

# DEPARTMENT OF REGULATORY AGENCIES

## Division of Insurance

### 3 CCR 702-4

#### LIFE ACCIDENT AND HEALTH

#### Amended Regulation 4-2-97

### CONCERNING THE REQUIREMENTS FOR PHARMACY BENEFIT MANAGERS TO REGISTER IN COLORADO

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#### **Section 1 Authority**

This regulation is being promulgated and adopted by the Commissioner of Insurance under the authority of § 10-16-122.1(2.5)(b)(I) and (4.7), C.R.S.

#### **Section 2 Scope and Purpose**

The purpose of this regulation is to provide the form and manner for a pharmacy benefit manager (PBM) to register annually with the Division pursuant to § 10-16-122.1(2.5)(b)(I), C.R.S.

#### **Section 3 Applicability**

This regulation applies to all PBMs doing business in the state of Colorado.

#### **Section 4 Definitions**

- A. "Carrier" shall have the same meaning as found at § 10-16-102(8), C.R.S.
- B. "PBM-affiliated pharmacy" shall have the same meaning as found at § 10-16-122.1(5)(c), C.R.S.
- C. "PBM network" shall have the same meaning as found at § 10-16-122.1(5)(d), C.R.S.
- D. "PBM services" means, for the purpose of this regulation, claims processing services and other prescription drug or device services, as defined in § 10-16-122.1(5)(a), (b), C.R.S.

- E. "Pharmacy benefit management firm", "pharmacy benefit manager", or "PBM" shall have the same meaning as found at § 10-16-102(49), C.R.S. and includes all PBMs doing business in the state, including a PBM that is not directly connected with a carrier.
- F. "Prescription drug" has the same meaning as set forth in § 12-280-103(42) C.R.S; except that the term includes only prescription drugs that are intended for human use.

## **Section 5 Initial Registration Application**

- A. By July 1, 2024, and each year thereafter, prior to doing business in Colorado, each PBM shall complete a pharmacy benefit manager registration application consistent with Section 5 of this regulation and submit it to the Division.
- B. The PBM shall provide as part of the registration application the following:
  - 1. PBM Officer and Business Contact Information
    - a. The name and address of the PBM;
    - b. The names, business addresses, and job titles of the principal officers of the PBM;
    - c. The name, business address, business telephone number, business email address, and job title of the officer or employee who should be contacted regarding any PBM regulatory compliance concerns; and
    - d. The business telephone number and business e-mail address where the PBMs personnel directly responsible for the processing of appeals from patients, providers and pharmacies may be contacted.
  - 2. PBM Organization Documents
    - a. A copy of the PBMs organizational documents, including Articles of Incorporation, Articles of Association, and partnership agreements of the PBM;
    - b. A copy of all by-laws or similar document(s), if any, regulating the conduct or the internal affairs of the PBM; and
    - c. The relevant documentation, such as policies and procedures, and a detailed explanation that demonstrates the PBM has adopted processes to ensure compliance with the requirements in sections 10-16-122.1, 10-16-122.3, 10-16-122.4, 10-16-122.5, 10-16-122.6, 10-16-122.7, and 10-16-122.9, C.R.S, including any written policies or procedures describing the appeals or dispute resolution processes between the PBM and a PBM-affiliated pharmacy, as applicable.
  - 3. Financial and Other Documents
    - a. The most recent year-end financial statement for the PBM;
    - b. A listing of all carriers the PBM contracts with to provide pharmacy benefit services for, in Colorado, including any non-ERISA self-funded or governmental plans;
    - c. The number of projected enrollees or beneficiaries in Colorado to be serviced by the applicant during the upcoming year for all contracted insurers; and

- d. A listing of any delegated or contracted companies that perform part of the PBMs services.

4. Required Responses

A certified statement indicating whether the PBM:

- a. Has been refused or denied a registration, license, or certification to act as or provide the services of a PBM in any state or federal entity, providing specific details separately for each such refusal or denial, if any, including the date, nature and disposition of the action;
- b. Has had any registration, license, or certification to act as or provide the services of a PBM suspended, revoked, or nonrenewed for any reason by any state or federal entity, providing specific details separately for each such suspension, revocation or nonrenewal, if any, including the date, nature, and disposition of the action; and
- c. Has had a business relationship with a carrier terminated for any finding by a court of law of fraudulent or illegal activities in connection with the administration of a pharmacy benefits plan, providing specific details regarding the termination.

C. Application Fee

The PBM shall provide as part of the registration application a nonrefundable filing fee of \$2,500.

