Burgos, Alexander N

From: Pfeiffer, Nadine
Sent: Tuesday, September 13, 2022 12:11 PM
To: Liebman, Brian R; Burgos, Alexander N
Subject: Thursday's RRC meeting

Hi Brian,
Since you will be recommending approval of the 10A NCAC 13F & G rules for the Medical Care Commission and the 10A NCAC 15 rules for the Radiation Protection Commission, I and the staff subject matter experts for those rules will not attend the RRC meeting on Thursday in person to allow for room for others to be in the meeting room. However we will be attending via WebEx to hear the Commission's decision and should any questions arise for those rules. If that happens, the people to unmute to answer any specific questions are Megan Lamphere for the 10A NCAC 13F & G rules for the Medical Care Commission and James Albright for the 10A NCAC 15 rules for the Radiation Protection Commission.

Thank 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

Burgos, Alexander N

Subject: FW: Submission of Technical Changes - NC Medical Care Commission - 10A NCAC 13F & 13G

From: Lamphere, Megan <megan.lamphere@dhhs.nc.gov>
Sent: Monday, September 12, 2022 5:13 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>; Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Kinsey, Libby <libby.kinsey@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Submission of Technical Changes - NC Medical Care Commission - 10A NCAC 13F & 13G

Thanks, Brian! I feel honored. Again, we appreciate your review and helpful suggestions!
Have a great week,
Megan

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Monday, September 12, 2022 5:04 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Lamphere, Megan <megan.lamphere@dhhs.nc.gov>; Kinsey, Libby <libby.kinsey@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Submission of Technical Changes - NC Medical Care Commission - 10A NCAC 13F & 13G

Hi all,

Thanks for the hard work on these. Bravo. You guys get the "most improved rule" award for 13F and 13G .0504. I will recommend approval of all rules at this week's meeting.

Unless I hear an objection, I'll send these on to Alex and Dana as the final versions for RRC review.

Best,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

Subject: FW: Submission of Technical Changes - NC Medical Care Commission - 10A NCAC 13F & 13G
Attachments: 10A NCAC 13F .0404.docx; 10A NCAC 13F .0407.docx; 10A NCAC 13F .0501 .docx; 10A NCAC 13F .0503.docx; 10A NCAC 13F .0504.docx; 10A NCAC 13F .0508.docx; 10A NCAC 13F .0905.docx; 10A NCAC 13F .1006.docx; 10A NCAC 13F .1008.docx; 10A NCAC 13F .1010.docx; 10A NCAC 13G .0404.docx; 10A NCAC 13G .0406.docx; 10A NCAC 13G .0501.docx; 10A NCAC 13G .0503.docx; 10A NCAC 13G .0504.docx; 10A NCAC 13G .0508.docx; 10A NCAC 13G .0903.docx; 10A NCAC 13G .0905.docx; 10A NCAC 13G .1005.docx; 10A NCAC 13G .1006.docx; Form0400PermRule 10A NCAC 13F .0504.docx; Form0400PermRule 10A NCAC 13G .0504.docx

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Friday, September 9, 2022 9:12 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Lamphere, Megan <megan.lamphere@dhhs.nc.gov>; Kinsey, Libby <libby.kinsey@dhhs.nc.gov>
Subject: Submission of Technical Changes - NC Medical Care Commission - 10A NCAC 13F & 13G

Brian,
We were notified of the technical changes on August 31, 2022 pursuant to G.S. 150B-21.10 for rules 10A NCAC 13 F .0404, .0407, .0501, .0503, .0504.0508, .0905, .1006, .1008, .1010 and 10A NCAC 13G .0404, .0406, .0501, .0503, .0504, .0508, .0903, .0905, .1005, .1006. In preparation for the September 15, 2022 RRC meeting, attached to this email you will find the amended text for those rules as requested in the Request for Technical Change document received, as well as the Agency's responses to the concerns raised in the "Request for Changes" document as seen in bold black font on the document. Because the titles of two rules have been revised as a result of the technical changes, attached are the two revised Submission of Permanent rule forms for those rules.

Should you have any questions regarding the attachments, please feel free to contact me.

Thank you,

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

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Burgos, Alexander N

From: Pfeiffer, Nadine
Sent: Friday, September 9, 2022 10:40 AM
To: Liebman, Brian R; Rules, Oah
Cc: Burgos, Alexander N
Subject: RE: Submission of Technical Changes - NC Radiation Protection Commission - 10A NCAC 15

Thank you.

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

Office: 919-855-3811
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nadine.pfeiffer@dhhs.nc.gov

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2701 Mail Service Center
Raleigh, NC 27699-2701

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Friday, September 9, 2022 10:39 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Rules, Oah <oah.rules@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Submission of Technical Changes - NC Radiation Protection Commission - 10A NCAC 15

I do not think you need to re-send the Rule, as there were no changes from the last submission, and you've already sent it to oah.rules. I'll just let Dana and Alex know this is the final version of the Rule.

Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Friday, September 9, 2022 10:37 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>; Rules, Oah <oah.rules@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Submission of Technical Changes - NC Radiation Protection Commission - 10A NCAC 15

Thank you, Brian. I will let staff at Radiation Protection who are responsible for drafting the rules for that Chapter know your decision.

Do I need to send the rule to OAH for the meeting like you had me do last month with the hospital rules?

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

Office: 919-855-3811
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809 Ruggles Drive, Edgerton Building
2701 Mail Service Center
Raleigh, NC 27699-2701

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Friday, September 9, 2022 10:34 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Rules, Oah <oah.rules@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Submission of Technical Changes - NC Radiation Protection Commission - 10A NCAC 15

Hi Nadine,

Thanks for the response, and the extensive explanation regarding the relationship between state and federal law here. I'll recommend approval of the revised rule to the Commission at the upcoming meeting.

Have a great weekend,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Tuesday, September 6, 2022 4:58 PM
To: Rules, Oah <oah.rules@oah.nc.gov>
Cc: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: Submission of Technical Changes - NC Radiation Protection Commission - 10A NCAC 15

We have been notified of the technical changes requested by Mr. Brian Liebman on August 29, 2022 pursuant to G.S. 150B-21.10 for Rule 10A NCAC 15 .1301. In preparation for the September 15, 2022 RRC meeting, attached to this email you will find the amended text for that rule as requested in the Request for Technical Change document received, as well as the Agency's responses to the concerns raised in the "Request for Changes" document as seen in bold black font on the document. In addition, to accompany the Agency's responses to the "Request for Changes" attached are these additional documents: the Nuclear Regulatory Commission Agreement with NC (original), the most recently

governor signed Nuclear Regulatory Commission Agreement with NC, and the Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements issued 8/27/20.

Should you have any questions regarding the attachments, please feel free to contact me.

Thank you,

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

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Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

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Raleigh, NC 27699-2701

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13F .0404

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

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:

In (1) and (2), lines 6 and 10, respectively, please consider changing "on or after" to "after September 30, 2022", as your effective date is October 1, 2022. Therefore, these requirements cannot apply to anyone hired ***on*** *September 30, 2022.* ***Changed to "after September 30, 2022.***

In (2)(b), line 22, what is a "social or recreation program"?
We have clarified this.

In (2)(b), line 23, what is a "patient activities program"?
We have modified this rule to be more specific that we are referring to experience in programming of adult recreational and/or activity programs, and one of those years must be with adults in a health care or long term care setting. This ("activities program") is an accepted and understood term by the regulated providers. It is also a term that is consistent with other types of regulated settings, such as nursing homes. There is also an adult care home rule that addresses the requirements for the "activity program."

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13F .0407

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

***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:

In (a)(1), line 5, should this read "…reflects the position's duties…"?
Yes and we have fixed this.

In (a)(3), line 12, add a hyphen between "131D" and "21.1". ***Hyphen added***

In (a)(5), line 15, what is a "substantiated" finding? 131E-256 talks about "findings", but I didn't see the term "substantiated" there. Please clarify.
We have deleted the term "substantiated" to be consistent with the HCPR statute. An employee cannot have any findings on the registry.

In (a)(6), lines 17-18, are you saying that staff shall be vaccinated against influenza, except as provided in 131D-9? It's a little unclear what you mean by "except as document otherwise according to exceptions in this law".
We have clarified this. Yes, we mean that if someone is not vaccinated due to an exception in the law, the facility will just need to document that.

In (a)(7) and (a)(8), when you say staff shall "have" a background check and "have" controlled substance screening results, what do you mean?
We have clarified this. We mean that these "checks" need to be completed prior to hire and the results should be in the staff's personnel file.

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13F .0501

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

***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:

In (a), line 9, please make "Directly" lowercase. ***Done***

In (a), line 13, the URL provided does not work. Please correct.
We have corrected this.

In (a), the Rule requires a program that is "established ***or*** *approved by the Department," which suggests to me that a facility can use the program provided by DHHS at the link in the Rule, or come up with its own, as long as the curriculum includes the 6 specified topics in the list under (a). However, this is not explicit in the Rule. Please edit to clarify.*
We removed "approved". There is one program that is established by the Department.

In (a), line 9, how are these programs approved by the Department? How is approval requested and upon what grounds will it be granted? Please edit to clarify.
Programs are not approved.

In (b), line 22, did you mean to make the requirement effective on October 1, 2022? If so, I would revise to "after September 30, 2022" because as written this would not apply to staff hired until October 2.
Yes, thank you. We have changed it.

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13F .0503

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

***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:

In (a), line 5, you refer to a "clinical skills evaluation" but elsewhere throughout the Rule, you refer to a "clinical skills validation." While in your responses to the pre-review, you indicate that the validation is included in the evaluation, that suggests to me that there are additional portions of the "evaluation" that aren't captured here. If "evaluation" and "validation" refer to the same thing, then please change (a) to reflect that. Otherwise, please clarify what else besides the validation is required as part of the evaluation.
We have clarified. The competency evaluation includes a written exam and a clinical skills validation.

In (c), line 21, what does it mean to "successfully complete" the examination? I know (b) says that the individual "shall score at least 90%" but there's no explicit tie between scoring a 90 and "successfully" completing the exam. Please revise (b) and/or (c) to make this clearer.
We have made a change to this rule due to a recent change in the process. certificates are no longer printed at the conclusion of the exam.

In (d), line 27, the Rule states—as amended—that the clinical skills portion "shall be conducted by a registered nurse or a licensed pharmacist ***consistent with their occupational licensing laws*** *and who has a current unencumbered license in North Carolina." It is unclear to me whether this means the nurse or pharmacist is to conduct the test consistent with their occupational licensing laws, or whether the nurse/pharmacist must be registered or licensed consistent with their respective occupational licensing laws. Please revise for clarity.*
We have revised this and clarified by striking "in accordance with their occupational licensing laws." If they are licensed, then they are licensed in accordance with their occupational licensing laws. The extra language is unnecessary.

In (d), the meaning of the sentence beginning with "This validation shall be completed…" remains unclear. While I understand, based on your answer in the pre-

review, that validations are to be performed on the duties the staff member performs, this is not evident from the language, largely because the sentence is written in the passive tense. Please revise for clarity.

We have clarified this to mean that the licensed nurse or pharmacist must validate the medication aide's skills and tasks for each skill or task that will done at the facility. Not all facilities have residents that require every skill or task to be completed.

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13F .0504

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

***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:

Generally to the Rule, does the agency have any rule or standard that governs the process of competency validation? I'm thinking along the lines of what you have in R. 0503.
We have made significant modifications to this rule in the hopes of clarifying it and addressing the questions below. Licensed health professional support and the competency evaluation and validation of unlicensed staff is a unique requirement for the adult care home setting. Staff providing care to residents in adult care homes are not licensed and are not certified nurse aides. The use of licensed health professionals to ensure these staff are competent to provide hands-on care, including some tasks that are typically only allowed to be performed by Nurse Aide I's and Nurse Aide II's by the NC Board of Nursing, is critical to ensuring that residents receive appropriate care that maintains their health, safety and dignity. The licensed health professionals designated in this rule to evaluate staff competency for various tasks are governed by their individual occupational licensing laws (and Practice Acts) in determining whether an individual has the knowledge, skills, and abilities to safely perform a task.

Also generally to this Rule, I think the language is unnecessarily convoluted. Beyond what I've written here, please make all efforts to simplify and clarify the language of this Rule, because as written, I would have to recommend objection for lack of clarity.

In (a), line 7, what do you mean by the phrase "…are competency validated by return demonstration…"?
Deleted

In (a), line 7, what is "return demonstration"?
Deleted

Also in (a), lines 8-10, the sentence, as amended reads "The facility shall assure the competency validation occurs prior to staff performing the task and ongoing

competency is assured through facility staff oversight and supervision." This sentence is ungrammatical and as such is unclear. Suggest revising by splitting into two sentences.
Done

Also in (a), lines 8-10, how must the facility ensure validation occurred and is ongoing? Paragraph (b) states who can validate, but nothing in the rule states what the facility must do for validation or maintaining validation.
Validation is a one-time requirement. Another rule requires a licensed health professional (LHP) to conduct quarterly assessments on residents who are receiving any of the 28 care tasks. If the LHP identifies any issues related to the care of the resident during assessment, they may retrain the staff on how to perform the care task.

