

House Bill 470

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

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 requirements relating to in-person pharmacies; to provide for related matters; to provide
8 for an effective date; to repeal conflicting laws; and for other purposes.

9 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

10 style="text-align:center">**SECTION 1.**

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

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 prior to conducting the initial ~~on-site~~ audit for each audit cycle and include in
26 such notice a comprehensive list of prescription numbers to be audited;

- 27 (2) Any audit which involves clinical or professional judgment must be conducted by or
 28 in consultation with a pharmacist;
- 29 (3) Any clerical or record-keeping error, including but not limited to a typographical
 30 error, scrivener's error, or computer error, regarding a required document or record ~~may~~
 31 shall not in and of itself constitute fraud. No such claim shall be subject to criminal
 32 penalties without proof of intent to commit fraud. No recoupment of the cost of drugs
 33 or medicinal supplies properly dispensed shall be allowed if such error has occurred and
 34 been resolved in accordance with paragraph (4) of this subsection; provided, however,
 35 that recoupment shall be allowed to the extent that such error resulted in an overpayment,
 36 ~~underpayment, or improper dispensing of drugs or medicinal supplies.~~ though
 37 recoupment shall be limited to the amount overpaid;
- 38 (4) A pharmacy shall be allowed at least 30 days following the conclusion of an ~~on-site~~
 39 audit or receipt of the preliminary audit report in which to correct a clerical or
 40 record-keeping error or produce documentation to address any discrepancy found during
 41 an audit, including to secure and remit an appropriate copy of the record from a hospital,
 42 physician, or other authorized practitioner of the healing arts for drugs or medicinal
 43 supplies written or transmitted by any means of communication if the lack of such a
 44 record or an error in such a record is identified in the course of an ~~on-site~~ audit or noticed
 45 within the preliminary audit report;
- 46 (5) A pharmacy may use the records of a hospital, physician, or other authorized
 47 practitioner of the healing arts for drugs or medicinal supplies written or transmitted by
 48 any means of communication for purposes of validating the pharmacy record with respect
 49 to orders or refills of a legend or narcotic drug;
- 50 (6) A finding of an overpayment or underpayment may be a projection based on the
 51 number of patients served having a similar diagnosis or on the number of similar orders
 52 or refills for similar drugs; however, recoupment of claims must be based on the actual
 53 overpayment or underpayment unless the projection for overpayment or underpayment
 54 is part of a settlement as agreed to by the pharmacy;
- 55 (7) Each pharmacy shall be audited under the same standards and parameters as other
 56 similarly situated pharmacies audited by the entity;
- 57 (8) The period covered by an audit may not exceed two years from the date the claim
 58 was submitted to or adjudicated by a managed care company, insurance company,
 59 third-party payor, pharmacy benefits manager, any entity licensed by the Department of
 60 Insurance, the Department of Community Health under Article 7 of Chapter 4 of Title 49,
 61 ~~or any entity that represents such companies, groups, or department, or a private person~~
 62 bringing a claim pursuant to Article 7B of Chapter 4 of Title 49;

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.

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

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

91 (h) The Commissioner of Insurance shall have enforcement authority over this Code
92 section and shall have authority to render a binding decision in any dispute between a
93 pharmacy benefits manager and a pharmacy arising out of an appeal regarding multisource
94 generic drug pricing. The Commissioner of Insurance shall not be bound by any arbitration
95 agreements between a pharmacy benefits manager and a pharmacy and shall not be bound
96 by any mediation or arbitration decisions.

97 (i) Any person, corporation, or business entity which violates any provision of this Code
98 section shall be subject to a civil penalty in the amount of \$1,000.00 for each act in

99 violation of this Code section or, if the violation was knowing and willful, a civil penalty
 100 of \$5,000.00 for each act in violation of this Code section.

101 (j) Any pharmacy or pharmacist injured as a result of a violation of this Code section may
 102 bring an action against the person, corporation, or business entity violating this Code
 103 section for the recovery of all actual damages occurring as a result thereof, plus attorney's
 104 fees."

105 **SECTION 2.**

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

109 "33-64-1.

110 As used in this chapter, the term:

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

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

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

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

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

122 (6) 'In-person pharmacy' means any pharmacy in which a patient has the choice to pick
 123 up lawfully prescribed drugs.

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

127 (8) 'Pharmacy' means a pharmacy or pharmacist licensed pursuant to Chapter 4 of Title
 128 26 or another dispensing provider.

129 ~~(6)~~(9) 'Pharmacy benefits management' means the service provided to a health plan or
 130 covered entity, directly or through another entity, including the procurement of
 131 prescription drugs to be dispensed to patients, or the administration or management of
 132 prescription drug benefits, including, but not limited to, any of the following:

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

- 134 (B) Claims processing, retail network management, or payment of claims to
 135 pharmacies for dispensing prescription drugs;
- 136 (C) Clinical or other formulary or preferred drug list development or management;
- 137 (D) Negotiation or administration of rebates, discounts, payment differentials, or other
 138 incentives for the inclusion of particular prescription drugs in a particular category or
 139 to promote the purchase of particular prescription drugs;
- 140 (E) Patient compliance, therapeutic intervention, or generic substitution programs; and
- 141 (F) Disease management.
- 142 ~~(7)~~(10) 'Pharmacy benefits manager' means a person, business entity, or other entity that
 143 performs pharmacy benefits management. The term includes a person or entity acting for
 144 a pharmacy benefits manager in a contractual or employment relationship in the
 145 performance of pharmacy benefits management for a covered entity. The term does not
 146 include services provided by pharmacies operating under a hospital pharmacy license.
 147 The term also does not include health systems while providing pharmacy services for
 148 their patients, employees, or beneficiaries, for indigent care, or for the provision of drugs
 149 for outpatient procedures."

