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From the Publisher

ABOUT THIS PUBLICATION

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

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

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

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

ABOUT RULES

Rules can be: made (all new text); amended (rules on file, changing text); repealed (removing text); or renumbered (moving rules to a different Section number).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

New rules in this publication (whether proposed or made) are denoted with underlining; repealed text is stricken.

WHERE IS A "CLEAN" COPY OF THE FINAL OR EXEMPT RULE PUBLISHED IN THE *REGISTER*?

The *Arizona Administrative Code* (A.A.C) contains the codified text of rules. The A.A.C. contains rules promulgated and filed by state agencies that have been approved by the Attorney General or the Governor's Regulatory Review Council. The *Code* also contains rules exempt from the rulemaking process.

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

LEGAL CITATIONS AND FILING NUMBERS

On the cover: Each agency is assigned a Chapter in the *Arizona Administrative Code* under a specific Title. Titles represent broad subject areas. The Title number is listed first; with the acronym A.A.C., which stands for the *Arizona Administrative Code*; following the Chapter number and Agency name, then program name. For example, the Secretary of State has rules on rulemaking in Title 1, Chapter 1 of the *Arizona Administrative Code*. The citation for this Chapter is 1 A.A.C. 1, Secretary of State, Rules and Rulemaking.very document filed in the office is assigned a file number. This number, enclosed in brackets, is located at the top right of the published documents in the *Register*. The original filed document is available for 10 cents a page.

Arizona Administrative REGISTER

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ADMINISTRATIVE REGISTER
This publication is available online for free at www.azsos.gov.

ADMINISTRATIVE CODE
A price list for the *Arizona Administrative Code* is available online at www.azsos.gov.

PUBLICATION DEADLINES

Publication dates are published in the back of the *Register*. These dates include file submittal dates with a three-week turnaround from filing to published document.

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Participate in the Process

Look for the Agency Notice

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

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

Attend a public hearing/meeting

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

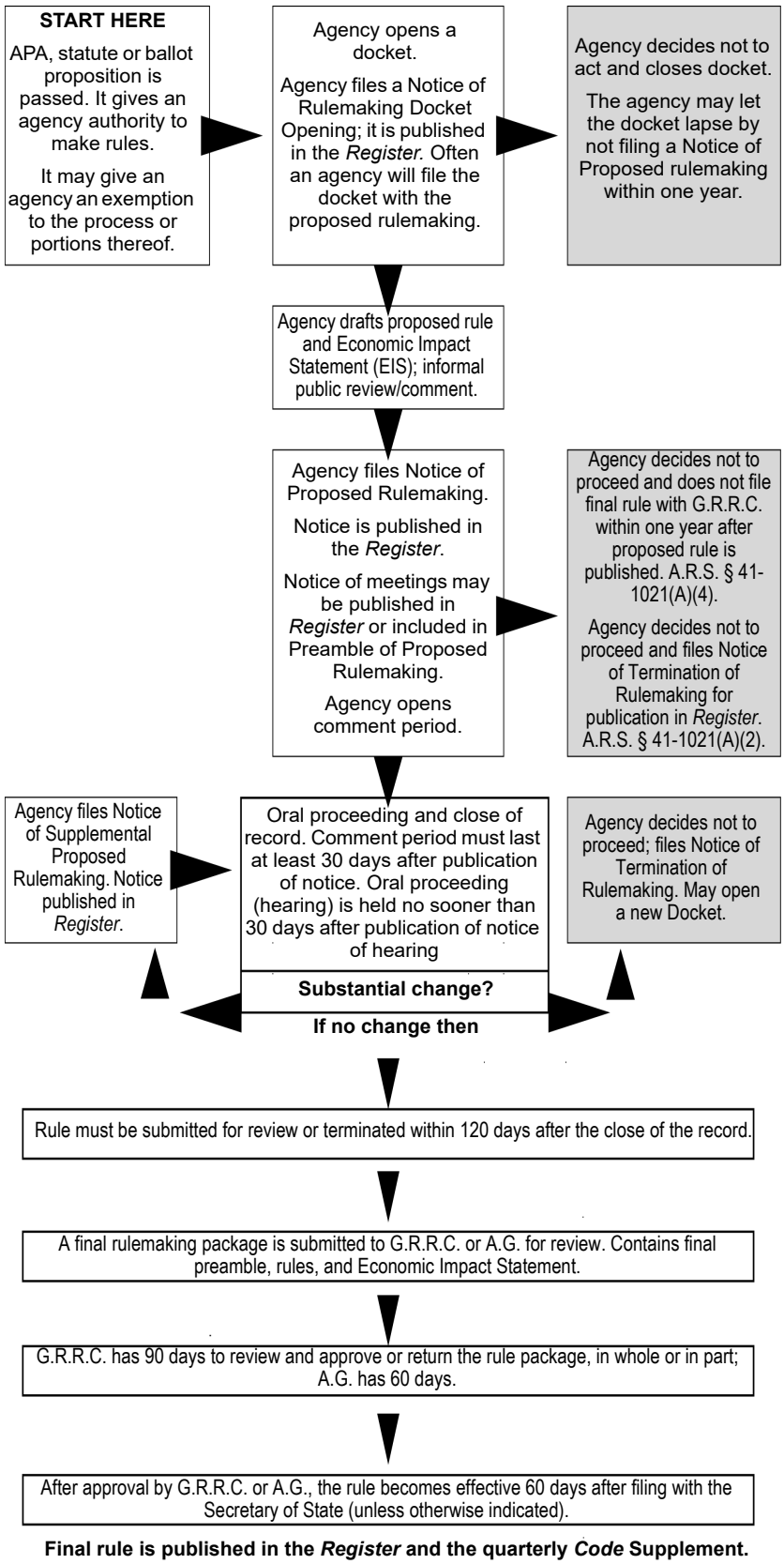
An agency may not have a public meeting scheduled on the Notice of Proposed Rulemaking. If not, you may request that the agency schedule a proceeding. This request must be put in writing within 30 days after the published Notice of Proposed Rulemaking.

Write the agency

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

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

Arizona Regular Rulemaking Process



Definitions

***Arizona Administrative Code* (A.A.C.):** Official rules codified and published by the Secretary of State's Office. Available online at www.azsos.gov.

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

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

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

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

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

Code of Federal Regulations (CFR): The *Code of Federal Regulations* is a codification of the general and permanent rules published in the *Federal Register* by the executive departments and agencies of the federal government.

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

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

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

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

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

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

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

Acronyms

A.A.C. – *Arizona Administrative Code*

A.A.R. – *Arizona Administrative Register*

APA – Administrative Procedure Act

A.R.S. – Arizona Revised Statutes

CFR – *Code of Federal Regulations*

EIS – Economic, Small Business, and Consumer Impact Statement

FR – *Federal Register*

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

U.S.C. – *United States Code*

About Preambles

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

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

The information in the Preamble differs between rulemaking notices used and the stage of the rulemaking.

NOTICES OF PROPOSED RULEMAKING

This section of the *Arizona Administrative Register* contains Notices of Proposed Rulemaking.

A proposed rulemaking is filed by an agency upon completion and submittal of a Notice of Rulemaking Docket Opening. Often these two documents are filed at the same time and published in the same *Register* issue.

When an agency files a Notice of Proposed Rulemaking under the Administrative Procedure Act (APA), the notice is published in the *Register* within three weeks of filing. See the publication schedule in the back of each issue of the *Register* for more information.

Under the APA, an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for making, amending, or repealing any rule (A.R.S. §§ 41-1013 and 41-1022).

The Office of the Secretary of State is the filing office and publisher of these rules. Questions about the interpretation of the proposed rules should be addressed to the agency that promulgated the rules. Refer to item #4 below to contact the person charged with the rulemaking and item #10 for the close of record and information related to public hearings and oral comments.

NOTICE OF PROPOSED RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 9. ~~EXPIRED~~DEPARTMENT OF HEALTH SERVICES PROCUREMENT ORGANIZATIONS

[R22-11]

PREAMBLE

1. Article, Part, or Section Affected (as applicable) — **Rulemaking Action**

Article 1	New Article
R9-9-101	New Section
R9-9-102	New Section
R9-9-103	New Section
R9-9-104	New Section
R9-9-105	New Section
R9-9-106	New Section
R9-9-107	New Section
R9-9-108	New Section
Table 1.1	New Table
Article 2	New Article
R9-9-201	New Section
R9-9-202	New Section
R9-9-203	New Section
R9-9-204	New Section
R9-9-205	New Section
Article 3	New Article
R9-9-301	New Section
R9-9-302	New Section
R9-9-303	New Section
R9-9-304	New Section
R9-9-305	New Section
Article 4	New Article
R9-9-401	New Section
R9-9-402	New Section
R9-9-403	New Section

2. Citations to the agency's statutory rulemaking authority to include authorizing statutes (general) and the implementing statutes (specific):

Authorizing statute: A.R.S. §§ 36-104(3) and 36-136(G)

Implementing statutes: A.R.S. §§ 36-851.01, 36-851.02, and 36-581.03

3. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the proposed rule:

Notice of Rulemaking Docket Opening: 27 A.A.R. 851, June 4, 2021

4. The agency's contact person who can answer questions about the rulemaking:

Name: Thomas Salow, Branch Chief
Address: Arizona Department of Health Services
Public Health Licensing Services
150 N. 18th Ave., Suite 400
Phoenix, AZ 85007-3232
Telephone: (602) 364-1935
Fax: (602) 364-3808
Email: Thomas.Salow@azdhs.gov
or
Name: Robert Lane, Chief
Address: Arizona Department of Health Services
Administrative Counsel and Rules
150 N. 18th Ave., Suite 200
Phoenix, AZ 85007
Telephone: (602) 542-1020
Fax: (602) 364-1150
Email: Robert.Lane@azdhs.gov

5. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

Laws 2016, Ch. 292 § 3, adds A.R.S. §§ 36-851.01, 36-851.02, and 36-851.03. A.R.S. § 36-851.01 requires that a person acting as a procurement organization in Arizona be licensed by the Arizona Department of Health Services (Department), except as provided in A.R.S. § 36-851.01(F). A.R.S. § 36-851.02 specifies requirements for accredited procurement organizations, and A.R.S. § 36-851.03 specifies requirements for procurement organizations that are not an accredited procurement organization. Additionally, Laws 2017, Ch. 171 in A.R.S. § 36-841 added a definition for "non-transplant anatomical donation organization" (NADO). Laws 2016, Ch. 292 adds requirements specific to a NADO's scope of practice including donor acceptability and acquisition, traceability, transport, preparation, packaging, labeling, storage, release, evaluation of intended use, distribution and final disposition of non-transplant anatomical donation. Laws 2016, Ch. 292 also requires the Department to "adopt rules relating to the licensure of procurement organizations and enforcement of those provisions." Additionally, the Department adopts rules that follow, as nearly as practicable, requirements equivalent to the accreditation requirements of a nationally recognized accrediting agency approved by the Department specified in A.R.S. § 36-851.03. The Department approves the American Association for Tissue Banks and the Standards for Non-Transplant Anatomical Donations, 2nd Edition. The rulemaking adds new: A.A.C. Title 9, Ch. 9; Article 1, Procurement Organization Licensure; Article 2, Administration for a Non-Accredited Procurement Organization; Article 3, Physical Plant; Transportation for a Non-Accredited Procurement Organization; and Article 4, Administration for an Accredited Procurement Organization. The Department plans to promulgate rules in Title 9, Ch. 9 through regular rulemaking according to A.R.S. Title 41**,** Chapter 6.

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

The Department did not review or rely on any study for this rulemaking.

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

Not applicable

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

In the 2022 Economic, Small Business, and Consumer Impact Statement, annual costs and benefits associated with the 9 A.A.C. 9 rulemaking are designated as minimal when more than $0 and less than $1,000, moderate when between $1,000 and $10,000, and substantial when greater than $10,000. Costs or benefits are indicated as significant when meaningful or important and not readily subject to quantification. No new FTEs are required due to this rulemaking. Currently, there are four accredited procurement organizations operating in Arizona and the four are accredited by the American Association of Tissue Banks (AATB).

The Department identifies affected persons as the Department, procurement organizations, contracted services providers, education and research facilities, and individuals responsible for a donor and donors. The Department anticipates it will incur a moderate cost related to promulgating rules and establishing a program to license NADOs, including the administration, application process, and inspections. The Department also anticipates that a moderate benefit may occur for having rules allowing the Department to inspect a NADO rather than responding to a concerned citizen reporting a public nuisance. NADOs may incur a moderate benefit for having an Arizona state license posted that allows individuals seeking services to confirm that a NADO is licensed by the state and is compliant with state laws. NADOs may incur a moderate cost related to the licensing fee. However, an accredited NADO who chooses to drop accreditation for Arizona state license may receive a significant benefit for reduced costs for no longer having to comply with AATB's required fees for accreditation. At is time, the Department has not collected information from the accredited NADOs that would indicate how minor or great their costs may be. Since accredited NADOs already operate according to the AATB Standards for Non-Transplant Anatomical Donations and the NADOs are mostly complaint with the proposed procurement organization rules, the Department expects NADOs' cost to be limited to the fee paid to obtain an Arizona license.

Contracted services providers who provide medical supplies and devices, reagents, testing materials, transport services, and other related devices, materials, and services are not expected to incur any additional costs or benefits from accredited NADOs. How-

ever, if a new NADO were to open, contracted services providers may receive a substantial benefit for selling goods and services to a newly established licensed NADO. Similarly, education and research facilities may receive a substantial benefit for having another source from whom non-transplant anatomical material and NTAD may be procured. Lastly, the Department expects individuals responsible for a donor and donors may receive a substantial benefit for having a state licensed NADO accepting their donation that will respect and use the donation as agreed to in the donor consent form. The Department does not expect individuals responsible for a donor or a donor will incur any costs related to the donation, since for many, the NADO services provided will include cremation at no costs to the donor or individuals responsible for a donor. The Department has determined that the benefits received for having rules that license NADOs in Arizona outweigh the potential costs associated with this rulemaking.

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

Name: Thomas Salow, Branch Chief
Address: Arizona Department of Health Services
Public Health Licensing Services
150 N. 18th Ave., Suite 400
Phoenix, AZ 85007-3232
Telephone: (602) 364-1935
Fax: (602) 364-3808
Email: Thomas.Salow@azdhs.gov
or
Name: Robert Lane, Chief
Address: Arizona Department of Health Services
Administrative Counsel and Rules
150 N. 18th Ave., Suite 200
Phoenix, AZ 85007
Telephone: (602) 542-8819
Fax: (602) 364-1150
Email: Robert.Lane@azdhs.gov

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

The Department has scheduled the following oral proceeding:

Date and time: Thursday, March 10, 2022 at 2:00 p.m.

Telephone: +1 470-228-6200 PIN: 531 044 181#

Close of record: 4:00 p.m., March 10, 2022

A person may submit written comments on the proposed rules no later than the close of record to either of the individuals listed in items #4 and #9.

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

There are no other matters prescribed by statutes applicable specifically to the Department or this specific rulemaking.

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

In R9-9-102, the rule specifies that a person may not act as a procurement organization in Arizona unless the person is licensed by the Department as a procurement organization and a general permit is not used. The Department cites A.R.S. § 36-851.01 that requires the Department to grant a procurement organization license to a person if the procurement organization is accredited by a nationally recognized accrediting agency approved by the Department or meets the requirements prescribed in rules adopted by the Department. Additionally, the Department cites A.R.S. § 41-1037(A)(2) and (3) that exempts the Department from requirement to issue a general permit specified in A.R.S. § 41-1037(A).

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

There are no federal rules applicable to the subject of the rule.

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

No business competitiveness analysis was submitted to the Department.

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

Not applicable

13. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 9. ~~EXPIRED~~DEPARTMENT OF HEALTH SERVICES PROCUREMENT ORGANIZATIONS

ARTICLE 1. PROCUREMENT ORGANIZATION LICENSURE

ARTICLE 2. ADMINISTRATION FOR A NON-ACCREDITED PROCUREMENT ORGANIZATION

ARTICLE 3. PHYSICAL PLANT; TRANSPORTATION FOR A NON-ACCREDITED PROCUREMENT ORGANIZATION

ARTICLE 4. ADMINISTRATION FOR AN ACCREDITED PROCUREMENT ORGANIZATION

ARTICLE 1. PROCUREMENT ORGANIZATION LICENSURE

R9-9-101. Definitions

In addition to the definitions in A.R.S. § 36-841, the following apply in this Chapter unless otherwise specified:

1. "Acceptability assessment" means the evaluation of available, if applicable, medical information about a donor to determine whether the donor meets qualifications as established by SOPs specified in R9-9-201(E)(4).
2. "Accrediting body" means a nationally recognized agency, approved by the Department, that provides certification for a person operating a procurement organization.
3. "Acquisition" means activities required to obtain a NTAD that is intended for use in education or research.
4. "Administrative completeness review time-frame" has the same meaning as in A.R.S. § 41-1072.
5. "Administrator" means the individual responsible for the services and activities provided by a procurement organization.
6. "Applicant" means an individual or business organization requesting approval to operate a procurement organization.
7. "Application packet" means the information, documents, and fees required by the Department for licensure of a procurement organization.
8. "Authorization" means permission given for NTAD acquisition by a donor or individual authorized by law.
9. "Business organization" means the same as "entity" in A.R.S. § 10-140.
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. "Controlling person" means an individual who, with respect to a business organization:
    a. Has the power to vote at least 10% of the outstanding voting securities of the business organization;
    b. If the business organization is a partnership, is a general partner or is a limited partner who holds at least 10% of the voting rights of the partnership;
    c. If the business organization is a corporation, association, or limited liability company, is the president, the chief executive officer, the incorporator, an agent, or any individual who owns or controls at least 10% of the voting securities; or
    d. Holds a beneficial interest in 10% or more of the liabilities of the business organization.
12. "Contracted services" means functions pertaining to the acquisition, screening, testing, preparing, storage, and distribution of NAM that another establishment agrees to perform.
13. "Department" means the Arizona Department of Health Services.
14. "Distribution" means a process that includes selection and evaluation of intended use of NAM for release to another procurement organization, an education facility, or a research facility.
15. "Donor consent form" means the same as "document of gift" defined A.R.S. § 36-841.
16. "Environmental services" means activities such as housekeeping, laundry, facility maintenance, or equipment maintenance.

17. "Exceptional release" means NAM that is approved for usage before a donor acceptability assessment or by a researcher requesting NAM that would not normally meet the established acceptability criteria.
18. "Final disposition" means the disposal of NAM through incineration, cremation, bio-cremation, burial, fully depleted by virtue of a particular use, or by another legal means.
19. "Licensee" means a person to whom the Department has issued a license to operate a non-transplant procurement organization or person designed by the licensee.
20. "Medical director" means a physician licensed in this state pursuant to A.R.S. Title 32, Chapter 13 or 17 who provides medical guidance for a licensed procurement organization according to A.R.S. § 36-851.03 or person designated by the medical director.
21. "Misuse" means to use NTAD and NAM for purposes other than for:
    a. Education or research, and
    b. Uses specified on a donor consent form.
22. "Modification" means the substantial improvement, enlargement, reduction, alternation, or other substantial change in the facility or another structure on the premises at a procurement organization.
23. "Non-transplant anatomical donation" or "NTAD" means a donation of a whole body, organs or tissues authorized and used for education and research prior to release to distribution inventory.
24. "Non-transplant anatomical material" or "NAM" means a whole body or parts of a body donated for use in education or research that has been prepared, packaged, labeled, and released to distribution inventory.
25. "Overall time-frame" means the same as in A.R.S. § 41-1072.
26. "Person" means the same as in A.R.S. § 36-841.
27. "Personnel member" means individuals identified as employees, students, or volunteer who provides services and activities for a procurement organization.
28. "Pest control" means activities that minimize the presence of insects and vermin in a procurement organization to ensure the quality of NTAD and NAM and the health and safety of persons occupying or visiting.
29. "Physical assessment" means a postmortem documented evaluation of a deceased donor's body that may identify evidence of: high-risk behaviors, signs of HIV infection or hepatitis infection, other viral or bacterial infections, and trauma.
30. "Premises" mean a facility and surrounding grounds that are:
    a. Designated by an applicant or a licensee;
    b. Used for providing procurement organization services and activities; and
    c. Licensed by the Department as a procurement organization.
31. "Preparation" means any activity performed other than donor screening, donor testing, acquisition, storage, distribution, or dispensing functions to enable the use of NAM for education or research. It includes, but is not limited to, cleaning, preservation, disarticulation, dissection, skeletonization, plastination, packaging, and labeling of NAM.
32. "Procurement organization" means the same as "non-transplant anatomical donation organization" as defined in A.R.S. § 36-841 and may be either accredited by an accrediting body or non-accredited.
33. "Quality management program" means ongoing activities designed and implemented by a procurement organization to improve the delivery of services and activities related to NAM.
34. "Quarantine" means the identification of NTAD or NAM as not acceptable or yet to be determined as eligible for use in education or research, including NTAD or NAM whose suitability has not been determined.
35. "Release" means NAM approved by a procurement organization in accordance with criteria established by the medical director for transfer to an approved education and research facility.
36. "Risk assessment" means collecting and evaluating relevant medical history and social behavior obtained from an individual or individuals who have knowledge about the donor.
37. "Standard operating policies and procedures" or "SOPs" means a group of documents detailing the specific purposes and services provided by a licensed procurement organization including activities and methods by staff and personnel members in support of conducting business operations.
38. "Storage" means a designated area that contains equipment, instruments, and supplies to maintain NTAD or NAM until distribution or final disposition.
39. "Substantive review time-frame" means the same as in A.R.S. § 41-1072.
40. "Traceability" means the method to locate NTAD and NAM during any step of NTAD including obtaining authorization, acquisition, transport, assessing donor acceptability, preparation, packaging, labeling, storage, release, evaluation intended use, distribution, and final disposition.
41. "Transfer" means the conveyance or relocation of NAM to:
    a. An education facility,
    b. A research facility,
    c. Another procurement organization, or
    d. A distribution inventory.
42. "Transport" means a method for relocating NAM from one place to another in a manner that provides conditions necessary to maintain the quality of the NAM for its intended use.
43. "Universal precautions" means the same as in A.R.S. § 32-1301.
44. "Working day" means a Monday, Tuesday, Wednesday, Thursday, or Friday that is not a state and federal holiday or a statewide furlough day.

R9-9-102. Licensure Requirements; Accreditation; Exemptions

A. A person may not act as a procurement organization in this state unless the person is licensed by the Department as a procurement organization.

B. A procurement organization shall provide a designated area for tissue recovery that does not operate in a funeral establishment specified in A.R.S. § 32-1301, for the recovery of whole bodies for medical research and education according to A.R.S. §§ 36-851.02(3) and 36-851.03(A)(5)(b).
C. A non-accredited procurement organization is subject to inspection by the Department at any time to evaluate compliance with A.R.S. Title 36, Chapter 7, Article 3 and this Chapter according to A.R.S. § 36-851.03(A)(5)(a) and (C).
D. An accredited procurement organization is subject to inspection by the Department at any time to evaluate compliance with requirements in A.R.S. § 36-851.02(2) and the rules adopted pursuant to A.R.S. § 36-851.02(2).
E. An accredited procurement organization whose certificate of accreditation has expired or is revoked, suspended, or denied by the accrediting body, shall provide written notification to the Department within ten working days of expiration or receipt of a revocation, suspension, or denial.
F. This Chapter does not apply to a procurement organization identified in A.R.S. § 36-851.01(F).

R9-9-103. Individuals to Act for an Applicant or Licensee
When an applicant or licensee is required by this Chapter to provide information on or sign an application form or other document, the following shall satisfy the requirement on behalf of the applicant or licensee:
1. If the applicant or licensee is an individual, the individual; and
2. If the applicant or licensee is a business organization, the individual who the business organization has designated to act on the business organization's behalf for purposes of this Chapter and who:
   a. Is a controlling person of the business organization,
   b. Is a U.S. citizen or legal resident, and
   c. Has an Arizona address.

R9-9-104. Application for Licensure
A. An applicant applying for a procurement organization license shall submit an application packet that contains:
1. An application, in a Department-provided format, according to A.R.S. § 36-851.01(A) that includes:
   a. The applicant's name, mailing address, e-mail address, and telephone number;
   b. The name or proposed name of the procurement organization, including the:
      i. Business street address;
      ii. Business mailing address, if different from the street address;
      iii. Telephone number;
      iv. E-mail address; and
      v. Tax ID number;
   c. If part of a business institution, the institution's:
      i. Name;
      ii. Street address;
      iii. Mailing address, if different from the street address;
      iv. Telephone number; and
      v. E-mail address;
   d. Whether the procurement organization is ready for a licensing inspection by the Department, if applicable;
   e. If the procurement organization is not ready for a licensing inspection specified in (d), the date the Department may perform a licensing inspection, if applicable;
   f. The name and contact information of an individual acting on behalf of the applicant specified in R9-9-103, if applicable;
   g. If applicable, the medical director's:
      i. Name,
      ii Telephone number,
      iii. E-mail address, and
      iv. License number;
   h. Whether the applicant complies with local zoning ordinances, building codes, and fire codes;
   i. Whether the applicant agrees to allow the department to submit supplemental requests for information under R9-9-108; and
   j. The applicant's signature and the date signed;
2. A copy of the procurement organization's current certificate of accreditation from an accrediting body, if applicable;
3. Documentation for the applicant that complies with A.R.S. § 41-1080;
4. A copy of the procurement organization labeled floor plan, including technical and administrative function areas, if applicable; and
5. A licensing fee of $2,000.

B. Upon receipt of the application packet in subsection (A), the Department shall conduct an inspection of the procurement organization, if applicable.
C. The Department shall issue or deny a license to an applicant as specified in R9-9-108.

R9-9-105. Application for License Renewal
A. A license is valid for two years from the date of issuance or renewal as specified in A.R.S. § 36-851.01(C).
B. At least 30 calendar days before the expiration date indicated on a procurement organization's license to operate a licensee shall submit to the Department an application packet for renewal of the license that contains:
1. An application, in a Department-provided format, that includes:
   a. The applicant's name, mailing address, e-mail address, and telephone number;
   b. The procurement organization's licensing number; and
   c. Whether the applicant agrees to allow the Department to submit supplemental requests for information under R9-9-108;

2. If applicable, documentation of the most recent certificate of accreditation from an accrediting body; and
3. A licensing renewal fee of $2,000.