In subparagraphs (b)(1)-(4), are the registered nurses, pharmacists, and therapists only those registered or licensed in North Carolina? ***Yes***

Subparagraphs (b)(1)-(4) are a list, meaning (1)-(3) should be ended with a semi-colon, and there should be an "and" or "or" following (3). ***Semicolons added, word "and" added following (3).***

Paragraph (c) is almost impossible to understand. Please revise to separate out the various ideas that are referenced here, and clearly state what you're requiring.
Revised to clarify.

In (c), line 28, what is a "temporary basis" Please define. ***Defined this. This is determined by the resident's physician.***

In (c), line 29, what is "unnecessary relocation of the resident"? Please define.
There are certain conditions and care needs that are not allowed to be provided for in adult care homes except when a physician certifies that the facility can provide that care on a temporary basis so the resident doesn't have to be relocated to a higher level of care or be discharged from the facility. Residents may be discharged from a hospital with a care need that is not typically provided by their adult care home, however, this provision allows the facility to provide that care/service on a short term basis, usually until the acute condition resolves. This rule seeks to ensure that the unlicensed staff have the knowledge and skill to perform these care tasks.

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13F .0508

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

***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:

On line 6, the Rule requires that persons be trained on resident assessment, without explicitly stating how that training requirement is to be satisfied. Is the training somehow contained in the Manual incorporated by reference?
We have clarified. The training is simply reading the manual.

On line 8, please revise to say "…Homes is herein incorporated…." ***Word added***
Done

On line 9, is the "instruction manual" the same as the "Resident Assessment Self-Instructional Manual for Adult Care Homes"? Please clarify.
Yes, we have clarified.

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13F .0905

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

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:

In (c)(2), lines 14-15, how is it determined that the calendar is "easily readable to residents within the community"?
We have changed this to "legible."

In (c), line 9, what do you mean by "as required in Rule .0404"?
We have deleted this phrase*.*

In (d), line 27, is it necessary to say "a minimum of 14 hours?" All rules set minimum requirements. If necessary, why?
We changed this to "at least 14 hours." Yes, we do feel it is necessary. If it is taken out, providers will assume that they can only provide 14 hours, but many actually do provide many more than 14 hours.

In (g), p. 2, line 6, is "typically" necessary? If so, why?
We have deleted "typically" and clarified what we mean here. The purpose of this rule is so that residents are not required to do things like cook, clean, etc. in the facility….things that are staff duties.

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13F .1006

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

***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:

In (b), line 7, it is unclear what you are requiring by "maintained in a safe manner". Please clarify.

Deleted this.

In (d), lines 13-14, please delete the "and" between "administration" and "administrator", replace with a comma, and add a comma between "administrator" and "or" so that the list of staff who may access the locked storage area is a grammatical list. I think you also need to add articles ("the administrator, "the administrator-in-charge"). ***Changes made***

In (i), line 32, what are you requiring when you say first aid supplies shall be stored in an "orderly" manner?

Deleted this phrase.

In (i), line 32, please consider revising "and stored separately from medications, and in an orderly manner" to "and stored in an orderly manner, separately from medications." ***Rewritten as suggested, however, deleted the phrase about "orderly manner."***

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13F .1008

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

***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:

In (a), line 4, define "readily retrievable." As written, it is unclear what you are requiring here.

Deleted this.

In (a), line 6, what are you requiring an "accurate reconciliation" with?

Accurate reconciliation of controlled substances. This is a known term and practice for the safe administration and documentation of controlled substances.

In (e), line 24, is it necessary to say "a minimum of?" All rules set minimum requirements.

Deleted this.

In (g), line 27, is the destruction of the controlled substance to be carried out in the same manner as prescribed in (d)?

In part, yes. We have added a line about how the dose should be destroyed to be consistent with (d). However, (d) is in reference to larger quantities of controlled substances, and (g) is referring to only one dose that gets contaminated. The one dose is documented on the resident's medication record and does not need to be witness by licensed health professionals.

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13F .1010

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

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:

In (a), lines 5-6, add commas and delete "and" where appropriate to make the list grammatical. It should read: "with the requirements of this Section, all applicable State and federal rules and regulations, and the facilities medication management policies and procedures." ***Language changed but kept the word "facility's" in the rule because we are referring to "an adult care home" not several in the rule.***

Made changes.

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13G .0404

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

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:

In (1) and (2), lines 6 and 10, respectively, please consider changing "on or after" to "after September 30, 2022", as your effective date is October 1, 2022. Therefore, these requirements cannot apply to anyone hired ***on*** *September 30, 2022.* ***Changed to "after September 30, 2022.***

In (2)(b), line 22, what is a "social or recreation program"?
We have clarified this.

In (2)(b), line 23, what is a "patient activities program"?
We have modified this rule to be more specific that we are referring to experience in programming of adult recreational and/or activity programs, and one of those years must be with adults in a health care or long term care setting. This ("activities program") is an accepted and understood term by the regulated providers. It is also a term that is consistent with other types of regulated settings, such as nursing homes. There is also an adult care home rule that addresses the requirements for the "activity program."

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13G .0406

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

***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:

In (a)(1), line 5, should this read "…reflects the position's duties…"?
Yes and we have fixed this.

In (a)(3), line 12, add a hyphen between "131D" and "21.1". ***Hyphen added***

In (a)(5), line 15, what is a "substantiated" finding? 131E-256 talks about "findings", but I didn't see the term "substantiated" there. Please clarify.
We have deleted the term "substantiated" to be consistent with the HCPR statute. An employee cannot have any findings on the registry.

In (a)(6), lines 17-18, are you saying that staff shall be vaccinated against influenza, except as provided in 131D-9? It's a little unclear what you mean by "except as document otherwise according to exceptions in this law".
We have clarified this. Yes, we mean that if someone is not vaccinated due to an exception in the law, the facility will just need to document that.

In (a)(7) and (a)(8), when you say staff shall "have" a background check and "have" controlled substance screening results, what do you mean?
We have clarified this. We mean that these "checks" need to be completed prior to hire and the results should be in the staff's personnel file.

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13G .0501

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

***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:

In (a), p.3, line 27, please make "Directly" lowercase. ***Done***

In (a), line 29, the URL provided does not work. Please correct.
We have corrected this.

In (b), p.4, line 2, did you mean to make the requirement effective on October 1, 2022? If so, I would revise to "after September 30, 2022" because as written this would not apply to staff hired until October 2.
Yes, thank you. We have changed it.

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13G .0503

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

***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:

In (a), lines 4-5, you refer to a "clinical skills evaluation" but elsewhere throughout the Rule, you refer to a "clinical skills validation." While in your responses to the pre-review, you indicate that the validation is included in the evaluation, that suggests to me that there are additional portions of the "evaluation" that aren't captured here. If "evaluation" and "validation" refer to the same thing, then please change (a) to reflect that. Otherwise, please clarify what else besides the validation is required as part of the evaluation.
We have clarified. The competency evaluation includes a written exam and a clinical skills validation.

In (c), line 21, what does it mean to "successfully complete" the examination? I know (b) says that the individual "shall score at least 90%" but there's no explicit tie between scoring a 90 and "successfully" completing the exam. Please revise (b) and/or (c) to make this clearer.
We have made a change to this rule due to a recent change in the process. certificates are no longer printed at the conclusion of the exam.

In (d), line 27, the Rule states—as amended—that the clinical skills portion "shall be conducted by a registered nurse or a licensed pharmacist ***consistent with their occupational licensing laws*** *and who has a current unencumbered license in North Carolina." It is unclear to me whether this means the nurse or pharmacist is to conduct the test consistent with their occupational licensing laws, or whether the nurse/pharmacist must be registered or licensed consistent with their respective occupational licensing laws. Please revise for clarity.*
We have revised this and clarified by striking "in accordance with their occupational licensing laws." If they are licensed, then they are licensed in accordance with their occupational licensing laws. The extra language is unnecessary.

In (d), the meaning of the sentence beginning with "This validation shall be completed…" remains unclear. While I understand, based on your answer in the pre-

review, that validations are to be performed on the duties the staff member performs, this is not evident from the language, largely because the sentence is written in the passive tense. Please revise for clarity.

We have clarified this to mean that the licensed nurse or pharmacist must validate the medication aide's skills and tasks for each skill or task that will done at the facility. Not all facilities have residents that require every skill or task to be completed.

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13G .0504

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

***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:

Generally to the Rule, does the agency have any rule or standard that governs the process of competency validation? I'm thinking along the lines of what you have in R. 0503.
We have made significant modifications to this rules in the hopes of clarifying it and addressing the questions below. Licensed health professional support and the competency evaluation and validation of unlicensed staff is a unique requirement for the adult care home setting. Staff providing care to residents in adult care homes are not licensed and are not certified nurse aides. The use of licensed health professionals to ensure these staff are competent to provide hands-on care, including some tasks that are typically only allowed to be performed by Nurse Aide I's and Nurse Aide II's by the NC Board of Nursing, is critical to ensuring that residents receive appropriate care that maintains their health, safety and dignity. The licensed health professionals designated in this rule to evaluate staff competency for various tasks are governed by their individual occupational licensing laws (and Practice Acts) in determining whether an individual has the knowledge, skills, and abilities to safely perform a task.

Also generally to this Rule, I think the language is unnecessarily convoluted. Beyond what I've written here, please make all efforts to simplify and clarify the language of this Rule, because as written, I would have to recommend objection for lack of clarity.

In (a), line 7, what do you mean by the phrase "…are competency validated by return demonstration…"?
Deleted

In (a), line 7, what is "return demonstration"?
Deleted

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

Also in (a), lines 8-10, the sentence, as amended reads "The facility shall assure the competency validation occurs prior to staff performing the task and ongoing competency is assured through facility staff oversight and supervision." This sentence is ungrammatical and as such is unclear. Suggest revising by splitting into two sentences.
Done

Also in (a), lines 8-10, how must the facility ensure validation occurred and is ongoing? Paragraph (b) states who can validate, but nothing in the rule states what the facility must do for validation or maintaining validation.
Validation is a one-time requirement. Another rule requires a licensed health professional (LHP) to conduct quarterly assessments on residents who are receiving any of the 28 care tasks. If the LHP identifies any issues related to the care of the resident during assessment, they may retrain the staff on how to perform the care task.

In subparagraphs (b)(1)-(4), are the registered nurses, pharmacists, and therapists only those registered or licensed in North Carolina?

Subparagraphs (b)(1)-(4) are a list, meaning (1)-(3) should be ended with a semi-colon, and there should be an "and" or "or" following (3). ***Semicolons added, word "and" added following (3).***

Paragraph (c) is almost impossible to understand. Please revise to separate out the various ideas that are referenced here, and clearly state what you're requiring.
Revised to clarify.

In (c), lines 27-28, what is a "temporary basis" Please define.
Defined this. This is determined by the resident's physician.

In (c), line 28, what is "unnecessary relocation of the resident"? Please define.
There are certain conditions and care needs that are not allowed to be provided for in adult care homes except when a physician certifies that the facility can provide that care on a temporary basis so the resident doesn't have to be relocated to a higher level of care or be discharged from the facility. Residents may be discharged from a hospital with a care need that is not typically provided by their adult care home, however, this provision allows the facility to provide that care/service on a short term basis, usually until the acute condition resolves. This rule seeks to ensure that the unlicensed staff have the knowledge and skill to perform these care tasks.

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13G .0508

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

***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:

On line 6, the Rule requires that persons be trained on resident assessment, without explicitly stating how that training requirement is to be satisfied. Is the training somehow contained in the Manual incorporated by reference?
We have clarified. The training is simply reading the manual.

On line 8, please revise to say "…Homes is herein incorporated…." ***Word added***

On line 9, is the "instruction manual" the same as the "Resident Assessment Self-Instructional Manual for Adult Care Homes"? Please clarify.
Yes, we have clarified.

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13G .0903

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

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:

In (a)(9), (14), (19), and (20), what does "well established" mean? Please define.
The definitions of "well-established" are added in (a)(9), (14), (19) and clarified in (20).

In (a)(23), p.2, line 3, what is "early" post-operative treatment? Please define.
Deleted "early"

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13G .0905

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

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:

In (c)(2), lines 14-15, how is it determined that the calendar is "easily readable to residents within the community"?
We have changed this to "legible."

In (c), line 9, what do you mean by "as required in Rule .0404"?
We have deleted this phrase*.*

In (d), line 27, is it necessary to say "a minimum of 14 hours?" All rules set minimum requirements. If necessary, why?
We changed this to "at least 14 hours." Yes, we do feel it is necessary. If it is taken out, providers will assume that they can only provide 14 hours, but many actually do provide many more than 14 hours.

In (g), p. 2, line 6, is "typically" necessary? If so, why?
We have deleted "typically" and clarified what we mean here. The purpose of this rule is so that residents are not required to do things like cook, clean, etc. in the facility….things that are staff duties.

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13G .1005

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

***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:

In (b), lines 10-11, it appears to me that the intent here is that the facility shall notify the physician when there is (1) a change in the resident's mental or physical ability to self administer, (2) when the resident refuses to comply with the physician's orders, or (3) when the resident refuses to comply with the facility's medication policies or procedures. The way it is currently written, it appears you're requiring the facility to notify the physician when there's a change in the facility's policies or procedures. Please revise for clarity. I think the easiest way to clarify this is to revise (b) into a list.

We have made this into a list for clarity.

