### **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: North Carolina Department of Health and Human Services RULE CITATION: 10A NCAC 14C. 1403, 10A NCAC 14C. 2703 RECOMMENDATION DATE: January 17, 2023 RECOMMENDED ACTION:

- X Note staff's comment
  - Object, based on:
    - Lack of statutory authority Unclear or ambiguous Unnecessary
  - X Failure to comply with the APA
  - Extend the period of review

#### COMMENT:

It is staff's opinion that the "finding of need" forms provided with both of these rules fail to comply with the APA's requirement that "[t]he statement must be signed by the head of the agency adopting the temporary rule."

#### I. Statutory Conflict

G.S. 150B-21.1(a4) states:

An agency must also prepare a written statement of its findings of need for a temporary rule stating why adherence to the notice and hearing requirements in G.S. 150B-21.2 would be contrary to the public interest and why the immediate adoption of the rule is required. If the temporary rule establishes a new fee or increases an existing fee, the agency shall include in the written statement that it has complied with the requirements of G.S. 12-3.1. The statement must be signed by the head of the agency adopting the temporary rule.

Both sources of statutory authority relevant to these rules (G.S. 131E-177 and G.S. 131E-183) give rulemaking authority to the Department of Health and Human Services. The head of the Department of Health and Human Services is the Secretary of Health and Human Services. G.S. 131E-177 further specifies that "[t]he Secretary of Health and Human Services shall have final decision-making authority with regard to all functions described in this section."

The finding of need form for both of these rules is signed by the "Director, Division of Health Services Regulation." The agency has indicated that the function of signing this form has been delegated under G.S. 143B-10(a), which provides:

Assignment of Functions. - Except as otherwise provided by this Chapter, the head of each principal State department may assign or reassign any function vested in him or in his department to any subordinate officer or employee of his department.

There is an obvious tension between the APA and the general delegation statute. The best way to harmonize these statutes is to understand the temporary rulemaking function as a specific exception to the general rulemaking function. Thus, the additional requirements in the APA provide specific language which would take priority over the general language in the delegation statute. Reading otherwise would render the final sentence of G.S. 150B-21.1(a4) unnecessary surplusage. Admittedly, the RRC's forms and rules suggest that such a delegation is possible. However, to the extent that those rules conflict with statute, the statute must control.

#### II. Factual Issue

If the Commission disagrees with my interpretation and determines that the APA allows delegation of this authority, the agency has not shown that it was delegated here.

The agency provided a copy of "DHHS Directive Number II-24", effective November 3, 2008. This directive is also posted on the Agency's public website. Notably, this delegation includes a line for the Secretary to sign, but the document provided does not have a signature. As such, it appears on its face to be incomplete.

Further, even if the delegation were complete, the substance of the delegation does not appear to cover the signing of "statements of need" for temporary rules. There is a general reference to "rule-making authority" which most naturally applies to permeant rulemaking. Additionally, the final

sentence of the Directive is "This delegation of authority shall not apply to any actions which by law, state policy, or NC Governor's Executive Order, may only be executed by the Secretary." As discussed above the relevant statutes assign these tasks to the Secretary.

#### **III. Recommended Action**

For the above reasons, the rule as currently presented fails to comply with the APA. However, because the only issue with this rule is the signature on the "Finding of Need" forms, staff recommends that the Commission approve the rule contingent on a technical change under 26 NCAC 05 .0114. The technical change required is that the finding of need form be signed by the Secretary of the Department of Health and Human Services.

#### Part 2. Adoption of Rules.

### § 150B-21.1. Procedure for adopting a temporary rule.

(a) Adoption. – An agency may adopt a temporary rule when it finds that adherence to the notice and hearing requirements of G.S. 150B-21.2 would be contrary to the public interest and that the immediate adoption of the rule is required by one or more of the following:

- (1) A serious and unforeseen threat to the public health, safety, or welfare.
- (2) The effective date of a recent act of the General Assembly or the United States Congress.
- (3) A recent change in federal or State budgetary policy.
- (4) A recent federal regulation.
- (5) A recent court order.
- (6) The need for a rule establishing review criteria as authorized by G.S. 131E-183(b) to complement or be made consistent with the State Medical Facilities Plan approved by the Governor, if the rule addresses a matter included in the State Medical Facilities Plan, and the proposed rule and a notice of public hearing is submitted to the Codifier of Rules prior to the effective date of the Plan.
- (7) The need for the Wildlife Resources Commission to establish any of the following:
  - a. No wake zones.
  - b. Hunting or fishing seasons, including provisions for manner of take or any other conditions required for the implementation of such season.
  - c. Hunting or fishing bag limits.
  - d. Management of public game lands as defined in G.S. 113-129(8a).
- (8) The need for the Secretary of State to implement the certification technology provisions of Article 11A of Chapter 66 of the General Statutes, to adopt uniform Statements of Policy that have been officially adopted by the North American Securities Administrators Association, Inc., for the purpose of promoting uniformity of state securities regulation, and to adopt rules governing the conduct of hearings pursuant to this Chapter.
- (9) The need for the Commissioner of Insurance to implement the provisions of G.S. 58-2-205.
- (10) The need for the State Chief Information Officer to implement the information technology procurement provisions of Article 15 of Chapter 143B of the General Statutes.
- (11) The need for the State Board of Elections to adopt a temporary rule after prior notice or hearing or upon any abbreviated notice or hearing the agency finds practical for one or more of the following:
  - a. In accordance with the provisions of G.S. 163-22.2.
  - b. To implement any provisions of state or federal law for which the State Board of Elections has been authorized to adopt rules.
  - c. The need for the rule to become effective immediately in order to preserve the integrity of upcoming elections and the elections process.
- (12) Repealed by Session Laws 2015-264, s. 22, effective October 1, 2015.
- (13), (14) Reserved.
- (15) Expired pursuant to Session Laws 2002-164, s. 5, effective October 1, 2004.
- (16) Expired pursuant to Session Laws 2003-184, s. 3, effective July 1, 2005.
- (17) To maximize receipt of federal funds for the Medicaid or NC Health Choice programs within existing State appropriations, to reduce Medicaid or NC

Health Choice expenditures, and to reduce Medicaid and NC Health Choice fraud and abuse.

(a1) Recodified as subdivision (a)(16) of this section by Session Laws 2004-156, s. 1.

(a2) A recent act, change, regulation, or order as used in subdivisions (2) through (5) of subsection (a) of this section means an act, change, regulation, or order occurring or made effective no more than 210 days prior to the submission of a temporary rule to the Rules Review Commission. Upon written request of the agency, the Commission may waive the 210-day requirement upon consideration of the degree of public benefit, whether the agency had control over the circumstances that required the requested waiver, notice to and opposition by the public, the need for the waiver, and previous requests for waivers submitted by the agency.