C. The Department shall renew or deny renewal of a license to operate as specified in R9-9-108.

R9-9-106. Changes Affecting a License

A. A licensee shall notify the Department in writing at least 30 calendar days before the effective date of:
1. Termination of operation, including:
   a. The proposed termination date; and
   b. The address and contact information for the location where the procurement organization records will be retained as required in R9-9-205;
2. A proposed modification, if applicable;
3. A change in the legal name of a procurement organization;
4. A change in the legal name of a licensee including the licensee's new name; and
5. A change in the address of a procurement organization, including the new address.

B. A licensee shall notify the Department in writing at least 30 calendar days after the effective date of a change in:
1. The e-mail address or mailing address of a procurement organization including the new e-mail address or mailing address;
2. The e-mail address or telephone number of a licensee, including the new e-mail address or telephone number;
3. An administrator, including the name, telephone number, and e-mail address;
4. A medical director, including the name and e-mail address; and
5. The name, telephone number, and e-mail address of an individual acting on behalf of the licensee specified in R9-9-103.

C. If the Department receives the notification of termination of operation in subsection (A)(1), the Department shall void the licensee's license to operate a procurement organization as of the termination date specified by the licensee.

D. If the Department receives a notification in subsection (A)(2) of a proposed modification, the Department:
1. May conduct an inspection of the premises as allowed by A.R.S. § 36-851.03(C); and
2. Shall issue to the licensee an amended license that incorporates the modification and retains the expiration date of the existing license, if the procurement organization is compliant with A.R.S. Title 36, Chapter 7, Article 3 and this Chapter.

E. If the Department receives a notification in subsection (A)(3) of a legal name change for a procurement organization, the Department shall issue to the licensee an amended license showing the licensee's legal name.

F. If the Department receives notice for a change in the legal name of a licensee in subsection (A)(4), the Department shall void licensee's license to operate upon issuance of a new license to operate.

G. If the Department receives the notice for a change in the address of a procurement organization in subsection (A)(5), the Department shall review the application for a new license, submitted consistent with R9-9-104.

H. An individual or business organization planning to take ownership of an existing procurement organization shall obtain a new license before beginning operation.

R9-9-107. Denial, Suspension, Revocation, Enforcement

A. The Department may:
1. Deny a license as specified in subsection (B);
2. Suspend or revoke a license under A.R.S. § 36-851.01(E) and subsection (B); or
3. Assess or impose a civil penalty under A.R.S. § 36-851.01(E) and subsection (B).

B. The Department may impose civil penalties, deny an application or suspend or revoke a license to operate a procurement organization, if:
1. An applicant or licensee does not meet the application requirements contained in R9-9-104 and R9-9-105, as applicable;
2. A licensee does not comply with requirements in A.R.S. §§ 36-851.01 through 36-851.03 and this Chapter, if applicable;
3. A licensee does not correct the deficiencies identified during an inspection according to the plan of correction;
4. An applicant or licensee provides false or misleading information to the Department; or
5. The nature or number of violations revealed by any type of inspection or investigation of a procurement organization poses a direct risk to the life, health, or safety of individuals on the premises.

C. In determining which action in subsection (A) is appropriate, the Department shall consider:
1. Repeated violations of statutes or rules,
2. Pattern of violations,
3. Severity of violations, and
4. Number of violations.

D. The Department may suspend or revoke an accredited procurement organization's license if the Department receives notice that the accredited procurement organization's accreditation has expired or has been suspended or revoked by the accrediting body.

E. An applicant or licensee may appeal the Department's determination in this Section according to A.R.S. Title 41, Chapter 6, Article 10.

R9-9-108. Time-frames

A. The overall time-frame for a license granted by the Department under this Chapter is set forth in Table 1.1. The applicant or licensee and the Department may agree in writing to extend the substantive review time-frame and the overall time-frame. An extension of the substantive review time-frame and the overall time-frame may not exceed 25% of the overall time-frame.

B. The administrative completeness review time-frame for a license granted by the Department under this Chapter is set forth in Table 1.1 and begins on the date that the Department receives an application packet:
1. The Department shall send a notice of administrative completeness or deficiencies to the applicant or licensee within the administrative completeness review time-frame:
   a. A notice of deficiencies shall list each deficiency and the information or items needed to complete the application;

b. The administrative completeness review time-frame and the overall time-frame are suspended from the date that the notice of deficiencies is sent until the date that the Department receives all of the missing information or items from the applicant or licensee;
c. If an applicant or licensee fails to submit to the Department all of the information or items listed in the notice of deficiencies within 120 calendar days after the date that the Department sent the notice of deficiencies or within a time period the applicant or licensee and the Department agree upon in writing, the Department shall consider the application withdrawn; and

2. If the Department issues a license during the administrative completeness review time-frame, the Department shall not issue a separate written notice of administrative completeness.

C. The substantive review time-frame is set forth in Table 1.1 and begins on the date of the notice of administrative completeness:
1. As part of the substantive review of an application for a license, the Department may conduct an inspection according to A.R.S. § 36-851.03(C) that may require more than one visit to complete.
2. The Department shall send a license or a written notice of denial of a license within the substantive review time-frame.
3. During the substantive review time-frame, the Department may make one comprehensive written request for additional information, unless the applicant or licensee has agreed in writing to allow the Department to submit supplemental requests for information:
   a. The Department shall send a comprehensive written request for additional information that includes a written statement of deficiencies, stating each statute and rule upon which noncompliance is based, if the Department determines that an applicant or licensee, and the procurement organization, including the premises are not in substantial compliance with A.R.S. Title 36, Chapter 7, Article 3 or this Chapter;
   b. An applicant or licensee shall submit to the Department all of the information requested in a comprehensive written request for additional information or a supplemental request for information, including, if applicable, documentation of the corrections required in a statement of deficiencies, within 30 calendar days after the date of the comprehensive written request for additional information or the supplemental request for information or within a time period the applicant or licensee and the Department agree upon in writing;
   c. The substantive review time-frame and the overall time-frame are suspended from the date that the Department sends a comprehensive written request for additional information or a supplemental request for information until the date that the Department receives all of the information requested, including, if applicable, documentation of corrections required in a statement of deficiencies; and
   d. If an applicant or licensee fails to submit to the Department all of the information requested in a comprehensive written request for additional information or a supplemental request for information, including, if applicable, documentation of corrections required in a statement of deficiencies, within the time prescribed in subsection (C)(3)(b), the Department shall deny the application.
4. The Department shall issue a license if the Department determines that the applicant or licensee and the procurement organization, including the premises, are in substantial compliance with A.R.S. Title 36, Chapter 7, Article 3 and this Chapter.
5. If the Department denies a license, the Department shall send to the applicant or licensee a written notice of denial setting forth the reasons for denial and all other information required by A.R.S. §§ 41-1076 and 41-1092.03.

Table 1.1. Time-frames (in calendar days)

Type of Approval	Statutory Authority	Overall Time-Frame	Administrative Completeness Review Time-Frame	Substantive Review Time-Frame
Application for Licensure	A.R.S. § 36-851.01	90	30	60
Application for License Renewal	A.R.S. § 36-851.01	30	10	20
Modification Change Request Affecting License	A.R.S. § 36-851.01	60	30	30

ARTICLE 2. ADMINISTRATION FOR A NON-ACCREDITED PROCUREMENT ORGANIZATION

R9-9-201. Administration

A. A licensee for a non-accredited procurement organization:
1. Is responsible for all issues of liability, ethical considerations, fiduciary issues, and compliance with applicable laws and regulations;
   a. SOPs for all activities and services the procurement organization provides;
   b. The qualifications for an administrator:
      i. Who has at least a bachelor's degree in a health science or other science related field, and
      ii. Is responsible for all services and activities at a procurement organization; and
   c. The qualifications for a medical director:
      i. Who is licensed pursuant to A.R.S. Title 32, Chapter 13 or 17; and
      ii. Provides medical guidance to determine donor eligibility;
2. Shall adopt a quality management program; and
3. Shall review and evaluate the effectiveness of the quality management program in R9-9-202 at least once every 12 months.

B. An administrator of a non-accredited procurement organization:
1. Is directly accountable to the licensee for the operation, including all services and activities, provided by or at the procurement organization;
2. Has the authority and responsibility to manage the procurement organization as specified in SOPs;

3. Designates, in writing, an individual who is on the procurement organization's premises and is available when the administrator is not present on the premises.

C. A medical director of a non-accredited procurement organization:
1. Shall provide medical guidance to determine and establish donor eligibility as established in R9-9-204; and
2. May be the same individual as the administrator, if the individual's qualifications include management for all services and activities provided at a procurement organization.

D. A licensee of a non-accredited procurement organization shall ensure that the following programs at the procurement organization are established and maintained in compliance with state and federal laws and regulations:
1. A safety awareness and blood-borne pathogen training program; and
2. A cleaning program that mitigates potential cross-contamination between NTAD.

E. A licensee of a non-accredited procurement organization shall ensure that:
1. The procurement organization complies with vital records requirements in A.R.S. § 36-325;
2. An identification system according to A.R.S. § 36-851.03(A)(3)(b) for donors:
   a. Is established and maintained, and
   b. Assigns a unique identification number according to A.R.S. § 36-851.03(A)(6)(a);
      i. For each donor, and
      ii. Used to identify all NAM from a donor that is recovered and distributed;
3. SOPs are established, documented, and implemented that includes:
   a. Job descriptions, duties, and qualifications, including required skills, knowledge, education, and experience for technicians and personnel members;
   b. Orientation and in-service education for technicians and personnel members;
   c. How a technician may submit a complaint related to services provided;
   d. Donor records, including electronic records;
   e. A quality management program, including incident reports;
   f. Ethical practices;
   g. An infectious control program;
   h. Security, including evacuation procedures in the event of fire or disaster;
   i. NTAD and NAM inventory controls; and
   j. Contracted services;
4. SOPs for all services and activities are established, documented, and implemented for:
   a. The proper use and maintenance of a donor consent form according to A.R.S. § 36-851.03(A)(3)(a);
   b. Protocols and materials used to screen end-users prior to release and transfer of NAM according to A.R.S. § 36-851.03(A)(3)(c);
   c. Donor screening and testing plan, including:
      i. Acceptability assessment,
      ii. Donor risk assessment,
      iii. Medical records review,
      iv. Donor eligibility, and
      v. Infectious disease testing;
   d. Acquisition of NTAD;
      i. Donor verification;
      ii. Donor identity;
      iii. Acquisition records;
      iv. Packaging, including packaging insert form that discloses disease status of tissue to the end-user;
      v. Labeling;
      vi. Transport; and
      vii. Storage;
   e. Preparation methods, including:
      i. Receipt of NAM;
      ii. Prevent airborne transmission, and
      iii. Quarantine and storage, if applicable;
   f. Release and transfer, including:
      i. End-user eligibility review;
      ii. Quality control review;
      iii. Release of NAM;
      iv. Exceptional release;
      v. Failing review process; and
      vi. Transfer to distribution for use, including out-of-state and international shipping;
   g. Final disposition of donation according to A.R.S. § 36-851.03(A)(3)(f) and consistent with:
      i. Board of Funeral Directors and Embalmers specified in 4 A.A.C. 12, Articles 3, 5, and 6;
      ii. Vital Records and Public Health Statistics specified in A.R.S. Title 36, Chapter 3;
      iii. Vital Records and Statistics specified in 9 A.A.C. 19;
      iv. Health menaces specified in A.R.S. Title 36, Chapter 6, Article 1;
      v. Disposition of Human Bodies specified in A.R.S. Title 36, Chapter 7; and
      vi. Communicable Diseases and Infestations specified in 9 A.A.C. 6;
5. SOPs that all NTAD acquired by the procurement organization shall bear a label that:

a. Is written, printed, or graphic material used to identify NTAD/NAM, blood specimens, or other donor specimens; and
b. States according to A.R.S. § 36-851.03(A)(6)(b):
i. The NTAD or NAM is not for transplant or clinical use;
ii. Any condition and any limitation regarding the use of the NTAD or NAM;
iii. That universal precautions shall be used; and
iv. The contact information for the procurement organization;
6. SOPs are:
a. Maintained at the procurement organization and copies available to the Department for review upon request;
b. Reviewed at least once every three years and updated as needed; and
c. Available to technicians and personnel members; and
7. A loss or theft of NTAD or NAM is documented and reported to the appropriate law enforcement agency within 24 hours of discovery.

F. An administrator of a non-accredited procurement organization shall immediately report suspected of misuse to NTAD or NAM.

G. An administrator of a non-accredited procurement organization shall ensure that a report specified in subsection (F) is documented and maintained in the donor's record as specified in R9-9-205(E).

H. A licensee of a non-accredited procurement organization shall ensure that the following information or documents are conspicuously posted on the premises:
1. The procurement organization's current license,
2. The name of the administrator and medical director,
3. The hours of operation, and
4. The evacuation plan listed in R9-9-302.

R9-9-202. Quality Management

A licensee of a non-accredited procurement organization shall ensure that:
1. A plan is established, documented, and implemented for an ongoing quality management program that, at a minimum, includes:
a. A method to identify, document, and evaluate incidents;
b. A method to collect data to evaluate procurement organization services provided;
c. A method to evaluate the data collected to identify a concern about the delivery of procurement organization services;
d. A method to make changes or take action as a result of the identification of a concern about the delivery of procurement organization services; and
e. The frequency of submitting a documented report required in subsection (2) to the licensee.
2. A documented report is submitted to the licensee that includes:
a. An identification of each concern about the delivery of procurement organization services; and
b. Any changes made or actions taken as a result of the identification of a concern about the delivery of procurement organization services.
3. The report required in subsection (2) and the supporting documentation for the report is maintained for 12 months by the procurement organization after the date the report is submitted to the licensee.

R9-9-203. Contracted Services

A licensee of a non-accredited procurement organization shall ensure that:
1. Contracted services are documented by agreement specified in SOPs.
2. If a procurement organization contracts with a laboratory for infectious disease testing of NAM, the contracted laboratory is registered with the Food and Drug Administration as a tissue establishment, specified in 21 C.F.R. § 1271.3, for testing and is either:
a. Certified to perform such testing on human specimens in accordance with Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. § 263a) and 42 C.F.R. Part 493; or
b. Meets equivalent requirements as determined by the Centers for Medicare and Medicaid Services.
3. A list of contracted service providers is maintained and includes a description of the specific services provided.

R9-9-204. Medical Director, Administrator, Technicians, and Personnel Members

A. A licensee of a non-accredited procurement organization shall ensure that the medical director:
1. Establishes, reviews, and approves all SOPs of a medical nature, including:
a. Donor eligibility related to:
i. Screenings,
ii. Testing plans,
iii. Acceptability assessment;
b. Sampling plan and methods verifying NTAD release;
c. Exceptional release criteria and processes of NAM; and
d. Pre-established release criteria;
2. Reviews all SOPs of a medical nature at least every three years;
3. Approves a designee having training and education for performing tasks and functions assigned by the medical director;
4. Has oversight and performs review of designee activities according to procedures established by the licensee;
5. Makes a determination regarding the eligibility criteria of each donor based on a comparison with predetermined donor criteria;
6. Prior to release for use or distribution, signs the donor eligibility statement and NAM disposition or release statement; and
7. Establish a criteria that ensures all appropriate parties are notified of confirmed positive infectious disease test results.

B. A licensee of a non-accredited procurement organization shall ensure that the administrator:
1. Has at least three years of experience in tissue banking or other related fields;

2. Shall define NTAD or NAM activities that a technician may provide;
3. Shall define the methods used to provide clinical oversight and training including when clinical oversight and training is provided to an individual or a group; and
4. Shall ensure a technician's personnel record includes:
   a. Documentation of all completed training and education; and
   b. A written job description, including all primary duties.

C. A licensee of a non-accredited procurement organization shall ensure that a technician:
1. Has the educational background, experience, and training sufficient to assure assigned tasks will be performed in accordance with the established SOPs;
2. Provides a copy of a transcript or diploma in health science or other field of science for which the technician received a degree or certificate, if applicable;
3. Demonstrates competency to perform assigned tasks; and
4. Has duties required by the technician described in a written job description.

D. A licensee of a non-accredited procurement organization shall ensure that:
1. The qualifications, skill, and knowledge required for each type of technician and personnel member is based on the activities and services a personnel member may provide as established in the personnel job description; and
2. A personnel member's qualifications, skills, and knowledge are verified and documented:
   a. Before the personnel member provides procurement organization services and
   b. According to SOPs.

E. A licensee of a non-accredited procurement organization shall ensure that a personnel member does not have direct interaction with NTAD and NAM unless specifically authorized by the licensee or administrator.

F. A licensee of a non-accredited procurement organization shall ensure a personnel record is established for the administrator, technicians, and personnel members that includes:
1. The individual's name, date of birth, home address, and contact telephone number;
2. The individual's starting date of employment or volunteer service and, if applicable, the ending date; and
3. Documentation applicable to an individual's duties, as required by SOPs, including the individual's:
   a. Education and experience;
   b. In service education and continuing education, if applicable;
   c. Evidence of freedom from infectious tuberculosis, if applicable; and
   d. Evidence of Hepatitis B vaccination or refusal of Hepatitis B vaccine for individuals whose job-related responsibilities involve the potential exposure to blood-borne pathogens, if applicable.

G. A licensee of a non-accredited procurement organization shall ensure that a personnel record is:
1. Maintained throughout an individual's period of employment or volunteer service in or for the procurement organization;
2. Maintained for at least three years after the last date that an individual's employment or volunteer service in or for the procurement organization; and
3. Provided to the Department when requested.

R9-9-205. Donor Records

A. A non-accredited procurement organization shall maintain a legible, reproducible record for each donor from whom it obtains NAM for at least 10 years beyond the date of final disposition according to A.R.S. § 36-851.03(A)(7).

B. To ensure traceability of NTAD and NAM, a non-accredited procurement organization shall:
1. Document each procedure performed on a NTAD and NAM related to processing and storing NAM;
2. For each document created in subsection (1), include:
   a. The date and time for each procedure completed; and
   b. The name of the technician who performed the procedure; and
3. Submit information required to register the death of a NTAD within seven calendar days after receiving the NTAD according to A.R.S. § 36-325.

C. A non-accredited procurement organization shall ensure a donor record is:
1. Confidential and kept in a location with controlled access,
2. Stored in a manner to prevent unauthorized access, and
3. Maintained in a manner to preserve the donor record's completeness and accuracy.

D. A non-accredited procurement organization shall ensure a donor record shall include the following donor information:
1. The donor's name;
2. The donor's unique identifying number specified in A.R.S. § 36-851.03(A)(6);
3. The donor's date of birth and date of death; and
4. The name and contact information of the person responsible for a donor's anatomical gift, if applicable.

E. A non-accredited procurement organization shall include the following donor records, as applicable:
1. Donor consent form or documentation of authorization for an anatomical gift includes:
   a. The intended use of the NAM;
   b. How the NAM may be used;
   c. A statement that the NAM will be treated with dignity at all times; and
   d. A statement that the NAM may require international export to an end-user;
2. Document of authorization – a legal record of the gift, to take place postmortem, permitting and defining the scope of the postmortem acquisition and use of NAM for education and research, signed or otherwise recorded by the authorizing person, pursuant to law;

3. Documentation of gift – the donor's legal record of the gift of NAM permitting and defining the scope of the postmortem acquisition and use of NAM for education and research. It must be signed or otherwise recorded by the donor or individual authorized under law to make a gift during the donor's lifetime;
4. Donor's death record specified in A.A.C. R9-19-303;
5. Human remains release form specified in A.A.C. R9-19-301;
6. Information for a death record specified in A.A.C. R9-19-302 for transporting human remains into the state;
7. Disposition-transit permit specified in A.A.C. R9-19-308;
8. Medical examiner's release of information specified in A.R.S. § 36-861;
9. All documents and permits that establish the chain of custody and identifies the individuals and organizations that had physical custody of the NAM;
10. Medical records, including:
    a. Donor's physical assessment;
    b. Risk assessment questionnaire;
    c. Pathology and laboratory testing and reports;
    d. Physician summaries;
    e. Transfusion or infusion information; and
    f. Plasma dilution calculations;
11. Information from the donor referral source;
12. Donor eligibility;
13. Donor acceptability assessment;
14. Physical assessment questionnaire;
15. Documentation related to distribution;
16. Serological results, when applicable;
17. Cremation authorization document;
18. Documentation related to NAM recovery, storage, and distribution activities;
19. Final disposition documentation, including all records demonstrating chain of custody; and
20. Documentation of the report in R9-9-201(F) and (G).

F. A donor's consent form shall be accessible to the donor's known consenter.

G. Upon demonstration of a legal right to acquire a donor's record, a non-accredited procurement organization shall provide access to:
1. An agent legally authorized or other individual designated at the time a donor gives consent;
2. An individual appointed by a court or authorized by state laws;
3. An individual of a procurement organization as identified by SOPs;
4. An individual from an approving accrediting body, if applicable; and
5. An individual from the Department or other regulatory agency authorized by state and federal laws or regulations.

H. Except for a donor record specified in subsection (A), a non-accredited procurement organization shall maintain documentation required by this Chapter for at least three years after the date of the documentation and provide copies of the documentation to the Department for review upon request.

ARTICLE 3. PHYSICAL PLANT; TRANSPORTATION FOR A NON-ACCREDITED PROCUREMENT ORGANIZATION

R9-9-301. General Plant Standards; Environmental Services

A. A licensee of a non-accredited procurement organization shall ensure that a procurement organization facility:
1. Is in a building that:
    a. Has a commercial occupancy according to the local zoning jurisdiction;
    b. Is free of any plumbing, electrical, ventilation, mechanical, or structural hazard that may jeopardize the security and quality of the NTAD, NAM, and the health or safety of the public;
    c. Has equipment and supplies to maintain NTAD and NAM in a safe and temperature-controlled state; and
    d. Provides a separate and designated area for tissue recovery.
2. Has premises that are:
    a. Sufficient to provide for a procurement organization's services and activities;
    b. Cleaned and disinfected according to the procurement organization's SOPs to prevent, minimize, and control illness and infection and mitigate potential cross-contamination between NTAD and NAM;
    c. Clean and free from accumulations of dirt, garbage, and rubbish; and
    d. Free from a condition or situation that may cause an individual to suffer physical injury;
3. Provides a restroom for clients:
    a. Free from contamination and cross-contamination of NAM; and
    b. Does not contain any items, materials, or devices associated with the preparation activities or technicians and personnel members;
4. Implements and documents a pest control program that:
    a. Requires a pest control service that uses certified applicators as specified in 3 A.A.C. 8, Article 2; and
    b. Retains annual pest control service records for at least 12 months from date of service; and
5. Does not maintain a public health nuisance or engage in any act, condition, or thing, specified in A.R.S. § 36-601, or any practice contrary to the health laws of this state.

B. A licensee of a non-accredited procurement organization shall ensure that a procurement organization:
1. Has preparation rooms that:
    a. Are maintained in a clean and sanitary condition at all times;
    b. Are only used for examining and preparing NTAD;

c. Contain equipment, instruments, and supplies necessary for examining and preparing NTAD and are disinfected or sterilized, as applicable, after each use to protect the health and safety of technicians and personnel members;
d. Have sanitary flooring, drainage, and ventilation;
e. Have proper and convenient receptacles for refuse, bandages, and all other waste materials; and
f. Are thoroughly cleansed and disinfected with a 1% solution of chlorinated soda, or other suitable and effective disinfectant:
i. Immediately after obvious spill of blood or other potentially infectious materials, and
ii. At the end of each shift or on a regular basis that provides equivalent safety for all work surfaces;

2. Has refrigeration equipment used to store NTAD and NAM that:
a. Is only used for NTAD and NAM;
b. Is maintained in working order and kept in a clean and sanitary condition;
c. If a walk-in cooler, maintains a temperature between 36°F and 45°F;
d. If a freezer, maintains a temperature at or below 32°F;
e. Is monitored by a temperature sensor system that:
i. Measures temperatures continuously and document when a unit is out of the required temperature range, and
ii. Alert technicians or other designated individuals when temperatures are outside of the acceptable limits; and

3. Has equipment at the procurement organization that is:
a. Sufficient to support the service;
b. Maintained in working condition;
c. Maintained in a clean and sanitary condition;
d. Used according to the manufacturer's recommendations;
e. If used during an examination or preparation of NTAD, cleaned and sanitized specified in subsection (B)(1)(f)(ii); and
f. If applicable, tested and calibrated according to the manufacturer's recommendations or, if there are no manufacturer's recommendations, as specified in SOPs.

C. A licensee of a non-accredited procurement organization shall maintain documentation of equipment tests, calibrations, and repairs for at least 12 months after the date of testing, calibration, or repair.

D. A licensee of a non-accredited procurement organization shall ensure that:
1. Biohazardous material or medical waste and other potentially hazardous materials are removed and disposed by a facility licensed by the Arizona Department of Environmental Quality pursuant to 18 A.A.C. 8 and 13; and
2. Combustible or flammable liquids are stored in a labeled containers or safety containers in a secured area and properly identified to ensure individuals health and safety.

R9-9-302. Emergency and Safety Standards

A. An administrator of a non-accredited procurement organization shall ensure:
1. SOPs for emergency transfer of NTAD and NAM to a designated back up storage facility with an acceptable coolant and monitoring system in the event of mechanical failure or loss of coolant, including:
a. Tolerance limits or temperatures and time limits;
b. Methods and actions to be taken; and
c. Specific labeling indicating that the transported NTAD and NAM shall remain untouched until returned to the licensed non-accredited procurement facility after the mechanical failure or loss of coolant has been restored;
2. There is a first aid kit available at a procurement organization;
3. There are smoke detectors installed according to building size and local zoning jurisdiction;
4. A smoke detector required in subsection (A)(3):
a. Is maintained in an operable condition; and
b. Is battery operated or, if hard-wired into the electrical system of a procurement organization, has a back-up battery;
5. A procurement organization has a portable fire extinguisher that is labeled 2A-10-BC by the Underwriters Laboratory and is readily available for use;
6. A portable fire extinguisher required in subsection (A)(5) is:
a. If a disposable fire extinguisher, replaced when the fire extinguisher’s indicator reaches the red zone; or
b. Serviced at least every 12 months and has a tag attached to the fire extinguisher that includes the date of service; and
7. A written fire and evacuation plan is established and maintained.

