

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2019

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SENATE BILL 432*
House Committee Substitute Favorable 8/13/19

Short Title: Birth Center & Pharm Benefits Mgr. Licensure.

(Public)

Sponsors:

Referred to:

April 1, 2019

1 A BILL TO BE ENTITLED
2 AN ACT TO ESTABLISH A LICENSURE PROCESS AND ANNUAL LICENSE FEES FOR
3 BIRTH CENTERS AND TO ESTABLISH STANDARDS AND CRITERIA FOR THE
4 REGULATION AND LICENSURE OF PHARMACY BENEFITS MANAGERS
5 PROVIDING CLAIMS PROCESSING SERVICES OR OTHER PRESCRIPTION DRUG
6 OR DEVICE SERVICES FOR HEALTH BENEFIT PLANS.

7 The General Assembly of North Carolina enacts:

8
9 **PART I. ESTABLISH LICENSURE PROCESS FOR BIRTH CENTERS**

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

12 "Part 4A. Birth Center Licensure Act.

13 **"§ 131E-153. Title; purpose.**

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

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

19 **"§ 131E-153.1. Definitions.**

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

- 22 (1) Birth center. – A facility licensed for the primary purpose of performing
23 normal, uncomplicated deliveries that is not a hospital or ambulatory surgical
24 facility and where births are planned to occur away from the mother's usual
25 residence following a low-risk pregnancy.
- 26 (2) Commission. – The North Carolina Birth Center Commission established
27 under G.S. 131E-153.7.
- 28 (3) Low-risk pregnancy. – A normal, uncomplicated prenatal course as
29 determined by documentation of adequate prenatal care and the anticipation
30 of a normal, uncomplicated labor and birth, as defined by reasonable and
31 generally accepted criteria adopted by professional groups for maternal, fetal,
32 and neonatal health care, and generally accepted by the health care providers
33 to whom they apply.

34 **"§ 131E-153.5. Review of birth center fee schedule.**

35 Every three years, the Department shall review and, as necessary, revise the Freestanding
36 Birth Center Fee Schedule to ensure that (i) the fees are sufficient to cover the costs of providing



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1 intrapartum, birth, postpartum, and initial newborn care and (ii) the cost for any State-mandated
2 newborn screening is reimbursed at no less than the cost of the screening.

3 **"§ 131E-153.6. Inspections.**

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

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

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

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

24 **"§ 131E-153.7. North Carolina Birth Center Commission; composition; powers and duties.**

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

- 27 (1) Adopt rules establishing standards for the licensure, operation, and regulation
28 of birth centers within the State in a manner consistent with the provisions and
29 purposes of this Part.
30 (2) Review and make recommendations to the Department about whether to
31 approve or disapprove birth center license applications.

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

- 33 (1) The North Carolina Obstetrical and Gynecological Society shall elect six
34 members who are licensed physicians providing obstetric care with a
35 minimum of two years' experience working with birth centers.
36 a. The North Carolina Obstetrical and Gynecological Society shall send
37 the names of four of the elected members to the Governor who shall
38 appoint two members to the Commission.
39 b. The North Carolina Obstetrical and Gynecological Society shall send
40 the names of two members to the Speaker of the House of
41 Representatives and one member shall be appointed by the General
42 Assembly upon the recommendation of the Speaker of the House of
43 Representatives, as provided in G.S. 120-121.
44 (2) The North Carolina Affiliate of the American College of Nurse-Midwives
45 shall elect six members who are certified midwives providing obstetric care
46 with a minimum of two years' experience working with birth centers.
47 a. The North Carolina Affiliate of the American College of
48 Nurse-Midwives shall send the names of four of the elected members
49 to the Governor who shall appoint two members to the Commission.
50 b. The North Carolina Affiliate of the American College of
51 Nurse-Midwives shall send the names of two members to the President

1 Pro Tempore of the Senate and one member shall be appointed by the
2 General Assembly upon the recommendation of the President Pro
3 Tempore of the Senate, as provided in G.S. 120-121.