- (a3) Unless otherwise provided by law, the agency shall:
  - (1) At least 30 business days prior to adopting a temporary rule, submit the rule and a notice of public hearing to the Codifier of Rules, and the Codifier of Rules shall publish the proposed temporary rule and the notice of public hearing on the Internet to be posted within five business days.
  - (2) At least 30 business days prior to adopting a temporary rule, notify persons on the mailing list maintained pursuant to G.S. 150B-21.2(d) and any other interested parties of its intent to adopt a temporary rule and of the public hearing.
  - (3) Accept written comments on the proposed temporary rule for at least 15 business days prior to adoption of the temporary rule.
  - (4) Hold at least one public hearing on the proposed temporary rule no less than five days after the rule and notice have been published. If notice of a public hearing has been published and that public hearing has been cancelled, the agency shall publish notice at least five days prior to the date of any rescheduled hearing.

(a4) An agency must also prepare a written statement of its findings of need for a temporary rule stating why adherence to the notice and hearing requirements in G.S. 150B-21.2 would be contrary to the public interest and why the immediate adoption of the rule is required. If the temporary rule establishes a new fee or increases an existing fee, the agency shall include in the written statement that it has complied with the requirements of G.S. 12-3.1. The statement must be signed by the head of the agency adopting the temporary rule.

(b) Review. - When an agency adopts a temporary rule it must submit the rule and the agency's written statement of its findings of the need for the rule to the Rules Review Commission. Within 15 business days after receiving the proposed temporary rule, the Commission shall review the agency's written statement of findings of need for the rule and the rule to determine whether the statement meets the criteria listed in subsection (a) of this section and the rule meets the standards in G.S. 150B-21.9. The Commission shall direct a member of its staff who is an attorney licensed to practice law in North Carolina to review the statement of findings of need and the rule. The staff member shall make a recommendation to the Commission, which must be approved by the Commission or its designee. The Commission's designee shall be a panel of at least three members of the Commission. In reviewing the statement, the Commission or its designee may consider any information submitted by the agency or another person. If the Commission or its designee finds that the statement meets the criteria listed in subsection (a) of this section and the rule meets the standards in G.S. 150B-21.9, the Commission or its designee must approve the temporary rule and deliver the rule to the Codifier of Rules within two business days of approval. The Codifier of Rules must enter the rule into the North Carolina Administrative Code on the sixth business day following receipt from the Commission or its designee.

(b1) If the Commission or its designee finds that the statement does not meet the criteria listed in subsection (a) of this section or that the rule does not meet the standards in G.S. 150B-21.9, the Commission or its designee must immediately notify the head of the agency. The agency may supplement its statement of need with additional findings or submit a new statement. If the agency provides additional findings or submits a new statement, the Commission or its designee must review the additional findings or new statement within five business days after the agency submits the additional findings or new statement. If the Commission or its designee again finds that the statement does not meet the criteria listed in subsection (a) of this section or that the rule does not meet the standards in G.S. 150B-21.9, the Commission or its designee must immediately notify the head of the agency and return the rule to the agency.

(b2) If an agency decides not to provide additional findings or submit a new statement when notified by the Commission or its designee that the agency's findings of need for a rule do not meet the required criteria or that the rule does not meet the required standards, the agency must notify the Commission or its designee of its decision. The Commission or its designee shall then return the rule to the agency. When the Commission returns a rule to an agency in accordance with this subsection, the agency may file an action for declaratory judgment in Wake County Superior Court pursuant to Article 26 of Chapter 1 of the General Statutes.

(b3) Notwithstanding any other provision of this subsection, if the agency has not complied with the provisions of G.S. 12-3.1, the Codifier of Rules shall not enter the rule into the Code.

(c) Standing. – A person aggrieved by a temporary rule adopted by an agency may file an action for declaratory judgment in Wake County Superior Court pursuant to Article 26 of Chapter 1 of the General Statutes. In the action, the court shall determine whether the agency's written statement of findings of need for the rule meets the criteria listed in subsection (a) of this section and whether the rule meets the standards in G.S. 150B-21.9. The court shall not grant an ex parte temporary restraining order.

(c1) Filing a petition for rule making or a request for a declaratory ruling with the agency that adopted the rule is not a prerequisite to filing an action under this subsection. A person who files an action for declaratory judgment under this subsection must serve a copy of the complaint on the agency that adopted the rule being contested, the Codifier of Rules, and the Commission.

(d) Effective Date and Expiration. – A temporary rule becomes effective on the date specified in G.S. 150B-21.3. A temporary rule expires on the earliest of the following dates:

- (1) The date specified in the rule.
- (2) The effective date of the permanent rule adopted to replace the temporary rule, if the Commission approves the permanent rule.
- (3) The date the Commission returns to an agency a permanent rule the agency adopted to replace the temporary rule.
- (4) The effective date of an act of the General Assembly that specifically disapproves a permanent rule adopted to replace the temporary rule.
- (5) 270 days from the date the temporary rule was published in the North Carolina Register, unless the permanent rule adopted to replace the temporary rule has been submitted to the Commission.

(e) Publication. – When the Codifier of Rules enters a temporary rule in the North Carolina Administrative Code, the Codifier must publish the rule in the North Carolina Register. (1973, c. 1331, s. 1; 1981, c. 688, s. 12; 1981 (Reg. Sess., 1982), c. 1232, s. 1; 1983, c. 857; c. 927, ss. 4, 8; 1985, c. 746, s. 1; 1985 (Reg. Sess., 1986), c. 1022, s. 1(1), 1(8); 1987, c. 285, ss. 10-12; 1991, c. 418, s. 1; 1991 (Reg. Sess., 1992), c. 900, s. 149; 1993, c. 553, s. 54; 1995, c. 507, s. 27.8(c); 1996, 2nd Ex. Sess., c. 18, ss. 7.10(c), (d); 1997-403, ss. 1-3; 1998-127, s. 2; 1998-212, s. 26B(h); 1999-434, s. 16; 1999-453, s. 5(a); 2000-69, ss. 3, 5; 2000-148, ss. 4, 5; 2001-126, s. 12; 2001-421, ss. 2.3, 5.3; 2001-424, ss. 27.17(b), (c), 27.22(a), (b); 2001-487, s.

