

Document No. 5240  
**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 Benefit 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) 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) The phone number and any other contact information provided to pharmacies and pharmacists pursuant to Section 38-71-2235(B) through which the pharmacy or pharmacist can obtain answers during normal business hours within a reasonable time to questions regarding networks, patient benefits, appeals, and other contractual or service issues.

(10) The notice that is provided to pharmacies or pharmacists pursuant to Section 38-72-2240(D)(2) upon the denial of an internal appeal that notifies the pharmacy or pharmacist of the right to request an external review of the internal appeal and the supporting documents describing the external review process.

(11) 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 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

(b) 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 of Pharmacy Benefits Managers

A. Pursuant to Section 38-71-2250 of the Code of Laws of South Carolina 1976, as amended, as often as the director deems appropriate, but not less frequently than once every five years, the director or his designee may examine or audit the books and records of a pharmacy benefits manager providing claims processing services or other prescription drug or device services for a health benefit plan that are relevant to determining if the pharmacy benefits manager is in compliance with the Act, applicable South Carolina law or requirements of this regulation. The recurring examination requirement begins January 1, 2025. Nothing in this regulation prevents the director or his designee from examining the books and records of a pharmacy benefits manager at any time that the director or his designee determines in his discretion that such an examination is necessary.

B. The pharmacy benefits manager shall 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 director or his designee promptly shall institute a civil action to recover the expenses of examination against a pharmacy benefits manager which refuses or fails to pay.

C. The information or data acquired during an examination is considered proprietary and confidential and is not subject to the South Carolina Freedom of Information Act.

### 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:

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

(b) 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

(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. 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 internal appeal processes. 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. External Review

##### A. Application of This Section

(1) This section applies to external review of denials by pharmacy benefit managers (PBMs) of internal appeals of provider reimbursements and appeals of recoupments arising out of pharmacy audits. The Director or his designee may delegate the review and resolution of a pharmacy's appeal under this paragraph to an independent review organization (IRO), and any decision by the IRO shall have the same force and effect as a decision by the Director.

(2) A contracted pharmacy that receives a provider's reimbursement for a drug subject to maximum allowable cost pricing that is less than the net amount that the network provider paid to the suppliers of the drug shall have the right, after denial of an internal appeal, to appeal the decision of the PBM to the Director for an external review.

(3) Any pharmacy that believes recoupment amounts arising out of a PBM's final audit report were calculated in violation of the Code shall have the right to appeal the recoupment to the Director or his

designee for an external review.

#### B. Requests for External Review

(1) An appeal filed pursuant to Section (A) of this regulation must:

(a) Be submitted electronically on a form made available by the Department on its website within 60 calendar days of the pharmacy's receipt of the PBM's final determination resolving the pharmacy's initial appeal or within 30 calendar days of the pharmacy's receipt of the PBM's final audit report; unless a different timeframe is approved in writing pursuant to subsection (2) of this regulation.

(b) Contain a summary of:

(i) The grounds of the appeal to the Director;

(ii) The relief requested by the pharmacy; and

(iii) The basis on which the pharmacy believes it is due the relief;

(c) Include a copy of the written decision rendered by the PBM;

(d) Contain a copy of the invoice(s) showing the pharmacy's purchase price for the drug or medical product or device at issue, if applicable;

(e) Contain a list of all discounts, price concessions, rebates or other reductions, excluding cash discounts, that were, or should have been, reported to the PBM including supporting documentation for each discount, price concession, rebate or other reduction, if applicable;

(f) Contain a certification by the applicant that all information submitted is true and accurate to the best of the applicant's knowledge; and

(g) Provide any other documentation or information requested by the director or his designee regarding the pharmacy's appeal.

(2) A pharmacy is not entitled to an external review of an appeal denial until the pharmacy has exhausted the PBM's internal appeal process.

(3) Within 7 business days from the date a request for an external review is filed or the date all information requested by the Director or his designee has been received, the Director or his designee shall:

(a) Assign an independent review organization from the list of approved independent review organizations compiled and maintained pursuant to Section E of this regulation to conduct an external review, and send the documents and any information considered in making the adverse determination to the independent review organization; or

(b) Inform the pharmacy in writing that the request does not meet the criteria for external review pursuant to this regulation and include the reason for nonacceptance.

