

The House Special Committee on Access to Quality Health Care offers the following substitute to HB 918:

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 revise various provisions relating to the practice of pharmacy;
3 to repeal provisions relating to required licensure as a pharmacy by pharmacy benefits
4 managers engaging in the practice of pharmacy; to revise provisions relating to "The
5 Pharmacy Audit Bill of Rights"; to revise pharmacy anti-steering provisions; to revise
6 various provisions of the Official Code of Georgia Annotated so as to provide for conforming
7 changes; to provide for related matters; to repeal conflicting laws; and for other purposes.

8 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

9 **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 repealing Code Section 26-4-110.1, relating to definitions, license
12 required, and condition for licensing pharmacy benefits managers as pharmacies.

13 **SECTION 2.**

14 Said article is further amended by revising Code Section 26-4-118, relating to the Pharmacy
15 Audit Bill of Rights, as follows:

16 "26-4-118.

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

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

- 26 (1) The entity conducting the ~~initial on-site~~ audit must give the pharmacy notice at least
27 14 days prior to conducting the ~~initial on-site~~ audit for each audit cycle and include in
28 such notice a comprehensive list of claims by prescription number to be audited, although
29 the final two digits may be omitted, and the cost of such claims shall not be used as a
30 criterion in determining which claims to audit. The audit shall not include more than 100
31 prescriptions per audit and an entity shall not audit more than 200 prescriptions in any 12
32 month period, provided that a refill shall not constitute a separate prescription;
- 33 (2) Any audit which involves clinical or professional judgment must be conducted by or
34 in consultation with a pharmacist;
- 35 (3) Any clerical or record-keeping error, including but not limited to a typographical
36 error, scrivener's error, ~~or~~ computer error, or omission error, regarding a **required**
37 prescription, front or back label, or other document or record shall not in and of itself
38 constitute fraud. No such claim shall be subject to criminal penalties without proof of
39 intent to commit fraud. No recoupment of the cost of drugs or medicinal supplies
40 properly dispensed shall be allowed if such error has occurred ~~and been resolved in~~
41 ~~accordance with paragraph (4) of this subsection;~~ provided, however, that recoupment
42 shall be allowed to the extent that such error resulted in an overpayment, though
43 recoupment shall be limited to the amount overpaid;
- 44 (4) A pharmacy shall be allowed at least ~~30~~ 60 days following the ~~conclusion of an~~
45 ~~on-site audit or~~ receipt of the preliminary audit report in which to correct a ~~clerical or~~
46 ~~record-keeping~~ any error or ~~produce documentation~~ to address any discrepancy found
47 during an audit which may be subject to recoupment for overpayment as provided for in
48 paragraph (12) of this subsection, including to secure and remit an appropriate copy of
49 the record from a hospital, physician, or other authorized practitioner of the healing arts
50 for drugs or medicinal supplies written or transmitted by any means of communication
51 if the lack of such a record or an error in such a record is identified in the course of an
52 ~~on-site~~ audit or noticed within the preliminary audit report;
- 53 (5) A pharmacy may use the records of a hospital, physician, or other authorized
54 practitioner of the healing arts for drugs or medicinal supplies written or transmitted by
55 any means of communication for purposes of validating the pharmacy record with respect
56 to orders or refills of a legend or narcotic drug;
- 57 (6) A finding of an overpayment or underpayment may be a projection based on the
58 number of patients served having a similar diagnosis or on the number of similar orders
59 or refills for similar drugs; however, recoupment of claims must be based on the actual
60 overpayment or underpayment unless the projection for overpayment or underpayment
61 is part of a settlement as agreed to by the pharmacy;

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

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

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

72 (10) The preliminary audit report must be delivered to the pharmacy within ~~120~~ 30 days
73 after conclusion of the audit. A final audit report shall be delivered to the pharmacy
74 within ~~six months~~ 60 days after receipt of the preliminary audit report or final appeal, as
75 provided for in subsection (c) of this Code section, whichever is later; ~~and~~