21(g); 2002-97, ss. 2, 3; 2002-164, s. 4.6; 2003-184, s. 3; 2003-229, s. 2; 2003-413, ss. 27, 29; 2004-156, s. 1; 2011-398, s. 4; 2013-360, s. 12H.9(d); 2013-413, s. 39; 2015-241, s. 7A.4(ee); 2015-264, s. 22; 2017-6, s. 3; 2018-146, ss. 3.1(a), (b), 6.1; 2020-3, s. 4.25(a).)

#### § 131E-177. Department of Health and Human Services is designated State Health Planning and Development Agency; powers and duties.

The Department of Health and Human Services is designated as the State Health Planning and Development Agency for the State of North Carolina, and is empowered to exercise the following powers and duties:

- (1) To establish standards and criteria or plans required to carry out the provisions and purposes of this Article and to adopt rules pursuant to Chapter 150B of the General Statutes, to carry out the purposes and provisions of this Article;
- (2) Adopt, amend, and repeal such rules and regulations, consistent with the laws of this State, as may be required by the federal government for grants-in-aid for health service facilities and health planning which may be made available by the federal government. This section shall be liberally construed in order that the State and its citizens may benefit from such grants-in-aid;
- (3) Define, by rule, procedures for submission of periodic reports by persons or health service facilities subject to agency review under this Article;
- (4) Develop policy, criteria, and standards for health service facilities planning; shall conduct statewide registration and inventories of and make determinations of need for health service facilities, health services as specified in G.S. 131E-176(16)f., and equipment as specified in G.S. 131E-176(16)f1., which shall include consideration of adequate geographic location of equipment and services; and develop a State Medical Facilities Plan;
- (5) Implement, by rule, criteria for project review;
- (6) Have the power to grant, deny, or withdraw a certificate of need and to impose such sanctions as are provided for by this Article;
- (7) Solicit, accept, hold and administer on behalf of the State any grants or devises of money, securities or property to the Department for use by the Department in the administration of this Article; and
- (8) Repealed by Session Laws 1987, c. 511, s. 1.
- (9) Collect fees for submitting applications for certificates of need.
- (10) The authority to review all records in any recording medium of any person or health service facility subject to agency review under this Article which pertain to construction and acquisition activities, staffing or costs and charges for patient care, including but not limited to, construction contracts, architectural contracts, consultant contracts, purchase orders, cancelled checks, accounting and financial records, debt instruments, loan and security agreements, staffing records, utilization statistics and any other records the Department deems to be reasonably necessary to determine compliance with this Article.

The Secretary of Health and Human Services shall have final decision-making authority with regard to all functions described in this section. (1977, 2nd Sess., c. 1182, s. 2; 1981, c. 651, s. 1; 1983, c. 713, s. 96; c. 775, ss. 1, 6; 1987, c. 511, s. 1; 1991, c. 692, s. 2; 1993, c. 7, s. 3; c. 383, ss. 2, 3; 1997-443, s. 11A.118(a); 2007-323, s. 30.4(a); 2011-284, s. 90.)

#### § 131E-183. Review criteria.

(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) (See note) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.
- (2) Repealed by Session Laws 1987, c. 511, s. 1.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.
- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.
- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.
- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.
- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:
  - a. The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and
  - b. The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
    - 1. Would be available under a contract of at least five years' duration;
    - 2. Would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
    - 3. Would cost no more than if the services were provided by the HMO; and
    - 4. Would be available in a manner which is administratively feasible to the HMO.
- (11) Repealed by Session Laws 1987, c. 511, s. 1.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.
- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
  - a. The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;
  - b. Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;
  - c. That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services

and the extent to which each of these groups is expected to utilize the proposed services; and

- d. That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.
- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.
- (15) through (18) Repealed by Session Laws 1987, c. 511, s. 1.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.
- (19) Repealed by Session Laws 1987, c. 511, s. 1.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.
- (21) Repealed by Session Laws 1987, c. 511, s. 1.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

(c) Repealed by Session Laws 1987, c. 511, s. 1. (1977, 2nd Sess., c. 1182, s. 2; 1981, c. 651, s. 7; 1983, c. 775, s. 1; c. 920, s. 2; 1983 (Reg. Sess., 1984), c. 1002, s. 10; 1985, c. 445, s. 1; 1987, c. 511, s. 1; 1991, c. 692, s. 6; c. 701, s. 2; 1993, c. 7, s. 6; 2001-242, s. 3.)

#### § 143B-10. Powers and duties of heads of principal departments.

(a) Assignment of Functions. – Except as otherwise provided by this Chapter, the head of each principal State department may assign or reassign any function vested in him or in his department to any subordinate officer or employee of his department.

(b) Reorganization by Department Heads. – With the approval of the Governor, each head of a principal State department may establish or abolish within his department any division. Each head of a principal State department may establish or abolish within his department any other administrative unit to achieve economy and efficiency and in accordance with sound administrative principles, practices, and procedures except as otherwise provided by law. When any such act of the head of the principal State department affects existing law the provisions of Article III, Sec. 5(10) of the Constitution of North Carolina shall be followed.

Each Department Head shall report all reorganizations under this subsection to the President of the Senate, the Speaker of the House of Representatives, the Chairmen of the Appropriations Committees in the Senate and the House of Representatives, and the Fiscal Research Division of the Legislative Services Office, within 30 days after the reorganization if the General Assembly is in session, otherwise to the Joint Legislative Committee on Governmental Operations and the Fiscal Research Division of the Legislative Services Office, within 30 days after the reorganization. The report shall include the rationale for the reorganization and any increased efficiency in operations expected from the reorganization.

(c) Department Staffs. – The head of each principal State department may establish necessary subordinate positions within the department, make appointments to those positions, and remove persons appointed to those positions, all within the limitations of appropriations and subject to the State Budget Act and the North Carolina Human Resources Act. All employees within a principal State department shall be under the supervision, direction, and control of the head of that department. The head of each principal State department may establish or abolish positions, transfer officers and employees between positions, and change the duties, titles, and compensation of existing offices and positions as the head of the department deems necessary for the efficient functioning of the department, subject to the State Budget Act and the North Carolina Human Resources Act and the limitations of available appropriations. For the purposes of the foregoing provisions, a member of a board, commission, council, committee, or other citizen group shall not be considered an "employee within a principal department." Nothing in this subsection shall be construed as authorizing the transfer of officers and employees between departments without express authorization of the General Assembly.

