**South Carolina General Assembly**

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**A30, R37, S520**

**STATUS INFORMATION**

General Bill

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Introduced in the Senate on February 9, 2023

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Currently residing in the Senate

Summary: Pharmacy benefits

**HISTORY OF LEGISLATIVE ACTIONS**

 Date Body Action Description with journal page number

 2/9/2023 Senate Introduced and read first time (Senate Journal‑page 9)

 2/9/2023 Senate Referred to Committee on **Banking and Insurance** (Senate Journal‑page 9)

 2/22/2023 Senate Committee report: Favorable **Banking and Insurance** (Senate Journal‑page 20)

 2/24/2023 Scrivener's error corrected

 3/1/2023 Senate Read second time (Senate Journal‑page 24)

 3/1/2023 Senate Roll call Ayes-39 Nays-0 (Senate Journal‑page 24)

 3/2/2023 Senate Read third time and sent to House (Senate Journal‑page 19)

 3/7/2023 House Introduced and read first time (House Journal‑page 15)

 3/7/2023 House Referred to Committee on **Labor, Commerce and Industry** (House Journal‑page 15)

 5/3/2023 House Committee report: Favorable with amendment **Labor, Commerce and Industry** (House Journal‑page 5)

 5/4/2023 House Read second time (House Journal‑page 33)

 5/4/2023 House Roll call Yeas-89 Nays-0 (House Journal‑page 34)

 5/4/2023 House Unanimous consent for third reading on next legislative day (House Journal‑page 36)

 5/5/2023 House Read third time and returned to Senate with amendments (House Journal‑page 12)

 5/9/2023 Senate Concurred in House amendment and enrolled (Senate Journal‑page 29)

 5/9/2023 Senate Roll call Ayes-44 Nays-0 (Senate Journal‑page 29)

 5/11/2023 Ratified R 37

 5/16/2023 Signed By Governor

 5/26/2023 Effective date See Act for Effective Date

 5/26/2023 Act No. 30

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**VERSIONS OF THIS BILL**

[02/09/2023](https://www.scstatehouse.gov/sess125_2023-2024/prever/520_20230209.docx)

[02/22/2023](https://www.scstatehouse.gov/sess125_2023-2024/prever/520_20230222.docx)

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(A30, R37, S520)

AN ACT TO AMEND THE SOUTH CAROLINA CODE OF LAWS BY AMENDING ARTICLE 18 OF CHAPTER 71, TITLE 38, RELATING TO PHARMACY AUDIT RIGHTS, SO AS TO EXPAND THE RIGHTS AND DUTIES OF PHARMACIES DURING AUDITS; BY AMENDING ARTICLE 21 OF CHAPTER 71, TITLE 38, RELATING TO PHARMACY BENEFITS MANAGERS, SO AS TO DEFINE TERMS AND MAKE CONFORMING CHANGES; BY ADDING ARTICLE 23 TO CHAPTER 71, TITLE 38 SO AS TO DEFINE TERMS AND OUTLINE RESPONSIBILITIES AND DUTIES OF PHARMACY SERVICES ADMINISTRATIVE ORGANIZATIONS; AND BY REPEALING SECTION 38-71-147 RELATING TO FREEDOM OF SELECTION AND PARTICIPATION IN HEALTH INSURANCE POLICIES OR HEALTH MAINTENANCE ORGANIZATION PLANS.

Be it enacted by the General Assembly of the State of South Carolina:

Pharmacy audit rights

SECTION 1. Article 18, Chapter 71, Title 38 of the S.C. Code is amended to read:

Article 18

Pharmacy Audit Rights

 Section 38‑71‑1810. (A) For the purposes of this article:

 (1) “Insurer” means an entity that provides health insurance coverage in this State as defined in Section 38‑71‑670(7) and Section 38‑71‑840(16).

 (2) “Responsible party” means the entity responsible for payment of claims for health care services other than:

 (a) the individual to whom the health care services were rendered; or

 (b) that individual's guardian or legal representative.

 (3) “Audit” means an evaluation, investigation, or review of claims paid to a pharmacy that takes place at the pharmacy location and does not include review of claims or claims payments that an insurer conducts as a normal course of business. Nothing in this definition limits the review of claims or claims payments through an electronic or algorithmic system designed to reduce fraud, waste, or abuse, provided that recoupments may not be calculated based on extrapolation pursuant to Section 38‑71‑1810(21).

 (4) “Abuse” means any practice that:

 (a)(i) is inconsistent with sound fiscal or business practices; or

 (ii) fails to meet professionally recognized standards for pharmacy services; and

 (b) directly or indirectly causes financial loss to a responsible party.

