12. Incorporations by reference and their location in the rules: None.
13. Was this rule previously adopted as an emergency rule? No.
14. The full text of the rules follows:

TITLE 19. ALCOHOL, HORSE AND DOG RACING, LOTTERY, AND GAMING

CHAPTER 2. ARIZONA RACING COMMISSION

ARTICLE 1. HORSE RACING

- Section
R19-2-103. Permit Applications
R19-2-106. Licensing

ARTICLE 3. GREYHOUND RACING

- Section
R19-2-303. Permit Applications
R19-2-306. Licensing

ARTICLE 1. HORSE RACING

R19-2-103. Permit Applications

- A. Any person or persons, associations, or corporation desiring to hold or conduct a horse racing meeting within the state of Arizona shall file with the Commission 10 copies of a permit application as set forth in A.R.S. § 5-107.
B. The Department shall not issue a permit until the applicant has furnished the Commission with evidence of compliance with A.R.S. § 23-901 et seq. (Worker's Workmen's Compensation) and A.R.S. § 23-1101 et seq. (Occupational Disease Insurance).
C. Permit applicants shall submit to the Commission the names of the proposed track officials at least 60 days prior to the beginning of their meet, along with a short biographical sketch of each official not previously licensed in the same capacity by the Department.
D. A permit application shall specify the number of races to be run on a daily basis.
E. Racing shall be conducted only on those days granted by permit.
F. Permit Application Time-Frames
1. Administrative completeness review time-frame
a. Within 728 days after receiving an application package, the Department shall determine whether the application package contains the information required by subsections (A), (B), (C), and (D).

b. If the application package is incomplete, the Department shall issue a written notice that specifies what information is required and return the application. If the application package is complete, the Department shall provide a written notice of administrative completeness.

c. The Department shall deem an application package withdrawn if the applicant fails to file a complete application package within 180 days of being notified that the application package is incomplete.

2. Substantive review time-frame. Within 30 days after receipt of a complete application package, the Commission, with the recommendation of the Department, shall determine whether the applicant meets all substantive requirements and issue a written notice granting or denying the permit.

3. Overall time-frame. For the purpose of A.R.S. § 41-1073, the Department establishes the following time-frames for issuing a permit.

a. Administrative completeness review time-frame: 728 days;

b. Substantive review time-frame: 30 days;

c. Overall time-frame: 758 days.

4. Renewal and temporary permit time-frames. The administrative completeness review time-frame is 30 days, the substantive review time-frame is 30 days, and the overall time-frame is 60 days, excluding time for mailing. The renewal or temporary permit is considered administratively complete unless the Department issues a written notice of deficiencies to the applicant. Temporary permits are valid until a full permit is awarded or until the Commission revokes the temporary permit.

R19-2-106. Licensing

- A. All persons participating in any capacity in a racing meeting, including all persons who perform services in connection

Arizona Administrative Register

Notices of Final Rulemaking

with the conduct of the racing meeting, shall be required to obtain a license from the Department, except:

1. Those persons performing services during a county fair race meet who are identified as volunteers volunteer help.
2. Any person owning less than 10% of all classifications and types of outstanding shares of stock of any permittee or licensee.

B. Applications

1. A person applying An application for a license shall complete the be made on a form prescribed by the Department. All applicants and all licensees are obligated to know and follow the provisions of the rules governing racing in the state of Arizona.
2. The Department may issue written instructions regarding as to the preparation and execution of the license application, and the which instructions may be a part of or separate from the application form, or both.
3. A schedule of license and fingerprint processing fees shall be displayed prominently at each track.
4. Each applicant 18 years of age or older shall submit to being fingerprinted. The fingerprints Said prints shall be taken by the Department or certified by a municipal police department, sheriff's office, or other recognized authority acceptable to the Department.

C. License applications shall be submitted to the Department office located on the grounds of a permittee or other designated facility.

D. License procedure

1. A license application shall be granted or denied by a steward and transmitted to the Director.
2. In considering each application for a license, the steward may require the applicant, as well as the such applicant's endorsers, to appear before the steward and show that the said applicant is qualified in every respect to receive the license requested. Ability as well as integrity shall be clearly shown by the applicant in order to receive a license.
3. An applicant who fails to pass the test for a trainer's license shall wait at least 6 months before retaking the test.
4. Administrative completeness review time-frame.
 - a. Within 85 days after receiving an application package, the Department shall determine whether the application package contains the information required by subsections (B), (C), and (D)(1), (D)(2), and (D)(3).
 - b. If the application package is incomplete, the Department shall issue a written notice that specifies what information is required and return the application. If the application package is complete, the Department shall provide a written notice of administrative completeness.
 - c. The Department shall deem an application package withdrawn if the applicant or licensee fails to file a complete application package within 10 days of being notified that the application package is incomplete.
5. Substantive review time-frame: Within 5 days after receipt of a complete application package, the Department shall determine whether the applicant or licensee meets all substantive requirements and issue a written notice granting or denying a license.

