RRC STAFF OPINION

PLEASE NOTE: THIS COMMUNICATION IS EITHER 1) ONLY THE RECOMMENDATION OF AN RRC STAFF ATTORNEY AS TO ACTION THAT THE ATTORNEY BELIEVES THE COMMISSION SHOULD TAKE ON THE CITED RULE AT ITS NEXT MEETING, OR 2) AN OPINION OF THAT ATTORNEY AS TO SOME MATTER CONCERNING THAT RULE. THE AGENCY AND MEMBERS OF THE PUBLIC ARE INVITED TO SUBMIT THEIR OWN COMMENTS AND RECOMMENDATIONS (ACCORDING TO RRC RULES) TO THE COMMISSION.

AGENCY: Medical Care Commission

RULE CITATION: 10A NCAC 13B .3801, .3903, .4103, .4104, .4106, .4305, .4603, .4801, .4805, .5102, .5105, .5406, .5408, .5411

RECOMMENDATION DATE: July 13, 2023

RECOMMENDED ACTION:

X Approve, but note staff's comment

Object, based on:

Lack of statutory authority

Unclear or ambiguous

Unnecessary

Failure to comply with the APA

Extend the period of review

COMMENT:

At the August 2022 meeting, the Commission objected to these Rules on the basis of lack of statutory authority, as no existing statute gave the Medical Care Commission the authority to regulate hospitals outside the grounds described in the Hospital Licensure Act (G.S. 131E, Article 5).

Subsequently, the General Assembly passed SL 2023-65, which in relevant part changes G.S. 143B-165 to give MCC the following rulemaking authority:

> The Commission shall adopt rules establishing standards for the licensure, inspection, and operation of, and the provision of care and services by, the different types of hospitals to be licensed under Articles 2 and 5 of Chapter 131E of the General Statutes.

Brian Liebman
Commission Counsel

The agency has submitted amended versions of its rules removing citations to G.S. 131E-75 and 131E-79 and substituting G.S. 143B-165 as the relevant rulemaking authority in its history notes. Given the statutory change, it is staff's opinion that the Commission's objections on the basis of lack of statutory authority have been satisfied, and staff now recommends approval of all rules.

Attached, please find the relevant portion of SL 2023-65, and a copy of the August 2022 staff opinion recommending objection, which the Commission previously adopted.

Brian Liebman
Commission Counsel

Health, Developmental Disabilities, and Substance Abuse Services; the Division of Child and Family Well-Being; and the Division of Health Benefits. Upon receipt of a notification from a director, the Rapid Response Team shall evaluate the information provided and coordinate a response to address the immediate needs of the juvenile, which may include any of the following:

(1) Identifying an appropriate level of care for the juvenile.
(2) Identifying appropriate providers or other placement for the juvenile.
(3) Making a referral to qualified services providers.
(4) Developing an action plan to ensure the needs of the juvenile are met.
(5) Developing a plan to ensure that relevant parties carry out any responsibilities to the juvenile."

PART IV. LAWS PERTAINING TO THE DIVISION OF HEALTH SERVICE REGULATION

MEDICAL CARE COMMISSION CLARIFICATION OF POWERS AND DUTIES

SECTION 4.1. G.S. 143B-165 reads as rewritten:

"**§ 143B-165. North Carolina Medical Care Commission – creation, powers and duties.**

There is hereby created the North Carolina Medical Care Commission of the Department of Health and Human Services with the power and duty to ~~promulgate~~ adopt rules ~~and regulations~~ to be followed in the construction and maintenance of public and private hospitals, medical centers, and ~~related~~ facilities ~~with the power and duty~~ regulated under Chapters 131D and 131E of the General Statutes; to adopt, amend and rescind rules ~~and regulations~~ under and not inconsistent with the laws of the State as necessary to carry out the provisions and purposes of this ~~Article.~~Article; and to protect the health, safety, and welfare of the individuals served by these facilities.