 (B) If a managed care organization, insurer, third‑party payor, or any entity that represents a responsible party conducts an audit of the records of a pharmacy, then, with respect to this audit, the pharmacy has a right to:

 (1) not have an audit initiated or scheduled during the first five days of any month without the express consent of the pharmacy, which shall cooperate with the auditor to establish an alternate date if the audit would fall within the excluded days, and no audit may be performed during a state of emergency declared by the Governor that applies to the pharmacy location unless the state of emergency extends beyond ninety days or is agreed to by the pharmacy location;

 (2) have an audit that involves clinical judgment be conducted with a pharmacist who is licensed and employed by or working under contract with the auditing entity;

 (3) not have clerical or recordkeeping errors, including typographical errors, scrivener's errors, and computer errors, on a required document or record considered fraudulent in the absence of any other evidence or serve as the sole basis of rejection of a claim; however, the provisions of this item do not prohibit recoupment of fraudulent payments;

 (4) have the auditing entity to provide the pharmacy, upon request, all records related to the audit in an electronic format or contained in digital media;

 (5) have at least thirty days to respond to an audit notice and to submit records requested by the auditing entity related to the audit in electronic format or by certified mail. If a pharmacy requests an extension during this thirty‑day period, it must be granted an additional thirty days to respond. The auditing entity must confirm receipt of all materials and documentation provided by the pharmacy to the auditing entity;

 (6) have the properly documented records of a hospital or of a person authorized to prescribe controlled substances for the purpose of providing medical or pharmaceutical care for their patients transmitted by any means of communication approved by the auditing entity in order to validate a pharmacy record with respect to a prescription or refill for a controlled substance or narcotic drug pursuant to federal and state regulations;

 (7) have a projection of an overpayment or underpayment based on either the number of patients served with a similar diagnosis or the number of similar prescription orders or refills for similar drugs; however, the provisions of this item do not prohibit recoupments of actual overpayments unless the projection for overpayment or underpayment is part of a settlement by the pharmacy;

 (8) prior to the initiation of an audit, if the audit is conducted for an identified problem, have the audit limited to claims that are identified by prescription number or by range of prescription numbers;

 (9) if an audit is conducted for a reason other than described in item (8), have the audit limited to one hundred selected prescriptions per pharmacy benefits manager;

 (10) if an audit reveals the necessity for a review of additional claims, the audit may be conducted on‑site;

 (11) except for audits initiated for the reason described in items (8) or (10), be subject to no more than one audit in one calendar year, unless fraud or misrepresentation is reasonably suspected;

 (12) be free of recoupments based on either of the following subitems unless defined within the billing, submission, or audit requirements set forth in the pharmacy provider manual not inconsistent with current State Board of Pharmacy Regulations, except for cases of Food and Drug Administration regulation or drug manufacturer safety programs in accordance with federal or state regulations:

 (a) documentation requirements in addition to, or exceeding requirements for, creating or maintaining documentation prescribed by the State Board of Pharmacy;

 (b) a requirement that a pharmacy or pharmacist perform a professional duty in addition to, or exceeding, professional duties prescribed by the State Board of Pharmacy unless otherwise agreed to by contract with the auditing entity;

 (13) be subject, so long as a claim is made within the contractual claim submission time period, to recoupment only following the correction of a claim and to have recoupment limited to amounts paid in excess of amounts payable under the corrected claim unless a prescription error occurs. For purposes of this subsection, a prescription error includes, but is not limited to, wrong drug, wrong strength, wrong dose, or wrong patient;

 (14) be subject to reversals of approval, except for Medicare claims, for drug, prescriber, or patient eligibility upon adjudication of a claim only in cases in which the pharmacy obtained the adjudication by fraud or misrepresentation of claim elements;

 (15) be audited under the same standards and parameters as other similarly situated pharmacies audited by the same entity;

 (16) have at least thirty days following receipt of the preliminary audit report to produce documentation to address any discrepancy found during an audit;

 (17) have the option of providing documentation in electronic format or by certified mail;

 (18) have the period covered by an audit limited to twenty‑four months from the date a claim was submitted to, or adjudicated by, a managed care organization, an insurer, a third‑party payor, or an entity that represents responsible parties, unless a longer period is permitted by or under federal law;

 (19) have the preliminary audit report delivered to the pharmacy within one hundred twenty days after conclusion of the audit;

 (20) have a final audit report delivered to the pharmacy within ninety days after the end of the appeals period;

 (21) not have the accounting practice of extrapolation used in calculating recoupments or penalties for audits, unless otherwise required by federal requirements or federal plans; and

 (22) have the right to an external review pursuant to Section 38‑71‑2240 for any denied appeals of recoupment if the pharmacy believes the recoupment amounts were calculated in violation of this article.

 (C) Notwithstanding Section 38‑71‑1840, the auditing entity shall provide the pharmacy, if requested, a masked list that provides a prescription number range the auditing entity is seeking to audit.

 Section 38‑71‑1820. (A) Each entity that conducts an audit of a pharmacy shall establish an appeals process under which a pharmacy may appeal an unfavorable preliminary audit report to the entity.

 (B) If, following the appeal, the entity finds that an unfavorable audit report or any portion of the unfavorable audit report is unsubstantiated, the entity shall dismiss the unsubstantiated portion of the audit report without any further proceedings.