76 (11) A pharmacy shall not be held responsible for any penalty or fee in connection with
77 an audit and there shall be no recoupment of funds from a pharmacy in connection with
78 claims for which the pharmacy has already been paid without first complying with the
79 requirements set forth in this Code section;

80 (12) There shall be no recoupment from a pharmacy except in cases of:

81 (A) Fraud;

82 (B) An error that resulted in an overpayment provided that recoupment shall be limited
83 to the amount overpaid; or

84 (C) A misfill; provided, however, that when a patient receives the correct drug in the
85 correct dosage and quantity pursuant to a prescription drug order then no misfill shall
86 be found to have occurred; and

87 (13) A pharmacy shall not be audited more than once every six months.

88 ~~(11) The audit criteria set forth in this subsection shall apply only to audits of claims~~
89 ~~submitted for payment after July 1, 2006.~~

90 Notwithstanding any other provision in this subsection, the agency conducting the audit
91 shall not use the accounting practice of extrapolation in calculating recoupments or
92 penalties for audits.

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

95 (d) Each entity conducting an audit shall establish an internal appeals process under which
96 a pharmacy shall have at least 30 days from the delivery of the preliminary audit report to
97 appeal an unfavorable preliminary audit report to the entity. If, following the appeal, the
98 entity finds that an unfavorable audit report or any portion thereof is unsubstantiated, the

99 entity shall dismiss the audit report or such portion without the necessity of any further
100 proceedings.

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

104 (f) This Code section shall not apply to any investigative audit ~~which involves~~ commenced
105 based upon an articulable suspicion of fraud, willful misrepresentation, or abuse, including
106 without limitation investigative audits under Article 7 of Chapter 4 of Title 49, Code
107 Section 33-1-16, or any other statutory provision which authorizes investigations relating
108 to insurance fraud.

109 (g) The provisions of ~~paragraph (3) of subsection (b)~~ of this Code section shall not apply
110 to the Department of Community Health conducting audits under Article 7 of Chapter 4 of
111 Title 49; provided, however, that the provisions of Code Section 49-4-151.1 shall apply to
112 such audits conducted by the Department of Community Health under Article 7 of Chapter
113 4 of Title 49.

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

116 (i) The Commissioner of Insurance shall have enforcement authority over this Code
117 section and shall promulgate rules and regulations to effectuate the provisions of this Code
118 section. The Commissioner of Insurance shall have the authority to investigate complaints
119 of alleged violations of this Code section; to prohibit recoupment; to order reimbursement
120 of any wrongful recoupment; to institute fines for violations of the law, rules, or
121 regulations; and to take any other actions pursuant to any authority granted pursuant to
122 Chapter 64 of Title 33, relating to the regulation and licensure of pharmacy benefits
123 managers."

124 SECTION 3.

125 Said article is further amended by revising Code Section 26-4-119, relating to pharmacy
126 anti-steering and transparency, as follows:

127 "26-4-119.

128 (a) This Code section shall be known and may be cited as the 'Pharmacy Anti-Steering and
129 Transparency Act.'

130 (b) The General Assembly finds that:

131 (1) The referral of a patient to a pharmacy by an affiliate for pharmacy care represents
132 a potential conflict of interest; and

133 (2) These referral practices may limit or eliminate competitive alternatives in the health
134 care services market, may result in overutilization of health care services, may increase

135 costs to the health care system, may adversely affect the quality of health care, may
 136 disproportionately harm patients in rural and medically underserved areas of Georgia, and
 137 shall be against the public policy of this state.

