A BILL

TO AMEND THE CODE OF LAWS OF SOUTH CAROLINA, 1976, BY ADDING ARTICLE 21 TO CHAPTER 71, TITLE 38 SO AS TO ESTABLISH A LICENSE REQUIREMENT FOR PHARMACY BENEFITS MANAGERS, TO PROHIBIT A PHARMACY BENEFITS MANAGER FROM RESTRICTING OR PENALIZING A PHARMACY FROM DISCLOSING CERTAIN INFORMATION, TO PROHIBIT A PHARMACY BENEFITS MANAGER FROM UNDERTAKING CERTAIN ACTIONS, TO SET CERTAIN REQUIREMENTS FOR A MAXIMUM ALLOWABLE COST LIST, AND TO AUTHORIZE THE DIRECTOR OF THE DEPARTMENT OF INSURANCE TO ENFORCE THE PROVISIONS OF THIS ARTICLE; TO AMEND SECTION 38-2-10, AS AMENDED, RELATING TO ADMINISTRATIVE PENALTIES, SO AS TO APPLY CERTAIN ADMINISTRATIVE PENALTIES TO PHARMACY BENEFITS MANAGERS; TO AMEND SECTION 38-71-1810, RELATING TO PHARMACY AUDIT RIGHTS, SO AS TO ALLOW A PHARMACY TO SUBMIT RECORDS IN AN ELECTRONIC FORMAT OR BY CERTIFIED MAIL AND TO PROHIBIT CERTAIN ERRORS FROM SERVING AS THE SOLE BASIS OF THE REJECTION OF A CLAIM; AND TO REPEAL ARTICLE 20 OF CHAPTER 71, TITLE 38 RELATING TO PHARMACY BENEFIT MANAGERS.

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

SECTION 1. Chapter 71, Title 38 of the 1976 Code is amended by adding:

“ARTICLE 21

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 Section 38-71-670(6) and 38-71-840(14), including the state health plan, as defined in Section 38-71-243(4).

(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 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) 'Network providers' means those pharmacists and pharmacies who provide covered health care services or supplies to an insured or a member pursuant to a contract with a network plan to act as a participating provider.

(7) '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.

(8) 'Pharmacist' has the same meaning as provided in Section 40-43-30(65).

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

(10) 'Pharmacy' has the same meaning as provided in Section 40-43-30(67).

(11) 'Pharmacy acquisition cost' means the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy's invoice.

(12) 'Pharmacy benefits manager' means a person, business, or entity excluding a health care insurer but including a wholly or partially owned or controlled subsidiary of a pharmacy benefits manager, that provides claims processing services or other prescription drug or device services, or both, for health benefit plans, or pursuant to a contract or under an employment relationship with a health care insurer, either directly or through an intermediary, manages the prescription drug benefit provided by the health care insurer including, but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug benefit, and controlling the cost of covered prescription drugs.

(13) '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.

(14) 'Specialty pharmacy service' means a service that must be provided to meet the Food and Drug Administration's limited distribution requirements or to ensure the appropriate dispensing of drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy. It does not include dispensing any drug that requires special attention if the network pharmacy is capable of appropriately dispensing the particular drug or drugs in question.

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 no individual with management or control of the pharmacy benefit 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 regarding the nature of treatment, risks, or alternatives thereto, the availability of alternate therapies, consultations, or tests, the decision of utilization reviewers or similar persons to authorize or deny services, the process that is used to authorize or deny health care services or benefits, or information on financial incentives and structures used by the insurer.

(B) A pharmacy or pharmacist may provide to an insured information regarding the insured's total cost for pharmacist services for a prescription drug.

(C) 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.

(D) A pharmacy benefits manager contract with a participating pharmacist or pharmacy may not prohibit, restrict, or limit disclosure of information to the director, law enforcement, or state and federal governmental officials investigating or examining a complaint or conducting a review of a pharmacy benefits manager's compliance with the requirements pursuant to this 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 including, without limitation, a fee for:

(a) the receipt and processing of a pharmacy claim;

(b) the development or management of claims processing services in a pharmacy benefits manager network; or

(c) participation in a pharmacy benefits manager network;

(3) require pharmacy accreditation standards or certification requirements inconsistent with, more stringent than, or in addition to requirements of the board of pharmacy, with the exception of pharmacies that provide specialty pharmacy services;

(4) reimburse an independent pharmacy or pharmacist in the State an amount less than the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager affiliate for providing the same pharmacist services. The amount must be calculated on a per-unit basis using the same generic product identifier or generic code number;

(5) charge a consumer a greater price for a drug than the pharmacy was reimbursed;

(6) require the use of mail order for filling prescriptions;

(7) Charge a fee related to the adjudication of a claim without providing the cause for each adjustment or fee;

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

(9) 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

(10) any combination thereof.

(B) A claim for pharmacist services may not be retroactively denied or reduced after adjudication of the claim unless the:

(1) original claim was submitted fraudulently;

(2) original claim payment was incorrect because the pharmacy or pharmacist had already been paid for the pharmacist services;

(3) pharmacist services were not properly rendered by the pharmacy or pharmacist; or

(4) adjustment was agreed upon by the pharmacy prior to the denial or reduction.

