

# Draft 02.12.25

## Pharmacy Benefit Manager Proposed Rulemaking

### Article 7. Licensing Provisions and Procedures

Table A. Licensing Time-frames

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License	Relevant A.R.S.	Administrative Completeness	Substantive Review	Overall Time-frame
Insurance				
Captive Insurer	§ 20-1098.01	150	30*	180
Certificate of Authority	§ 20-216	210	90*	300
Certificate of Exemption	§ 20-401.05	92	30	122
Health Care Services Organization	§ 20-1052	210	90	300
Hospital, Medical, Dental, and Optometric Service Corporation	§ 20-825	210	90	300
Life Care Provider Permit	§ 20-1803	60*	30*	90
Life Settlement Provider	§ 20-3202	60	60	120
Mechanical Reimbursement Reinsurer	§ 20-1096.04	210	90	300
Prepaid Dental Plan Organization	§ 20-1004	210	90	300
Prepaid Legal Insurer*	§ 20-1097.02	45	15	60*
Qualifying Surplus Lines Insurer	§ 20-413	45	30	75

Reinsurance Intermediary	§ 20-486.01	120	60	180
Insurance Professional				
Adjuster	§ 20-321.01	60	60	120
Bail Bond Agent	§ 20-340.01	60	60	120
Certified Application Counselor	§ 20-336.04	60	60	120
Life Settlement Broker	§ 20-3202	60	60	120
Limited Travel Agent	§ 20-3553	60	60	120
Navigator	§ 20-336.03	60	60	120
Nonresident Insurance Producer (Agent/Broker)	§ 20-287	60	60	120
Portable Electronics Insurance Adjuster	§ 20-321.01	60	60	120
Portable Electronics Insurance Vendor	§ 20-1693.01	60	60	120
Rental Car Agent	§ 20-331	60	60	120
Resident Insurance Producer (Agent/Broker)	§ 20-285	60	60	120
Risk Management Consultant	§ 20-331.01	60	60	120
Self-service Storage Agents	§ 20-332	60	60	120
Surplus Lines Broker	§ 20-411	60	60	120
Temporary License	§ 20-294	60	60	120
Title Insurance Agent	§ 20-1580	60	60	120

Variable Contract Agent	§ 20-2662	60	60	120
Other				
Pharmacy Benefit Manager*	§ 20-3333	30	90*	120
Rating Organization*	§ 20-361	30	30	60*
Rate Service Organization	§ 20-389	60	60	120
Third Party Administrator	§ 20-485.12	45	45	90
Senior Residential Entrance Fee Contracts: Provider Registration	§ 44-6952	60	60	120
Service Company	§ 20-1095.01	30	30	60
Utilization Review Agent	§ 20-2505	30	90	120
Risk Retention Groups				
Risk Retention Group (Foreign)	§ 20-2403	60	0	60
Risk Purchasing Groups	§ 20-2407	30	30	60

\* Statutory time-frames

## **New Article and Rules:**

### Article 25. Pharmacy Benefit Managers

R20-6-2501. Definitions

R20-6-2502. Application for Certificate of Authority; Fee Required

R20-6-2503. Notice of Modification

R20-6-2504. Term of Certificate of Authority

R20-6-2505. Renewal of a Certificate of Authority; Fee Required

R20-6-2506. Utilization Review

R20-6-2507. Records Retention; Examination Costs

**R20-6-2501. Definitions**

The following terms apply to this Article:

“Certificate of Good Standing” as used in A.R.S. § 20-3333(B)(1)(f) means the same as defined under A.R.S. § 10-128.

“Department” means the Arizona Department of Insurance and Financial Institutions, Insurance Division.

“Director of the Department” means the same as defined under A.R.S. § 20-102.

“Health plan” as used in A.R.S. § 20-3333(R) means the same as “Health care plan” as defined under A.R.S. § 20-3151.

“Insurer” means the same as defined under A.R.S. § 20-3321(5).

“Material modification” as used in A.R.S. § 20-3333(D) means a change to any of the information required to be submitted to the Department under A.R.S. § 20-3333(B)(1)(a) through (e), a notification that the licensee is no longer in good standing with the Arizona Corporation Commission, or a change in the description of the Pharmacy Benefit Manager’s services, facilities, or personnel.

“Overall time frame” means the same as defined under A.R.S. § 41-1072(2).