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

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

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

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

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

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

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

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

27 **§ 131E-153.8. Rules.**

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

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

- 33 a. All documentation required for accreditation by the CABC shall be
34 submitted as part of a licensure application.
35 b. Copies of interim status reports provided to the CABC shall be
36 submitted within 15 days after the reports are provided to the CABC.
37 c. Copies of all reports and responses from the CABC regarding
38 reaccreditation site visits shall be submitted within 15 days after
39 receipt.
40 d. Information about root cause analysis, remedial action, or training
41 associated with unexpected occurrences involving death or serious
42 physical injury and reportable adverse outcomes shall be submitted
43 within 15 days after completion of the analysis, remedial action, or
44 training.
45 e. A notification of loss of CABC accreditation shall be immediately
46 reported to the Department.

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

- 50 (3) Second trimester ultrasound. – A requirement that the birth center recommend
51 an ultrasound during the second trimester of pregnancy, ideally when the

1 pregnant person is between 18 and 22 weeks pregnant, consistent with
2 recommendations of the American College of Obstetricians and
3 Gynecologists concerning ultrasound in pregnancy. If a pregnant person
4 declines this screening test, the birth center shall document the informed
5 refusal in the medical record.

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

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

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

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

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

33 **"§ 131E-153.9. Confidential information.**

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

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

42 **"§ 131E-153.2. Licensure requirement.**

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

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

47 (1) The name of the applicant.

48 (2) The site and location of the birth center.

49 (3) Documentation that the birth center meets the licensure standards adopted by
50 the Commission pursuant to G.S. 131E-153.8.

51 (4) Any other information the Department deems necessary.

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

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

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

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

17 (g) Notwithstanding subsection (a) of this section, birth centers that are operating in this
18 State on the date this act becomes effective and that are accredited by the Commission for the
19 Accreditation of Birth Centers (CABC) and that remain continually accredited, shall be allowed
20 to continue operations as the Commission is constituted and promulgates permanent rules. Within
21 90 days of the effective date of the Commission's permanent rules regarding licensure
22 applications, such unlicensed birth centers operating in this State shall submit a completed
23 licensure application, together with the requisite fee, to the Division of Health Service
24 Regulation. The application and fee shall be received or postmarked no later than 90 days after
25 the rules promulgated by the Commission are adopted.

26 **"§ 131E-153.3. Adverse action on a license.**

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

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

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

36 **"§ 131E-153.4. Limitations of services.**

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

40 (b) The following limitations apply to the services performed at a licensed birth center:

41 (1) Surgical procedures are limited to those normally accomplished during an
42 uncomplicated birth, such as episiotomy and repair, as determined by the
43 Commission.

44 (2) No abortions may be performed.

45 (3) No general or conduction anesthesia may be performed.

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

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

50 **"§ 131E-153.10. Penalties.**

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

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

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

23 **SECTION 2.** The criminal offense in G.S. 131E-153.6(b), as enacted by Section 1(a)
24 of this act, becomes effective December 1, 2019, and applies to offenses committed on or after
25 that date. Section 1(b) of this act becomes effective one year after the rules promulgated by the
26 North Carolina Birth Center Commission are adopted and applies to licenses granted on or after
27 that date. Section 1(c) of this act becomes effective one year after the rules promulgated by the
28 North Carolina Birth Center Commission are adopted and applies to criminal offenses committed
29 on or after that date. The Codifier of Rules shall notify the Revisor of Statutes of the effective
30 date of rules adopted as required by this act. Except as otherwise provided, this act is effective
31 when it becomes law.
32

33 **PART II. ESTABLISH STANDARDS FOR PHARMACY BENEFITS MANAGERS**

34 **SECTION 3.(a)** G.S. 58-56A-10 is recodified as G.S. 58-56A-40.

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

37 "Article 56A.

38 "Pharmacy Benefits Management.

39 **"§ 58-56A-1. Definitions.**

40 The following definitions apply in this Article:

- 41 (1) Claim. – A request from a pharmacy or pharmacist to be reimbursed for the
42 cost of filling, or refilling a prescription for a drug or for providing a medical
43 supply or device.
44 (2) Claims processing service. – The administrative services performed in
45 connection with the processing and adjudicating of claims relating to
46 pharmacist services that include either or both of the following:
47 a. Receiving payments for pharmacist services.
48 b. Making payments to pharmacists or pharmacies for pharmacist
49 services.

