

## Burgos, Alexander N

---

**Subject:** FW: Submission of Permanent Rule Technical Changes - 10A NCAC 13B  
**Attachments:** Response to RRC Staff Attorney for Hospital Rules 7-25-22.pdf

---

**From:** Pfeiffer, Nadine <[nadine.pfeiffer@dhhs.nc.gov](mailto:nadine.pfeiffer@dhhs.nc.gov)>  
**Sent:** Wednesday, July 27, 2022 8:58 AM  
**To:** Rules, Oah <[oah.rules@oah.nc.gov](mailto:oah.rules@oah.nc.gov)>  
**Cc:** Liebman, Brian R <[brian.liebman@oah.nc.gov](mailto:brian.liebman@oah.nc.gov)>; Randolph, Kimberly <[krandolph@ncdoj.gov](mailto:krandolph@ncdoj.gov)>; Conley, Azzie <[azzie.conley@dhhs.nc.gov](mailto:azzie.conley@dhhs.nc.gov)>  
**Subject:** Submission of Permanent Rule Technical Changes - 10A NCAC 13B

We have been notified of the technical changes requested by Mr. Brian Liebman on June 3, 2022 pursuant to G.S. 150B-21.10 for the following rules: 10A NCAC 13B .3801, .3903, .4103, .4104, .4106, .4305, .4603, .4801, .4805, .5102, .5406, and .5408. In preparation for the August 18, 2022 RRC meeting, attached to this email you will find the amended text for rules 10A NCAC 13B .3801, .3903, .4305, .4805, and .5408 as requested in the Request for Technical Change document received, as well as the Agency's responses to the concerns raised in the "Request for Changes" document as seen in bold black font on the document. In addition, to accompany the Agency's responses to the "Request for Changes" attached is an additional document titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22" that addresses the statutory authority concerns and staff opinion issued by Mr. Liebman on June 7, 2022 for these rules.

Should you have any questions regarding the attachments, please feel free to contact me. \*\*\*Please note, I will be on annual leave August 3 through August 9.

Thank you,

**Nadine Pfeiffer**  
Rules Review Manager  
Division of Health Service Regulation  
[NC Department of Health and Human Services](http://www.ncdhhs.gov)

Office: 919-855-3811  
Fax: 919-733-2757  
[nadine.pfeiffer@dhhs.nc.gov](mailto:nadine.pfeiffer@dhhs.nc.gov)

809 Ruggles Drive, Edgerton Building  
2701 Mail Service Center  
Raleigh, NC 27699-2701

---

Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized State official. Unauthorized disclosure of juvenile, health, legally privileged, or otherwise confidential information, including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this email in error, please notify the sender immediately and delete all records of this email.

---

Email correspondence to and from this address may be subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized state official.

Agency Response to  
Hospital Rules Statutory Authority Opinion  
by Brian Lieberman

The Medical Care Commission (“MCC”) was created by the General Assembly in 1973. Pursuant to N.C. Gen. Stat. § 143B-165:

(6) The Commission has the duty to adopt rules and regulations and *standards* with respect to the different types of hospitals to be licensed under the provisions of Article 13A of Chapter 131 of the General Statutes of North Carolina.

N.C. Gen. Stat. § 143B-165(6)(*emphasis added*).

Chapter 131, Article 13A, the Hospital Licensing Act (Attachment A) was repealed and replaced with Chapter 131E, Article 5, the Hospital Licensure Act. The North Carolina General Statutes Annotated for Chapter 131 (Attachment B) includes as *Cross References* “[a]s to health care facilities and services, see now Chapter 131E.” Although, the reference to Article 13A was not changed in N.C. Gen. Stat. § 143B-165(6), the General Assembly did not remove the duty of the MCC to promulgate standards for hospital. The Hospital Licensing Act and the Hospital Licensure Act are in reference to facilities that provide medical and nursing care to two or more individuals in excess of 24 hours. Both are in reference to the same type of facility, a hospital. See N.C. Gen. Stat. § 131E-76(3).

The purpose of Article 5 of Chapter 131E, the Hospital Licensure Act (the “Hospital Licensure Act”) is to “establish hospital licensing requirements which promote public health, safety and welfare and to provide for the development, *establishment and enforcement of basic standards for the care and treatment of patients in hospitals.*” See N.C. Gen. Stat. § 131E-75 (*emphasis added*).

Article 5.

Hospital Licensure Act.

Part 1. Article Title and Definitions.

**§ 131E-75. Title; purpose.**

- (a) This Article shall be known as the "Hospital Licensure Act."
- (b) The purpose of this article is to establish hospital licensing requirements which promote public health, safety and welfare and to provide for the development, establishment and enforcement of basic standards for the care and treatment of patients in hospitals.

