Agency Name: Department of Insurance

Statutory Authority: 1-23-110, 38-3-110, 38-71-2200, and 38-71-2210, et seq.

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- 01/09/2024 Received President of the Senate & Speaker 05/08/2024

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 provided for in the Regulation

Document No. 5241

**DEPARTMENT OF INSURANCE**

CHAPTER 69

Statutory Authority: 1976 Code Sections 1‑23‑110, 38‑3‑110, 38‑71‑2200, and 38‑71‑2210, et seq.

69‑78. Pharmacy Services Administrative Organizations. (New)

**Synopsis:**

The Department is proposing to add Regulation 69‑78 to outline the new requirement regarding licensure of Pharmacy Services Administrative Organizations with the Department of Insurance. This regulation supports Section 38‑71‑2210, et seq. which was added during the 2023 legislative session and outlines the process for these companies to apply for licensure with the Department.

The Notice of Drafting was published in the *State Register* on July 28, 2023.

**Instructions:**

Please print the regulation as shown below.

**Text:**

69‑78. Pharmacy Services Administrative Organizations.

Section I. Purpose

 The purpose of this regulation is to implement Act No. 30 of 2023 (“the Act”) regarding Pharmacy Services Administrative Organizations (“PSAOs”) and to provide licensing, reporting and activity standards for PSAOs.

Section II. Licensure Requirements

 A. Initial License and Renewal. On or after January 1, 2024, a PSAO seeking to do business in SC shall apply for a license on a form and in accordance with a licensing schedule prescribed by the Director or his designee. The terms “Director” and “designee” have the meaning set forth in Section 38‑1‑20 of the Code of Laws of South Carolina 1976, as amended.

 B. The initial licensing schedule shall be set by bulletin or order of the Director. In 2024, and thereafter, a PSAO license shall be renewed annually no later than March 1 of each year.

 C. Each application for a license shall be certified by an officer or authorized representative of the applicant and shall contain a statement that certifies the PSAO is in compliance with Section 38‑71‑2310 et seq. of the Code of Laws of South Carolina 1976, as amended. All proprietary information submitted by the PSAO under Section II of this regulation shall be considered confidential under Sections 38‑71‑2340 and 30‑4‑40 of the Code of Laws of South Carolina 1976, as amended.

 D. The PSAO shall provide as part of the application for licensure the following:

 (1) A non‑refundable filing fee of $1,000 for initial licensure and $500 for renewal licenses;

 (2) A copy of the basic organizational document of the PSAO such as the articles of incorporation, articles of association, partnership agreement, trust agreement or other applicable documents, and all amendments thereto;

 (3) A copy of the bylaws, organizational or similar document(s), if any, regulating the conduct or the internal affairs of the applicant;

 (4) A copy of the PSAO’s provider manual and written agreement(s) entered into with pharmacists or pharmacies;

 (5) For the two preceding calendar years, a listing of pharmacy providers with which the PSAO was contracted in this State to perform services;

 (6) The relevant documentation, such as a policies and procedures manual, that demonstrates the PSAO has adopted processes to ensure compliance with the requirements in Section 38‑71‑2330 of the Code of Laws of South Carolina 1976, as amended;

 (7) A certified statement that indicates whether the applicant or officer with management or control:

 (a) has been refused or denied a registration, license or certification to act as or provide the services of a PSAO in any state, providing specific details separately for each refusal or denial, if any, including the date, nature and disposition of the action; and

 (b) has had any registration, license or certification to act as or provide the services of a PSAO 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 attaching a copy of any relevant final order or similar document imposing the suspension, revocation or nonrenewal;

 (8) A description of whether the applicant has had a business relationship with a‑ pharmacy or pharmacist terminated for any fraudulent or illegal activities in connection with the administration of a pharmacy benefits plan (if so, attach specific details separately explaining this termination, including the date, and nature of the termination);

 (9) Has an officer with management or control of the PSAO been convicted of a felony or violated any of the requirements of state law applicable to PSAOs; and

 (10) Any other relevant information deemed necessary by the Director or his designee to evaluate the application for licensure or compliance with the requirements of the Act and this regulation.