 (C) Each entity conducting an audit shall provide a copy, if required under the terms of the contract with the responsible party, of the audit findings to the plan sponsor after completion of any appeals process.

 Section 38‑71‑1830. (A) Recoupments of any funds disputed on the basis of an audit must occur only after final internal disposition of the audit, including the appeals process as provided for in Section 38‑71‑1820 or the external review pursuant to Section 38‑71‑2240, unless fraud or misrepresentation is reasonably suspected.

 (B) Recoupment on an audit must be refunded to the responsible party as contractually agreed upon by the parties involved in the audit.

 (C) The entity conducting the audit may charge or assess the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:

 (1) the responsible party or payor and the entity conducting the audit have entered into a contract that explicitly states the percentage charge or assessment to the responsible party; and

 (2) a commission or other payment to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

 Section 38‑71‑1840. The provisions of this article do not apply to an audit, review, or investigation:

 (1) that involves alleged insurance fraud or abuse, Medicare fraud or abuse, or other fraud or misrepresentation;

 (2) conducted by or on the behalf of the Department of Health and Human Services in the performance of its duties in administering Medicaid under Titles XIX and XXI of the Social Security Act; or

 (3) notwithstanding the exemptions under subitems (1) and (2) of this section, contracts between the South Carolina Department of Health and Human Services and Medicaid‑managed care organizations must include provisions for biannual audits of Medicaid‑managed care organizations’ pharmacy pricing and include limitations on any pharmacy benefits manager contract arrangements that bill the Medicaid program for more than the total price paid to pharmacies for actual claims.

Pharmacy benefits managers

SECTION 2. Article 21, Chapter 71, Title 38 of the S.C. Code is amended to read:

Article 21

Pharmacy Benefits Managers

 Section 38‑71‑2200. As used in this article:

 (1) “Claim” means a request from a pharmacy or pharmacist to be reimbursed for the cost of administering, filling, or refilling a prescription for a drug or for providing a medical supply or device.

 (2) “Claims processing services” means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include:

 (a) receiving payments for pharmacist services;

 (b) making payments to pharmacists or pharmacies for pharmacist services; or

 (c) both receiving and making payments.

 (3) “Health benefit plan” means any individual, blanket, or group plan, policy, or contract for health care services issued or delivered by a health care insurer in this State as defined in Sections 38‑71‑670(6) and 38‑71‑840(14), including the state health plan as defined in Section 1‑11‑710. Notwithstanding this section, the state health plan is not subject to the provisions of this title unless specifically referenced.

 (4) “Health care insurer” means an entity that provides health insurance coverage in this State as defined in Section 38‑71‑670(7) and Section 38‑71‑840(16).

 (5) “Maximum Allowable Cost List” means a listing of generic drugs used by a pharmacy benefits manager to set the maximum allowable cost at which reimbursement to a pharmacy or pharmacist may be made.

 (6) “Other prescription drug or device services” means services other than claims processing services, provided directly or indirectly by a pharmacy benefits manager, whether in connection with or separate from claims processing services, including without limitation:

 (a) negotiating rebates, discounts, or other financial incentives and arrangements with drug companies;

 (b) disbursing or distributing rebates;

 (c) managing or participating in incentive programs or arrangements for pharmacist services;

 (d) negotiating or entering into contractual arrangements with pharmacists or pharmacies, or both;

 (e) developing formularies;

 (f) designing prescription benefit programs; or

 (g) advertising or promoting services.

 (7) “Pharmacist” has the same meaning as provided in Section 40‑43‑30(65).

 (8) “Pharmacist services” means products, goods, and services, or any combination of products, goods, and services, provided as a part of the practice of pharmacy.

 (9) “Pharmacy” has the same meaning as provided in Section 40‑43‑30(67).

 (10) “Pharmacy benefits manager” means an entity that contracts with pharmacists or pharmacies on behalf of an insurer, third-party administrator, or the South Carolina Public Employee Benefit Authority to:

 (a) process claims for prescription drugs or medical supplies or provide retail network management for pharmacies or pharmacists;

 (b) pay pharmacies or pharmacists for prescription drugs or medical supplies; or

 (c) negotiate rebates with manufacturers for drugs paid for or procured as described in this article.

 (11) “Pharmacy benefits manager affiliate” means a pharmacy or pharmacist that directly or indirectly, through one or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership or control with a pharmacy benefits manager.

 (12) “Pharmacy Services Administrative Organization” (PSAO) means an entity that has contracted with pharmacy clients in the State to conduct business on their behalf with third‑party payers or pharmacy benefits managers. PSAOs provide administrative services to pharmacies and negotiate and enter into contracts with third‑party payers or pharmacy benefits managers on behalf of pharmacies.