(1) The North Carolina Medical Care Commission ~~has the duty to~~ shall adopt statewide plans for the construction and maintenance of hospitals, medical centers, and ~~related facilities,~~ facilities regulated under Chapters 131D and 131E of the General Statutes, or such other plans as may be found desirable and necessary ~~in order~~ to meet the requirements and receive the benefits of any applicable federal ~~legislation with regard thereto.~~legislation.
(2) The Commission ~~is authorized to~~ may adopt such rules ~~and regulations~~ as may be necessary to carry out the intent and purposes of Article ~~13~~ 4 of Chapter ~~131~~ 131E of the General ~~Statutes of North Carolina.~~Statutes.
~~(3) The Commission may adopt such reasonable and necessary standards with reference thereto as may be proper to cooperate fully with the Surgeon General or other agencies or departments of the United States and the use of funds provided by the federal government as contained and referenced in Article 13 of Chapter 131 of the General Statutes of North Carolina.~~
(4) The Commission ~~shall have~~ has the power and duty to approve projects in the amounts of grants-in-aid from funds supplied by the federal and State governments for the planning and construction of hospitals and other related medical facilities ~~according to the provisions of Article 13~~ in accordance with Articles 4 and 5 of Chapter ~~131~~ 131E of the General ~~Statutes of North Carolina.~~Statutes.
(5) Repealed by Session Laws 1981 (Regular Session, 1982), c. 1388, s. 3.
(6) The Commission ~~has the duty to~~ shall adopt rules ~~and regulations and standards with respect to~~ establishing standards for the licensure, inspection, and operation of, and the provision of care and services by, the different types of hospitals to be licensed under ~~the provisions of Article 13A~~ Articles 2 and 5 of Chapter ~~131~~ 131E of the General ~~Statutes of North Carolina.~~Statutes.

(7) The Commission ~~is authorized and empowered to~~ may adopt such ~~rules and regulations,~~ rules, not inconsistent with the laws of this State, as may be required by the federal government ~~for~~ to secure federal grants-in-aid for medical facility services and ~~licensure which may be made available to the State by the federal government.~~ licensure. This section ~~is to~~ shall be liberally construed in order that the State and its citizens may benefit from such grants-in-aid.

(8) The Commission shall adopt such ~~rules and regulations,~~ rules, consistent with the provisions of this Chapter. All rules ~~and regulations not inconsistent with the provisions of this Chapter heretofore~~ adopted by the ~~North Carolina Medical Care~~ Commission since the enactment of Chapter 131E of the General Statutes that are not inconsistent with the provisions of this Chapter shall remain in full force and effect ~~unless and~~ until repealed or superseded by action of the ~~North Carolina Medical Care~~ Commission. All rules ~~and regulations~~ adopted by the Commission shall be enforced by the Department of Health and Human Services.

(9) The Commission ~~shall have the power and duty to~~ may adopt rules ~~and regulations with regard to~~ concerning emergency medical services in accordance with the provisions of Article ~~26~~ 7 of Chapter ~~130~~ 131E and Article 56 of Chapter 143 of the General ~~Statutes of North Carolina.~~Statutes.

(10) The Commission ~~shall have the power and duty to~~ shall adopt rules for the operation of nursing homes, as defined by Article 6 of Chapter 131E of the General Statutes.

(11) The Commission ~~is authorized to~~ may adopt ~~such~~ rules as ~~may be~~ necessary to ~~carry out the provisions of Part C of Article 6, and Article 10,~~ establish standards for the licensure, inspection, and operation of, and the provision of care and services by, facilities licensed under Articles 6 and 10 of Chapter 131E of the General ~~Statutes of North Carolina.~~Statutes.