B. An administrator of a non-accredited procurement organization shall:
1. Obtain a fire inspection conducted according to the time-frame established by the local fire department or the State Fire Marshal;
2. Make any repairs or corrections stated on the fire inspection report; and
3. Maintain documentation of a current fire inspection for at least two years.

R9-9-303. Security Standards; NTAD/NAM Inventory Controls

A. A licensee of a non-accredited procurement organization shall ensure that access to the enclosed-locked areas where NTAD and NAM is located is limited to individuals authorized by the licensee or administrator.

B. To prevent unauthorized access to NTAD and NAM inventory, an administrator of a non-accredited procurement organization shall:
1. Have personnel or security equipment to deter and prevent unauthorized entrance into limited access areas that includes:
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 devices;
b. Exterior lighting to facilitate surveillance; and
c. Electronic monitoring using video cameras shall provide coverage of:
i. Entrances to and exits from limited access areas;
ii. Entrances to and exits from the buildings; and
iii. Entrances and exits capable of identifying any activity occurring within the limited access area.

2. Maintain video recordings from the video cameras for at least 30 calendar days.
3. Have a failure notification system that provides an audible and visual notification of any failure in the electronic monitoring system.
4. Have battery backup for video cameras and recording equipment to support in the event of a power outage.
5. SOPs:
   a. That restricts access to the areas of the building that contain NTAD and NAM inventory and donor records;
   b. That provides for identification of authorized individuals; and
   c. For conducting electronic monitoring.

C. A licensee of a non-accredited procurement organization shall establish and implement a NTAD and NAM inventory tracking system that:
1. Contains all NTAD received and NAM released for distribution;
2. Lists release documentation verified for each NAM prior to transferring NAM to inventory;
3. Documents the date, time, and location for NAM transferred for use, including the name of the individual performing the transfer;
4. Documents the date, time, and location for NAM that is moved between locations controlled by the procurement organization, including the name of the individual overseeing the move; and
5. Ensures NAM that can no longer be used is removed from inventory and disposed according to applicable SOPs.

R9-9-304. Transportation Standards

A. If a non-accredited procurement organization owns and maintains a vehicle for transporting NAM, an administrator shall ensure the vehicle is:
1. Not used for a purpose other than transporting NTAD and NAM or conducting procurement organization business;
2. Only operated by a procurement organization technician or designated individual authorized to transport NTAD or NAM;
3. Maintained in clean and sanitary condition; and
4. Locked and secured at all times during transport of NTAD or NAM.

B. If using another vehicle for transporting NTAD or NAM, an administrator of a non-accredited procurement organization shall ensure that the other vehicle:
1. Is properly equipped for the transportation of NAM;
2. Is compliant with all state laws and rules pertaining to transporting humans remains; and
3. If transport is by air, complies with applicable standards established by the International Air Transport Association and Transport Security Administration.

C. An administrator of a non-accredited procurement organization shall ensure that NTAD and NAM transported into the state has information of death documentation specified in A.A.C. R9-19-302 prior to transport.

R9-9-305. Sanitation Standards and Reporting

A. A licensee of a non-accredited procurement organization shall ensure that:
1. Areas used to receive, prepare, label, package, and store NAM are:
   a. Properly ventilated, and
   b. Protected from dust, dirt, flies, and other contamination.
2. All refuse and waste products produced from receiving, preparing, packaging, distributing, and transporting NAM are removed from the premises as needed.
3. All transport vehicles, trays, other receptacles, racks, tables, shelves, knives, saws, other utensils, or machinery used to move, handle, separate, package or other processes be cleaned as specified in SOPs and this Article.

B. A technician or personnel member of a non-accredited procurement organization shall report to the administrator or medical director:
1. Any concern related to receiving, preparing, packaging, distributing, or transporting NTAD or NAM that may adversely affect the health and safety of others.
2. Any personal health condition experienced related to receiving, preparing, packaging, distributing, or transporting NTAD or NAM.

C. If an administrator or medical director of a non-accredited procurement organization determines a health condition in subsection (B)(1) has occurred, the administrator or medical director shall:
1. Follow SOPs to secure the area and eliminate exposure to others;
2. Notify appropriate health and law enforcement agencies, as applicable; and
3. Report the incident to the Department within five working days of determination that a health condition in subsection (B)(2) has occurred.

D. A licensee, administrator, or medical director of a non-accredited procurement organization shall report a health condition experienced by a technician or personnel member to the Department within five calendar days of determination that the individual has a personal health condition specified in subsection (B)(1).

ARTICLE 4. ADMINISTRATION FOR AN ACCREDITED PROCUREMENT ORGANIZATION

R9-9-401. General Responsibilities

A. A licensee of an accredited procurement organization shall provide a copy of a renewed accreditation to the Department within 30 calendar days from the date of issuance.

B. A licensee of an accredited procurement organization shall ensure that a procurement organization facility is in a building that provides a separate and designated area for tissue recovery according to A.R.S. § 36-851.02(3).

C. A licensee of an accredited procurement organization shall ensure SOPs are established, documented, and implemented that cover:
1. Labeling;

2. Packaging, including a packaging insert form that discloses disease status of tissue to end-user according to A.R.S. § 36-851.02(2)(d);
3. Transport;
4. Distribution; and
5. Final disposition.

R9-9-402. Donor Consent; NTAD and NAM Identification

In addition to the requirements in Article 1, a licensee of an accredited procurement organization shall ensure that:

1. A donor consent form includes:
   a. The intended use of the NAM,
   b. How the NAM may be used,
   c. A statement that the NAM will be treated with dignity at all times, and
   d. A statement that the NAM may require international export to an end-user.
2. A donor consent form is maintained in the donor's record and retained for at least 10 years beyond the date of final disposition.
3. An electronic identification system for donors is established and maintained for NTAD or NAM;
   a. Assigns a unique identifier using a combination of letters, numbers, and symbols for NTAD or NAM;
   b. Tracks the complete history of all NAM; and
   c. Records the date and staff member involved in each significant step of the operation from the time of NTAD acquisition through final disposition.
4. The information required to register the death of a NTAD is submitted within seven calendar days after receiving the NTAD according to A.R.S. § 36-325.

R9-9-403. Tissue End-Users

A. A licensee of an accredited procurement organization shall establish, document, and implement SOPs to properly screen an end-user that includes:

1. A written request for NAM, including:
   a. The name, address and affiliation of educator and research accepting responsibility for the acceptance, use, and disposition of the NAM;
   b. A description of the intended use;
   c. The date and the approximate duration of NAM use;
   d. A description of the venue in which the NAM will be used and the security measures for the safe and ethical utilization of the venue;
   e. An assurance that universal precautions will be used when handling NAM;
   f. The proposed final disposition of the NAM;
   g. An agreement to comply with procurement organization's policies, as applicable;
   h. An outline of proposed promotional materials to be disseminated in connection with the use of NAM; and
   i. Other supporting documentation that is relevant to the request; and
2. The criteria for approving requested NAM for use, including:
   a. The acceptability of the educator and researcher for NAM utilization;
   b. The appropriateness of the intended use;
   c. Type of venue in which the NAM will be used;
   d. Proposed final disposition of the NAM unless returned to the procurement organization; and
   e. Proposed promotional materials.

B. A licensee of an accredited procurement organization shall establish, document, and implement a procedure that allows an end-users to request an exceptional release of NAM.

NOTICE OF PROPOSED RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 11. DEPARTMENT OF HEALTH SERVICES HEALTH CARE INSTITUTION FACILITY DATA

[R22-12]

PREAMBLE

1. Article, Part, or Section Affected (as applicable)	Rulemaking Action
R9-11-101	Amend
R9-11-201	Amend
R9-11-202	Amend
R9-11-203	Amend
R9-11-205	Amend
R9-11-301	Amend
R9-11-402	Amend
R9-11-502	Amend
Article 6	New Article
R9-11-601	New Section

R9-11-602	New Section
R9-11-603	New Section
R9-11-604	New Section

2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. § 36-136(G)
Implementing statute: A.R.S. §§ 36-125.04, 36-125.05, 36-436, 36-436.01, 36-436.02, 36-436.03, 36-2901.08

3. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the proposed rule:

Notice of Rulemaking Docket Opening: 27 A.A.R. 2701, November 19, 2021

4. The agency's contact person who can answer questions about the rulemaking:

Name: S. Robert Bailey, Bureau Chief
Address: Arizona Department of Health Services
Bureau of Public Health Statistics
150 N. 18th Ave., Suite 581
Phoenix, AZ 85007-3248
Telephone: (602) 364-3049
Fax: (602) 364-0082
Email: Steven.Bailey@azdhs.gov

or

Name: Robert Lane, Office Chief
Address: Arizona Department of Health Services
Office of Administrative Counsel and Rules
150 N. 18th Ave., Suite 200
Phoenix, AZ 85007
Telephone: (602) 542-1020
Fax: (602) 364-1150
Email: Robert.Lane@azdhs.gov

5. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

Laws 2018, Ch. 293, amended Arizona Revised Statutes (A.R.S.) § 36-104 to require the Arizona Department of Health Services (Department) to adopt rules "prescribing the designated database information to be collected by health professional regulatory boards" pursuant to A.R.S. Title 32, Chapter 32, Article 5. Laws 2019, Ch. 215, added A.R.S. § 36-171 to require the Department to adopt rules to establish and maintain the health care professionals workforce data repository containing the designated database information collected and transferred to the Department pursuant to A.R.S. Title 32, Chapter 32, Article 5. The Department plans to adopt these rules, consistent with recommendations of the Health Care Professionals Workforce Data Repository Advisory Committee, in Arizona Administrative Code (A.A.C.) Title 9, Chapter 11, which currently contains Articles implementing several statutes related to the reporting of data about health care institutions. The Department has identified several changes to the rules in these Articles that would improve the rules, make them more effective, and reduce the burden on reporting health care institutions. After receiving an exception from the rulemaking moratorium established by Executive Order 2019-01 to adopt rules to comply with Laws 2018, Ch. 293, and Laws 2019, Ch. 215, and approval to add to this rulemaking changes to the other Articles in the Chapter identified in a five-year-review report, the Department is proceeding with the rulemaking.

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

The Department did not review or rely on any study for this rulemaking.

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

Not applicable

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

The Department anticipates that the rulemaking may affect the Department; the Boards, as defined in A.R.S. § 32-3249; those persons requesting designated database information and summary reports; health care institutions reporting to the Department under Articles 2 through 5; individuals applying to or regulated by a Board; and the general public. Annual costs/revenues changes are designated as minimal when more than $0 and $1,000 or less, moderate when between $1,000 and $10,000, and substantial when $10,000 or greater in additional costs or revenues. A cost is listed as significant when meaningful or important, but not readily subject to quantification.

The Department believes that having rules in Articles 2 through 5 that are clearer and easier to understand may provide a significant benefit to the Department and to health care institutions reporting to the Department under Articles 2 through 5 of the Chapter. The Department estimates that the cost to the Department of setting up and implementing a health professionals workforce data repository, to comply with Laws 2018, Ch. 293 and Laws 2019, Ch. 215, may be substantial. However, these costs are the result of the statutory changes, rather than the rules. The Department also anticipates that preparing and providing designated database information and summary reports to requesters may cause the Department to incur substantial costs as well. These costs will be

off-set by the fees charged to requesters of designated database information and summary reports.

The Arizona Medical Board, Board of Nursing, Arizona Board of Osteopathic Examiners in Medicine and Surgery, Board of Physical Therapy, Board of Psychologist Examiners, and Board of Behavioral Health Examiners are the health profession regulatory boards affected by these rules. The Department anticipates that requesting, storing, and transferring to the Department the indicated information may result in a substantial cost to a Board, the bulk of which is due to statutory requirements rather than the rules. The Department has included in the rules provisions to minimize or mitigate these costs.

The Department believes that many persons, including local governments, may be requesters of designated database information and summary reports. These persons may find information about the number, types, and distribution of health professionals useful in achieving their various goals, but obtaining the data *de novo* may be costly and difficult, inaccurate, or impossible. The Department anticipates that having access to information contained in the health professionals workforce data repository may provide a significant benefit to those requesting designated database information and summary reports. Those persons requesting designated database information and summary reports may incur as much as a moderate cost for the information or report, but the amount of these costs is at the discretion of the requester.

Under the rules, individuals applying to or regulated by one of the Boards listed above are subject to the Board's request for the information specified in R9-11-602(B) at the time of initial application or renewal. Much of the information being requested is already being required by some of the Boards. If a Board collected none of the information specified in R9-11-602(B) as part of its regulatory function, the Department estimates that an individual responding to the Board's request for this information would incur minimal costs for the time they spend providing the information. These individuals may receive a significant benefit from actions taken by a requestor of designated database information based on the information received. The Department anticipates that the general public may also receive a significant benefit from the rulemaking by increasing the information upon which persons may make decisions related to the locations and staffing of health care institutions.

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

Name: S. Robert Bailey, Bureau Chief
Address: Arizona Department of Health Services
Bureau of Public Health Statistics
150 N. 18th Ave., Suite 581
Phoenix, AZ 85007-3248
Telephone: (602) 364-3049
Fax: (602) 364-0082
Email: Steven.Bailey@azdhs.gov
or
Name: Robert Lane, Office Chief
Address: Arizona Department of Health Services
Office of Administrative Counsel and Rules
150 N. 18th Ave., Suite 200
Phoenix, AZ 85007
Telephone: (602) 542-1020
Fax: (602) 364-1150
Email: Robert.Lane@azdhs.gov

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

The Department has scheduled the following oral proceeding:

Date and time: Monday, March 7, 2022, at 2:30 p.m.
Location: 150 N. 18th Ave., Room 540B
Phoenix, AZ 85007
Teleconferencing: meet.google.com/yyd-ftmi-xum
Call-in number: (US) +1 440-467-2810 PIN: 119 255 644#
Close of record: Monday, March 7, 2022, at 4:00 p.m.

A person may submit written comments on the proposed rules no later than the close of record to either of the individuals listed in items 4 and 9.

A person with a disability may request a reasonable accommodation, such as a sign language interpreter, by contacting Robert Lane at Robert.Lane@azdhs.gov or (602) 542-1020. Requests should be made as early as possible to allow time to arrange the accommodation.

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

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

Not applicable

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal

law and if so, citation to the statutory authority to exceed the requirements of federal law:
Not applicable

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

12. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:
Not applicable

13. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 11. DEPARTMENT OF HEALTH SERVICES

HEALTH CARE INSTITUTION FACILITY AND HEALTH PROFESSIONALS WORKFORCE DATA

ARTICLE 1. DEFINITIONS

Section
R9-11-101. Definitions

ARTICLE 2. ANNUAL FINANCIAL STATEMENTS AND UNIFORM ACCOUNTING REPORTS

Section
R9-11-201. Definitions
R9-11-202. Hospital Annual Financial Statement
R9-11-203. Hospital Uniform Accounting Report
R9-11-205. Hospice Uniform Accounting Report

ARTICLE 3. RATES AND CHARGES SCHEDULES

Section
R9-11-301. Definitions

ARTICLE 4. HOSPITAL INPATIENT DISCHARGE REPORTING

Section
R9-11-402. Reporting Requirements

ARTICLE 5. EMERGENCY DEPARTMENT DISCHARGE REPORTING

Section
R9-11-502. Reporting Requirements

ARTICLE 6. HEALTH PROFESSIONALS WORKFORCE DATABASE

Section
R9-11-601. Definitions
R9-11-602. Designated Database Information
R9-11-603. Transfer of Data from a Board
R9-11-604. Requests for Release of Designated Database Information and Reports

ARTICLE 1. DEFINITIONS

R9-11-101. Definitions

In this Chapter, unless otherwise specified:

1. "Admission" or "admitted" means documented acceptance by a health care institution of an individual as an inpatient of a hospital, a resident of a nursing care institution, or a patient of a hospice.
2. "AHCCCS" means the Arizona Health Care Cost Containment System, established under A.R.S. § 36-2902.
3. "Allowance" means a charity care discount, self-pay discount, or contractual adjustment.
4. "Arizona facility ID" means a unique code assigned to a hospital by the Department to identify the source of inpatient discharge or emergency department discharge information.
5. "Assisted living facility" means the same as in A.R.S. § 36-401.
6. "Attending provider" means the medical practitioner who has primary responsibility for the services a patient receives during an episode of care.
7. "Available bed" means an inpatient bed or resident bed, as defined in A.R.S. § 36-401, for which a hospital, nursing care institution, or hospice has health professionals and commodities to provide services to a patient or resident.
8. "Bill" means a statement for money owed to a health care institution for the provision of the health care institution's services.
9. "Business day" means any day of the week other than a Saturday, a Sunday, a legal holiday, or a day on which the Department is authorized or obligated by law or executive order to close.
10. "Calendar day" means any day of the week, including a Saturday or a Sunday.

11. "Cardiopulmonary resuscitation" means the same as in A.R.S. § 36-3251.
12. "Charge" means a specific dollar amount set by a health care institution for the use or consumption of a unit of service provided by the health care institution.
13. "Charge source" means the unit within a health care institution that provided services to an individual for which the individual's payer source is billed.
14. "Charity care" means services provided without charge to an individual who meets certain financial criteria established by a health care institution.
15. "Chief administrative officer" means the same as in A.A.C. R9-10-101.
16. "Chief financial officer" means an individual who is responsible for the financial records of a health care institution.
17. "Classification" means a designation that indicates the types of services a hospital provides.
18. "Clinical evaluation" means an examination performed by a medical practitioner on the body of an individual for the presence of disease or injury to the body, and review of any laboratory test results for the individual.
19. "Code" means a single number or letter, a set of numbers or letters, or a combination of numbers and letters that represents specific information.
20. "Commodity" means a non-reusable material, such as a syringe, bandage, or IV bag, utilized by a patient or resident.
21. "Contractual adjustment" means the difference between charges billed to a payer source and the amount that is paid to a health care institution based on an established agreement between the health care institution and the payer source.
22. "Control number" means a unique number assigned by a hospital for an individual's specific episode of care.
23. "Department" means the Arizona Department of Health Services.
24. "Designee" means a person assigned by the governing authority of a health care institution or by an individual acting on behalf of the governing authority to gather information for or report information to the Department.
25. "Diagnosis" means the identification of a disease or injury, by an individual authorized by law to make the identification, that is a cause of an individual's current medical condition.
26. "Discharge" means a health care institution's termination of services to a patient or resident for a specific episode of care.
27. "Discharge status" means the disposition of a patient, including whether the patient ~~was~~:
    a. ~~Discharged~~ Was discharged home,
    b. ~~Transferred~~ Was transferred to another health care institution, or
    c. Died.
28. "DNR" means Do Not Resuscitate, a document prepared for a patient indicating that cardiopulmonary resuscitation is not to be used in the event that the patient's heart stops beating.
~~29. "E-code" means an International Classification of Diseases code that is used:~~
    ~~a. In conjunction with other International Classification of Diseases codes that identify the principal and secondary diagnoses for an individual; and~~
    ~~b. To further designate the individual's injury or illness as being caused by events such as:~~
        ~~i. An external cause of injury, such as a car accident;~~
        ~~ii. A poisoning; or~~
        ~~iii. An unexpected complication associated with treatment, such as an adverse reaction to a medication or a surgical error.~~
~~30.~~29. "Electronic" means the same as in A.R.S. § 36-301.
~~31.~~30. "Emergency" means the same as in A.A.C. ~~R9-10-201~~ R9-10-101.
~~32.~~31. "Emergency department" means the unit within a hospital that is designed for the provision of emergency services.
~~33.~~32. "Emergency services" means the same as in A.A.C. ~~R9-10-201~~ R9-10-101.
~~34.~~33. "Episode of care" means medical services, nursing services, or health-related services provided by a hospital to a patient for a specific period of time, ending with a discharge.
~~35.~~34. "Fiscal year" means a consecutive 12-month period established by a health care institution for accounting, planning, or tax purposes.
~~36.~~35. "Governing authority" means the same as in A.R.S. § 36-401.
~~37.~~36. "Health care institution" means the same as in A.R.S. § 36-401.
~~38.~~37. "Health-related services" means the same as in A.R.S. § 36-401.
~~39.~~38. "Home health agency" means the same as in A.R.S. § 36-151.
~~40.~~39. "Home health services" means the same as in A.R.S. § 36-151.
~~41.~~40. "Home office" means the person that is the owner of and controls the functioning of a nursing care institution.
~~42.~~41. "Hospice" means the same as in A.R.S. § 36-401.
~~43.~~42. "Hospital" means the same as in A.A.C. ~~R9-10-201~~ R9-10-101.
~~44.~~43. "Hospital administrator" means the same as "chief administrative officer" or "administrator" in A.A.C. ~~R9-10-201~~ R9-10-101.
~~45.~~44. "Hospital services" means the same as in A.A.C. R9-10-201.
~~46.~~45. "Inpatient" means ~~the same as in A.A.C. R9-10-201~~ an individual admitted to a hospital and billed as an inpatient according to the hospital's policies and procedures.
~~47.~~46. "International Classification of Diseases Code" means a code included in a set of codes such as the ~~ICD-9-CM or~~ ICD-10-CM codes, which is used by a hospital for billing purposes.
~~48.~~47. "Licensed capacity" means the same as in A.R.S. § 36-401.
~~49.~~48. "Management company" means an entity that:
    a. Acts as an intermediary between the governing authority of a nursing care institution and the individuals who work in the nursing care institution,
    b. Takes direction from the governing authority of the nursing care institution, and
    c. Ensures that the directives of the governing authority of the nursing care institution are carried out.
~~50.~~49. "Medical practitioner" means an individual who is:

a. Licensed:
   i. As a physician;
   ii. As a dentist, under A.R.S. Title 32, Chapter 11, Article 2;
   iii. As a podiatrist, under A.R.S. Title 32, Chapter 7;
   iv. As a registered nurse practitioner, under A.R.S. Title 32, Chapter 15;
   v. As a physician assistant, under A.R.S. Title 32, Chapter 25; or
   vi. To use or prescribe drugs or devices for the evaluation, diagnosis, prevention, or treatment of illness, disease, or injury in human beings in this state; or
b. Licensed in another state and authorized by law to use or prescribe drugs or devices for the evaluation, diagnosis, prevention, or treatment of illness, disease, or injury in human beings in this state.

~~51.~~50. "Medical record number" means a unique number assigned by a hospital to an individual for identification purposes.
~~52.~~51. "Medical services" means the same as in A.R.S. § 36-401.
~~53.~~52. "Medicare" means a federal health insurance program established under Title XVIII of the Social Security Act.
~~54.~~53. "National provider identifier" means the unique number assigned by the Centers for Medicare and Medicaid Services to a health care institution, physician, registered nurse practitioner, or other medical practitioner to submit claims and transmit electronic health information to all payer sources.
~~55.~~54. "Newborn" means a human:
a. Whose birth took place in the reporting hospital, or
b. Who was:
   i. Born outside a hospital,
   ii. Admitted to the reporting hospital within 24 hours of birth, and
   iii. Admitted to the reporting hospital before being admitted to any other hospital.

~~56.~~55. "Nursing care institution" means the same as in A.R.S. § 36-446.
~~57.~~56. "Nursing care institution administrator" means the same as in A.R.S. § 36-446.
~~58.~~57. "Nursing services" means the same as in A.R.S. § 36-401.
~~59.~~58. "Patient" means the same as in A.A.C. R9-10-101.
~~60.~~59. "Payer source" means an individual or an entity, such as a private insurance company, AHCCCS, or Medicare, to which a health care institution sends a bill for the services provided to an individual by the health care institution.
~~61.~~60. "Physician" means an individual licensed as a doctor of allopathic medicine under A.R.S. Title 32, Chapter 13, as a doctor of naturopathic medicine under A.R.S. Title 32, Chapter 14, or as a doctor of osteopathic medicine under A.R.S. Title 32, Chapter 17.
~~62.~~61. "Principal diagnosis" means the reason established after a clinical evaluation of a patient to be chiefly responsible for a specific episode of care.
~~63.~~62. "Principal procedure" means the procedure judged by an individual working on behalf of a hospital to be:
a. The most significant procedure performed during an episode of care, or
b. The procedure most closely associated with a patient's principal diagnosis.

~~64.~~63. "Priority of visit" means the urgency with which a patient required medical services during an episode of care.
~~65.~~64. "Procedure" means a set of activities performed on a patient that:
a. Is intended to diagnose or treat a disease, illness, or injury;
b. Requires the individual performing the set of activities be trained in the set of activities; and
c. May be invasive in nature or involve a risk to the patient from the activities themselves or from anesthesia.

~~66.~~65. "Prospective payment system" means a system of classifying episodes of care for billing and reimbursement purposes, based on factors such as diagnoses, age, and sex.
~~67.~~66. "Refer" means to direct an individual to a health care institution for services provided by the health care institution.
~~68.~~67. "Referral source" means a code designating the entity that referred or transferred a patient to a hospital.
~~69.~~68. "Registered nurse practitioner" means an individual who meets the definition of registered nurse practitioner in A.R.S. § 32-1601, and is licensed under A.R.S. Title 32, Chapter 15.
~~70.~~69. "Reporting period" means the specific fiscal year, calendar year, or portion of the fiscal or calendar year for which a health care institution is reporting data to the Department.
~~71.~~70. "Residence" means the place where an individual lives, such as:
a. A private home,
b. A nursing care institution, or
c. An assisted living facility.

~~72.~~71. "Resident" means the same as in A.A.C. R9-10-101~~:~~.
~~a. A.A.C. R9-10-701, or~~
~~b. A.A.C. R9-10-901.~~

~~73.~~72. "Revenue code" means a code for a unit of service that a hospital includes on a bill for hospital services.
~~74.~~73. "Secondary diagnosis" means any diagnosis for an individual other than the principal diagnosis.
~~75.~~74. "Self-pay discount" means a reduction in charges billed to an individual.
~~76.~~75. "Service" means an activity performed as part of medical services, hospital services, nursing services, emergency services, health-related services, hospice services, home health services, or supportive services.
~~77.~~76. "Supportive services" means the same as in A.R.S. § 36-151.
~~78.~~77. "Transfer" means discharging an individual from a health care institution so the individual may be admitted to another health care institution.
~~79.~~78. "Trauma center" means the same as in:
a. A.R.S. § 36-2201, or

b. A.R.S. § 36-2225.

~~80.~~79. "Treatment" means the same as in A.A.C. R9-10-101.

