GENERAL ASSEMBLY OF NORTH CAROLINA
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S **4**

SENATE BILL 432*

House Committee Substitute Favorable 8/13/19
House Committee Substitute #2 Favorable 9/11/19
House Committee Substitute #3 Favorable 10/22/19

Short Title: Birth Center & Pharm Benefits Mgr. Licensure. (Public)

Sponsors:

Referred to:

April 1, 2019

A BILL TO BE ENTITLED

AN ACT TO ESTABLISH A LICENSURE PROCESS AND ANNUAL LICENSE FEES FOR BIRTH CENTERS AND TO ESTABLISH STANDARDS AND CRITERIA FOR THE REGULATION AND LICENSURE OF PHARMACY BENEFITS MANAGERS PROVIDING CLAIMS PROCESSING SERVICES OR OTHER PRESCRIPTION DRUG OR DEVICE SERVICES FOR HEALTH BENEFIT PLANS, TO PREVENT INSURERS FROM REQUIRING INSUREDS TO TAKE DRUGS WITH BLACK BOX WARNINGS, AND TO REQUIRE INSURERS TO PROVIDE COVERAGE FOR PRESCRIPTION DRUGS DURING THE PREAUTHORIZATION PROCESS.

The General Assembly of North Carolina enacts:

PART I. ESTABLISH LICENSURE PROCESS FOR BIRTH CENTERS

SECTION 1.(a) Article 6 of Chapter 131E of the General Statutes is amended by adding a new Part to read:

"Part 4A. Birth Center Licensure Act.

"**§ 131E-153. Title; purpose.**

(a) This Part shall be known as the "Birth Center Licensure Act."

(b) The purpose of this Part is to establish licensing requirements for birth centers that promote public health, safety, and welfare and to provide for the development, establishment, and enforcement of basic standards for the care and treatment of mothers and infants in birth centers.

"**§ 131E-153.1. Definitions.**

As used in this Part, unless otherwise specified, the following terms have the following meanings:

(1) Birth center. – A facility licensed for the primary purpose of performing normal, uncomplicated deliveries that is not a hospital or ambulatory surgical facility and where births are planned to occur away from the mother's usual residence following a low-risk pregnancy.

(2) Commission. – The North Carolina Birth Center Commission established under G.S. 131E-153.7.

(3) Low-risk pregnancy. – A normal, uncomplicated prenatal course as determined by documentation of adequate prenatal care and the anticipation of a normal, uncomplicated labor and birth, as defined by reasonable and generally accepted criteria adopted by professional groups for maternal, fetal,

and neonatal health care, and generally accepted by the health care providers to whom they apply.

"**§ 131E-153.5. Review of birth center fee schedule.**

Every three years, the Department shall review and, as necessary, revise the Freestanding Birth Center Fee Schedule to ensure that (i) the fees are sufficient to cover the costs of providing intrapartum, birth, postpartum, and initial newborn care and (ii) the cost for any State-mandated newborn screening is reimbursed at no less than the cost of the screening.

"**§ 131E-153.6. Inspections.**

(a) The Department shall make, or cause to be made, inspections of birth centers as it deems necessary to investigate unexpected occurrences involving death or serious physical injury and reportable adverse outcomes identified in the rules adopted by the Commission under G.S. 131E-153.8. Any birth center licensed under this Part shall, at all times, be subject to inspections by the Department according to the rules of the Commission.

(b) Authorized representatives of the Department shall have, at all times, the right of proper entry upon any and all parts of the premises of any place in which entry is necessary to carry out the provisions of this Part or the rules adopted by the Commission, and it shall be unlawful for any person to resist a proper entry by such authorized representative upon any premises other than a private dwelling. However, no representative shall, by this entry onto the premises, endanger the health or well-being of any patient being treated in the birth center.

(c) To enable the Department to determine compliance with this Part and with the rules adopted by the Commission under this Part, and to investigate complaints made against a birth center licensed under this Part, the Department has the authority to investigate birth centers in the same manner as it investigates hospitals under G.S. 131E-80(d).

(d) Information received by the Commission and the Department through filed reports, license applications, or inspections that are required or authorized by the provisions of this Part may be disclosed publicly except where this disclosure would violate applicable laws concerning patient records and patient confidentiality. However, no such public disclosure shall identify the patient involved without permission of the patient or court order.

"**§ 131E-153.7. North Carolina Birth Center Commission; composition; powers and duties.**

(a) There is created the North Carolina Birth Center Commission of the Department of Health and Human Services. The Commission has the power and duty to do the following:

(1) Adopt rules establishing standards for the licensure, operation, and regulation of birth centers within the State in a manner consistent with the provisions and purposes of this Part.

(2) Review and make recommendations to the Department about whether to approve or disapprove birth center license applications.