- 1 ~~(1)(3)~~ Health benefit plan. – As defined in G.S. 58-50-110~~(11)~~. ~~This definition~~
2 ~~specifically excludes the State Health Plan for Teachers and State~~
3 ~~Employees.G.S. 58-3-167.~~
- 4 ~~(1a)(4)~~ Insured. – An individual covered by a health benefit plan.
- 5 ~~(2)(5)~~ Insurer. – Any entity that provides or offers a health benefit plan.
- 6 ~~(6)~~ Maximum allowable cost list. – A listing of generic or multiple source drugs
7 used by a pharmacy benefits manager to set the maximum allowable cost on
8 which reimbursement of a pharmacy is made.
- 9 ~~(3)(7)~~ Maximum allowable cost price. – The maximum ~~per unit reimbursement for~~
10 amount that a pharmacy benefits manager will reimburse a pharmacy for the
11 cost of generic or multiple source prescription drugs, medical products, or
12 devices.
- 13 ~~(8)~~ Out-of-pocket costs. – With respect to the acquisition of a drug, the amount to
14 be paid by the insured under the plan or coverage, including any cost-sharing,
15 co-payment, coinsurance, or deductible.
- 16 ~~(9)~~ Pharmacy services administration organization. – An entity operating within
17 the State that contracts with independent pharmacies to conduct business on
18 their behalf with third-party payers. PSAOs provide administrative services to
19 pharmacies and negotiate and enter into contracts with third-party payers or
20 pharmacy benefits managers on behalf of pharmacies. A person or entity is
21 PSAO under this Article if it performs one or more of the following
22 administrative services to pharmacies:
- 23 a. Assistance with claims.
- 24 b. Assistance with audits.
- 25 c. Centralized payment.
- 26 d. Certification in specialized care programs.
- 27 e. Compliance support.
- 28 f. Setting flat fees for generic drugs.
- 29 g. Assistance with store layout.
- 30 h. Inventory management.
- 31 i. Marketing support.
- 32 j. Management and analysis of payment and drug dispensing data.
- 33 k. Provision of services for retail cash cards.
- 34 ~~(3a)(10)~~ Pharmacist. – A person licensed to practice pharmacy under Article 4A of
35 Chapter 90 of the General Statutes.
- 36 ~~(11)~~ Pharmacist services. – Products, goods, or services provided as a part of the
37 practice of pharmacy.
- 38 ~~(4)(12)~~ Pharmacy. – A pharmacy registered with the North Carolina Board of
39 Pharmacy.
- 40 ~~(5)(13)~~ Pharmacy benefits manager. – An entity who contracts with a pharmacy on
41 behalf of an insurer or third-party administrator to administer or manage
42 prescription drug ~~benefits~~.benefits to perform any of the following functions:
- 43 a. Processing claims for prescription drugs or medical supplies or
44 providing retail network management for pharmacies or pharmacists.
- 45 b. Paying pharmacies or pharmacists for prescription drugs or medical
46 supplies.
- 47 c. Negotiating rebates with manufacturers for drugs paid for or procured
48 as described in this Article.
- 49 ~~(14)~~ Pharmacy benefits manager affiliate. – A pharmacy or pharmacist that directly
50 or indirectly, through one or more intermediaries, owns or controls, is owned

1 or controlled by, or is under common ownership or control with a pharmacy
2 benefits manager.

3 ~~(6)~~(15) Third-party administrator. – As defined in G.S. 58-56-2.

4 **"§ 58-56A-2. Licensure.**

5 (a) A person or organization may not establish or operate as a pharmacy benefits manager
6 in this State for health benefit plans without obtaining a license from the Commissioner of the
7 Department of Insurance.

8 (b) The Commissioner shall prescribe the application for a license to operate in this State
9 as a pharmacy benefits manager and may charge an initial application fee of two thousand dollars
10 (\$2,000) and an annual renewal fee of one thousand five hundred dollars (\$1,500), provided the
11 pharmacy benefits manager application form must collect only the following information:

12 (1) The name, address, and telephone contact number of the pharmacy benefits
13 manager.

14 (2) The name and address of the pharmacy benefits manager's agent for service
15 of process in the State.

16 (3) The name and address of each person with management or control over the
17 pharmacy benefits manager.

18 (4) The name and address of each person with a beneficial ownership interest in
19 the pharmacy benefits manager.

20 (5) A signed statement indicating that, to the best of the applicant's knowledge,
21 no officer with management or control of the pharmacy benefit manager has
22 been convicted of a felony or has violated any of the requirements of State or
23 federal law applicable to pharmacy benefits managers, or, if the applicant
24 cannot provide that statement, a signed statement describing the relevant
25 conviction or violation.