138 (c) As used in this Code section, the term:

139 (1) 'Affiliate' means a person licensed under Title 33 which, either directly or indirectly
 140 through one or more intermediaries:

141 (A) Has an investment or ownership interest in a pharmacy licensed in or holding a
 142 nonresident pharmacy permit in Georgia;

143 (B) Shares common ownership with a pharmacy licensed in or holding a nonresident
 144 pharmacy permit in Georgia; or

145 (C) Has as an investor or ownership interest holder a pharmacy licensed in or holding
 146 a nonresident pharmacy permit in Georgia.

147 (2) 'Referral' means:

148 (A) Ordering of a patient to a pharmacy by an affiliate either orally or in writing,
 149 including online messaging;

150 (B) Ordering of a patient to a pharmacy that has an affiliate either orally or in writing,
 151 including online messaging by a person licensed under Title 33 as a result of an
 152 arrangement or agreement between the person and the pharmacy's affiliate;

153 ~~(B)~~(C) Offering or implementing plan designs that require patients to utilize affiliated
 154 pharmacies or other pharmacies with affiliates, or that increase plan or patient costs,
 155 including requiring patients to pay the full cost for a prescription when patients choose
 156 not to use affiliated pharmacies or other pharmacies with affiliates; or

157 ~~(C)~~(D) Patient or prospective patient specific advertising, marketing, or promotion of
 158 a pharmacy by an affiliate or other person licensed under Title 33 as a result of an
 159 arrangement or agreement with the pharmacy's affiliate.

160 Subject to the foregoing, this term shall not include a pharmacy's inclusion by an affiliate
 161 or other person licensed under Title 33 as a result of an arrangement or agreement with
 162 the pharmacy's affiliate in communications to patients, including patient and prospective
 163 patient specific communications, regarding network pharmacies and prices, provided that
 164 the affiliate or other person licensed under Title 33 includes information regarding
 165 eligible nonaffiliate pharmacies in such communications and the information provided
 166 is accurate.

167 (d) A pharmacy licensed in or holding a nonresident pharmacy permit in Georgia shall be
 168 proscribed from:

169 (1) Transferring or sharing records relative to prescription information containing patient
 170 identifiable and prescriber identifiable data to or from an affiliate for any commercial
 171 purpose; provided, however, that nothing shall be construed to prohibit the exchange of

172 prescription information between a pharmacy and its affiliate for the limited purposes of
 173 pharmacy reimbursement; formulary compliance; pharmacy care; public health activities
 174 otherwise authorized by law; or utilization review by a health care provider; or

175 (2) Presenting a claim for payment to any individual, third-party payor, affiliate, or other
 176 entity for a service furnished pursuant to a referral from an affiliate or other person
 177 licensed under Title 33.; ~~provided, however, that this shall not apply to referrals from an~~
 178 ~~affiliate for limited distribution prescription drugs requiring special handling and not~~
 179 ~~commonly carried at retail pharmacies or oncology clinics or practices.~~

180 (e) This Code section shall not be construed to prohibit a pharmacy from entering into an
 181 agreement with an affiliate to provide pharmacy care to patients, provided that the
 182 pharmacy does not receive referrals in violation of subsection (d) of this Code section and
 183 the pharmacy provides the disclosures required in subsection (f) of this Code section.

184 (f) If a pharmacy licensed or holding a nonresident pharmacy permit in this state has an
 185 affiliate, it shall annually file with the board a disclosure statement identifying all such
 186 affiliates.

187 (g) In addition to any other remedy provided by law, a violation of this Code section by
 188 a pharmacy shall be grounds for disciplinary action by the board pursuant to its authority
 189 granted in this chapter.

190 (h) A pharmacist who fills a prescription that violates subsection (d) of this Code section
 191 shall not be liable under this Code section.