(b) The Commission shall consist of seven members appointed as follows:

(1) The North Carolina Obstetrical and Gynecological Society shall elect six members who are licensed physicians providing obstetric care with a minimum of two years' experience working with birth centers.

a. The North Carolina Obstetrical and Gynecological Society shall send the names of four of the elected members to the Governor who shall appoint two members to the Commission.

b. The North Carolina Obstetrical and Gynecological Society shall send the names of two members to the Speaker of the House of Representatives and one member shall be appointed by the General Assembly upon the recommendation of the Speaker of the House of Representatives, as provided in G.S. 120-121.

(2) The North Carolina Affiliate of the American College of Nurse-Midwives shall elect six members who are certified midwives providing obstetric care with a minimum of two years' experience working with birth centers.

a. The North Carolina Affiliate of the American College of Nurse-Midwives shall send the names of four of the elected members to the Governor who shall appoint two members to the Commission.

b. The North Carolina Affiliate of the American College of Nurse-Midwives shall send the names of two members to the President Pro Tempore of the Senate and one member shall be appointed by the General Assembly upon the recommendation of the President Pro Tempore of the Senate, as provided in G.S. 120-121.

(3) The Governor shall appoint one public member. The public member shall not be eligible for appointment under subdivisions (1) and (2) of this subsection, but shall have professional experience and familiarity with the administrative aspects of obstetrical care practices or facilities, including, but not limited to, birth centers.

Any appointment to fill a vacancy on the Commission created by the resignation, dismissal, death, or disability of a member shall be for the balance of the unexpired term.

(c) Members appointed pursuant to subsection (b) of this section shall serve for a term of four years and no member shall serve more than two consecutive terms.

(d) The Governor may remove any member of the Commission from office for misfeasance, malfeasance, or nonfeasance in accordance with the provisions of G.S. 143B-13 of the Executive Organization Act of 1973.

(e) A vacancy on the Commission created by death, resignation, or otherwise, shall be filled in the same manner as the original appointment, except that all unexpired terms of Commission members appointed by the General Assembly shall be filled in accordance with G.S. 120-122. Appointees to fill vacancies shall serve the remainder of the unexpired term and until their successors are appointed and qualified.

(f) The members of the Commission shall receive per diem and necessary travel and subsistence expenses in accordance with the provisions of G.S. 138-5.

(g) A majority of the Commission shall constitute a quorum for the transaction of business.

(h) All clerical and other services required by the Commission shall be supplied by the Secretary of Health and Human Services.

"**§ 131E-153.8. Rules.**

(a) The North Carolina Birth Center Commission shall adopt rules establishing the following requirements for all birth centers seeking a license to operate in the State:

(1) Accreditation. – A requirement that the birth center obtain and maintain accreditation with the Commission for the Accreditation of Birth Centers (CABC) and provide the following related information to the Department:

a. All documentation required for accreditation by the CABC shall be submitted as part of a licensure application.

b. Copies of interim status reports provided to the CABC shall be submitted within 15 days after the reports are provided to the CABC.

c. Copies of all reports and responses from the CABC regarding reaccreditation site visits shall be submitted within 15 days after receipt.

d. Information about root cause analysis, remedial action, or training associated with unexpected occurrences involving death or serious physical injury and reportable adverse outcomes shall be submitted within 15 days after completion of the analysis, remedial action, or training.

e. A notification of loss of CABC accreditation shall be immediately reported to the Department.

(2) Risk status. – A requirement that the birth center establish procedures specifying the criteria by which each pregnant person's risk status will be evaluated at admission and during labor, pursuant to CABC standards.

(3) Second trimester ultrasound. – A requirement that the birth center recommend an ultrasound during the second trimester of pregnancy, ideally when the pregnant person is between 18 and 22 weeks pregnant, consistent with recommendations of the American College of Obstetricians and Gynecologists concerning ultrasound in pregnancy. If a pregnant person declines this screening test, the birth center shall document the informed refusal in the medical record.

(4) Targeted ultrasound. – A requirement that the birth center conduct a targeted ultrasound for further evaluation of maternal-fetal health consistent with those indications included in the recommendations of the American College of Obstetricians and Gynecologists concerning ultrasound practice in pregnancy. If a pregnant person receiving care at a licensed birth center and intending to give birth out-of-hospital declines a targeted ultrasound for maternal or fetal indications, the birth center shall deem the pregnant person ineligible for intrapartum care at the birth center, inform the patient of this determination in writing, and refer the person for a hospital birth.

(5) Transfer of patients to higher levels of care. – A requirement that the birth center develop and submit as part of the licensure application process a plan for complying with the standards of the Commission for Accreditation of Birth Centers with respect to transfer of care procedures.

(6) Sentinel events and adverse outcomes. – Each licensed birth center shall report unexpected occurrences involving death or serious physical injury and any other adverse outcomes identified by the Commission, to the CABC and the Department within a time frame established by the Commission. For each occurrence, the birth center shall conduct root cause analysis, remedial action, training, or a combination of these, to address these occurrences as per CABC guidelines. The Department shall investigate all unexpected occurrences involving death or serious physical injury and all reportable adverse outcomes identified by the Commission in the rules.