 (13) “Specialized delivery drug” means a prescription drug that meets a majority of the following criteria, as set forth by the manufacturer, FDA, or other applicable law or regulatory body and:

 (a) requires special handling or storage;

 (b) requires complex and extended patient education or counseling;

 (c) requires intensive monitoring;

 (d) requires clinical oversight; or

 (e) requires product support services; and the drug is used to treat chronic and complex, or rare medical conditions:

 (i) that can be progressive; or

 (ii) that can be debilitating or fatal if left untreated or undertreated.

 Section 38‑71‑2210. (A)(1) A person or organization may not establish or operate as a pharmacy benefits manager in this State for health benefit plans without obtaining a license from the Director of the Department of Insurance.

 (2) The director shall prescribe the application for a license to operate in this State as a pharmacy benefits manager and may charge an initial application fee of one thousand dollars and an annual renewal fee of five hundred dollars, provided the pharmacy benefits manager application form must collect the following information:

 (a) the name, address, and telephone contact number of the pharmacy benefits manager;

 (b) the name and address of the pharmacy benefits manager's agent for service of process in the State;

 (c) the name and address of each person with management or control over the pharmacy benefits manager;

 (d) the name and address of each person with a beneficial ownership interest in the pharmacy benefits manager;

 (e) a signed statement indicating that, to the best of their knowledge, no officer with management or control of the pharmacy benefits manager has been convicted of a felony or has violated any of the requirements of state law applicable to pharmacy benefits managers, or, if the applicant cannot provide such a statement, a signed statement describing the relevant conviction or violation; and

 (f) in the case of a pharmacy benefits manager applicant that is a partnership or other unincorporated association, limited liability company, or corporation, and has five or more partners, members, or stockholders:

 (i) the applicant shall specify its legal structure and the total number of its partners, members, or stockholders who, directly or indirectly, own, control, hold with the power to vote, or hold proxies representing ten percent or more of the voting securities of any other person; and

 (ii) the applicant shall agree that, upon request by the department, it shall furnish the department with information regarding the name, address, usual occupation, and professional qualifications of any other partners, members, or stockholders who, directly or indirectly, own, control, hold with the power to vote, or hold proxies representing ten percent or more of the voting securities of any other person.

 (3) An applicant or a pharmacy benefits manager that is licensed to conduct business in the State shall, unless otherwise provided for in this chapter, file a notice describing any material modification of this information.

 (B) The director may promulgate regulations establishing the licensing and reporting requirements of pharmacy benefits managers consistent with the provisions of this article.

 (C) The fees and penalties assessed pursuant to this article must be retained by the department for the administration of this chapter.

 Section 38‑71‑2220. (A) In any participation contracts between pharmacy benefits managers and pharmacists or pharmacies providing prescription drug coverage for health benefit plans, no pharmacy or pharmacist may be prohibited, restricted, or penalized in any way from disclosing to any covered person any health care information that the pharmacy or pharmacist deems appropriate within their scope of practice.

 (B) A pharmacy or pharmacist must not be proscribed by a pharmacy benefits manager from discussing information regarding the total cost for pharmacist services for a prescription drug or from selling a more affordable alternative to the insured if a more affordable alternative is available, but a pharmacy benefits manager may proscribe a pharmacy or pharmacist from sharing proprietary or confidential information.

 (C) A pharmacy benefits manager contract with a participating pharmacist or pharmacy may not prohibit, restrict, or limit disclosure of information to the director investigating or examining a complaint or conducting a review of a pharmacy benefits manager's compliance with the requirements pursuant to this act. The information or data acquired during an examination or review pursuant to this section is considered proprietary and confidential and is not subject to the South Carolina Freedom of Information Act.

 Section 38‑71‑2230. (A) A pharmacy benefits manager or representative of a pharmacy benefits manager shall not:

 (1) cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading;

 (2) charge a pharmacist or pharmacy a fee related to the adjudication of a claim unless the fee is:

 (a) agreed to by a Pharmacy Services Administrative Organization acting on behalf of a pharmacy that it represents; or

 (b) identified and agreed to in contract and identified and reported on the remittance advice;

 (3) engage in an anticompetitive pattern of reimbursing independent or unaffiliated pharmacies or pharmacists in this State consistently less than the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager affiliate for providing the same pharmacist services or prescription drug unless the difference in reimbursement is justified according to uniform, defined standards that apply to each network provider;

 (4) collect or require a pharmacy or pharmacist to collect from an insured a copayment for a prescription drug at the point of sale in an amount that exceeds the lesser of:

 (a) the contracted copayment amount;

 (b) the amount an individual would pay for a prescription drug if that individual was paying cash; or

 (c) the contracted amount for the drug;

 (5) require the use of mail order for filling prescriptions unless required to do so by the health benefit plan or the health benefit plan design;

 (6) Reserved;

 (7) penalize or retaliate against a pharmacist or pharmacy for exercising rights provided pursuant to the provisions of this chapter;

 (8) prohibit a pharmacist or pharmacy from offering and providing direct and limited delivery services including incidental mailing services, to an insured as an ancillary service of the pharmacy; or

 (9) any combination thereof.