N.C. Gen. Stat. § 131E-75.

The Hospital Licensure Act requires and expressly authorizes the MCC to promulgate rules necessary to carry out the Article. Pursuant to N.C. Gen. Stat. § 131E-79(a) & (b), the Commission is mandated to promulgate rules to carry out the Article and the North Carolina Department of

Health and Human Services (“Department” or “Agency”) is then charged with enforcing these rules, including the rules that establish basic standards of safe care for patients. *See* N.C. Gen. Stat. §§ 131E-75(b) and -79(a) & (b).

**§ 131E-79. Rules and enforcement.**

- (a) The Commission shall promulgate rules necessary to implement this Article.
- (b) The Department shall enforce this Article and the rules of the Commission.

N.C. Gen. Stat. § 131E-79.

The Department is charged with the responsibility of determining if an initial license should be issued to a hospital and determining if the license should be renewed on an annual basis. *See* N.C. Gen. Stat. § 131E-77(a) & (d).

**§ 131E-77. Licensure requirement.**

- (a) No person or governmental unit shall establish or operate a hospital in this state without a license. An infirmary is not required to obtain a license under this Part.
- (b) The Commission shall prescribe by rule that any licensee or prospective applicant seeking to make specified types of alteration or addition to its facilities or to construct new facilities shall submit plans and specifications before commencement to the Department for preliminary inspection and approval or recommendations with respect to compliance with the applicable rules under this Part.
- (c) An applicant for licensing under this Part shall provide information related to as requested by the Department. The required information shall be submitted by the applicant on forms provided by the Department and established by rule.
- (d) Upon receipt of an application for a license, the Department shall issue a license if it finds that the applicant complies with the provisions of this Article and the rules of the Commission. The Department *shall renew* each license in accordance with the rules of the Commission...

N.C. Gen. Stat. § 131E-77(a) & (d)(*emphasis added*).

In issuing and renewing licenses, the Department is required to assess if a hospital is meeting the “requirements which promote public health, safety and welfare to provide for the development, establishment and enforcement of basic standards for the care and treatment of patients” including “information related to hospital operations as requested by the Department.” *See* N.C. Gen. Stat. §§ 131E-75(b) and -77(d).

The licensing of a hospital encompasses ongoing regulation beyond that of the initial license. *See* N.C. Gen. Stat. § 131E-77(a). After the Department issues an initial license, the Department has “the authority to deny, suspend, revoke, annul, withdraw, recall, cancel, or amend a license...” after issuance. *See* N.C. Gen. Stat. § 131E-78(a). The Department inspects the hospital to validate continuing compliance with providing the basic standards of care and treatment of patients. *See* N.C. Gen. Stat. § 131E-80(a) & (d). To aid in this process, the Department has the

authority to inspect hospital records involving admission, discharge, medication, and treatment. *See* N.C. Gen. Stat. § 131E-80(d). When the hospital is in compliance with this Part and the rules, the Department issues a renewal license. N.C. Gen. Stat. § 131E-77(d).

Therefore, the regulated hospitals must be informed of the operational standards related to the health, safety, and basic standards of care and treatment of the patients, that the Department will survey during complaint and compliance inspections, to maintain its license and avoid adverse action on the license. *See* N.C. Gen. Stat. § 131E-80(d). For example, Rule 10A NCAC 13B .4103 outlines exactly what the Department will be reviewing for facilities providing emergency services to ensure all patients receive fair, timely, and consistent treatment, including medical direction, in an emergency.

In turn, the Department must establish, through rules, the operational minimum standards related to the health, safety and basic standards of care and treatment of patients it will use during complaint and compliance inspections, in order for regulated hospitals to ensure compliance. For example, when a patient goes to the hospital for imaging services, they have some assurance that the employee is qualified, supervised by a physician, the equipment is safe, and the radiation exposure is handled appropriately. *See* Rule 10 NCAC 13B .4805. In both examples, Rules 10A NCAC 13B .4103 and 10A NCAC 13B .4805, the Agency has set the standard, informed the hospitals of the standards and will conduct inspections for compliance according to the standards in order to protect the public's health, safety, and welfare.