150 **SECTION 3.**

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

153 "33-64-7.

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

157 **SECTION 4.**

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

159 "33-64-9.

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

164 (1) Include in such contract or renewal the basis of the methodology and sources utilized
 165 to determine multi-source generic drug pricing, such as maximum allowable cost or any
 166 successive benchmark pricing formula; update such pricing information at least every
 167 five calendar days; and establish a reasonable process for the prompt notification of such
 168 pricing updates to network pharmacies in a useable and searchable format; and

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

173 (b) A pharmacy benefits manager shall reimburse pharmacies for drugs subject to
174 multi-source generic drug pricing based upon pricing information which has been updated
175 within five calendar days as set forth in paragraph (1) of subsection (a) of this Code
176 section; provided, however, that pharmacies shall not be reimbursed at or below their
177 acquisition costs.

178 (c) In order to subject a prescription drug to multi-source generic drug pricing or place a
179 particular prescription drug on a multi-source generic list, the pharmacy benefits manager
180 shall, at a minimum, ensure that:

181 (1) The drug must have at least three or more nationally available, therapeutically
182 equivalent, multiple source generic drugs with a significant cost difference;

183 (2) The products must be listed as therapeutically and pharmaceutically equivalent or 'A'
184 or 'AB' rated in the Food and Drug Administration's most recent version of the 'Orange
185 Book'; and

186 (3) The drug product must be available for purchase without limitations by all
187 pharmacies in the state from national or regional wholesalers and not obsolete or
188 temporarily unavailable.

189 (d) Upon each contract execution or renewal between a pharmacy benefits manager and
190 a plan sponsor or between a pharmacy benefits manager and a plan sponsor's contracting
191 representative or agent, a pharmacy benefits manager shall:

192 (1) Include in the contract or renewal the basis of the methodology and sources utilized
193 to establish multi-source generic drug pricing. Applicable lists shall be updated to the
194 plan sponsor whenever there is a change;

195 (2) If a pharmacy benefits manager utilizes a multi-source generic list for drugs
196 dispensed at retail but does not utilize an identical list for drugs dispensed by mail,
197 disclose to the plan sponsor either in the contract or in writing no later than 21 business
198 days from the implementation of the practice; and

199 (3) Disclose to the plan sponsor whether or not it is using the identical multi-source
200 generic list with respect to billing the plan sponsor as it does when reimbursing all
201 network pharmacies. If multiple multi-source generic lists are used, the pharmacy
202 benefits manager must disclose to the plan sponsor any difference between the amount
203 paid to any pharmacy and the amount charged to the plan sponsor.

204 (e) All contracts between a pharmacy benefits manager and a contracted pharmacy or
205 between a pharmacy benefits manager and a pharmacy's contracting representative or

206 agent, such as a pharmacy services administrative organization, shall include a process to
207 internally appeal, investigate, and resolve disputes regarding multi-source generic drug
208 pricing. The process shall include the following:

209 (1) The right to appeal shall be limited to 60 days following reimbursement of the initial
210 claim;

211 (2) A requirement that appeals shall be investigated and resolved within seven business
212 days; and

213 (3) A telephone number at which a network pharmacy may contact the pharmacy
214 benefits manager and speak with an individual who is responsible for processing appeals.

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

219 (g) For appeals that are upheld, the pharmacy benefits manager shall make an adjustment
220 retroactive to the date of initial claim adjudication. The pharmacy benefits manager shall
221 make the adjustment effective for all pharmacies in this state with which the pharmacy
222 benefits manager is contracted within five business days of the conclusion of the appeal.

223 (h) Appeals shall be upheld if:

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

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

229 (i) The Commissioner shall have enforcement authority over this Code section and shall
230 have authority to render a binding decision in any dispute between a pharmacy benefits
231 manager and a pharmacy arising out of an appeal regarding multi-source generic drug
232 pricing. The Commissioner shall not be bound by any arbitration agreements between a
233 pharmacy benefits manager and a pharmacy and shall not be bound by any mediation or
234 arbitration decisions.

235 (j) Any person, corporation, or business entity which violates any provision of this Code
236 section shall be subject to a civil penalty in the amount of \$1,000.00 for each act in
237 violation of this Code section or, if the violation was knowing and willful, a civil penalty
238 of \$5,000.00 for each act in violation of this Code section.

239 (k) Any pharmacy or pharmacist injured as a result of a violation of this Code section may
240 bring an action against that person, corporation, or business entity violating this Code
241 section for the recovery of all actual damages occurring as a result thereof, plus attorneys'
242 fees.

243 33-64-10.

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

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

257 (c) The Commissioner shall have authority to enforce the provisions of this Code section
258 and shall have authority to render a binding decision in any dispute between a pharmacy
259 benefits manager or any other type of insurer and a pharmacy arising out of this Code
260 section. The Commissioner shall not be bound by any arbitration agreements between a
261 pharmacy benefits manager and a pharmacy and shall not be bound by any mediation or
262 arbitration decisions.

263 (d) Any person, corporation, or business entity which violates any provision of this Code
264 section shall be subject to a civil penalty in the amount of \$1,000.00 for each act in
265 violation of this Code section or, if the violation was knowing and willful, a civil penalty
266 of \$5,000.00 for each act in violation of this Code section.

267 (e) Any person, pharmacy, or pharmacist injured as a result of a violation of this Code
268 section may bring an action against that person, corporation, or business entity violating
269 this Code section for the recovery of all actual damages occurring as a result thereof, plus
270 attorneys' fees."

271 **SECTION 5.**

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

274 **SECTION 6.**

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