 (B) No pharmacy benefits manager shall, directly or indirectly, impose retroactive fees, reductions, or recoupments of the amount paid to a pharmacist or pharmacy for any claim for prescription drugs other than the Medicare Part D Program as set forth in 42 U.S.C. 1395w‑102 and 42 C.F.R. 423 or as provided in this subsection.

 (C) Notwithstanding subsection (B), a pharmacy benefits manager may make or permit a reduction or recoupment of payment for pharmacist or pharmacy services for:

 (1) claims submitted fraudulently;

 (2) claims where the pharmacist or pharmacy was previously paid for the same pharmacy goods or services;

 (3) claims not properly rendered or billed by the pharmacy or pharmacist; or

 (4) otherwise in accordance with state pharmacy audit laws.

 (D) This section does not preclude a pharmacy benefits manager from engaging in claims reconciliation activities relating to brand effective rates and generic effective rates if:

 (1) such activities are agreed to by a Pharmacy Services Administrative Organization acting on behalf of a pharmacy it represents and identified in the contract; or

 (2) if a pharmacy is not represented by a Pharmacy Services Administrative Organization, such activities are permitted if:

 (a) they are agreed to by a pharmacy and identified in a contract;

 (b) they do not result in a retroactive reduction or recoupment of payment to a pharmacist or pharmacy for a previously adjudicated covered claim, unless the pharmacy or pharmacist has clearly consented to retroactive reductions as part of participation in the program and the reductions are explained in an annual reconciliation statement; and

 (c) a pharmacy is allowed to choose not to participate in programs that include the activities. A pharmacy benefits manager offering different terms and conditions including, but not limited to, differing reimbursement rates, for participation versus nonparticipation in the activities shall not constitute a violation of Section 38‑71‑2230(A)(7).

 (E) This subsection may not be construed to limit overpayment recovery efforts as set forth in Section 38‑59‑250.

 A pharmacy may not be subject to a charge‑back or recoupment for a clerical or recordkeeping error in a required document or record, including a typographical or computer error, unless the error resulted in overpayment to the pharmacy.

 (F) Termination of a pharmacy or pharmacist from a pharmacy benefits manager network does not release the pharmacy benefits manager from the obligation to make any payment due to the pharmacy or pharmacist for pharmacist services properly rendered according to the contract.

 (G) A pharmacy benefits manager must not directly or indirectly engage in patient steering to a pharmacy that is a pharmacy benefits manager affiliate without first making a written disclosure to the patient informing such patient of the pharmacy benefits manager’s relationship with the pharmacy and providing the patient with access to information about unaffiliated, in‑network pharmacies that are located near the patient. A pharmacy benefits manager must not prohibit a patient from choosing to use an alternative in‑network pharmacy.

 (H) Nothing in this article abridges the right of a pharmacist to refuse to fill or refill a prescription as referenced in Section 40‑43‑86(E)(6) of the South Carolina Pharmacy Practice Act.

 Section 38‑71‑2235. (A) A pharmacy benefits manager must perform its duties to a health benefit plan or health care insurer exercising good faith and fair dealing.

 (B) A pharmacy benefits manager must provide during normal business hours a phone number through which a pharmacy or pharmacist can obtain answers within a reasonable time to questions regarding networks, patient benefits, appeals, and other contractual or service issues.

 (C) A pharmacy benefits manager may not prohibit a pharmacy services administrative organization or pharmacy from sharing information directly with the department.

 Section 38‑71‑2240. (A) Before a pharmacy benefits manager places or continues to place a particular drug on a Maximum Allowable Cost List, the drug must:

 (1) be listed as “A” or “B” rated in the most recent version of the Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, or has an “NR” or “NA” rating, or a similar rating, by a nationally recognized reference;

 (2) be available for purchase in the State from national or regional wholesalers operating in this State; and

 (3) not be obsolete.

 (B) A pharmacy benefits manager shall:

 (1) provide a process for network pharmacy providers to readily access the maximum allowable cost specific to that provider;

 (2) update its Maximum Allowable Cost List at least once every seven calendar days;

 (3) provide a process for each pharmacy subject to the Maximum Allowable Cost List to access any updates to the Maximum Allowable Cost List;

 (4) ensure that dispensing fees are not included in the calculation of maximum allowable cost;

 (5) establish a reasonable internal appeal procedure by which a contracted pharmacy can appeal the provider's reimbursement for a drug subject to maximum allowable cost pricing if the reimbursement for the drug is less than the net amount that the network provider paid to the suppliers of the drug. The reasonable internal appeal procedure must include:

 (a) a dedicated telephone number and email address or website for the purpose of submitting internal appeals; and

 (b) the ability to submit an internal appeal directly to the pharmacy benefits manager regarding the pharmacy benefits plan or program or through a pharmacy service administrative organization if the pharmacy service administrative organization has a contract with the pharmacy benefits manager that allows for the submission of such appeals;

 (6) participate in a reasonable external review procedure by which a contracted pharmacy can request an external review of a pharmacy benefits manager’s denial of an internal appeal by an independent review organization in accordance with the procedures promulgated by the director in subsection (F) of this section; and

 (7) permit an unaffiliated retail pharmacy to participate in programs that reconcile payments with actual cost on the same basis as retail pharmacy benefits manager affiliates.

