**A** **BILL**

TO AMEND THE CODE OF LAWS OF SOUTH CAROLINA, 1976, BY ADDING ARTICLE 22 TO CHAPTER 71, TITLE 38 SO AS TO ENACT THE “PHARMACY PATIENT PROTECTION ACT”, TO PROVIDE FOR THE LICENSURE AND REGISTRATION OF PHARMACY BENEFIT MANAGERS, TO PROVIDE FOR THE REQUIREMENTS OF A CERTIFICATE OF REGISTRATION, AND TO PROVIDE FOR THE CONDITIONS UNDER WHICH A PRESCRIPTION BENEFITS MANAGER SHALL OPERATE; TO REQUIRE CERTAIN FINANCIAL AND UTILIZATION INFORMATION BE MADE AVAILABLE FOR REVIEW; TO PROVIDE REQUIREMENTS FOR RECORD KEEPING; TO PROVIDE FOR PRICING GUIDELINES THAT MUST BE USED; TO PROVIDE THAT A PHARMACY BENEFITS MANAGER MAY NOT DISCRIMINATE WHEN CONTRACTING WITH PHARMACIES ON THE BASIS OF COPAYMENTS OR DAYS OF SUPPLY; AND TO AUTHORIZE THE DIRECTOR OF THE DEPARTMENT OF INSURANCE TO MAKE RULES AND PROMULGATE REGULATIONS TO IMPLEMENT THIS ARTICLE.

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

SECTION 1. The purpose of this act is to require the registration of a pharmacy benefit manager. This act is intended to promote, preserve, and protect the public health, safety, and welfare through oversight of a pharmacy benefit manager.

SECTION 2. Chapter 71, Title 38 of the 1976 Code is amended by adding:

“Article 22

Pharmacy Patient Protection

Section 38‑71‑2200. This article may be cited as the ‘Pharmacy Patient Protection Act’.

Section 38‑71‑2210. For purposes of this article:

(1) ‘Director’ means the Director of the Department of Insurance.

(2)(a) ‘Covered entity’ means:

(i) a nonprofit hospital or medical service corporation, health insurer, health benefit plan, or health maintenance organization;

(ii) a health program administered by a department or the State in the capacity of provider of health coverage; or

(iii) an employer, labor union, or other group of persons organized in the State that provides health coverage to covered individuals who are employed or reside in the State.

(b) The term does not include a:

(i) self‑funded plan that is exempt from state regulation pursuant to the Employee Retirement Income Security Act (ERISA);

(ii) plan issued for coverage for federal employees; or

(iii) health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income, long term care, or other limited benefit health insurance policies and contracts.

(3) ‘Covered individual’ means a member, participant, enrollee, contract holder or policy holder, or beneficiary of a covered entity who is provided health coverage by the covered entity. ‘Covered individual’ includes a dependent or other person provided health coverage through a policy, contract, or plan for a covered individual.

(4) ‘Department’ means Department of Insurance.

(5) ‘Health benefit plan’ means a policy, contract, certificate, or agreement offered or issued by a health carrier to provide, deliver, arrange for, pay for, or reimburse any of the cost of health care services, including prescription drug benefits.

(6) ‘Pharmacist’ means an individual licensed as a pharmacist by the State Board of Pharmacy.

(7) ‘Pharmacist services’ means the:

(a) interpretation, evaluation, and dispensing of prescription drug orders in the patient’s best interest;

(b) participation in drug and device selection, drug administration, prospective drug reviews, and drug or drug‑related research;

(c) provision of patient counseling and the provision of those acts or services necessary to provide pharmacy care and drug therapy management;

(d) responsibility for compounding and labeling of drugs and devices, except labeling by a manufacturer, repackager, or distributor, of nonprescription drugs and commercially packaged legend drugs and devices; and

(e) proper and safe storage of drugs and devices and maintenance of proper records for them; or

(f) offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, education, management, and control of a pharmacy.

(8) ‘Pharmacy’ means a location for which a pharmacy permit is required and in which prescription drugs and devices are maintained, compounded, and dispensed for patients by a pharmacist. This definition includes a location where pharmacy‑related services are provided by a pharmacist.