(7) Reporting requirements. – A requirement and standards for licensed birth centers to regularly report outcome and other data that the Commission shall analyze and distribute on a regular basis.

(b) The Department shall enforce this Part and any rules adopted by the Commission under this Part.

"**§ 131E-153.9. Confidential information.**

The Commission, its members, and staff, may release confidential or nonpublic information to any health care licensure board in this State, or another state, or authorized North Carolina Department of Health and Human Services personnel with enforcement or investigative responsibilities concerning issuance, denial, annulment, suspension, or revocation of a license, or the voluntary surrender of a license by a licensee of the Commission, including the reasons for the action, or an investigative report made by the Commission."

SECTION 1.(b) Part 4A of Article 6 of Chapter 131E of the General Statutes is amended by adding new sections to read:

"**§ 131E-153.2. Licensure requirement.**

(a) No person shall establish or operate a birth center in this State without obtaining a license from the Department under this Part.

(b) The Department shall provide applications for birth center licensure. Each application filed with the Department shall contain all of the following information:

(1) The name of the applicant.
(2) The site and location of the birth center.
(3) Documentation that the birth center meets the licensure standards adopted by the Commission pursuant to G.S. 131E-153.8.
(4) Any other information the Department deems necessary.

(c) Upon receipt of an application for a birth center license, the Department shall issue a license upon the recommendation of the Commission if the Department finds that the applicant is in compliance with the provisions of this Part and any rules adopted by the Commission under this Part. The license is valid for a period of one year from the date of issuance and must designate the number and types of beds and the number of rooms on the licensed premises. The Department shall charge the applicant a nonrefundable annual license fee in the amount of four hundred dollars ($400.00) plus a nonrefundable annual per–birthing room fee of seventeen dollars and fifty cents ($17.50). This fee shall be credited to the Department as a departmental receipt and applied to offset costs for licensing and inspecting birth centers.

(d) The Department shall renew each license in accordance with rules adopted by the Commission under G.S. 131E-153.8.

(e) The Department shall issue a birth center license only for the premises and persons named in the license. A birth center license is not transferable or assignable except with the written approval of the Department.

(f) The operator shall post the license on the licensed premises in an area accessible to the public.

(g) Notwithstanding subsection (a) of this section, birth centers that are operating in this State on the date this act becomes effective and that are accredited by the Commission for the Accreditation of Birth Centers (CABC) and that remain continually accredited, shall be allowed to continue operations as the Commission is constituted and promulgates permanent rules. Within 90 days of the effective date of the Commission's permanent rules regarding licensure applications, such unlicensed birth centers operating in this State shall submit a completed licensure application, together with the requisite fee, to the Division of Health Service Regulation. The application and fee shall be received or postmarked no later than 90 days after the rules promulgated by the Commission are adopted.

"**§ 131E-153.3. Adverse action on a license.**

(a) The Department may deny, suspend, or revoke a license in any case when it finds a substantial failure to comply with the provisions of this Part or any rule adopted under this Part.

(b) The Secretary or a designee may suspend the admission of any new patients to a birth center if the conditions of the birth center are detrimental to the health or safety of any patient. This suspension shall remain in effect until the Secretary, or the Secretary's designee, is satisfied that conditions or circumstances merit the removal of the suspension. The authority under this subsection is in addition to the authority to suspend or revoke the license of a birth center.

(c) A birth center may contest any adverse action on its license under this section in accordance with Chapter 150B of the General Statutes.

"**§ 131E-153.4. Limitations of services.**

(a) A birth center licensed under this Part shall not assert, represent, offer, provide, or imply that the center is rendering or may render care or services other than the services it is permitted to render within the scope of the license issued.

(b) The following limitations apply to the services performed at a licensed birth center:
(1) Surgical procedures are limited to those normally accomplished during an uncomplicated birth, such as episiotomy and repair, as determined by the Commission.
(2) No abortions may be performed.
(3) No general or conduction anesthesia may be performed.

(4) No vaginal birth after cesarean (VBAC) or trial of labor after cesarean (TOLAC) may be performed."

SECTION 1.(c) Part 4A of Article 6 of Chapter 131E of the General Statutes is amended by adding a new section to read:

"**§ 131E-153.10. Penalties.**

A person who owns, in whole or in part, or operates a birth center without a license is guilty of a Class 3 misdemeanor and upon conviction is subject only to a fine of not more than fifty dollars ($50.00) for the first offense and not more than five hundred dollars ($500.00) for each subsequent offense. Each day of continuing violation after conviction is considered a separate offense."

SECTION 1.(d) By December 1, 2019, the Department of Health and Human Services shall review and, as necessary, revise its current Freestanding Birth Center Fee Schedule to ensure that (i) the fees are sufficient to cover the costs of providing intrapartum, birth, postpartum, and initial newborn care and (ii) the cost for any State-mandated newborn screening is reimbursed at no less than the cost of the screening. The Department shall also develop a birth center licensure application containing the elements outlined in G.S. 131E-153.2(b) and shall make it available upon adoption of the rules by the North Carolina Birth Center Commission.