 (C) A pharmacy must be allowed no less than ten calendar days after the applicable fill date to file an internal appeal or request for an external review of a denied internal appeal.

 (D) If an internal appeal is initiated, the pharmacy benefits manager shall within ten calendar days after receipt of notice of the appeal either:

 (1) if the internal appeal is upheld:

 (a) notify the pharmacy or pharmacist or his designee of the decision;

 (b) make the change in the maximum allowable cost effective as of the date the internal appeal is resolved;

 (c) permit the appealing pharmacy or pharmacist to reverse and rebill the claim in question; and

 (d) 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 internal appeal is resolved; or

 (2) if the internal appeal is denied:

 (a) provide the appealing pharmacy or pharmacist the reason for the denial, the National Drug Code number, and the name of the national or regional pharmaceutical wholesalers operating in this State; and

 (b) notify the pharmacy or pharmacist in writing of the right to request an external review of the internal appeal and include clear and concise documents describing the external review process.

 (E) A pharmacy may request an external review of a denied internal appeal if the pharmacy believes the pharmacy benefits manager erred in denying an internal appeal which resulted in a reimbursement amount inconsistent with the provisions of this section.

 (F)(1) The director must promulgate regulations to establish an external review process to facilitate the review of a denied internal appeal. The external review process must be consistent with the Health Carrier External Review Act pursuant to Article 19 of this chapter, to the degree possible, given the unique operations of a pharmacy benefits manager, the prescription drug industry, and the provisions of this section. At a minimum, the director must promulgate regulations regarding the following:

 (a) the appropriate time frames for all parties to the external review to submit documentation and respond accordingly;

 (b) the qualifications and selection of independent review organizations; and

 (c) the time frame for an independent review organization to render its decision.

 (2) If the independent review organization determines the pharmacy benefits manager reimbursed a pharmacy or pharmacist in an amount inconsistent with the provisions of this section, the pharmacy benefits manager must:

 (a) make the change in the maximum allowable cost 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; and

 (c) 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.

 (3) An external review decision is binding on the pharmacy benefits 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 Maximum Allowable Cost List 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. The director must establish a reasonable filing fee associated with a pharmacist’s request for an external review, which is to be retained by the department for administration of this chapter. The director may require a pharmacy or pharmacist to pay for costs related to the external review if the director determines the pharmacy or pharmacist has abused the external review process.

 (5) 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.

 (G) The provisions of this section:

 (1) do not apply to the Maximum Allowable Cost List maintained by the State Medicaid Program, the Medicaid-managed care organizations under contract with the South Carolina Department of Health and Human Services or the South Carolina Public Employee Benefit Authority; and

 (2) apply to the pharmacy benefits manager employed by the South Carolina Public Employee Benefit Authority if, at any time, the South Carolina Public Employee Benefit Authority engages the services of a pharmacy benefits manager to maintain the Maximum Allowable Cost List.

Section 38‑71‑2245. (A)(1) A pharmacy benefits manager may neither limit an insured from selecting an in‑network pharmacy or pharmacist of the insured’s choice nor deny the right of a pharmacy or pharmacist to participate in a network if the pharmacy or pharmacist meets the requirements for network participation set forth by the pharmacy benefits manager, and the pharmacy or pharmacist agrees to the contract terms, conditions, and rates of reimbursements.

 (2) A pharmacy benefits manager may not impose any pharmacy accreditation standards or recertification requirements for network participation that unreasonably exceed state or federal requirements for licensure as a pharmacy in this State unless authorized under this chapter.

 (B) Notwithstanding subsection (A), a pharmacy benefits manager may for specialized delivery drugs specify requirements for network participation that:

 (1) directly relate to the ability of the pharmacy or pharmacist to store, handle, or deliver a prescription drug in a manner that ensures the quality, integrity, or safety of the drug, its delivery, or its use; or

 (2) relate to quality metrics that affect a pharmacy’s or pharmacist’s ability to participate, provided that the pharmacy benefits manager applies such terms equally to all network participants.

 (C) For prescription drugs that qualify as a high‑cost prescription drug, subsection (A) of this section does not apply to a pharmacy benefits manager. A high‑cost prescription drug is defined as a prescription drug whose current or prior year’s annual average wholesale price exceeded 300 percent of the Federal Poverty Level for a single‑member household.

 (D) A pharmacy benefits manager must provide notification of any changes to all applicable specialized delivery drug lists and high‑cost prescription drug lists and must make such lists available on a website and upon request to participating pharmacies. A pharmacy may appeal a classification determination to the Department of Insurance.