~~81.~~80. "Type of" means a specific subcategory of the following that is provided, enumerated, or utilized by a health care institution:

a. An employee or contracted worker;
b. An accounting concept, such as asset, liability, or revenue;
c. A non-covered ancillary charge;
d. A payer source;
e. A charge source;
f. A medical condition; or
g. A service.

~~82.~~81. "Type of bed" means a category of available bed that specifies the services provided to an individual occupying the available bed.

~~83.~~82. "Unit" means an area within a health care institution that is designated by the health care institution to provide a specific type of service.

~~84.~~83. "Unit of service" means a procedure, service, commodity, or other item or group of items provided to a patient or resident for which a health care institution bills a payer source a specific amount.

~~85.~~84. "Written notice" means a document that is provided:

a. In person,
b. By delivery service,
c. By facsimile transmission,
d. By electronic mail, or
e. By mail.

ARTICLE 2. ANNUAL FINANCIAL STATEMENTS AND UNIFORM ACCOUNTING REPORTS

R9-11-201. Definitions

In this Article, unless otherwise specified:

1. "Accredited" means the same as in A.R.S. § 36-422.
2. "ALTCS" means the Arizona Long-term Care System established under A.R.S. § 36-2932.
3. "Asset" means the same as "asset" in generally accepted accounting principles.
~~4. "Assisted living facility-based hospice" means a hospice that operates as a part of an assisted living facility.~~
~~5.~~4. "Audit" means the same as "audit" in generally accepted accounting principles.
~~6.~~5. "Bereavement services" means activities provided by or on behalf of a hospice to the family or friends of an individual that are intended to comfort the family or friends before and after the individual's death.
~~7.~~6. "Building improvement" means an addition to or reconstruction, removal, or replacement of any portion or component of an existing building that affects licensed capacity, increases the useful life of an available bed, or enhances resident safety.
~~8.~~7. "Caseload" means the number of assigned patients for which an individual working for a hospice is to provide hospice services.
~~9.~~8. "Certified nursing assistant" means the same as "nursing assistant" in A.R.S. § 32-1601.
~~10.~~9. "Chaplain" means an individual trained to offer support, prayer, and spiritual guidance to a patient and the patient's family.
~~11.~~10. "Continuous care" means hospice services provided in a patient's residence to a patient who requires nursing services to be available 24 hours a day.
~~12.~~11. "Contracted worker" means an individual who:
   a. Performs:
      i. Hospital services in a hospital,
      ii. Nursing services or health-related services in a nursing care institution,
      iii. Hospice services for a hospice, or
      iv. Labor as a medical record coder or transcriptionist for a hospital; and
   b. Is paid by a person with whom the hospital, nursing care institution, or hospice has a written agreement to provide hospital services, nursing services, health-related services, hospice services, or medical record coder or transcriptionist labor.
~~13.~~12. "Covered services" means hospice services that are provided to an individual by a hospice and are paid for by a payer source.
~~14.~~13. "Daily census" means a count of the number of patients to whom hospice services were provided during a 24-hour period.
~~15.~~14. "Direct care" means services provided to a resident that require hands-on contact with the resident.
~~16.~~15. "Direction" means the same as in A.R.S. § 36-401.
~~17.~~16. "Employee" means an individual other than a contracted worker who works for a health care institution for compensation and provides or assists in the provision of a service to patients or residents.
~~18.~~17. "Employee-related expenses" means costs incurred by an employer to pay for the employer's portion of Social Security taxes, Medicare taxes, and other costs such as health insurance.
~~19.~~18. "Equity" means the same as "equity" in generally accepted accounting principles.
~~20.~~19. "Expense" means the same as "expense" in generally accepted accounting principles.
~~21.~~20. "Free-standing" means that a health care institution does not operate as part of another health care institution.
~~22.~~21. "FTE" means full-time equivalent position, which is a job for which a health care institution expects to pay an individual for 2,080 hours per year.
~~23.~~22. "Generally accepted accounting principles" means the set of financial reporting standards administered by the Financial Accounting Standards Board, the Governmental Accounting Standards Board, or other specialized bodies dealing with accounting and auditing matters.
~~24.~~23. "Health professional" means the same as in A.R.S. § 32-3201.
~~25. "Home health agency-based hospice" means a hospice that operates as part of a home health agency.~~

~~26.~~24. "Hospice administrator" means the chief administrative officer for a hospice.
~~27.~~25. "Hospice chief financial officer" means an individual who is responsible for the financial records of a hospice.
~~28.~~26. "Hospice inpatient facility" means the same as in A.A.C. ~~R9-10-801~~ R9-10-101.
~~29.~~27. "Hospice ~~service~~ services" means the ~~same as in A.A.C. R9-10-801~~ activities described in A.A.C. R9-10-612.
~~30.~~28. "Hospice service agency" means the same as in A.R.S. § 36-401.
~~31. "Hospital-based hospice" means a hospice that operates as a part of a hospital.~~
~~32.~~29. "Income" means the same as "income" in generally accepted accounting principles.
~~33.~~30. "Inpatient services" means ~~the same as in A.A.C. R9-10-801~~ sleeping accommodations and assistance, such as personal care and food preparation, provided to a patient at one of the following health care institutions:
a. A hospice inpatient facility licensed under 9 A.A.C. 10, Article 6;
b. A hospital licensed under 9 A.A.C. 10, Article 2; or
c. A nursing care institution licensed under 9 A.A.C. 10, Article 4.
~~34. "Inpatient surgery" means surgery that requires a patient to receive inpatient services in a hospital.~~
~~35.~~31. "Level of care" means a designation that indicates the scope of medical services, nursing services, and health-related services that are provided to a patient or resident.
~~36.~~32. "Liability" means the same as "liability" in generally accepted accounting principles.
~~37.~~33. "Licensed nurse" means a registered nurse practitioner, registered nurse, or practical nurse.
~~38.~~34. "Licensee" means the same as in R9-10-101.
~~39.~~35. "Median length of stay" means the midpoint in the number of patient care days for all patients who were discharged from a hospice during a specific period of time.
~~40.~~36. "Medicaid" means a federal health insurance program, administered by states, for individuals who meet specific income criteria established, in Arizona, by AHCCCS.
~~41.~~37. "Medical record coder" means an individual who assigns codes to a patient's diagnoses and procedures for billing purposes.
~~42.~~38. "Medical record transcriptionist" means an individual who copies and edits dictation from medical practitioners into medical records.
~~43.~~39. "Medical records" mean the same as in A.R.S. § 12-2291.
~~44.~~40. "Medicare cost report" means the annual financial and statistical documents submitted to the United States Department of Health and Human Services as required by Title XVIII of the Social Security Act.
~~45.~~41. "Medicare-certified" means that a health care institution is authorized by the United States Department of Health and Human Services to bill Medicare for services provided to patients or residents who are eligible to receive Medicare.
~~46.~~42. "Midnight census" means a count of the number of patients or residents in a health care institution at 12:00 a.m.
~~47.~~43. "Net assets" means the same as "net assets" in generally accepted accounting principles.
~~48.~~44. "Non-covered ancillary services" means activities, such as rehabilitation services, laboratory tests, or x-rays, provided to an individual in a health care institution that are paid for by:
a. A payer source other than ALTCS, or
b. ALTCS to an entity that is not a health care institution.
~~49.~~45. "Nursery patient" means a newborn who was born in a hospital and not admitted to a type of bed that is counted toward the hospital's licensed capacity.
~~50. "Nursing care institution-based hospice" means a hospice that operates as a part of a nursing care institution.~~
~~51.~~46. "Nursing personnel" means the individuals authorized by a health care institution to provide nursing services to a patient or resident.
~~52.~~47. "Occupancy rate" means the midnight census divided by the number of available beds, expressed as a percent.
~~53.~~48. "Operating expense" means the same as "operating expense" in generally accepted accounting principles.
~~54.~~49. "Outpatient hospice services" means hospice services provided at a location outside a hospice inpatient facility.
~~55. "Outpatient surgery" means surgery that does not require a patient to receive inpatient services in a hospital.~~
~~56.~~50. "Owner" means the same as in A.A.C. R9-10-101.
~~57.~~51. "Patient care day" means a calendar day during which a hospice provides hospice services to a patient.
~~58.~~52. "Patient day" means a period during which a patient received inpatient services with:
a. The time between the midnight census on two successive calendar days counting as one period, and
b. The day of discharge being counted only when the patient is admitted and discharged on the same day.
~~59.~~53. "Person" means the same as in A.R.S. § 41-1001.
~~60.~~54. "Practical nurse" means an individual licensed under A.R.S. Title 32, Chapter 15, Article 2, to practice practical nursing, as defined in A.R.S. § 32-1601.
~~61.~~55. "Registered nurse" means an individual licensed under A.R.S. Title 32, Chapter 15, Article 2, to practice professional nursing, as defined in A.R.S. § 32-1601.
~~62.~~56. "Rehabilitation services" means the same as in A.A.C. ~~R9-10-201~~ R9-10-101.
~~63.~~57. "Resident day" means a period during which a resident received nursing services or health-related services provided by a nursing care institution with:
a. The time between the midnight census on two successive calendar days counting as one period, and
b. The day of discharge being counted only when the resident is admitted and discharged on the same day.
~~64.~~58. "Respite care services" means the same as in A.R.S. § 36-401.
~~65.~~59. "Revenue" means the same as "revenue" in generally accepted accounting principles.
~~66.~~60. "Routine home care" means hospice services provided in a patient's residence to a patient who does not require nursing services to be available 24 hours a day.
~~67.~~61. "Rural" means the same as in A.R.S. § 36-2171.
~~68.~~62. "Self-pay" means that charges for hospice services are billed to an individual.

~~69.~~63. "Social worker" means an individual licensed according to A.R.S. §§ 32-3291, 32-3292, or 32-3293.
~~70.~~64. "Statement of cash flows" means the same as "statement of cash flows" in generally accepted accounting principles.
~~71.~~65. "Surgery" means the excision of a part of a patient's body or the incision into a patient's body for the correction of a deformity or defect; repair of an injury; or diagnosis, amelioration, or cure of disease.
~~72.~~66. "Turnover rate" means:
a. For a hospital, a percent calculated by dividing the number of individuals employed by the hospital who resign or retire from or are dismissed by the hospital during a reporting period by the average number of individuals employed during the reporting period; or
b. For a nursing care institution, a percent calculated by dividing the number of employees who resign or retire from or are dismissed by a nursing care institution during a reporting period by the average number of employees during the reporting period.
~~73.~~67. "Uniform accounting report" means a document that meets the requirements of A.R.S. § 36-125.04 and contains the information required in R9-11-203 for hospitals, R9-11-204 for nursing care institutions, and R9-11-205 for hospices.
~~74.~~68. "Unscheduled medical services" means the same as in A.R.S. § 36-401.
~~75.~~69. "Urban" means an area not defined as "rural."
~~76.~~70. "Urgent care unit" means a facility under a hospital's license that is:
a. Located within one-half mile of the hospital, and
b. Designated by the hospital for the provision of unscheduled medical services for medical conditions that are of a less critical nature than emergency medical conditions.
~~77.~~71. "Vacancy rate" means a percent calculated by dividing the number of unfilled FTEs at the end of a hospital's reporting period by the sum of the unfilled FTEs and filled FTEs at the end of the hospital's reporting period.
~~78.~~72. "Volunteer" means the same as in A.A.C. ~~R9-10-801~~ R9-10-101.

R9-11-202. Hospital Annual Financial Statement

A. A hospital administrator or designee shall submit to the Department, no later than 120 calendar days after the ending date of the hospital's fiscal year:
1. An annual financial statement prepared according to generally accepted accounting principles;
2. A report of an audit by an independent certified public accountant of the annual financial statement required in subsection (A)(1); and
3. An attestation, signed and dated by the hospital administrator or designee, that the hospital is not passing on the cost of the hospital assessment, established in A.R.S. § 36-2901.08(A), to a patient or a third-party payor that is responsible for paying for the patient's care.

B. If a hospital is part of a group of health care institutions that prepares a combined annual financial statement and is included in the combined annual financial statement, the hospital administrator or designee may submit the combined annual financial statement if the combined annual financial statement:
1. Is prepared according to generally accepted accounting principles,
2. Identifies the hospital, and
3. Contains a financial statement specific to the hospital.

C. The Department shall grant a hospital a 30-day extension for submitting an annual financial statement and report of the audit of the annual financial statement required in subsection (A) if the hospital administrator or designee submits a written request for an extension that:
1. Includes the name, physical address, mailing address, and telephone number of the hospital;
2. Includes the name, telephone number, mailing address, and e-mail address of:
a. The hospital administrator; and
b. An individual, in addition to the hospital administrator, who may be contacted about the extension request;
3. Includes the date the hospital's annual financial statement and audit of the annual financial statement is due to the Department;
4. Specifies that the hospital is requesting a 30-day extension from submitting the annual financial statement and report of the audit of the annual financial statement required in subsection (A); and
5. Is submitted to the Department at least 30 calendar days before the annual financial statement and report of the audit of the annual financial statement is due to the Department.

D. The Department shall send a written notice of approval of a 30-day extension to a hospital that submits a request for an extension that meets the requirements specified in subsection (C) within seven business days after receiving the request.

E. If a request by a hospital administrator or designee for a 30-day extension does not meet the requirements specified in subsection (C), the Department shall provide to the hospital a written notice that specifies the missing or incomplete information. If the Department does not receive the missing or incomplete information within 10 calendar days after the date on the written notice, the Department shall consider the hospital's request withdrawn.

F. Before the end of the 30-day extension specified in subsection (C), a hospital administrator or designee may request an additional extension for submitting an annual financial statement and report of the audit of the annual financial statement by submitting a written request that:
1. Includes the information specified in subsections (C)(1) through (C)(3),
2. Specifies for how many calendar days the hospital is requesting an extension from submitting the annual financial statement and report of the audit of the annual financial statement,
3. Is submitted to the Department at least 14 calendar days before the annual financial statement and report of the audit of the annual financial statement is due to the Department, and
4. Includes the reasons for the additional extension request.

G. In determining whether to approve or deny a request for a hospital to receive an additional extension as specified in subsection (F) for submitting an annual financial statement and report of the audit of the annual financial statement, the Department shall consider the following:
1. The reasons for the additional extension request provided according to subsection (F)(4);
2. The length of time for which the additional extension is being requested according to subsection (F)(2); and
3. If the hospital has a history of the following items:
   a. Repeated violations of the same statutes or rules,
   b. Patterns of noncompliance with statutes or rules,
   c. Types of violations of statutes or rules,
   d. Total number of violations of statutes or rules,
   e. Length of time during which violations of statutes or rules have been occurring, and
   f. Noncompliance with an agreement between the Department and the hospital.

H. The Department shall send written notice of approval or denial to a hospital that requests an additional extension specified in subsection (F) for submitting an annual financial statement and report of the audit of the annual financial statement within seven business days after receiving the request.

I. If the Department denies a request for an additional extension specified in subsection (F), a hospital may appeal the denial according to A.R.S. Title 41, Chapter 6, Article 10.

J. If a hospital administrator or designee does not submit an annual financial statement and a report of an audit of the annual financial statement according to this Section, the Department may assess civil penalties as specified in A.R.S. § 36-126.

R9-11-203. Hospital Uniform Accounting Report

A. A hospital administrator or designee shall submit a uniform accounting report to the Department, in a format specified by the Department, no later than 150 calendar days after the ending date of the hospital's fiscal year.

B. A hospital administrator or designee shall submit a copy of the hospital's Medicare cost report, if applicable, as part of the uniform accounting report required in subsection (A).

C. The uniform accounting report required in subsection (A) shall include the following information:
1. The name, physical address, mailing address, county, and telephone number of the hospital;
2. The name, telephone number, and e-mail address of the:
   a. Hospital administrator,
   b. Hospital chief financial officer, and
   c. Individual who prepared the uniform accounting report;
3. The identification number assigned to the hospital:
   a. By the Department;
   b. By AHCCCS, if applicable;
   c. By Medicare, if applicable; and
   d. As the hospital's national provider identifier;
4. The hospital's classification;
5. Whether the entity that is the owner of the hospital is:
   a. Not for profit;
   b. For profit; or
   c. A federal, state, or local government agency;
6. Whether or not the hospital is Medicare-certified;
7. The ~~ending date~~ beginning and ending dates of the hospital's reporting period;
8. If the hospital began operations during the hospital's reporting period, the date on which the hospital began operations;
9. The date the uniform accounting report was submitted to the Department;
10. The licensed capacity, for each type of bed, at the end of the reporting period;
11. The licensed capacity at the end of the reporting period;
12. The number of available beds, for each type of bed, at the end of the reporting period;
13. The number of available beds at the end of the reporting period;
14. The number of admissions, for each type of bed, during the reporting period;
15. The total number of admissions during the reporting period;
16. The total number of patient days:
   a. During the reporting period, and
   b. For each type of bed during the reporting period;
17. The average occupancy rate for the reporting period;
18. The number of ~~inpatient~~ surgeries during the reporting period that required a patient to receive inpatient services in the hospital;
19. The number of ~~outpatient~~ surgeries during the reporting period that did not require a patient to receive inpatient services in the hospital;
20. The number of births during the reporting period;
21. The number of nursery patient admissions during the reporting period;
22. The number of patient days for nursery patients during the reporting period;
23. The number of episodes of care during the reporting period provided by the:
   a. Emergency department,
   b. Urgent care unit, and
   c. Trauma center;
24. The total number of episodes of care during the reporting period provided by the emergency department, urgent care unit, or trauma center;

25. The number of episodes of care in the emergency department, urgent care unit, or trauma center during the reporting period for which the patient was subsequently admitted to the hospital;
26. The total number of FTEs at the end of the reporting period;
27. The turnover rate for the reporting period;
28. The vacancy rate for the reporting period;
29. The number of FTEs, for each type of employee, during the reporting period;
30. The vacancy rate, for each type of employee, for the reporting period;
31. The number of medical record coder FTEs during the reporting period;
32. The vacancy rate for medical record coders for the reporting period;
33. The number of medical record transcriptionist FTEs during the reporting period;
34. The vacancy rate for medical record transcriptionists for the reporting period;
35. For individuals who worked for the hospital as contracted workers during the reporting period, the number of hours worked by registered nurses;
36. The amount of revenue generated, for each type of revenue, by the hospital during the reporting period;
37. The amount of allowances given, for each type of allowance, by the hospital during the reporting period;
38. The total amount of revenue generated and allowances given by the hospital during the reporting period;
39. The operating expenses incurred, for each type of operating expense, by the hospital during the reporting period;
40. The total operating expenses incurred by the hospital during the reporting period;
41. The difference between the amount identified in subsection (C)(38) and the amount identified in subsection (C)(40);
42. The income and expenses, other than revenue and operating expenses, for each type of income received and expense incurred by the hospital during the reporting period;
43. The amount of assets, for each type of asset, of the hospital at the end of the reporting period;
44. The total amount of assets of the hospital at the end of the reporting period;
45. The amount of liabilities, for each type of liability, of the hospital at the end of the reporting period;
46. The total amount of liabilities of the hospital at the end of the reporting period;
47. The amount of net assets, for each type of net asset, of the hospital at the end of the reporting period;
48. The total amount of net assets of the hospital at the end of the reporting period;
49. The difference between the amount identified in subsection (C)(48) and the amount identified in subsection (C)(46); and
50. The statement of cash flows required in A.R.S. § 36-125.04(C)(3), unless the statement of cash flows has been submitted as part of the annual financial statement required in R9-11-202.

D. A hospital administrator or designee shall:
1. On a form provided by the Department:
   a. Attest that, to the best of the knowledge and belief of the hospital administrator or designee, the information submitted according to subsections (B) and (C) is accurate and complete; or
   b. If the hospital administrator or designee has personal knowledge that the information submitted according to subsections (B) and (C) is not accurate or not complete:
      i. Identify the information that is not accurate or not complete;
      ii. Describe the circumstances that make the information not accurate or not complete;
      iii. State what actions the hospital is taking to correct the inaccurate information or make the information complete; and
      iv. Attest that, to the best of the knowledge and belief of the hospital administrator or designee, the information submitted according to subsections (B) and (C), except the information identified in subsection (D)(1)(b)(i), is accurate and complete; and
2. Submit the form specified in subsection (D)(1) as part of the uniform accounting report required in subsection (A).

E. A hospital administrator who receives a request from the Department for revision of a uniform accounting report not prepared according to subsections (B), (C), and (D) shall ensure that the revised uniform accounting report is submitted to the Department:
1. Within 21 calendar days after the date on the Department's letter requesting an initial revision, and
2. Within seven calendar days after the date on the Department's letter requesting a second revision.

F. If a hospital administrator or designee does not submit a uniform accounting report according to this Section, the Department may assess civil penalties as specified in A.R.S. § 36-126.

R9-11-205. Hospice Uniform Accounting Report

A. A hospice administrator or designee shall submit a uniform accounting report to the Department, in a format specified by the Department, within 150 calendar days after the end of the hospice's fiscal year.

B. A hospice administrator or designee shall submit a copy of the hospice's Medicare and Medicaid cost reports, if applicable, as part of the uniform accounting report required in subsection (A).

C. The uniform accounting report required in subsection (A) shall include the following information:
1. The name, physical address, mailing address, county, and telephone number of the hospice;
2. The identification number assigned to the hospice:
   a. By the Department;
   b. By AHCCCS, if applicable;
   c. By Medicare, if applicable; and
   d. As the hospice's national provider identifier;
3. The beginning and ending dates of the hospice's reporting period;
4. If the hospice began operations during the hospice's reporting period, the date on which the hospice began operations;
5. The name, telephone number, and e-mail address of the:
   a. Hospice administrator,
   b. Hospice chief financial officer, and

c. Individual who prepared the uniform accounting report;
6. The date the uniform accounting report was submitted to the Department;
7. Whether the hospice operates as a:
a. Hospice service agency, or
b. Hospice service agency with one or more hospice inpatient facilities;
8. Whether the entity that is the owner of the hospice is:
a. Not for profit;
b. For profit; or
c. A federal, state, or local government agency;
9. Whether or not the hospice is Medicare-certified;
10. The entity by which the hospice is accredited, if applicable;
11. Whether the hospice provides hospice services in an area that:
a. Is equal to or more than two-thirds urban,
b. Is equal to or more than two-thirds rural, or
c. Is less than two-thirds urban and less than two-thirds rural;
~~12. Whether the hospice is:~~
~~a. Free-standing,~~
~~b. A hospital-based hospice,~~
~~c. A nursing care institution-based hospice,~~
~~d. An assisted living facility-based hospice, or~~
~~e. A home health agency-based hospice;~~
~~13.~~12.If the hospice operates one or more hospice inpatient facilities, list for each hospice inpatient facility:
a. The identification number assigned to the hospice inpatient facility by the Department;
~~b. Whether the hospice inpatient facility is:~~
~~i. Located within a hospital;~~
~~ii. Located within a nursing care institution;~~
~~iii. Located within an assisted living facility; or~~
~~iv. Not located within a hospital, nursing care institution, or assisted living facility;~~
~~c.~~b. The levels of care provided;
~~d.~~c. The licensed capacity of the hospice inpatient facility;
~~e.~~d. The total number of available beds at the beginning and end of the reporting period; and
~~f.~~e. The average occupancy rate for the reporting period;
~~14.~~13.The number of patients during the reporting period that were:
a. Referred to the hospice,
b. Admitted to the hospice,
c. Died while admitted to the hospice, and
d. Discharged from the hospice while living;
~~15.~~14.The number of patient care days, for all patients, during the reporting period in which the hospice provided:
a. Routine home care,
b. Respite care services,
c. Continuous care, and
d. Inpatient services;
~~16.~~15.The total number of patient care days during the reporting period for all patients;
~~17.~~16.The average daily census for the reporting period, calculated as the number specified in subsection ~~(C)(16)~~ (C)(15) divided by the number of days in the reporting period;
~~18.~~17.Average length of stay, calculated as the number of patient care days for patients discharged during the reporting period divided by the sum of the numbers specified in subsections ~~(C)(14)(c)~~ (C)(13)(c) and ~~(C)(14)(d)~~ (C)(13)(d);
~~19.~~18.Median length of stay for patients discharged during the reporting period;
~~20.~~19.The number of patients admitted to the hospice during the reporting period:
a. By gender;
b. By age group;
c. By race and ethnicity;
d. From:
i. A private home owned or leased by, or on behalf of, a patient;
ii. An assisted living facility;
iii. A nursing care institution;
iv. A hospital; and
v. A hospice;
e. With a principal diagnosis of:
i. Cancer,
ii. Heart disease,
iii. Dementia,
iv. Lung disease,
v. Kidney disease,
vi. Stroke or coma,
vii. Liver disease,

viii. HIV-related disease,
ix. Motor neuron disorder,
x. Unspecified debility, and
xi. A disease not specified in subsections ~~(C)(20)(e)(i)~~ (C)(19)(e)(i) through ~~(C)(20)(e)(x)~~ (C)(19)(e)(x); and

f. Whose payer source is:
i. Medicare,
ii. AHCCCS,
iii. Self-pay,
iv. A private insurance company, and
v. A payer source not specified in subsections ~~(C)(20)(f)(i)~~ (C)(19)(f)(i) through ~~(C)(20)(f)(iv)~~ (C)(19)(f)(iv);

~~21.~~20. The total number of patient care days during the reporting period that the hospice provided hospice services to a patient whose principal diagnosis was related to:
a. Cancer,
b. Heart disease,
c. Dementia,
d. Lung disease,
e. Kidney disease,
f. Stroke or Coma,
g. Liver disease,
h. HIV-related disease,
i. Motor neuron disorder,
j. Unspecified debility, and
k. Any other disease not specified in subsections ~~(C)(21)(a)~~ (C)(20)(a) through ~~(C)(21)(j)~~ (C)(20)(j);

~~22.~~21. The number of FTEs providing hospice services, for each type of employee, during the reporting period;

~~23.~~22. The total number of FTEs providing hospice services during the reporting period;

~~24.~~23. The average caseload during the reporting period for a licensed nurse, calculated as the total number of patients assigned to licensed nurses working for the hospice during the reporting period, divided by the total number of licensed nurses working for the hospice during the reporting period, for:
a. Outpatient hospice services, and
b. Hospice services provided in hospice inpatient facilities;

~~25.~~24. The average caseload during the reporting period for a social worker, calculated as the total number of patients assigned to social workers working for the hospice during the reporting period, divided by the total number of social workers working for the hospice during the reporting period, for:
a. Outpatient hospice services, and
b. Hospice services provided in hospice inpatient facilities;

~~26.~~25. The average caseload during the reporting period for nursing personnel other than a licensed nurse, calculated as the total number of patients assigned to nursing personnel other than licensed nurses working for the hospice during the reporting period, divided by the total number of nursing personnel other than licensed nurses working for the hospice during the reporting period, for:
a. Outpatient hospice services, and
b. Hospice services provided in hospice inpatient facilities;

~~27.~~26. The average caseload during the reporting period for a chaplain, calculated as the total number of patients assigned to chaplains working for the hospice during the reporting period, divided by the total number of chaplains working for the hospice during the reporting period, for:
a. Outpatient hospice services, and
b. Hospice services provided in hospice inpatient facilities;

~~28.~~27. The number of individuals who received bereavement services from the hospice during the reporting period;

~~29.~~28. The number of individuals from the hospice who provided bereavement services during the reporting period;

~~30.~~29. The total number of volunteers during the reporting period;

~~31.~~30. The total number of hours that volunteers provided hospice services during the reporting period;

~~32.~~31. The number of patient care days during the reporting period, for whom:
a. The payer source was:
i. Medicare,
ii. AHCCCS,
iii. Self-pay,
iv. A private insurance company, and
v. A payer source not specified in subsections ~~(C)(32)(a)(i)~~ (C)(31)(a)(i) through ~~(C)(32)(a)(iv)~~ (C)(31)(a)(iv), and
b. There was no payer source identified;

~~33.~~32. The total number of patient care days specified in ~~subsections (C)(32)~~ subsection (C)(31);

~~34.~~33. The total amount of money billed, during the reporting period to:
a. Medicare,
b. AHCCCS,
c. Self-pay,
d. A private insurance company, and
e. A payer source not specified in subsections ~~(C)(34)(a)~~ (C)(33)(a) through ~~(C)(34)(d)~~ (C)(33)(d);

~~35.~~34. The total amount of money billed during the reporting period;

~~36.~~35.The amount of revenue generated, for each type of revenue, by the hospice during the reporting period;
~~37.~~36.The amount of allowances given, for each type of allowance, by the hospice during the reporting period;
~~38.~~37.The total amount of revenue generated and allowances given by the hospice during the reporting period;
~~39.~~38.The operating expenses incurred, for each type of operating expense, by the hospice during the reporting period;
~~40.~~39.The total operating expenses incurred by the hospice during the reporting period;
~~41.~~40.The difference between the amount identified in subsection ~~(C)(38)~~ (C)(37) and the amount identified in subsection ~~(C)(40)~~ (C)(39);
~~42.~~41.The income and expenses, other than revenue and operating expenses, for each type of income received and expense incurred by the hospice during the reporting period;
~~43.~~42.The amount of assets, for each type of asset, of the hospice at the end of the reporting period;
~~44.~~43.The total amount of assets of the hospice at the end of the reporting period;
~~45.~~44.The amount of liabilities, for each type of liability, of the hospice at the end of the reporting period;
~~46.~~45.The total amount of liabilities of the hospice at the end of the reporting period;
~~47.~~46.The amount of net assets, for each type of net asset, of the hospice at the end of the reporting period;
~~48.~~47.The total amount of net assets of the hospice at the end of the reporting period;
~~49.~~48.The difference between the amount identified in subsection ~~(C)(48)~~ (C)(47) and the amount identified in subsection ~~(C)(46)~~ (C)(45); and
~~50.~~49.The statement of cash flows required in A.R.S. § 36-125.04(C)(3).

