House Bill 470 (AS PASSED HOUSE AND SENATE)

By: Representatives Knight of the 130th, Carter of the 175th, Shaw of the 176th, Taylor of the 173rd, Parrish of the 158th, and others

A BILL TO BE ENTITLED

AN ACT

To amend Article 6 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacies, so as to change certain provisions relating to "The Pharmacy Audit Bill of Rights"; to amend Chapter 64 of Title 33 of the Official Code of Georgia Annotated, relating to regulation and licensure of pharmacy benefits managers, so as to define certain terms; to impose certain requirements for the use of maximum allowable cost pricing by pharmacy benefits managers; to provide for enforcement of such requirements; to provide for related matters; to provide for effective dates; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

Article 6 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacies, is amended by revising Code Section 26-4-118, relating to "The Pharmacy Audit Bill of Rights," as follows:

"26-4-118.

(a) This Code section shall be known and may be cited as 'The Pharmacy Audit Bill of Rights.'

(b) Notwithstanding any other law, when an audit of the records of a pharmacy is conducted by a managed care company, insurance company, third-party payor, pharmacy benefits manager, any entity licensed by the Department of Insurance, the Department of Community Health under Article 7 of Chapter 4 of Title 49, ~~or~~ any entity that represents such companies, groups, or department, or a private person bringing a claim pursuant to Article 7B of Chapter 4 of Title 49, it shall be conducted in accordance with the following bill of rights:

(1) The entity conducting the initial on-site audit must give the pharmacy notice at least ~~one week~~ 14 days prior to conducting the initial on-site audit for each audit cycle and

include in such notice a comprehensive list of claims by prescription number to be audited, although the final two digits may be omitted;

(2) Any audit which involves clinical or professional judgment must be conducted by or in consultation with a pharmacist;

(3) Any clerical or record-keeping error, including but not limited to a typographical error, scrivener's error, or computer error, regarding a required document or record ~~may~~ shall not in and of itself constitute fraud. No such claim shall be subject to criminal penalties without proof of intent to commit fraud. No recoupment of the cost of drugs or medicinal supplies properly dispensed shall be allowed if such error has occurred and been resolved in accordance with paragraph (4) of this subsection; provided, however, that recoupment shall be allowed to the extent that such error resulted in an overpayment, ~~underpayment, or improper dispensing of drugs or medicinal supplies.~~ though recoupment shall be limited to the amount overpaid;

(4) A pharmacy shall be allowed at least 30 days following the conclusion of an on-site audit or receipt of the preliminary audit report in which to correct a clerical or record-keeping error or produce documentation to address any discrepancy found during an audit, including to secure and remit an appropriate copy of the record from a hospital, physician, or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication if the lack of such a record or an error in such a record is identified in the course of an on-site audit or noticed within the preliminary audit report;

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

(6) A finding of an 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;

(7) Each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies audited by the entity;

(8) The period covered by an audit may not exceed two years from the date the claim was submitted to or adjudicated by a managed care company, insurance company, third-party payor, pharmacy benefits manager, any entity licensed by the Department of Insurance, the Department of Community Health under Article 7 of Chapter 4 of Title 49, ~~or~~ any entity that represents such companies, groups, or department;

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

(10) The preliminary audit report must be delivered to the pharmacy within 120 days after conclusion of the audit. A final audit report shall be delivered to the pharmacy within six months after receipt of the preliminary audit report or final appeal, as provided for in subsection (c) of this Code section, whichever is later; and

(11) The audit criteria set forth in this subsection shall apply only to audits of claims submitted for payment after July 1, 2006. Notwithstanding any other provision in this subsection, the agency conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits.

(c) Recoupments of any disputed funds shall only occur after final internal disposition of the audit, including the appeals process as set forth in subsection (d) of this Code section.

(d) Each entity conducting an audit shall establish an internal appeals process under which a pharmacy shall have at least 30 days from the delivery of the preliminary audit report to appeal an unfavorable preliminary audit report to the entity. If, following the appeal, the entity finds that an unfavorable audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or such portion without the necessity of any further proceedings.

(e) Each entity conducting an audit shall provide a copy of the final audit report, after completion of any review process, to the plan sponsor at its request or in an alternate format.

(f) This Code section shall not apply to any investigative audit which involves fraud, willful misrepresentation, or abuse, including without limitation investigative audits under Article 7 of Chapter 4 of Title 49, Code Section 33-1-16, or any other statutory provision which authorizes investigations relating to insurance fraud.

(g) The provisions of paragraph (3) of subsection (b) of this Code section shall not apply to the Department of Community Health conducting audits under Article 7 of Chapter 4 of Title 49.

(h) The entity conducting the audit may not pay the agent or employee who is conducting the audit based on a percentage of the amount recovered.

(i) The Commissioner of Insurance shall have enforcement authority over this Code section and shall have the authority granted pursuant to Chapter 64 of Title 33, relating to the regulation and licensure of pharmacy benefits managers."

SECTION 2.

Chapter 64 of Title 33 of the Official Code of Georgia Annotated, relating to regulation and licensure of pharmacy benefits managers, is amended by revising Code Section 33-64-1, relating to definitions, as follows:

"33-64-1.

As used in this chapter, the term:

(1) 'Business entity' means a corporation, association, partnership, sole proprietorship, limited liability company, limited liability partnership, or other legal entity.

(2) 'Commissioner' means the Commissioner of Insurance.

(3) 'Covered entity' means an employer, labor union, or other group of persons organized in this state that provides health coverage to covered individuals who are employed or reside in this state.