(d) Appointment of Committees or Councils. – The head of each principal department may create and appoint committees or councils to consult with and advise the department. The General Assembly declares its policy that insofar as feasible, such committees or councils shall consist of no more than 12 members, with not more than one from each congressional district. If any department head desires to vary this policy, he must make a request in writing to the Governor, stating the reasons for the request. The Governor may approve the request, but may only do so in writing. Copies of the request and approval shall be transmitted to the Joint Legislative Commission on Governmental Operations. The members of any committee or council created by the head of a principal department shall serve at the pleasure of the head of the principal department and may be paid per diem and necessary travel and subsistence expenses within the limits of appropriations and in accordance with the provisions of G.S. 138-5, when approved in advance by the Director of the Budget. Per diem, travel, and subsistence payments to members of the committees or councils created in connection with federal programs shall be paid from federal funds unless otherwise provided by law.

An annual report listing these committees or councils, the total membership on each, the cost in the last 12 months and the source of funding, and the title of the person who made the appointments shall be made to the Joint Legislative Commission on Governmental Operations by March 31 of each year.

(e) Departmental Management Functions. – All management functions of a principal State department shall be performed by or under the direction and supervision of the head of that principal State department. Management functions shall include planning, organizing, staffing, directing, coordinating, reporting, and budgeting.

(f) Custody of Records. – The head of a principal State department shall have legal custody of all public records as defined in G.S. 132-1.

(g) Budget Preparation. – The head of a principal State department shall be responsible for the preparation of and the presentation of the department budget request which shall include all funds requested and all receipts expected for all elements of the department.

(h) Plans and Reports. – Each principal State department shall submit to the Governor an annual plan of work for the next fiscal year prior to the beginning of that fiscal year. Each principal State department shall submit to the Governor an annual report covering programs and activities for each fiscal year. These plans of work and annual reports shall be made available to the General Assembly. These documents will serve as the base for the development of budgets for each principal State department of State government to be submitted to the Governor.

(i) Reports to Governor; Public Hearings. – Each head of a principal State department shall develop and report to the Governor legislative, budgetary, and administrative programs to accomplish comprehensive, long-range coordinated planning and policy formulation in the work of his department. To this end, the head of the department may hold public hearings, consult with and use the services of other State agencies, employ staff and consultants, and appoint advisory and technical committees to assist in the work.

(j) Departmental Rules and Policies. – The head of each principal State department and the Director of the Office of State Human Resources may adopt:

- (1) Rules consistent with law for the custody, use, and preservation of any public records, as defined in G.S. 132-1, which pertain to department business;
- (2) Rules, approved by the Governor, to govern the management of the department, which shall include the functions of planning, organizing, staffing, directing, coordinating, reporting, budgeting, and budget preparation which affect private rights or procedures available to the public;
- (3) Policies, consistent with law and with rules established by the Governor and with rules of the State Human Resources Commission, which reflect internal management procedures within the department. These may include policies governing the conduct of employees of the department, the distribution and performance of business and internal management procedures which do not affect private rights or procedures available to the public and which are listed in (e) of this section. Policies establishing qualifications for employment shall be adopted and filed pursuant to Chapter 150B of the General Statutes; all other policies under this subdivision shall not be adopted or filed pursuant to Chapter 150B of the General Statutes.

Rules adopted under (1) and (2) of this subsection shall be subject to the provisions of Chapter 150B of the General Statutes.

This subsection shall not be construed as a legislative grant of authority to an agency to make and promulgate rules concerning any policies and procedures other than as set forth herein. (1973, c. 476, s. 10; c. 1416, ss. 1, 2; 1977, 2nd Sess., c. 1219, s. 46; 1983, c. 76, ss. 1, 2; c. 641, s. 8; c. 717, s. 78; 1985 (Reg. Sess., 1986), c. 955, ss. 97, 98; 1987, c. 738, s. 147; c. 827, s. 1; 1991 (Reg. Sess., 1992), c. 1038, s. 15; 2006-203, s. 101; 2013-382, s. 9.1(c); 2019-250, s. 5.8.)

### **DHHS Directive Number II-24**

| Title:                   | Delegation of Authority to Director, Division of Health Service |
|--------------------------|-----------------------------------------------------------------|
|                          | Regulation                                                      |
| <b>Effective Date:</b>   | November 3, 2008                                                |
| <b>Revision History:</b> | July 11, 2007; January 1, 2002                                  |
| Authority:               | G.S. 143B-10; 143B-137.1                                        |

#### **Purpose**

The purpose of this directive is to delegate, clarify and specifically confirm certain authorities of the Secretary of the North Carolina Department of Health and Human Services (NC DHHS) to the Director of the Division of Health Service Regulation.

#### **Delegation of Authority**

As provided in G.S. 143B-10(a), the Secretary of the DHHS delegates the following functions concerning management and administration to the Director of the Division of Health Service Regulation, subject to state and departmental policy:

- 1. The functions of management, related to the Division of Health Service Regulation, as defined in G.S. 143B-10, which include: planning, organizing, staffing, directing, coordinating, reporting and budgeting.
- 2. The management authority to develop and carry out procedures and programs, including, but not limited to:
  - A. Purchasing and contracting, subject to the state purchasing and contract rules and DHHS Directives(s);
  - B. Programs for which the Director has rule-making or enforcement authority or supports the rule-making or enforcement authority of a commission;
  - C. Certification of health care facilities and services for Medicare and Medicaid reimbursement, Titles XVIII and XIX of the Social Security Act;

- D. Serve as the primary licensing and certification unit within the department and work with other divisions and commissions having rule-making authority over facilities and services subject to licensure or certification by the division; and
- E. Determine if any person, program or facility is subject to licensure by the division and seek legal remedies to restrain persons from operating a facility without a license or in a manner that threatens the health, safety or welfare of individuals in the facility.
- 3. Rule-making authority (in coordination with the Office of the General Counsel) for the following:
  - A. Satellite jail/work release units (G.S. 153A-230.4);
  - B. Certificate of Need (G.S. 131E, Article 9);
  - C. Procedures for termination of clinical hospital services by a for-profit corporation assuming ownership through lease or sale of a public hospital (G.S. 131E, Article 2);
  - D. Cardiac Rehabilitation licensing (G.S. 131E, Article 8);
  - E. Certification of Abortion Clinics (G.S. 14-45.1);
  - F. Suspension of Admissions for Adult Care Homes {G.S. 131D-2(h)};
  - G. Medical Facilities Planning Program, to include the State Medical Facilities Plan (G.S. 131E, Article 4 and Article 9);
  - H. Certificate of Public Advantage Programs (G.S. 131E, Article 9A and G.S. 90, Article 1E);
  - I. Exceptions for Underserved Areas (G.S. 90-408);
  - J. Certification of statewide data processors (G.S. 131E, Article 11A); and
  - K. Adverse action against hospitals and freestanding ambulatory surgical centers for violations under the Medical Care Data Act (G.S. 131E, Article 11A).
- 4. Unless otherwise specified by statute or rule, the authority to issue declaratory rulings:
  - A. As to the validity or applicability of any rule which has been adopted by the division or the Medical Care Commission;
  - B. As to the validity or applicability of any rule which has been adopted by the Social Services Commission relating to local confinement facilities (G.S. 153A-220); or
  - C. As to the applicability of any statute, rule or order administered by the division to a given set of facts (G.S. 150B-4).
- 5. The management functions of a commission, as defined in G.S. 143B-14(d), which include planning, organizing, staffing, directing, coordinating, reporting and budgeting for those commissions assigned to the division. In particular, the