D. A hospice administrator or designee shall:
1. On a form provided by the Department:
   a. Attest that, to the best of the knowledge and belief of the hospice administrator or designee, the information submitted according to subsections (B) and (C) is accurate and complete; or
   b. If the hospice administrator or designee has personal knowledge that the information submitted according to subsections (B) and (C) is not accurate or not complete:
      i. Identify the information that is not accurate or not complete;
      ii. Describe the circumstances that make the information not accurate or not complete;
      iii. State what actions the hospice is taking to correct the inaccurate information or make the information complete; and
      iv. Attest that, to the best of the knowledge and belief of the hospice administrator or designee, the information submitted according to subsections (B) and (C), except the information identified in subsection (D)(1)(b)(i), is accurate and complete; and
2. Submit the form specified in subsection (D)(1) as part of the uniform accounting report required in subsection (A).

E. A hospice administrator who receives a request from the Department for revision of a uniform accounting report not prepared according to subsections (B), (C), and (D) shall ensure that the revised uniform accounting report is submitted to the Department:
1. Within 21 calendar days after the date on the Department's letter requesting an initial revision, and
2. Within seven calendar days after the date on the Department's letter requesting a second revision.

F. If a hospice administrator or designee does not submit a uniform accounting report according to this Section, the Department may assess civil penalties as specified in A.R.S. § 36-126.

ARTICLE 3. RATES AND CHARGES SCHEDULES

R9-11-301. Definitions

In this Article, unless otherwise specified:
1. "Adolescent" means an individual the hospital designates as an adolescent based on the hospital's criteria.
2. "Adult" means the same as in A.A.C. R9-10-201.
3. "Behavioral health service" means the same as in ~~A.A.C. R9-20-101~~ A.R.S. § 36-401.
4. "Blood bank cross match" means a laboratory analysis, performed by a facility that stores and preserves donated blood, to test the compatibility of a quantity of blood donated by one individual with another individual who is the intended recipient of the blood.
5. "Complete blood count with differential" means enumerating the number of red blood cells, platelets, and white blood cells in a sample of an individual's blood, and including in the enumeration of white blood cells the number of each type of white blood cell.
6. "Contrast medium" means a substance opaque to x-rays, radio waves, or electromagnetic radiation that enhances an image of internal body structures.
7. "CT" means Computed Tomography, a diagnostic procedure in which x-ray measurements from many angles are used to provide images of internal body structures.
8. "Current rates and charges information" means the most recent rates and charges schedule for a health care institution on file with the Department, and all documents changing the most recent rates and charges schedule.
9. "Drug" means the same as in A.R.S. § 32-1901.
10. "EEG" means electroencephalogram, a diagnostic procedure used to measure the electrical activity of the brain.
11. "EKG" means electrocardiogram, a diagnostic procedure used to measure the electrical activity of the heart.
12. "Facility" means a building and associated personnel and equipment that perform a particular service or activity.
13. "Formulary" means a list of drugs that are available to a patient through a hospital.
14. "Home health agency" means the same as in A.R.S. § 36-151.
15. "Home health agency administrator" means the chief administrative officer for a home health agency.
16. "Hospital department" means a subdivision of a hospital providing administrative oversight for one or more charge sources.
17. "Implementation date" means the month, day, and year a health care institution intends to begin using specific rates and charges when billing a patient or resident.

18. "Intensive care bed" means an available bed used to provide intensive care services, as defined in A.A.C. R9-10-201, to a patient.
19. "IVP" means intravenous pyelography, a diagnostic procedure that uses an injection of a contrast medium into a vein and x-rays to provide images of the kidneys, ureters, bladder, and urethra.
20. "Labor and delivery" means services provided to a woman related to childbirth.
21. "Lithotripsy" means a procedure that uses sound waves to break up hardened deposits of mineral salts inside the human body.
22. "Mark-up" means the difference between the dollar amount a hospital pays for a drug, commodity, or service and the charge billed to a patient.
23. "MRI" means Magnetic Resonance Imaging, a diagnostic procedure that uses a magnetic field and radio waves to provide images of internal body structures.
24. "Neonate" means the same as in A.A.C. R9-10-201.
25. "Nursery bed" means an available bed used to provide hospital services to a neonate.
26. "Outpatient treatment center" means the same as in A.A.C. R9-10-101.
27. "Outpatient treatment center administrator" means the chief administrative officer for an outpatient treatment center.
28. "Overview form" means a document:
    a. Submitted by a hospital to the Department as part of a rates and charges schedule or a change to the hospital's current rates and charges information, and
    b. That contains the information required in R9-11-302(B)(2) for the hospital.
29. "Pediatric" means the same as in A.A.C. R9-10-201.
30. "Pediatric bed" means an available bed used to provide hospital services to a pediatric patient.
31. "Physical therapy" means the same as in A.R.S. § 32-2001.
32. "Post-hospital extended care services" means the services that are described in and meet the requirements of 42 CFR 409.31.
33. "Private room" means a room that contains one available bed.
34. "Rate" means a specific dollar amount per unit of service set by a health care institution.
35. "Rates and charges schedule" means a document that meets the requirements of A.R.S. Title 36, Chapter 4, Article 3 and contains the information required in R9-11-302(B) for hospitals, R9-11-303(A)(2) for nursing care institutions, R9-11-304(A)(2) for home health agencies, or R9-11-305(A)(2) for outpatient treatment centers.
36. "Rehabilitation bed" means a type of bed used to provide services to a patient to restore or to optimize the patient's functional capability.
37. "Review" means an analysis of a document to ensure that the document is in compliance with the requirements of this Article.
38. "Semi-private room" means a room that contains two available beds.
39. "Skilled nursing bed" means an available bed used for a patient requiring skilled nursing services.
40. "Skilled nursing services" means nursing services provided by an individual licensed under A.R.S. Title 32, Chapter 15.
41. "Small volume nebulizer" means a device that:
    a. Holds liquid medicine that is turned into a mist by an air compressor, and
    b. Is used for treatments lasting less than 20 minutes.
42. "Swing bed" means an available bed for which a hospital has been granted an approval from the Centers for Medicare and Medicaid Services to provide post-hospital extended care services and be reimbursed as a swing-bed hospital.
43. "Swing-bed hospital" means the same as in 42 CFR 413.114.
44. "Trauma team activation" means a notification by a health care institution:
    a. That alerts individuals designated by the health care institution to respond to a particular type of emergency;
    b. That is based on a patient's triage information; and
    c. For which the health care institution uses Revenue Category 068X of the National Uniform Billing Committee, UB-04 Data Specifications Manual to bill charges.
45. "Ultrasound" means a diagnostic procedure that uses high-frequency sound waves to provide images of internal body structures.

ARTICLE 4. HOSPITAL INPATIENT DISCHARGE REPORTING

R9-11-402. Reporting Requirements

A. A hospital administrator shall ensure that the following information, in a format specified by the Department, is submitted to the Department with the inpatient discharge report required in subsection (C):
1. The name of the hospital;
2. The hospital's Arizona facility ID and national provider identifier;
3. The name, mailing address, telephone number, and e-mail address of the individual at the hospital whom the Department may contact about the inpatient discharge report;
4. If the entity submitting the inpatient discharge report to the Department is different from the hospital:
    a. The name of the entity submitting the inpatient discharge report to the Department; and
    b. The name, mailing address, telephone number, and e-mail address of the individual at the entity specified in subsection (A)(4)(a) who prepared the inpatient discharge report;
5. The reporting period; and
6. The name of the electronic file containing the inpatient discharge report specified in subsection (C).

B. A hospital administrator or designee shall on a form provided by the Department:
1. Attest that, to the best of the knowledge and belief of the hospital administrator or designee, the information submitted according to subsection (C) is accurate and complete; or
2. If the hospital administrator or designee has personal knowledge that the information submitted according to subsection (C) is not accurate or not complete:
    a. Identify the information that is not accurate or not complete;

b. Describe the circumstances that make the information not accurate or not complete;
c. State what actions the hospital is taking to correct the inaccurate information or make the information complete; and
d. Attest that, to the best of the knowledge and belief of the hospital administrator or designee, the information submitted according to subsection (C), except the information identified in subsection (B)(2)(a), is accurate and complete.

C. A hospital administrator shall ensure that an inpatient discharge report:
1. Is prepared and named in a format specified by the Department;
2. Uses codes and a coding format specified by the Department for data items specified in subsection (C)(3) that require codes; and
3. Contains the following information for each inpatient discharge that occurred during the reporting period specified in subsection (A)(5):
   a. The Arizona facility ID and national provider identifier for the hospital;
   b. A code indicating that the information submitted about the patient is for an inpatient episode of care;
   c. The patient's medical record number;
   d. The patient's control number;
   e. The patient's name;
   f. The patient's mailing address;
   g. If the patient is not a resident of the United States, a code indicating the country in which the patient resides;
   h. A code indicating that the patient is homeless, if applicable;
   i. The patient's date of birth and last four digits of the patient's Social Security number;
   j. Codes indicating the patient's gender, race, ethnicity, and marital status;
   k. The date and a code indicating the hour the patient was admitted to the hospital;
   l. A code indicating the priority of visit;
   m. A code indicating the referral source;
   n. The date and a code indicating the hour the patient was discharged from the hospital;
   o. A code indicating the patient's discharge status;
   p. If the patient is a newborn, the patient's birth weight in grams;
   q. Whether the patient has a DNR known to the hospital;
   r. The date the bill for hospital services was created;
   s. The total charges billed for the episode of care;
   t. A code indicating the expected payer source;
   u. For each unit of service billed for the episode of care, the:
      i. Revenue code;
      ii. Charge billed; and
      iii. HIPPS code, if applicable;
   v. The DRG code for the episode of care;
   w. The code designating the version of the set of International Classification of Diseases codes used to prepare the bill for the episode of care;
   x. The International Classification of Diseases codes for the patient's admitting, principal, and secondary diagnoses;
   y. If applicable, the ~~E-codes~~ external cause of injury codes or location of injury codes associated with the episode of care;
   z. If applicable, the state in which an accident leading to the episode of care occurred;
   aa. If applicable, the date of the onset of symptoms leading to the episode of care;
   bb. If a procedure was performed during the episode of care:
      i. The International Classification of Diseases codes for the principal procedure and any other procedures performed during the episode of care, and
      ii. The dates the principal procedure and any other procedures were performed;
   cc. The name, state license number, and, if applicable, national provider identifier of the patient's attending provider;
   dd. The code for the state licensing board that issued the license for the patient's attending provider;
   ee. The name, state license number, and, if applicable, national provider identifier of the medical practitioner who performed the patient's principal procedure, if applicable;
   ff. The code for the state licensing board that issued the license for the medical practitioner who performed the patient's principal procedure, if applicable;
   gg. The name, state license number, and, if applicable, national provider identifier of any other medical practitioner associated with the patient's episode of care; and
   hh. The code for the state licensing board that issued the license for each of the individuals specified in subsection (C)(3)(gg).

D. A hospital administrator shall ensure that the report specified in subsection (C), the information specified in subsection (A), and the attestation statement specified in subsection (B) are submitted to the Department at least twice each calendar year, according to the following schedule:
1. For initial electronic submission of reports for individual inpatient discharges on a real-time basis, within 48 hours after the discharge; and
2. For bulk submission of inpatient discharges or completion of an electronic submission:
   ~~1.~~a. For each inpatient discharge between January 1 and June 30, the reports, information, and attestation statement shall be submitted after June 30 and no later than August 15; and
   ~~2.~~b. For each inpatient discharge between July 1 and December 31, the reports, information, and attestation statement shall be submitted after December 31 and no later than February 15.

E. A hospital administrator who receives a request from the Department for revision of a report not prepared according to subsections (A), (B), and (C) shall ensure that the revised report is submitted to the Department:
1. Within 21 calendar days after the date on the Department's letter requesting an initial revision, and

2. Within seven calendar days after the date on the Department's letter requesting a second revision.

F. If a hospital administrator or designee does not submit the report specified in subsection (C), the information specified in subsection (A), and the attestation statement specified in subsection (B) according to this Section, the Department may assess civil penalties as specified in A.R.S. § 36-126.

ARTICLE 5. EMERGENCY DEPARTMENT DISCHARGE REPORTING

R9-11-502. Reporting Requirements

A. A hospital administrator shall ensure that the following information, in a format specified by the Department, is submitted to the Department as part of the emergency department discharge report required in subsection (C):
1. The name of the hospital;
2. The hospital's Arizona facility ID and national provider identifier;
3. The name, mailing address, telephone number, and e-mail address of the individual at the hospital whom the Department may contact about the emergency department discharge report;
4. If the entity submitting the emergency department discharge report to the Department is different from the hospital:
   a. The name of the entity submitting the emergency department discharge report to the Department; and
   b. The name, mailing address, telephone number, and e-mail address of the individual at the entity specified in subsection (A)(4)(a) who prepared the emergency department discharge report;
5. The reporting period; and
6. The name of the electronic file containing the emergency department discharge report specified in subsection (C).

B. A hospital administrator or designee shall on a form provided by the Department:
1. Attest that, to the best of the knowledge and belief of the hospital administrator or designee, the information submitted according to subsection (C) is accurate and complete; or
2. If the hospital administrator or designee has personal knowledge that the information submitted according to subsection (C) is not accurate or not complete:
   a. Identify the information that is not accurate or not complete;
   b. Describe the circumstances that make the information not accurate or not complete;
   c. State what actions the hospital is taking to correct the inaccurate information or make the information complete; and
   d. Attest that, to the best of the knowledge and belief of the hospital administrator or designee, the information submitted according to subsection (C), except the information identified in subsection (B)(2)(a), is accurate and complete.

C. A hospital administrator shall ensure that an emergency department discharge report:
1. Is prepared and named in a format specified by the Department;
2. Uses codes and a coding format specified by the Department for data items specified in subsection (C)(3) that require codes; and
3. Contains the following information for each emergency department discharge that occurred during the reporting period specified in subsection (A)(5):
   a. The Arizona facility ID and national provider identifier for the hospital;
   b. A code indicating that the information submitted about the patient is for an emergency department episode of care;
   c. The patient's medical record number;
   d. The patient's control number;
   e. The patient's name;
   f. The patient's mailing address;
   g. If the patient is not a resident of the United States, a code indicating the country in which the patient resides;
   h. A code indicating that the patient is homeless, if applicable;
   i. The patient's date of birth and last four digits of the patient's Social Security number;
   j. Codes indicating the patient's gender, race, ethnicity, and marital status;
   k. The date and a code indicating the hour the episode of care began;
   l. A code indicating the priority of visit;
   m. A code indicating the referral source;
   n. The date and a code indicating the hour the patient was discharged from the emergency department;
   o. A code indicating the patient's discharge status;
   p. Whether the patient has a DNR known to the hospital;
   q. The date the patient's bill was created;
   r. The total charges billed for the episode of care;
   s. A code indicating the expected payer source;
   t. For each unit of service billed for the episode of care, the:
      i. Revenue code;
      ii. Charge billed; and
      iii. HCPCS code, if applicable;
   u. The code designating the version of the set of International Classification of Diseases codes used to prepare the bill for the episode of care;
   v. The International Classification of Diseases code designating the reason for the patient initiating the episode of care;
   w. The International Classification of Diseases codes for the patient's principal and, if applicable, secondary diagnoses;
   x. If applicable, the ~~E-codes~~ external cause of injury codes or location of injury codes associated with the episode of care;
   y. If applicable, the state in which an accident leading to the episode of care occurred;
   z. If applicable, the date of the onset of symptoms leading to the episode of care;
   aa. For each procedure performed during the episode of care:

i. The applicable International Classification of Diseases, HCPCS/CPT codes for the principal procedure and any other procedures performed during the episode of care; and
ii. The dates the principal procedure and any other procedures were performed;
bb. The name, state license number, and, if applicable, national provider identifier of the patient's attending provider;
cc. The code for the state licensing board that issued the license for the patient's attending provider;
dd. The name, state license number, and, if applicable, national provider identifier of the medical practitioner who performed the patient's principal procedure, if applicable;
ee. The code for the state licensing board that issued the license for the medical practitioner who performed the patient's principal procedure, if applicable;
ff. The name, state license number, and, if applicable, national provider identifier of any other medical practitioner associated with the patient's episode of care; and
gg. The code for the state licensing board that issued the license for each of the individuals specified in subsection (C)(3)(ff).

D. A hospital administrator shall ensure that the report specified in subsection (C), the information specified in subsection (A), and the attestation statement specified in subsection (B) are submitted to the Department at least twice each calendar year, according to the following schedule:
1. For initial electronic submission of reports for individual emergency department discharges on a real-time basis, within 48 hours after the discharge; and
2. For bulk submission of emergency department discharges or completion of an electronic submission:
~~1.~~a. For each emergency department discharge between January 1 and June 30, the report, information, and attestation statement shall be submitted after June 30 and no later than August 15; and
~~2.~~b. For each emergency department discharge between July 1 and December 31, the report, information, and attestation statement shall be submitted after December 31 and no later than February 15.

E. A hospital administrator who receives a request from the Department for revision of an emergency department discharge report not prepared according to subsections (A), (B), and (C) shall ensure that the revised report is submitted to the Department:
1. Within 21 calendar days after the date on the Department's letter requesting an initial revision, and
2. Within seven calendar days after the date on the Department's letter requesting a second revision.

F. If a hospital administrator or designee does not submit the report specified in subsection (C), the information specified in subsection (A), and the attestation statement specified in subsection (B) according to this Section, the Department may assess civil penalties as specified in A.R.S. § 36-126.

ARTICLE 6. HEALTH PROFESSIONALS WORKFORCE DATABASE

R9-11-601. Definitions

In addition to the definitions in A.R.S. § 32-3249 and R9-11-101, the following definitions apply in this Article unless otherwise specified:
1. "Direct patient care" means the same as in A.A.C. R9-15-101.
2. "Primary practice location" means the facility in which an individual provides direct patient care for the majority of time during a year.

R9-11-602. Designated Database Information

A. A Board shall establish a process for requesting the information in subsection (B):
1. From an individual applying for an initial license, certification, or registration, at the time of application; and
2. From an individual regulated by the Board, in compliance with A.R.S. § 32-3249.01(A).

B. Except as specified in subsection (C), a Board shall request the following information about an individual, in a Department-provided format:
1. The individual's name;
2. The individual's date of birth;
3. The individual's gender;
4. The individual's race and ethnicity;
5. If applicable, the individual's National Provider Number;
6. Whether the individual is able to provide services to patients or clients in a language other than English and, if so, in which languages;
7. The type of license, certification, or registration held by the individual or for which the individual is applying;
8. The individual's professional license, registration, or certification number, if applicable;
9. The beginning and end date of the individual's current license, certification, or registration, if applicable;
10. The individual's highest level of training or education related to the individual's license, certification, or registration;
11. The individual's highest level of education in another field;
12. The individual's current employment status;
13. Whether the individual is currently providing direct patient care related to the individual's license, certification, or registration, as applicable, on a regular basis in Arizona and, if so:
a. The zip code of the individual's primary practice location;
b. The type of facility in which the individual is providing direct patient care at the primary practice location;
c. The number of weeks worked over the previous 12 months at the primary practice location;
d. The average hours worked per week at the primary practice location, including the percentage of time spent in:
i. Direct patient care;
ii. Administration, including any paperwork not part of direct patient care;
iii. Research;
iv. Teaching or education; or
v. Other specified activities;

e. Whether the individual expects a change in subsection (B)(13)(b), (c), or (d) in the next 12 months; and
f. If the individual expects to reduce the time spent providing direct patient care in the next 12 months, the reason for the change; and

14. If the individual is a physician, physician assistant, or registered nurse practitioner, whether the individual provides primary care services, as defined in A.A.C. R9-24-201.

R9-11-603. Transfer of Data from a Board

A. A Board shall transfer the designated database information collected according to R9-11-602 to the Department:
1. Within 60 calendar days after the effective date of this Section and on or before April 30 each year thereafter;
2. In a secure format specified by the Department and agreed to by the Board and the Department, based on the capabilities and limitations of the Board's data system that is used for storing the collected designated database information; and
3. Without the Board needing to change the format of the designated database information in the Board's data system.

B. For an initial transfer of designated database information each year, a Board shall transfer to the Department:
1. The designated database information specified in R9-11-602(B) that is already collected by the Board as part of the Board's licensing, certification, or registration process; and
2. Any other collected designated database information specified in R9-11-602, even if the information is incomplete.

C. The Department shall:
1. Review the designated database information transmitted by each Board according to subsection (B) for completeness and consistency with the designated database information specified in R9-11-602(B)(1) through (13) and, if applicable, R9-11-602(B)(14);
2. Notify each Board of:
   a. Inconsistencies with the designated database information specified in R9-11-602(B)(1) through (14), and
   b. Incomplete information about individuals regulated by the Board;
3. Compile the designated database information transmitted by each Board into a single data set, stored in the health care professionals workforce data repository specified in A.R.S. § 36-171(A); and
4. Post the availability of designated database information on the Department's website.

D. Based on the information provided by the Department according to subsection (C)(2), a Board shall each year:
1. Review the process established by the Board according to R9-11-602(A), and
2. Make changes to the process that improve the consistency and completeness of the designated database information that will be transferred to the Department in the subsequent year.

R9-11-604. Requests for Release of Designated Database Information and Reports

A. Designated database information is confidential, subject to the disclosure provisions of A.R.S. § 32-3249.01(B) and (C) and 9 A.A.C. 1, Article 3.

B. The Department:
1. Shall release designated database information in an annual data set;
2. May release designated database information in a customized data set; and
3. May release reports summarizing the designated database information, based upon information requested.

C. A person may request the release of designated database information by submitting to the Department:
1. A written request, in a Department-provided format, that includes:
   a. The name, mailing address, email address, and telephone number of the person submitting the request;
   b. If applicable, the name, title, email address, and telephone number of an individual from an organization specified according to subsection (C)(1)(a);
   c. The address to which released designated database information is to be sent;
   d. In which of Department-specified, secure formats the person is requesting the released designated database information to be sent;
   e. If requesting the release of designated database information in a customized data set according to subsection (B)(2), the specific designated database information being requested, including:
      i. The specific Board or Boards,
      ii. The time period for the requested designated database information, and
      iii. Any other descriptors for the requested designated database information;
   f. The reason the person is requesting the release of designated database information;
   g. A description of the methods to be used by the person to ensure the privacy and security of released designated database information;
   h. Attestations that the person requesting the release of designated database information:
      i. Shall not use or disclose any portion of the released designated database information for any purpose other than a purpose specified according to subsection (C)(1)(f);
      ii. Shall safeguard the released designated database information from unauthorized access, including ensuring that the designated database information is not re-released to another person;
      iii. Shall not attempt to reidentify or contact individuals based on released designated database information;
      iv. Shall notify the Department upon learning the identity of an individual in the released designated database information;
      v. Understands that failure to ensure the privacy and security of released designated database information may result in denial of future releases of designated database information;
      vi. Understands that the Department retains ownership of the released designated database information;
      vii. Shall retain designated database information for a period of no more than five years from the date of release; and
      viii. Shall submit a certificate of destruction, in a Department-provided format, to the Department upon destruction of the released designated database information; and

i. The dated signature of the individual specified according to subsection (C)(1)(b); and

2. Either:
   a. A fee of $100 for the release of designated database information in an annual data set, or
   b. A fee that covers the costs of the Department in producing and releasing designated database information in a customized data set.