(9) ‘Pharmacy benefits management’ means the administration or management of prescription drug benefits provided by a covered entity for the benefit of a covered individual.

(10) ‘Pharmacy benefits manager’ (PBM) means a person, business, or other entity that performs pharmacy benefits management. The term includes a person or entity acting for a PBM in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity and includes, but is not limited to, a mail‑order pharmacy.

(11) ‘Pharmacy network provider’ means a pharmacist or pharmacy that has a contractual relationship with a health benefit plan or PBM to provide prescription drugs to covered individuals.

Section 38‑71‑2220. This article applies to a PBM that provides claims processing services, other prescription drug or device services, or both, to covered individuals who are residents of this State.

Section 38‑71‑2230. (A) A person or organization may not act or operate as a PBM in this State without a valid certificate of registration issued by the department. A PBM who acts without registering must be fined not less than five thousand dollars nor more than ten thousand dollars for each violation.

(B) A person seeking a certificate of registration to act as a PBM shall file with the department an application on a form prescribed and furnished by the department with a filing fee of fifty dollars and include the following information:

(1) all basic organizational documents of the PBM, such as the articles of incorporation, articles of association, bylaws, and other applicable documents and all amendments to those documents;

(2) names, addresses, official positions, and professional qualifications of the individuals who are responsible for the conduct of the affairs of the PBM, including all members of the board of directors, board of trustees, executive committee, other governing board or committee, the principal officers in the case of a corporation, the partners or members in the case of a partnership or association, and a person who exercises control or influence over the affairs of the PBM;

(3) name and address of the agent for service of process in this State;

(4) a detailed description of the claims processing services, pharmacy services, insurance services, other prescription drug or device services, audit procedures for network pharmacies, and other administrative services to be provided; and

(5) other information as the director requires.

(C) The PBM shall renew its registration on an annual basis and the director may promulgate regulations to set forth the requirements for renewals.

(D) The department may not issue a certificate of registration if it determines that the PBM or a principal of the PBM is not competent, trustworthy, financially responsible, or of good personal and business reputation, or has had an insurance license or pharmacy license denied for cause by any state.

Section 38‑71‑2240. (A)(1) A PBM shall not intervene in the delivery or transmission of prescriptions from the prescriber to the pharmacist or pharmacy for the purpose of:

(a) influencing the prescriber’s choice of therapy;

(b) influencing the patient’s choice of pharmacist or pharmacy; or

(c) altering the prescription information including, but not limited to, switching the prescribed drug without the express authorization of the prescriber.

(2) Nothing in this section prohibits a PBM from acting in accordance with the provisions of Chapter 117, Title 44.

(B) If a PBM makes a substitution in which the substitute drug costs more than the prescribed drug, the PBM shall disclose to the covered entity and covered individual the cost of both drugs and any benefit or payment directly or indirectly accruing to the PBM as a result of the substitution.

Section 38‑71‑2250. (A) A PBM shall notify a covered entity, in writing, of an activity, policy, practice, ownership interest, or affiliation of the PBM that directly or indirectly presents a conflict of interest with the duties imposed by this article.

(B)(1) A PBM shall make available for review by a covered entity:

(a) all financial and utilization information requested by the covered entity relating to the provision of benefits to covered individuals through that covered entity and all financial and utilization information relating to services to that covered entity;

(b) all financial terms and arrangements for remuneration of any kind that apply between the PBM and any prescription drug manufacturer or labeler including, but not limited to, formulary management and drug‑switch programs, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies and data sales fees; and

(c) whether there is a difference between the price paid to a retail pharmacy and the amount billed to the covered entity for said purchase.

(2) A PBM providing this information or a covered entity may designate this material as confidential. This information may not be disclosed without the consent of the PBM or covered entity, except where required by law.

