Burgos, Alexander N

Subject: FW: Technical changes DHHS DHSR 10A NCAC 14C rules

From: Mitchell, Micheala L < Micheala. Mitchell@dhhs.nc.gov>

Sent: Friday, December 9, 2022 3:23 PM

To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Peaslee, William W <bill.peaslee@oah.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Technical changes DHHS DHSR 10A NCAC 14C rules

Thank you both!

Micheala Mitchell, JD

(she/her/hers)
Section Chief, Hea

Section Chief, Healthcare Planning and CON Section

NC Department of Health and Human Services

Division of Health Service Regulation

809 Ruggles Drive, Edgerton Building

2704 Mail Service Center Raleigh, NC 27699-2704 Office: 919 855 3879

Micheala.Mitchell@dhhs.nc.gov

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From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>

Sent: Friday, December 9, 2022 3:02 PM

To: Peaslee, William W <bill.peaslee@oah.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>

Subject: RE: Technical changes DHHS DHSR 10A NCAC 14C rules

Thank you for the opportunity to discuss the rule with you.

Nadine Pfeiffer

Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811

Fax: 919-733-2757

nadine.pfeiffer@dhhs.nc.gov

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

From: Peaslee, William W < bill.peaslee@oah.nc.gov>

Sent: Friday, December 9, 2022 2:48 PM

To: Pfeiffer, Nadine < nadine.pfeiffer@dhhs.nc.gov >

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>

Subject: RE: Technical changes DHHS DHSR 10A NCAC 14C rules

Thank you for our telephone conversation today. We discussed what the agency intended by the employment of the word "document" in line 16 of 10 NCAC 14C .3803. I understand that the agency intends that the applicant will make a statement or provide some written affirmation to the effect that the applicant meets the qualifications set forth in the State Medical Facilities Plan.

If the agency's intention is different, please let me know prior to the RRC meeting on December 15, 2022.

Thank you.

William W. Peaslee Rules Review Commission Counsel / Legislative Liaison

Office of Administrative Hearings 1711 New Hope Church Road Raleigh NC, 27609 (984) 236-1939 Bill.Peaslee@oah.nc.gov

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

From: Pfeiffer, Nadine < nadine.pfeiffer@dhhs.nc.gov >

Sent: Friday, December 9, 2022 12:23 PM

To: Peaslee, William W <bill.peaslee@oah.nc.gov>

Cc: Burgos, Alexander N < alexander.burgos@oah.nc.gov >; Mitchell, Micheala L < Micheala.Mitchell@dhhs.nc.gov >

Subject: RE: Technical changes DHHS DHSR 10A NCAC 14C rules

Good Afternoon Bill,

Please see our answers to your additional questions for these rules:

In Rule 10 NCAC 14C .3803, Line 14, is the "application" a form or a process? In (a), is the applicant documenting that it <u>has been qualified</u> to apply for the beds? Or is that which is being "document[ed]" what will be considered in the determination of qualification?

Line 14 refers to the "applicant" rather than the application. The application is a form. (See, 10A NCAC 14C .0203) The applicant is documenting that it is a qualified applicant in the application.

In Rule 10A NCAC 14C .4001, there may have been a misunderstanding of the Request for Changes regarding Lines 33 and 36. The agency is using the very term it is defining in the definition. Its like saying a "widget" is a "widget which is

red". That still does not define "widget". What's a widget? As written the definitions sound more like requirements the agency is mandating. In which case, the beds are being licensed pursuant to what authority?

Rule (attached) -rewritten to remove definition of term and added refer by reference to licensing rules in Code in (4) and (5). Please note according to the Rules Style guide pg 21, incorporation by reference was only done for (4).

Keeping my hopes up this will clarify everything for you!!! © Please let us know if you need anything else.

Nadine Pfeiffer

Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811 Fax: 919-733-2757

nadine.pfeiffer@dhhs.nc.gov

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

Burgos, Alexander N

Subject: FW: Technical changes DHHS DHSR 10A NCAC 14C rules

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>

Sent: Friday, December 9, 2022 10:57 AM

To: Peaslee, William W <bill.peaslee@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Technical changes DHHS DHSR 10A NCAC 14C rules

Thank you. I will contact the Section Chief for our Healthcare Planning and Certificate of Need Section for the answers to these questions.

Nadine Pfeiffer

Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811 Fax: 919-733-2757

nadine.pfeiffer@dhhs.nc.gov

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

From: Peaslee, William W < bill.peaslee@oah.nc.gov >

Sent: Friday, December 9, 2022 10:53 AM

To: Pfeiffer, Nadine <<u>nadine.pfeiffer@dhhs.nc.gov</u>>
Cc: Burgos, Alexander N <<u>alexander.burgos@oah.nc.gov</u>>
Subject: RE: Technical changes DHHS DHSR 10A NCAC 14C rules

Good morning,

In Rule 10 NCAC 14C .3803, Line 14, is the "application" a form or a process? In (a), is the applicant documenting that it has been qualified to apply for the beds? Or is that which is being "document[ed]" what will be considered in the determination of qualification?

In Rule 10A NCAC 14C .4001, there may have been a misunderstanding of the Request for Changes regarding Lines 33 and 36. The agency is using the very term it is defining in the definition. Its like saying a "widget" is a "widget which is red". That still does not define "widget". What's a widget? As written the definitions sound more like requirements the agency is mandating. In which case, the beds are being licensed pursuant to what authority?

Please respond by 5:00 pm today.

William W. Peaslee Rules Review Commission Counsel / Legislative Liaison Office of Administrative Hearings 1711 New Hope Church Road Raleigh NC, 27609 (984) 236-1939 Bill.Peaslee@oah.nc.gov

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Burgos, Alexander N

From: Pfeiffer, Nadine

Sent: Thursday, December 8, 2022 11:45 AM

To: Peaslee, William W
Cc: Burgos, Alexander N

Subject: Technical changes DHHS DHSR 10A NCAC 14C rules

Attachments: Request for Tech Chg 14C Response RRC.docx; 10A NCAC 14C .2801.docx; 10A NCAC 14C

.2803.docx; 10A NCAC 14C .3801.docx; 10A NCAC 14C .3803.docx; 10A NCAC 14C .4001.docx; 10A

NCAC 14C .4003.docx

Hi Bill,

We were notified of the technical changes on December 1, 2022 pursuant to G.S. 150B-21.10 for the following rules: 10A NCAC 14C 1102, .2003, .2801, .2803, .3801, .3803, .4001, and .4003. No technical changes were requested for Rule 10A NCAC 14C .2001. In preparation for the December 15, 2002 RRC meeting, attached to this email you will find the amended text for rules 10A NCAC 14C .2801, .2803, .3801, .3803, .4001, and .4003 as requested in the Request for Technical Change document received. No changes were made to rules 10A NCAC 14C .1102 and .2003, therefore those rules are not attached. The Agency's responses to the concerns raised in the "Request for Changes" document may be seen in bold black font on the document.

Should you have any questions regarding the attachments or the Agency's responses, or should you have any follow up questions or concerns, please feel free to contact me. I will be back in touch with you to let you know who will be attending the meeting virtually next week.

Thank you very much!

Nadine Pfeiffer

Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811 Fax: 919-733-2757

nadine.pfeiffer@dhhs.nc.gov

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

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

RULE CITATION: 10A NCAC 14C .1102

DEADLINE FOR RECEIPT:

<u>PLEASE NOTE:</u> 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:

Generally, to the rule: The rule uses the term "adult care home"; however, there appears to be multiple definitions for this term, including G.S. 131E-101, 131E-176, and 131D-2.1.

The definition of "adult care home" that is germane to this rule, is G.S. 131E-176 (found in Article 9-Certificate of Need). G.S. 131D, incorporated by reference into G.S. 131E-176, relates to the inspection and licensure of adult care homes. G.S. 131E-101 distinguishes adult care homes from nursing homes for the purpose of licensure (Article 6-Healthcare Facility Licensure Act).

On line 28, "times 365 days" is colloquial and unclear because numbers are multiplied, not days. Deleting "days" would increase clarity.

This language has been and is currently utilized in need methodologies in various iterations of the State Medical Facilities Plan, each of which has been approved by the Governor. The regulated public understands the meaning of the phrase "times 365 days."

In subparagraphs (b)(1) and (c)(1): is "projected utilization" a term that will be understood consistently by the regulated public? **Yes**

Will "assumptions and methodology" be consistently understood among the regulated public? Yes Is there something specific you are looking for? No. There is a range of historical information and data that can be used to project utilization. The Agency requests that the applicant describe the methodology and assumptions that it uses to project utilization, whatever that methodology and those assumptions may be.

The rule as written requires applicants to submit certain materials but does not seem to indicate who will approve the applications or how they will be evaluated. Is this information located elsewhere in rule or statute?

The rules contain the following provisions regarding who will approve/evaluate applications:

10A NCAC 14C .0202 (3) "Competitive review" means two or more applications submitted to begin review in the same review period proposing the same new institutional health service in the same service area and the CON Section determines that approval of one application may require denial of another application included in the same review period.

10A NCAC 14C.0202 (4) "CON Section" means the Healthcare Planning and Certificate of Need Section of the Division of Health Service Regulation.

The statutes contain the following provisions regarding who will approve/evaluate applications:

§ 131E-177(6). 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.... power to grant, deny, or withdraw a certificate of need and to impose such sanctions as are provided for by this Article; and

§ 131E-177(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.

§ 131E-183 enumerates the review criteria that an applicant must conform to, and provides, in relevant part, that: 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.

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

RULE CITATION: 10A NCAC 14C .2001

DEADLINE FOR RECEIPT:

<u>PLEASE NOTE:</u> 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:

No changes.

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

RULE CITATION: 10A NCAC 14C .2003

DEADLINE FOR RECEIPT:

<u>PLEASE NOTE:</u> 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:

Is "projected utilization" (line 12) a term that will be understood consistently by the regulated public? **Yes**

The rule as written requires applicants to submit certain materials but does not seem to indicate who will approve the applications or how they will be evaluated. Is this information located elsewhere in rule or statute?

The rules contain the following provisions regarding who will approve/evaluate applications:

10A NCAC 14C .0202 (3) "Competitive review" means two or more applications submitted to begin review in the same review period proposing the same new institutional health service in the same service area and the CON Section determines that approval of one application may require denial of another application included in the same review period.

10A NCAC 14C.0202 (4) "CON Section" means the Healthcare Planning and Certificate of Need Section of the Division of Health Service Regulation.

The statutes contain the following provisions regarding who will approve/evaluate applications:

§ 131E-177(6). 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.... power to grant, deny, or withdraw a certificate of need and to impose such sanctions as are provided for by this Article; and § 131E-177(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.

§ 131E-183 enumerates the review criteria that an applicant must conform to, and provides, in relevant part, that: 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.

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

RULE CITATION: 10A NCAC 14C .2801

DEADLINE FOR RECEIPT:

<u>PLEASE NOTE:</u> 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:

Is "days of care" (line 30) a defined term?

The phrase "days of care" is a term of art used in the healthcare industry by the regulated public. The term is referenced used over 100 times in the State Medical Facilities Plan which is approved annually by the Governor.

The phrase "inpatient rehab days of care" is unclear. Does it mean "days of inpatient rehab care"?

It does. However, the phrase "inpatient rehabilitation days of care" is in the State Medical Facilities Plan and is utilized and understood by the regulated public as explained in the paragraph above.

Replace "rehab" with "rehabilitation". Neither the statutes nor the code uses "rehab". Rule revised throughout with wording spelled out.

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

RULE CITATION: 10A NCAC 14C .2803

DEADLINE FOR RECEIPT:

<u>PLEASE NOTE:</u> 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:

Is "projected utilization" (line 12) a term that will be understood consistently by the regulated public? **Yes**

In item 2, the verb "document" (line 15) is used, while "project" is used in most of the similar rules (e.g., .1102(b)(2) & (b)3), .2003 line 14). This suggests a distinction, is this intentional? No. Word "document" replaced with "project" in rule.

The rule as written requires applicants to submit certain materials but does not seem to indicate who will approve the applications or how they will be evaluated. Is this information located elsewhere in rule or statute?

The rules contain the following provisions regarding who will approve/evaluate applications:

10A NCAC 14C .0202 (3) "Competitive review" means two or more applications submitted to begin review in the same review period proposing the same new institutional health service in the same service area and the CON Section determines that approval of one application may require denial of another application included in the same review period.

10A NCAC 14C.0202 (4) "CON Section" means the Healthcare Planning and Certificate of Need Section of the Division of Health Service Regulation.

The statutes contain the following provisions regarding who will approve/evaluate applications:

§ 131E-177(6). 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.... power to grant, deny, or withdraw a certificate of need and to impose such sanctions as are provided for by this Article; and

§ 131E-177(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.

§ 131E-183 enumerates the review criteria that an applicant must conform to, and provides, in relevant part, that: 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.

Replace "rehab" with "rehabilitation". Neither the statutes nor the code uses "rehab". Rule revised throughout with wording spelled out.

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

RULE CITATION: 10A NCAC 14C .3801

DEADLINE FOR RECEIPT:

<u>PLEASE NOTE:</u> 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:

Is "days of care" (line 20) a defined term?

The phrase "days of care" is a term of art used in the healthcare industry by the regulated public. The term is referenced used over 100 times in the State Medical Facilities Plan which is approved annually by the Governor.

The phrase "acute care days of care" is unclear. Does it mean "days of acute care"? It does. However, the phrase "acute care days of care" is in the State Medical Facilities Plan and is utilized and understood by the regulated public as explained in response to the question above.

On line 21, "divided by 365 days" is colloquial and unclear because numbers are divided, not days. Deleting "days" would increase clarity.

This language has been and is currently utilized in need methodologies in various iterations of the State Medical Facilities Plan, each of which has been approved by the Governor. The regulated public understands the meaning of the phrase "divided by 365 days."

On line 26, there is a missing comma between "approved" and "and". Rule revised

The definition of "occupancy rate" in the other rules ends with "expressed as a percentage." Should this be included in line 27? Yes. Text added "expressed as a percentage" to the definition.

Subparagraph (10) (starting at line 34) does not appear to be defining the phrase "Target occupancy percentage". Instead, it appears to set standards for target occupancy percentages. Placing this in a definition rule is unclear. One way to make this clearer would be to move these targets into .3803 as a separate item or paragraph. Moved text to rule .3803 as a Sublevel item.

Please retype the rule accordingly	y and resubmit it to	our office at 1711 Ne	ew Hope Church
Road, Raleigh, North Carolina 27	7609.		

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

RULE CITATION: 10 NCAC 14C .3803

DEADLINE FOR RECEIPT:

<u>PLEASE NOTE:</u> 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:

In Subparagraph (1), in what way is the applicant to "document" their qualifications? The rule states that an applicant proposing to develop acute care beds pursuant to a need determination in the annual State Medical Facilities Plan (SMFP) must document that it is a qualified applicant. The section of the SMFP that addresses the need methodology for acute care beds enumerates 3 requirements that an applicant must meet in order to apply for these beds. An applicant must address those requirements in its application. These requirements are known and understood by the regulated public.

Is "projected utilization" (lines 17 and 23) a term that will be understood consistently by the regulated public? **Yes**

The rule as written requires applicants to submit certain materials but does not seem to indicate who will approve the applications or how they will be evaluated. Is this information located elsewhere in rule or statute?

The rules contain the following provisions regarding who will approve/evaluate applications:

10A NCAC 14C .0202 (3) "Competitive review" means two or more applications submitted to begin review in the same review period proposing the same new institutional health service in the same service area and the CON Section determines that approval of one application may require denial of another application included in the same review period.

10A NCAC 14C .0202 (4) "CON Section" means the Healthcare Planning and Certificate of Need Section of the Division of Health Service Regulation.

The statutes contain the following provisions regarding who will approve/evaluate applications:

§ 131E-177(6). 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.... power to grant, deny, or withdraw a certificate of need and to impose such sanctions as are provided for by this Article; and

§ 131E-177(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.

§ 131E-183 enumerates the review criteria that an applicant must conform to, and provides, in relevant part, that: 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.

Please note: percentage target occupancy percentages moved to this Rule from Rule .3801 in lines (5)(a) through (d).

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

RULE CITATION: 10A NCAC 14C .4001

DEADLINE FOR RECEIPT:

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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:

Generally, to the Rule: Unless "HI" and "HR" are elsewhere defined, do not use abbreviations. Wording of abbreviations written out throughout rule.

On page 1, line 28, "divided by 365 days" is colloquial and unclear because numbers are divided, not days. Deleting "days" would increase clarity.

The phrase "days of care" is a term of art used in the healthcare industry by the regulated public. The term is referenced used over 100 times in the State Medical Facilities Plan which is approved annually by the Governor.

On page 1, lines 31 and 34, the agency uses the term it is defining in the definition of the term. This is unclear and ambiguous. Wording of "hospice inpatient facility" and "hospice residential care facility" written out throughout rule.

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

RULE CITATION: 10A NCAC 14C .4003

DEADLINE FOR RECEIPT:

<u>PLEASE NOTE:</u> 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:

Generally, to the Rule: Unless "HI" and "HR" are elsewhere defined, do not use abbreviations. Wording of "hospice inpatient facility" and "hospice residential care facility" written out throughout rule.

In subparagraphs (a)(1) and (b)(1): is "projected utilization" a term that will be understood consistently by the regulated public? **Yes**

In subparagraphs (a)(2) and (b)(2), the verb "document" (lines 26 and 34) is used, while "project" is used in most of the similar rules (e.g., .1102(b)(2) & (b)3), .2003 line 14). This suggests a distinction, is this intentional? It is not.

In subparagraphs (a)(2) and (b)(2), the verb "document" (lines 26 and 34) is used, in what way must particulars be documented? **Text replaced with the word "project"**

On line 24, there is a missing a comma between "existing" and "approved". Rule revised

The rule as written requires applicants to submit certain materials but does not seem to indicate who will approve the applications or how they will be evaluated. Is this information located elsewhere in rule or statute?

The rules contain the following provisions regarding who will approve/evaluate applications:

10A NCAC 14C .0202 (3) "Competitive review" means two or more applications submitted to begin review in the same review period proposing the same new institutional health service in the same service area and the CON Section determines that approval of one application may require denial of another application included in the same review period.

10A NCAC 14C.0202 (4) "CON Section" means the Healthcare Planning and Certificate of Need Section of the Division of Health Service Regulation.