The Supreme Court has said, since early times, that to require proficiency and skill in the business mentioned is, an exercise of the police power “for the protection of the public against incompetents and impostors.” *State. v. Call*, 121 N.C. 643, 28 S.E. 517 (1897). It is upon the same principles “that the Legislature has required a license of physicians, surgeons, osteopaths, chiropractors, chiropodists, dentists, opticians, barbers, and others[.]” *Roach v Durham*, 204 N.C. 587, 591, 169 S.E. 149, 151 (1993) (citations and quotation marks omitted). The Legislature has determined that the same is true for hospitals. The MCC is responsible for developing the hospital rules for licensing and safety standards similar to the other agencies created by the General Assembly for the various other licenses issued in North Carolina. *Igram v. N.C. State Bd. Of Plumbing, Heating and Fire Sprinkler, Contrs.*, 269 N.C. App. 476, 839 S.E.2d 74 (2020).

The requirement for express authority does not equate to a requirement for the Legislature to specify, subject by subject, each area of rule promulgation to an agency. The General Assembly has not specifically enumerated every area of rule promulgation with any of the agencies creating rules for licensing. Instead, the General Assembly expressly authorizes the agencies to promulgate rules.

The Dental Examiners, for example, have authority to create rules to govern the practice of dentistry in N.C. Gen. Stat. § 90-48. Based on this authority, Rules 21 NCAC 16P .0101-.0105 is used to regulate communications concerning dental services and advertising which are not specified topics for rules addressed in the Article. Similarly, Rule 21 NCAC 16T .010 requires a record retention period of 10 years even though the Legislature did not specifically instruct the Dental Examiners to set a period for record retention.

The Board of Chiropractic Examiners has authority to create rules necessary to carry out and enforce the provisions of the Chapter 90, Article 8. *See* N.C. Gen. Stat. § 90-142. This express authority has resulted in the creation of rules such as 21 NCAC 10 .0208 Acupuncture and 21 NCAC 10 .0305 Prepaid Treatment Plans. The words “acupuncture” and “prepaid treatment plans” are not in Chapter 90, Article 8; instead, the Legislature gave express authority for creation of these rules for protection of the public under the practice of medicine and allied occupations.

The same is true here; the Legislature gave express authority for the creation of rules for protection of the public in hospitals and medical facilities. A hospital license is a representation to the public that the hospital will adhere to basic standards for the care and treatment of patients established by the MCC and enforced by the Department, which promote public health, safety, and welfare. *See* N.C. Gen. Stat. §§ 131E-75(b) and -79(a) & (b). A renewed license is a representation to the public that the hospital continues to adhere to the basic standards for the care and treatment of patients that promote public health, safety, and welfare. *Id.*

The hospital rules listed below are necessary for the protection of the health, safety, and welfare of patients in hospitals in North Carolina and provide minimum standards for the care and treatment of patients. The MCC respectfully requests the Rules Review Commission find that these rules are within the authority delegated to the MCC by the General Assembly.

10A NCAC 13B .3801	Nurse Executive
10A NCAC 13B .3903	Preservation of Medical Records
10A NCAC 13B .4103	Provision of Emergency Services
10A NCAC 13B .4104	Medical Director
10A NCAC 13B .4106	Policies and Procedures
10A NCAC 13B .4305	Organization of Neonatal Services
10A NCAC 13B .4603	Surgical and Anesthesia Staff
10A NCAC 13B .4801	Organization
10A NCAC 13B .4805	Safety
10A NCAC 13B .5102	Policies and Procedures
10A NCAC 13B .5105	Sterile Supply Services
10A NCAC 13B .5406	Discharge Criteria For Inpatient Rehabilitation Facilities or Units
10A NCAC 13B .5408	Comprehensive Inpatient Rehabilitation Program Staffing Requirements
10A NCAC 13B .5411	Repealed

A

# THE NORTH CAROLINA MEDICAL CARE COMMISSION

## CHAPTER 131. GENERAL STATUTES OF NORTH CAROLINA

### ARTICLE 13A

#### HOSPITAL LICENSING ACT

Sec. 131-126.1. *Definitions.*—As used in this article. (a) "Hospital" means an institution devoted primarily to the rendering of medical, surgical, obstetrical, or nursing care, which maintains and operates facilities for the diagnosis, treatment or care of two or more nonrelated individuals suffering for illness, injury or deformity, or where obstetrical or other medical or nursing care is rendered over a period exceeding twenty-four hours.

The term "hospital" for clarification purposes, includes, but not by way of limitation, an institution that receives patients and renders for them diagnostic, medical, surgical and nursing care; and "hospital" means also an allied institution that provides for patients diagnostic, medical, surgical and nursing care in branches of medicine such as obstetric, pediatric, orthopedic, and eye, ear, nose and throat and cardiac services, and in the diagnosis and treatment of mental and neurological ailments, and in the diagnosis and treatment and care of chronic diseases and transmissible diseases.