 E. Review Process

 (1) Initial and Renewal License Applications

 For initial and renewal license applications, the Director or his designee shall review the application under Section II.D of this regulation, and may:

 (a) approve the application and issue the applicant a PSAO license; or

 (b) notify the applicant, in writing, that the application is incomplete and request additional information to complete the review; and, if the missing or requested information is not received within thirty (30) calendar days from the date of the notification, the Director or his designee may deny the application; or

 (c) deny the application; and

 (i) provide written notice to the applicant that the application has been denied stating or explaining the basis of the denial; and

 (ii) advise the applicant that it may appeal the denial by requesting a hearing in accordance with Section 38‑3‑210 of the Code of Laws of South Carolina 1976, as amended, before the South Carolina Administrative Law Court.

 (2) Standards of Review

 (a) The Director or his designee shall deny an initial or renewal application for licensure for the following reasons:

 (i) the PSAO operates, or proposes to operate, in a hazardous condition and the services it administers, or proposes to administer, for a pharmacist or pharmacy in this State may be hazardous to the public; or

 (ii) the PSAO has violated the requirements of the Act, this regulation or other applicable South Carolina law; or

 (iii) the PSAO has failed to timely submit information to complete review of the application under Section II of this regulation.

 (b) In lieu of a denial of a renewal application, the Director or his designee may permit the PSAO to submit to the Director or his designee a corrective action plan to cure or correct deficiencies falling under Section II of this regulation, impose an administrative penalty under Section 38‑2‑10 et seq. of the Code of Laws of South Carolina, 1976 as amended, or both.

Section III. Contract Review

 A. Prohibited Contract Language

No contract entered into by a PSAO shall contain language in violation of Sections 38‑71‑2310 *et seq* of the Code of Laws of South Carolina 1976, as amended or other applicable provision of South Carolina law.

 B. Waiver Prohibited

The prohibitions set forth Sections 38‑71‑2310 *et seq* of the Code of Laws of South Carolina 1976, as amended cannot be waived by contract.

Section IV. Examinations

 Pursuant to Section 38‑71‑2340 of the Code of Laws of South Carolina 1976, as amended, the Director or his designee may examine the affairs of a PSAO for compliance with the requirements of the Act, applicable South Carolina law or requirements of this regulation as often as he deems appropriate, but not less frequently than once every five years. The PSAO must pay the charges incurred in the examination, including the expenses of the director or his designee and the expenses and compensation of his examiners and assistants. The information or data acquired during an examination pursuant to Section 38‑71‑2340 is considered proprietary and confidential and is not subject to the South Carolina Freedom of Information Act.

Section V. Record Keeping Requirements

 A. PSAOs shall maintain a record keeping system that shall track a detailed breakdown of the prescription numbers, amounts, and contractual basis for each recoupment and regular updates on the status of appeals for a period of five years.

 B. A request under this Subsection shall be considered a special report pursuant to Section 38‑13‑160 of the South Carolina Code of Laws 1976, as amended, and all information submitted in the response shall be confidential. The requirements of this Subsection shall apply for appeals or challenges beginning with the first quarter of 2024.

 C. PSAO Complaints.

 (1) The PSAO shall designate the name, address, and phone number, including an electronic mail contact, of the organization which shall be responsible for responding to the Department for complaints the Department has received. The PSAO shall be subject to Section 38‑13‑70 of the Code of Laws of South Carolina 1976, as amended related to the time period for a response to the Department.

 (2) The Department shall review any complaints, and upon determination of a violation of the Act or this regulation, institute regulatory action in accordance with the requirements set forth in Section VII of this regulation.

Section VI. Confidentiality

 The Department may report on its activities relating to the implementation of the Act and this regulation in compliance with the confidentiality requirements set forth in the Act and this regulation.

Section VII. Penalties

 Violations of this regulation shall be subject to the penalties set forth in Section 38‑2‑10 through 38‑2‑30 of the Code of Laws of South Carolina 1976, as amended.

Section VIII. Severability

 Any section or provision of this regulation held by a court to be invalid or unconstitutional shall be considered severable and will not affect the validity of any other section or provision of this regulation.

Section IX. Conflict

 If any provision of this regulation is inconsistent with the Act, the provisions of the Act control.

**Fiscal Impact Statement:**

The Department of Insurance estimates that the costs incurred by the State and its political subdivisions in complying with the proposed PBM regulations supporting recent statutory amendments will be approximately $668,907.

**Statement of Rationale:**

These regulations are added to provide licensing, reporting and activity standards for PSAOs.