(12) The Commission shall adopt ~~rules, including temporary rules pursuant to G.S. 150B-13,~~ rules providing for the accreditation of facilities that perform mammography procedures and for laboratories evaluating screening pap smears. Mammography accreditation standards shall address, but are not limited to, the quality of mammography equipment used and the skill levels and other qualifications of personnel who administer mammographies and personnel who interpret mammogram results. The Commission's standards shall be no less stringent than those established by the United States Department of Health and Human Services for Medicare/Medicaid coverage of screening mammography. These rules shall also specify procedures for waiver of these accreditation standards on an individual basis for any facility providing screening mammography to a significant number of patients, but only if there is no accredited facility located nearby. The Commission may grant a waiver subject to any conditions it deems necessary to protect the health and safety of patients, including requiring the facility to submit a plan to meet accreditation standards.

(13) The Commission ~~shall have the power and duty to~~ shall adopt rules establishing standards for the ~~inspection and licensure of~~ licensure, inspection, and operation of, and the provision of care and services by, adult care ~~homes and operation of adult care~~ homes, as defined by Article 1 of Chapter 131D of the General Statutes, and for personnel requirements of staff employed in adult care homes, except ~~where~~ when rule-making authority is assigned by law to the Secretary.

(14) The Commission shall adopt rules establishing standards for the following with respect to facilities used as multiunit assisted housing with services, as defined by Article 1 of Chapter 131D of the General Statutes:

a. Registration and deregistration.
b. Disclosure statements.
c. Agreements for services.
d. Personnel requirements.
e. Resident admissions and discharges."

PART V. LAWS PERTAINING TO THE DIVISION OF MENTAL HEALTH, DEVELOPMENTAL DISABILITIES, AND SUBSTANCE ABUSE SERVICES

TECHNICAL CHANGES/POPULATIONS COVERED BY LME/MCOS

SECTION 5.1.(a) G.S. 122C-115 reads as rewritten:

"**§ 122C-115. Duties of counties; appropriation and allocation of funds by counties and cities.**

…

(e) Beginning ~~on the date that capitated contracts under Article 4 of Chapter 108D of the General Statutes begin,~~ July 1, 2021, LME/MCOs shall cease managing Medicaid services for all Medicaid recipients ~~other than recipients described in G.S. 108D-40(a)(1), (4), (5), (6), (7), (10), (11), (12), and (13).~~ who are enrolled in a standard benefit plan.

(e1) Until BH IDD tailored plans become operational, all of the following shall occur:

(1) LME/MCOs shall continue to manage the Medicaid services that are covered by the LME/MCOs under the combined 1915(b) and (c) waivers for Medicaid recipients ~~described in G.S. 108D-40(a)(1), (4), (5), (6), (7), (10), (11), (12), and (13).~~who are covered by the those waivers and who are not enrolled in a standard benefit plan.

(2) The Division of Health Benefits shall negotiate actuarially sound capitation rates directly with the LME/MCOs based on the change in composition of the population being served by the LME/MCOs.

(3) Capitation payments under contracts between the Division of Health Benefits and the LME/MCOs shall be made directly to the LME/MCO by the Division of Health Benefits.

(f) ~~Entities~~ LME/MCOs operating the BH IDD tailored plans under G.S. 108D-60 may continue to manage the behavioral health, intellectual and developmental disability, and traumatic brain injury services for any Medicaid recipients ~~described in G.S. 108D-40(a)(4), (5), (7), (10), (11), (12), and (13) under any contract with the Department in accordance with G.S. 108D-60(b).~~who are not enrolled in a BH IDD tailored plan."

SECTION 5.1.(b) G.S. 108D-60(b) reads as rewritten:

"(b) The Department may contract with entities operating BH IDD tailored plans under a capitated or other arrangement for the management of behavioral health, intellectual and developmental disability, and traumatic brain injury services for any recipients ~~excluded from PHP coverage under G.S. 108D-40(a)(4), (5), (7), (10), (11), (12), and (13).~~who are not enrolled in a BH IDD tailored plan."