Director shall provide staff support to:

- A. The Emergency Medical Services Advisory Council established by G.S. 143-510;
- B. The NC State Health Coordinating Council, established by NC Governor's Executive Order;
- C. The Medical Care Commission to facilitate its rule-making and advisory and other actions as specified in General Statutes; and
- D. The Penalty Review Committee established by G.S. 131D-34(h).
- 6. The Director shall provide staffing for enforcement and implementation of the Medical Care Commission's rules, including but not limited to:
  - A. Rules for the licensure of hospitals (G.S. 131E, Article 5);
  - B. Rules for the licensure of nursing homes (G.S. 131E, Article 6, Part A);
  - C. Rules for the implementation and enforcement of the Nursing Home Patient's Bill of Rights (G.S. 131E, Article 6, Part B);
  - D. Rules for the implementation, establishment and maintenance of a statewide trauma system; licensure of ambulance providers, certification of emergency medical personnel, the permitting and inspection of ambulances, and carry out the purposes of Article 56 of Chapter 143 of the G.S. (G.S. 131E, Article 7 and Article 7A; G.S. 143, Article 56);
  - E. Rules governing the issuance of bonds under the Health Care Facilities Finance Act (G.S. 131A);
  - F. Rules for the licensure of ambulatory surgical (operating room) facilities (G.S. 131E, Article 6, Part D);
  - G. Rules for the licensure of nursing pools (G.S. 131E, Article 6, Part E);
  - H. Rules for the licensure of hospices (G.S. 131E, Article 10);
  - I. Rules for the licensure of home care agencies (G.S. 131E, Article 6, Part C);
  - J. Rules for the licensure of adult care homes (G.S. 131D);
  - K. Rules necessary to carry out a program for the construction and enlargement of local hospitals (G.S. 131E-Article 4); and
  - L. Rules for the implementation, establishment and maintenance of health care personnel registries (G.S. 131E-256, Article 15 and 42 CFR 483).
- 7. The management authority to develop and carry out programs under the rulemaking authority of commissions not staffed by the division and to develop rules under G.S. 150B for such programs, not inconsistent with law, including, but not limited to the Local Confinement Facilities (G.S. 153A-220) and Licensed Mental Health Facilities (G.S. 122C, Article 2).
- 8. In connection with appeals of an administrative decision regarding any law, rule or policy adopted by the Director or the Medical Care Commission or regarding any permit or license issued, penalty imposed or other action taken by the division

or other action within the responsibility of the division that may be appealed, the authority to ensure compliance with all applicable provisions of the Administrative Procedure Act, G.S., Chapter 150B, including specifically the authority to issue a final agency decision in contested cases unless otherwise specified by statute or rule (G.S. 150B-36). If the initial administrative decision which is the subject matter of the appeal was made by the Director, the Director shall so advise the Secretary, and the Secretary shall ensure compliance with the laws, rules, and make (or designate an appropriate designee to make) the final agency decision. The Director shall be the "head of agency" under Rule 18 of the NC Rules of Appellate Procedure with regard to settling the record on appeal.

- 9. Develop and approve a portable Do Not Resuscitate (DNR) order form as required by G.S. 90-21.16(c).
- 10. The Director may serve as the Secretary of the Medical Care Commission at its discretion.
- 11. The Director shall be responsible for coordinating the division's monitoring functions with other divisions and local partners to ensure compliance with state and federal requirements.
- 12. The Director shall be responsible for ensuring that the division is familiar with and adheres to the department's policy and procedures manual.

This delegation of authority shall not deprive the Secretary from performing, in lieu of the Director of the Division of Health Service Regulation, any of the acts set forth above. This delegation of authority may be amended or withdrawn by the Secretary at any time without notice. This delegation of authority shall not apply to any actions which by law, state policy, or NC Governor's Executive Order, may only be executed by the Secretary.

APPROVED

Dempsey Benton, Secretary Department of Health and Human Services



# TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

**VOLUME:** 

**ISSUE:** 

| 1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHSR                                                                                                                                                                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2. Rule citation & name: 10A NCAC 14C .1403 Performance Standards                                                                                                                                                                                                                                                                                                                                  |
| 3. Action: Adoption Amendment Repeal                                                                                                                                                                                                                                                                                                                                                               |
| 4. Was this an Emergency Rule: Yes Effective date:                                                                                                                                                                                                                                                                                                                                                 |
| 5. Provide dates for the following actions as applicable:                                                                                                                                                                                                                                                                                                                                          |
| a. Proposed Temporary Rule submitted to OAH: 11/07/22                                                                                                                                                                                                                                                                                                                                              |
| b. Proposed Temporary Rule published on the OAH website: 11/08/22                                                                                                                                                                                                                                                                                                                                  |
| c. Public Hearing date: 11/28/22                                                                                                                                                                                                                                                                                                                                                                   |
| d. Comment Period: 11/16/22 – 12/09/22                                                                                                                                                                                                                                                                                                                                                             |
| e. Notice pursuant to G.S. 150B-21.1(a3)(2): 11/07/22                                                                                                                                                                                                                                                                                                                                              |
| f. Adoption by agency on: 1/05/23                                                                                                                                                                                                                                                                                                                                                                  |
| g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 01/27/23                                                                                                                                                                                                                                                         |
| h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a                                                                                                                                                                                                                                                                                                                          |
| 6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review.                                                                                                                                                                                                                                                                                  |
| A serious and unforeseen threat to the public health, safety or welfare.                                                                                                                                                                                                                                                                                                                           |
| The effective date of a recent act of the General Assembly or of the U.S. Congress.<br>Cite:                                                                                                                                                                                                                                                                                                       |
| Effective date:                                                                                                                                                                                                                                                                                                                                                                                    |
| A recent change in federal or state budgetary policy.                                                                                                                                                                                                                                                                                                                                              |
| Effective date of change:<br>A recent federal regulation.                                                                                                                                                                                                                                                                                                                                          |
| Cite:                                                                                                                                                                                                                                                                                                                                                                                              |
| Effective date:                                                                                                                                                                                                                                                                                                                                                                                    |
| Cite order:                                                                                                                                                                                                                                                                                                                                                                                        |
| <ul> <li>State Medical Facilities Plan.</li> <li>Other:</li> </ul>                                                                                                                                                                                                                                                                                                                                 |
| Explain: Several subject matters are addressed in the State Medical Facilities Plan (SMFP). The acute care bed need determination methodology was changed in the 2023 SMFP. Revisions to existing Certificate of Need rules are required to compliment or to be made consistent with the SMFP signed by the governor on December 16, 2022. The effective date of the 2023 SMFP is January 1, 2023. |