D. A person may request the release of a report summarizing the designated database information or specific portions of the designated database information by submitting to the Department:

1. A written request, in a Department-provided format, that includes:
   a. The name, mailing address, email address, and telephone number of the person submitting the request;
   b. If applicable, the name, title, email address, and telephone number of an individual from an organization specified according to subsection (C)(1)(a);
   c. The address to which the released report is to be sent;
   d. The specific designated database information to be included in the summarized report, including:
      i. The specific Board or Boards,
      ii. The time period of the requested designated database information, and
      iii. Any other descriptors of the requested designated database information; and
   e. The dated signature of the individual specified according to subsection (D)(1)(b); and
2. A fee that covers the costs of the Department in producing and releasing the report.

NOTICE OF PROPOSED RULEMAKING

TITLE 20. COMMERCE, FINANCIAL INSTITUTIONS, AND INSURANCE

CHAPTER 6. DEPARTMENT OF INSURANCE AND FINANCIAL INSTITUTIONS INSURANCE DIVISION

[R22-13]

PREAMBLE

1. Article, Part, or Section Affected (as applicable) — **Rulemaking Action**

Article 13	New Article
R20-6-1301	New Section
R20-6-1302	New Section
R20-6-1303	New Section
R20-6-1304	New Section
R20-6-1305	New Section
Exhibit A	New Exhibit

2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. § 20-143

Implementing statute: Laws 2020, Chap. 4, Sec. 8. (SB1523)

3. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the proposed rule:

Notice of Rulemaking Docket Opening: 28 A.A.R. 347, February 4, 2022 (*in this issue*)

4. The agency's contact person who can answer questions about the rulemaking:

Name: Mary E. Kosinski

Address: Department of Insurance and Financial Institutions
100 N. 15th Ave., Suite 261
Phoenix, AZ 85007-2630

Telephone: (602) 364-3476

Email: mary.kosinski@difi.az.gov

5. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

In 2020, the Arizona Legislature enacted the Arizona Mental Health Parity Act (also known as "Jake's Law") at A.R.S. §§ 20-3501 through 20-3505 to implement the provisions of the federal Mental Health Parity and Addiction Equity Act ("MHPAEA" 42 U.S.C. 300gg-26 and implementing regulations) on the state level. It also charged the Department of Insurance and Financial Institutions ("Department") to: "adopt by rule both of the following: 1. Forms or worksheets that health care insurers must use to prepare the reports required by section 20-3502 . . . and 2. Standards to determine compliance with the mental health parity and addiction equity act." Laws 2020, Chap. 4, Sec. 8. (SB1523).

MHPAEA generally establishes that health insurance issuers that provide mental health or substance use disorder (MH/SUD) benefits may not, among other things, impose less favorable benefit limitations on MH/SUD benefits than on medical/surgical benefits. State insurance authorities, the U.S. Department of Health and Human Services, and the U.S. Department of Labor (U.S. DOL) have jurisdiction over applicable individual and group health insurance policies. MHPAEA regulations establish standards related to health care insurers' application of financial requirements (e.g., deductibles and co-payments), quantitative treatment

limitations (e.g., visit limits), and nonquantitative treatment limitations (e.g., step therapy, prior authorization). Health care insurers cannot apply financial requirements (FRs) or quantitative treatment limitations (QTLs) to MH/SUD policy benefits that are more restrictive than the predominant financial requirements or treatment limitations that apply to substantially all medical/surgical benefits. Nor can health care insurers impose nonquantitative treatment limitations (NQTLs) with respect to MH/SUD benefits in any classification unless the processes, strategies, evidentiary standards, or other factors used in applying the NQTL to MH/SUD benefit classifications are comparable to those used with medical surgical/benefits classifications.

This rulemaking is intended to fulfill the Legislature's charge to create forms and worksheets that health care insurers must use to prepare the reports required by A.R.S. § 20-3502 and establish standards to determine compliance with MHPAEA.

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

The Department did not review and does not propose to rely on any study relevant to this rulemaking.

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

The rulemaking does not diminish a previous grant of authority granted to the Department.

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

Pursuant to A.R.S. § 41-1055(A):

- The conduct the rulemaking is designed to change is the practice of health care insurers that provide mental health or substance use disorder ("MH/SUD") benefits to provide those benefits on parity with the provision of medical and surgical ("Med/Surg") benefits. This means that limitations health care insurers impose on MH/SUD benefits can be no more stringent or less favorable than the limitations the health care insurer imposes on Med/Surg benefits.
- The failure of a health care insurer to provide MH/SUD benefits on parity with Med/Surg benefits may result in having an insured unable to obtain MH/SUD medical care because the limitations imposed on those benefits are more stringent or less favorable than imposed on other types of benefits.
- It is not presumed that the health care insurers in Arizona are non-compliant with the parity requirements of the Arizona Mental Health Parity Act (A.R.S. §§ 20-3501 through 20-3505). However, the reporting requirements of the rulemaking will ensure that health care insurers remain in compliance with the Act.
- The costs incurred by health care insurers are not expected to impact revenues or payroll expenditures. Instead, the costs incurred are compliance costs driven by the reporting requirements imposed by the proposed rulemaking. Many health care insurers are already familiar with MHPAEA and have been complying through federal regulations imposed on portions of their business. These already incurred costs are not expected to change appreciably under the proposed rulemaking. Additional costs, however, may arise in order to comply with the additional statutory reporting requirements. But, these costs are not anticipated to impact revenues or payroll expenditures.
- Groups participating in the listening sessions allowed under the bill generally requested that the Department demonstrate that it has selected an alternative that imposes the least burden and costs to persons regulated by the rule under A.R.S. § 41-1052 although they did not enumerate any anticipated costs.
- The employee listed in Item 9 may be contacted to submit or request additional data on the information included in the economic, small business and consumer impact statement.

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

Name: Mary E. Kosinski

Address: Department of Insurance and Financial Institutions
100 N. 15th Ave., Suite 261
Phoenix, AZ 85007-2630

Telephone: (602) 364-3476

Email: mary.kosinski@difi.az.gov

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

No proceeding is currently scheduled. Persons who wish to request an Oral Proceeding on this rulemaking should make a written request to the person listed in item 9. Requests must be received within 30 days of the publication of this Notice of Proposed Rulemaking. A.R.S. § 41-1023(C). If requested, the Oral Proceeding will be conducted at least 30 days after the receipt of any such request.

In lieu of an oral proceeding, interested parties may submit public comments to: public_comments@difi.az.gov. Please use "Mental Health Parity II" in the subject line of the e-mail.

If no one requests an oral proceeding, the public comment period will close 30 days after the publication date of this Notice of Proposed Rulemaking. If anyone requests an oral proceeding, the public comment period will close at 11:59 p.m., on the date of the oral proceeding.

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

No other matters prescribed by statute are applicable to the Department or to any specific rule or class of rules.

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

permit is not used:

The rule does not require a permit and does not use a general permit. Instead, the rule is designed to provide guidance to health care insurers on the reporting requirements of A.R.S. § 20-3502 and the standards to determine compliance with MHPAEA.

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

The Mental Health Parity and Addiction Equity Act ("MHPAEA") (42 U.S.C. 300gg-26 and implementing regulations) is applicable to the subject of the rule. The rule is not more stringent than the federal law and complies with the statutory mandates established by the Legislature. **(**Laws 2020, Chap. 4, Sec. 8.) Instead, the rule requires health care insurers to submit their analyses that demonstrate their compliance with the provisions of MHPAEA.

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

No formal analysis has been submitted to the Department that compares the rule's impact of the competitiveness of business in this state to the impact of business in other states.

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

The rule does not incorporate any reference material into the rule as specified at A.R.S. § 41-1028. However, the rule has multiple references to portions of the federal act for consistency and clarity for insurers having to comply with the Act.

13. The full text of the rules follows:

TITLE 20. COMMERCE, FINANCIAL INSTITUTIONS, AND INSURANCE

CHAPTER 6. DEPARTMENT OF INSURANCE AND FINANCIAL INSTITUTIONS INSURANCE DIVISION

ARTICLE 13. ~~RESERVED~~MENTAL HEALTH PARITY

Section

ARTICLE 13. ~~RESERVED~~MENTAL HEALTH PARITY

R20-6-1301. Definitions

The definitions in A.R.S. § 20-3501 and the following definitions apply to this Article:

"Arizona Mental Health Parity Act" means the statutes found at A.R.S. §§ 20-3501 through 20-3505.

"Coverage unit" has the meaning prescribed at 45 C.F.R. § 146.136(a) "Coverage unit."

"Department of Insurance and Financial Institutions (Department)" has the meaning prescribed at A.R.S. § 20-101.

"CMS MHPAEA tool" means the Microsoft Excel Mental Health Parity tool maintained by the Center for Medicare and Medicaid Services.

"Financial requirements (FR)" has the meaning at 45 C.F.R. § 146.136(a) "Financial requirements."

"Health care insurer" has the meaning prescribed at A.R.S. § 20-3501(2).

"Health plan" has the meaning prescribed at A.R.S. § 20-3501(3).

"Inpatient, in-network benefits" are benefits furnished on an inpatient basis and within a network of contracted providers under a health plan.

"Inpatient, out-of-network benefits" are benefits furnished on an inpatient basis by providers without a contract under a health plan or for a health plan that has no network of providers.

"Large group health plan" is a health plan issued to an employer group that is not a small employer as defined at A.R.S. § 20-2301(A)(20).

"Medical/surgical (Med/Surg) benefits" has the meaning prescribed at 45 C.F.R. § 146.136(a) "Medical/surgical benefits."

"Mental (MH) health benefits" has the meaning prescribed at 45 C.F.R.§ 146.136(a) "Mental health benefits."

"MHPAEA" means the Mental Health Parity and Addiction Equity Act prescribed in A.R.S. § 20-3501(4).

"Nonquantitative treatment limitation (NQTL)" is a limitation that restricts the scope or duration of benefits for treatment under a health plan or coverage. Illustrations of NQTLs include: medical management standards limiting or excluding benefits based on medical necessity or appropriateness or based on whether the treatment is experimental or investigative as identified under 45 C.F.R. 146.136(c)(4)(ii)(A); formulary design for prescription drugs as identified under 45 C.F.R. 146.136(c)(4)(ii)(B); network tier design (for health plans with multiple network tiers such as preferred providers and participating providers) as identified under 45 C.F.R.

146.136(c)(4)(ii)(C); standards for provider admission to participate in a network, including reimbursement rates as identified under 45 C.F.R. 146.136(c)(4)(ii)(D); methods for determining usual, customary, and reasonable charges as identified under 45 C.F.R. 146.136(c)(4)(ii)(E); refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as "fail-first policies" or "step therapy protocols") as identified under 45 C.F.R. 146.136(c)(4)(ii)(F); exclusions based on failure to complete a course of treatment; and restrictions based on geographic location as identified under 45 C.F.R. 146.136(c)(4)(ii)(G), facility type, provider specialty, and other criteria than limit the scope or duration of benefits for services provided under the health plan or coverage as identified under 45 C.F.R. 146.136(c)(4)(ii)(H).

"Outpatient, in-network benefits" are benefits furnished on an outpatient basis and within a network of providers established or recognized under a health plan.

"Outpatient, out-of-network benefits" are benefits furnished on an outpatient basis and outside any network of providers established or recognized under a health plan or under a health plan that has no network of providers.

"Predominant test" means that if a type of FR or QTL applies to substantially all of the Med/Surg benefits in a classification, the predominant level of the FR or QTL is the level that applies to more than 1/2 of the Med/Surg benefits in that classification subject to the FR or QTL. If no single level can be determined, the health plan (or health insurance issuer) may combine levels until the combination of levels applies to more than 1/2 of Med/Surg benefits subject to the FR or QTL in the classification. The least restrictive level within the combination is considered the predominant level of that type of classification. For this purpose, a health plan may combine the most restrictive levels first with each less restrictive level added to the combination until the combination applies to more than 1/2 of the benefits subject to the FR or QTL.

"Quantitative treatment limitation (QTL)" is a limitation on the scope or duration of a benefit that can be expressed numerically that includes day or visit limits such as "50 outpatient visits per year." QTLs include annual, episode, and lifetime day and visit limits such as number of treatments, number of visits, or days of coverage.

"Substance use disorder (SUD) benefits has the meaning prescribed at 45 C.F.R.§ 146.136(a) "Substance use disorder benefits."

"Substantially all test" means that a FR or QTL applies to at least 2/3 of all Med/Surg benefits in a classification of benefits for a coverage unit. (For this purpose, benefits expressed as subject to a zero level of a type of FR are treated as not subject to that type of FR. In addition, benefits expressed as subject to an unlimited QTL are treated as not subject to that type of QTL.) If a type of FR or QTL does not apply to at least 2/3 of all Med/Surg benefits in a classification, then that type of FR or QTL cannot be applied to MH or SUD benefits in that classification.

R20-6-1302. Medical Necessity Criteria and NQTL Reporting

A. Health care insurers subject to the reporting requirement. A health care insurer that issues health plans in Arizona is required to file the reports required by this Section with the Department.

B. Health plans subject to reporting. A health care insurer shall submit a report for all health plans it offers in this state (including grandfathered and non-grandfathered health plans) that meet all of the criteria listed in subsections (B)(1) through (B)(4) of this Section. If a health care insurer determines that the information to be reported varies by network plan, or varies in the individual, small group, or large group market, the health care insurer must submit a separate report for each variation.

1. The health plan offers MH and/or SUD benefits in addition to Med/Surg benefits.
2. The health plan offers MH and/or SUD benefits in at least one of the following classifications:
   a. Inpatient, in-network;
   b. Inpatient, out-of-network;
   c. Outpatient, in-network;
   d. Outpatient, out-of-network;
   e. Emergency care; or
   f. Prescription drugs.
3. The health plan is offered on a group (large or small) or individual basis.
4. The health plan has not received and notified the Department of an increased cost exemption pursuant to 45 C.F.R. 146.136(g).

C. Health plans exempt from reporting. A health plan that meets the criteria of Subsection (B) above is exempt from reporting under this Article if it is one of the following types of health plans:

1. A small group grandfathered health plan;
2. A small group non-grandfathered health plan subject to the HHS transitional policy; or
3. A health plan that meets the definition of excepted benefit provided in 45 C.F.R. 146.145(b) or 45 C.F.R. 148.220.

D. Required reports. A health care insurer shall file a separate report for each fully insured product network type the health care insurer issues in Arizona. If the information to be reported varies by network or health plan, or varies in the individual, small group or large group market, the health care insurer must file a separate report for each variation.

E. Triennial Reports.

1. Existing health care insurers. Beginning on March 15, 2023 and every third year thereafter, a health care insurer issuing health plans and collecting premium in Arizona as of January 1, 2022 shall file a triennial report with the Department for each health plan subject to reporting.
2. Entering or re-entering health care insurers. On or before March 15 of the second year an entering or re-entering health care insurer issues health plans and collects premiums in Arizona, the health care insurer shall file an original triennial report with the Department for each health plan subject to reporting. Following the filing of the original triennial report, the health care insurer shall submit subsequent triennial reports on the schedule described in subsection (E)(1) of this Section.
3. Due date for triennial reports. Triennial reports are due on or before March 15 of each reporting year.
4. Content of the original triennial report. Health care insurers shall file an original triennial report with the Department under A.R.S. § 20-3502(B) that provides the required information in Exhibit A.

5. Subsequent triennial reports.
   a. A health care insurer must file an updated triennial report, including the information required in Exhibit A, unless the health care insurer can attest that it has made no changes since the previously filed triennial report.
   b. As required by A.R.S. § 20-3502(E), a health care insurer shall file the following with the Department for each health plan subject to reporting:
      i. An updated triennial report, including the information required in Exhibit A; or
      ii. The last triennial report filed with the Department and a written attestation that the health care insurer has made no changes since it filed the previous triennial report.

F. Annual Reports. Pursuant to A.R.S. § 20-3502(E), on or before March 15 of each intervening year between the filing of a triennial report, a health care insurer shall file:
1. A report that summarizes any changes made to its medical necessity criteria and NQTLs (Exhibit A, Parts I, II, and III);
2. A written attestation by an officer or director of the health care insurer that the health care insurer is in compliance with MHPAEA; and
3. If requested by the Department, any additional data required by the Department including Exhibit A, Part IV.

G. Additional information. At any time after a health care insurer files a report under this Section, the Department may request additional information, including an updated triennial or annual report, by contacting the health care insurer and making the request in writing. The health care insurer shall provide contact information to the Department when it files any of the reports required by this Section. The Department may set a deadline for a health care insurer to respond to its request and specify the format for the response.

R20-6-1303. FR and QTL Reporting

A. Method of reporting. A health care insurer that issues health plans in Arizona and whose policy forms are not exempt from the form filing requirement shall demonstrate its compliance with the FR and QTL parity requirements of MHPAEA through its form and rate filings with the Department.

B. Department's authority to require additional data. In addition to the forms filed by a health care insurer, the Department may require a health care insurer to submit additional data relating to its methods for meeting the MHPAEA FR and QTL standards. The Department may utilize the CMS MHPAEA tool and may request samples of a health care insurer's internal testing to demonstrate compliance with the substantially all and predominant tests within each classification of benefits for a health plan.

C. Separate consolidated report for large group health plans. The Department may require a health care insurer that issues large group health plans to file a consolidated report that demonstrates compliance with the substantially all and predominant tests within each classification of benefits for a sample of large group health plans with similar benefit structures.

D. Special rule for FRs - Prescription Drug Classification. The multi-tiered prescription drug benefits exception of A.R.S. § 20-3502(D)(1) applies to the FRs for the prescription drug classification. For example, a health plan applies 4 tiers as follows: Tier 1: Generic Drugs for which the health plan pays 90%; Tier 2: Preferred Brand-name Drugs for which the health plan pays 80%; Tier 3: Non-preferred Brand-name Drugs for which the health plan pays 60%; and Tier 4: Specialty Drugs for which the health plan pays 50%. These FRs are applied without regard to whether a drug is prescribed for Med/Surg or MH/SUD benefits. In addition, the process for certifying a particular drug within a tier complies with the rules for NQTLs. Therefore, the FRs applied to prescription drug benefits meet the parity requirements under MHPAEA.

E. Special rules for FRs and QTLs.
1. In-network Classifications. The multiple network tiers exception of A.R.S. § 20-3502(D)(2) applies to the FRs and QTLs for the in-network classifications. For example, a health plan has 2 tiers of in-network providers: Tier 1: Preferred provider; and Tier 2: Participating provider. Placement of a provider into a tier complies with the rules for NQTLs and is determined without regard to whether the provider specializes in the treatment of Med/Surg conditions or MH/SUD disorders. The in-network classifications are divided into 2 subclassifications: 1. In-network preferred; and 2. In-network participating. The health plan does not impose any FR or QTL on MH/SUD benefits in either subclassification that is more restrictive than the predominant FR or QTL that applies to all Med/Surg benefits in each subclassification. Therefore, the FRs or QTLs applied to the in-network subclassifications that reflect the provider tiers meet the parity requirements under MHPAEA.
2. Outpatient Classifications. The sub-classification permitted for the office visits exception of A.R.S. § 20-3502(D)(3) applies to the FRs and QTLs for the outpatient classifications. For example, a health plan divides the outpatient, in-network classification into 2 subclassifications: 1. In-network office visits; and 2. All other outpatient, in-network items and services. The health plan does not impose any FR or QTL on MH/SUD benefits in either subclassification that is more restrictive than the predominant FR or QTL that applies to Med/Surg benefits in each subclassification. Therefore, the FRs or QTLs applied to the outpatient subclassifications for office visits and all other outpatient items and services meet the parity requirements under MHPAEA.

   The health plan cannot use a subclassification for generalists and specialists. The only subclassifications permitted for the in-network classifications are: 1. Office visits (such as physician visits); and 2. All other outpatient items and services (such as outpatient surgery, facility charges for day treatment centers, laboratory charges, or other medical items).

R20-6-1304. Additional Information or Data

According to A.R.S. § 20-3502(F), the Department is not prohibited from otherwise requesting information or data that is necessary to verify compliance with MHPAEA and the Arizona Mental Health Parity Act.

R20-6-1305. Confidentiality of Information

According to A.R.S. § 20-3502(G), all documents, reports, or other materials provided to the Department under this Article are confidential and are not subject to disclosure and are subject to the restrictions of A.R.S. § 20-157.01(B).

Exhibit A. Medical Necessity Criteria and NQTL Reports

Medical Necessity Criteria and NQTL Reports

Instructions for Exhibit A:

Submit an Exhibit A for each fully insured, major medical health plan subject to reporting under Section R20-6-1303(B). Please submit the information in a word-searchable PDF file which is organized and identified by the numbered sections that appear below.

Part I: Identify Plan and Reporting Year.

Instructions for Part I:

The reporting year is the year, from January 1 through December 31, immediately preceding the submission of this Exhibit A.

Reporting Year:		
Health Care Insurer Name:		
Health Care Insurer NAIC Company Code:		
Network Name(s):		
Service Area: (List all counties in the service area for these networks)		
Covered Lives: (List the number of covered lives enrolled in plans in these networks in the reporting year)		
Plan Types: (Check all that apply)	☐Individual ACA-Compliant	☐Small Group ACA-Compliant
	☐Individual Transitional, plans include MH/SUD benefits	☐Small Group Transitional, plans include MH/SUD benefits
	☐Individual Grandfathered, plans include MH/SUD benefits	☐Large Group Fully Insured, plans include MH/SUD benefits
Product Types: (Check all that apply)	☐PPO	☐HMO (HCSO)
	☐POS	☐Indemnity

Part II: Medical necessity criteria.

Instructions for Part II:

To comply with A.R.S. § 20-3502(B)(1), describe the process that is used to develop or select medical necessity criteria for the plan and reporting year identified in Part I. When the plan describes the process used to develop or select criteria for MH/SUD benefits, then it must also describe the process used to develop or select criteria for Med/Surg benefits.

To comply with A.R.S. § 20-3502(B)(1), report:

A. Describe the process used to develop or select medical necessity criteria for MH/SUD benefits.

B. Describe the process used to develop or select medical necessity criteria for Med/Surg benefits.

Part III: Identify all NQTLs.

Instructions for Part III:

To comply with A.R.S. § 20-3502(B)(2), identify all NQTLs that are applied to MH/SUD benefits and all NQTLs that are applied to Med/Surg benefits for the plan and reporting year identified in Part I. NQTLs shall be identified within each classification of benefits.

A. Identify and report all NQTLs applied to MH/SUD benefits:

1. All NQTLs applied to In-Patient, In-Network Classification.
2. All NQTLs applied to In-Patient, Out-of-Network Classification
3. All NQTLs applied to Out-Patient, In-Network Classification
4. All NQTLs applied to Out-Patient, Out-of-Network Classification
5. All NQTLs applied to Emergency Care
6. All NQTSs applied to Prescription Benefits

B. Identify and report all NQTLs applied to Med/Surg benefits:

1. All NQTLs applied to In-Patient, In-Network Classification.
2. All NQTLs applied to In-Patient, Out-of-Network Classification
3. All NQTLs applied to Out-Patient, In-Network Classification
4. All NQTLs applied to Out-Patient, Out-of-Network Classification
5. All NQTLs applied to Emergency Care
6. All NQTSs applied to Prescription Benefits

Part IV: Demonstrate parity through analysis.

Instructions for Part IV:

To comply with A.R.S. § 20-3502(B)(3), for each NQTL listed in Part III, demonstrate through analysis that the process, strategy, evidentiary standard, and other factor of applying the NQTL to MH/SUD benefits in a classification of benefits, as written and in operation, is comparable to, and applied not more stringently than, any process, strategy, evidentiary standard or other factor used in applying the NQTL to Med/Surg benefits in the same classification. The report should define each "Other Factor" and include qualitative and quantitative statistical data to support and explain the analysis.

Identify and report on the NQTLs reported in Part III as follows:

A. Classification - Inpatient, in-network
1. Process
   a. Process applying NQTL to MH/SUD benefit.
   b. Process applying NQTL to Med/Surg benefit.
   c. Analysis showing that the process of applying the NQTL to MH/SUD benefits, as written, is comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that the process of applying the NQTL to MH/SUD benefits, in operation, is comparable to and not applied more stringently than to Med/Surg benefits.
2. Strategy
   a. Strategy applying NQTL to MH/SUD benefit.
   b. Strategy applying NQTL to Med/Surg benefit.
   c. Analysis showing that the strategy of applying the NQTL to MH/SUD benefits, as written, is comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that the strategy of applying the NQTL to MH/SUD benefits, in operation, is comparable to and not applied more stringently than to Med/Surg benefits.
3. Evidentiary Standard
   a. Evidentiary standard applying NQTL to MH/SUD benefit.
   b. Evidentiary standard applying NQTL to Med/Surg benefit.
   c. Analysis showing that the evidentiary standard of applying the NQTL to MH/SUD benefits, as written, is comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that the evidentiary standard of applying the NQTL to MH/SUD benefits, in operation, is comparable to and not applied more stringently than to Med/Surg benefits.
4. Other Factor
   a. Other factor applying NQTL to MH/SUD benefit.
   b. Other factor applying NQTL to Med/Surg benefit.
   c. Analysis showing that other factors used to apply the NQTL to MH/SUD benefits, as written, are comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that other factors used to apply the NQTL to MH/SUD benefits, in operation, are comparable to and not applied more stringently than to Med/Surg benefits.