The statutes contain the following provisions regarding who will approve/evaluate applications:

§ 131E-177(6). 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.... power to grant, deny, or withdraw a certificate of need and to impose such sanctions as are provided for by this Article; and

§ 131E-177(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.

§ 131E-183 enumerates the review criteria that an applicant must conform to, and provides, in relevant part, that: 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.

10A NCAC 14C.	2801 is readopted with changes as published in 37:02 NCR 170-174 as follows:
SECTI	ON .2800 - CRITERIA AND STANDARDS FOR REHABILITATION SERVICES
10A NCAC 14C	.2801 DEFINITIONS
The definitions in	this Rule will apply to all rules in this Section.
(1)	"Rehabilitation Facility" means a facility as defined in G.S. 131E-176.
(2)	"Rehabilitation" means the process to maintain, restore or increase the function of disabled
	individuals so that an individual can live in the least restrictive environment, consistent with his or
	her objective.
(3)	"Outpatient Rehabilitation Clinic" is defined as a program of coordinated and integrated outpatient
	services, evaluation, or treatment with emphasis on improving the functional level of the person in
	coordination with the patient's family.
(4)	"Rehabilitation Beds" means inpatient beds for which a need determination is set forth in the current
	State Medical Facilities Plan and which are located in a hospital licensed pursuant to G.S. 131E-77.
(5)	"Traumatic Brain Injury" is defined as an insult to the brain that may produce a diminished or altered
	state of consciousness which results in impairment of cognitive abilities or physical functioning. It
	can also result in the disturbance of behavioral or emotional functioning. These impairments may
	be either temporary or permanent and cause partial or total functional disability or psychological
	maladjustment.
(6)	"Stroke" (cerebral infarction, hemorrhage) is defined as the sudden onset of a focal neurologic
	deficit due to a local disturbance in the blood supply to the brain.
(7)	"Spinal Cord Injury" is defined as an injury to the spinal cord that results in the loss of motor or
	sensory function.
(8)	"Pediatric Rehabilitation" is defined as inpatient rehabilitation services provided to persons 14 years
	of age or younger.
The following def	initions shall apply to this Section:
(1)	"Approved rehabilitation [(rehab)] beds" means [rehab] rehabilitation beds that were issued a
	certificate of need but are not licensed as [rehab] rehabilitation beds as of the application deadline
	for the review period.
(2)	"Average daily census (ADC)" means the total number of inpatient [rehab] rehabilitation days of
	care provided during a full fiscal year of operation divided by 365 days.
(3)	"Existing [rehab] rehabilitation beds" means [rehab] rehabilitation beds that are licensed as [rehab]
	rehabilitation beds as of the application deadline for the review period.
(4)	"Occupancy rate" means the ADC divided by the total number of existing, approved, and proposed
	[rehab] rehabilitation beds expressed as a percentage.
	\$ECTI 10A NCAC 14C The definitions in (1) (2) (3) (4) (5) (6) (7) (8) The following def (1) (2) (3)

1	<u>(5)</u>	"Proposed [rehab] rehabilitation beds" means the [rehab] rehabilitation beds proposed in the
2		application under review.
3		
4	History Note:	Authority G.S. 131E-177; 131E-183(b);
5		Eff. May 1, 1991;
6		Amended Eff. February 1, 1993;
7		Temporary Amendment Eff. February 1, 2006;
8		Amended Eff. November 1, 2006. 2006;
9		Readopted Eff. January 1, 2023.

1	10A NCAC 14C	2.2803 is readopted with changes as published in 37:02 NCR 170-174 as follows:
2		
3	10A NCAC 140	C .2803 PERFORMANCE STANDARDS
4	(a) An applican	t proposing to establish new rehabilitation beds shall not be approved unless the average occupancy,
5	over the nine r	nonths immediately preceding the submittal of the application, of the total number of licensed
6	rehabilitation be	ds within the facility in which the new beds are to be operated was at least 80 percent.
7	(b) An applicar	t proposing to establish new rehabilitation beds shall not be approved unless occupancy is projected
8	to be 80 percen	t for the total number of rehabilitation beds to be operated in the facility no later than two years
9	following comp	letion of the proposed project.
10	An applicant pr	oposing to develop [rehab] <mark>rehabilitation</mark> beds pursuant to a need determination in the annual State
11	Medical Facilitie	es Plan in effect as of the first day of the review period shall:
12	(1)	provide projected utilization of all existing, approved, and proposed [rehab] rehabilitation beds on
13		the hospital license during each of the first three full fiscal years of operation following completion
14		of the project;
15	(2)	[document] project that the occupancy rate for all existing, approved, and proposed [rehab]
16		rehabilitation beds on the hospital license shall be at least 70 percent during the third full fiscal year
17		of operation following completion of the project; and
18	(3)	provide the assumptions and methodology used to provide the projected utilization and occupancy
19		rate required in Items (1) and (2) of this Rule.
20		
21	History Note:	Authority G.S. 131E-177; 131E-183; <u>131E-183(b);</u>
22		Eff. November 1, 1996. <u>1996:</u>
23		Readopted Eff. January 1, 2023.