SECTION 1.(e) The initial appointments to the North Carolina Birth Center Commission under G.S. 131E-153.7(b) shall be made not later than 60 days after the effective date of this act. In order to provide for staggering of terms under G.S. 131E-153.7(b), the initial term of office for each member appointed under G.S. 131E-153.7(b)(1)a. and (b)(2)b. shall be two years. The initial term of office for each member appointed under G.S. 131E-153.7(b)(1)b. and (b)(2)a. shall be three years, and the initial term for the member appointed under G.S. 131E-153.7(b)(3) shall be one year. Subsequent appointments shall be for the full four-year term in accordance with G.S. 131E-153.7(c). The partial terms to provide for the initial staggering of terms shall not count as full terms for purposes of the limitation in G.S. 131E-153.7(c).

SECTION 2. The criminal offense in G.S. 131E-153.6(b), as enacted by Section 1(a) of this act, becomes effective December 1, 2019, and applies to offenses committed on or after that date. Section 1(b) of this act becomes effective one year after the rules promulgated by the North Carolina Birth Center Commission are adopted and applies to licenses granted on or after that date. Section 1(c) of this act becomes effective one year after the rules promulgated by the North Carolina Birth Center Commission are adopted and applies to criminal offenses committed on or after that date. The Codifier of Rules shall notify the Revisor of Statutes of the effective date of rules adopted as required by this act. Except as otherwise provided, this part is effective when it becomes law.

PART II. ESTABLISH STANDARDS FOR PHARMACY BENEFITS MANAGERS

SECTION 3.(a) G.S. 58-56A-10 is repealed.

SECTION 3.(b) Article 56A of Chapter 58 of the General Statutes, as amended by Section 3(a) of this act, reads as rewritten:

"Article 56A.

"Pharmacy Benefits Management.

"**§ 58-56A-1. Definitions.**

The following definitions apply in this Article:

(1) Claim. – A request from a pharmacy or pharmacist to be reimbursed for the cost of filling or refilling a prescription for a drug or for providing a medical supply or device.

(2) Claims processing service. – The administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include either or both of the following:

a. Receiving payments for pharmacist services.
b. Making payments to pharmacists or pharmacies for pharmacist services.

~~(1)~~(3) Health benefit plan. – ~~As defined in G.S. 58-50-110(11). This definition specifically excludes the State Health Plan for Teachers and State Employees.~~An accident and health insurance policy or certificate; a nonprofit hospital or medical service corporation contract; a health maintenance organization subscriber contract; a plan provided by a multiple employer welfare arrangement; a plan provided by another benefit arrangement, to the extent permitted by the Employee Retirement Income Security Act of 1974, as amended, or by any waiver of or other exception to that act provided under federal law or regulation; or any plan implemented or administered by the State Health Plan for Teachers and State Employees. "Health benefit plan" does not mean any plan implemented or administered by the North Carolina or United States Department of Health and Human Services, or any successor agency, or its representatives. "Health benefit plan" does not mean any plan consisting of one or more of any combination of benefits described in G.S. 58-68-25(b).

~~(1a)~~(4) Insured. – An individual covered by a health benefit plan.

~~(2)~~(5) Insurer. – Any entity that provides or offers a health benefit plan.

(6) Maximum allowable cost list. – A listing of generic or multiple source drugs used by a pharmacy benefits manager to set the maximum allowable cost on which reimbursement of a pharmacy is made.

~~(3)~~(7) Maximum allowable cost price. – The maximum ~~per unit reimbursement for~~ amount that a pharmacy benefits manager will reimburse a pharmacy for the cost of generic or multiple source prescription drugs, medical products, or devices.

(8) Out-of-pocket costs. – With respect to the acquisition of a drug, the amount to be paid by the insured under the plan or coverage, including any cost-sharing, co-payment, coinsurance, or deductible.

(9) Pharmacy services administration organization. – An entity operating within the State that contracts with independent pharmacies to conduct business on their behalf with third-party payers. PSAOs provide administrative services to pharmacies and negotiate and enter into contracts with third-party payers or pharmacy benefits managers on behalf of pharmacies. A person or entity is a PSAO under this Article if it performs one or more of the following administrative services to pharmacies:

a. Assistance with claims.
b. Assistance with audits.
c. Centralized payment.
d. Certification in specialized care programs.
e. Compliance support.
f. Setting flat fees for generic drugs.
g. Assistance with store layout.
h. Inventory management.
i. Marketing support.
j. Management and analysis of payment and drug dispensing data.
k. Provision of services for retail cash cards.

~~(3a)~~(10) Pharmacist. – A person licensed to practice pharmacy under Article 4A of Chapter 90 of the General Statutes.

(11) Pharmacist services. – Products, goods, or services provided as a part of the practice of pharmacy.

~~(4)~~(12) Pharmacy. – A pharmacy registered with the North Carolina Board of Pharmacy.