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC ~~13F .1006~~ *We believe this is for 13G .1006

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

***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:

In (b), line 7, it is unclear what you are requiring by "maintained in a safe manner". Please clarify. ***Deleted this.***

In (d), lines 13-14, please delete the "and" between "administration" and "administrator", replace with a comma, and add a comma between "administrator" and "or" so that the list of staff who may access the locked storage area is a grammatical list. I think you also need to add articles ("the administrator, "the administrator-in-charge"). ***Changes made***

In (i), line 32, what are you requiring when you say first aid supplies shall be stored in an "orderly" manner? ***Deleted this phrase.***

In (i), line 32, please consider revising "and stored separately from medications, and in an orderly manner" to "and stored in an orderly manner, separately from medications." ***Rewritten as suggested, however, deleted the phrase about "orderly manner."***

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13F .1008
*****This is a duplicate request – see prior responses for this rule**

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

***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:

*****This is a duplicate request – see prior responses for this rule**

In (a), line 4, define "readily retrievable." As written, it is unclear what you are requiring here.

In (a), line 6, what are you requiring an "accurate reconciliation" with?

In (e), line 24, is it necessary to say "a minimum of?" All rules set minimum requirements.

In (g), line 27, is the destruction of the controlled substance to be carried out in the same manner as prescribed in (d)?

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13F .1010
*****This is a duplicate request – see prior responses for this rule**

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

***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:

*****This is a duplicate request – see prior responses for this rule**

In (a), lines 5-6, add commas and delete "and" where appropriate to make the list grammatical. It should read: "with the requirements of this Section, all applicable State and federal rules and regulations, and the facilities medication management policies and procedures."

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

Brian Liebman
Commission Counsel
Date submitted to agency: August 31, 2022

10A NCAC 13F .0404 is readopted with changes as published in 36:18 NCR 1487-1495 as follows:

10A NCAC 13F .0404 QUALIFICATIONS OF ACTIVITY DIRECTOR

~~There shall be a designated adult~~ Adult care ~~home~~ homes shall have an activity director who meets the following qualifications:

(1) The activity director ~~(employed~~ hired ~~on or~~ after ~~August 1, 1991)~~ September 30, 2022 shall meet a minimum educational requirement by being ~~at least~~ a high school graduate or certified under the GED ~~Program or by passing an alternative examination established by the Department of Health & Human Services.~~ Program.

(2) The activity director hired ~~on or~~ after ~~July 1, 2005~~ September 30, 2022 shall ~~have completed or~~ complete, within nine months of employment or assignment to this position, the basic activity course for assisted living activity directors offered by community colleges or a comparable activity course as determined by the Department based on instructional hours and content. ~~A person with a degree in recreation administration or therapeutic recreation or who is state or nationally certified as a Therapeutic Recreation Specialist or certified by the National Certification Council for Activity Professionals meets this requirement as does a person who completed the activity coordinator course of 48 hours or more through a community college before July 1, 2005.~~ An activity director shall be exempt from the required basic activity course if one or more of the following applies:

(a) be a licensed recreational therapist or be eligible for certification as a therapeutic recreation specialist as defined by the North Carolina Recreational Therapy Licensure Act in accordance with G.S. 90C;

(b) have two years of experience working in [~~a social or~~] programming for an adult recreation or activities program within the last five years, one year of which was full-time in [~~a patient~~] an activities program for patients or residents in a health care or long term care setting;

(c) be a licensed occupational therapist or licensed occupational therapy assistant in accordance with G.S. 90, Article 18D; or

(d) be certified as an Activity Director by the National Certification Council for Activity Professionals.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Eff. January 1, 1977;
Readopted Eff. October 31, 1977;
Amended Eff. April 1, 1987; April 1, 1984;
Temporary Amendment Eff. July 1, 2003;
Amended Eff. June 1, 2004;
Temporary Amendment Eff. July 1, 2004;

Amended Eff. July 1, ~~2005.~~ 2005;

Readopted Eff. October 1, 2022.

10A NCAC 13F .0407 is readopted with changes as published in 36:18 NCR 1487-1495 as follows:

10A NCAC 13F .0407 OTHER STAFF QUALIFICATIONS

(a) Each staff person at an adult care home shall:

(1) have a job description that reflects ~~actual~~ the [~~positions,~~] position's duties and responsibilities and is signed by the administrator and the employee;

(2) be able to ~~apply~~ implement all of the adult care home's accident, fire ~~safety~~ safety, and emergency procedures for the protection of the residents;

(3) be informed of the confidential nature of resident information and shall protect and preserve ~~such~~ the information from unauthorized use and ~~disclosure.~~ disclosure, in accordance with ~~Note: G.S. 131D-2(b)(4), 131D-21(6),~~ G.S. 131D-21(6) and ~~131D-21.1~~ ~~govern the disclosure of such information;~~ [~~131D-21.1;~~] 131D-21.1;

(4) not hinder or interfere with the exercise of the rights guaranteed under the Declaration of Residents' Rights in G.S. 131D-21;

(5) have no ~~substantiated~~ findings listed on the North Carolina Health Care Personnel Registry according to G.S. 131E-256;

(6) have documented annual immunization against influenza virus according to G.S. 131D-9, ~~except as documented otherwise according to exceptions in this law;~~ and exceptions as provided in the law shall be documented in the staff person's personnel record;

(7) have a criminal background check completed in accordance with G.S. ~~114-19.10 and~~ ~~131D-40;~~ 131D-40 and results available in the staff person's personnel file;

(8) have [~~results of the~~] an examination and screening for the presence of controlled substances completed in accordance with G.S. [~~131D-45;~~] 131D-45 and results available in the staff person's personnel file;

~~(8)~~(9) maintain a ~~valid~~ current driver's license if responsible for transportation of residents; and

~~(9)~~(10) be willing to ~~work~~ cooperate with ~~bona fide~~ state and local inspectors ~~and the monitoring and licensing agencies toward meeting and maintaining~~ when determining and maintaining compliance with the rules of this Subchapter.

(b) ~~Any~~ At all times, there shall be at least one staff ~~member left~~ person in the facility ~~left~~ in charge of ~~the~~ resident care ~~of residents~~ who shall be 18 years or older.

(c) If licensed practical nurses are employed by the facility and practicing in their licensed capacity as governed by ~~their practice act and occupational licensing laws,~~ the North Carolina Board of Nursing, there shall be ~~continuous availability of~~ a registered nurse ~~consistent~~ available in accordance with the rules set forth in ~~Rules~~ 21 NCAC 36 ~~.0224(i)~~ .0224 and 21 NCAC 36 ~~.0225.~~ .0225, which are hereby incorporated by reference including subsequent amendments.

~~Note: The practice of licensed practical nurses is governed by their occupational licensing laws.~~

History Note: *Authority G.S. 131D-2.16; ~~131D-4.5;~~ 131D 4.5(4); 143B-165;*
Eff. January 1, 1977;
Readopted Eff. October 31, 1977;
Amended Eff. April 1, 1984;
Temporary Amendment Eff. September 1, 2003; July 1, 2003.
Amended Eff. June 1, ~~2004.~~ 2004;
Readopted Eff. October 1, 2022.

10A NCAC 13F .0501 is readopted with changes as published in 36:18 NCR 1487-1495 as follows:

SECTION .0500 - STAFF ORIENTATION, TRAINING, COMPETENCY AND CONTINUING EDUCATION

10A NCAC 13F .0501 PERSONAL CARE TRAINING AND COMPETENCY

(a) ~~An adult care home~~ The facility shall assure that staff who provide or directly supervise staff who provide personal care to residents ~~successfully~~ complete an 80-hour personal care training and competency evaluation program established [~~or approved~~] by the Department. For the purpose of this Rule, ~~Directly supervise~~ [~~"Directly~~] "directly supervise" means being on duty in the facility to oversee or direct the performance of staff duties. ~~Copies~~ A copy of the 80-hour training and competency evaluation program ~~are~~ is available ~~at the cost of printing and mailing by contacting the Division of Health Service Regulation, Adult Care Licensure Section, 2708 Mail Service Center, Raleigh, NC 27699-2708.~~ online at [~~https://info.ncdhhs.gov/dhsr/acls/training/PCA-trainingmanual.html,~~] https://info.ncdhhs.gov/dhsr/acls/training/index.html#80hr, at no cost. The 80-hour personal care training and competency evaluation program curriculum shall include:

(1) observation and documentation skills;

(2) basic nursing skills, including special health-related tasks;

(3) activities of daily living and personal care skills;

(4) cognitive, behavioral, and social care;

(5) basic restorative services; and

(6) residents' rights as established by G.S. 131D-21.

(b) The facility shall assure that training specified in Paragraph (a) of this Rule is ~~successfully~~ completed within six months after hiring for staff hired after ~~September 1, 2003.~~ [~~October 1, 2022.~~] September 30, 2022. Documentation of the successful completion of the 80-hour training and competency evaluation program shall be maintained in the facility and available for ~~review.~~ review by the Division of Health Service Regulation and the county department of social services.

(c) The facility shall assure that staff who perform or directly supervise staff who perform personal care receive training and supervision on the performance of individual job assignments prior to meeting the training and competency requirements of this Rule. Documentation of training shall be maintained in the facility and available for review by the Division of Health Service Regulation and the county department of social services.

~~(c)~~(d) The Department shall exempt staff from the 80-hour training and competency evaluation program who are:

(1) licensed health professionals;

(2) listed on the Nurse Aide Registry; or

(3) documented as having ~~successfully~~ completed ~~a 40-45 or 75-80 hour training program or competency evaluation program approved by the Department since January 1, 1996 according to Rule .0502 of this Section.~~ one of the following previously approved training programs:

(A) a 40-hour or 75-hour training and competency evaluation program prior to July 1, 2000; or

(B) a 45-hour or 80-hour training and competency evaluation program for training exemption from July 1, 2000 through August 31, 2003.

~~(d) The facility shall assure that staff who perform or directly supervise staff who perform personal care receive on-the-job training and supervision as necessary for the performance of individual job assignments prior to meeting the training and competency requirements of this Rule. Documentation of the on-the-job training shall be maintained in the facility and available for review.~~

History Note: *Authority G.S. 131D-2.16; 131D-4.3; 131D-4.5; 143B-165;*
Temporary Adoption Eff. January 1, 1996;
Eff. May 1, 1997;
Temporary Amendment Eff. December 1, 1999;
Amended Eff. July 1, 2000;
Temporary Amendment Eff. September 1, 2003;
Amended Eff. June 1, ~~2004.~~ 2004;
Readopted Eff. October 1, 2022.

10A NCAC 13F .0503 is readopted with changes as published in 36:18 NCR 1487-1495 as follows:

10A NCAC 13F .0503 MEDICATION ADMINISTRATION COMPETENCY

(a) The competency evaluation for medication administration required in Rule .0403 of this Subchapter shall consist of a written examination and a clinical skills ~~evaluation~~ validation to determine competency in the following areas:

(1) medical abbreviations and terminology;

(2) transcription of medication orders;

(3) obtaining and documenting vital signs;

(4) procedures and tasks involved with the preparation and administration of oral (including liquid, sublingual and inhaler), topical (including transdermal), ophthalmic, otic, and nasal medications;

(5) infection control procedures;

(6) documentation of medication administration;

(7) monitoring for reactions to medications and procedures to follow when there appears to be a change in the resident's condition or health status based on those reactions;

(8) medication storage and disposition;

(9) ~~regulations~~ rules pertaining to medication administration in adult care facilities; and

(10) the facility's medication administration policy and procedures.

(b) An individual shall score at least 90% on the written examination which shall be a standardized examination established by the Department.

(c) ~~A certificate of successful completion of the written examination shall be issued to each participant successfully completing the examination.~~ [~~who successfully completes the examination as required in Paragraph (b) of this rule.~~] ~~A copy of the certificate shall be maintained and available for review in the facility. The certificate is transferable from one facility to another as proof of successful completion of the written examination.~~ ~~A medication study guide for the written examination is available at no charge by contacting the Division of Health Service Regulation, Adult Care Licensure Section, 2708 Mail Service Center, Raleigh, NC 27699-2708.~~ Verification of an individual's completion of the written examination and results can be obtained at no charge on the North Carolina Adult Care Medication Aide Testing website at https://mats.ncdhhs.gov/test-result.

(d) The clinical skills validation portion of the competency evaluation shall be conducted by a registered nurse or a ~~registered~~ licensed pharmacist ~~consistent with their occupational licensing laws and~~ who has a current unencumbered license in North Carolina. ~~This validation shall be completed for those medication administration tasks to be performed in the facility.~~ The registered nurse or licensed pharmacist shall conduct a clinical skills validation for each medication administration task or skill that will be performed in the facility. Competency validation by a registered nurse is required for unlicensed staff who perform any of the personal care tasks related to medication administration listed in Subparagraphs (a)(4), (a)(7), (a)(11), (a)(14), and (a)(15) as specified in Rule .0903 of this Subchapter.

(e) The Medication Administration Skills Validation Form shall be used to document successful completion of the clinical skills validation portion of the competency evaluation for those medication administration tasks to be performed in the facility employing the medication aide. The form requires the following:

(1) name of the staff and adult care home;

(2) satisfactory completion date of demonstrated competency of task or skill with the instructor's initials or signature;

(3) if staff needs more training on skills or tasks, it should be noted with the instructor's signature; and

(4) staff and instructor signatures and date after completion of tasks.