D. Attestation Form

- 1. By July 1, 2024, and each year thereafter, each PBM operating in Colorado shall annually complete the "Pharmacy Benefit Manager Attestation" in Appendix A and submit to the Division.
- 2. A PBM shall make the following attestations:
  - a. All the information submitted in the application including attachments are true and complete;
  - b. The PBM understands that submitting any false information may result in sanctions by the Commissioner pursuant to section 10-16.122.1(2.5)(b)(II), (4.5), C.R.S.;
  - c. The PBM will provide any additional information required by this regulation requested by the Division to complete the registration; and
  - d. The PBM is in compliance with sections 10-16-122.1, 10-16-122.3, 10-16-122.4, 10-16-122.5, 10-16-122.6, 10-16-122.7, and 10-16-122.9, C.R.S., as applicable.

- E. A PBM providing services to less than 100 covered individuals in Colorado and unable to provide a required document in section 5 may submit to the Division an exception request. The request must list the required document and provide a brief explanation.

**Section 6      Renewal Application**

- A. Each PBM operating in Colorado shall complete a renewal application and attestation form on an annual basis. Renewal applications shall be due one year following the initial application approval date.
- B. The PBM shall provide as part of the renewal application the information in section 5.B. and the attestation in section 5.D.
- C. The PBM shall submit a non-refundable renewal application fee of \$2,500.

## **Section 7      Application Review**

Upon receipt of a completed application for registration or renewal as required by sections 5 and 6, the Division shall review the application and may take the following actions:

- A. Approve the application;
- B. Notify the applicant, in writing, that the application is incomplete and request additional information to complete the review; or
- C. Deny a registration pursuant to section 10-16-122.1(2.5)(b)(II), C.R.S.

If a PBM registration is denied pursuant to Section 5 of this regulation, the Division shall:

- 1. Provide written notice to the applicant PBM that the application has been denied and the grounds therefore; and
  - 2. Advise the applicant PBM that it may request a hearing in accordance with sections 24-4-104 and 24-4-105, C.R.S.
- D. Suspend, revoke, or refuse to issue, continue, or renew a registration pursuant to section 10-16-122.1(2.5)(b)(II), C.R.S.

If a PBM registration is suspended, revoked, or otherwise refused to be issued, continued, or renewed pursuant to Section 5.D of this regulation, the Division shall:

- 1. Provide the PBM notice in writing of objective facts or conduct supporting the Division's decision;
  - 2. Allow the PBM an opportunity to submit written data, views, and arguments with respect to these facts or conduct asserted by the Division.
- E. The commissioner may utilize a third-party vendor to process PBM registration applications and renewals in accordance with section 10-16-122.1(4.7), C.R.S.

## **Section 8      Discipline**

- A. The Division may impose sanctions on a PBM for any violation of applicable laws in Title 10 during its registration, consistent with sections 24-4-104 and 24-4-105, C.R.S., including, but not limited to, suspension of registration, revocation of registration, and imposition of civil penalties.
- B. The Division may enforce applicable laws in Title 10 against an unregistered PBM, including, but not limited to, issuing a cease and desist order.

## **Section 9      Confidentiality**

Information submitted by the PBM to the Division in accordance with this regulation is subject to public inspection only to the extent allowed under the Colorado Open Records Act, and in no case shall trade secret, confidential, or proprietary information be disclosed to any person who is not otherwise authorized to access such information.

A PBM shall submit a “Confidentiality Index” if the PBM desires confidential treatment of a document submitted under this regulation, identifying which documents are confidential and the justification for confidentiality. Any information not marked as confidential or otherwise confidential under state law may be disclosed pursuant to the Colorado Open Records Act.

#### **Section 10      Severability**

If any provision of this regulation or the application of it to any person or circumstance is for any reason held to be invalid, the remainder of this regulation shall not be affected.

#### **Section 11      Enforcement**

Noncompliance with this regulation may result in the imposition of any of the sanctions made available in the Colorado statutes pertaining to the business of insurance, or other laws, which include the imposition of civil penalties, issuance of cease and desist orders, and/or suspensions or revocation of license, subject to the requirements of due process.

#### **Section 12      Effective Date**

This amended regulation shall become effective on January 30, 2026.

#### **Section 13      History**

New regulation effective January 30, 2024.  
Amended regulation effective January 30, 2026.

## **Appendix A Pharmacy Benefit Manager Attestation**

I hereby certify, under penalty of perjury, that all the information submitted in this application including attachments are true and complete. I am aware that submitting false information may result in sanctions by the Commissioner. I hereby certify that I will furnish any additional information required by this regulation upon request to complete the registration.

If applicable, I hereby certify, under penalty of perjury, that the entity applying for registration as a PBM is in compliance with 10-16-122.1, 10-16-122.3, 10-16-122.4, 10-16-122.5, 10-16-122.6, 10-16-122.7, 10-16-122.9, C.R.S.

Print Name of Officer or Authorized Representative:

Date:

Signature:

Title: