



# 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, DHR

2. Rule citation & name: 10A NCAC 14C .1403 Performance Standards

3. Action:  Adoption  Amendment  Repeal

4. Was this an Emergency Rule:  Yes  No 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.  
Cite:  
Effective date:
- A recent change in federal or state budgetary policy.  
Effective date of change:
- A recent federal regulation.  
Cite:  
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). 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.

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

The change to the existing Certificate of Need (CON) performance standards rule for the criteria and standards for neonatal services is required to compliment or to be made consistent with the State Medical Facilities Plan (SMFP) that will become effective January 1, 2023. The acute care bed need determination methodology found in the SMFP underwent substantial changes as a result of a workgroup directed by the State Health Coordinating Council (SHCC). The revised need methodology was approved for inclusion in the 2023 SMFP by the SHCC on September 28, 2022 and subsequently signed for approval by the governor on December 16, 2022. This rule is being revised to reflect the need methodology change for neonatal services for removing an exception for an applicant in a defined neonatal service area to demonstrate an unmet need if a need is determined in the SMFP. This temporary rule amendment adoption is required for an applicant's compliance with a CON application submission for new Level III or Level IV neonatal services beds in accordance with the 2023 SMFP.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

Yes

Agency submitted request for consultation on:

Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

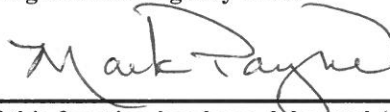
E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Micheala Mitchell, Chief

Phone: 919-855-3879

E-Mail: micheala.mitchell@dhhs.nc.gov

10. Signature of Agency Head\*:



\* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark Payne

Title: Director, Division of Health Service Regulation

E-Mail: mark.payne@dhhs.nc.gov

**RULES REVIEW COMMISSION USE ONLY**

Action taken:

Submitted for RRC Review:

Date returned to agency:

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Department of Health and Human Services

RULE CITATION: 10A NCAC 14C .1403

**DEADLINE FOR RECEIPT: January 13, 2023**

***PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*The temporary rule finding of need form must be signed by “the head of the agency adopting the temporary rule.” G.S. 150B-21.1(a4). Please resubmit the forms with the agency head’s signature.*

*Note also that the directive you provided is unsigned and has a former Secretary’s name in the signature box. You will need to correct this if you intend to use a delegated signer on a future permanent rule.*

*Regarding subparagraphs (a)(1) and (a)(2), neonatal bed is already defined in 10A NCAC 14C .1401 as “a licensed acute care bed used to provide Level II, III or IV neonatal services”. Consider omitting the parenthetical (i.e., the sum of Level II, Level III, and Level IV beds) to increase readability.*

*On line 13, strikethrough “The” and replace with “the”.*

*Paragraph (a) does not identify the type of project covered by the rule, while subparagraphs (a)(1) and (a)(2) repeat the same introductory language. This could be written more clearly. Consider:*

(a) If an applicant is proposing a project that increases the total number of neonatal beds in a facility, ~~At the~~ 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

Seth Ascher  
Commission Counsel

Date submitted to agency: January 10, 2023

- (3) ~~The~~the applicant shall document the assumptions and provide data supporting the methodology used for each projection in this rule.

*As written, paragraph (b) defines how to calculate “the need for Level III and Level IV beds”, but not what to compare that to determine if that need is unmet. Is “unmet need” (lines 15-16) defined in rule or statute?*

*As written, paragraph (b) only requires an applicant to “document that an unmet need exists” and not that a proposed project is the size of that unmet need. Is that the agency’s intention?*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Seth Ascher  
Commission Counsel  
Date submitted to agency: January 10, 2023

1 10A NCAC 14C .1403 is amended under temporary procedures as follows:

2  
3 **10A NCAC 14C .1403 PERFORMANCE STANDARDS**

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

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

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

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

32  
33 *History Note: Authority G.S. 131E-177(1); 131E-183(b);*  
34 *Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule*  
35 *becomes effective, whichever is sooner;*  
36 *Eff. January 4, 1994;*  
37 *Temporary Amendment Eff. March 15, 2002;*

1                    *Amended Eff. April 1, 2003;*  
2                    *Temporary Amendment Eff. February 1, 2009;*  
3                    *Amended Eff. November 1, 2009;*  
4                    *Temporary Amendment Eff. February 1, 2010;*  
5                    *Amended Eff. November 1, ~~2010~~ 2010;*  
6                    *Temporary Amendment Eff. January 27, 2023.*



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- 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.  
Cite:  
Effective date:
- A recent change in federal or state budgetary policy.  
Effective date of change:
- A recent federal regulation.  
Cite:  
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 contrary to the public interest and the immediate adoption of the rule is required?

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 workgroup directed by the State Health Coordinating Council (SHCC). The revised need methodology was approved for inclusion in the 2023 SMFP by the SHCC on September 28, 2022 and subsequently signed for approval by the governor on December 16, 2022. This rule is being revised so that performance standards reflective of the MRI need methodology changes shall be used by 2023 CON applicants for MRI services. This temporary rule amendment adoption is required for an 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:  
Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

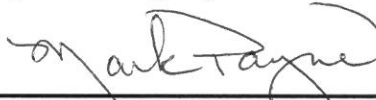
E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Micheala Mitchell, Chief

Phone: 919-855-3879

E-Mail: micheala.mitchell@dhhs.nc.gov

10. Signature of Agency Head\*:



\* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark Payne

Title: Director, Division of Health Service Regulation

E-Mail: mark.payne@dhhs.nc.gov

**RULES REVIEW COMMISSION USE ONLY**

Action taken:

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REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

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RULE CITATION: 10A NCAC 14C .2703

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*Note also that the directive you provided is unsigned and has a former Secretary’s name in the signature box. You will need to correct this if you intend to use a delegated signer on a future permanent rule.*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

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

2  
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 entity  
11 that provided mobile MRI services at host sites located in the proposed fixed MRI scanner service  
12 area during the 12 months before the application deadline for the review period;
- 13 (4) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity  
14 that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service  
15 area;
- 16 (5) provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (4) of this  
17 Paragraph and the proposed fixed MRI scanner during each of the first three full fiscal years of  
18 operation following completion of the project;
- 19 (6) provide the assumptions and methodology used to project the utilization required by Subparagraph  
20 (5) of this Paragraph;
- 21 (7) project that the fixed MRI scanners identified in Subparagraphs (1) and (2) of this Paragraph and  
22 the proposed fixed MRI scanner shall perform during the third full fiscal year of operation following  
23 completion of the project as follows:
- 24 (A) ~~3,364 or more adjusted MRI procedures per fixed MRI scanner if there are four or more~~  
25 ~~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) ~~2,643~~ 3,058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed  
31 MRI 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
- 34 (8) project that the mobile MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall  
35 perform ~~3,328~~ 3,120 or more adjusted MRI procedures per mobile MRI scanner during the third full  
36 fiscal year of ~~operation~~ operations following completion of the project.

1 (b) An applicant proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State  
2 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;
- 6 (2) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity  
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;
- 11 (4) identify the approved fixed MRI scanners owned or operated by the applicant or a related entity that  
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 (7) provide the assumptions and methodology used to project the utilization required by Subparagraph  
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;~~
- 29 (B) ~~3,123 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI~~  
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  
32 more fixed MRI scanners in the fixed MRI scanner service area;
- 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 (E)(C) ~~1,204~~ 1,310 or more adjusted MRI procedures per MRI scanner if there are no fixed MRI  
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, ~~2022~~ 2022;*  
25 *Temporary Amendment Eff. January 27, 2023.*