| rule is required?<br>The change to the existing Certificate of Need (CON) performed<br>neonatal services is required to compliment or to be made constant to be the event of the even of | onsistent with the State Medical Facilities Plan (SMFP) that will<br>determination methodology found in the SMFP underwent<br>he State Health Coordinating Council (SHCC). The revised need<br>by the SHCC on September 28, 2022 and subsequently signed<br>alle is being revised to reflect the need methodology change for<br>t in a defined neonatal service area to demonstrate an unmet |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                              |
| 8. Rule establishes or increases a fee? (See G.S. 12-3.1)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                              |
| <ul> <li>Yes</li> <li>Agency submitted request for consultation on:<br/>Consultation not required. Cite authority:</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                              |
| 9. Rule-making Coordinator: Nadine Pfeiffer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 10. Signature of Agency Head*:                                                                                                                                                                                                                                                                                                                                                               |
| Phone: 919-855-3811                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Mark Payne                                                                                                                                                                                                                                                                                                                                                                                   |
| E-Mail: Nadine.pfeiffer@dhhs.nc.gov                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | * If this function has been delegated (reassigned) pursuant                                                                                                                                                                                                                                                                                                                                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | to G.S. 143B-10(a), submit a copy of the delegation with this form.                                                                                                                                                                                                                                                                                                                          |
| Agency contact, if any: Micheala Mitchell, Chief                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Typed Name: Mark Payne                                                                                                                                                                                                                                                                                                                                                                       |
| Phone: 919-855-3879                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Title: Director, Division of Health Service Regulation                                                                                                                                                                                                                                                                                                                                       |
| E-Mail: micheala.mitchell@dhhs.nc.gov                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | E-Mail: mark.payne@dhhs.nc.gov                                                                                                                                                                                                                                                                                                                                                               |
| RULES REVIEW COMMISSION USE ONLY                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                              |
| Action taken: Su                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | ubmitted for RRC Review:                                                                                                                                                                                                                                                                                                                                                                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                              |
| Date returned to agency:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                              |
| Date returned to agency:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                              |

 10A NCAC 14C .1403 is amended under temporary procedures with changes as follows:

| 3  | 10A NCAC 140                         | C.1403 PERFORMANCE STANDARDS                                                                                                                    |
|----|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| 4  | (a) <mark>An</mark> <u>If an app</u> | licant is proposing a project that increases the total number of neonatal beds in a facility, the applicant                                     |
| 5  | shall demonstrat                     | te that the proposed project is capable of meeting the following standards:                                                                     |
| 6  | (1)                                  | if an applicant is proposing to increase the total number of neonatal beds (i.e., the sum of Level II,                                          |
| 7  |                                      | Level III [III,] and Level IV beds), the overall average annual occupancy of the combined number                                                |
| 8  |                                      | of existing Level II, Level III, and Level IV beds in the facility is at least 75 percent, over the 12                                          |
| 9  |                                      | months immediately preceding the submittal of the proposal;                                                                                     |
| 10 | (2)                                  | if an applicant is proposing to increase the total number of neonatal beds (i.e., the sum of Level II,                                          |
| 11 |                                      | Level III [III,] and Level IV beds), the projected overall average annual occupancy of the combined                                             |
| 12 |                                      | number of Level II, Level III, and Level IV beds proposed to be operated during the third year                                                  |
| 13 |                                      | of operation of the proposed project shall be at least 75 percent; and                                                                          |
| 14 | (3)                                  | The the applicant shall document the assumptions and provide data supporting the methodology                                                    |
| 15 |                                      | used for each projection in this <del>rule.</del> Rule.                                                                                         |
| 16 | (b) If an applica                    | nt proposes to develop a new Level III or Level IV service, the applicant shall document that an unmet                                          |
| 17 | need exists in th                    | e applicant's defined neonatal service area, unless the State Medical Facilities Plan includes a need                                           |
| 18 | determination fo                     | r neonatal beds in the service area. area. The need for Level III and Level IV beds shall be computed                                           |
| 19 | for the applicant                    | 's neonatal service area by:                                                                                                                    |
| 20 | (1)                                  | identifying the annual number of live births occurring annually at all hospitals within the proposed                                            |
| 21 |                                      | neonatal service area, using the latest available data compiled by the State Center for Health                                                  |
| 22 |                                      | Statistics;                                                                                                                                     |
| 23 | (2)                                  | identifying the low birth weight rate (percent of live births below 2,500 grams) for the births                                                 |
| 24 |                                      | $identified \ in \ \underline{Subparagraph} (1) \ of \ this \ Paragraph, using \ the \ latest \ available \ data \ compiled \ by \ the \ State$ |
| 25 |                                      | Center for Health Statistics;                                                                                                                   |
| 26 | (3)                                  | dividing the low birth weight rate identified in Subparagraph (2) of this Paragraph by .08 and                                                  |
| 27 |                                      | subsequently multiplying the resulting quotient by four; and                                                                                    |
| 28 | (4)                                  | determining the need for Level III and Level IV beds in the proposed neonatal service area as the                                               |
| 29 |                                      | product of:                                                                                                                                     |
| 30 |                                      | (A) the product derived in <u>Subparagraph</u> (3) of this Paragraph, and                                                                       |
| 31 |                                      | (B) the quotient resulting from the division of the number of live births in the initial year of the                                            |
| 32 |                                      | determination identified in <u>Subparagraph</u> (1) of this Paragraph by the number 1000.                                                       |
| 33 |                                      |                                                                                                                                                 |
| 34 | History Note:                        | Authority G.S. 131E-177(1); 131E-183(b);                                                                                                        |
| 35 |                                      | Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule                                                  |
| 36 |                                      | becomes effective, whichever is sooner;                                                                                                         |
| 37 |                                      | Eff. January 4, 1994;                                                                                                                           |

| 1 | Temporary Amendment Eff. March 15, 2002;        |
|---|-------------------------------------------------|
| 2 | Amended Eff. April 1, 2003;                     |
| 3 | Temporary Amendment Eff. February 1, 2009;      |
| 4 | Amended Eff. November 1, 2009;                  |
| 5 | Temporary Amendment Eff. February 1, 2010;      |
| 6 | Amended Eff. November 1, <del>2010.</del> 2010; |
| 7 | Temporary Amendment Eff. January 27, 2023.      |



## TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

**VOLUME:** 

**ISSUE:** 

| 1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHSR                                                                                                                                                                                                                                                                                                                                                         |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2. Rule citation & name: 10A NCAC 14C .2703 Performance Standards                                                                                                                                                                                                                                                                                                                                                                          |
| 3. Action: Adoption Amendment Repeal                                                                                                                                                                                                                                                                                                                                                                                                       |
| 4. Was this an Emergency Rule: Yes Effective date:                                                                                                                                                                                                                                                                                                                                                                                         |
| 5. Provide dates for the following actions as applicable:                                                                                                                                                                                                                                                                                                                                                                                  |
| a. Proposed Temporary Rule submitted to OAH: 11/07/22                                                                                                                                                                                                                                                                                                                                                                                      |
| b. Proposed Temporary Rule published on the OAH website: 11/08/22                                                                                                                                                                                                                                                                                                                                                                          |
| c. Public Hearing date: 11/28/22                                                                                                                                                                                                                                                                                                                                                                                                           |
| d. Comment Period: 11/16/22 – 12/9/22                                                                                                                                                                                                                                                                                                                                                                                                      |
| e. Notice pursuant to G.S. 150B-21.1(a3)(2): 11/07/22                                                                                                                                                                                                                                                                                                                                                                                      |
| f. Adoption by agency on: 01/05/23                                                                                                                                                                                                                                                                                                                                                                                                         |
| g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 01/27/23                                                                                                                                                                                                                                                                                                 |
| h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a                                                                                                                                                                                                                                                                                                                                                                  |
| 6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review.                                                                                                                                                                                                                                                                                                                          |
| <ul> <li>A serious and unforeseen threat to the public health, safety or welfare.</li> <li>The effective date of a recent act of the General Assembly or of the U.S. Congress.<br/>Cite:</li> </ul>                                                                                                                                                                                                                                        |
| Effective date:                                                                                                                                                                                                                                                                                                                                                                                                                            |
| A recent change in federal or state budgetary policy.<br>Effective date of change:                                                                                                                                                                                                                                                                                                                                                         |
| A recent federal regulation.                                                                                                                                                                                                                                                                                                                                                                                                               |
| Cite:<br>Effective date:                                                                                                                                                                                                                                                                                                                                                                                                                   |
| A recent court order.                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Cite order:  State Medical Facilities Plan.                                                                                                                                                                                                                                                                                                                                                                                                |
| Other:                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Explain: Several subject matters are addressed in the State Medical Facilities Plan (SMFP). Changes were made to the chapter in the 2023 SMFP addressing the magnetic resonance imaging scanner need methodology. Revisions to an existing Certificate of Need rule are required to compliment or to be made consistent with the SMFP signed by the governor on December 16, 2022. The effective date of the 2023 SMFP is January 1, 2023. |
|                                                                                                                                                                                                                                                                                                                                                                                                                                            |

| 7. Why is adherence to notice and hearing requirements rule is required?                                                                                                                                                                                                                                                                             | s contrary to the public interest and the immediate adoption of the                                                             |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|--|
| The change to the existing Certificate of Need (CON) performance standards rule for the criteria and standards for magnetic resonance imaging (MRI) scanners is required to compliment or to be made consistent with the State Medical Facilities Plan (SMFP) that will become effective January 1, 2023. The MRI need methodology found in the SMFP |                                                                                                                                 |  |
| underwent substantial changes as a result of a workgrou                                                                                                                                                                                                                                                                                              | up directed by the State Health Coordinating Council (SHCC). The                                                                |  |
| subsequently signed for approval by the governor on De                                                                                                                                                                                                                                                                                               | the 2023 SMFP by the SHCC on September 28, 2022 and<br>ecember 16, 2022. This rule is being revised so that performance         |  |
| temporary rule amendment adoption is required for an                                                                                                                                                                                                                                                                                                 | ges shall be used by 2023 CON applicants for MRI services. This applicant's compliance with a CON application submission for an |  |
| MRI need determination in the 2023 SMFP.                                                                                                                                                                                                                                                                                                             |                                                                                                                                 |  |
|                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                 |  |
|                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                 |  |
|                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                 |  |
|                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                 |  |
|                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                 |  |
|                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                 |  |
| 8. Rule establishes or increases a fee? (See G.S. 12-3.1)                                                                                                                                                                                                                                                                                            |                                                                                                                                 |  |
| Yes                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                 |  |
| Agency submitted request for consultation on:<br>Consultation not required. Cite authority:                                                                                                                                                                                                                                                          |                                                                                                                                 |  |
| 🖾 No                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                 |  |
|                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                 |  |
| 9. Rule-making Coordinator: Nadine Pfeiffer                                                                                                                                                                                                                                                                                                          | 10. Signature of Agency Head*:                                                                                                  |  |
| Phone: 919-855-3811                                                                                                                                                                                                                                                                                                                                  | marktayne                                                                                                                       |  |
| E-Mail: Nadine.pfeiffer@dhhs.nc.gov                                                                                                                                                                                                                                                                                                                  | * If this function has been delegated (reassigned) pursuant<br>to G.S. 143B-10(a), submit a copy of the delegation with         |  |
| Agency contact, if any: Micheala Mitchell, Chief                                                                                                                                                                                                                                                                                                     | this form.<br>Typed Name: Mark Payne                                                                                            |  |
| Phone: 919-855-3879                                                                                                                                                                                                                                                                                                                                  | Title: Director, Division of Health Service Regulation                                                                          |  |
|                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                 |  |
| E-Mail: micheala.mitchell@dhhs.nc.gov                                                                                                                                                                                                                                                                                                                | E-Mail: mark.payne@dhhs.nc.gov                                                                                                  |  |
| RULES REVIEW COMMISSION USE ONL<br>Action taken:                                                                                                                                                                                                                                                                                                     | Submitted for RRC Review:                                                                                                       |  |
|                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                 |  |
|                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                 |  |
|                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                 |  |
| Date returned to agency:                                                                                                                                                                                                                                                                                                                             |                                                                                                                                 |  |