The term "hospital" as used in this article does not apply to a welfare institution, the primary purpose of which is to provide domiciliary and/or custodial care to its residents, and it does not apply to an infirmary which such institution may maintain to provide medical and nursing care for its residents.

Further to distinguish a "hospital" from a "welfare institution," as the term is used in this article, the latter means orphanages; penal and correctional institutions; home for the county or city poor, aged, and infirm; nursing homes for the mentally and physically infirm; homes for the aged; and convalescent and rest homes; and homes for pregnant women who require public assistance and/or custodial care or obstetrical and nursing care in such home, or nursing care prior to or subsequent to delivery in a "hospital."

(b) "Person" means any individual, firm, partnership, corporation, company, association, or joint stock association; and includes any trustee, receiver, assignee or other similar representative thereof.

(c) "Governmental unit" means the state, or any county, municipal or other political subdivision or any department, division, board or other agency of any of the foregoing.

(d) "Commission" means the North Carolina Medical Care Commission as established by chapter 1096 of the Session Laws of 1945, as amended, and as the same may be hereafter amended.

Sec. 131-126.2 *Purpose.*—The purpose of this article is to provide for the development, establishment and enforcement of basic standards (1) for the care and treatment of individuals in hospitals and (2) for the construction, maintenance and operation of such hospitals, which, in the light of existing knowledge, will ensure safe and adequate treatment of such individuals in hospitals, provided, that nothing in this article shall be construed as repealing any of the provisions of article 27 of chapter 130 of the General Statutes of North Carolina.

Sec. 131-126.3. *Licensure.*—After July 1st, 1947, no person or governmental unit, acting severally or jointly with any other person or governmental unit shall establish, conduct or maintain a hospital in this state without a license. None of the provisions of Chapter 104C of the General Statutes shall apply to X-ray facilities in or as a part of any hospital or medical facility which is, or will upon its completion become, subject to the provisions of law relating to the licensing thereof by the North Carolina Medical Care Commission pursuant to this Article.

Sec. 131-126.4. *Application for license.*—Licenses shall be obtained from the Commission. Applications shall be upon such forms and shall contain such information as the said Commission may reasonably require, which may include affirmative evidence of ability to comply with such reasonable standards, rules and regulations as may be lawfully prescribed hereunder.

Sec. 131-126.5. *Issuance and renewal of license.*—Upon receipt of an application for license, the Commission shall issue a license if it finds that the applicant and hospital facilities comply with the provisions of this article and the regulations of the said Commission. Each such license, unless sooner suspended or revoked, shall be renewable annually without charge upon filing of the license, and approval by the Commission, of an annual report upon such uniform dates and containing such information in such form as the Commission shall prescribe by regulation. Each license shall be issued only for the premises and persons or governmental units named in the application and shall not be transferable or assignable except with the written approval of the Commission. Licenses shall be posted in a conspicuous place on the licensed premises as prescribed by regulation of the said Commission.

Sec. 131-126.6. *Denial or revocation of license; hearings and review.*—The Commission shall have the authority to deny, suspend or revoke a license in any case where it finds that there has been a substantial failure to comply with the provisions of this article or the rules, regulations or minimum standards promulgated under this article.

Such denial, suspension, or revocation shall be effected by mailing to the applicant or licensee by registered mail, or by personal service of, a notice setting forth the particular reasons for such action. Such denial, suspension, or revocation shall become effective thirty days after the mailing or

B

GENERAL STATUTES  
OF  
NORTH CAROLINA

ANNOTATED



2021 EDITION



## CHAPTER 131. PUBLIC HOSPITALS.

§§ 131-1 through 131-188: Repealed by Session Laws 1983, c. 775, s. 1.

### Cross References.

As to health care facilities and services, see now Chapter 131E.

### Editor's Note.

Session Laws 1983, c. 775, s. 3, provides: "Sec. 3. Notwithstanding the foregoing, any unit of government, or units of government acting jointly, that as of December 31, 1983, is operating a hospital or hospitals pursuant to Articles 2 or 2A of Chapter 131 of the General Statutes may continue to operate pursuant to the provisions of those Articles as they existed on December 31, 1983, to the extent that those Articles are inconsistent with this Chapter. However, a unit of government that has been operating a hospital pursuant to those Articles may choose to continue operations under the provisions of one of the Parts of Article 2 of this Chapter by adopting an appropriate resolution and by satisfying all other requirements of the relevant Part of Article 2 of this Chapter."