 (E) The provisions of this section do not apply to the coverage provided to employees, retirees, and their eligible dependents pursuant to Section 1‑11‑710 by the South Carolina Public Employee Benefit Authority or through its contracted pharmacy benefits manager.

 Section 38‑71‑2250. (A) The director shall enforce this article.

 (B)(1) As often as the director deems appropriate, but not less frequently than once every five years, the director 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 this act. 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.

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

 (C) Violations of this article are subject to the penalties provided in Sections 38‑2‑10 through 38‑2‑30.

 (D) The director may promulgate regulations regarding pharmacy benefits managers that are not inconsistent with this article.

 Section 38‑71‑2260. (A) Nothing in this act is intended or may be construed to be in conflict with existing relevant federal law.

 (B) Other than the antisteering provisions contained in Section 38‑71‑2230(G), this article does not apply to the South Carolina Department of Health and Human Services in the performance of its duties in administering Medicaid under Titles XIX and XXI of the Social Security Act or to the Medicaid-managed care organizations under contract with the South Carolina Department of Health and Human Services.

 (C) Notwithstanding the exemption under subsection (B), contracts between the South Carolina Department of Health and Human Services and Medicaid‑managed care organizations must include provisions for biannual audits of Medicaid‑managed care organizations’ pharmacy pricing mechanisms and include limitations on any pharmacy benefits manager contract arrangements that bill the Medicaid program for more than the total price paid to pharmacies for actual claims.

Pharmacy services administrative organizations

SECTION 3. Chapter 71, Title 38 of the S.C. Code is amended by adding:

 Article 23

 Pharmacy Services Administrative Organizations

 Section 38‑71‑2310. As used in this article:

 (1) “Pharmacist” has the same meaning as provided in Section 40‑43‑30(65).

 (2) “Pharmacy” has the same meaning as provided in Section 40‑43‑30(67).

 (3) “Pharmacy services” has the same meaning as provided in Section 38‑71‑2200(8).

 (4) “Pharmacy benefits manager” or “PBM” has the same meaning as provided in Section 38‑71‑2200(10).

 (5) “Pharmacy Services Administrative Organization” (PSAO) means an entity that has contracted with pharmacy clients in the State to conduct business on their behalf with third‑party payers or pharmacy benefits managers. PSAOs provide administrative services to pharmacies and negotiate and enter into contracts with third‑party payers or pharmacy benefits managers on behalf of pharmacies.

 (6) “PSAO‑pharmacy contract” means a contractual agreement between a PSAO and a pharmacy by which a PSAO agrees to negotiate with third‑party payers or pharmacy benefits managers on behalf of a pharmacy.

 Section 38‑71‑2320. (A)(1) A person or organization may not establish or operate as a pharmacy services administrative organization in this State for prescription drug coverage or benefits without obtaining a license from the director.

 (2) The director shall prescribe the application for a license to operate in this State as a pharmacy services administrative organization and may charge an initial application fee of one thousand dollars and an annual renewal fee of five hundred dollars, provided the pharmacy services administrative organization application form must collect the following information:

 (a) the name, address, and telephone contact number of the pharmacy services administrative organization;

 (b) the name and address of the pharmacy services administrative organization’s agent for service of process in the State;

 (c) the name and address of each person with management or control over the pharmacy services administrative organization;

 (d) the name and address of each person with a beneficial ownership interest in the pharmacy services administrative organization;

 (e) a signed statement indicating that, to the best of their knowledge, no officer with management or control of the pharmacy services administrative organization has been convicted of a felony or has violated any of the requirements of state law applicable to pharmacy services administrative organization, or, if the applicant cannot provide such a statement, a signed statement describing the relevant conviction or violation; and

 (f) in the case of a pharmacy services administrative organization applicant that is a partnership or other unincorporated association, limited liability company, or corporation, and has five or more partners, members, or stockholders:

 (i) the applicant shall specify its legal structure and the total number of its partners, members, or stockholders who, directly or indirectly, own, control, hold with the power to vote, or hold proxies representing ten percent or more of the voting securities of any other person; and

 (ii) the applicant shall agree that, upon request by the department, it shall furnish the department with information regarding the name, address, usual occupation, and professional qualifications of any other partners, members, or stockholders who, directly or indirectly, own, control, hold with the power to vote, or hold proxies representing ten percent or more of the voting securities of any other person.

 (3) An applicant or a pharmacy services administrative organization that is licensed to conduct business in the State shall, unless otherwise provided for in this chapter, file a notice describing any material modification of this information.

 (B) The director may promulgate regulations establishing the licensing and reporting requirements of pharmacy services administrative organizations consistent with the provisions of this article.

 (C) The fees and penalties assessed pursuant to this article must be retained by the department for the administration of this chapter.