B. Classification - Inpatient, out-of-network
1. Process
   a. Process applying NQTL to MH/SUD benefit.
   b. Process applying NQTL to Med/Surg benefit.
   c. Analysis showing that the process of applying the NQTL to MH/SUD benefits, as written, is comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that the process of applying the NQTL to MH/SUD benefits, in operation, is comparable to and not applied more stringently than to Med/Surg benefits.
2. Strategy
   a. Strategy applying NQTL to MH/SUD benefit.
   b. Strategy applying NQTL to Med/Surg benefit.
   c. Analysis showing that the strategy of applying the NQTL to MH/SUD benefits, as written, is comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that the strategy of applying the NQTL to MH/SUD benefits, in operation, is comparable to and not applied more stringently than to Med/Surg benefits.
3. Evidentiary Standard
   a. Evidentiary standard applying NQTL to MH/SUD benefit.
   b. Evidentiary standard applying NQTL to Med/Surg benefit.
   c. Analysis showing that the evidentiary standard of applying the NQTL to MH/SUD benefits, as written, is comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that the evidentiary standard of applying the NQTL to MH/SUD benefits, in operation, is comparable to and not applied more stringently than to Med/Surg benefits.
4. Other Factor
   a. Other factor applying NQTL to MH/SUD benefit.
   b. Other factor applying NQTL to Med/Surg benefit.
   c. Analysis showing that other factors used to apply the NQTL to MH/SUD benefits, as written, are comparable to and not applied more stringently than to Med/Surg benefits.

d. Analysis showing that other factors used to apply the NQTL to MH/SUD benefits, in operation, are comparable to and not applied more stringently than to Med/Surg benefits.

C. Classification - Outpatient, in-network

1. Process
   a. Process applying NQTL to MH/SUD benefit.
   b. Process applying NQTL to Med/Surg benefit.
   c. Analysis showing that the process of applying the NQTL to MH/SUD benefits, as written, is comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that the process of applying the NQTL to MH/SUD benefits, in operation, is comparable to and not applied more stringently than to Med/Surg benefits.
2. Strategy
   a. Strategy applying NQTL to MH/SUD benefit.
   b. Strategy applying NQTL to Med/Surg benefit.
   c. Analysis showing that the strategy of applying the NQTL to MH/SUD benefits, as written, is comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that the strategy of applying the NQTL to MH/SUD benefits, in operation, is comparable to and not applied more stringently than to Med/Surg benefits.
3. Evidentiary Standard
   a. Evidentiary standard applying NQTL to MH/SUD benefit.
   b. Evidentiary standard applying NQTL to Med/Surg benefit.
   c. Analysis showing that the evidentiary standard of applying the NQTL to MH/SUD benefits, as written, is comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that the evidentiary standard of applying the NQTL to MH/SUD benefits, in operation, is comparable to and not applied more stringently than to Med/Surg benefits.
4. Other Factor
   a. Other factor applying NQTL to MH/SUD benefit.
   b. Other factor applying NQTL to Med/Surg benefit.
   c. Analysis showing that other factors used to apply the NQTL to MH/SUD benefits, as written, are comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that other factors used to apply the NQTL to MH/SUD benefits, in operation, are comparable to and not applied more stringently than to Med/Surg benefits.

D. Classification - Outpatient, out-of-network

1. Process
   a. Process applying NQTL to MH/SUD benefit.
   b. Process applying NQTL to Med/Surg benefit.
   c. Analysis showing that the process of applying the NQTL to MH/SUD benefits, as written, is comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that the process of applying the NQTL to MH/SUD benefits, in operation, is comparable to and not applied more stringently than to Med/Surg benefits.
2. Strategy
   a. Strategy applying NQTL to MH/SUD benefit.
   b. Strategy applying NQTL to Med/Surg benefit.
   c. Analysis showing that the strategy of applying the NQTL to MH/SUD benefits, as written, is comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that the strategy of applying the NQTL to MH/SUD benefits, in operation, is comparable to and not applied more stringently than to Med/Surg benefits.
3. Evidentiary Standard
   a. Evidentiary standard applying NQTL to MH/SUD benefit.
   b. Evidentiary standard applying NQTL to Med/Surg benefit.
   c. Analysis showing that the evidentiary standard of applying the NQTL to MH/SUD benefits, as written, is comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that the evidentiary standard of applying the NQTL to MH/SUD benefits, in operation, is comparable to and not applied more stringently than to Med/Surg benefits.
4. Other Factor
   a. Other factor applying NQTL to MH/SUD benefit.
   b. Other factor applying NQTL to Med/Surg benefit.
   c. Analysis showing that other factors used to apply the NQTL to MH/SUD benefits, as written, are comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that other factors used to apply the NQTL to MH/SUD benefits, in operation, are comparable to and not applied more stringently than to Med/Surg benefits.

E. Classification - Emergency care

1. Process
   a. Process applying NQTL to MH/SUD benefit.
   b. Process applying NQTL to Med/Surg benefit.
   c. Analysis showing that the process of applying the NQTL to MH/SUD benefits, as written, is comparable to and not applied more stringently than to Med/Surg benefits.

d. Analysis showing that the process of applying the NQTL to MH/SUD benefits, in operation, is comparable to and not applied more stringently than to Med/Surg benefits.

2. Strategy
   a. Strategy applying NQTL to MH/SUD benefit.
   b. Strategy applying NQTL to Med/Surg benefit.
   c. Analysis showing that the strategy of applying the NQTL to MH/SUD benefits, as written, is comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that the strategy of applying the NQTL to MH/SUD benefits, in operation, is comparable to and not applied more stringently than to Med/Surg benefits.
3. Evidentiary Standard
   a. Evidentiary standard applying NQTL to MH/SUD benefit.
   b. Evidentiary standard applying NQTL to Med/Surg benefit.
   c. Analysis showing that the evidentiary standard of applying the NQTL to MH/SUD benefits, as written, is comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that the evidentiary standard of applying the NQTL to MH/SUD benefits, in operation, is comparable to and not applied more stringently than to Med/Surg benefits.
4. Other Factor
   a. Other factor applying NQTL to MH/SUD benefit.
   b. Other factor applying NQTL to Med/Surg benefit.
   c. Analysis showing that other factors used to apply the NQTL to MH/SUD benefits, as written, are comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that other factors used to apply the NQTL to MH/SUD benefits, in operation, are comparable to and not applied more stringently than to Med/Surg benefits.

F. Classification - Prescription benefits

1. Process
   a. Process applying NQTL to MH/SUD benefit.
   b. Process applying NQTL to Med/Surg benefit.
   c. Analysis showing that the process of applying the NQTL to MH/SUD benefits, as written, is comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that the process of applying the NQTL to MH/SUD benefits, in operation, is comparable to and not applied more stringently than to Med/Surg benefits.
2. Strategy
   a. Strategy applying NQTL to MH/SUD benefit.
   b. Strategy applying NQTL to Med/Surg benefit.
   c. Analysis showing that the strategy of applying the NQTL to MH/SUD benefits, as written, is comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that the strategy of applying the NQTL to MH/SUD benefits, in operation, is comparable to and not applied more stringently than to Med/Surg benefits.
3. Evidentiary Standard
   a. Evidentiary standard applying NQTL to MH/SUD benefit.
   b. Evidentiary standard applying NQTL to Med/Surg benefit.
   c. Analysis showing that the evidentiary standard of applying the NQTL to MH/SUD benefits, as written, is comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that the evidentiary standard of applying the NQTL to MH/SUD benefits, in operation, is comparable to and not applied more stringently than to Med/Surg benefits.
4. Other Factor
   a. Other factor applying NQTL to MH/SUD benefit.
   b. Other factor applying NQTL to Med/Surg benefit.
   c. Analysis showing that other factors used to apply the NQTL to MH/SUD benefits, as written, are comparable to and not applied more stringently than to Med/Surg benefits.
   d. Analysis showing that other factors used to apply the NQTL to MH/SUD benefits, in operation, are comparable to and not applied more stringently than to Med/Surg benefits.

NOTICES OF SUPPLEMENTAL PROPOSED RULEMAKING

This section of the *Arizona Administrative Register* contains Notices of Supplemental Proposed Rulemaking.

After an agency has filed a Notice of Proposed Rulemaking and it is published in the *Register*, an agency may decide to make substantial changes to the rule. The agency prepares a Notice of Supplemental Proposed Rulemaking with these proposed changes and the notice is published under the deadline schedule in the back of the *Register*.

The Notice of Supplemental Proposed Rulemaking shall be published in the *Register* before holding any oral proceedings (A.R.S. § 41-1022).

The Office of the Secretary of State is the filing agency and publisher of these rules. Questions about the interpretation of the proposed rules should be addressed to the agency that promulgated the rules. Refer to item #4 below to contact the person charged with the rulemaking and item #11 for the close of record and information related to public hearings and oral comments.

NOTICE OF SUPPLEMENTAL PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R22-15]

PREAMBLE

1. Citations to the agency's Notice of Rulemaking Docket Opening, Notice of Proposed Rulemaking, and any other Notices of Supplemental Proposed Rulemaking (if applicable) as published in the *Register* as specified in R1-1-409(A). A list of any other related notices published in the *Register* as specified in R1-1-409(A):

Notice of Rulemaking Docket Opening: 27 A.A.R. 1232, August 13, 2021

Notice of Proposed Rulemaking: 27 A.A.R. 1219, August 13, 2021

2. Articles, Parts, or Sections Affected (as applicable)Rulemaking Action

R4-23-411	Amend
R4-23-1104	Amend

3. Citations to the agency's statutory authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. § 32-1904(A)(1) and (B)

Implementing statute: A.R.S. §§ 32-1923.01, 32-1925, 32-1961, and 32-1974

4. The agency's contact person who can answer questions about the rulemaking:

Name:	Kamlesh Gandhi
Address:	Board of Pharmacy 1616 W. Adams St., Suite 120 Phoenix, AZ 85007
Telephone:	(602) 771-2740
Fax:	(602) 771-2749
Email:	kgandhi@azpharmacy.gov
Website:	www.azpharmacy.gov

5. An agency's justification and reason why a rule should be made, amended, repealed, or renumbered, to include an explanation about the rulemaking:

The Board is amending its rules to allow pharmacy technicians to perform additional duties when the duty is delegated by the pharmacist on duty. This expansion of duties performed by a pharmacy technician is consistent with the evolving national landscape for pharmacy technicians. The Board is also making minor changes needed to align the rules with statute or to incorporate changes implemented during the COVID19 emergency.

An exemption from Executive Order 2021-02 was provided by Trista Guzman Glover in an email dated May 18, 2021. Ms Guzman Glover authorized the Board to submit the rulemaking to the Council in an email dated October 27, 2021. As a result of opinions expressed by the Council, the Board decided to amend the proposed rulemaking. An exemption from Executive Order 2021-02 for this supplemental proposed rulemaking was provided by Ms Guzman Glover in an email dated January 6, 2022.

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

The Board did not review or rely on a study in its evaluation of or justification for either rule in this rulemaking.

7. An explanation of the substantial change that resulted in this supplemental notice:

At its December 7, 2021, meeting, members of the Council expressed reluctance to approve R4-23-1104(B)(5), which authorized a pharmacy technician who was trained and working under the supervision of the pharmacist on duty to administer an immunization or vaccine. The provision has been removed in this supplemental notice and a provision added at R4-23-1104(B)(5)(a) excluding a

pharmacy technician from administering an immunization or vaccine unless specifically authorized by statute or rule.

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

Not applicable

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

Expanding the duties performed by pharmacy technicians will enable pharmacy permittees to serve the public more efficiently and effectively.

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

Name: Kamlesh Gandhi
Address: Board of Pharmacy
1616 W. Adams St., Suite 120
Phoenix, AZ 85007
Telephone: (602) 771-2740
Fax: (602) 771-2749
Email: kgandhi@azpharmacy.gov
Website: www.azpharmacy.gov

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

An oral proceeding regarding the proposed rules will be held as follows:

Date: Wednesday, March 9, 2022
Time: 9:00 a.m.
Location: Board of Pharmacy
1616 W. Adams St., Suite 120
Phoenix, AZ 85007

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

None

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

Under A.R.S. § 41-1037(A)(2), the license issued to a pharmacy technician under A.R.S. § 32-1923.01 is not a general permit. A.R.S. § 32-1923.01 requires the Board to assess individual qualifications before issuing the license.

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

No rule in this rulemaking is more stringent than federal law. There are numerous federal laws with which individuals dealing with drugs must comply but none is directly applicable to this rulemaking.

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

No analysis was submitted.

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

None

14. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 4. PROFESSIONAL PRACTICES

Section
R4-23-411. Pharmacist-administered or Intern-administered Immunizations

ARTICLE 11. PHARMACY TECHNICIANS

Section
R4-23-1104. Pharmacy Technicians and Pharmacy Technician Trainees

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-411. Pharmacist-administered or Intern-administered Immunizations

A. Authorization to administer immunizations, vaccines, and emergency medications, as defined at A.R.S. § 32-1974(N), to an eligible adult patient or eligible minor patient. As used in this Section, "eligible adult patient" means an eligible patient 13 years of age or older and "eligible minor patient" means an eligible patient at least three years of age but less than 13 years of age. A pharmacist or

an intern in the presence of and under the immediate personal supervision of a pharmacist~~,~~ may administer, without a prescription, immunizations, vaccines, and emergency medications to an eligible adult patient or eligible minor patient, if:

1. Both the pharmacist and intern meet the qualifications and standards specified by A.R.S. § 32-1974 and this Section;
2. The Board authorizes both the pharmacist and intern as specified in subsection (D);
3. For an eligible adult patient, the immunization or vaccine is:
   a. Recommended for adults by the United States Centers for Disease Control and Prevention; or
   b. Recommended by the United States Centers for Disease Control and Prevention's Health Information for International Travel;
4. For an eligible adult patient, the immunization or vaccine is not on the Arizona Department of Health Services list specified in A.A.C. R9-6-1301 as required under A.R.S. § 32-1974(I);
5. For an eligible minor patient, the immunization or vaccine is for influenza or a booster dose as described under A.R.S. § 32-1974(B)(2); and
6. For an eligible minor patient, any immunizations or vaccines other than influenza or a booster dose as described under A.R.S. § 32-1974(B)(2) are administered in response to a public health emergency declared by the Governor under A.R.S. § 36-787.

B. A pharmacist or an intern in the presence of and under the immediate personal supervision of a pharmacist, may administer, with a prescription, any immunizations, vaccines, and emergency medications to an eligible adult patient or eligible minor patient, if:

1. Both the pharmacist and intern meet the qualifications and standards specified by A.R.S. § 32-1974 and this Section; and
2. The Board authorizes both the pharmacist and intern as specified in subsection (D).

C. A pharmacist or intern who is authorized to administer immunizations, vaccines, and emergency medications to an eligible adult patient or eligible minor patient shall:

1. Not delegate the authority to any other pharmacist, intern, or employee <u>not specifically authorized by rule</u>; and
2. Maintain their current certificate for inspection by the Board or its designee or review by the public.

D. Qualifications to administer immunizations, vaccines, and emergency medications to an eligible adult patient or eligible minor patient. After receipt of a completed application form, the Board shall authorize the administration of immunizations, vaccines, and emergency medications to an eligible adult patient or eligible minor patient by a pharmacist or intern who meets the following qualifications:

1. Has a current license to practice pharmacy in this state,
2. Successfully completes a training program specified in subsection (E), and
3. Has a current certificate in basic cardiopulmonary resuscitation.

E. Immunizations training program requirements. A training program for pharmacists or interns to administer immunizations, vaccines, and emergency medications to an eligible adult patient or eligible minor patient shall include the following courses of study:

1. Basic immunology and the human immune response;
2. Mechanics of immunity, adverse effects, dose, and administration schedule of available vaccines;
3. Response to an emergency situation as a result of the administration of an immunization, vaccine, or medication including administering an emergency medication to counteract the adverse effects of the immunization, vaccine, or medication given;
4. Administration of intramuscular injections;
5. Other immunization administration methods; and
6. Recordkeeping and reporting requirements specified in subsection (F).

F. Recordkeeping and reporting requirements.

1. A pharmacist or intern authorized under this Section to administer immunizations, vaccines, and emergency medications to an eligible patient shall provide to the pharmacy the following information and documentation regarding each immunization, vaccine, or emergency medication administered:
   a. The name, address, and date of birth of the patient;
   b. The date of administration and site of injection;
   c. The name, dose, manufacturer's lot number, and expiration date of the vaccine, immunization, or emergency medication;
   d. The name and address of the patient's identified primary-care provider or physician;
   e. The name of the pharmacist or intern administering the immunization, vaccine, or emergency medication;
   f. A record of the pharmacist's or intern's consultation with the patient determining that the patient is an eligible patient as defined in R4-23-110;
   g. Consultation or other professional information provided to the patient by the pharmacist or intern;
   h. The name and date of the immunization or vaccine information sheet provided to the patient; and
   i. For an immunization or vaccine given to an eligible minor patient, a consent form signed by the minor's parent or guardian.
2. As required under A.R.S. § 32-1974(F)(1), the pharmacist or intern shall provide a written or electronic report to the patient's primary-care provider or physician containing the documentation required in subsection (F)(1)(a) through (d). The pharmacy shall document the time and date the report is sent and make the record of compliance with this subsection available in the pharmacy or on request, within 72 hours, for inspection by the Board or its designee.
3. A pharmacy's pharmacist-in-charge or permittee shall maintain the records required in subsection (F)(1) in the pharmacy or database for a minimum of seven years from the administration date.

G. Confidentiality of records. A pharmacist, intern, pharmacy permittee, or pharmacist-in-charge shall comply with applicable state and federal privacy statutes and rules when releasing patient health information.

H. Pharmacist-administered or intern-administered adult immunizations that require a prescription order. A pharmacist or intern authorized by the Board to administer adult immunizations or vaccines shall not administer any immunization or vaccine listed in A.A.C. R9-6-1301 without a prescription order. In addition to filing a prescription order as required in A.R.S. § 32-1964, a pharmacist or pharmacy intern who administers an immunization or vaccine listed in A.A.C. R9-6-1301 shall comply with the recordkeeping requirements of subsection (F)(1).

ARTICLE 11. PHARMACY TECHNICIANS

R4-23-1104. Pharmacy Technicians and Pharmacy Technician Trainees

A. Permissible tasks of a pharmacy technician trainee. Acting in compliance with all applicable statutes and rules and under the supervision of a pharmacist, a pharmacy technician trainee licensed under R4-23-1103 may assist ~~a graduate intern, pharmacy~~ an intern~~,~~ or pharmacist with the following when applicable to the pharmacy practice site:

1. Record on the original prescription order the serial number of the prescription medication and date dispensed;
2. Initiate or accept verbal or electronic refill authorization from a medical practitioner or medical practitioner's agent and record, on the original prescription order or by an alternative method approved by the Board or its designee, the medical practitioner's name, patient name, name and quantity of prescription medication, specific refill information, and name of medical practitioner's agent, if any;
3. Record information in the refill record or patient profile;
4. Enter information for a new or refill prescription medication as required under A.R.S. § 32-1964;
5. Type and affix a label for the prescription medication. A pharmacist or ~~graduate or pharmacy~~ intern working under the supervision of a pharmacist shall verify the accuracy of the label as described under R4-23-402(A)(11);
6. Reconstitute a prescription medication, if a pharmacist checks the ingredients and procedure before reconstitution and verifies the final product after reconstitution;
7. Retrieve, count, or pour a prescription medication, if a pharmacist verifies the contents of the prescription medication against the original prescription medication container or by an alternative drug identification method approved by the Board or its designee;
8. Prepackage drugs in accordance with R4-23-402(A); and
9. Measure, count, pour, or otherwise prepare and package a drug needed for hospital inpatient dispensing, if a pharmacist verifies the accuracy, measuring, counting, pouring, preparing, packaging, and safety of the drug before the drug is delivered to a patient care area.

B. Permissible tasks of a pharmacy technician. Acting in compliance with all applicable statutes and rules and under the supervision of a pharmacist, a pharmacy technician licensed under R4-23-1102 may:

1. Perform the tasks listed in subsection (A);
2. After completing a pharmacy technician drug compounding training program developed by the pharmacy permittee or pharmacist-in-charge under R4-23-1105(C), assist a pharmacist~~, graduate intern,~~ or ~~pharmacy~~ intern in compounding prescription medications and sterile or non-sterile pharmaceuticals in accordance with written policies and procedures, if the preparation, accuracy, and safety of the final product is verified by a pharmacist before dispensing;
3. Perform a final technology-assisted verification of product if the pharmacy technician is qualified under R4-23-1104.01(D); ~~and~~
4. If technology-assisted verification is performed, type and affix a label for the prescription medication. A pharmacist or ~~graduate or pharmacy~~ intern shall verify the accuracy of the label as described under R4-23-402(A)(12)~~.~~; and
5. Perform any task if the task is delegated to the pharmacist on duty after the pharmacist on duty ensures the pharmacy technician is trained to do the task and evidence of the training exists in the pharmacy file. A pharmacist on duty shall not delegate or attempt to delegate the following tasks to a pharmacy technician:
   a. Administering an immunization or vaccine unless authority for the administration is specifically provided by statute or rule,
   b. Administering an emergency medication,
   c. Counseling a patient,
   d. Conducting a drug utilization review,
   e. Performing any task that requires the exercise of clinical judgment,
   f. Issuing a prescription order,
   g. Receiving a new prescription order for a controlled substance, or
   h. Transferring by telephone an existing prescription order for a controlled substance.

C. A trained and licensed pharmacy technician or pharmacy technician trainee who performs a task as authorized under subsections (A) and (B) shall ensure the task is performed accurately.

D. Prohibited activities. A pharmacy technician or pharmacy technician trainee shall not perform a professional practice reserved for a pharmacist~~, graduate intern,~~ or ~~pharmacy~~ intern in accordance with R4-23-402 or R4-23-653 unless otherwise allowed by rule.

E. A pharmacy technician or pharmacy technician trainee shall wear a badge indicating name and title while on duty.

F. Before employing a pharmacy technician or pharmacy technician trainee, a pharmacy permittee or pharmacist-in-charge shall develop, implement, review, and revise in the manner described in R4-23-653(A) and comply with policies and procedures outlined in subsection (G) for pharmacy technician and pharmacy technician trainee tasks.

G. A pharmacy permittee or pharmacist-in-change shall ensure policies and procedures required under subsection (F) include the following:

1. For all practice sites:
   a. Supervisory controls and verification procedures to ensure the quality and safety of pharmaceutical service;
   b. Employment performance expectations for a pharmacy technician and pharmacy technician trainee;
   c. The tasks a pharmacy technician or pharmacy technician trainee may perform as specified under subsections (A) and (B);
   d. Pharmacist and patient communication;
   e. Reporting, correcting, and avoiding medication and dispensing errors;
   f. Security procedures for:
      i. Confidentiality of patient prescription records, and
      ii. The pharmacy area;
   g. Automated medication distribution system;
   h. Compounding procedures for pharmacy technicians; and
   i. Brief overview of state and federal pharmacy statutes and rules;
2. For community and limited-service pharmacy practice sites:

a. Prescription dispensing procedures for:
   i. Accepting a new written prescription order,
   ii. Accepting a refill request,
   iii. Selecting a drug product,
   iv. Counting and pouring,
   v. Labeling, and
   vi. Obtaining refill authorization; and
b. Computer data-entry procedures for:
   i. New and refill prescriptions,
   ii. Patient's drug allergies,
   iii. Drug-drug interactions,
   iv. Drug-food interactions,
   v. Drug-disease state contraindications,
   vi. Refill frequency,
   vii. Patient's disease and medical condition,
   viii. Patient's age or date of birth and gender, and
   ix. Patient profile maintenance; and

3. For hospital pharmacy practice sites:
   a. Medication order procurement and data entry,
   b. Drug preparation and packaging,
   c. Outpatient and inpatient drug delivery, and
   d. Inspection of drug storage and preparation areas and patient care areas.

NOTICES OF FINAL RULEMAKING

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

The final published notice includes a preamble and text of the rules as filed by the agency.

Economic Impact Statements are not published but are filed by the agency with their final notice.

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

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

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 11. STATE BOARD OF DENTAL EXAMINERS

[R22-14]

PREAMBLE

1. Article, Part, or Section Affected (as applicable) — **Rulemaking Action**

R4-11-1202	Amend
R4-11-1206	Amend
R4-11-1207	Amend

2. Citations to the agency's statutory rulemaking authority to include both the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. § 32-1207

Implementing statute: A.R.S. §§ 32-1201 et seq.

3. The effective date for the rules:

March 14, 2022

a. If the agency selected a date earlier than the 60 day effective date as specified in A.R.S. § 41-1032(A), include the earlier date and state the reason or reasons the agency selected the earlier effective date as provided in A.R.S. § 41-1032(A)(1) through (5):

Not applicable

b. If the agency selected a date later than the 60 day effective date as specified in A.R.S. § 41-1032(A), include the later date and state the reason or reasons the agency selected the later effective date as provided in A.R.S. § 41-1032(B):

Not applicable

4. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the final rulemaking package:

Notice of Rulemaking Docket Opening: 27 A.A.R. 1232, August 13, 2021

Notice of Proposed Rulemaking: 27 A.A.R. 1217, August 13, 2021

5. The agency's contact person who can answer questions about the rulemaking:

Name: Ryan P. Edmonson, Executive Director

Address: State Board of Dental Examiners
1740 W. Adams St., Suite 2470
Phoenix, AZ 85007

Telephone: (602) 542-4493

Email: ryan.edmonson@dentalboard.az.gov

6. An agency's justification and reason why a rule should be made, amended, repealed, or renumbered, to include an explanation about the rulemaking:

The Board needs to amend its rules to update the license renewal deadlines consistent with SB1013 (2021).

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

No study was reviewed.

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

Not applicable

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

There is little to no economic, small business, or consumer impact, other than the cost to the Board to prepare the rule package, because the rulemaking simply clarifies statutory requirements that already exist. Thus, the economic impact is minimized.

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

There were no changes between the proposed rulemaking and the final rulemaking.

11. An agency's summary of the public or stakeholder comments made about the rulemaking and the agency response to the comments:

The Board received no written comments regarding the rulemaking. No one attended the oral proceeding on September 24, 2021.

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

None

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

The Board issues general permits to licensees who meet the criteria established in statute and rule.

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

Not applicable

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

No analysis was submitted.

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

No materials are incorporated by reference.

14. Whether the rule was previously made, amended, or repealed as an emergency rule. If so, cite the notice published in the *Register* as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:

Not applicable

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 11. STATE BOARD OF DENTAL EXAMINERS

ARTICLE 12. CONTINUING DENTAL EDUCATION AND RENEWAL REQUIREMENTS

Section

ARTICLE 12. CONTINUING DENTAL EDUCATION AND RENEWAL REQUIREMENTS

R4-11-1202. Continuing Dental Education Compliance and Renewal Requirements

A. When applying for a renewal license, certificate, or restricted permit, a licensee, certificate holder, or restricted permit holder shall complete a renewal application provided by the Board.