“Pay the fee” means to submit to the Department the fee required to accompany the initial application for or renewal of the Pharmacy Benefit Manager’s certificate of authority. The initial application fee is \$500 and the renewal fee is \$500. In lieu of direct

payment of the fee, the applicant or licensee may submit proof of payment of the fee. All fees are non-refundable.

“Person” means the same as defined under A.R.S. § 20-105.

“Pharmacy Benefit Manager” means the same as defined under A.R.S. § 20-3321(10).

“Records” as used in Section R20-6-2507 includes records, books, documentation, and other data.

“Utilization Review Plan” means the same as defined under A.R.S. § 20-2501(A)(17).

**R20-6-2502.** Application for Certificate of Authority; Fee Required

**A.** A person seeking to be licensed as a Pharmacy Benefit Manager in this State shall file an application for a certificate of authority on a form prescribed by the Director of the Department which shall be transmitted for review and approval through an electronic online system as required by the Director of the Department under A.R.S. § 20-3333(B). The applicant shall pay the fee to the Department at the time it submits its application.

**B.** Beginning January 1, 2025, a person shall not operate as a Pharmacy Benefit Manager in this state without a certificate of authority.

**C.** The Department deems an application as filed with the Director of the Department when the Department receives a completed application and the required fee from an applicant.

**D.** The Director of the Department may require, at the Director’s discretion, that an applicant for a certificate of authority under A.R.S. § 20-3333(A) submit information that discloses biographical, employment and business financial history, criminal activity, fingerprints, or any other information that relates to the ability to operate as a Pharmacy Benefit Manager for principals, principal officers, and individuals responsible for the

conduct of the activities of the Pharmacy Benefit Manager if necessary for the protection of residents of this State.

**E.** An applicant shall have a period to remedy disqualifications to licensure pursuant to A.R.S. § 20-3333(C).

1. If the Director of the Department determines that an applicant is not qualified to be licensed after the overall time frame for the application is complete, the Director of the Department shall provide a written notification to the applicant of the Director's intent to deny the application that specifies the disqualifications to licensure.

2. The applicant shall have 60 days from the date of the Director's notification to inform the Director of the Department that it has remedied the disqualifications.

3. If the applicant fails to respond to the Director of the Department within 60 days, or the Director of the Department determines that the applicant has failed to remedy the disqualifications to licensure, the Director of the Department shall deny the application.

4. The Director of the Department's denial of the application is an appealable agency action within the meaning of A.R.S. 41-1092(4).

**F.** The Department shall notify an applicant of the approval of the certificate of authority and the effective date and expiration date of the certificate. No paper certificate is required.

**R20-6-2503.** Notice of Modification

The Notice of Modification required to be filed with the Director of the Department under A.R.S. § 20-3333(D) applies to a Pharmacy Benefit Manager that holds a certificate of

authority issued by the Department. The Notice of Modification shall be filed on a form and in the manner approved by the Director of the Department.

**R20-6-2504. Term of Certificate of Authority**

**A.** The Pharmacy Benefit Manager certificate of authority is a biennial certificate. If the Pharmacy Benefit Manager fails to timely file a complete renewal application and pay the fee to the Director of the Department, the certificate of authority of a Pharmacy Benefit Manager expires on the last day of the 24th month after the effective date of the initial approval of the certificate of authority or any renewal.

**B.** If not timely renewed, a certificate of authority may expire during any period of suspension or restriction under A.R.S. § 20-3333(G).

**R20-6-2505. Renewal of the Certificate of Authority; Fee Required**

**A.** To renew its certificate of authority, a Pharmacy Benefit Manager shall file a renewal application on a form prescribed by the Director of the Department and pay the fee on or before the expiration of the Pharmacy Benefit Manager's certificate of authority. The form shall be transmitted for review through an electronic online system as required by the Director of the Department.

**B.** The Director of the Department may require, at the Director's discretion, that an applicant for renewal of a certificate of authority under A.R.S. § 20-3333(K) submit information that discloses biographical, employment and business financial history, criminal activity, fingerprints, or any other information that relates to the ability to operate as a Pharmacy Benefit Manager for principals, principal officers, and individuals responsible for the conduct of the activities of the Pharmacy Benefit Manager if necessary for the protection of residents of this State.