6. Overall time-frame: For the purpose of A.R.S. § 41-1073, the Department establishes the following time-frames for issuing a license.

- a. Administrative completeness review time-frame: 85 days.
- b. Substantive review time-frame: 5 days.
- c. Overall time frame: 90 days.

7. Temporary license time-frames. All licenses are temporary for 90 days under A.R.S. § 5-108(F). Unless the Department denies the applicant, the temporary license automatically becomes a license after 90 days. The administrative completeness review time-frame for a temporary license is 1 day, the substantive review time-frame is 1 day, and the overall time-frame is 2 days, excluding time for mailing. A temporary license is considered administratively complete unless the Department issues a written notice of deficiencies to the applicant.

E. Denials

1. A license may be denied if the applicant:
 - a. Habitually has Has been or habitually is intoxicated or a user of narcotics within the grounds of the permittee pursuant to A.R.S. § 36-2501(A)(8);
 - b. Has failed to disclose the true ownership or interest in any horse.
2. Whenever a license is denied, the Department shall report the reasons for the denial shall be reported in writing to the applicant and to the Association of Racing Commissioners International, Inc. and the North American Pari-mutuel Regulators Association.

F. General requirements and restrictions

1. A licensee who is employed in more than 1 category or who changes from 1 category to another shall must be licensed in each category.
2. A licensee who is an official at different types of tracks (horse, harness, or greyhound) shall must be licensed at each type of track.
3. The Department shall not license a A person under 16 years of age may not be licensed in any capacity other than as an owner, and shall not license a no person under 18 shall be licensed as an official, trainer or assistant trainer. Any person owner under 18, licensed as an owner, shall have a parent or guardian sign the such owner's license application, the parent or guardian assuming full financial responsibility for the applicant, before that person can be licensed.
4. Each license shall expire on the 30th day of June, 1995, and every 3rd year thereafter, except that:
 - a. Apprentice jockey licenses expire as provided in R19-2-109(D)(1)(c).
 - b. One-year licenses may be issued for mutuel workers, concession workers, and peace officers. Such licenses shall expire on the 30th day of June, 1995, and every year thereafter.
5. All persons, when present in the barn area of a horse track, in paddock areas, or in any other restricted area shall must wear, in full view, a their photo identification badge badges issued by the Department or a pass issued by the permittee in full view.

G. Fees

1st Year 2nd Year 3rd Year

1. Three-year licenses:
 - a. New stable name: \$124 \$112 \$100
 - b. Owner/trainer, jockey agent, jockey, or

Notices of Final Rulemaking

- | | | | | |
|----|--|----|----|----|
| | apprentice jockey: | 75 | 50 | 25 |
| c. | Owner, trainer, assistant trainer, veterinarian, authorized agent, official, lessee, lessor, or stable name renewal: | 36 | 24 | 12 |
| d. | Occupational license: | 15 | 10 | 5 |
| 2. | One-year licenses: | 7 | | |
| 3. | Duplicate license: | 5 | 5 | 5 |
| 4. | Temporary claiming license: | 36 | 36 | 36 |
| 5. | Authorized agent when licensed in another category: | 5 | 5 | 5 |
| 6. | Authorized agent when not licensed in another category: | 36 | 24 | 12 |
- H. All licenses are temporary under A.R.S. § 5-108(F) until completion of necessary The Department shall perform background investigation, including fingerprint fingerprinting processing through the Department of Public Safety and the FBI, and research and review of records of the Association of Racing Commissioners International, Inc., the North American Pari-mutuel Regulators Association, information systems, courts, law enforcement agencies, and the Department within time-frame prescribed in R19-2-106(D)(4).
- I. Authorized agents
1. A person may hold a license ~~An authorized agent may be licensed solely as an authorized agent or be licensed as an authorized agent and may also be licensed in another category.~~
 2. The principal shall sign the application for a license on behalf of as an authorized agent shall be signed by the principal and clearly set forth the powers of the agent, including whether the agent is empowered to collect money from the permittee. The application ~~Such instrument shall be either notarized or signed in the presence of a Department employee and a copy filed with the horsemen's horsemen's bookkeeper and with the Department.~~
 3. The principal shall change ~~Changes in an agent's powers or revoke revocation of an agent's authority shall be in writing, that is either notarized or signed in the presence of a Department official, and shall be filed with the Department and the horsemen's bookkeeper.~~

