

The Senate Committee on Insurance and Labor offers the following substitute to HB 470:

A BILL TO BE ENTITLED
AN ACT

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

9 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

10 Article 6 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to
11 pharmacies, is amended by revising Code Section 26-4-118, relating to "The Pharmacy Audit
12 Bill of Rights," as follows:
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14 "26-4-118.

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

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

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

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

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

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

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

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

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

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

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

- 63 (9) An audit may not be initiated or scheduled during the first seven calendar days of any
64 month due to the high volume of prescriptions filled during that time unless otherwise
65 consented to by the pharmacy;
- 66 (10) The preliminary audit report must be delivered to the pharmacy within 120 days
67 after conclusion of the audit. A final audit report shall be delivered to the pharmacy
68 within six months after receipt of the preliminary audit report or final appeal, as provided
69 for in subsection (c) of this Code section, whichever is later; and
- 70 (11) The audit criteria set forth in this subsection shall apply only to audits of claims
71 submitted for payment after July 1, 2006. Notwithstanding any other provision in this
72 subsection, the agency conducting the audit shall not use the accounting practice of
73 extrapolation in calculating recoupments or penalties for audits.
- 74 (c) Recoupments of any disputed funds shall only occur after final internal disposition of
75 the audit, including the appeals process as set forth in subsection (d) of this Code section.
- 76 (d) Each entity conducting an audit shall establish an internal appeals process under which
77 a pharmacy shall have at least 30 days from the delivery of the preliminary audit report to
78 appeal an unfavorable preliminary audit report to the entity. If, following the appeal, the
79 entity finds that an unfavorable audit report or any portion thereof is unsubstantiated, the
80 entity shall dismiss the audit report or such portion without the necessity of any further
81 proceedings.
- 82 (e) Each entity conducting an audit shall provide a copy of the final audit report, after
83 completion of any review process, to the plan sponsor at its request or in an alternate
84 format.
- 85 (f) This Code section shall not apply to any investigative audit which involves fraud,
86 willful misrepresentation, or abuse, including without limitation investigative audits under
87 Article 7 of Chapter 4 of Title 49, Code Section 33-1-16, or any other statutory provision
88 which authorizes investigations relating to insurance fraud.
- 89 (g) The provisions of paragraph (3) of subsection (b) of this Code section shall not apply
90 to the Department of Community Health conducting audits under Article 7 of Chapter 4 of
91 Title 49.
- 92 (h) The entity conducting the audit may not pay the agent or employee who is conducting
93 the audit based on a percentage of the amount recovered.
- 94 (i) The Commissioner of Insurance shall have enforcement authority over this Code
95 section and shall have the authority granted pursuant to Chapter 64 of Title 33, relating to
96 the regulation and licensure of pharmacy benefits managers."

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SECTION 2.

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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:

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"33-64-1.

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As used in this chapter, the term:

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

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

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(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.

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(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.

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(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.

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(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.

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

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~~(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:

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

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

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

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(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;

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

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~~(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

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

143 **SECTION 3.**

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

146 "33-64-7.

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

150 **SECTION 4.**

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

152 "33-64-9.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

197 (g) Appeals shall be upheld if:

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

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

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

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SECTION 5.

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Sections 1 and 6 and this section of this Act shall become effective on July 1, 2015. Sections

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2, 3, and 4 of this Act shall become effective on January 1, 2016.

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SECTION 6.

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