

Note from the Codifier: The OAH website includes notices and the text of proposed temporary rules as required by G.S. 150B-21.1(a1). Prior to the agency adopting the temporary rule, the agency must hold a public hearing no less than five days after the rule and notice have been published and must accept comments for at least 15 business days.
For questions, you may contact the Office of Administrative Hearings at 984-236-1850 or email oah.postmaster@oah.nc.gov.

TITLE 10A – DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice is hereby given in accordance with G.S. 150B-21.1(a3) that the HHS - Division of Health Service Regulation intends to amend the rules cited as 10A NCAC 14C .1403 and .2703.

Codifier of Rules received for publication the following notice and proposed temporary rule(s) on: November 7, 2022.

Public Hearing:

Date: November 28, 2022

Time: 10:00 a.m.

Location: Dorothea Dix Park, Edgerton Building, Room 026, 809 Ruggles Drive, Raleigh, NC 27603

Reason for Proposed Temporary Action: State Medical Facilities Plan. Several subject matters are addressed in the State Medical Facilities Plan (SMFP). Changes were made to the chapters in the 2023 SMFP addressing the neonatal beds and Magnetic Resonance Imaging (MRI) Scanner need methodology. Revisions to an existing Certificate of Need (CON) rule are required to complement or be made consistent with the SMFP. The effective date of the 2023 SMFP is January 1, 2023. These rules reflect the methodology changes in the SMFP and are being amended under temporary procedures so that correct performance standards reflective of the need methodology changes shall be used by 2023 CON applicants for neonatal services and MRI services. These temporary rule amendments are required for an applicant's compliance with a CON application submission for neonatal beds in a service area and an MRI need determination in the 2023 SMFP.

Comment Procedures: Comments from the public shall be directed to: Nadine Pfeiffer, 809 Ruggles Drive, 2701 Mail Service Center, Raleigh, NC 27699-2701; email DHSR.RulesCoordinator@dhhs.nc.gov. The comment period begins November 16, 2022 and ends December 9, 2022.

CHAPTER 14 - DIRECTOR, DIVISION OF HEALTH SERVICE REGULATION

SUBCHAPTER 14C – CERTIFICATE OF NEED REGULATIONS

SECTION .1400 – CRITERIA AND STANDARDS FOR NEONATAL SERVICES

10A NCAC 14C .1403 PERFORMANCE STANDARDS

(a) An applicant shall demonstrate that the proposed project is capable of meeting the following standards:

- (1) if an applicant is proposing to increase the total number of neonatal beds (i.e., the sum of Level II, Level ~~III~~ III, and Level IV beds), the overall average annual occupancy of the combined number of existing Level II, Level ~~III~~ III, and Level IV beds in the facility is at least 75 percent, over the 12 months immediately preceding the submittal of the proposal;
- (2) if an applicant is proposing to increase the total number of neonatal beds (i.e., the sum of Level II, Level ~~III~~ III, and Level IV beds), the projected overall average annual occupancy of the combined number of Level II, Level ~~III~~ III, and Level IV beds proposed to be operated during the third year of operation of the proposed project shall be at least 75 percent; and
- (3) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this rule.

(b) If an applicant proposes to develop a new Level III or Level IV service, the applicant shall document that an unmet need exists in the applicant's defined neonatal service ~~area, unless the State Medical Facilities Plan includes a need determination for neonatal beds in the service area.~~ area. The need for Level III and Level IV beds shall be computed for the applicant's neonatal service area by:

- (1) identifying the ~~annual~~ number of live births occurring annually at all hospitals within the proposed neonatal service area, using the latest available data compiled by the State Center for Health Statistics;
- (2) identifying the low birth weight rate (percent of live births below 2,500 grams) for the births identified in Subparagraph (1) of this Paragraph, using the latest available data compiled by the State Center for Health Statistics;
- (3) dividing the low birth weight rate identified in Subparagraph (2) of this Paragraph by .08 and subsequently multiplying the resulting quotient by four; and
- (4) determining the need for Level III and Level IV beds in the proposed neonatal service area as the product of:
 - (A) the product derived in Subparagraph (3) of this Paragraph, and
 - (B) the quotient resulting from the division of the number of live births in the initial year of the determination identified in Subparagraph (1) of this Paragraph by the number 1000.

SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER

10A NCAC 14C .2703 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a fixed 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:

- (1) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;
- (2) identify the approved fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;
- (3) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed fixed MRI scanner service area 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;
- (5) provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed MRI scanner during each of the first three full fiscal years of operation following completion of the project;
- (6) provide the assumptions and methodology used to project the utilization required by Subparagraph (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;~~
 - (B) ~~3,123 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI scanners in the fixed MRI scanner service area;~~
 - (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;
 - (D)(B) ~~2,643~~ 3,058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or
 - (E)(C) ~~1,204~~ 1,310 or more adjusted MRI procedures per MRI scanner if there are no existing 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:

- (1) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service area during the 12 months before the application deadline for the review period;
- (2) 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 mobile MRI scanner service area;
- (3) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;
- (4) identify the approved fixed MRI scanners owned or operated by the applicant or a related entity that will be located in the proposed mobile MRI scanner service area;
- (5) identify the existing and proposed host sites for each mobile MRI scanner identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile MRI scanner;
- (6) provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed mobile MRI scanner during each of the first three full fiscal years of operation following completion of the project;
- (7) provide the assumptions and methodology used to project the utilization required by Subparagraph (6) of this Paragraph;
- (8) project that the mobile MRI scanners identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile MRI scanner shall perform ~~3,328~~ 3,120 or more adjusted MRI procedures per MRI scanner during the third full fiscal year of ~~operation~~ operations following completion of the project; and
- (9) project that the fixed MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall perform during the third full fiscal year of ~~operation~~ operations 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;~~
 - (B) ~~3,123 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI scanners in the fixed MRI scanner service area;~~
 - (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;
 - (D)(B) ~~2,643~~ 3,058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or

~~(E)(C)~~ ~~1,201~~ 1,310 or more adjusted MRI procedures per MRI scanner if there are no fixed MRI scanners in the fixed MRI scanner service area.

Authority G.S. 131E-177(1); 131E-183(b).