Copies of this form and instructions for its use may be obtained at no cost ~~by contacting the Adult Care Licensure Section, Division of Health Service Regulation, 2708 Mail Service Center, Raleigh, NC 27699-2708.~~ on the Adult Care Licensure website, https://info.ncdhhs.gov/dhsr/acls/pdf/medchklst.pdf. The completed form shall be maintained and available for review in the facility and is not transferable from one facility to another.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Temporary Adoption Eff. January 1, 2000; December 1, 1999;
Eff. July 1, 2000;
Temporary Amendment Eff. July 1, 2003;
Amended Eff. June 1, ~~2004.~~ 2004;
Readopted Eff. October 1, 2022.

SUBMISSION FOR PERMANENT RULE

1. Rule-Making Agency: N.C. Medical Care Commission

2. Rule citation & name (name not required for repeal): 10A NCAC 13F .0504/COMPETENCY EVALUATION AND VALIDATION FOR LICENSED HEALTH PROFESSIONAL SUPPORT TASKS

3. Action:
☐ **ADOPTION** ☒ **AMENDMENT** ☐ **REPEAL** ☐ **READOPTION** ☐ **REPEAL through READOPTION**

4. Rule exempt from RRC review?
☐ **Yes. Cite authority:**
☒ **No**

5. Rule automatically subject to legislative review?
☐ **Yes. Cite authority:**
☒ **No**

6. Notice for Proposed Rule:

☒ **Notice Required**
Notice of Text published on: 03/15/22
Link to Agency notice: https://info.ncdhhs.gov/dhsr/ruleactions.html
Hearing on: 04/28/22
Adoption by Agency on: 08/12/22
☐ **Notice not required under G.S.:**
Adoption by Agency on:

7. 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**

8. Fiscal impact. Check all that apply.

☒ **This Rule was part of a combined analysis.**

☐ **State funds affected**
☐ **Local funds affected**
☐ **Substantial economic impact (≥$1,000,000)**
☒ **Approved by OSBM**
☒ **No fiscal note required**

9. REASON FOR ACTION

9A. What prompted this action? Check all that apply:

☒ **Agency**
☐ **Court order / cite:**
☐ **Federal statute / cite:**
☐ **Federal regulation / cite:**
☐ **Legislation enacted by the General Assembly**
Cite Session Law:
☐ **Petition for rule-making**
☐ **Other:**

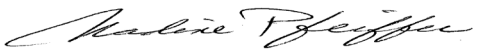
9B. Explain: Rule 10A NCAC 13F .0504 is being amended to clarify text and allow an immunizing pharmacist to validate staff competency for specific personal care tasks.

10. Rulemaking Coordinator: Nadine Pfeiffer

Phone: 919-855-3811
E-Mail: nadine.pfeiffer@dhhs.nc.gov

Additional agency contact, if any:
Phone:
E-Mail:

11. Signature of Agency Head* or Rule-making Coordinator:



***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: Nadine Pfeiffer
Title: Rule-making Coordinator

RRC AND OAH USE ONLY

Action taken:

☐ RRC extended period of review:
☐ RRC determined substantial changes:
☐ Withdrawn by agency
☐ Subject to Legislative Review
☐ Other:

10A NCAC 13F .0504 is amended with changes as published in 36:18 NCR 1487-1495 as follows:

10A NCAC 13F .0504 COMPETENCY EVALUATION AND VALIDATION FOR LICENSED HEALTH PROFESSIONAL SUPPORT TASKS

~~(a) An adult care home~~ [~~The facility~~] ~~shall assure that non licensed personnel and licensed personnel~~ [~~non licensed staff and licensed staff~~] ~~not practicing in their licensed capacity as governed by their practice act and~~ [~~in accordance with~~] ~~occupational licensing laws are competency validated by return demonstration for any personal care task specified in Subparagraph (a)(1) through (28) of Rule .0903 of this~~ ~~Subchapter~~ [~~Subchapter. The facility shall assure the competency validation occurs~~] ~~prior to staff performing the task and that their ongoing competency is assured through facility staff oversight and supervision.~~

(a) When a resident requires one or more of the personal care tasks listed in Subparagraphs (a)(1) through (a)(28) of Rule .0903 of this Subchapter, the task may be delegated to non-licensed staff or licensed staff not practicing in their licensed capacity after a licensed health professional has validated the staff person is competent to perform the task.

(b) The licensed health professional shall evaluate the staff person's knowledge, skills, and abilities that relate to the performance of each personal care task. The licensed health professional shall validate that the staff person has the knowledge, skills, and abilities and can demonstrate the performance of the task(s) prior to the task(s) being performed on a resident.

~~(b)~~(c) ~~Competency~~ Evaluation and validation of competency shall be performed by the following licensed health ~~professionals:~~ professionals in accordance with his or her North Carolina occupational licensing laws:

(1) A registered nurse shall validate the competency of staff who perform any of the personal care tasks specified in Subparagraphs (a)(1) through ~~(28)~~ (a)(28) of Rule .0903 of this ~~Subchapter.~~ Subchapter;

(2) In lieu of a registered nurse, a licensed respiratory care practitioner ~~licensed under G.S. 90, Article 38,~~ may validate the competency of staff who perform personal care tasks specified in Subparagraphs (a)(6), (a)(11), (a)(16), (a)(18), ~~(a)(19)~~(a)(19), and (a)(21) of Rule .0903 of this ~~Subchapter.~~ Subchapter;

(3) In lieu of a registered nurse, a ~~registered~~ licensed pharmacist may validate the competency of staff who perform the personal care ~~task~~ tasks specified in Subparagraph (a)(8) and (a)(11) of Rule .0903 of this Subchapter. An immunizing pharmacist may validate the competency of staff who perform the personal care task specified in Subparagraph (a)(15) of Rule .0903 of this [~~Subchapter.~~] Subchapter; and

(4) In lieu of a registered nurse, an occupational therapist or physical therapist may validate the competency of staff who perform personal care tasks specified in Subparagraphs (a)(17) and (a)(22) through ~~(27)~~ (a)(27) of Rule .0903 of this Subchapter.

~~(c) Competency validation of staff, according to Paragraph (a) of this Rule, for the licensed health professional support tasks specified in Paragraph (a) of Rule .0903 of this Subchapter and the performance of these tasks is limited exclusively to these tasks except in those cases in which a physician acting under the authority of G.S. 131D-2.2(a)~~

~~certifies that non-licensed personnel can be competency validated to perform other tasks on a temporary basis to meet the resident's needs and prevent unnecessary~~ ~~relocation.~~ [~~relocation of the resident.~~]

(d) If a physician certifies that care can be provided to a resident in an adult care home on a temporary basis in accordance with G.S. 131D-2.2(a), the facility shall ensure that the staff performing the care task(s) authorized by the physician are competent to perform the task(s) in accordance with Paragraphs (b) and (c) of this Rule. For the purpose of this Rule, "temporary basis" means a length of time as determined by the resident's physician to meet the care needs of the resident and prevent the resident's relocation from the adult care home.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Temporary Adoption Eff. September 1, 2003;
Eff. July 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 6, 2018;
Amended Eff. October 1, 2022; July 1, 2021.

10A NCAC 13F .0508 is amended with changes as published in 36:18 NCR 1487-1495 as follows [Note: The update shown of the website address in italics was amended pursuant to G.S. 150B-21.5(a)(4) effective April 1, 2022]:

10A NCAC 13F .0508 ASSESSMENT TRAINING

The person or persons designated by the administrator to perform resident assessments as required by Rule .0801 of this Subchapter shall ~~successfully~~ ~~complete training on resident assessment~~ read the Resident Assessment Self-Instructional Manual for Adult Care Homes established by the Department and certify completion by signature on the last page of the manual before performing the required resident assessments. Registered nurses are exempt from ~~the assessment training.~~ this requirement. The Resident Assessment Self-Instructional Manual for Adult Care Homes is herein incorporated by reference including subsequent amendments and [~~editions.~~] ~~The instruction manual on resident assessment~~ editions and is available on the ~~internet~~ Adult Care Licensure website, ~~*http://facility-services.state.nc.us/gcpage.htm,* or it is available at the cost of printing and mailing from the Division of Health Service Regulation, Adult Care Licensure Section, 2708 Mail Service Center, Raleigh, NC 27699-2708.~~ *https://info.ncdhhs.gov/dhsr/acls/pdf/assessmentmanual.pdf,* at no cost.

History Note: *Authority G.S. 131D-2.15; 131D-2.16; 131D-4.5; 143B-165;*
Temporary Adoption Eff. September 1, 2003;
Eff. June 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 6, ~~2018.~~ 2018;
Amended Eff. October 1, 2022; April 1, 2022.

10A NCAC 13F .0905 is amended with changes as published in 36:18 NCR 1487-1495 as follows:

10A NCAC 13F .0905 ACTIVITIES PROGRAM

(a) Each adult care home shall develop a program of activities designed to promote the residents' active involvement with each other, their families, and the community.

(b) The program shall be designed to promote active involvement by all residents but is not to require any individual to participate in any activity against his or her will. If there is a question about a resident's ability to participate in an activity, the resident's physician shall be consulted to obtain a statement regarding the resident's capabilities.

(c) The activity ~~director, as required in Rule .0404 of this Subchapter,~~ director shall:

(1) use information on the residents' interests and capabilities as documented upon admission and updated as needed to arrange for or provide planned individual and group activities for the residents, taking into account the varied interests, ~~capabilities~~ capabilities, and possible cultural differences of the residents;

(2) prepare a monthly calendar of planned group activities ~~which shall be~~ ~~easily~~ ~~readable~~ ~~with large print,~~ [~~to residents within the community,~~] in a format that is legible and shall be posted in a ~~prominent~~ location accessible to residents by the first day of each month, and updated when there are any changes;

(3) involve community resources, such as recreational, volunteer, ~~religious, aging and developmentally disabled associated agencies,~~ and religious organizations, to enhance the activities available to residents;

(4) evaluate and document the overall effectiveness of the activities program at least every six months with input from the residents to determine what have been the most valued activities and to elicit suggestions of ways to enhance the program;

(5) encourage residents to participate in activities; and

(6) assure there are ~~adequate supplies~~, supplies necessary for planned activities, ~~supervision~~ supervision, and assistance to enable each resident to participate. Aides and other facility staff may be used to assist with activities.

(d) There shall be ~~a minimum of~~ at least 14 hours of a variety of planned group activities per week that include activities that promote socialization, physical interaction, group accomplishment, creative expression, increased ~~knowledge~~ knowledge, and learning of new skills. ~~Homes that care exclusively for residents with HIV disease are exempt from this requirement as long as the facility can demonstrate planning for each resident's involvement in a variety of activities. Examples of group activities are group singing, dancing, games, exercise classes, seasonal parties, discussion groups, drama, resident council meetings, book reviews, music appreciation, review of current events and spelling bees.~~

(e) Residents shall have the opportunity to participate in activities involving one to one interaction and activity by oneself that promote enjoyment, a sense of accomplishment, increased knowledge, learning of new skills, and creative

expression. ~~Examples of these activities are crafts, painting, reading, creative writing, buddy walks, card playing, and nature walks.~~

(f) Each resident shall have the opportunity to participate in at least one outing every other month. Residents interested in being involved in the community more frequently shall be encouraged to do so.

(g) ~~Each resident~~ Residents shall have the opportunity to participate in ~~meaningful work type and~~ volunteer service activities in the ~~home~~ facility or in the ~~community, but participation shall be on an entirely voluntary basis, never forced upon residents and not assigned in place of staff.~~ community. Participation in volunteer activities shall not be required of residents and shall not involve any duties or responsibilities that are [~~typically performed by~~] outlined in the job descriptions of facility staff.

History Note: *Authority G.S. 131D-2.16; ~~131D-4.5; 143B-165;~~ 131D-4.1; 131D-4.3;*
Eff. January 1, 1977;
Readopted Eff. October 31, 1977;
Amended Eff. April 1, 1987; April 1, 1984;
Temporary Amendment Eff. July 1, 2003;
Amended Eff. July 1, 2004;
Temporary Amendment Eff. July 1, 2004 (This temporary amendment replaces the permanent rule approved by RRC on May 20, 2004);
Amended Eff. July 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 6, ~~2018.~~ 2018;
Amended Eff. October 1, 2022.

10A NCAC 13F .1006 is readopted with changes as published in 36:18 NCR 1487-1495 as follows:

10A NCAC 13F .1006 MEDICATION STORAGE

(a) Medications that are self-administered and stored in the resident's room shall be stored in a safe and secure manner as specified ~~in~~ by the adult care home's medication storage policy and procedures.

(b) All prescription and non-prescription medications stored by the facility, including those requiring refrigeration, shall be maintained ~~in a safe manner~~ under locked security except when under the ~~immediate or~~ direct physical supervision of staff in charge of medication administration.

(c) The medication storage area shall be ~~clean, well lighted, well ventilated,~~ routinely cleaned, include functional lighting, ventilated to circulate fresh air, large enough to store medications in an orderly manner, and located in areas other than the bathroom, kitchen or utility room. Medication carts shall be ~~clean~~ routinely cleaned and medications shall be stored in an orderly manner.

(d) ~~Accessibility to locked~~ Locked storage areas for medications shall only be accessible by staff responsible for medication ~~administration and administrator~~ administration, the administrator, or ~~person in charge.~~ the administrator-in-charge.

