Senate Bill 408

By: Senator Carter of the 1st

A BILL TO BE ENTITLED

AN ACT

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 requirements relating to in-person pharmacy; to amend Code Section 26-4-118 of the Official Code of Georgia Annotated, relating to the Pharmacy Audit Bill of Rights, so as to provide for applicability to certain entities licensed by the Commissioner of Insurance; to provide for related matters; to provide for an effective date; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

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) 'In-person pharmacy' means the lawful delivery or dispensing of prescription drugs by a pharmacy without employing the mails or other common carriers.

(7) '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.

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

~~(6)~~(9) '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 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)~~(10) '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."

SECTION 2.

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 3.

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

″33-64-9.

(a) Any pharmacy benefits manager that uses maximum allowable cost pricing or maximum allowable cost list pricing to determine reimbursement for in-network or out-of-network pharmacists and other licensed dispensing providers shall:

(1) Beginning on January 1 of each calendar year, include in contracts or agreements with pharmacies, pharmacists, or other licensed dispensing providers the maximum allowable cost methodology, basis of the methodology, and sources used to determine the maximum allowable cost for each drug;

(2) Provide updates on the pricing information to pharmacies, pharmacists, and other licensed dispensing providers every seven calendar days;

(3) Disclose in the contract with the covered individual or covered entity, as applicable:

(A) The basis and methodology used to determine maximum allowable cost pricing;

(B) Whether the pharmacy benefits manager utilizes a maximum allowable cost list for drugs dispensed by mail; and

(C) Whether it is using identical maximum allowable cost lists for all in-network pharmacies, pharmacists, or other licensed dispensing providers; and, if multiple maximum allowable cost lists are utilized, the pharmacy benefits manager shall disclose to the covered individual or covered entity any difference between the amount paid to any pharmacy, pharmacist, or other licensed dispensing provider and the amount charged to the covered individual or covered entity;

(4) Notify the covered individual or covered entity, as applicable:

(A) Of any material changes or amendments to the maximum allowable cost plan within 15 days of such changes; and

(B) If the pharmacy benefits manager begins to use a maximum allowable cost list for drugs dispensed by mail, not more than 90 days nor less than 21 days before implementing such practice; and

(5) Establish or maintain a reasonable process for:

(A) The timely elimination or modification of products on the maximum allowable cost list to reflect general market conditions; and

(B) Administrative appeals to allow a pharmacy, pharmacist, or other licensed dispensing provider to contest the listed maximum allowable cost rate, and such procedure shall:

(i) Require a pharmacy benefits manager to respond in writing within 15 calendar days to a pharmacy, pharmacist, or other licensed dispensing provider who has contested a maximum allowable cost rate in writing; and

(ii) Retroactively make adjustments for all pharmacies, pharmacists, and licensed dispensing providers in the pharmacy benefits managers' networks if an appealing person is successful in his or her appeal. Such adjustments shall be retroactive to the date of the appealed price change.

(b) Before a drug requiring a prescription can be placed on a maximum allowable cost list by a pharmacy benefits manager, such drug shall:

(1) Have at least three or more nationally available, therapeutically equivalent, multiple source drugs;

(2) Have a cost difference between manufacturers of at least 10 percent;

(3) Be listed in the federal Food and Drug Administration's 'Orange Book' as 'A' rated or as therapeutically and pharmaceutically equivalent;

(4) Be available for purchase without limitations by all pharmacies in this state from licensed national or regional wholesalers and not be obsolete or unavailable for a period of 14 calendar days or more; and

(5) Be reviewed by the pharmacy benefits manager every seven calendar days and adjust prices based on such review.

33-64-10.

(a) A pharmacy benefits manager, or any other type of insurer licensed under this title, may not require covered individuals or covered entities to have different copayments, deductibles, fees, limitations on benefits, or other conditions or requirements for the use of an in-person pharmacy as compared to mail service pharmacy.

(b) Subsection (a) of this Code section shall only apply if the in-person pharmacy accepts from the pharmacy benefits manager or other insurer licensed under this title the same pricing, terms, and conditions or other requirements related to the cost of prescriptions and the cost and quality of dispensing prescriptions that the pharmacy benefits manager or other insurer has established for a mail service pharmacy and any of such pharmacy's affiliates, including any affiliated pharmacy benefits manager, pursuant to the policy; provided however, that nothing in this subsection shall be construed to require, as a basis of reimbursement under this Code section or any other law, a retail or specialty pharmacy to employ the mails or other common carriers to dispense or deliver prescription drugs.″

SECTION 4.

Code Section 26-4-118 of the Official Code of Georgia Annotated, relating to the Pharmacy Audit Bill of Rights, is amended by revising subsection (b) and by adding a new subsection to read as follows:

"(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, entity licensed by the Commissioner of Insurance pursuant to Title 33, the Department of Community Health under Article 7 of Chapter 4 of Title 49, ~~or~~ any entity that represents such companies, groups, entities, or department, or any individual 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 prior to conducting the initial on-site audit for each audit cycle;

(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 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.

(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, 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."

"(h) The Commissioner of Insurance shall be authorized to enforce the provisions of this Code section involving audits conducted by an entity licensed by the Commissioner of Insurance pursuant to Title 33. For audits conducted by entities or individuals not licensed by the Commissioner of Insurance, an aggrieved pharmacist may seek recourse pursuant to subsection (d) of this Code section or may seek a judicial remedy in a court of competent jurisdiction."

SECTION 5.

This Act shall become effective upon its approval by the Governor or upon its becoming law without such approval.

SECTION 6.

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