 Section 38‑71‑2330. (A) A pharmacy service administrative organization must:

 (1) act as a fiduciary to a pharmacy and perform its duties to a pharmacy exercising good faith and fair dealing;

 (2) in the event of a dispute between a pharmacy and a pharmacy benefits manager or third‑party payer, ensure and facilitate timely communication from the pharmacy to the pharmacy benefits manager or third‑party payer;

 (3) forward any and all notices of appeals from a pharmacy to the pharmacy benefits manager or third‑party payer in a timely manner and provide in a timely manner information that has been requested as part of an appeal to the external review organization and, upon request, the department;

 (4) provide during normal business hours a phone number through which a pharmacy or pharmacist can obtain answers within a reasonable time to questions regarding networks, contracts, appeals, and other contractual or service issues; and

 (5) provide a detailed breakdown of the prescription numbers, amounts, and contractual basis for each recoupment and regular updates on the status of appeals.

 (B) In connection with any appeal, a third‑party payer or pharmacy benefits manager’s notice or provision of information to a PSAO is deemed to be notice or provision of information to the pharmacy on whose behalf the PSAO has contracted.

 (C) A PSAO‑pharmacy contract must include a provision that requires the PSAO to provide to the pharmacy a copy of any contract, amendments, payment schedules, or reimbursement rates within three calendar days after the execution of a contract, or an amendment to a contract, signed on behalf of the pharmacy.

 (D) Prior to entering into a PSAO‑pharmacy contract, a PSAO must furnish to a pharmacy a written disclosure of ownership or control. This disclosure must include the extent of any ownership or control by any parent company, subsidiary, or other organization that:

 (1) provides pharmacy services;

 (2) provides prescription drug or devices services; or

 (3) manufactures, sells, or distributes prescription drugs, biologicals, or medical devices.

 (E) Any PSAO‑pharmacy contract must provide that the PSAO must notify the pharmacy in writing within five calendar days of any material change in its ownership or control related to any company, subsidiary, or other organization outlined in subsection (D).

 (F) A PSAO that owns or is owned by, in whole or in part, any entity that manufactures, sells, or distributes prescription drugs, biologicals, or medical devices must not, as a condition of entering into a PSAO‑pharmacy contract, require that the pharmacy purchase any drugs or medical devices from the entity with which the PSAO has an ownership interest, or an entity with an ownership interest in the PSAO.

 (G) A PSAO that owns or is owned by, in whole or in part, any entity that manufactures, sells, or distributes prescription drugs, biologicals, or medical devices must disclose to the Department of Insurance any agreement with a pharmacy in which the pharmacy purchases prescription drugs, biologicals, or medical devices from a PSAO or any entity that owns or is owned by, in whole or in part, the PSAO.

 Section 38‑71‑2340. (A) The director shall enforce this article.

 (B)(1) As often as the director deems appropriate, but not less frequently than once every five years, the director may examine or audit the books and records of a pharmacy services administrative organization providing prescription drug coverage or benefits on behalf of pharmacies or pharmacy benefits managers that are relevant to determining if the pharmacy services administrative organization is in compliance with this act. The pharmacy services administrative organization 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 director or his designee promptly must institute a civil action to recover the expenses of examination against a pharmacy services administrative organization which refuses or fails to pay.

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

 (C) Violations of this article are subject to the penalties provided in Sections 38‑2‑10 through 38‑2‑30.

 (D) The director may promulgate regulations regarding pharmacy services administrative organizations that are not inconsistent with this article.

 Section 38‑71‑2350. (A) Nothing in this act is intended or may be construed to be in conflict with existing relevant federal law.

 (B) This article does not apply to the South Carolina Department of Health and Human Services in the performance of its duties in administering Medicaid under Titles XIX and XXI of the Social Security Act or to the Medicaid‑managed care organizations under contract with the South Carolina Department of Health and Human Services.

Repeal

SECTION 4. Section 38‑71‑147 of the S.C. Code is repealed.

Department of Insurance study

SECTION 5. The Department of Insurance must commission a study of the cost of applying the provisions of Articles 18, 21, and 23 of this chapter to payors that are not currently included in the definition of pharmacy benefits manager. This study must be delivered to the Senate and House of Representatives before January 1, 2024.

Severability

SECTION 6. If any section, subsection, paragraph, subparagraph, sentence, clause, phrase, or word of this act is for any reason held to be unconstitutional or invalid, such holding shall not affect the constitutionality or validity of the remaining portions of this act, the General Assembly hereby declaring that it would have passed this act, and each and every section, subsection, paragraph, subparagraph, sentence, clause, phrase, and word thereof, irrespective of the fact that any one or more other sections, subsections, paragraphs, subparagraphs, sentences, clauses, phrases, or words hereof may be declared to be unconstitutional, invalid, or otherwise ineffective.

Time effective

SECTION 7. This act takes effect January 1, 2024, but the recurring examinations by the Department of Insurance provided for in Sections 38-71-2250(B)(1) and 38-71-2340(B)(1) must not begin before January 1, 2025.

Ratified the 11th day of May, 2023.

Approved the 16th day of May, 2023.

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