~~(5)~~(13) Pharmacy benefits ~~manager.~~ manager or PBM. – An entity who contracts with a pharmacy on behalf of an insurer or third-party administrator to administer or manage prescription drug ~~benefits.~~benefits to perform any of the following functions:

a. Processing claims for prescription drugs or medical supplies or providing retail network management for pharmacies or pharmacists.

b. Paying pharmacies or pharmacists for prescription drugs or medical supplies.

c. Negotiating rebates with manufacturers for drugs paid for or procured as described in this Article.

(14) Pharmacy benefits manager affiliate. – A pharmacy or pharmacist that directly or indirectly, through one or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership or control with a pharmacy benefits manager.

~~(6)~~(15) Third-party administrator. – As defined in G.S. 58-56-2.

"**§ 58-56A-2. Licensure.**

(a) No person shall act as, offer to act as, or hold himself or herself out as a PBM in this State without a valid PBM license issued by the Commissioner. Licenses shall be renewed annually. Failure to submit a complete renewal application shall result in the expiration of the license of the PBM as a matter of law; provided, however, the Commissioner may grant the PBM an extension of time for good cause.

(b) Each application for the issuance or renewal of a license shall be made upon a form prescribed by the Commissioner. An application for licensure shall be accompanied by a nonrefundable initial application fee of two thousand dollars ($2,000), and an annual renewal application shall be accompanied by an annual renewal fee of one thousand five hundred dollars ($1,500). An application for the issuance of a license shall include or be accompanied by the following information and documents:

(1) All organizational documents of the PBM, including any articles of incorporation, articles of association, partnership agreement, trade name certificate, or trust agreement, any other applicable documents, and all amendments to these documents.

(2) The bylaws, rules, regulations, or similar documents regulating the internal affairs of the PBM.

(3) The names, addresses, official positions, and professional qualifications of the individuals who are responsible for the conduct of affairs of the PBM, including (i) all members of the board of directors, board of trustees, executive committee, or other governing board or committee, (ii) the principal officers in the case of a corporation or the partners or members in the case of a partnership or association, (iii) all shareholders holding directly or indirectly ten percent (10%) or more of the voting securities of the PBM, and (iv) any other person who exercises control or influence over the affairs of the PBM.

(4) Annual financial statements or reports for the two most recent years that prove the applicant is solvent and any other information the Commissioner may require in order to review the current financial condition of the applicant.

(5) A general description of the business operations, including information on staffing levels and activities proposed in this State and nationwide. The description must provide details setting forth the PBM's capability to provide

a sufficient number of experienced and qualified personnel in the areas of claims processing, record keeping, and underwriting.

(6) A signed statement indicating that, to the best of the applicant's knowledge, no officer with management or control of the PBM has been convicted of a felony or has violated any of the requirements of State or federal law applicable to PBMs, or, if the applicant cannot provide that statement, a signed statement describing the relevant conviction or violation.

(7) Any other pertinent information required by rules of the Commissioner.

The information required by subdivisions (1) through (7) of this subsection, including any trade secrets, shall be kept confidential; provided that the Commissioner may use that information in any judicial or administrative proceeding instituted against the PBM. An application for the renewal of a license shall include or be accompanied by any changes in the information required by subdivisions (1) through (7) of this subsection.

(c) Each applicant shall make available for inspection by the Commissioner copies of all contracts with insurers or other persons using the services of the PBM.

(d) The Commissioner may refuse to issue a license if the Commissioner determines that the PBM, or any individual responsible for the conduct of affairs of the PBM as defined in subdivision (b)(3) of this section, is not competent, trustworthy, financially responsible in accordance with subsection (b) of this section, or of good personal and business reputation, or has had an insurance or a PBM license denied, suspended, or revoked for cause by any state.

(e) If the Commissioner finds that an applicant has not fully met the requirements for licensing, the Commissioner shall refuse to issue the license and shall notify in writing the applicant of the denial, stating the grounds for the denial. The application may also be denied for any reason for which a license may be suspended or revoked or not renewed under G.S. 58-56A-40. In order for an applicant to be entitled to a review of the Commissioner's action to determine the reasonableness of the action, the applicant must make a written demand upon the Commissioner for a review no later than 30 days after service of the notification upon the applicant. The review shall be completed without undue delay, and the applicant shall be notified promptly in writing of the outcome of the review. In order for an applicant who disagrees with the outcome of the review to be entitled to a hearing under Article 3A of Chapter 150B of the General Statutes, the applicant must make a written demand upon the Commissioner for a hearing no later than 30 days after service upon the applicant of the notification of the outcome.

(f) A PBM shall notify the Commissioner of any material change in its ownership, control, or other fact or circumstance affecting its qualification for licensure in the State within 10 business days after the change takes effect.

(g) The Commissioner may adopt rules establishing additional licensing and reporting requirements for PBMs consistent with the provisions of this Article.

