



# SENATE BILL 432: Birth Center & Pharm Benefits Mgr. Licensure.

2019-2020 General Assembly

<b>Committee:</b>	House Rules, Calendar, and Operations of the House	<b>Date:</b>	October 22, 2019
<b>Introduced by:</b>	Sen. Ballard	<b>Prepared by:</b>	Jason Moran-Bates Staff Attorney
<b>Analysis of:</b>	PCS to Third Edition S432-CSBC-86		

**OVERVIEW:** Part I of the PCS to Senate Bill 432 establishes licensing requirements for birth centers including the creation of a NC Birth Center Commission, limitations of services, fees, inspections, a criminal penalty for operating a birth center without a license, and requirements for rules to be adopted by the Commission.<sup>1</sup>

Part II of the PCS would require pharmacy benefits managers (PBMs) to be licensed. It would also add to the consumer protections in G.S. 58-56A-3, restrict PBMs from prohibiting pharmacies from taking certain actions, and establish rules for claim overpayments and PBM networks. It would increase the Commissioner's ability to take enforcement action against PBMs. Finally, it would prevent insurers from requiring that insureds take prescription drugs with black box warnings and require insured to cover prescription drugs during the pre-authorization process.

## PART I: ESTABLISH LICENSURE PROCESS FOR BIRTH CENTERS

### BILL ANALYSIS:

**Section 1(a)** establishes the Birth Center Licensure Act in Part 4A, Article 6, of Chapter 131E, to provide licensing requirements for birth centers and including the following broad components:

- **Definitions** (G.S. 131E-153.1) – Defines the following terms: "birth center", "commission" and "low-risk pregnancy" A birth center is defined as 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.
- **Licensure** (G.S. 131E-153.2) – A birth center in the State must obtain a license from the Department of Health and Human Services. Information required on the licensure application is specified in the bill. Upon receipt of the application, the Department will issue a license upon the recommendation of the NC Birth Center Commission. The Department may charge a \$400 nonrefundable annual license fee plus a nonrefundable annual per birthing room fee of \$17.50.<sup>2</sup>

The licensure requirement will not become effective until one year after the rules promulgated by the NC Birth Center Commission are adopted. Accredited birth centers that are in operation on the date the act becomes effective will be permitted to continue operating while the Commission develops permanent rules

<sup>1</sup> The contents of Part I of the PCS were originally part of H575, which was given a favorable report by the House Rules Committee on July 8, 2019. It passed the House 114-1 on July 10, 2019.

<sup>2</sup> By way of comparison, fees for other health care-related facilities are as follows: adult care homes, \$315-360 based on the number of beds, plus \$17.50 per bed; ambulatory surgical facilities, \$850, plus \$75 per operating room; general acute hospitals, ranges from \$250-950 based on the number of beds, plus \$17.50 per bed; hospices, \$400; nursing homes, \$420, plus \$17.50 per bed; other hospitals, \$500, plus \$17.50 per bed; and registered multiunit assisted housing, \$350.

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for licensure. Within 90 days of the adoption of permanent rules regarding licensure applications, these birth centers must submit to the Commission a license application and the required fee.

- **NC Birth Center Commission** (G.S. 131E-153.7) – The Commission will consist of seven members (three licensed physicians providing obstetric care, three certified nurse midwives providing obstetric care, and one public member) and is charged with adopting rules establishing standards for licensure, operation and regulation of birth centers and reviewing and making recommendations to the Department about whether to approve or disapprove birth center license applications. The Governor appoints five members, the Speaker appoints one member, and the President Pro Tempore of the Senate appoints one member. **Section 1(d)** of the bill provides for the staggering of terms by setting the initial terms of office.
- **Adverse Action on a License** (G.S. 131E-153.3) – The Department is allowed to deny, suspend, or revoke a license when there is substantial failure to comply, and the Secretary may suspend admission of a patient if the conditions of the birth center are detrimental to the health or safety of the patient.
- **Limitations of Services** (G.S. 131E-153.4) – The following limitations apply to services at a licensed birth center:
  - Surgical procedures are limited to those normally accomplished during an uncomplicated birth, such as episiotomy and repair, as determined by the Commission.
  - No abortions may be performed.
  - No general or conduction anesthesia may be performed.
  - No Vaginal Birth After Cesarean (VBAC) or Trial of Labor After Cesarean (TOLAC) may be performed.
- **Inspections** (G.S. 131E-153.6) – The Department has 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 provision of the Part or rules adopted by the Commission. Further, the Department is authorized to inspect the birth centers as it deems necessary to investigate unexpected occurrences involving death of serious physical injury.
- **Rules** (G.S. 131E-153.8) – The NC Birth Center Commission is required to adopt rules for the following: accreditation; risk status; second trimester ultrasound; targeted ultrasound; transfer of patients to higher levels of care; sentinel events and adverse outcomes; and reporting requirements.
- **Confidential Information** (G.S. 131E-153.9) – Outlines when confidential or nonpublic information can be released.
- **Birth Center Fee Schedule** (G.S. 131E-153.5) – The Department is allowed to review and revise the Freestanding Birth Center Fee Schedule. **Section 1(b)** of the bill would require the Department of Health and Human Services by December 1, 2019, to review and revise if necessary, the Freestanding Birth Center Fee schedule to ensure fees are sufficient to cover the costs of providing care and the cost for any State-mandated newborn screening program is reimbursed at no less than the cost of the screening.
- **Penalties.** – The bill creates two new criminal offenses. It make it unlawful for a person to resist proper entry by an authorized representative of DHHS on the premises of a birth center. This provision would become effective December 1, 2019, and apply to offenses committed on or after that date. It also creates a Class 3 misdemeanor for a person to operate a birth center without a license. This provision would become effective one year after the rules are adopted by the Commission to coincide with when the licensing provision becomes effective, and apply to offenses committed on or after that date.