1	10A NCAC 14C .3801 is readopted with changes as published in 37:02 NCR 170-174 as follows:
2	
3	SECTION .3800 - CRITERIA AND STANDARDS FOR ACUTE CARE <u>HOSPITAL</u> BEDS
4	
5	10A NCAC 14C .3801 DEFINITIONS
6	The following definitions shall apply to all Rules in this Section:
7	(1) "Acute care beds" means acute care beds licensed by the Division of Health Service Regulation in
8	accordance with standards in 10A NCAC 13B .6200, and located in hospitals licensed pursuant to
9	G.S. 131E-79.
10	(2) "Average daily census" means the number of days of inpatient acute care provided in licensed acute
11	care beds in a given year divided by 365 days.
12	(3) "Campus" shall have the same meaning as defined in G.S. 131E 176(2c).
13	(4) "Service Area" means the single or multi county area as used in the development of the acute care
14	bed need determination in the applicable State Medical Facilities Plan.
15	The following definitions shall apply to this Section:
16	(1) "Applicant hospital" means the hospital where the applicant proposes to develop the new acute care
17	beds and includes all campuses on one license.
18	(2) "Approved beds" means acute care beds in a hospital that were issued a certificate of need but are
19	not licensed as of the application deadline for the review period.
20	(3) "Average daily census (ADC)" means the total number of acute care days of care provided during
21	a full fiscal year of operation divided by 365 days.
22	(4) "Existing beds" means acute care beds in a hospital that are licensed as of the application deadling
23	for the review period.
24	(5) "Hospital system" means all hospitals in the proposed service area owned or operated by the
25	applicant or a related entity.
26	(6) "Occupancy rate" means the ADC divided by the total number of existing. [approved] approved
27	and proposed acute care hospital [beds.] beds expressed as a percentage.
28	(7) "Proposed beds" means the acute care beds proposed to be developed in a hospital in the application
29	under review.
30	(8) "Qualified applicant" shall have the same meaning as defined in the annual State Medical Facilities
31	Plan in effect as of the first day of the review period.
32	(9) "Service area" shall have the same meaning as defined in the annual State Medical Facilities Plan
33	in effect as of the first day of the review period.
34	[(10) "Target occupancy percentage" means:
35	(a) 66.7 percent if the ADC is less than 100;
36	(b) 71.4 percent if the ADC is 100 to 200;
37	(c) 75.2 percent if the ADC is 201 to 399; or

1		(d) 78.0 percent if the ADC is greater than 400.
2		
3	History Note:	Authority G.S. 131E-177(1); 131E-183; 131E-183(b);
4		Temporary Adoption Eff. January 1, 2004;
5		Eff. August 1, 2004. <u>2004;</u>
6		Readopted Eff. January 1, 2023.

10A NCAC 14C	2.3803 is readopted with changes as published in 37:02 NCR 170-174 as follows:
10A NCAC 140	C .3803 PERFORMANCE STANDARDS
(a) An applican	t proposing to develop new acute care beds shall demonstrate that the projected average daily census
(ADC) of the tot	tal number of licensed acute care beds proposed to be licensed within the service area, under common
ownership with	the applicant, divided by the total number of those licensed acute care beds is reasonably projected to
be at least 66.7	percent when the projected ADC is less than 100 patients, 71.4 percent when the projected ADC is
100 to 200 patie	nts, and 75.2 percent when the projected ADC is greater than 200 patients, in the third operating year
following compl	letion of the proposed project or in the year for which the need determination is identified in the State
Medical Facilitie	es Plan, whichever is later.
(b) An applican	t proposing to develop new acute care beds shall provide all assumptions and data used to develop the
projections requ	ired in this rule and demonstrate that they support the projected inpatient utilization and average daily
census.	
An applicant pro	oposing to develop new acute care beds in a hospital pursuant to a need determination in the annual
State Medical Fa	acilities Plan in effect as of the first day of the review period shall:
<u>(1)</u>	document that it is a qualified applicant;
(2)	provide projected utilization of the existing, approved, and proposed acute care beds for the
	applicant hospital during each of the first three full fiscal years of operation following completion
	of the project:
(3)	project an occupancy rate of the existing, approved, and proposed acute care beds for the applicant
	hospital during the third full fiscal year of operation following completion of the project that equals
	or exceeds the target occupancy percentage;
<u>(4)</u>	provide projected utilization of the existing, approved, and proposed acute care beds for the hospital
	system during each of the first three full fiscal years of operation following completion of the
	project:
<u>(5)</u>	project an average occupancy rate of the existing, approved, and proposed acute care beds for the
	hospital system during the third full fiscal year of operation following completion of the project that
	equals or exceeds the target occupancy [percentage; and] percentage of:
	(a) 66.7 percent if the ADC is less than 100;
	(b) 71.4 percent if the ADC is 100 to 200;
	(c) 75.2 percent if the ADC is 201 to 399; or
	(d) 78.0 percent if the ADC is greater than 400; and
<u>(6)</u>	provide the assumptions and methodology used to project the utilization and occupancy rates
	required in Items (2), (3), (4), and (5) of this Rule.
History Note:	Authority G.S. 131E-177(1); 131E-183; <u>131E-183(b);</u>
	Temporary Adoption Eff. January 1, 2004;
	10A NCAC 14C (a) An applicant (ADC) of the totolownership with- be at least 66.7 100 to 200 paties following compited following