"**§ 58-56A-3. Consumer protections.**

(a) A pharmacy or pharmacist shall have the right to provide an insured information regarding the amount of the insured's cost share for a prescription drug. Neither a pharmacy nor a pharmacist shall be penalized by a ~~pharmacy benefits manager~~ PBM for discussing any information described in this section or for selling a lower-priced drug to the insured if one is available.

(b) A ~~pharmacy benefits manager~~ PBM shall not, through contract, prohibit a pharmacy from offering and providing direct and limited delivery services to an insured as an ancillary service of the pharmacy, as delineated in the contract between the ~~pharmacy benefits manager~~ PBM and the pharmacy.

(b1) A PBM shall not prohibit a pharmacist or pharmacy from charging a minimal shipping and handling fee to the insured for a mailed or delivered prescription if the pharmacist or pharmacy discloses all of the following to the insured before delivery:

(1) The fee will be charged.

(2) The fee may not be reimbursed by the health benefit plan, insurer, or PBM.
(3) The charge is specifically agreed to by the health benefit plan or PBM.

(c) A ~~pharmacy benefits manager~~ PBM shall not charge, or attempt to collect from, an insured a co-payment that exceeds the total submitted charges by the network pharmacy.

(c1) When calculating an insured's contribution to any out-of-pocket maximum, deductible, copayment, coinsurance, or any other cost-sharing requirement, the insurer or PBM shall include any cost-sharing amount paid by the insured or on the insured's behalf for a prescription drug that is either of the following:

(1) Without an AB-rated generic equivalent.
(2) With an AB-rated generic equivalent if the insured has obtained authorization for the drug through any of the following:
a. Prior authorization from the insurer or PBM.
b. A step therapy protocol.
c. The exception or appeal process of the insurer or PBM.

(c2) For purposes of this section, the term "generic equivalent" means a drug that has an identical amount of the same active ingredients in the same dosage form; meets applicable standards of strength, quality, and purity according to the United States Pharmacopeia or other nationally recognized compendium; and which, if administered in the same amount, would provide comparable therapeutic effects. For purposes of this section, the term "generic equivalent" does not include a drug that is listed by the United States Food and Drug Administration as having unresolved bioequivalence concerns according to the Administration's most recent publication of approved drug products with therapeutic equivalence evaluations.

(d) Any contract for the provision of a network to deliver health care services between a ~~pharmacy benefits manager~~ PBM and insurer shall be made available for review by the ~~Department.~~Department and shall disclose all incentives, discounts, and rebates received by the PBM and the entities who benefit from the incentives, discounts, and rebates, including amounts retained by the PBM, whether in the form of money, reduction in costs, or any other benefit to the PBM.

~~(e) The Department shall report to the Attorney General any violations of this section or G.S. 58-56A-4 in accordance with G.S. 58-2-40(5).~~

"**§ 58-56A-4. Pharmacy and pharmacist protections.**

(a) A ~~pharmacy benefits manager~~ PBM may only charge a fee or otherwise hold a pharmacy responsible for a fee relating to the adjudication of a claim if the fee is reported on the remittance advice of the adjudicated claim or is set out in contract between the ~~pharmacy benefits manager~~ PBM and the pharmacy. No fee or adjustment for the receipt and processing of a claim, or otherwise related to the adjudication of a claim, shall be charged without a justification on the remittance advice or as set out in contract and agreed upon by the pharmacy or pharmacist for each adjustment or fee. This section shall not apply with respect to claims under an employee benefit plan under the Employee Retirement Income Security Act of 1974 or Medicare Part D.

(b) Nothing in this Article shall abridge the right of a pharmacist to refuse to fill or refill a prescription if the pharmacist believes it would be harmful to the patient, it is not in the patient's best interest, or there is a question as to the prescription's validity.

(c) A PBM shall not prohibit or in any way restrict a pharmacy or pharmacist from dispensing any prescription drug, including specialty drugs dispensed by a credentialed and accredited pharmacy, allowed to be dispensed under a license to practice pharmacy under Article 4A of Chapter 90 of the General Statutes.

(d) A PBM shall not coerce, steer, or entice an insurance provider or an insured to other entities that operate under the umbrella of the PBM, including mail order pharmacies, insurance companies, or pharmacies operating under the umbrella companies of the PBM.

(e) A PBM shall not penalize or retaliate against a pharmacist or pharmacy for exercising rights provided under this Article. This subsection does not apply to breach of contract between a pharmacy and a PBM.

(f) A claim for pharmacist services may not be retroactively denied or reduced after adjudication of the claim unless any of the following apply:

(1) The original claim was submitted fraudulently.

(2) The original claim payment was incorrect because the pharmacy or pharmacist had already been paid for the pharmacist services.

(3) The pharmacist services were not rendered by the pharmacy or pharmacist.

(4) The adjustments were agreed to by the pharmacy or pharmacist.

(5) The adjustments were part of an attempt to limit overpayment recovery efforts by a PBM.

(g) Nothing in this section shall be construed to limit overpayment recovery efforts by a PBM.