(4) Within 7 business days after the independent review organization's receipt from the Director or his designee of the request for external review, the independent review organization shall determine whether all the information, certifications, and forms required to process the external review have been provided. The independent review organization shall immediately notify the pharmacy provider and/or Pharmacy Benefits Manager in writing if additional information is required.

(5) If the request for an external review is not:

(a) complete, the independent review organization shall inform the pharmacy provider what information or materials are needed to make the request complete; or

(b) accepted for external review, the independent review organization shall inform the pharmacy and the PBM in writing of the reasons for its nonacceptance.

(6) If a request for external review is accepted for external review, the independent review organization shall notify the PBM and the pharmacy.

(7) Upon receipt of the request for external review, the independent review organization shall render a decision within 30 days unless a written extension is granted by the Director or his designee

#### C. External Review Findings

(1) If the independent review organization determines the pharmacy benefits manager reimbursed a pharmacy or pharmacist in an amount inconsistent with the provisions of this Regulation and Section 38-71-2230 *et seq.*, the pharmacy benefit manager must

(a) Promptly make the change in the reimbursement rate effective as of the date the external review is resolved;

(b) Permit the appealing pharmacy or pharmacist to reverse and rebill the claim in question;

(c) Reimburse the pharmacy the amount of the filing fee; and

(d) Promptly make the change effective for each similarly situated pharmacy as defined by the payor subject to the Maximum Allowable Cost List effective as of the date the external review is resolved.

(2) If the independent review organization determines the recoupments of any funds disputed on the basis of an audit were calculated in violation of 38-71-1810 et seq, then the pharmacy benefit manager must promptly refund any amounts due to the responsible party as contractually agreed upon by the parties in the audit and the PBM must reimburse the pharmacy the amount of the filing fee.

(3) An external review decision is binding on the pharmacy benefit manager and the appealing pharmacy or pharmacist. An appealing pharmacy or pharmacist may not file a subsequent request for an external review involving the same type of prescription drug unless there is an update to the reimbursement metric that would change the circumstances of the pharmacy's or pharmacist's reimbursement.

(4) The pharmacy benefits manager must pay for all costs related to the external review except for the initial filing fee if not reimbursable by the PBM under subsections (C)(1) or (2) of this regulation.

(5) The filing fee associated with a pharmacist's request for an external review is to be retained by the department for administration of Chapter 71. This filing fee shall be set by the department and published on its website.

(6) If the Director determines the pharmacy or pharmacist has abused the external review process, he may require the pharmacy or pharmacist to pay for costs related to the external review.

#### D. Confidentiality

The information or data acquired during an appeal pursuant to this section is considered proprietary and confidential and is not subject to the South Carolina Freedom of Information Act.

#### E. Approval of Independent Review Organizations

(1) The Director or his designee shall approve independent review organizations eligible to be assigned to conduct external reviews to ensure that an independent review organization satisfies the minimum qualifications established under subsection (F) of this regulation.

(2) The Director or his designee shall develop an application form for initially approving and for reapproving independent review organizations to conduct external reviews.

(3)(a) An independent review organization wishing to be approved to conduct external reviews under this regulation shall submit the application form and include with the form all documentation and information necessary for the Director or his designee to determine if the independent review organization satisfies the minimum qualifications established under subsection (F) of this regulation.

(b) The Director or his designee may charge an application fee that independent review organizations shall submit to the Director or his designee with an application for approval and reapproval.

(4)(a) Except as provided in item (2), an approval is effective for two years.

(b) The independent review organization must notify the Director or his designee of any material changes in qualifications, including removal or loss of accreditation by a nationally recognized private accrediting entity, approved by the Director or his designee pursuant to this subsection. Whenever the Director or his designee determines that an independent review organization no longer satisfies the minimum requirements established under subsection (F) of this regulation or has violated a provision of this regulation, the Director or his designee shall terminate the approval of the independent review organization and remove the independent review organization from the list of independent review organizations approved to conduct external reviews under this regulation that is maintained by the Director or his designee.

(5) An independent review organization accredited by a nationally recognized private accrediting entity with established and maintained standards for independent review organizations that meet the minimum qualifications established pursuant to subsection (F) of this regulation, which accrediting entity has been approved by the director or his designee, may be deemed to meet the minimum qualification requirements set forth in subsection (F) of this regulation.