**EFFECTIVE DATE:** The criminal offense in G.S. 131E-153.6(b), as enacted by Section 1(a) of this act, would be effective December 1, 2019, and apply to offenses committed on or after that date. Section 1(b) of this act would be 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 would be 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.

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## **PART II: ESTABLISH STANDARDS FOR PHARMACY BENEFITS MANAGERS**

Section 3.(a) would repeal G.S. 58-56A-10.

Section 3.(b) would make several changes, including the addition of new sections, to Article 56A.

- 58-56A-1, an existing section, would add new definitions for "claim," "claims processing service," "maximum allowable cost list," "out-of-pocket costs," "pharmacy services administration organization," "pharmacist services," and "pharmacy benefits manager affiliate." The definition of "health benefit plan" would be amended to include the State Health Plan for Teachers and State Employees.
- 58-56A-2, a new section, would prohibit PBMs from operating without a license. The initial application fee would be \$2,000, and annual renewal fees would be \$1,500. Applicants would have to provide corporate and financial documents to the Department of Insurance as part of the application process. This section would also establish procedures for the Department to deny license applications.
- 58-56A-3, an existing section, would be amended to extend its current consumer protection provisions. Under the new language, PBMs could not prohibit pharmacies from charging a shipping and handling fee for mailed prescriptions. Insurers would also be required to count any amounts paid by a third party on behalf of an insured when computing the insured's maximum out-of-pocket contribution for a drug that (1) does not have a generic equivalent, or (2) has a generic equivalent, but only if the insured has gone through a prior authorization process.
- 58-56A-4, an existing section, would be extensively amended. It would:
  - Prohibit PBMs from charging fees not on the remittance form or agreed to in advance by then pharmacy.
  - Allow pharmacists to refuse to fill prescriptions if they believed the prescription was not in the patient's best interest, or if there were a question about the validity of the prescription.
  - PBMs would be prohibited from preventing pharmacies from dispensing any drug, including specialty drugs, and from retaliating against pharmacies.
  - Retroactive denials or reductions of paid claims would be prohibited in most circumstances.
- 58-56A-5, an existing section, would be amended to prohibit PBMs from including dispensing fees in the maximum allowable cost price. PBMs would also be required to establish a procedure for pharmacies to appeal PBMs' reimbursement decisions.
- 58-56A-20, a new section, would create new rules for PBM networks.
  - PBMs could require different accreditation standards for different pharmacies, so long as they do not discriminate against independent pharmacies, and the standards are not more stringent than federal and State requirements.
  - All network pharmacies must be able to participate on the same terms, without benefit differentials.
  - Pay-for-performance networks must use a nationally-recognized entity used to aid performance measures.

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- Payments due a pharmacy must be paid even if the pharmacy is terminated from the network.
- 58-56A-25, a new section, would prevent PBMs from sharing information in a manner that violated HIPAA.
- 58-56A-35, a new section, would allow the Commissioner to examine the books and records of a PBM and refer violations of this Article to the Attorney General. PBMs would bear the cost of the examinations, and any information submitted to the Department would not be a public record.
- 58-56A-40, a new section, would allow the Commissioner to deny, suspend, or revoke a PBM's license in several circumstances.
- 58-3-222, a new section, would prevent insurers from requiring insureds to take drugs that have an FDA black box warning and would require insurers to cover a prescription drug during the pre-authorization process for that drug. Insurers would not be required to approve drugs undergoing pre-authorization review.

**EFFECTIVE DATE:** Section 3 would be effective March 1, 2020, and apply to any contracts entered into on or after that date. Section 3.5 would be effective October 1, 2020 and would apply to insurance contracts issued, renewed, or amended on or after that date.

*\*Trina Griffin and Theresa Matula of the Legislative Analysis Division substantially contributed to this summary.*