SECTION 5.1.(c) G.S. 122C-3 reads as rewritten:

"**§ 122C-3. Definitions.**

The following definitions apply in this Chapter:

…

(2b) ~~"Behavioral~~ Behavioral health and intellectual/developmental disabilities tailored ~~plan"~~ plan or ~~"BH~~ BH IDD tailored ~~plan" has the same meaning as~~ plan. – As defined in G.S. 108D-1.

RRC STAFF OPINION

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AGENCY: Medical Care Commission

RULE CITATION: 10A NCAC 13B .3801, .3903, .4103, .4104, .4106, .4305, .4603, .4801, .4805, .5102, .5105, .5406, .5408, .5411

RECOMMENDED ACTION:

Approve, but note staff's comment

X Object, based on:

X Lack of statutory authority (All Rules)

Unclear or ambiguous

Unnecessary

Failure to comply with the APA

Extend the period of review

COMMENT:

These rules set standards for the licensing of hospitals, and are before RRC as part of the agency's scheduled readoption. The rules cover a broad array of aspects including hospital staffing, administration, and the provision of medical care. Among other things, these rules include detailed requirements that hospitals hire and maintain certain personnel, job responsibilities and required credentials for such personnel, requirements and policy statements relating to the preservation of medical records, standards for the provision of emergency services, standards for organization of neonatal care, requirements for the establishment and review of safety standards for imaging services, requirements for the establishment and review of written infection control policies and procedures, and staffing and discharge requirements for inpatient rehabilitation facilities.

Brian Liebman
Commission Counsel
Issued August 5, 2022

It is staff's opinion that the set of rules before you exceeds the grasp of the agency's statutory authority. The Medical Care Commission ("MCC" or the "Commission") draws its rulemaking authority from G.S. 131E-79(a), which states: "The Commission shall promulgate rules **necessary to implement this Article**[,]" referring to Article 5 of Chapter 131E, titled the "Hospital Licensure Act."

Review of the Hospital Licensure Act reveals that while certain provisions of Article 5 go on to discuss *inter alia*, aspects of license enforcement, requirements for granting or denying hospital privileges, discharge from facilities, and confidentiality of medical records, the statute generally directs *the hospital*, rather than MCC, to develop the policies, procedures, and requirements that are a condition of licensure. Hospitals must submit any plans and specifications for their facilities to MCC upon application for a license, and MCC may request information related to hospital operations during the application process, but MCC is not empowered to specifically set those requirements, policies, and procedures by rule.

Moreover, the rules before you delve into issues that are not specifically governed by the Hospital Licensure Act, and as such cannot be "necessary to implement" those statutes. *Inter alia*, there is no statutory requirement that a hospital maintain the position of nurse executive (Rule .3801) or medical director (Rule .4104), or maintain certain levels of inpatient rehabilitation staffing (Rule .5408). There are no statutory requirements related to preservation of medical records, other than that they are confidential and are not public records under Chapter 132 (Rule .3903). There are no statutory requirements related to establishment of emergency services procedures (Rule .4103). The word "neonatal" does not appear within Article 5 (Rule .4305), nor does any reference to radiological services (Rules .4801 and .4805). Part 4 of Article 5 deals with discharge from hospitals, yet only makes requirements related to a patient's refusal to leave, and fair billing practices. There are no discharge criteria required by Article 5 (Rule .5406).

To this, the agency makes two principal responses. MCC argues that its authority to adopt the rules before you stems from G.S. 131E-75, which is the title and purpose section of the Hospital Licensure Act. Therein, the legislature directed that Article 5's purpose was 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." G.S. 131E-75(b) (2021). Thus, the agency contends that in determining whether to issue, deny, or take any other action with respect to a hospital's

license, it is "required to assess if a hospital is meeting the 'requirements which promote public health, safety, and welfare….'" and is consequently *required* to establish "operational minimum standards"—a phrase that does not appear within Article 5 of Chapter 131E—for hospitals through rulemaking. The agency goes on to argue that there is no requirement for the General Assembly to specifically enumerate "every area of rule promulgation with any of the agencies creating rules for licensing," bolstering its point by referring to several allegedly equivalent statutory provisions.

