House Bill 918 (AS PASSED HOUSE AND SENATE)

By: Representatives Cooper of the 43rd, Knight of the 130th, Hatchett of the 150th, England of the 116th, Gravley of the 67th, 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, 1 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 managers engaging in the practice of pharmacy; to revise provisions relating to "The 4 Pharmacy Audit Bill of Rights"; to revise pharmacy anti-steering provisions; to revise 5 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 Audit Bill of Rights, as follows: 15 16 "26-4-118. (a) This Code section shall be known and may be cited as 'The Pharmacy Audit Bill of 17 18 Rights.' (b) Notwithstanding any other law, when an audit of the records of a pharmacy is 19 20 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 21 Community Health under Article 7 of Chapter 4 of Title 49, or any entity that represents 22 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:

(1) The entity conducting the initial on-site audit must give the pharmacy notice at least
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, and the cost of such claims shall not be used as a
criterion in determining which claims to audit. The audit shall not include more than 100
prescriptions per audit and an entity shall not audit more than 200 prescriptions in any 12
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 error, scrivener's error, or computer error, or omission error, regarding a required 36 37 prescription, front or back label, or other document or record shall not in and of itself constitute fraud. No such claim shall be subject to criminal penalties without proof of 38 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 paragraph (12) of this subsection, including to secure and remit an appropriate copy of 48 the record from a hospital, physician, or other authorized practitioner of the healing arts 49 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 on-site audit or noticed within the preliminary audit report; 52

(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;

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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, third-party payor, pharmacy benefits manager, any entity licensed by the Department of 66 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; (9) An audit may not be initiated or scheduled during the first seven calendar days of any 69 70 month due to the high volume of prescriptions filled during that time unless otherwise consented to by the pharmacy; 71 72 (10) The preliminary audit report must be delivered to the pharmacy within $\frac{120}{30}$ days 73 after conclusion of the audit. A final audit report shall be delivered to the pharmacy within six months 60 days after receipt of the preliminary audit report or final appeal, as 74 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. (11) The audit criteria set forth in this subsection shall apply only to audits of claims 88 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 a pharmacy shall have at least 30 days from the delivery of the preliminary audit report to 96 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 H. B. 918 - 3 -

(7) Each pharmacy shall be audited under the same standards and parameters as other

- 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 <u>commenced</u>
- 105 <u>based upon an articulable suspicion of</u> fraud, willful misrepresentation, or abuse, including
- 106 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 relatingto 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
- such audits conducted by the Department of Community Health under Article 7 of Chapter
- 113 4 of Title 49.
- (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.
- (i) The Commissioner of Insurance shall have enforcement authority over this Code
 section and shall promulgate rules and regulations to effectuate the provisions of this Code
- 118 <u>section</u>. The Commissioner of Insurance shall have the authority to investigate complaints
- 119 <u>of alleged violations of this Code section; to prohibit recoupment; to order reimbursement</u>
- 120 <u>of any wrongful recoupment; to institute fines for violations of the law, rules, or</u> 121 <u>regulations; and to take any other actions pursuant to any authority granted pursuant to</u>
- regulations; and to take any other actions pursuant to any authority granted pursuant to
 Chapter 64 of Title 33, relating to the regulation and licensure of pharmacy benefits
- 122 Chapter 04 of The 55, relating to the regulation and needsure of pharmacy benefits123 managers."
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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:
- (1) The referral of a patient to a pharmacy by an affiliate for pharmacy care representsa 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