ARTICLE 3. GREYHOUND RACING

R19-2-303. Permit Applications

- A. Any person or persons, associations, or corporation desiring to hold or conduct a horse racing meeting within the state of Arizona shall file with the Commission 10 copies of a permit application as set forth in A.R.S. § 5-107.
- B. The Department shall not issue a permit ~~No permit shall be issued until the applicant has furnished the Commission with evidence of compliance with A.R.S. § 23-901 et seq. (Worker's Workmen's Compensation) and A.R.S. § 23-1101 et seq. (Occupational Disease Insurance).~~
- C. Permit applicants shall submit to the Commission the names of the proposed track officials at least 60 days prior to the beginning of their meet, along with a short biographical sketch of each official not previously licensed in the same capacity by the Department.
- D. A permit application shall specify the number of races to be run on a daily basis.
- E. Racing shall be conducted only on those days granted by permit.
- F. Permit Application Time-Frames.
 1. Administrative completeness review time-frame.

- a. Within 728 days after receiving an application package, the Department shall determine whether the application package contains the information required by subsections (A), (B), (C), and (D).
 - b. If the application package is incomplete, the Department shall issue a written notice that specifies what information is required and return the application. If the application package is complete, the Department shall provide a written notice of administrative completeness.
 - c. The Department shall deem an application package withdrawn if the applicant fails to file a complete application package within 180 days of being notified that the application package is incomplete.
2. Substantive review time-frame. Within 30 days after receipt of a complete application package, the Commission, with the recommendation of the Department, shall determine whether the applicant meets all substantive requirements and issue a written notice granting or denying a permit.
 3. Overall time-frame. For the purpose of A.R.S. § 41-1073, the Department establishes the following time-frames for issuing a license:
 - a. Administrative completeness review time-frame: 728 days.
 - b. Substantive review time-frame: 30 days.
 - c. Overall time-frame: 758 days.
 4. Renewal and temporary permit time-frames. The administrative completeness review time-frame is 30 days, the substantive review time-frame is 30 days, and the overall time-frame is 60 days, excluding time for mailing. The renewal or temporary permit is considered administratively complete unless the Department issues a written notice of deficiencies to the applicant. Temporary permits are valid until a full permit is awarded or until the Commission revokes the temporary permit.

R19-2-306. Licensing

- A. All persons participating in any capacity in a racing meeting, including all persons who perform services in connection with the conduct of the racing meeting, shall be required to obtain a license from the Department, except:
 1. Those persons performing services during a county fair race meet who are identified as volunteers ~~volunteer help.~~
 2. Any person owning less than 10% of all classifications and types of outstanding shares of stock of any permittee or licensee.
- B. Applications
 1. A person applying ~~An application for a license shall complete the be made on a form prescribed by the Department. All applicants and all licensees are obligated to know and follow the provisions of the rules governing racing in the state of Arizona.~~
 2. The Department may issue written instructions regarding as to the preparation and execution of the license application, and the which instructions may be a part of or separate from the application form, or both.
 3. A schedule of license and fingerprint processing fees will be displayed prominently at each track.
 4. Each applicant 18 years of age or older shall submit to being fingerprinted. The fingerprints ~~Said prints shall be taken by the Department or certified by a municipal police department, sheriff's office, or other recognized authority acceptable to the Department.~~

Notices of Final Rulemaking

- C. License applications shall be submitted to the Department office located on the grounds of a permittee or at another designated facility.
- D. License procedure
1. A license application shall be granted or denied by a steward and transmitted to the Director.
 2. In considering each application for a license, the steward may require the applicant, as well as ~~the~~ such applicant's endorsers, to appear before the steward and show that ~~the~~ said applicant is qualified in every respect to receive the license requested. Ability as well as integrity shall be clearly shown by the applicant in order to receive a license.
 3. An applicant who fails to pass the test for a trainer's license must wait at least 6 months before retaking the test.
 4. Administrative completeness review time-frame.
 - a. Within 85 days after receiving an application package, the Department shall determine whether the application package contains the information required by subsections (B), (C), and (D)(1), (D)(2), and (D)(3).
 - b. If the application package is incomplete, the Department shall issue a written notice that specifies what information is required and return the application. If the application package is complete, the Department shall provide a written notice of administrative completeness.
 - c. The Department shall deem an application package withdrawn if the applicant or licensee fails to file a complete application package within 10 days of being notified that the application package is incomplete.
 5. Substantive review time-frame. Within 5 days after receipt of a complete application package, the Department shall determine whether the applicant or licensee meets all substantive requirements and issue a written notice granting or denying a license.
 6. Overall time-frame. For the purpose of A.R.S. § 41-1073, the Department establishes the following time-frames for issuing a license:
 - a. Administrative completeness review time-frame: 85 days.
 - b. Substantive review time-frame: 5 days.
 - c. Overall time-frame: 90 days.
 7. Temporary license time-frames. All licenses are temporary for 90 days under A.R.S. § 5-108(F). Unless the Department denies the applicant, the temporary license automatically becomes a license after 90 days. The administrative completeness review time-frame for a temporary license is 1 day, the substantive review time-frame is 1 day, and the overall time-frame is 2 days, excluding time for mailing. A temporary license is considered administratively complete unless the Department issues a written notice of deficiencies to the applicant.
- E. Denials
1. A license may be denied if the applicant:
 - a. ~~Habitually has~~ Has been or ~~habitually~~ is intoxicated or a user of narcotics within the grounds of the permittee pursuant to A.R.S. § 36-2501(A)(8),
 - b. Has failed to disclose the true ownership or interest in any greyhound.
 2. Whenever a license is denied, ~~the Department shall report~~ the Department shall report the reasons for the denial ~~shall be reported~~ in