1 10A NCAC 14C .2703 is amended under temporary procedures as follows:

| 2 |  |
|---|--|
|   |  |
|   |  |
|   |  |

24

25

#### 3 10A NCAC 14C .2703 PERFORMANCE STANDARDS

- 4 (a) An applicant proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State
   5 Medical Facilities Plan in effect as of the first day of the review period shall:
- 6 (1) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity and 7 located in the proposed fixed MRI scanner service area;
- 8 (2) identify the approved fixed MRI scanners owned or operated by the applicant or a related entity and 9 located in the proposed fixed MRI scanner service area;
- 10(3)identify the existing mobile MRI scanners owned or operated by the applicant or a related entity11that provided mobile MRI services at host sites located in the proposed fixed MRI scanner service12area during the 12 months before the application deadline for the review period;
- (4) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity
   that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service
   area;
- 16(5)provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (4) of this17Paragraph and the proposed fixed MRI scanner during each of the first three full fiscal years of18operation following completion of the project;
- 19(6)provide the assumptions and methodology used to project the utilization required by Subparagraph20(5) of this Paragraph;
- (7) project that the fixed MRI scanners identified in Subparagraphs (1) and (2) of this Paragraph and
   the proposed fixed MRI scanner shall perform during the third full fiscal year of operation following
   completion of the project as follows:
  - (A) 3,364 or more adjusted MRI procedures per fixed MRI scanner if there are four or more fixed MRI scanners in the fixed MRI scanner service area;
- 26
   (B) 3,123 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI

   27
   scanners in the fixed MRI scanner service area;
- 28 (C)(A) 2,883 3,494 or more adjusted MRI procedures per fixed MRI scanner if there are two or
   29 more fixed MRI scanners in the fixed MRI scanner service area;
- 30(D)(B)2,6433,058or more adjusted MRI procedures per fixed MRI scanner if there is one fixed31MRI scanner in the fixed MRI scanner service area; or
- 32 (E)(C) 1,201 1,310 or more adjusted MRI procedures per MRI scanner if there are no existing 33 fixed MRI scanners in the fixed MRI scanner service area; and
- (8) project that the mobile MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall
   perform 3,328 3,120 or more adjusted MRI procedures per mobile MRI scanner during the third full
   fiscal year of operation operations following completion of the project.

(b) An applicant proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State
Medical Facilities Plan in effect as of the first day of the review period shall:

3 (1)identify the existing mobile MRI scanners owned or operated by the applicant or a related entity 4 that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service 5 area during the 12 months before the application deadline for the review period; identify the approved mobile MRI scanners owned or operated by the applicant or a related entity 6 (2) 7 that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner 8 service area; 9 (3) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that 10 are located in the proposed mobile MRI scanner service area; identify the approved fixed MRI scanners owned or operated by the applicant or a related entity that 11 (4)12 will be located in the proposed mobile MRI scanner service area; 13 (5) identify the existing and proposed host sites for each mobile MRI scanner identified in 14 Subparagraphs (1) and (2) of this Paragraph and the proposed mobile MRI scanner; 15 (6)provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (4) of this 16 Paragraph and the proposed mobile MRI scanner during each of the first three full fiscal years of 17 operation following completion of the project; 18 provide the assumptions and methodology used to project the utilization required by Subparagraph (7)19 (6) of this Paragraph; 20 (8) project that the mobile MRI scanners identified in Subparagraphs (1) and (2) of this Paragraph and 21 the proposed mobile MRI scanner shall perform 3,328 3,120 or more adjusted MRI procedures per 22 MRI scanner during the third full fiscal year of operation operations following completion of the 23 project; and 24 (9) project that the fixed MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall 25 perform during the third full fiscal year of operation operations following completion of the project 26 as follows: 27 (A)3,364 or more adjusted MRI procedures per fixed MRI scanner if there are four or more 28 fixed MRI scanners in the fixed MRI scanner service area; 3,123 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI 29 <del>(B)</del> 30 scanners in the fixed MRI scanner service area; 31 (C)(A) 2,883 3,494 or more adjusted MRI procedures per fixed MRI scanner if there are two or more fixed MRI scanners in the fixed MRI scanner service area; 32 33 (D)(B) 2,643 3,058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed 34 MRI scanner in the fixed MRI scanner service area; or 35 1,201 1,310 or more adjusted MRI procedures per MRI scanner if there are no fixed MRI (E)(C) 36 scanners in the fixed MRI scanner service area. 37

| 1  | History Note: | Authority G.S. 131E-177(1); 131E-183(b);                                                       |
|----|---------------|------------------------------------------------------------------------------------------------|
| 2  |               | Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule |
| 3  |               | becomes effective, whichever is sooner;                                                        |
| 4  |               | Eff. February 1, 1994;                                                                         |
| 5  |               | Temporary Amendment Eff. January 1, 1999;                                                      |
| 6  |               | Temporary Amendment Eff. January 1, 1999 Expired on October 12, 1999;                          |
| 7  |               | Temporary Amendment Eff. January 1, 2000;                                                      |
| 8  |               | Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking       |
| 9  |               | originally proposed to be effective August 2000;                                               |
| 10 |               | Temporary Amendment Eff. January 1, 2001;                                                      |
| 11 |               | Temporary Amendment effective January 1, 2001 amends and replaces a permanent rulemaking       |
| 12 |               | originally proposed to be effective April 1, 2001;                                             |
| 13 |               | Temporary Amendment Eff. January 1, 2002;                                                      |
| 14 |               | Temporary Amendment Eff. January 1, 2002 amends and replaces the permanent rule effective,     |
| 15 |               | August 1, 2002;                                                                                |
| 16 |               | Temporary Amendment Eff. January 1, 2003;                                                      |
| 17 |               | Amended Eff. August 1, 2004; April 1, 2003;                                                    |
| 18 |               | Temporary Amendment Eff. January 1, 2005;                                                      |
| 19 |               | Amended Eff. November 1, 2005;                                                                 |
| 20 |               | Temporary Amendment Eff. February 1, 2006;                                                     |
| 21 |               | Amended Eff. November 1, 2006;                                                                 |
| 22 |               | Temporary Amendment Eff. February 1, 2008;                                                     |
| 23 |               | Amended Eff. November 1, 2008;                                                                 |
| 24 |               | Readopted Eff. January 1, <del>2022.</del> 2022;                                               |
| 25 |               | <u>Temporary Amendment Eff. January 27, 2023.</u>                                              |