"**§ 58-56A-5. Maximum allowable cost ~~price.~~list.**

(a) In order to place a prescription drug on the maximum allowable cost ~~price~~ list, the drug must be available for purchase by pharmacies in North Carolina from national or regional wholesalers, must not be obsolete, and must meet one of the following conditions:

(1) The drug is listed as "A" or "B" rated in the most recent version of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.

(2) The drug has a "NR" or "NA" rating, or a similar rating, by a nationally recognized reference.

(b) A ~~pharmacy benefits manager~~ PBM shall adjust or remove the maximum allowable cost price for a prescription drug to remain consistent with changes in the national marketplace for prescription drugs. A review of the maximum allowable cost prices for removal or modification shall be completed by the ~~pharmacy benefits manager~~ PBM at least once every seven business days, and any removal or modification shall occur within seven business days of the review. A ~~pharmacy benefits manager~~ PBM shall provide a means by which the contracted pharmacies may promptly review current prices in an electronic, print, or telephonic format within one business day of the removal or modification.

(c) A PBM shall ensure that dispensing fees are not included in the calculation of maximum allowable cost price.

(d) A PBM shall establish an administrative appeals procedure by which a contracted pharmacy or pharmacist, or a designee, can appeal the provider's reimbursement for a prescription drug subject to maximum allowable cost pricing if the reimbursement for the drug is less than the net amount that the network provider paid to the suppliers of the drug. The reasonable administrative appeal procedure must include all of the following:

(1) A dedicated telephone number and e-mail address or Web site for the purpose of submitting administrative appeals.

(2) The ability to submit an administrative appeal directly to the PBM regarding the pharmacy benefits plan or program or through a pharmacy service administrative organization if the pharmacy service administrative organization has a contract with the PBM that allows for the submission of such appeals.

(3) No less than 14 calendar days after the applicable fill date to file an administrative appeal.

(4) If an appeal is initiated, then the PBM shall, within 14 calendar days after receipt of notice of the appeal, do either of the following:

a. If the appeal is upheld, the PBM shall notify the pharmacy or pharmacist, or designee, of the decision, make the change in the

maximum allowable cost effective as of the date the appeal is resolved, permit the appealing pharmacy or pharmacist to reverse and rebill the claim in question, and make the change effective for each similarly situated pharmacy, as defined by the payer subject to the maximum allowable cost list, effective as of the date the appeal is resolved.

b. If the appeal is denied within 10 days of the denial, the PBM shall provide the appealing pharmacy or pharmacist the reason for the denial, the National Drug Code number, and the names of the national or regional pharmaceutical wholesalers operating in this State.

"**§ 58-56A-20. Pharmacy benefits manager networks.**

(a) A PBM may maintain more than one network for different pharmacy services. Each individual network may have terms and conditions and require different pharmacy accreditation standards or certification requirements for participating in the network provided that the pharmacy accreditation standards or certification requirements are applied without regard to a pharmacy's or pharmacist's status as an independent pharmacy or pharmacy benefits manager affiliate. Each individual pharmacy location as identified by its National Council for Prescription Drug Program identification number may have access to more than one network so long as the pharmacy location meets the pharmacy accreditation standards or certification requirements of each network.

(b) A PBM shall not deny the right to any properly licensed pharmacist or pharmacy, or a pharmacy wholesaler or pharmacy services administration organization, to participate in a network on the same terms and conditions as other participants in the network.

(c) Pharmacy performance measure or pay-for-performance networks shall utilize a nationally recognized entity aiding in improving pharmacy performance measures. The following applies to pharmacy performance measures:

(1) A PBM may not impose a fee on a pharmacy, or otherwise penalize the pharmacy, if the pharmacy's scores or metrics fall within the criteria identified by a nationally recognized entity aiding in improving pharmacy performance measures.

(2) If a PBM imposes a fee on a pharmacy for scores or metrics that do not fall within the criteria identified by a nationally recognized entity aiding in improving pharmacy performance measures, then the PBM is limited to applying the fee to the professional dispensing fee as contained in the pharmacy contract. Pharmacies owing performance measurement fees shall be subject to the North Carolina prompt payment requirements.

(d) A pharmacist or pharmacy that is a member of a pharmacy service administration organization that enters into a contract with a health benefit plan issuer or a PBM on the pharmacy's behalf is entitled to receive from the pharmacy service administration organization a copy of the contract provisions applicable to the pharmacy, including each provision relating to the pharmacy's rights and obligations under the contract.

(e) Termination of a pharmacy or pharmacist from a PBM network does not release the PBM from the obligation to make any payment due to the pharmacy or pharmacist for pharmacist services properly rendered according to the contract. This subsection does not apply in cases of fraud, waste, or abuse.

"**§ 58-56A-25. Pharmacy benefits manager affiliate disclosure; sharing of data.**

A PBM shall not, in any way that is prohibited by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), transfer or share records relative to prescription information containing patient-identifiable and prescriber-identifiable data to a pharmacy benefits manager affiliate.