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.

(C) 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.

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 access to its Maximum Allowable Cost List to each pharmacy subject to the Maximum Allowable Cost List;

(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; and

(5) provide a reasonable administrative appeal procedure to allow pharmacies to appeal maximum allowable costs and reimbursements made under a maximum allowable cost for a specific drug or drugs as not meeting the requirements of this section or being below the pharmacy acquisition cost. The reasonable administrative appeal procedure must include:

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

(b) the ability to submit an administrative appeal directly to the pharmacy benefits manager regarding the pharmacy benefits plan or program or through a pharmacy service administrative organization.

(C) A pharmacy must be allowed no less than ten calendar days to file an administrative appeal.

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

(1) if the appeal is upheld:

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

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

(c) provide the National Drug Code number that the increase or change is based on to the pharmacy or pharmacist; 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 appeal is resolved;

(2) if the appeal is denied, 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 that have the drug currently in stock at a price below the Maximum Allowable Cost List; or

(3) if the National Drug Code number provided by the pharmacy benefits manager is not available below the pharmacy acquisition cost from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of prescription drugs for resale, then the pharmacy benefits manager shall adjust the Maximum Allowable Cost List above the appealing pharmacy's pharmacy acquisition cost and permit the pharmacy to reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the previous maximum allowable cost.

(E) A pharmacy or pharmacist may decline to provide the pharmacist services to a patient or pharmacy benefits manager if, as a result of a Maximum Allowable Cost List, a pharmacy or pharmacist is to be paid less than the pharmacy acquisition cost of the pharmacy providing pharmacist services.

(F) The provisions of this section:

(1) do not apply to the Maximum Allowable Cost List maintained by the State Medicaid Program or the South Carolina Public Employee Benefit Authority; and

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

(G) A violation of this section is a prohibited practice pursuant to this article and the South Carolina Unfair Trade Practices Act.

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

(B)(1) 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 to determine 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) This article is applicable to a contract or health benefit plan issued, renewed, recredentialed, amended, or extended on and after January 1, 2020 with the exception of the state health plan and plans offered on a federal exchange. For those plans this article is applicable January 1, 2021.

(B) A contract existing on the date of licensure of the pharmacy benefits manager shall comply with the requirements of this article as a condition of licensure for the pharmacy benefits manager.

(C) Nothing in this act is intended or may be construed to be in conflict with existing relevant federal law.

(D) 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."

SECTION 2. Section 38-2-10 of the 1976 Code, as last amended by Act 219 of 2018, is further amended to read:

"Section 38-2-10. (A) Unless otherwise specifically provided by law, the following administrative penalties apply for each violation of the insurance laws of this State or federal insurance laws subject to enforcement by the Department of Insurance:

(1) If the violator is an insurer, pharmacy benefits manager, or a health maintenance organization licensed in this State, the director or his designee shall fine the violator in an amount not to exceed fifteen thousand dollars, suspend or revoke the violator's authority to do business in this State, or both. If the violation is wilful, the director or his designee shall fine the violator in an amount not to exceed thirty thousand dollars, suspend or revoke the violator's authority to do business in this State, or both.

(2) If the violator is a person, other than an insurer, pharmacy benefits manager, or a health maintenance organization, licensed by the director or his designee in this State, the director or his designee shall fine the person in an amount not to exceed two thousand five hundred dollars, suspend or revoke the license of the person, or both. If the violation is wilful, the director or his designee shall fine the person in an amount not to exceed five thousand dollars, suspend or revoke the license of the person, or both.

(B) The penalties in subsection (A) are in addition to any criminal penalties provided by law or any other remedies provided by law. The administrative proceedings in subsection (A) do not preclude civil or criminal proceedings from taking place before, during, or after the administrative proceeding."

SECTION 3. A.Section 38-71-1810(B) of the 1976 is amended to read:

"(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) have at least fourteen days' advance notice of the initial audit for each audit cycle with no audit to be 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;

(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 record-keeping 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~~, if required under the terms of the contract with the auditing entity,~~ 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) submit records related to the audit in electronic format or by certified mail;

(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;

~~(6)~~(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;

~~(7)~~(8) 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;

~~(8)~~(9) 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;

~~(9)~~(10) 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;

~~(10)~~(11) be audited under the same standards and parameters as other similarly situated pharmacies audited by the same entity;

~~(11)~~(12) have at least thirty days following receipt of the preliminary audit report to produce documentation to address any discrepancy found during an audit;

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

~~(12)~~(14) 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;

~~(13)~~(15) have the preliminary audit report delivered to the pharmacy within one hundred twenty days after conclusion of the audit;

~~(14)~~(16) have a final audit report delivered to the pharmacy within ninety days after the end of the appeals period; and

~~(15)~~(17) not have the accounting practice of extrapolation used in calculating recoupments or penalties for audits, unless otherwise required by federal requirements or federal plans.

B. The provisions of this section are effective upon approval by the Governor."

SECTION 4. Article 20 of Chapter 71, Title 38 is repealed.

SECTION 5. 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 6. Except where otherwise provided, this act takes effect on January 1, 2020.

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