**C.** The Department deems a renewal application as filed with the Director of the Department when the Director of the Department receives the complete renewal application and the renewal fee.

**D.** Upon expiration of a certificate of authority that is not timely renewed, a Pharmacy Benefit Manager shall cease its operations as a Pharmacy Benefit Manager.

**E.** A Pharmacy Benefit Manager whose certificate of authority has expired shall file a new application for a certificate of authority to the Director of the Department pursuant to A.R.S. § 20-3333(B) and R20-6-2502.

**R20-6-2506. Utilization Review**

**A.** A Pharmacy Benefit Manager may contract with a utilization review agent certified by the Department pursuant to A.R.S. § 20-2504 or exempt from certification under A.R.S. § 20-2502(B) to perform utilization review for pharmaceutical claims on behalf of the Pharmacy Benefit Manager.

**B.** If a Pharmacy Benefit Manager performs utilization review for a health care insurer for pharmaceutical claims, the Pharmacy Benefit Manager shall perform the duties required of a certified utilization review agent including:

1. Conducting utilization review in accordance with the utilization review plan that is on file with the Department;
2. Adopting a utilization review plan that includes a summary description of review guidelines, protocols and procedures, standards and criteria to be used in evaluating pharmaceutical services covered by the health care insurer, and the provisions by which patients or pharmacies may seek reconsideration or appeal of the decisions made by the Pharmacy Benefit Manager that complies with Arizona law;



3. Ensuring that the personnel conducting utilization review have current licenses that are in good standing and without restrictions from a state professional licensing agency in the United States;
4. Having policies and procedures to ensure that a representative of the Pharmacy Benefit Manager that conducts utilization review is available:
  - a. To receive and send notices and acknowledgements of appeals and is reasonably accessible to patients and pharmacies in this state and the Department; and
  - b. To receive phone calls for 40 hours each week during normal business hours;
5. Having policies and procedures to ensure that the personnel conducting utilization review will follow all applicable state and federal laws to protect the confidentiality of individual medical records; and
6. Having a copy of the materials or a description of the procedure designed to inform patients and pharmacies, as appropriate, of the requirements of the utilization review plan.

**C.** If a Pharmacy Benefit Manager performs utilization review for a health care insurer for pharmaceutical claims, the Pharmacy Benefit Manager shall comply with the appeals processes of a utilization review agent as described under A.R.S. Title 20, Chapter 15, Article 2, including:

1. Adopting processes for the review, reconsideration, and appeal of denials of pharmaceutical claims consistent with the Pharmacy Benefit Manager's utilization review plan;
2. Providing at least the following levels of review, as applicable:
  - a. An expedited review and expedited appeal pursuant to A.R.S. § 20-2534;

- b. An initial appeal pursuant to A.R.S. § 20-2535; and
  - c. An external independent review pursuant to A.R.S. § 20-2537;
3. Providing a separate information packet complying with A.R.S. § 20-2533(H) that is approved by the Director of the Department with the member's policy, evidence of coverage, or similar document at the time of coverage or renewal of coverage;
  4. Notification to the insured, at the time of a denial, of their right to appeal and whether a voluntary internal appeal is available to them pursuant to A.R.S. § 20-2536; and
  5. Ensuring that for an issue of medical necessity or appropriateness, not whether a claim or service is covered, the initial appeal process is performed as prescribed by A.R.S. § 20-2535.

**R20-6-2507. Records Retention; Compliance Costs**

**A.** Every Pharmacy Benefit Manager shall keep its corporate and business records as originals or as copies of the originals made by reproduction methods that accurately preserve the records.

**B.** Notwithstanding the confidential nature of a pharmacy benefit manager's information, the Director of the Department may use the information in any proceedings instituted against the pharmacy benefit manager by the Department.

**C.** The Pharmacy Benefit Manager shall keep its records for the periods required in Table 1. Pharmacy Benefit Manager Retention Schedule. This Section does not prohibit record retention for longer periods than required. This Section does not prohibit a Pharmacy Benefit Manager from keeping any other type of record not required.

D. A Pharmacy Benefit Manager shall pay the costs of review of its records to determine compliance by the Department.

**Table 1. Pharmacy Benefit Manager Retention Schedule**

<b>Type of Record</b>	<b><u>Retention Period</u></b> <b><u>(Years)</u></b>
Pharmacy Benefit Plan	5
Utilization Review Plan	Continuous