As an initial matter, with respect to the agency's reference to other rules not currently before RRC, staff cannot and does not opine as to whether those agencies have authority under their respective statutes to adopt the cited rules. The scope of this opinion is limited to the Rules submitted for review by MCC. Here, the agency is authorized only to "promulgate rules necessary to implement" Article 5 of Chapter 131E. G.S. 131E-79(b) (2021). While the agency is correct that G.S. 131E-75 enunciates the *purpose* of the other provisions of Article 5, this language cannot be read as an open-ended grant of *authority* for MCC to promulgate any rule that could conceivably "promote public health, safety and welfare" or concern the "basic standards for the care and treatment of patients in hospitals" outside of the boundaries of the statutory scheme. As noted above, the rules impose deep, granular requirements upon hospitals with respect to issues that are at best tangentially referenced within the bounds of Article 5, and at worst mentioned nowhere within these statutes. Thus, it is staff's opinion that G.S. 131E-75(b) is not an adequate statutory basis for the rules before you.

Finally, MCC appears to argue that it has additional rulemaking authority for these rules under G.S. 143B-165(6), which states:

> (6) The Commission [MCC] 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 (emphasis added).

The General Assembly repealed Chapter 131 and replaced it with Chapter 131E in 1983. Specifically, the pre-existing Hospital Licensing Act (Article 13A, Chapter 131) was replaced with the Hospital Licensure Act (Article 5, Chapter 131E), which contained the current text of G.S. 131E-79(a) providing MCC with rulemaking authority. While the current iteration of the statutory scheme replaces Article 13A of Chapter 131, there is no evidence that the legislature intended, by citing to the repealed statutes, to refer to Article 5, Chapter 131E. *See Lundsford v. Mills*, 367 N.C. 618, 623, 766 S.E.2d 297, 301 (2014) (in ascertaining legislative intent, one

should "give effect to the words actually used in a statute and not . . . delete words used or . . . insert words not used."). Contrarily, the legislature refers explicitly to Chapter 131E elsewhere within G.S. 143B-165. *See, e.g.*, G.S. 131E-165(11) (2021) ("The Commission is authorized to adopt such rules as may be necessary to carry out the provisions of Part C of Article 6, and Article 10, of Chapter 131E of the General Statutes of North Carolina."). If the legislature wished for G.S. 143B-165 to refer to Article 5 of Chapter 131E, it could have amended the statutory text. As it chose not to, but rather included a new, independent grant of rulemaking authority within Article 5, it is staff's opinion that G.S. 143B-165(6) does not provide MCC with an additional source of rulemaking authority with respect to hospital licensure.

Consequently, staff recommends RRC object for lack of statutory authority.

Brian Liebman
Commission Counsel
Issued August 5, 2022

RRC STAFF OPINION

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AGENCY: Medical Care Commission

RULE CITATION: 10A NCAC 13B .4805

RECOMMENDATION DATE: July 13, 2023

RECOMMENDED ACTION:

X Approve, but note staff's comment

Object, based on:

Lack of statutory authority

Unclear or ambiguous

Unnecessary

Failure to comply with the APA

Extend the period of review

COMMENT:

In addition to the overarching objection for lack of statutory authority, the Commission objected to this Rule at the August 2022 meeting for ambiguity. Specifically, the issue related to language in paragraph (c), wherein MCC required the hospital's governing authority to appoint a radiation safety committee and specified that membership shall include "a physician approved by the medical staff experienced in the handling of radio-active isotopes and their therapeutic use[.]"

Subsequently, MCC has revised the rule to remove the experience requirement. As such, it is staff's opinion that the agency has satisfied the Commission's objection and recommends approval of the Rule.

Brian Liebman
Commission Counsel