26 (c) An applicant or a pharmacy benefits manager that is licensed to conduct business in
27 the State shall, unless otherwise provided for in this Article, file a notice describing any material
28 modification of the information required to be provided under this section.

29 (d) The Commissioner may adopt rules establishing the licensing requirements of
30 pharmacy benefits managers consistent with the provisions of this section.

31 **"§ 58-56A-3. Consumer protections.**

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

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

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

43 (1) The fee will be charged.

44 (2) The fee may not be reimbursed by the health benefit plan, insurer, or pharmacy
45 benefits manager.

46 (3) The charge is specifically agreed to by the health benefit plan or pharmacy
47 benefits manager.

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

50 (c1) To the extent allowable under federal and State law, when calculating an insured's
51 overall contribution to any out-of-pocket maximum or any cost-sharing requirement under a

1 health benefit plan, an insurer shall include any amounts paid by the insured or paid on behalf of
2 the insured by another person.

3 (d) Any contract for the provision of a network to deliver health care services between a
4 pharmacy benefits manager and insurer shall be made available for review by the Department.

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

7 **"§ 58-56A-4. Pharmacy and pharmacist protections.**

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

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

19 (c) A pharmacy or pharmacist shall not be prohibited or in any way restricted by a
20 pharmacy benefits manager from dispensing any prescription drug, including specialty drugs
21 dispensed by a credentialed and accredited pharmacy, allowed to be dispensed under a license to
22 practice pharmacy under Article 4A of Chapter 90 of the General Statutes.

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

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

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

31 (1) The original claim was submitted fraudulently.

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

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

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

36 (5) The adjustments were part of an attempt to limit overpayment recovery efforts
37 by a pharmacy benefits manager.

38 (g) Nothing in this section shall be construed to limit overpayment recovery efforts by a
39 pharmacy benefits manager.

40 **"§ 58-56A-5. Maximum allowable cost price.**

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

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

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

49 (b) A pharmacy benefits manager shall adjust or remove the maximum allowable cost
50 price for a prescription drug to remain consistent with changes in the national marketplace for
51 prescription drugs. A review of the maximum allowable cost prices for removal or modification

1 shall be completed by the pharmacy benefits manager at least once every seven business days,
2 and any removal or modification shall occur within seven business days of the review. A
3 pharmacy benefits manager shall provide a means by which the contracted pharmacies may
4 promptly review current prices in an electronic, print, or telephonic format within one business
5 day of the removal or modification.

6 (c) A pharmacy benefits manager shall ensure that dispensing fees are not included in the
7 calculation of maximum allowable cost price.

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

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

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

21 (3) No less than 10 calendar days after the applicable fill date to file an
22 administrative appeal.

23 (4) If an appeal is initiated, then the pharmacy benefits manager shall, within 10
24 calendar days after receipt of notice of the appeal, do either of the following:

25 a. If the appeal is upheld, the pharmacy benefits manager shall notify the
26 pharmacy or pharmacist, or designee, of the decision, make the change
27 in the maximum allowable cost effective as of the date the appeal is
28 resolved, permit the appealing pharmacy or pharmacist to reverse and
29 rebill the claim in question, and make the change effective for each
30 similarly situated pharmacy, as defined by the payer subject to the
31 Maximum Allowable Cost List, effective as of the date the appeal is
32 resolved.

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

38 **"§ 58-56A-20. Pharmacy benefits manager networks.**

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

48 (b) A pharmacy benefits manager shall not deny the right to any properly licensed
49 pharmacist or pharmacy to participate in a network on the same terms and conditions of other
50 participants in the network.

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

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

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

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

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

24 **"§ 58-56A-25. Pharmacy benefits manager affiliate disclosure; sharing of data.**

25 A pharmacy benefits manager shall not, in any way that is prohibited by HIPAA, transfer or
26 share records relative to prescription information containing patient-identifiable and
27 prescriber-identifiable data to a pharmacy benefits manager affiliate.

28 **"§ 58-56A-35. Enforcement.**

29 (a) The Commissioner may make an examination of the affairs of any pharmacy benefits
30 manager pursuant to the services that it provides for an insurer or a health benefit plan that are
31 relevant to determining if the pharmacy benefits manager is in compliance with this Article.
32 When making an examination, the Commissioner may retain attorneys, independent actuaries,
33 independent certified public accountants, or other professionals and specialists as examiners. The
34 pharmacy benefits manager shall bear the cost of retaining those persons.