- 1 Eff. August 1, 2004. <u>2004.</u>
- 2 <u>Readopted Eff. January 1, 2023.</u>

1	10A NCAC 14C	.4001 is readopted with changes as published in 37:02 NCR 170-174 as follows:
2		
3	SECTION.	4000 - CRITERIA AND STANDARDS FOR HOSPICE INPATIENT FACILITIES AND
4		HOSPICE RESIDENTIAL CARE FACILITIES
5		
6	10A NCAC 14C	.4001 DEFINITIONS
7	The following de	finitions shall apply to all rules in this Section:
8	(1)	"Bereavement counseling" means counseling provided to a hospice patient's family or significant
9		others to assist them in dealing with issues of grief and loss.
10	(2)	"Caregiver" means the person whom the patient designates to provide the patient with emotional
11		support, physical care, or both.
12	(3)	"Care plan" means a plan as defined in 10A NCAC 13K .0102 of the Hospice Licensing Rules.
13	(4)	"Home like" means furnishings of a hospice inpatient facility or a hospice residential care facility
14		as defined in 10A NCAC 13K .1110 or .1204 of the Hospice Licensing Rules.
15	(5)	"Hospice" means any coordinated program of home care as defined in G.S. 131E 176(13a).
16	(6)	"Hospice inpatient facility" means a facility as defined in G.S. 131E 176(13b).
17	(7)	"Hospice residential care facility" means a facility as defined in G.S. 131E 176(13c).
18	(8)	"Hospice service area" means for residential care facilities, the county in which the hospice
19		residential care facility will be located and the contiguous counties for which the hospice residential
20		care facility will provide services.
21	(9)	"Hospice services" means services as defined in G.S. 131E 201(5b).
22	(10)	"Hospice staff" means personnel as defined in 10A NCAC 13K .0102 of the Hospice Licensing
23		Rules.
24	The following de	finitions shall apply to this Section:
25	<u>(1)</u>	"Approved beds" means [HI or HR] hospice inpatient facility or hospice residential care facility
26		beds that were issued a certificate of need but are not licensed as of the application deadline for the
27		review period.
28	(2)	"Average daily census (ADC)" means the total number of days of care provided in the [HI or HR]
29		hospice inpatient facility or hospice residential care facility beds during a full fiscal year of operation
30		divided by 365 days.
31	(3)	"Existing beds" means [HI or HR] hospice inpatient facility or hospice residential care facility beds
32		that are licensed as of the application deadline for the review period.
33	<u>(4)</u>	"Hospice inpatient facility [(HH)] beds" means [HI] hospice inpatient facility beds licensed to
34		provide palliative and supportive medical and other health services to meet the physical,
35		psychological, social, spiritual, and special needs of terminally ill patients in an inpatient setting.
36	<u>(5)</u>	"Hospice residential care facility [(HR)) beds" means [HR] hospice residential care facility beds
37		licensed to provide palliative and supportive medical and other health services to meet the physical,

1		psychological, social, spiritual, and special needs of terminally ill patients in a group residential
2		setting.
3	<u>(6)</u>	"Occupancy rate" means the ADC divided by the total number of existing, approved, and proposed
4		[HI or HR] hospice inpatient facility or hospice residential care facility beds expressed as a
5		percentage.
6	<u>(7)</u>	"Proposed beds" means the [HI or HR] hospice inpatient facility or hospice residential care facility
7		beds proposed in the application under review.
8		
9	History Note:	Authority G.S. 131E-177(1); 131E-183(b);
10		Temporary Adoption Eff. February 1, 2006;
11		Eff. November 1, 2006. <u>2006:</u>
12		Readopted Eff. January 1, 2023.