(e) Medications intended for topical or external use, except for ophthalmic, ~~otic~~ otic, and transdermal medications shall be stored in a designated area separate from the medications intended for oral and injectable use. Ophthalmic, ~~otic~~ otic, and transdermal medications may be stored with medications intended for oral and injectable use. Medications shall be stored apart from cleaning agents and hazardous chemicals.

(f) Medications requiring refrigeration shall be stored at 36 degrees F to 46 degrees F (2 degrees C to 8 degrees C).

(g) Medications shall not be stored in a refrigerator containing non-medications and non-medication related items, except when stored in a separate container. The container shall be locked when storing medications unless the refrigerator is locked or is located in a locked medication area.

(h) The facility may possess a stock of non-prescription medications or the following prescription legend medications for general or common ~~use:~~ use in accordance with physicians' orders:

(1) irrigation solutions in single unit quantities exceeding 49 ml. and related diagnostic agents;

(2) diagnostic agents;

(3) vaccines; and

(4) water for injection and normal saline for injection.

~~Note: A prescribing practitioner's order is required for the administration of any medication as stated in Rule .1004(a) of this Section.~~

(i) First aid supplies shall be immediately ~~available,~~ available to staff within the facility, stored out of sight of residents and ~~visitors~~ visitors, and stored separately from [~~medications, and~~] ~~in a secure and~~ [~~an~~] ~~orderly manner.~~ medications.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Eff. July 1, ~~2005.~~ 2005;
Readopted Eff. October 1, 2022.

10A NCAC 13F .1008 is readopted with changes as published in 36:18 NCR 1487-1495 as follows:

10A NCAC 13F .1008 CONTROLLED SUBSTANCES

(a) An adult care home shall assure a ~~readily retrievable~~ record of controlled substances by documenting the receipt, ~~administration~~ administration, and disposition of controlled substances. These records shall be maintained with the resident's record in the facility and in such an order that there can be accurate ~~reconciliation.~~ reconciliation of controlled substances.

(b) Controlled substances may be stored together in a common location or container. If Schedule II medications are stored together in a common location, the Schedule II medications shall be under double lock.

(c) Controlled substances that are expired, ~~discontinued~~ discontinued, or no longer required for a resident shall be returned to the pharmacy within 90 days of the expiration or discontinuation of the controlled substance or following the death of the resident. The facility shall document the resident's name; the name, strength and dosage form of the controlled substance; and the amount returned. There shall also be documentation by the pharmacy of the receipt or return of the controlled substances.

(d) If the pharmacy will not accept the return of a controlled substance, the administrator or the administrator's designee shall destroy the controlled substance within 90 days of the expiration or discontinuation of the controlled substance or following the death of the resident. The destruction shall be witnessed by a licensed pharmacist, dispensing practitioner, or designee of a licensed pharmacist or dispensing practitioner. The destruction shall be conducted so that no person can use, administer, ~~sell~~ sell, or give away the controlled substance. Records of controlled substances destroyed shall include the resident's name; the name, strength and dosage form of the controlled substance; the amount destroyed; the method of destruction; and, the signature of the administrator or the administrator's designee and the signature of the licensed pharmacist, dispensing practitioner or designee of the licensed pharmacist or dispensing practitioner.

(e) Records of controlled substances returned to the pharmacy or destroyed by the facility shall be maintained by the facility for ~~a minimum of~~ three years.

(f) Controlled substances that are expired, discontinued, prescribed for a deceased ~~resident~~ resident, or deteriorated shall be stored securely in a locked area separately from actively used medications until disposed of.

(g) A dose of a controlled substance accidentally contaminated or not administered shall be destroyed at the facility. The destruction shall be conducted so that no person can use, administer, sell, or give away the controlled substance. The destruction shall be documented on the medication administration record (MAR) or the controlled substance record showing the time, date, quantity, manner of ~~destruction~~ destruction, and the initials or signature of the person destroying the substance.

(h) The facility shall ensure that all known drug diversions are reported to the pharmacy, local law enforcement ~~agency~~ agency, and Health Care Personnel Registry as required by ~~state~~ State law, and that all suspected drug diversions are reported to the pharmacy. There shall be documentation of the contact and action taken.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*

Eff. July 1, ~~2005.~~ 2005;

Readopted Eff. October 1, 2022.

10A NCAC 13F .1010 is readopted with changes as published in 36:18 NCR 1487-1495 as follows:

10A NCAC 13F .1010 PHARMACEUTICAL SERVICES

(a) An adult care home shall allow the residents the right to choose a pharmacy provider as long as the pharmacy provides services that are in accordance with requirements of this ~~Section and~~ Section, all applicable ~~state~~ State and federal rules and ~~regulations~~ regulations, and the facility's medication management policies and procedures.

(b) There shall be a current, written agreement with a licensed pharmacist or a prescribing practitioner for pharmaceutical care services in accordance with Rule .1009 of this Section. The written agreement shall include a statement of the responsibility of each party.

(c) The facility shall assure the provision of pharmaceutical services to meet the needs of the residents including procedures that assure the accurate ordering, ~~receiving~~ receiving, and administering of all medications prescribed on a routine, emergency, or as needed basis.

(d) The facility shall assure the provision of medication for residents on temporary leave from the facility or involved in day activities out of the facility. The facility shall have written policies and procedures for a resident's temporary leave of absence. The policies and procedures shall facilitate safe administration by assuring that upon receipt of the medication for a leave of absence the resident or the person accompanying the resident is able to identify the medication, dosage, and administration time for each medication provided for the temporary leave of absence. The policies and procedures shall include ~~at least~~ the following provisions:

(1) The amount of resident's medications provided shall be sufficient and necessary to cover the duration of the resident's absence. For the purposes of this Rule, sufficient and necessary means the amount of medication to be administered during the leave of absence or only a current dose pack, card, or container if the current dose pack, card, or container has enough medication for the planned absence;

(2) ~~Written~~ written and verbal instructions for each medication to be released for the resident's absence shall be provided to the resident or the person accompanying the resident upon the medication's release from the facility and shall ~~include at least:~~ include:

(A) the name and strength of the medication;

(B) the directions for administration as prescribed by the resident's physician; and

(C) any cautionary information from the original prescription package if the information is not on the container released for the leave of absence;

(3) ~~The~~ the resident's medication shall be provided in a capped or closed container that will protect the medications from contamination and spillage; and

(4) ~~Labeling~~ labeling of each of the resident's individual medication containers for the leave of absence shall be legible, include at least the name of the resident and the name and strength of the medication, and be affixed to each container.

The facility shall maintain documentation in the resident's record of medications provided for the resident's leave of absence, including the quantity released from the facility and the quantity returned to the facility. The documentation

of the quantities of medications released from and returned to the facility for a resident's leave of absence shall be verified by signature of the facility staff and resident or the person accompanying the resident upon the medications' release from and return to the facility.

(e) The facility shall assure that accurate records of the receipt, use, and disposition of medications are maintained in the facility and available upon request for review.

(f) A facility with 12 or more beds shall have a current, written agreement with a pharmacy provider for dispensing services. The written agreement shall include a statement of the responsibility of each party.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Eff. July 1, 2005;
Amended Eff. April 1, ~~2015.~~ 2015;
Readopted Eff. October 1, 2022.

10A NCAC 13G .0404 is readopted with changes as published in 36:18 NCR 1487-1495 as follows:

10A NCAC 13G .0404 QUALIFICATIONS OF ACTIVITY DIRECTOR

~~There shall be a designated family~~ Adult care ~~home~~ homes shall have an activity director who meets the following qualifications: ~~qualifications set forth in this Rule.~~

(1) The activity director ~~(employed~~ hired ~~on or~~ after ~~August 1, 1991)~~ September 30, 2022 shall meet a minimum educational requirement by being ~~at least~~ a high school graduate or certified under the GED ~~Program or by passing an alternative examination established by the Department of Health & Human Services.~~ Program.

(2) The activity director hired ~~on or~~ after ~~July 1, 2005~~ September 30, 2022 shall have ~~completed or~~ complete, within nine months of employment or assignment to this position, the basic activity course for assisted living activity directors offered by community colleges or a comparable activity course as determined by the Department based on instructional hours and content. ~~A person with a degree in recreation administration or therapeutic recreation or who is state or nationally certified as a Therapeutic Recreation Specialist or certified by the National Certification Council for Activity Professional meets this requirement as does a person who completed the activity coordinator course of 48 hours or more through a community college before July 1, 2005.~~ An activity director shall be exempt from the required basic activity course if one or more of the following applies:

(a) be a licensed recreational therapist or be eligible for certification as a therapeutic recreation specialist as defined by the North Carolina Recreational Therapy Licensure Act in accordance with G.S. 90C;

(b) have two years of experience working in [~~a social or~~] programming for an adult recreation or activities program within the last five years, one year of which was full-time in [~~a patient~~] an activities program for patients or residents in a health care or long term care setting;

(c) be a licensed occupational therapist or licensed occupational therapy assistant in accordance with G.S. 90, Article 18D; or

(d) be certified as an Activity Director by the National Certification Council for Activity Professionals.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Eff. April 1, 1984;
Amended Eff. July 1, 1990; April 1, 1987; January 1, 1985;
ARRC Objection Lodged March 18, 1991;
Amended Eff. August 1, 1991;
Temporary Amendment Eff. July 1, 2004;
Amended Eff. July 1, ~~2005.~~ 2005;

Readopted Eff. October 1, 2022.

10A NCAC 13G .0406 is readopted with changes as published in 36:18 NCR 1487-1495 as follows:

10A NCAC 13G .0406 OTHER STAFF QUALIFICATIONS

(a) Each staff person of a family care home shall:

(1) have a job description that reflects ~~actual~~ the [~~positions,~~] position's ~~duties~~ duties, and responsibilities and is signed by the administrator and the employee;

(2) be able to ~~apply~~ implement all of the family care home's accident, fire ~~safety~~ safety, and emergency procedures for the protection of the residents;

(3) be informed of the confidential nature of resident information and shall protect and preserve ~~such~~ the information from unauthorized use and ~~disclosure;~~ disclosure, in accordance with ~~Note: G.S. 131D-2(b)(4),~~ G.S. 131D-21(6), and ~~G.S. 131D-21.1 govern the disclosure of such the information;~~ [~~G.S. 131D-21.1;~~] G.S. 131D-21.1;

(4) not hinder or interfere with the exercise of the rights guaranteed under the Declaration of Residents' Rights in G.S. 131D-21;

(5) have no ~~substantiated~~ findings listed on the North Carolina Health Care Personnel Registry according to G.S. 131E-256;

(6) have documented annual immunization against influenza virus according to G.S. 131D-9, ~~except as documented otherwise according to exceptions in this law;~~ and exceptions as provided in the law shall be documented in the staff person's personnel record;

(7) have a criminal background check completed in accordance with ~~G.S. 114-19.10 and~~ G.S. ~~131D-40;~~ 131D-40 and results available in the staff person's personnel file;

(8) have [~~results of the~~] an examination and screening for the presence of controlled substances completed in accordance with G.S. [~~131D-45;~~] 131D-45 and results available in the staff person's personnel file;

~~(8)~~(9) maintain a ~~valid~~ current driver's license if responsible for transportation of residents; and

~~(9)~~(10) be willing to ~~work~~ cooperate with ~~bona fide~~ state and local inspectors ~~and the monitoring and licensing agencies toward meeting and maintaining~~ when determining and maintaining compliance with the rules of this Subchapter.

(b) ~~Any~~ At all times, there shall be at least one staff ~~member~~ person in the facility ~~left~~ in charge of ~~the~~ resident care ~~of residents~~ who shall be 18 years or older.

(c) If licensed practical nurses are employed by the facility and practicing in their licensed capacity as governed by ~~their practice act and occupational licensing laws,~~ the North Carolina Board of Nursing, there shall be ~~continuous availability of~~ a registered nurse ~~consistent~~ available in accordance with the rules set forth in ~~Rules~~ 21 NCAC 36 ~~.0224(i)~~ .0224 and 21 NCAC 36 ~~.0225.~~ .0225, which are hereby incorporated by reference including subsequent amendments.

~~Note: The practice of licensed practical nurses is governed by their occupational licensing laws.~~

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Eff. January 1, 1977;
Readopted Eff. October 31, 1977;
Amended Eff. April 1, 1984;
Temporary Amendment Eff. December 1, 1999;
Amended Eff. July 1, 2000;
Temporary Amendment Eff. September 1, 2003;
Amended Eff. June 1, ~~2004.~~ 2004;
Readopted Eff. October 1, 2022.