192 (i) This Code section shall not apply to:

193 ~~(A)~~(1) Any licensed group model health maintenance organization with an exclusive
 194 medical group contract which operates its own pharmacies which are licensed under Code
 195 Section ~~26-4-110.~~ 26-4-110;

196 ~~(B)~~(2) Any hospital or related institution; or

197 ~~(C)~~(3) Any referrals by an affiliate for pharmacy services and prescriptions to patients
 198 in skilled nursing facilities, intermediate care facilities, continuing care retirement
 199 communities, home health agencies, or hospices; ~~or~~

200 ~~(D) Any care management organization, as defined in Chapter 21A of Title 33."~~

201 SECTION 4.

202 Chapter 64 of Title 33 of the Official Code of Georgia Annotated, relating to regulation and
 203 licensure of pharmacy benefits managers, is amended in Code Section 33-64-10, relating to
 204 administration of claims by pharmacy benefits manager, by revising paragraph (c)(4) as
 205 follows:

206 "(4) Any licensed group model health maintenance organization with an exclusive
 207 medical group contract and which operates its own pharmacies which are licensed under
 208 Code Section ~~26-4-110.1~~ 26-4-110."

209 **SECTION 5.**

210 Said chapter is further amended in Code Section 33-64-11, relating to prohibited activities
 211 of pharmacy benefits manager, by revising paragraph (c)(4) as follows:

212 "(4) Any licensed group model health maintenance organization with an exclusive
 213 medical group contract and which operates its own pharmacies which are licensed under
 214 Code Section ~~26-4-110.1~~ 26-4-110."

215 **SECTION 6.**

216 Code Section 49-4-148 of the Official Code of Georgia Annotated, relating to recovery of
 217 Medicaid benefits from third party liable for sickness, injury, disease, or disability, is
 218 amended by revising subsection (b) as follows:

219 "(b) All insurers, as defined in Code Section 33-24-57.1, including but not limited to group
 220 health plans as defined in Section 607(1) of the federal Employee Retirement Security Act
 221 of 1974, managed care entities as defined in Code Section 33-20A-3, which offer health
 222 benefit plans, as defined in Code Section 33-24-59.5, pharmacy ~~benefit~~ benefits managers,
 223 as defined in Code Section ~~26-4-110.1~~ 33-64-1, and any other parties that are, by statute,
 224 contract, or agreement, legally responsible for payment of a claim for a health care item or
 225 service shall comply with this subsection. Such entities set forth in this subsection shall:

226 (1) Cooperate with the department in determining whether a person who is a recipient
 227 of medical assistance may be covered under that entity's health benefit plan and eligible
 228 to receive benefits thereunder for the medical services for which that medical assistance
 229 was provided and respond to any inquiry from the state regarding a claim for payment for
 230 any health care item or service submitted not later than three years after such item or
 231 service was provided;

232 (2) Accept the department's authorization for the provision of medical services on behalf
 233 of a recipient of medical assistance as the entity's authorization for the provision of those
 234 services;

235 (3) Comply with the requirements of Code Section 33-24-59.5, regarding the timely
 236 payment of claims submitted by the department for medical services provided to a
 237 recipient of medical assistance and covered by the health benefit plan, subject to the
 238 payment to the department of interest as provided in that Code section for failure to
 239 comply;

- 240 (4) Provide the department, on a quarterly basis, eligibility and claims payment data
241 regarding applicants for medical assistance or recipients for medical assistance;
- 242 (5) Accept the assignment to the department or a recipient of medical assistance or any
243 other entity of any rights to any payments for such medical care from a third party; and
- 244 (6) Agree not to deny a claim submitted by the department solely on the basis of the date
245 of submission of the claim, type or format of the claim, or a failure to present proper
246 documentation at the point-of-sale which is the basis of the claim, if:
- 247 (A) The claim is submitted to the department within three years from when the item
248 or service was furnished; and
- 249 (B) Any action by the department to enforce its rights with respect to such claim
250 commenced within six years of the department's submission of the claim.
- 251 The requirements of paragraphs (2) and (3) of this subsection shall only apply to a health
252 benefit plan which is issued, issued for delivery, delivered, or renewed on or after April 28,
253 2001."

254 **SECTION 7.**

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