1	10A NCAC 14C .4003 is readopted with changes as published in 37:02 NCR 170-174 as follows:
2	
3	10A NCAC 14C .4003 PERFORMANCE STANDARDS
4	(a) An applicant proposing to develop hospice inpatient facility beds or hospice residential care facility beds shall
5	demonstrate that:
6	(1) the average occupancy rate of the licensed hospice beds, for each level of care, in the facility is
7	projected to be at least 50 percent for the last six months of the first operating year following
8	completion of the project;
9	(2) the average occupancy rate for the licensed hospice beds, for each level of care, in the facility is
10	projected to be at least 65 percent for the second operating year following completion of the project;
11	and
12	(3) if the application is submitted to address the need for hospice residential care beds, each existing
13	hospice residential care facility which is located in the hospice service area operated at an occupancy
14	rate of at least 65 percent for the 12 month period reported on that facility's most recent Licensure
15	Renewal Application Form.
16	(b) An applicant proposing to add hospice inpatient facility beds to an existing hospice inpatient facility shall
17	document that the average occupancy of the licensed hospice inpatient facility beds in its existing facility was at least
18	65 percent for the nine months immediately preceding the submittal of the proposal.
19	(c) An applicant proposing to add residential care beds to an existing hospice residential care facility shall document
20	that the average occupancy of the licensed hospice residential care beds in its existing facility was at least 65 percent
21	for the nine months immediately preceding the submittal of the proposal.
22	(a) An applicant proposing to develop new [HI] hospice inpatient facility beds pursuant to a need determination in
23	the annual State Medical Facilities Plan in effect as of the first day of the review period shall:
24	(1) provide projected utilization of all [existing] existing, approved, and proposed [H] hospice inpatient
25	facility beds on the license during each of the first three full fiscal years of operation following
26	completion of the project;
27	(2) [document] project that the occupancy rate for all existing, approved, and proposed [HI] hospice
28	inpatient facility beds on the license shall be at least 65 percent during the third full fiscal year of
29	operation following completion of the project; and
30	(3) provide the assumptions and methodology used to provide the projected utilization and occupancy
31	rate required by Subparagraphs (1) and (2) of this Paragraph.
32	(b) An applicant proposing to develop new [HR] hospice residential care facility beds shall:
33	(1) provide projected utilization of all existing, approved, and proposed [HR] hospice residential care
34	facility beds on the license during each of the first three full fiscal years of operation following
35	completion of the project;

1	(2)	[document] project that the occupancy rate for all existing, approved, and proposed [HR] hospice
2		residential care facility beds on the license shall be at least 65 percent during the third full fiscal
3		year of operation following completion of the project; and
4	(3)	provide the assumptions and methodology used to provide the projected utilization and occupancy
5		rate required by Subparagraphs (1) and (2) of this Paragraph.
6		
7	History Note:	Authority G.S. 131E-177(1); <u>131E-183(b);</u>
8		Temporary Adoption Eff. February 1, 2006;
9		Eff. November 1, 2006;
10		Temporary Amendment Eff. February 1, 2008;
11		Amended Eff. November 1, 2008. <u>2008:</u>
12		Readopted Eff. January 1, 2023.

Burgos, Alexander N

From: Pfeiffer, Nadine

Sent: Thursday, December 1, 2022 4:43 PM

To: Peaslee, William W

Cc: Burgos, Alexander N; Ascher, Seth M
Subject: RE: Request for Changes DHHS DHSR

Thank you. I will share this document with our Healthcare Planning and Certificate of Need Section team responsible for writing these rules for their input in responding to your technical change requests and comments.

Nadine Pfeiffer

Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811 Fax: 919-733-2757

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

From: Peaslee, William W <bill.peaslee@oah.nc.gov>

Sent: Thursday, December 1, 2022 4:29 PM

To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Ascher, Seth M <seth.ascher@oah.nc.gov>

Subject: Request for Changes DHHS DHSR

Good afternoon.

I'm the attorney who reviewed the Rules submitted by the Department of Health and Human Services for the December 2022 RRC meeting. The RRC will formally review these Rules at its meeting on Thursday, December 15, 2022, at 9:00 a.m. The meeting will be a hybrid of in-person and WebEx attendance, and an evite should be sent to you as we get closer to the meeting. If there are any other representatives from your agency who will want to attend virtually, let me know prior to the meeting, and we will get evites out to them as well.

Please submit the revised Rules and forms to me via email, no later than <u>5 p.m. on December 9, 2022.</u>

In the meantime, please let me know if you have any questions or concerns.

William W. Peaslee Rules Review Commission Counsel / Legislative Liaison

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