- writing to the applicant and to the Association of Racing Commissioners International, Inc. and the North American Pari-mutuel Regulators Association.
- F. General requirements and restrictions
1. A licensee who is employed in more than 1 category or who changes from 1 category to another ~~shall~~ must be licensed in each category.
 2. A licensee who is an official at different types of tracks (horse, harness, or greyhound) ~~shall~~ must be licensed at each type of track.
 3. ~~The Department shall not license a~~ A person under 16 years of age ~~may not be licensed~~ in any capacity other than as an owner; and shall not license a ~~no~~ person under 18 ~~shall be licensed~~ as an official, trainer, or assistant trainer. Any person ~~owner~~ under 18, licensed as an owner, shall have a parent or guardian sign ~~the~~ such owner's license application, ~~the parent or guardian~~ assuming full financial responsibility for the applicant, before that person can be licensed.
 4. Each license shall expire on the 31st day of January, 1996, and every 3rd year thereafter, except that one-year licenses may be issued for mutuel workers, concession workers, lead-outs, cool-outs and peace officers. Such licenses shall expire on the 31st day of January, 1996, and every year thereafter.
 5. All persons, when present in the kennel area of a greyhound track, in paddock areas, or in any other restricted area, shall wear ~~a~~ in full view their photo identification ~~badge~~ badges issued by the Department or ~~pass~~ passes issued by the permittee ~~in full view.~~
- G. Fees:
- | | 1st Year | 2nd Year | 3rd Year |
|---|----------|----------|----------|
| 1. Three-year licenses: | | | |
| a. New kennel name: | \$124 | \$112 | \$100 |
| b. Owner/trainer: | 75 | 50 | 25 |
| c. Racing kennel, breeding farm, or other operation: | 75 | 50 | 25 |
| d. Owner, trainer, veterinarian, official, lessee, lessor, assistant trainer, kennel name renewal, or kennel owner: | 36 | 24 | 12 |
| e. Occupational license: | 15 | 10 | 5 |
| 2. One-year licenses: | 7 | | |
| 3. Duplicate license: | 5 | 5 | 5 |
| 4. Authorized agent when licensed in another category: | 5 | 5 | 5 |
| 5. Authorized agent when not licensed in another category: | 36 | 24 | 12 |
- H. All licenses are temporary under A.R.S. § 5-108(F) ~~until completion of necessary~~ The Department shall perform a background investigation, including fingerprint fingerprinting processing through the Department of Public Safety and the FBI, and research and review of records of the Association of Racing Commissioners International, Inc., the North American Pari-mutuel Regulators Association, information systems, courts, law enforcement agencies, and the Department within the time-frame prescribed in R19-2-306(D)(4).
- I. Authorized agents
1. ~~A person may hold a license~~ An authorized agent may be licensed solely as an authorized agent or be licensed as an authorized agent and may also be licensed in another category.

2. The principal shall sign the application for a license as an authorized agent ~~shall be signed by the principal~~ and clearly set forth the powers of the agent, including whether the agent is empowered to collect money from the permittee. The application ~~Such instrument~~ shall be either notarized or signed in the presence of a Department employee and a copy filed with the track bookkeeper. ~~If there is a separate the written instrument is a~~

power of attorney, the principal shall file a copy of the said instrument ~~shall be filed~~ with the bookkeeper and the Department.

3. The principal shall change ~~Changes in~~ an agent's powers or revoke ~~revocation of~~ an agent's authority shall be in writing; that is either notarized or signed in the presence of a Department official, and ~~shall be~~ filed with the Department and the track bookkeeper.