B. Before receiving a renewal license or certificate, each licensee or certificate holder shall possess a current form of one of the following:

1. A current cardiopulmonary resuscitation (CPR) healthcare provider certificate from the American Red Cross, the American Heart Association, or another certifying agency;
2. Advanced cardiac life support (ACLS) course completion confirmation from the American Heart Association or another agency. The confirmation must indicate that the course was completed within two years immediately before submitting a renewal application; or
3. Pediatric advanced life support (PALS) course completion confirmation from the American Heart Association or another agency. The confirmation must indicate that the course was completed within two years immediately before submitting a renewal application.

C. A licensee or certificate holder shall include an affidavit affirming the licensee's or certificate holder's completion of the prescribed credit hours of recognized continuing dental education with a renewal application. A licensee or certificate holder shall include on the affidavit the licensee's or certificate holder's name, license or certificate number, the number of hours completed in each category, and the total number of hours completed for activities defined in R4-11-1209(A)(4).

D. A licensee or certificate holder shall submit a written request for an extension before the ~~June 30~~ renewal deadline prescribed in A.R.S. §§ 32-1236, 32-1276.02, 32-1287, and 32-1297.06. If a licensee or certificate holder fails to meet the credit hour requirement because of military service, dental or religious missionary activity, residence in a foreign country, or other extenuating circumstances

as determined by the Board, the Board, upon written request, may grant an extension of time to complete the recognized continuing dental education credit hour requirement.

E. The Board shall:
1. Only accept recognized continuing dental education credits accrued during the prescribed period immediately before license or certificate renewal, and
2. Not allow recognized continuing dental education credit accrued in a renewal period in excess of the amount required in this Article to be carried forward to the next renewal period.

F. A licensee or certificate holder shall maintain documentation of attendance for each program for which credit is claimed that verifies the recognized continuing dental education credit hours the licensee or certificate holder participated in during the most recently completed renewal period.

G. Each year, the Board shall audit continuing dental education requirement compliance on a random basis or when information is obtained which indicates a licensee or certificate holder may not be in compliance with this Article. A licensee or certificate holder selected for audit shall provide the Board with documentation of attendance that shows compliance with the continuing dental education requirements within 60 days from the date the licensee or certificate holder received notice of the audit by certified mail.

H. If a licensee or certificate holder is found to not be in compliance with the continuing dental education requirements, the Board may take any disciplinary or non-disciplinary action authorized by A.R.S. Title 32, Chapter 11.

R4-11-1206. Restricted Permit Holders - Dental

In addition to the requirements in R4-11-1202, a dental restricted permit holder shall comply with the following requirements:
1. When applying for renewal under A.R.S. § 32-1238, the restricted permit holder shall provide information to the Board that the restricted permit holder has completed 24 credit hours of recognized continuing dental education yearly.
2. To determine whether to grant the renewal, the Board shall only consider recognized continuing dental education credits accrued ~~between July 1 and June 30~~ during the 36 months immediately before the ~~restricted permit holder submits the~~ renewal ~~application~~ deadline prescribed in A.R.S. § 32-1236.
3. A dental restricted permit holder shall complete the 24 hours of recognized continuing dental education before renewal as follows:
   a. At least 12 credit hours in one or more of the subjects enumerated in R4-11-1203(1);
   b. No more than six credit hours in one or more of the subjects enumerated in R4-11-1203(2);
   c. At least one credit hour in the subjects enumerated in R4-11-1203(3);
   d. At least one credit hour in the subjects enumerated in R4-11-1203(4)~~.~~;
   e. At least three credit hours in the subjects enumerated in R4-11-1203(5); and
   f. At least one credit hour in the subjects enumerated in R4-11-1203(6).

R4-11-1207. Restricted Permit Holders - Dental Hygiene

In addition to the requirements in R4-11-1202, a dental hygiene restricted permit holder shall comply with the following:
1. When applying for renewal under A.R.S. § 32-1292, the restricted permit holder shall provide information to the Board that the restricted permit holder has completed 18 credit hours of recognized continuing dental education yearly.
2. To determine whether to grant renewal, the Board shall only consider recognized continuing dental education credits accrued ~~between July 1 and June 30~~ during the 36 months immediately before the ~~restricted permit holder submits the~~ renewal ~~application~~ deadline prescribed in A.R.S. § 32-1287.
3. A dental hygiene restricted permit holder shall complete the 18 hours of recognized continuing dental education before renewal as follows:
   a. At least 9 credit hours in one or more of the subjects enumerated in R4-11-1204(1);
   b. No more than three credit hours in one or more of the subjects enumerated in R4-11-1204(2);
   c. At least one credit hour in the subjects enumerated in R4-11-1204(3);
   d. At least two credit hours in the subjects enumerated in R4-11-1204(4) and
   e. At least three credit hours in the subjects enumerated in R4-11-1204(5).

NOTICES OF RULEMAKING DOCKET OPENING

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

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

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

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

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

NOTICE OF RULEMAKING DOCKET OPENING

DEPARTMENT OF INSURANCE AND FINANCIAL INSTITUTIONS
INSURANCE DIVISION

[R22-16]

1. Title and its heading: 20, Commerce, Financial Institutions, and Insurance
Chapter and its heading: 6, Department of Insurance and Financial Institutions - Insurance Division
Article and its heading: 13, Mental Health Parity and Addiction Equity Act
Section numbers: R20-6-1301 through R20-6-1305, Exhibit A (*Sections may be added, deleted or modified, as necessary*)

2. The subject matter of the proposed rule:

The federal Mental Health Parity and Addiction Equity Act ("MHPAEA") generally prevents health insurance issuers that provide mental health or substance use disorder (MH/SUD) benefits from, among other things, imposing less favorable benefit limitations on MH/SUD benefits than on medical/surgical benefits. State insurance authorities, the U.S. Department of Health and Human Services, and the U.S. Department of Labor (U.S. DOL) have jurisdiction over applicable individual and group health insurance policies. MHPAEA regulations establish standards related to insurers' application of financial requirements (e.g., deductibles and co-payments), quantitative treatment limitations (e.g., visit limits), and nonquantitative treatment limitations (e.g., step therapy, prior authorization). Health insurers cannot apply financial requirements (FRs) or quantitative treatment limitations (QTLs) to MH/SUD policy benefits that are more restrictive than the predominant financial requirements or treatment limitations that apply to substantially all medical/surgical benefits. Nor can health insurers impose nonquantitative treatment limitations (NQTLs) with respect to MH/SUD benefits in any classification unless the processes, strategies, evidentiary standards, or other factors used in applying the NQTL to MH/SUD benefit classifications are comparable to those used with medical surgical/benefits classifications. The Department of Insurance and Financial Institutions ('Department") is issuing rules regarding the standards and tools insurers must follow when reporting information to the Department pursuant to A.R.S. § 20-3502(F)(2). The Department will create a new Article 13 (currently reserved) titled "Mental Health Parity and Addiction Equity Act" in Title 20, Article 6, A.A.C.

3. A citation to all published notices relating to the proceeding:

Notice of Proposed Rulemaking: 28 A.A.R. 330, February 4, 2022 (*in this issue*)

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

Name: Mary Kosinski
Address: Department of Insurance and Financial Institutions
100 N. 15th Ave., Suite 261
Phoenix, AZ 85007-2630
Telephone: (602) 364-3476
Email: mary.kosinski@difi.az.gov

5. The time during which the agency will accept written comments and the time and place where oral comments may be made:

To be determined

6. A timetable for agency decisions or other action on the proceeding, if known:

To be determined

GOVERNOR EXECUTIVE ORDER

RULEMAKING MORATORIUM

Executive Order 2022-01 is being reproduced in each issue of the *Arizona Administrative Register* as a notice to the public regarding state agencies' rulemaking activities.

This order has been reproduced in its entirety as submitted.

EXECUTIVE ORDER 2022-01

Moratorium on Rulemaking to Promote Job Creation and Economic Development; Internal Review of Administrative Rules

[M22-03]

WHEREAS, government regulations should be as limited as possible; and

WHEREAS, burdensome regulations inhibit job growth and economic development; and

WHEREAS, in 2015 the State of Arizona implemented a moratorium on all new regulatory rulemaking by State agencies through executive order, and renewed the moratorium in 2016, 2017, 2018, 2019, 2020 and 2021; and

WHEREAS, the State of Arizona eliminated or improved 231 burdensome regulations in 2021 and for a total of 3,047 needless regulations eliminated or improved since 2015; and

WHEREAS, estimates show these eliminations saved job creators nearly $11.6 million in operating costs in 2021 for a total of over $169.1 million in savings since 2015; and

WHEREAS, in 2021, for every one new necessary rule added to the Administrative Code, 25 have been repealed or improved; and

WHEREAS, COVID-19 has been hard on small businesses and the economy, and administrative barriers should be removed for their sake; and

WHEREAS, all government agencies of the State of Arizona should continue to promote customer service oriented principles for the people that it serves; and

WHEREAS, each State agency shall continue to conduct a critical and comprehensive review of its administrative rules and take action to reduce the regulatory burden, administrative delay and legal uncertainty associated with government regulation while protecting the health, peace and safety of residents; and

WHEREAS, each State agency should continue to evaluate its administrative rules using any available and reliable data and performance metrics; and

WHEREAS, Article 5, Section 4 of the Arizona Constitution and Title 41, Chapter 1, Article 1 of the Arizona Revised Statutes vests the executive power of the State of Arizona in the Governor.

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

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

4. A State agency subject to this Order shall not publicize any directives, policy statements, documents or forms on its website unless such are explicitly authorized by the Arizona Revised Statutes or Arizona Administrative Code. Any material that is not specifically authorized must be removed immediately.
5. A State agency that issues occupational or professional licenses shall prominently post on the agency's website landing page all current state policies that ease licensing burdens and the exact steps applicants must complete to receive their license using these policies. State agencies should provide information that applies to all applicants, but have a designated area on the landing page that includes licensing information specifically for military spouses, active duty service members and veterans and all policies that make it easier for these applicant groups to receive their license. Examples of reduced licensing burdens include "universal recognition" of out-of-state licenses, availability of temporary licenses, fee waivers, exam exemptions and/or allowing an applicant to substitute military education or experience for licensing requirements. A landing page feature may link to an internal agency web page with more information, if necessary. All information must be easy to locate and written in clear and concise language.
6. A State agency that issues occupational or professional licenses must track veteran and military spouse status of applicants immediately and report that information to the Governor's Office on an annual basis, starting July 1, 2022.
7. All State agencies that are required to issue occupational or professional licenses by "universal recognition" (established by A.R.S. § 32-4302) must track all applications received for this license type immediately and report that information to the Governor's Office on an annual basis, starting July 1, 2021. Before any agency denies a professional or occupational license applied for under A.R.S. § 32-4302, the agency shall submit the application and justification for denial to the Office of the Governor for review before any official action is taken by the agency. The Governor's Office should be notified of any required timeframes, whether in statute or rule, for approval or denial of the license by the agency.
8. For the purposes of this Order, the term "State agencies" includes, without limitation, all executive departments, agencies, offices, and all state boards and commissions, except for: (a) any State agency that is headed by a single elected State official; (b) the Corporation Commission; and (c) any board or commission established by ballot measure during or after the November 1998 general election. Those state agencies, boards and commissions excluded from this Order are strongly encouraged to voluntarily comply with this Order in the context of their own rulemaking processes.
9. This Order does not confer any legal rights upon any persons and shall not be used as a basis for legal challenges to rules, approvals, permits, licenses or other actions or to any inaction of a State agency. For the purposes of this Order, "person," "rule" and "rulemaking" have the same meanings prescribed in section 41-1001, Arizona Revised Statutes.
10. This Executive Order shall expire when the provisions of this executive order are adopted in statute and become law.

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

Douglas A. Ducey
GOVERNOR

DONE at the Capitol in Phoenix on this nineteenth day of January in the year Two Thousand and Twenty Two and of the Independence of the United States of America the Two Hundred and Forty-Sixth.

ATTEST:

Katie Hobbs
SECRETARY OF STATE

REGISTER INDEXES

The *Register* is published by volume in a calendar year (See "General Information" in the front of each issue for more information).

Abbreviations for rulemaking activity in this Index include:

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

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

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

SUMMARY RULEMAKING
PROPOSED SUMMARY
PSMN = Proposed Summary new Section
PSMM = Proposed Summary amended Section
PSMR = Proposed Summary repealed Section
PSM# = Proposed Summary renumbered Section
FINAL SUMMARY
FSMN = Final Summary new Section
FSMM = Final Summary amended Section
FSMR = Final Summary repealed Section
FSM# = Final Summary renumbered Section

EXPEDITED RULEMAKING
PROPOSED EXPEDITED
PEN = Proposed Expedited new Section
PEM = Proposed Expedited amended Section
PER = Proposed Expedited repealed Section
PE# = Proposed Expedited renumbered Section
SUPPLEMENTAL EXPEDITED
SPEN = Supplemental Proposed Expedited new Section
SPEM = Supplemental Proposed Expedited amended Section
SPER = Supplemental Proposed Expedited repealed Section
SPE# = Supplemental Proposed Expedited renumbered Section
FINAL EXPEDITED
FEN = Final Expedited new Section
FEM = Final Expedited amended Section
FER = Final Expedited repealed Section
FE# = Final Expedited renumbered Section

EXEMPT RULEMAKING
EXEMPT
XN = Exempt new Section
XM = Exempt amended Section
XR = Exempt repealed Section
X# = Exempt renumbered Section
EXEMPT PROPOSED
PXN = Proposed Exempt new Section
PXM = Proposed Exempt amended Section
PXR = Proposed Exempt repealed Section
PX# = Proposed Exempt renumbered Section
EXEMPT SUPPLEMENTAL PROPOSED
SPXN = Supplemental Proposed Exempt new Section
SPXR = Supplemental Proposed Exempt repealed Section
SPXM = Supplemental Proposed Exempt amended Section
SPX# = Supplemental Proposed Exempt renumbered Section
FINAL EXEMPT RULEMAKING
FXN = Final Exempt new Section
FXM = Final Exempt amended Section
FXR = Final Exempt repealed Section
FX# = Final Exempt renumbered Section

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

RECODIFICATION OF RULES
RC = Recodified

REJECTION OF RULES
RJ = Rejected by the Attorney General

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

RULE EXPIRATIONS
EXP = Rules have expired
See also "emergency expired" under emergency rulemaking

CORRECTIONS
C = Corrections to Published Rules

2022 *Arizona Administrative Register*
Volume 28 Page Guide

RULEMAKING ACTIVITY INDEX

Rulemakings are listed in the Index by Chapter, Section number, rulemaking activity abbreviation and volume page number. Use the page guide above to determine the *Register* issue number to review the rule. Headings for the Subchapters, Articles, Parts, and Sections are not indexed.

THIS INDEX INCLUDES RULEMAKING ACTIVITY THROUGH ISSUE 4 OF VOLUME 28.

OTHER NOTICES AND PUBLIC RECORDS INDEX

Other legal notices required to be published under the Administrative Procedure Act, such as Rulemaking Docket Openings, are included in this Index by volume page number. Notices of Agency Ombudsman, Substantive Policy Statements, Proposed Delegation Agreements, and other applicable public records as required by law are also listed in this Index by volume page number.

THIS INDEX INCLUDES OTHER NOTICE ACTIVITY THROUGH ISSUE 4 OF VOLUME 28.

RULES EFFECTIVE DATES CALENDAR

A.R.S. § 41-1032(A), as amended by Laws 2002, Ch. 334, § 8 (effective August 22, 2002), states that a rule generally becomes effective 60 days after the day it is filed with the Secretary of State's Office. The following table lists filing dates and effective dates for rules that follow this provision. Please also check the rulemaking Preamble for effective dates.

January		**February**		**March**		**April**		**May**		**June**	
Date Filed	Effective Date	Date Filed	Effective Date	Date Filed	Effective Date	Date Filed	Effective Date	Date Filed	Effective Date	Date Filed	Effective Date
1/1	3/2	2/1	4/2	3/1	4/30	4/1	5/31	5/1	6/30	6/1	7/31
1/2	3/3	2/2	4/3	3/2	5/1	4/2	6/1	5/2	7/1	6/2	8/1
1/3	3/4	2/3	4/4	3/3	5/2	4/3	6/2	5/3	7/2	6/3	8/2
1/4	3/5	2/4	4/5	3/4	5/3	4/4	6/3	5/4	7/3	6/4	8/3
1/5	3/6	2/5	4/6	3/5	5/4	4/5	6/4	5/5	7/4	6/5	8/4
1/6	3/7	2/6	4/7	3/6	5/5	4/6	6/5	5/6	7/5	6/6	8/5
1/7	3/8	2/7	4/8	3/7	5/6	4/7	6/6	5/7	7/6	6/7	8/6
1/8	3/9	2/8	4/9	3/8	5/7	4/8	6/7	5/8	7/7	6/8	8/7
1/9	3/10	2/9	4/10	3/9	5/8	4/9	6/8	5/9	7/8	6/9	8/8
1/10	3/11	2/10	4/11	3/10	5/9	4/10	6/9	5/10	7/9	6/10	8/9
1/11	3/12	2/11	4/12	3/11	5/10	4/11	6/10	5/11	7/10	6/11	8/10
1/12	3/13	2/12	4/13	3/12	5/11	4/12	6/11	5/12	7/11	6/12	8/11
1/13	3/14	2/13	4/14	3/13	5/12	4/13	6/12	5/13	7/12	6/13	8/12
1/14	3/15	2/14	4/15	3/14	5/13	4/14	6/13	5/14	7/13	6/14	8/13
1/15	3/16	2/15	4/16	3/15	5/14	4/15	6/14	5/15	7/14	6/15	8/14
1/16	3/17	2/16	4/17	3/16	5/15	4/16	6/15	5/16	7/15	6/16	8/15
1/17	3/18	2/17	4/18	3/17	5/16	4/17	6/16	5/17	7/16	6/17	8/16
1/18	3/19	2/18	4/19	3/18	5/17	4/18	6/17	5/18	7/17	6/18	8/17
1/19	3/20	2/19	4/20	3/19	5/18	4/19	6/18	5/19	7/18	6/19	8/18
1/20	3/21	2/20	4/21	3/20	5/19	4/20	6/19	5/20	7/19	6/20	8/19
1/21	3/22	2/21	4/22	3/21	5/20	4/21	6/20	5/21	7/20	6/21	8/20
1/22	3/23	2/22	4/23	3/22	5/21	4/22	6/21	5/22	7/21	6/22	8/21
1/23	3/24	2/23	4/24	3/23	5/22	4/23	6/22	5/23	7/22	6/23	8/22
1/24	3/25	2/24	4/25	3/24	5/23	4/24	6/23	5/24	7/23	6/24	8/23
1/25	3/26	2/25	4/26	3/25	5/24	4/25	6/24	5/25	7/24	6/25	8/24
1/26	3/27	2/26	4/27	3/26	5/25	4/26	6/25	5/26	7/25	6/26	8/25
1/27	3/28	2/27	4/28	3/27	5/26	4/27	6/26	5/27	7/26	6/27	8/26
1/28	3/29	2/28	4/29	3/28	5/27	4/28	6/27	5/28	7/27	6/28	8/27
1/29	3/30			3/29	5/28	4/29	6/28	5/29	7/28	6/29	8/28
1/30	3/31			3/30	5/29	4/30	6/29	5/30	7/29	6/30	8/29
1/31	4/1			3/31	5/30			5/31	7/30		

July		**August**		**September**		**October**		**November**		**December**	
Date Filed	Effective Date	Date Filed	Effective Date	Date Filed	Effective Date	Date Filed	Effective Date	Date Filed	Effective Date	Date Filed	Effective Date
7/1	8/30	8/1	9/30	9/1	10/31	10/1	11/30	11/1	12/31	12/1	1/30
7/2	8/31	8/2	10/1	9/2	11/1	10/2	12/1	11/2	1/1	12/2	1/31
7/3	9/1	8/3	10/2	9/3	11/2	10/3	12/2	11/3	1/2	12/3	2/1
7/4	9/2	8/4	10/3	9/4	11/3	10/4	12/3	11/4	1/3	12/4	2/2
7/5	9/3	8/5	10/4	9/5	11/4	10/5	12/4	11/5	1/4	12/5	2/3
7/6	9/4	8/6	10/5	9/6	11/5	10/6	12/5	11/6	1/5	12/6	2/4
7/7	9/5	8/7	10/6	9/7	11/6	10/7	12/6	11/7	1/6	12/7	2/5
7/8	9/6	8/8	10/7	9/8	11/7	10/8	12/7	11/8	1/7	12/8	2/6
7/9	9/7	8/9	10/8	9/9	11/8	10/9	12/8	11/9	1/8	12/9	2/7
7/10	9/8	8/10	10/9	9/10	11/9	10/10	12/9	11/10	1/9	12/10	2/8
7/11	9/9	8/11	10/10	9/11	11/10	10/11	12/10	11/11	1/10	12/11	2/9
7/12	9/10	8/12	10/11	9/12	11/11	10/12	12/11	11/12	1/11	12/12	2/10
7/13	9/11	8/13	10/12	9/13	11/12	10/13	12/12	11/13	1/12	12/13	2/11
7/14	9/12	8/14	10/13	9/14	11/13	10/14	12/13	11/14	1/13	12/14	2/12
7/15	9/13	8/15	10/14	9/15	11/14	10/15	12/14	11/15	1/14	12/15	2/13
7/16	9/14	8/16	10/15	9/16	11/15	10/16	12/15	11/16	1/15	12/16	2/14
7/17	9/15	8/17	10/16	9/17	11/16	10/17	12/16	11/17	1/16	12/17	2/15
7/18	9/16	8/18	10/17	9/18	11/17	10/18	12/17	11/18	1/17	12/18	2/16
7/19	9/17	8/19	10/18	9/19	11/18	10/19	12/18	11/19	1/18	12/19	2/17
7/20	9/18	8/20	10/19	9/20	11/19	10/20	12/19	11/20	1/19	12/20	2/18
7/21	9/19	8/21	10/20	9/21	11/20	10/21	12/20	11/21	1/20	12/21	2/19
7/22	9/20	8/22	10/21	9/22	11/21	10/22	12/21	11/22	1/21	12/22	2/20
7/23	9/21	8/23	10/22	9/23	11/22	10/23	12/22	11/23	1/22	12/23	2/21
7/24	9/22	8/24	10/23	9/24	11/23	10/24	12/23	11/24	1/23	12/24	2/22
7/25	9/23	8/25	10/24	9/25	11/24	10/25	12/24	11/25	1/24	12/25	2/23
7/26	9/24	8/26	10/25	9/26	11/25	10/26	12/25	11/26	1/25	12/26	2/24
7/27	9/25	8/27	10/26	9/27	11/26	10/27	12/26	11/27	1/26	12/27	2/25
7/28	9/26	8/28	10/27	9/28	11/27	10/28	12/27	11/28	1/27	12/28	2/26
7/29	9/27	8/29	10/28	9/29	11/28	10/29	12/28	11/29	1/28	12/29	2/27
7/30	9/28	8/30	10/29	9/30	11/29	10/30	12/29	11/30	1/29	12/30	2/28
7/31	9/29	8/31	10/30			10/31	12/30			12/31	3/1

REGISTER PUBLISHING DEADLINES

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

Deadline Date Friday, 5:00 p.m. *(*earlier date due to holiday)*	***Register* Publication Date**	**Oral Proceeding may be scheduled on or after**
Thursday December 30, 2021*	January 21, 2022	February 22, 2022
January 7, 2022	January 28, 2022	February 28, 2022
January 14, 2022	February 4, 2022	March 7, 2022
January 21, 2022	February 11, 2022	March 14, 2022
January 28, 2022	February 18, 2022	March 21, 2022
February 4, 2022	February 25, 2022	March 28, 2022
February 11, 2022	March 4, 2022	April 4, 2022
February 18, 2022	March 11, 2022	April 11, 2022

GOVERNOR'S REGULATORY REVIEW COUNCIL DEADLINES

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

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

GOVERNOR'S REGULATORY REVIEW COUNCIL DEADLINES FOR 2021/2022

(MEETING DATES ARE SUBJECT TO CHANGE)

[M21-61]

DEADLINE FOR PLACEMENT ON AGENDA*	FINAL MATERIALS SUBMITTED TO COUNCIL	DATE OF COUNCIL STUDY SESSION	DATE OF COUNCIL MEETING
Tuesday December 21, 2021	*Tuesday* January 18, 2022	*Tuesday* January 25, 2022	*Tuesday* February 1, 2022
Tuesday January 18, 2022	*Tuesday* February 15, 2022	*Tuesday* February 22, 2022	*Tuesday* March 1, 2022
Tuesday February 15, 2022	*Tuesday* March 22, 2022	*Tuesday* March 29, 2022	*Tuesday* April 5, 2022
Tuesday March 22, 2022	*Tuesday* April 19, 2022	*Tuesday* April 26, 2022	*Tuesday* May 3, 2022
Tuesday April 19, 2022	*Tuesday* May 17, 2022	*Tuesday* May 24, 2022	***Wednesday*** June 1, 2022
Tuesday May 17, 2022	*Tuesday* June 21, 2022	*Tuesday* June 28, 2022	***Wednesday*** July 6, 2022
Tuesday June 21, 2022	*Tuesday* July 19, 2022	*Tuesday* July 26, 2022	*Tuesday* August 2, 2022
Tuesday July 19, 2022	*Tuesday* August 23, 2022	*Tuesday* August 30, 2022	***Wednesday*** September 7, 2022
Tuesday August 23, 2022	*Tuesday* September 20, 2022	*Tuesday* September 27, 2022	*Tuesday* October 4, 2022
Tuesday September 20, 2022	*Tuesday* October 18, 2022	*Tuesday* October 25, 2022	*Tuesday* November 1, 2022
Tuesday October 18, 2022	*Tuesday* November 22, 2022	*Tuesday* November 29, 2022	*Tuesday* December 6, 2022

***** Materials must be submitted by **5 PM** on dates listed as a deadline for placement on a particular agenda. Placement on a particular agenda is not guaranteed.