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H	01/14/2020	Referred to Committee		
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Document No. 4932
DEPARTMENT OF INSURANCE
CHAPTER 69

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

69-77. Pharmacy Benefits Managers.

Synopsis:

Regulation 69-77 is a new regulation promulgated to implement the provisions of Act No. 48 of 2019 (“the Act”) regarding the licensure and regulation of pharmacy benefits managers.

The Notice of Drafting was published in the *State Register* on August 23, 2019.

Instructions:

Print regulation as shown below. All other items and sections remain unchanged.

Text:

69-77. Pharmacy Benefits Managers.

Section I. Purpose

The purpose of this regulation is to implement Act No. 48 of 2019 (“the Act”) regarding pharmacy benefits managers and to provide licensing, reporting and activity standards for pharmacy benefits managers.

Section II. Licensure Requirements

A. **Initial License and Renewal.** On or after January 1, 2021, a pharmacy benefits manager 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 2022, and thereafter, a pharmacy benefits manager 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 pharmacy benefits manager is in compliance with Section 38-71-2220 of the Code of Laws of South Carolina 1976, as amended. All proprietary information submitted by the pharmacy benefits manager under Section II of this regulation shall be considered confidential under Sections 38-71-2250 and 30-4-40 of the Code of Laws of South Carolina 1976, as amended.

D. The pharmacy benefits manager 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 pharmacy benefits manager, 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 pharmacy benefits manager’s provider manual and written agreement(s), excluding pricing information, but including audit procedures, which it uses for contracts entered into with pharmacists, pharmacies or pharmacy services administrative organizations in administration of pharmacy benefits for health care insurers in this State or a representative written agreement and provider manual,

excluding pricing information, but including audit procedures, for each type of network provider, which it uses for contracts entered into with pharmacists, pharmacies or pharmacy services administrative organizations in administration of pharmacy benefits for health care insurers in this State;

(5) For the two preceding calendar years, a listing of health care insurers with which the pharmacy benefits manager was contracted in this State to perform claims processing services and the number of enrollees or beneficiaries covered by each health care insurer;

(6) The relevant documentation, such as a policies and procedures manual, that demonstrates the pharmacy benefits manager has adopted processes to ensure compliance with the requirements in Section 38-71-2240 of the Code of Laws of South Carolina 1976, as amended, including any written policies or procedures describing the appeals dispute resolution process for in-network or contracted pharmacists or pharmacies;

(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 pharmacy benefits manager or third-party administrator in any state, providing specific details separately for each such 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 such 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 an insurer 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); and

(9) 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 pharmacy benefits manager 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) 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 pharmacy benefits manager operates, or proposes to operate, in a hazardous condition and the services it administers, or proposes to administer, for health care insurers in this State may be hazardous to the insurance-buying public; or

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

(iii) the pharmacy benefits manager 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 pharmacy benefits manager 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. Contract Review

(1) Prohibited Contract Language

No contract entered into by a pharmacy benefits manager and a pharmacist or pharmacy which relates to participation or administration of a pharmacy benefits plan or program of a health care insurer shall contain language in violation of the Sections 38-71-2200 *et seq* of the Code of Laws of South Carolina 1976, as amended or other applicable provision of South Carolina law.

(2) Waiver Prohibited

The prohibitions set forth Sections 38-71-2220 *et seq* of the Code of Laws of South Carolina 1976, as amended cannot be waived by contract.

B. Marketing and Advertising

Pursuant to Section 38-71-2230, a pharmacy benefits manager shall not cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading. The Department does not review or otherwise pre-approve marketing materials prior to their use. It is the responsibility of the pharmacy benefits manager to ensure that its marketing materials comply with the laws of the State of South Carolina.

Section IV. Examinations

A. Examination of Pharmacy Benefits Managers.

(1) Pursuant to Section 38-71-2250 of the Code of Laws of South Carolina 1976, as amended, the Director or his designee may examine the affairs of a pharmacy benefits manager for compliance with the requirements of the Act, applicable South Carolina law or requirements of this regulation.

(2) Any examination permitted under this Section shall follow the examination procedures and requirements applicable to health care insurers under Chapter 13, Title 38 of the Code of Laws of South Carolina 1976, as amended.

B. A pharmacy benefits manager shall not be regularly examined under the same time periods as insurers as required under Section 38-13-10 of the Code of Laws of South Carolina 1976, as amended, however, the Director or his designee may examine the pharmacy benefits manager pursuant to Section 38-71-2250 at any time he or she believes it reasonably necessary to ensure compliance with the Act, the provisions of this regulation, or Title 38.

Section V. Record Keeping Requirements

A. Maximum Allowable Costs

In order to facilitate any examination conducted by the Director pursuant to Section IV of this regulation, pharmacy benefits managers shall maintain a record keeping system which shall track and monitor the following statistical information:

(1) the number of challenges or appeals the pharmacy benefits manager received under the maximum allowable cost provisions of the Act;

(2) the outcomes of each of those challenges or appeals, whether denied or upheld by the pharmacy benefits manager, and sufficient information to determine compliance with Section 38-71-2240. This information must include the following:

(i) notice to the challenging pharmacy of the appeal results and the information required by Section 38-71-2240; and

(ii) documentation of any changes made for similarly situated pharmacies as outlined in the Act.

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 2021.

C. Pharmacy Provider Complaints Related to Maximum Allowable Cost List Compliance under Section 38-71-2240 of the Code of Laws of South Carolina 1976, as amended.

(1) The pharmacy benefits manager 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 from pharmacy providers for alleged Maximum Allowable Cost List violations. The pharmacy benefits manager 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) A pharmacy provider or other person acting on its behalf shall make reasonable efforts to exhaust any internal appeal requirements of the pharmacy benefits manager prior to the filing of a complaint with the Department. However, a pharmacy provider shall not be required to exhaust internal appeal requirements of the pharmacy benefits manager if a pharmacy benefits manager has failed to abide by its Maximum Allowable Cost List appeal processes as described in Section 38-71-2240. A pharmacy benefits manager shall not be held responsible for failure to provide communication or timely processing in the event that a provider or pharmacy has not submitted sufficient information for the pharmacy benefits manager to process the appeal.

(3) The Department shall review the 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 VIII of this regulation.

(4) The Department may refer any complaints to the Office of the South Carolina Attorney General for investigation or other enforcement action in accordance with Section 38-3-110 of the Code of Laws of South Carolina 1976, as amended.

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. Transition of Licensing Status

A. The Director or his designee shall publish by order or bulletin the plan and timeframe for transitioning licenses from the third-party administrator license to the pharmacy benefits manager license.

B. Pharmacy benefits managers engaged exclusively or solely with administration of pharmacy benefits of self-funded health benefit plans in this State shall comply with the registration requirements of Chapter 51 of Title 38 of the Code of Laws of South Carolina 1976, as amended. For pharmacy benefits managers engaged in the administration of pharmacy benefits for both fully insured health benefits plans and self-funded health plans, a pharmacy benefits manager must comply with the Act and this regulation with respect to the provisions that apply to its fully insured health benefits plans.

Section VIII. 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 IX. 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 X. Conflict

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

Fiscal Impact Statement:

The South Carolina Department of Insurance estimates that no additional costs will be incurred by the State and its political subdivisions in complying with the proposed revisions to Regulation 69-77.

Statement of Rationale:

The proposed changes are needed to implement the new pharmacy benefits manager legislation.