35 (b) Pending, during, and after the examination of any pharmacy benefits manager, the
36 Commissioner shall not make public the information or data acquired, and the information or
37 data acquired during an examination is considered proprietary and confidential and is not a public
38 record under Chapter 132 of the General Statutes.

39 (c) The Commissioner may, after notice and hearing, promulgate reasonable rules and
40 regulations as are necessary or proper to carry out the provisions of this Article.

41 (d) Violations of this Article are subject to the penalties under G.S. 58-56A-40. After
42 notice and hearing, a pharmacy benefits manager may also be subject to revocation of, or a refusal
43 to renew, a license to operate in this State as a result of violations of this Article.

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

46 **"§ 58-56A-40. Civil Penalties for violations; administrative procedure.**

47 (a) Whenever the Commissioner has reason to believe that a pharmacy benefits manager
48 has violated any of the provisions of this Article with such frequency as to indicate a general
49 business practice, the Commissioner may, after notice and opportunity for a hearing, proceed
50 under the appropriate subsections of this section.

1 (b) If, under subsection (a) of this section, the Commissioner finds a violation of this
2 Article, the Commissioner may order the payment of a monetary penalty ~~as provided in~~
3 ~~subsection (c) of this section~~ or petition the Superior Court of Wake County for an order directing
4 payment of restitution as provided in subsections (d) and (e) of this section, or both. Each day
5 during which a violation occurs constitutes a separate violation.

6 (c) If the Commissioner orders the payment of a monetary penalty pursuant to subsection
7 (b) of this section, the penalty shall not be less than one hundred dollars (\$100.00) nor more than
8 one thousand dollars (\$1,000) per day for each prescription drug resulting from the pharmacy
9 benefit manager's failure to comply with G.S. 58-56A-5. In determining the amount of the
10 penalty, the Commissioner shall consider the degree and extent of harm caused by the violation,
11 the amount of money that inured to the benefit of the violator as a result of the violation, whether
12 the violation was committed willfully, and the prior record of the violator in complying or failing
13 to comply with laws, rules, or orders applicable to the violator. The clear proceeds of the penalty
14 shall be remitted to the Civil Penalty and Forfeiture Fund in accordance with G.S. 115C-457.2.
15 Payment of the civil penalty under this section shall be in addition to payment of any other
16 penalty for a violation of the criminal laws of this State.

17 (d) Upon petition of the Commissioner to the court pursuant to subsection (b) of this
18 section, the court may order the pharmacy benefits manager who committed a violation ~~specified~~
19 ~~in subsection (b) of this section under this Article~~ to make restitution in an amount that would
20 make whole any pharmacist harmed by the violation. The petition may be made at any time and
21 also in any appeal of the Commissioner's order.

22 (e) Upon petition of the Commissioner to the court pursuant to subsection (b) of this
23 section, the court may order the pharmacy benefits manager who committed a violation ~~specified~~
24 ~~in subsection (b) of this section under this Article~~ to make restitution to the Department for
25 expenses under subsection (f) of this section, incurred in the investigation, hearing, and any
26 appeals associated with the violation in such amount that would reimburse the agency for the
27 expenses. The petition may be made at any time and also in any appeal of the Commissioner's
28 order.

29 (f) The Commissioner may contract with consultants and other professionals with
30 relevant expertise as necessary and appropriate to conduct investigation, hearing, and appeals
31 activities as provided in this section. ~~Such~~ These contracts shall not be subject to G.S. 114-2.3,
32 G.S. 147-17, or Articles 3, 3C, and 8 of Chapter 143 of the General Statutes, together with rules
33 and procedures adopted under those Articles concerning procurement, contracting, and contract
34 review.

35 (g) Nothing in this section prevents the Commissioner from negotiating a mutually
36 acceptable agreement with any pharmacy benefits manager as to any civil penalty or restitution.

37 (h) Unless otherwise specifically provided for, all administrative proceedings under this
38 Article are governed by Chapter 150B of the General Statutes. Appeals of the Commissioner's
39 orders under this section shall be governed by G.S. 58-2-75."

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

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

47 **SECTION 3.(d)** This section is effective March 1, 2020, and applies to any contracts
48 entered into on or after that date.

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