"**§ 58-56A-35. Enforcement.**

(a) The Commissioner may make an examination of the affairs of any PBM pursuant to the services that it provides for an insurer or a health benefit plan that are relevant to determining if the PBM is in compliance with this Article. The Commissioner may contract with consultants and other professionals with relevant experience as necessary and appropriate to conduct an examination or audit of a PBM. The PBM shall bear the cost of retaining those persons. The Commissioner shall institute a civil action to recover the expenses of an examination against a PBM which refuses or fails to pay the expenses.

(b) All working papers, information, documents, and copies thereof produced by, obtained by, or disclosed to the Commissioner or any other person in connection with an examination or audit under this section are confidential, are not subject to subpoena, are not public records under Chapter 132 of the General Statutes, and shall not be made public by the Commissioner or any other person. The Commissioner may use the documents, materials, or other information in the furtherance of any regulatory or legal action brought as part of the Commissioner's official duties.

(c) The Commissioner shall report to the Attorney General any violations of this Article, in accordance with G.S. 58-2-40(5).

"**§ 58-56A-40. Grounds for suspension, revocation, or nonrenewal of license.**

(a) The Commissioner may suspend, revoke, or refuse to renew the license of a PBM, in accordance with the provisions of Article 3A of Chapter 150B of the General Statutes, for any one or more of the following causes:

(1) The PBM is using methods or practices in the conduct of its business that render its further transaction of business in this State hazardous or injurious to insured persons or the public.

(2) The PBM has violated any administrative rule, subpoena, or order of the Commissioner, or has violated any provision of this Chapter.

(3) The PBM has refused to be examined or to produce its accounts, records, and files for examination, or any of its officers has refused to give information with respect to its affairs or has refused to perform any other legal obligation as to that examination, when required by the Commissioner.

(4) The PBM is an affiliate of or under the same general management, interlocking directorate, or ownership as another PBM or insurer that unlawfully transacts business in this State without having a license.

(5) The PBM at any time fails to meet any qualification for which issuance of the license could have been refused had the failure then existed and been known to the Commissioner at the time of the application.

(6) The PBM, or any officer with management control of the PBM, has been convicted of, or has entered a plea of guilty or nolo contendere to, a felony without regard to whether judgment was withheld.

(7) The PBM has had an insurance, third-party administrator, or a PBM license denied, suspended, or revoked for cause by any state, or has been assessed an administrative fine by any state, or has been subject to a cease and desist order.

(8) The PBM is insolvent or financially impaired. "Financially impaired" means that the PBM is unable or potentially unable to fulfill its contractual obligations.

(9) The financial condition or business practices of the PBM otherwise pose an imminent threat to the public health, safety, or welfare of the residents of this State.

(b) Notwithstanding the notice and hearing requirements of subsection (a) of this section, the Commissioner may order summary suspension of a PBM license, in accordance with the provisions of G.S. 150B-3, upon a written finding that the public health, safety, or welfare requires emergency action. The order shall be effective on the date specified in the order or on

service of the certified copy of the order at the last known address of the licensee, whichever is later, and shall remain effective during the proceedings. The proceedings shall be promptly commenced and determined."

SECTION 3.(c) G.S. 58-2-40(5) reads as rewritten:

"(5) Report in detail to the Attorney General any violations of the laws relative to PBMs, insurance companies, associations, orders and bureaus or the business of insurance; and the Commissioner may institute civil actions or criminal prosecutions either by the Attorney General or another attorney whom the Attorney General may select, for any violation of the provisions of Articles 1 through 64 of this Chapter."

SECTION 3.(d) G.S. 58-56-2 reads as rewritten:

"**§ 58-56-2. Definitions.**

The following definitions apply in this Article:

…

(5) Third party administrator. A person who directly or indirectly solicits or effects coverage of, underwrites, collects charges or premiums from, or adjusts or settles claims on residents of this State, or residents of another state from offices in this State, in connection with life or health insurance or annuities, except any of the following:

…

m. A PBM licensed pursuant to G.S. 58-56A-2.

…."

SECTION 3.(e) This section becomes effective March 1, 2020, and applies to any contracts entered into on or after that date.

SECTION 3.5.(a) Article 3 of Chapter 58 of the General Statutes is amended by adding a new section to read:

"**§ 58-3-222. Prescription drug patient protections.**

(a) If an insurer offers coverage for prescription drugs, it shall not require any insured to take any drug with a boxed warning as defined in 21 C.F.R. § 201.57.

(b) If an insurer offers coverage for prescription drugs and requires preauthorization as a condition to providing coverage for a drug, that insurer shall provide immediate coverage for the drug during the period of time it takes the insurer to conduct the preauthorization review. Nothing in this subsection shall be construed to require an insurer to approve a drug undergoing a preauthorization review."

SECTION 3.5.(b) This section becomes effective October 1, 2020, and applies to insurance contracts issued, renewed, or amended on or after that date.

SECTION 4. Except as otherwise provided, this act is effective when it becomes law.