Section 38‑71‑2260. (A) When an audit of records of a pharmacist or pharmacy is conducted by a covered entity, a PBM, the State or its political subdivisions, or another entity representing the State or its political subdivisions, the audit must be conducted in the following manner:

(1) notice must be given to the pharmacy or pharmacist at least one week before conducting the initial on‑sight audit for each audit cycle;

(2) an audit performed under this section which involves clinical or professional judgment must be conducted by or in consultation with a pharmacist licensed by this State under Chapter 43, Title 40 and practicing pharmacy within this State;

(3) a clerical or record‑keeping error, such as a typographical error, scrivener’s error, or computer error, regarding a required document or record, in and of itself, does not constitute fraud; however, a claim may be subject to recoupment. Notwithstanding another provision of law, a claim is not subject to criminal penalties without proof of intent to commit fraud;

(4) a pharmacy or pharmacist may use the records of a hospital, physician, or other authorized practitioner of the healing arts, for drugs or medical supplies written or transmitted by any means of communication for purposes of validating pharmacy records with respect to orders or refills of a legend or narcotic drug;

(5) a finding of overpayment or underpayment may be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs; however, recoupment of claims must be based on the actual overpayment or underpayment unless the projection for overpayment or underpayment is part of a settlement as agreed to by the pharmacy or pharmacist;

(6) a pharmacy or pharmacist must be audited under the standards and parameters as other similarly situated pharmacies or pharmacists audited by a covered entity, a PBM, the State or its political subdivisions, or another entity representing this State or its political subdivisions;

(7) a pharmacy or pharmacist is allowed at least thirty days following receipt of the preliminary audit report in which to produce documentation to address a discrepancy found during an audit;

(8) the period covered by an audit may not exceed two years from the date the claim was submitted to or adjudicated by a covered entity, a PBM, the State or its political subdivisions, or another entity representing this State or its political subdivisions;

(9) an audit must not be initiated or scheduled during the first seven calendar days of a month due to the high volume of prescriptions filled during that time unless otherwise consented to by the pharmacy or pharmacist;

(10) the preliminary audit report must be delivered to the pharmacy or pharmacist within one hundred twenty days after conclusion of the audit. A final audit report must be delivered to the pharmacy or pharmacist within six months after receipt of the preliminary audit report or final appeal, whichever is later; and

(11) notwithstanding another provision of law, an audit of a pharmacy or pharmacist may not use the accounting practice of extrapolation in calculating recoupments or penalties for audits.

(B) Recoupments of disputed funds only may occur after final internal disposition of the audit, including the appeal process as provided in subsection (C).

(C) A covered entity conducting an audit under this section shall establish an appeals process under which a pharmacy or pharmacist may appeal an unfavorable preliminary audit report to a covered entity, a PBM, the State or its political subdivisions, or another entity representing this State or its political subdivisions. If, following the appeal, it is determined that an unfavorable audit report or a portion of it is unsubstantiated, the audit report or that portion of it must be dismissed without the necessity of further proceedings.

Section 38‑71‑2270. (A) Reimbursement by a PBM under a contract to a pharmacist or pharmacy for prescription drugs and other products and supplies that is calculated according to a formula that uses a nationally recognized reference in the pricing calculation, shall use the most current nationally recognized reference price or amount in the actual or constructive possession of the PBM or its agent.

(B) To comply with this section, a PBM is required to update the nationally recognized reference prices or amounts used for calculation of reimbursement for prescription drugs and other products and supplies no less than every three business days.

Section 38‑71‑2280. (A) A PBM may not discriminate when contracting with a pharmacy on the basis of copayments or days of supply. A contract must apply the same coinsurance, copayment, and deductible to covered drug prescriptions filled by a pharmacy including a mail‑order pharmacy or pharmacist who participates in the network.

(B) Notwithstanding another provision of law, a PBM may not mandate basic recordkeeping that is more stringent than that required by the laws of this State, including the Pharmacy Practice Act or federal laws or regulations.

(C) A PBM may not discriminate when advertising which pharmacies are participating pharmacies as pharmacy network providers. A list of participating pharmacies must be complete and all inclusive.

Section 38‑71‑2290. The Director of the Department of Insurance is authorized to make rules and promulgate regulations in accordance with Chapter 23, Title 1 (Administrative Procedures Act) to implement and enforce this article.”

SECTION 3. 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.

SECTION 4. This act takes effect upon approval by the Governor.

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