- 20 costs to the health care system, may adversely affect the quality of health care, may 135 disproportionately harm patients in rural and medically underserved areas of Georgia, and 136 137 shall be against the public policy of this state. 138 (c) As used in this Code section, the term: (1) 'Affiliate' means a person licensed under Title 33 which, either directly or indirectly 139 140 through one or more intermediaries: 141 (A) Has an investment or ownership interest in a pharmacy licensed in or holding a nonresident pharmacy permit in Georgia; 142 143 (B) Shares common ownership with a pharmacy licensed in or holding a nonresident 144 pharmacy permit in Georgia; or (C) Has as an investor or ownership interest holder a pharmacy licensed in or holding 145 146 a nonresident pharmacy permit in Georgia. 147 (2) 'Referral' means: (A) Ordering of a patient to a pharmacy by an affiliate either orally or in writing, 148 149 including online messaging; (B) Ordering of a patient to a pharmacy that has an affiliate either orally or in writing, 150 including online messaging by a person licensed under Title 33 as a result of an 151 152 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 pharmacies or other pharmacies with affiliates, or that increase plan or patient costs, 154 155 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 a pharmacy by an affiliate or other person licensed under Title 33 as a result of an 158 159 arrangement or agreement with the pharmacy's affiliate. Subject to the foregoing, this term shall not include a pharmacy's inclusion by an affiliate 160 or other person licensed under Title 33 as a result of an arrangement or agreement with 161 the pharmacy's affiliate in communications to patients, including patient and prospective 162 patient specific communications, regarding network pharmacies and prices, provided that 163 the affiliate or other person licensed under Title 33 includes information regarding 164 eligible nonaffiliate pharmacies in such communications and the information provided 165 is accurate. 166 (d) A pharmacy licensed in or holding a nonresident pharmacy permit in Georgia shall be 167 proscribed from: 168 (1) Transferring or sharing records relative to prescription information containing patient 169 170 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

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- prescription information between a pharmacy and its affiliate for the limited purposes of 172 pharmacy reimbursement; formulary compliance; pharmacy care; public health activities 173 174 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 entity for a service furnished pursuant to a referral from an affiliate or other person 176 177 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 pharmacy does not receive referrals in violation of subsection (d) of this Code section and 182 183 the pharmacy provides the disclosures required in subsection (f) of this Code section.
- (f) If a pharmacy licensed or holding a nonresident pharmacy permit in this state has an 184 affiliate, it shall annually file with the board a disclosure statement identifying all such 185 186 affiliates.
- (g) In addition to any other remedy provided by law, a violation of this Code section by 187 a pharmacy shall be grounds for disciplinary action by the board pursuant to its authority 188 189 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 26-4-110.1 <u>26-4-110;</u>

- 196 (B)(2) Any hospital or related institution; or
- (C)(3) Any referrals by an affiliate for pharmacy services and prescriptions to patients 197
- in skilled nursing facilities, intermediate care facilities, continuing care retirement 198
- communities, home health agencies, or hospices; or 199
- (D) Any care management organization, as defined in Chapter 21A of Title 33." 200
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SECTION 4.

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

- 206 "(4) Any licensed group model health maintenance organization with an exclusive
 207 medical group contract and which operates its own pharmacies <u>which are licensed under</u>
 208 Code Section 26.4, 110, 1.26.4, 110, "
- 208 Code Section 26-4-110.1 <u>26-4-110</u>."
- Said chapter is further amended in Code Section 33-64-11, relating to prohibited activitiesof pharmacy benefits manager, by revising paragraph (c)(4) as follows:

SECTION 5.

212 "(4) Any licensed group model health maintenance organization with an exclusive
213 medical group contract and which operates its own pharmacies <u>which are licensed under</u>

214 Code Section 26-4-110.1 <u>26-4-110.</u>"

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SECTION 6.

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

- "(b) All insurers, as defined in Code Section 33-24-57.1, including but not limited to group 219 health plans as defined in Section 607(1) of the federal Employee Retirement Security Act 220 221 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 <u>33-64-1</u>, 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 of medical assistance may be covered under that entity's health benefit plan and eligible 227 228 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 any health care item or service submitted not later than three years after such item or 230 231 service was provided;
- (2) Accept the department's authorization for the provision of medical services on behalf
 of a recipient of medical assistance as the entity's authorization for the provision of those
 services;
- (3) Comply with the requirements of Code Section 33-24-59.5, regarding the timely
 payment of claims submitted by the department for medical services provided to a
 recipient of medical assistance and covered by the health benefit plan, subject to the
 payment to the department of interest as provided in that Code section for failure to
 comply;

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

- 251 The requirements of paragraphs (2) and (3) of this subsection shall only apply to a health
- benefit plan which is issued, issued for delivery, delivered, or renewed on or after April 28,
- 253 2001."
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SECTION 7.

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