10A NCAC 13G .0501 is readopted with changes as published in 36:18 NCR 1487-1495 as follows:

SECTION .0500 – STAFF ORIENTATION, TRAINING, COMPETENCY AND CONTINUING EDUCATION

10A NCAC 13G .0501 PERSONAL CARE TRAINING AND COMPETENCY

~~(a) The facility shall assure that personal care staff and those who directly supervise them in facilities without heavy care residents successfully complete a 25-hour training program, including competency evaluation, approved by the Department according to Rule .0502 of this Section. For the purposes of this Subchapter, heavy care residents are those for whom the facility is providing personal care tasks listed in Paragraph (i) of this Rule. Directly supervise means being on duty in the facility to oversee or direct the performance of staff duties.~~

~~(b) The facility shall assure that staff who perform or directly supervise staff who perform personal care tasks listed in Paragraph (i) of this Rule in facilities with heavy care residents successfully complete an 80-hour training program, including competency evaluation, approved by the Department according to Rule .0502 of this Section and comparable to the State-approved Nurse Aide I training.~~

~~(c) The facility shall assure that training specified in Paragraphs (a) and (b) of this Rule is successfully completed six months after hiring for staff hired after July 1, 2000. Staff hired prior to July 1, 2000, shall have completed at least a 20-hour training program for the performance or supervision of tasks listed in Paragraph (i) of this Rule or a 75-hour training program for the performance or supervision of tasks listed in Paragraph (j) of this Rule. The 20 and 75-hour training shall meet all the requirements of this Rule except for the interpersonal skills and behavioral interventions listed in Paragraph (j) of this Rule, within six months after hiring.~~

~~(d) The Department shall have the authority to extend the six-month time frame specified in Paragraph (c) of this Rule up to six additional months for a maximum allowance of 12 months for completion of training upon submittal of documentation to the Department by the facility showing good cause for not meeting the six-month time frame.~~

~~(e) Exemptions from the training requirements of this Rule are as follows:~~

~~(1) The Department shall exempt staff from the 25-hour training requirement upon successful completion of a competency evaluation approved by the Department according to Rule .0502 of this Section if staff have been employed to perform or directly supervise personal care tasks listed in Paragraph (h) and the interpersonal skills and behavioral interventions listed in Paragraph (j) of this Rule in a comparable long-term care setting for a total of at least 12 months during the three years prior to January 1, 1996, or the date they are hired, whichever is later.~~

~~(2) The Department shall exempt staff from the 80-hour training requirement upon successful completion of a 15-hour refresher training and competency evaluation program or a competency evaluation program approved by the Department according to Rule .0502 of this Section if staff have been employed to perform or directly supervise personal care tasks listed in Paragraph (i) and the interpersonal skills and behavioral interventions listed in Paragraph (j) of this Rule in a~~

comparable long-term care setting for a total of at least 12 months during the three years prior to January 1, 1996, or the date they are hired, whichever is later.

(3) The Department shall exempt staff from the 25 and 80 hour training and competency evaluation who are or have been licensed health professionals or Certified Nursing Assistants.

(f) The facility shall maintain documentation of the training and competency evaluations of staff required by the rules of this Subchapter. The documentation shall be filed in an orderly manner and made available for review by representatives of the Department.

(g) The facility shall assure that staff who perform or directly supervise staff who perform personal care tasks listed in Paragraphs (h) and (i), and the interpersonal skills and behavioral interventions listed in Paragraph (j) of this Rule receive on the job training and supervision as necessary for the performance of individual job assignments prior to meeting the training and competency requirements of this Rule.

(h) For the purposes of this Rule, personal care tasks which require a 25 hour training program include, but are not limited to the following:

(1) assist residents with toileting and maintaining bowel and bladder continence;

(2) assist residents with mobility and transferring;

(3) provide care for normal, unbroken skin;

(4) assist with personal hygiene to include mouth care, hair and scalp grooming, care of fingernails, and bathing in shower, tub, bed basin;

(5) trim hair;

(6) shave resident;

(7) provide basic first aid;

(8) assist residents with dressing;

(9) assist with feeding residents with special conditions but no swallowing difficulties;

(10) assist and encourage physical activity;

(11) take and record temperature, pulse, respiration, routine height and weight;

(12) trim toenails for residents without diabetes or peripheral vascular disease;

(13) perineal care;

(14) apply condom catheters;

(15) turn and position;

(16) collect urine or fecal specimens;

(17) take and record blood pressure if a registered nurse has determined and documented staff to be competent to perform this task;

(18) apply and remove or assist with applying and removing prosthetic devices for stable residents if a registered nurse, licensed physical therapist or licensed occupational therapist has determined and documented staff to be competent to perform the task; and

(19) apply or assist with applying ace bandages, TED's and binders for stable residents if a registered nurse has determined and documented staff to be competent to perform the task.

~~(i) For the purposes of this Rule, personal care tasks which require a 80-hour training program are as follows:~~

~~(1) assist with feeding residents with swallowing difficulty;~~

~~(2) assist with gait training using assistive devices;~~

~~(3) assist with or perform range of motion exercises;~~

~~(4) empty and record drainage of catheter bag;~~

~~(5) administer enemas;~~

~~(6) bowel and bladder retraining to regain continence;~~

~~(7) test urine or fecal specimens;~~

~~(8) use of physical or mechanical devices attached to or adjacent to the resident which restrict movement or access to one's own body used to restrict movement or enable or enhance functional abilities;~~

~~(9) non-sterile dressing procedures;~~

~~(10) force and restrict fluids;~~

~~(11) apply prescribed heat therapy;~~

~~(12) care for non-infected pressure ulcers; and~~

~~(13) vaginal douches.~~

~~(j) For purposes of this Rule, the interpersonal skills and behavioral interventions include, but are not limited to the following:~~

~~(1) recognition of residents' usual patterns of responding to other people;~~

~~(2) individualization of appropriate interpersonal interactions with residents;~~

~~(3) interpersonal distress and behavior problems;~~

~~(4) knowledge of and use of techniques, as alternatives to the use of restraints, to decrease residents' intrapersonal and interpersonal distress and behavior problems; and~~

~~(5) knowledge of procedures for obtaining consultation and assistance regarding safe, humane management of residents' behavioral problems.~~

(a) The facility shall assure that staff who provide or directly supervise staff who provide personal care to residents complete an 80-hour personal care training and competency evaluation program established by the Department. For the purpose of this Rule, [~~"Directly~~] "directly supervise" means being on duty in the facility to oversee or direct the performance of staff duties. A copy of the 80-hour training and competency evaluation program is available online at [~~https://info.ncdhhs.gov/dhsr/acls/training/PCA-trainingmanual.html,~~] https://info.ncdhhs.gov/dhsr/acls/training/index.html#80hr, at no cost. The 80-hour personal care training and competency evaluation program curriculum shall include:

(1) observation and documentation skills;

(2) basic nursing skills, including special health-related tasks;

(3) activities of daily living and personal care skills;

(4) cognitive, behavioral, and social care;

(5) basic restorative services; and

(6) residents' rights as established by G.S. 131D-21.

(b) The facility shall assure that training specified in Paragraph (a) of this Rule is completed within six months after hiring for staff hired after [~~October 1, 2022.~~] September 30, 2022. Documentation of the successful completion of the 80-hour training and competency evaluation program shall be maintained in the facility and available for review by the Division of Health Service Regulation and the county department of social services.

(c) The facility shall assure that staff who perform or directly supervise staff who perform personal care receive training and supervision for the performance of individual job assignments prior to meeting the training and competency requirements of this Rule. Documentation of training shall be maintained in the facility and available for review by the Division of Health Service Regulation and the county department of social services.

(d) The Department shall exempt staff from the 80-hour training and competency evaluation program who are:

(1) licensed health professionals;

(2) listed on the Nurse Aide Registry; or

(3) documented as having completed one of the following previously approved training programs:

(A) a 20-hour or 75-hour training and competency evaluation program prior to July 1, 2000; or

(B) a 25-hour or 80-hour training and competency evaluation program from July 1, 2000 through September 30, 2017.

History Note: *Authority G.S. 131D-2.16; 131D-4.3; 131D-4.5; 143B-165;*
Temporary Adoption Eff. January 1, 1996;
Eff. May 1, 1997;
Temporary Amendment Eff. December 1, 1999;
Amended Eff. July 1, ~~2000.~~ 2000;
Readopted Eff. October 1, 2022.

10A NCAC 13G .0503 is readopted with changes as published in 36:18 NCR 1487-1495 as follows:

10A NCAC 13G .0503 MEDICATION ADMINISTRATION COMPETENCY EVALUATION

(a) The competency evaluation for medication administration shall consist of a written examination and a clinical skills ~~evaluation~~ validation to determine competency in the following areas:

(1) medical abbreviations and terminology;

(2) transcription of medication orders;

(3) obtaining and documenting vital signs;

(4) procedures and tasks involved with the preparation and administration of oral (including liquid, sublingual and inhaler), topical (including transdermal), ophthalmic, otic, and nasal medications;

(5) infection control procedures;

(6) documentation of medication administration;

(7) monitoring for reactions to medications and procedures to follow when there appears to be a change in the resident's condition or health status based on those reactions;

(8) medication storage and disposition;

(9) ~~regulations~~ rules pertaining to medication administration in adult care facilities; and

(10) the facility's medication administration policy and procedures.

(b) An individual shall score at least 90% on the written examination which shall be a standardized examination established by the Department.

(c) ~~A certificate of successful completion of the written examination shall be issued to each participant successfully completing the examination.~~ [~~who successfully completes the examination as required in Paragraph (b) of this Rule.~~] ~~A copy of the certificate shall be maintained and available for review in the facility. The certificate is transferable from one facility to another as proof of successful completion of the written examination.~~ ~~A medication study guide for the written examination is available at no charge by contacting the Division of Health Service Regulation, Adult Care Licensure Section, 2708 Mail Service Center, Raleigh, NC 27699-2708.~~ Verification of an individual's completion of the written examination and results can be obtained at no charge on the North Carolina Adult Care Medication Aide Testing website at https://mats.ncdhhs.gov/test-result.

(d) The clinical skills validation portion of the competency evaluation shall be conducted by a registered nurse or a ~~registered~~ licensed pharmacist ~~consistent with their occupational licensing laws~~ and who has a current unencumbered license in North Carolina. ~~This validation shall be completed for those medication administration tasks to be performed in the facility.~~ The registered nurse or licensed pharmacist shall conduct a clinical skills validation for each medication administration task or skill that will be performed in the facility. Competency validation by a registered nurse is required for unlicensed staff who perform any of the personal care tasks related to medication administration listed in Subparagraphs (a)(4), (a)(7), (a)(11), (a)(14), and (a)(15) as specified in Rule .0903 of this Subchapter.

(e) The Medication Administration Skills Validation Form shall be used to document successful completion of the clinical skills validation portion of the competency evaluation for those medication administration tasks to be performed in the facility employing the medication aide. The form requires the following:

(1) name of the staff and adult care home;

(2) satisfactory completion date of demonstrated competency of task or skill with the instructor's initials or signature;

(3) if staff needs more training on skills or tasks, it should be noted with the instructor's signature; and

(4) staff and instructor signatures and date after completion of tasks.

Copies of this form and instructions for its use may be obtained at no cost ~~by contacting the Adult Care Licensure Section, Division of Health Service Regulation, 2708 Mail Service Center, Raleigh, NC 27699-2708~~. on the Adult Care Licensure website, https://info.ncdhhs.gov/dhsr/acls/pdf/medchklst.pdf. The completed form shall be maintained and available for review in the facility and is not transferable from one facility to another.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Temporary Adoption Eff. January 1, 2000; December 1, 1999;
Eff. July 1, ~~2000.~~ 2000;
Readopted Eff. October 1, 2022.

SUBMISSION FOR PERMANENT RULE

1. Rule-Making Agency: N.C. Medical Care Commission

2. Rule citation & name (name not required for repeal): 10A NCAC 13G .0504/COMPETENCY EVALUATION AND VALIDATION FOR LICENSED HEALTH PROFESSIONAL SUPPORT TASKS

3. Action:
☐ **ADOPTION** ☐ **AMENDMENT** ☐ **REPEAL** ☒ **READOPTION** ☐ **REPEAL through READOPTION**

4. Rule exempt from RRC review?
☐ **Yes. Cite authority:**
☒ **No**

5. Rule automatically subject to legislative review?
☐ **Yes. Cite authority:**
☒ **No**

6. Notice for Proposed Rule:

☒ **Notice Required**
Notice of Text published on: 03/15/22
Link to Agency notice: https://info.ncdhhs.gov/dhsr/ruleactions.html
Hearing on: 04/28/22
Adoption by Agency on: 08/12/22
☐ **Notice not required under G.S.:**
Adoption by Agency on:

7. 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**

8. Fiscal impact. Check all that apply.

☒ **This Rule was part of a combined analysis.**

☐ **State funds affected**
☐ **Local funds affected**
☐ **Substantial economic impact (≥$1,000,000)**
☒ **Approved by OSBM**
☒ **No fiscal note required**

9. REASON FOR ACTION

9A. What prompted this action? Check all that apply:

☒ **Agency**
☐ **Court order / cite:**
☐ **Federal statute / cite:**
☐ **Federal regulation / cite:**
☐ **Legislation enacted by the General Assembly**
Cite Session Law:
☐ **Petition for rule-making**
☒ **Other: G.S. 150B-21.3A.(c)(2)(g)**

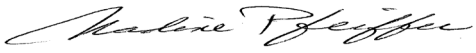
9B. Explain: Pursuant to GS 150B-21.3A, Periodic Review and Expiration of Existing Rules, all rules are reviewed at least every 10 years, or they shall expire. As a result of the periodic review of Subchapter 10A NCAC 13G, Licensing of Family Care Homes, this rule was determined as "Necessary With Substantive Public Interest," requiring readoption. With input from a stakeholder workgroup, this rule has been updated with technical changes to correct repealed statutes, clarify text, and allow an immunizing pharmacist to validate staff competency for specific personal care tasks.