(4) 'Covered individual' means a member, participant, enrollee, contract holder, policy holder, or beneficiary of a covered entity who is provided health coverage by a covered entity.

(5) 'Health system' means a hospital or any other facility or entity owned, operated, or leased by a hospital and a long-term care home.

(6) 'Maximum allowable cost' means the per unit amount that a pharmacy benefits manager reimburses a pharmacist for a prescription drug, excluding dispensing fees and copayments, coinsurance, or other cost-sharing charges, if any.

(7) 'Pharmacy' means a pharmacy or pharmacist licensed pursuant to Chapter 4 of Title 26 or another dispensing provider.

~~(6)~~(8) 'Pharmacy benefits management' means the service provided to a health plan or covered entity, directly or through another entity, including the procurement of prescription drugs to be dispensed to patients, or the administration or management of prescription drug benefits, including, but not limited to, any of the following:

(A) Mail ~~service~~ order pharmacy;

(B) Claims processing, retail network management, or payment of claims to pharmacies for dispensing prescription drugs;

(C) Clinical or other formulary or preferred drug list development or management;

(D) Negotiation or administration of rebates, discounts, payment differentials, or other incentives for the inclusion of particular prescription drugs in a particular category or to promote the purchase of particular prescription drugs;

(E) Patient compliance, therapeutic intervention, or generic substitution programs; and

(F) Disease management.

~~(7)~~(9) 'Pharmacy benefits manager' means a person, business entity, or other entity that performs pharmacy benefits management. The term includes a person or entity acting for

a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity. The term does not include services provided by pharmacies operating under a hospital pharmacy license. The term also does not include health systems while providing pharmacy services for their patients, employees, or beneficiaries, for indigent care, or for the provision of drugs for outpatient procedures. The term also does not include services provided by pharmacies affiliated with a facility licensed under Code Section 31-44-4 or a licensed group model health maintenance organization with an exclusive medical group contract and which operates its own pharmacies which are licensed under Code Section 26-4-110.″

SECTION 3.

Said chapter is further amended by revising Code Section 33-64-7, relating to a limitation on the Commissioner to extend rules and regulations, as follows:

″33-64-7.

The Commissioner may not enlarge upon or extend the provisions of this chapter through any act, rule, or regulation; provided, however, that the Commissioner is authorized to enforce any provision of this chapter.″

SECTION 4.

Said chapter is further amended by adding a new Code section to read as follows:

″33-64-9.

(a) Upon each contract execution or renewal between a pharmacy benefits manager and a pharmacy or between a pharmacy benefits manager and a pharmacy's contracting representative or agent, such as a pharmacy services administrative organization, a pharmacy benefits manager shall, with respect to such contract or renewal:

(1) Include in such contract or renewal the sources utilized to determine multi-source generic drug pricing, such as maximum allowable cost or any successive benchmark pricing formula, and update such pricing information at least every five business days, provided that such pricing information update shall be at least every 14 business days for those contracts pursuant to Article 7 of Chapter 4 of Title 49; and

(2) Maintain a procedure to eliminate products from the multi-source generic list of drugs subject to such pricing or modify multi-source generic drug pricing within five business days when such drugs do not meet the standards and requirements of this Code section in order to remain consistent with pricing changes in the marketplace.

(b) A pharmacy benefits manager shall reimburse pharmacies for drugs subject to multi-source generic drug pricing based upon pricing information which has been updated

within five business days as set forth in paragraph (1) of subsection (a) of this Code section.

(c) A pharmacy benefits manager may not place a drug on a multi-source generic list unless there are at least two therapeutically equivalent, multi-source generic drugs, or at least one generic drug available from only one manufacturer, generally available for purchase by network pharmacies from national or regional wholesalers.

(d) All contracts between a pharmacy benefits manager and a contracted pharmacy or between a pharmacy benefits manager and a pharmacy's contracting representative or agent, such as a pharmacy services administrative organization, shall include a process to internally appeal, investigate, and resolve disputes regarding multi-source generic drug pricing. The process shall include the following:

(1) The right to appeal shall be limited to 14 calendar days following reimbursement of the initial claim; and

(2) A requirement that the health benefit plan issuer or pharmacy benefits manager shall respond to an appeal described in subsection (a) of this Code section no later than 14 calendar days after the date the appeal was received by such health benefit plan issuer or pharmacy benefits manager.

(e) For appeals that are denied, the pharmacy benefits manager shall provide the reason for the denial and identify the national drug code of a drug product that may be purchased by contracted pharmacies at a price at or below the maximum allowable cost.

(f) If the appeal is successful, the health benefit plan issuer or pharmacy benefits manager shall:

(1) Adjust the maximum allowable cost price that is the subject of the appeal effective on the day after the date the appeal is decided;

(2) Apply the adjusted maximum allowable cost price to all similarly situated pharmacists and pharmacies as determined by the health plan issuer or pharmacy benefits manager; and

(3) Allow the pharmacist or pharmacy that succeeded in the appeal to reverse and rebill the pharmacy benefits claim giving rise to the appeal.

(g) Appeals shall be upheld if:

(1) The pharmacy being reimbursed for the drug subject to the multi-source generic drug pricing in question was not reimbursed as required in subsection (b) of this Code section; or

(2) The drug subject to the multi-source generic drug pricing in question does not meet the requirements set forth in subsection (c) of this Code section.

(h) The Commissioner shall have enforcement authority over this Code section."

SECTION 5.

Sections 1 and 6 and this section of this Act shall become effective on July 1, 2015. Sections 2, 3, and 4 of this Act shall become effective on January 1, 2016.

SECTION 6.

All laws and parts of laws in conflict with this Act are repealed.