(6) The Director or his designee shall maintain and periodically update a list of approved independent review organizations and approved nationally recognized private accrediting entities.

#### F. Standards for Approval of Independent Review Organizations

(1) To be approved to conduct external reviews, an independent review organization shall have and maintain written policies and procedures that govern all aspects of the external review process that include, at a minimum:

(a) a quality assurance mechanism in place that ensures:

(i) that external reviews are conducted within the specified time frames and required notices are provided in a timely manner;

(ii) the selection of qualified and impartial non-clinical and clinical peer reviewers to conduct external reviews on behalf of the independent review organization and suitable matching of reviewers to specific cases;

(iii) the confidentiality of medical and treatment records and clinical and non-clinical review criteria; and

(iv) that any person employed by or under contract with the independent review organization adheres to the requirements of this regulation;

(b) a toll-free telephone service to receive information on a 24-hour-day, 7-day-a-week basis related to external reviews that is capable of accepting, recording, or providing appropriate instruction to incoming telephone callers during other than normal business hours; and

(c) agree to maintain and provide to the director or his designee the information set out in Subsection H.

(2) All non-clinical peer reviewers assigned by an independent review organization to conduct external reviews that involve non-clinical judgment must have appropriate qualifications in routine business practices, such as audits, accounting, provider reimbursements, or pharmacy reimbursements. All clinical peer reviewers assigned by an independent review organization to conduct external reviews that involve clinical judgment must be appropriate health care providers and include a pharmacist.

(3) An independent review organization may not own or control, be a subsidiary of or in any way be owned or controlled by, or exercise control with a PBM, health benefit plan, or a national, state, or local trade association of health benefit plans, PBMs, pharmacy or health care providers.

(4) In addition to the requirements set forth in subsections (F)(1),(2),and (3), to be approved to conduct an external review of a specified case, neither the independent review organization selected to conduct the external review nor any non-clinical or clinical peer reviewer assigned by the independent review organization to conduct the external review may have a material professional, familial, or financial conflict of interest with:

(a) the PBM that is the subject of the external review;

(b) the pharmacy or the covered person whose treatment is the subject of the external review;

(c) any officer, director, or management employee of the PBM that is the subject of the external review;

(d) the developer, wholesaler, or manufacturer of the principal drug, device, procedure, or other therapy whose prescription is the subject of the external review.

#### G. Liability of Independent Review Organizations and Personnel

No independent review organization, or employee, officer, or director of an independent review organization or health care professional who furnishes services to an independent review organization is liable to any person for any acts or omissions arising out of or related to an external review conducted pursuant to this regulation, except for cases of willful and intentional misconduct.

#### H. External Review; Written Records; Reports

(1)(a) An independent review organization assigned to conduct an external review shall maintain written records in the aggregate and by health carrier on all requests for external review for which it conducted an external review during a calendar year and submit a report to the director or his designee, as required under item (b).

(b) Each independent review organization required to maintain written records on all requests for external review pursuant to item (a) for which it was assigned to conduct an external review shall submit to the director or his designee, no later than March first of each year and upon request by the director or his designee, a report in the format specified by the director or his designee.

(2) The report shall include in the aggregate and for each health carrier and its affiliated PBM:

- (a) the total number of requests for external review and the manner in which they were resolved;
  - (b) the average length of time for resolution;
  - (c) a summary of the types of coverages or cases for which an external review was sought, as provided in the format required by the director or his designee; and
  - (d) any other information the director or his designee may request or require.
- (3) The independent review organization shall retain the written records required pursuant to this subsection for at least three years.
- (4) The director or his designee shall make the reports required in this section available to any person for inspection and copying upon request.

**I. PBM to Inform Pharmacy of Rights Related to External Review**

(1) Each PBM shall include in the provider agreement or pharmacy manual a written notice to the pharmacy including a description of the external review procedures. This written notice shall also be provided to the pharmacy following a denied internal appeal and a denied recoupment.

(2) The description required under subsection (1) shall include a statement of the right of the pharmacy to contact the director or his designee for assistance. The statement shall include the telephone number, email address and mailing address of the director or his designee.

**Section IX. 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 X. 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 XI. 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 amendments are made to ensure consistency between the regulation and changes that were made to the PBM laws during the 2023 Legislative Session.