10. Rulemaking Coordinator: Nadine Pfeiffer

Phone: 919-855-3811
E-Mail: nadine.pfeiffer@dhhs.nc.gov

Additional agency contact, if any:
Phone:
E-Mail:

11. Signature of Agency Head* or Rule-making Coordinator:



***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: Nadine Pfeiffer
Title: Rule-making Coordinator

RRC AND OAH USE ONLY

Action taken:

☐ RRC extended period of review:
☐ RRC determined substantial changes:
☐ Withdrawn by agency
☐ Subject to Legislative Review
☐ Other:

10A NCAC 13G .0504 is readopted with changes as published in 36:18 NCR 1487-1495 as follows:

10A NCAC 13G .0504 COMPETENCY EVALUATION AND VALIDATION FOR LICENSED HEALTH PROFESSIONAL SUPPORT TASKS

~~(a) A family care home~~ [~~The facility~~] ~~shall assure that non-licensed personnel and licensed personnel~~ [~~non-licensed staff and licensed staff~~] ~~not practicing in their licensed capacity as governed by their practice act and~~ [~~in accordance with~~] ~~occupational licensing laws are competency validated by return demonstration for any personal care task specified in Subparagraph (a)(1) through (28) of Rule .0903 of this Subchapter~~ [~~Subchapter. The facility shall assure the competency validation occurs~~] ~~prior to staff performing the task and that their ongoing competency is assured through facility staff oversight and supervision.~~

(a) When a resident requires one or more of the personal care tasks listed in Subparagraphs (a)(1) through (a)(28) of Rule .0903 of this Subchapter, the task may be delegated to non-licensed staff or licensed staff not practicing in their licensed capacity after a licensed health professional has validated the staff person is competent to perform the task.

~~(b)~~(c) ~~Competency~~ Evaluation and validation of competency shall be performed by the following licensed health ~~professionals:~~ professionals in accordance with his or her North Carolina occupational licensing laws:

(1) A registered nurse shall validate the competency of staff who perform any of the personal care tasks specified in Subparagraphs (a)(1) through ~~(28)~~ (a)(28) of Rule .0903 of this ~~Subchapter.~~ Subchapter;

(2) In lieu of a registered nurse, a licensed respiratory care practitioner ~~licensed under G.S. 90, Article 38,~~ may validate the competency of staff who perform personal care tasks specified in Subparagraphs (a)(6), (11), (16), (18), ~~(19)~~(19), and (21) of Rule .0903 of this ~~Subchapter.~~ Subchapter;

(3) In lieu of a registered nurse, a ~~registered~~ licensed pharmacist may validate the competency of staff who perform the personal care ~~task~~ tasks specified in Subparagraph (a)(8) and (11) of Rule .0903 of this Subchapter. An immunizing pharmacist may validate the competency of staff who perform the personal care task specified in Subparagraph (a)(15) of Rule .0903 of this [~~Subchapter.~~] Subchapter; and

(4) In lieu of a registered nurse, an occupational therapist or physical therapist may validate the competency of staff who perform personal care tasks specified in Subparagraphs (a)(17) and (a)(22) through ~~(27)~~ (a)(27) of Rule .0903 of this Subchapter.

~~(c) Competency validation of staff, according to Paragraph (a) of this Rule, for the licensed health professional support tasks specified in Paragraph (a) of Rule .0903 of this Subchapter and the performance of these tasks is limited exclusively to these tasks except in those cases in which a physician acting under the authority of G.S. 131D-2(a1)~~ [~~131D-2.2(a)~~] ~~certifies that non-licensed personnel can be competency validated to perform other tasks on a temporary basis to meet the resident's needs and prevent unnecessary relocation.~~ [~~relocation of the resident.~~]

(d) If a physician certifies that care can be provided to a resident in a family care home on a temporary basis in accordance with G.S. 131D-2.2(a), the facility shall ensure that the staff performing the care task(s) authorized by the physician are competent to perform the task(s) in accordance with Paragraphs (b) and (c) of this Rule. For the purpose

of this Rule, "temporary basis" means a length of time as determined by the resident's physician to meet the care needs of the resident and prevent the resident's relocation from the family care home.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Temporary Adoption Eff. September 1, 2003;
Eff. July 1, ~~2004.~~ 2004;
Readopted Eff. October 1, 2022.

10A NCAC 13G .0508 is readopted with changes as published in 36:18 NCR 1487-1495 as follows [Note: The update shown of the website address in italics was amended pursuant to G.S. 150B-21.5(a)(4) effective April 1, 2022]:

10A NCAC 13G .0508 ASSESSMENT TRAINING

The person or persons designated by the administrator to perform resident assessments as required by Rule .0801 of this Subchapter shall ~~successfully~~ ~~complete training on resident assessment~~ read the Resident Assessment Self-Instructional Manual for Adult Care Homes established by the Department and certify completion by signature on the last page of the manual before performing the required resident assessments. Registered nurses are exempt from ~~the assessment training.~~ this requirement. The Resident Assessment Self-Instructional Manual for Adult Care Homes is herein incorporated by reference including subsequent amendments and [~~editions.~~] ~~The instruction manual on resident assessment~~ editions and is available on the ~~internet~~ Adult Care Licensure website, ~~*http://facility-services.state.nc.us/gcpage.htm,* or it is available at the cost of printing and mailing from the Division of Health Service Regulation, Adult Care Licensure Section, 2708 Mail Service Center, Raleigh, NC 27699-2708.~~ *https://info.ncdhhs.gov/dhsr/acls/pdf/assessmentmanual.pdf,* at no cost.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Temporary Adoption Eff. September 1, 2003;
Eff. June 1, 2004;
Amended April 1, ~~2022;~~ 2022;
Readopted Eff. October 1, 2022.

10A NCAC 13G .0903 is readopted with changes as published in 36:18 NCR 1487-1495 as follows:

10A NCAC 13G .0903 LICENSED HEALTH PROFESSIONAL SUPPORT

(a) ~~A family care home~~ The facility shall assure that an appropriate licensed health ~~professional,~~ professional participates in the on-site review and evaluation of the residents' health status, care ~~plan~~ plan, and care provided for residents requiring one or more of the following personal care tasks:

(1) applying and removing ace bandages, ~~ted~~ TED hose, binders, and braces and splints;

(2) feeding techniques for residents with swallowing problems;

(3) bowel or bladder training programs to regain continence;

(4) enemas, suppositories, break-up and removal of fecal impactions, and vaginal douches;

(5) positioning and emptying of the urinary catheter bag and cleaning around the urinary catheter;

(6) chest physiotherapy or postural drainage;

(7) clean dressing changes, excluding packing wounds and application of prescribed enzymatic debriding agents;

(8) collecting and testing of fingerstick blood samples;

(9) care of well-established colostomy or ~~ileostomy~~ ileostomy. For the purpose of this Rule, "well-established colostomy or ileostomy" means ~~(having~~ having a healed surgical site without sutures or ~~drainage);~~ drainage;

(10) care for pressure ulcers, up to and including a Stage II pressure ~~ulcer~~ ulcer, which is a superficial ulcer presenting as an abrasion, ~~blister~~ blister, or shallow crater;

(11) inhalation medication by machine;

(12) forcing and restricting fluids;

(13) maintaining accurate intake and output data;

(14) medication administration through a well-established gastrostomy feeding ~~tube~~ tube. For the purpose of this Rule, "well-established gastrostomy feeding tube" means ~~(having~~ having a healed surgical site without sutures or drainage and through which a feeding regimen has been successfully ~~established);~~ established;

(15) medication administration through subcutaneous ~~injection;~~ injection in accordance with Rule .1004(q) except for anticoagulant medications;

~~Note: Unlicensed staff may only administer subcutaneous injections as stated in Rule .1004(q) of this Subchapter;~~

(16) oxygen administration and monitoring;

(17) the care of residents who are physically restrained and the use of care practices as alternatives to restraints;

(18) oral suctioning;

(19) care of well-established tracheostomy, not to include ~~indo-tracheal~~ endotracheal ~~suctioning;~~ suctioning. For the purpose of this Rule, "well-established tracheostomy" means the stoma is well-healed and the airway is patent;

(20) administering and monitoring of tube feedings through a well-established gastrostomy feeding tube ~~(see description in Subparagraph (14) of this Paragraph);~~ in accordance with Subparagraph (a)(14) of this Rule;

(21) the monitoring of continuous positive air pressure devices (CPAP and BIPAP);

(22) application of prescribed heat therapy;

(23) application and removal of prosthetic devices except as used in ~~early~~ post-operative treatment for shaping of the extremity;

(24) ambulation using assistive devices that requires physical assistance;

(25) range of motion exercises;

(26) any other prescribed physical or occupational therapy;

(27) transferring semi-ambulatory or non-ambulatory residents; or

(28) nurse aide II tasks according to the scope of practice as established in the Nursing Practice Act and rules promulgated under that ~~act~~ Act in 21 NCAC 36.

(b) The appropriate licensed health professional, as required in Paragraph (a) of this Rule, is:

(1) a registered nurse licensed under G.S. 90, Article 9A, for tasks listed in Subparagraphs (a)(1) through (28) of this Rule;

(2) an occupational therapist licensed under G.S. 90, Article 18D or physical therapist licensed under ~~G.S. 90-270.24, Article 18B~~ G.S. 90-270.90, Article 18E, for tasks listed in Subparagraphs (a)(17) and (a)(22) through (27) of this Rule;

(3) a respiratory care practitioner licensed under G.S. 90, Article 38, for tasks listed in Subparagraphs (a)(6), (11), (16), (18), ~~(19)~~ (19), and (21) of this Rule; or

(4) a registered nurse licensed under G.S. 90, Article 9A, for tasks that can be performed by a nurse aide II according to the scope of practice as established in the Nursing Practice Act and rules promulgated under that ~~act~~ Act in 21 NCAC 36.

(c) The facility shall assure that participation by a registered nurse, ~~occupational therapist~~ occupational therapist, respiratory care practitioner, or physical therapist in the on-site review and evaluation of the residents' health status, care ~~plan~~ plan, and care provided, as required in Paragraph (a) of this Rule, is completed within ~~the first~~ 30 days after ~~of~~ admission or within 30 days from the date a resident develops the need for the task and at least quarterly thereafter, and includes the following:

(1) performing a physical assessment of the resident as related to the resident's diagnosis or current condition requiring one or more of the tasks specified in Paragraph (a) of this Rule;

(2) evaluating the resident's progress to care being provided;

(3) recommending changes in the care of the resident as needed based on the physical assessment and evaluation of the progress of the resident; and

(4) documenting the activities in Subparagraphs (1) through (3) of this Paragraph.

~~(d) The facility shall assure action is taken in response to the licensed health professional review and documented, and that the physician or appropriate health professional is informed of the recommendations when necessary.~~

(d) The facility shall follow-up and implement recommendations made by the licensed health professional including referral to the physician or appropriate health professional when indicated. The facility shall document follow-up on all recommendations made by the licensed health professional.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Temporary Adoption Eff. January 1, 1996;
Eff. May 1, 1997;
Temporary Amendment Eff. December 1, 1999;
Amended Eff. July 1, 2000;
Temporary Amendment Eff. September 1, 2003;
Amended Eff. June 1, ~~2004.~~ 2004;
Readopted Eff. October 1, 2022.

10A NCAC 13G .0905 is readopted with changes as published in 36:18 NCR 1487-1495 as follows:

10A NCAC 13G .0905 ACTIVITIES PROGRAM

(a) Each family care home shall develop a program of activities designed to promote the residents' active involvement with each other, their families, and the community.

(b) The program shall be designed to promote active involvement by all residents but is not to require any individual to participate in any activity against his or her will. If there is a question about a resident's ability to participate in an activity, the resident's physician shall be consulted to obtain a statement regarding the resident's capabilities.

(c) The activity ~~director, as required in Rule .0404 of this Subchapter,~~ director shall:

(1) use information on the residents' interests and capabilities as documented upon admission and updated as needed to arrange for or provide planned individual and group activities for the residents, taking into account the varied interests, ~~capabilities~~ capabilities, and possible cultural differences of the residents;

(2) prepare a monthly calendar of planned group activities ~~which shall be~~ ~~easily~~ ~~readable~~ ~~with large print,~~ [~~to residents within the community,~~] in a format that is legible and shall be posted in a ~~prominent~~ location accessible to residents by the first day of each month, and updated when there are any changes;

(3) involve community resources, such as recreational, volunteer, ~~religious, aging and developmentally disabled associated agencies,~~ and religious organizations, to enhance the activities available to residents;

(4) evaluate and document the overall effectiveness of the activities program at least every six months with input from the residents to determine what have been the most valued activities and to elicit suggestions of ways to enhance the program;

(5) encourage residents to participate in activities; and

(6) assure there are ~~adequate supplies,~~ supplies necessary for planned activities, ~~supervision~~ supervision, and assistance to enable each resident to participate. Aides and other facility staff may be used to assist with activities.

(d) There shall be ~~a minimum of~~ at least 14 hours of a variety of planned group activities per week that include activities that promote socialization, physical interaction, group accomplishment, creative expression, increased ~~knowledge~~ knowledge, and learning of new skills. ~~Homes that care exclusively for residents with HIV disease are exempt from this requirement as long as the facility can demonstrate planning for each resident's involvement in a variety of activities. Examples of group activities are group singing, dancing, games, exercise classes, seasonal parties, discussion groups, drama, resident council meetings, book reviews, music appreciation, review of current events and spelling bees.~~

(e) Residents shall have the opportunity to participate in activities involving one to one interaction and activity by oneself that promote enjoyment, a sense of accomplishment, increased knowledge, learning of new skills, and creative

expression. ~~Examples of these activities are crafts, painting, reading, creative writing, buddy walks, card playing, and nature walks.~~

(f) Each resident shall have the opportunity to participate in at least one outing every other month. Residents interested in being involved in the community more frequently shall be encouraged to do so.