Session Laws 1989, c. 283, effective June 12, 1989, amends G.S. 131-7. Session Laws 1989, c. 283, ss. 1 and 2 provide:

"Section 1. G.S. 131-7, as it applies to hospitals continuing to operate under Article 2, Chapter 131 of the North Carolina General Statutes pursuant to Section 3, Chapter 775 of the 1983 Session Laws, is amended by rewriting the first sentence to read: 'Should a majority of the qualified voters upon the question be in favor of establishing such county, township, or town hospital, the governing body shall proceed at once to appoint seven trustees chosen from the citizens at large with reference to their fitness for such office, all residents of the county, township or town, who shall constitute a board of trustees for such public hospital.'

"Sec. 2. G.S. 131-7 is amended by deleting the phrase 'No practicing physician may serve as a trustee,' and substituting 'One practicing physician may serve as a trustee.'"

Session Laws 1999-377, s. 1, effective August 4, 1999, amends G.S. 131-4 as it applies to hospitals continuing to operate under Article 2, Chapter 131 of the North Carolina General Statutes pursuant to Section 3, Chapter 775 of the 1983 Session Laws, by adding a new subdivision to read:

"(4) Extension of Tax Levy. Prior to or following the expiration of the tax levy specified in subdivision (3) of this section, a new petition may be presented to the governing body of any

county in which a township is located, signed by 200 resident freeholders of such township asking that an annual tax continue to be levied for the maintenance, operation, and improvement of the public hospital, after the expiration of the tax levy specified in subdivision (3). The procedure for submitting the petition and holding an election on the issue of continuing the tax levy shall be the same as the procedure for the petition and election for establishment of the initial tax levy, provided that the requirement that 150 of the 200 petitioners not be residents of the city, town, or village where the hospital is to be located shall not apply. The tax to be levied under such new election shall not exceed one twenty-fifth of one cent ( $\frac{1}{25}$  of 1 cent) on the dollar (\$1.00) for a period of time not exceeding 30 years and shall be for the issue of county or township bonds to provide funds for the maintenance and improvement of the public hospital."

Session Laws 1999-377, s. 2, amends G.S. 131-5 by adding a sentence providing that the procedure for submission of the issue of continuation of the tax levy is to be the same as set forth previously in G.S. 131-5, so long as the tax is not to exceed one twenty-fifth of one cent on the dollar, and by providing the statement to be used on ballots when the issue is submitted.

Session Laws 1999-377, s. 3, provides that all hospitals which continue to operate under Article 2 of Chapter 131, of the General Statutes pursuant to Section 3 of Chapter 775 of the 1983 Session Laws, shall, in addition to the powers granted in that article have the powers set forth in G.S. 131E-7(a)(1), (3), (5), (6), 131E-7(b), 131E-7(c), 131E-7.1, 131E-11, 131E-23(1), (2), (5), (6), (7), (8), (10), (11), (12), (13), (14), (15), (16), (17), (18), (19), (23), (24), (25), (26), (27), (28), (30), (31), (32), (33), (34), 131E-26, and 131E-27.

Session Laws 1999-377, s. 4, provides that any hospital continuing to operate under Article 2 of Chapter 131, pursuant to Section 3 of Chapter 775 of the 1983 Session Laws, shall be considered a "public hospital" within the meaning of G.S. 159-39 and a "unit of local government" within the meaning of G.S. 160A-20.

Session Laws 2018-81, s. 2(a), (b), provides: "(a) All hospitals that continue to operate under Article 2 of Chapter 131 of the General Statutes pursuant to Section 3 of Chapter 775 of the 1983 Session Laws may, in addition to the powers and authorities set forth in said Article

2 of Chapter 131 of the General Statutes, exercise each of the powers, authorities, and exemptions set forth in the following provisions of Chapter 131E of the General Statutes, singly or in combination:

- "(1) G.S. 131E-7(a)(1), (3), (5), and (6).
- "(2) G.S. 131E-7(b).
- "(3) G.S. 131E-7(c).
- "(4) G.S. 131E-7(f).
- "(5) G.S. 131E-7.1.
- "(6) G.S. 131E-8.
- "(7) G.S. 131E-10.
- "(8) G.S. 131E-11.
- "(9) G.S. 131E-13.
- "(10) G.S. 131E-14.1.

- "(11) G.S. 131E-23(a)(1) through (38).
- "(12) G.S. 131E-23(b).
- "(13) G.S. 131E-23(d).
- "(14) G.S. 131E-26.
- "(15) G.S. 131E-27.
- "(16) G.S. 131E-32.
- "(17) G.S. 131E-47.1.

"(b) This act amends and adds to the powers and authorities previously conveyed by Section 3 of S.L. 1999-377 to hospitals that continue to operate under Article 2 of Chapter 131 of the General Statutes. This act is not intended to alter or amend the remaining provisions of S.L. 1999-377."