(g) ~~Each resident~~ Residents shall have the opportunity to participate in ~~meaningful work type and~~ volunteer service activities in the ~~home~~ facility or in the ~~community, but participation shall be on an entirely voluntary basis, never forced upon residents and not assigned in place of staff.~~ community. Participation in volunteer activities shall not be required of residents and shall not involve any duties or responsibilities that are [~~typically performed by~~] outlined in the job descriptions of facility staff.

History Note: *Authority G.S. 131D-2.16; ~~143B-165;~~ 131D-4.1; 131D-4.3;*
Eff. January 1, 1977;
Readopted Eff. October 31, 1977;
Amended Eff. August 3, 1992; April 1, 1987; April 1, 1984;
Temporary Amendment Eff. July 1, 2004;
Amended Eff. July 1, ~~2005.~~ 2005;
Readopted Eff. October 1, 2022.

10A NCAC 13G .1005 is readopted with changes as published in 36:18 NCR 1487-1495 as follows:

10A NCAC 13G .1005 SELF-ADMINISTRATION OF MEDICATIONS

(a) The facility shall permit residents who are competent and physically able ~~to self-administer~~ to self-administer their medications if the following requirements are met:

(1) the self-administration is ordered by a physician or other person legally authorized to prescribe medications in North Carolina and documented in the resident's record; and

(2) specific instructions for administration of prescription medications are printed on the medication label.

(b) ~~When there is a change in the resident's mental or physical ability to self-administer or resident non-compliance with the physician's orders or the facility's medication policies and procedures, the facility~~ [~~staff~~] ~~shall notify the physician.~~ The facility shall notify the physician when:

(1) there is a change in the resident's mental or physical ability to self-administer;

(2) the resident is non-compliant with the physician's orders; or

(3) the resident is non-compliant with the facility's medication policies and procedures.

A resident's right to refuse medications does not imply the inability of the resident to self-administer medications.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Temporary Adoption Eff. December 1, 1999;
Eff. July 1, ~~2000.~~ 2000;
Readopted Eff. October 1, 2022.

10A NCAC 13G .1006 is readopted with changes as published in 36:18 NCR 1487-1495 as follows:

10A NCAC 13G .1006 MEDICATION STORAGE

(a) Medications that are self-administered and stored in the resident's room shall be stored in a safe and secure manner as specified ~~in~~ by the facility's medication storage policy and procedures.

(b) All prescription and non-prescription medications stored by the facility, including those requiring refrigeration, shall be maintained ~~in a safe manner~~ under locked security except when under the ~~immediate or~~ direct physical supervision of staff in charge of medication administration.

(c) The medication storage area shall be ~~clean, well lighted, well ventilated,~~ routinely cleaned, include functional lighting, ventilated to circulate fresh air, large enough to store medications in an orderly manner, and located in areas other than the bathroom, kitchen or utility room. Medication carts shall be ~~clean~~ routinely cleaned and medications shall be stored in an orderly manner.

(d) ~~Accessibility to locked~~ Locked storage areas for medications shall only be by staff responsible for medication ~~administration and administrator~~ administration, the administrator, or ~~person in charge.~~ the administrator-in-charge.

(e) Medications intended for topical or external use, except for ophthalmic, ~~otic~~ otic, and transdermal medications, shall be stored in a designated area separate from the medications intended for oral and injectable use. Ophthalmic, ~~otic~~ otic, and transdermal medications may be stored with medications intended for oral and injectable use. Medications shall be stored apart from cleaning agents and hazardous chemicals.

(f) Medications requiring refrigeration shall be stored at 36 degrees F to 46 degrees F (2 degrees C to 8 degrees C).

(g) Medications shall not be stored in a refrigerator containing non-medications and non-medication related items, except when stored in a separate container. The container shall be locked when storing medications unless the refrigerator is locked or is located in a locked medication area.

(h) The facility shall only possess a stock of non-prescription medications or the following prescription legend medications for general or common ~~use:~~ use in accordance with physicians' orders:

(1) irrigation solutions in single unit quantities exceeding 49 ml. and related diagnostic agents;

(2) diagnostic agents;

(3) vaccines; and

(4) water for injection and normal saline for injection.

~~Note: A prescribing practitioner's order is required for the administration of any medication as stated in Rule .1004 (a) of this Section.~~

(i) First aid supplies shall be immediately ~~available,~~ available to staff within the facility, stored out of sight of residents and ~~visitors~~ visitors, and stored separately from [~~medications, and~~] ~~in a secure and~~ [~~an~~] ~~orderly manner.~~ medications.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Temporary Adoption Eff. December 1, 1999;
Eff. July 1, ~~2000.~~ 2000;
Readopted Eff. October 1, 2022.

Burgos, Alexander N

Subject: FW: 10A NCAC 13B Objection Letter

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Tuesday, August 23, 2022 8:35 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: 10A NCAC 13B Objection Letter

Thank you for the clarification on the rule with 1995 outstanding objection, Brian.

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: 10A NCAC 13B Objection Letter

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Monday, August 22, 2022 5:06 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: 10A NCAC 13B Objection Letter

Hi Nadine,

Thanks for letting me know your timetable. I'll keep an eye out for MCC's response for the November meeting then.

I believe the Rule to which the 1995 objection remains applicable is .4801.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Monday, August 22, 2022 2:34 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: 10A NCAC 13B Objection Letter

Thank you, Brian. We will take these objections before our next regularly scheduled Medical Care Commission meeting on November 4th. Within 10 days of that meeting, we will send you the MCC's response to this action by the RRC.

One question for clarification please. The staff opinion stated all the rules were objected to due to lack of statutory authority and gave the reasons for the objection. However at the RRC meeting on Thursday, you told the Commission that of these rules there were 2 rules that had additional statutory objections from 1995, one of which had been satisfied with the submitted rewritten rules and one objection that was still outstanding. Please tell me which rule that 1995 objection still remains.

Thank you.

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

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Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

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Raleigh, NC 27699-2701

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Monday, August 22, 2022 11:05 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: 10A NCAC 13B Objection Letter

Good morning,

Attached, please find a letter regarding the RRC's objection to the above captioned rules considered at last week's meeting.

Please do not hesitate to contact me with any questions or concerns.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

From: Pfeiffer, Nadine
Sent: Monday, August 22, 2022 2:34 PM
To: Liebman, Brian R
Cc: Randolph, Kimberly; Burgos, Alexander N
Subject: RE: 10A NCAC 13B Objection Letter

Thank you, Brian. We will take these objections before our next regularly scheduled Medical Care Commission meeting on November 4th. Within 10 days of that meeting, we will send you the MCC's response to this action by the RRC.

One question for clarification please. The staff opinion stated all the rules were objected to due to lack of statutory authority and gave the reasons for the objection. However at the RRC meeting on Thursday, you told the Commission that of these rules there were 2 rules that had additional statutory objections from 1995, one of which had been satisfied with the submitted rewritten rules and one objection that was still outstanding. Please tell me which rule that 1995 objection still remains.

Thank you.

Nadine Pfeiffer
Rules Review Manager
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Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

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

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Monday, August 22, 2022 11:05 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: 10A NCAC 13B Objection Letter

Good morning,

Attached, please find a letter regarding the RRC's objection to the above captioned rules considered at last week's meeting.

Please do not hesitate to contact me with any questions or concerns.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings

(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

From: Liebman, Brian R
Sent: Monday, August 22, 2022 11:05 AM
To: Pfeiffer, Nadine
Cc: Randolph, Kimberly; Burgos, Alexander N
Subject: 10A NCAC 13B Objection Letter
Attachments: 08.2022 MCC Objection Letter.pdf

Good morning,

Attached, please find a letter regarding the RRC's objection to the above captioned rules considered at last week's meeting.

Please do not hesitate to contact me with any questions or concerns.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

From: Pfeiffer, Nadine
Sent: Friday, August 12, 2022 3:39 PM
To: Liebman, Brian R
Cc: Conley, Azzie; Randolph, Kimberly; Hill, Greta D; Burgos, Alexander N
Subject: RE: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Brian,
Received. Disheartened. Will send to Dana.

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

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Raleigh, NC 27699-2701

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Friday, August 12, 2022 3:18 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>; Randolph, Kimberly <krandolph@ncdoj.gov>; Hill, Greta D <greta.hill@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Hi all,

Thanks for submitting these revised Rules. I think these Rules are as clear as they can be, and I don't have any further requests. I have issued a separate staff opinion on Rule .4805, as I believe the Rule remains ambiguous, given that it does not specify what amount of experience is required to satisfy (c)(1). It is attached here.

While I'm not recommending approval, you'll need to send the final version of all of your rules to Dana for filing. I think I have all the final versions, but given that we've gone through 3 versions, I want to make sure. Please just copy me on your submission.

Thanks and have a great weekend,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Thursday, August 11, 2022 12:56 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>; Randolph, Kimberly <krandolph@ncdoj.gov>; Hill, Greta D <greta.hill@dhhs.nc.gov>
Subject: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Hi Brian,
In response to your additional questions for the MCC rules at 10A NCAC 13B emailed to us on 8/9/22, please see the following revised attached rules: 10A NCAC 13B .3801, .3903, .4805, and .5406. Also attached is a document containing your additional questions and our responses in light blue font.

Thanks!

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

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nadine.pfeiffer@dhhs.nc.gov

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2701 Mail Service Center
Raleigh, NC 27699-2701

Burgos, Alexander N

Subject: FW: [External] Permission to speak at the RRC meeting

---

From: Randolph, Kimberly <Krandolph@ncdoj.gov>
Sent: Friday, August 12, 2022 12:12 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: Re: [External] Permission to speak at the RRC meeting

Thanks Brian.

Sent from my iPhone

Burgos, Alexander N

Subject: FW: [External] Permission to speak at the RRC meeting

---

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Friday, August 12, 2022 9:46 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Randolph, Kimberly <krandolph@ncdoj.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: [External] Permission to speak at the RRC meeting

Hi Nadine,

If y'all just want to attend, I think that's fine, and there's no deadline on that. Only caveat to that is I think this may be a well-attended meeting, so you might need to sit in the overflow room if it's too crowded.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

From: Pfeiffer, Nadine
Sent: Thursday, August 11, 2022 5:16 PM
To: Liebman, Brian R; Randolph, Kimberly
Cc: Burgos, Alexander N
Subject: RE: [External] Permission to speak at the RRC meeting

Also, Brian, I know you all like to keep the attendees down to 2/agency but will make accommodations for others if needed. Besides Kim and Dr. Meier attending, I would also like to attend the meeting in person that day. I will confirm if Azzie Conley, Section Chief for the Acute and Home Care Licensure and Certification Section would like to attend in person. Is there a deadline for letting you know this?

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

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Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

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2701 Mail Service Center
Raleigh, NC 27699-2701

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Thursday, August 11, 2022 5:12 PM
To: Randolph, Kimberly <krandolph@ncdoj.gov>
Cc: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: [External] Permission to speak at the RRC meeting

Hi Kim,

Thanks for letting me know. I will let the Commission know to expect you both.

Have a great day,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Randolph, Kimberly <Krandolph@ncdoj.gov>
Sent: Thursday, August 11, 2022 4:30 PM

To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Subject: [External] Permission to speak at the RRC meeting

Hey Brian,

I hope you are well!

I would like to request permission to speak at the RRC meeting regarding the readoption of the hospital rules next week for the following:

Kim Randolph – Assistant Attorney General, DOJ
Dr. John Meier – Chair, Medical Care Commission

Please let me know if you need anything additional. Thank you.

Kim Randolph
Assistant Attorney General
Health Service Section
(919) 716-0270 - Direct
(919) 716-6756 - Fax
krandolph@ncdoj.gov
P.O. Box 629 Raleigh, NC 27602-0629
ncdoj.gov

Burgos, Alexander N

Subject: FW: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Wednesday, August 10, 2022 9:57 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Brian,
Email received. We will have answers to your questions by your deadline.

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

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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: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Tuesday, August 9, 2022 12:35 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Good morning,

I have a few further questions regarding these rules. I'm copying my original change request and the agency response below, and then adding my follow up in red.

Rule .3801

In (c), line 11, what "required functions" are you referring to? ***The state licensed and Medicare certified, accreditation organizations, and regulated providers are knowledgeable of the regulations and daily operations which define the various functions warranting the development and implementation of policies and procedures for patient care.***

This really isn't responsive to my question. The rule requires the nurse executive to establish policies and procedures to "accomplish required functions" but does not state what they are.

In (d), who is evaluating the quality and efficiency of nursing services? Under what framework? ***The state licensed and Medicare certified, accreditation organizations, and regulated providers are knowledgeable of the regulations and daily operations. Hospitals define parameters for staffing related to patient care acuity and needs to ensure the delivery of safe and quality care. Staffing is patient care directed.***

Again, this really isn't responsive. If you're having a meeting to "evaluate the quality and efficacy of nursing services" it seems obvious that someone or some group has to actually make the evaluation. I assume that same person/group would make changes thereafter based on the evaluation. The rule doesn't identify that person/group.

In (e)(2), would it change the meaning to say "…standards, ~~and~~ policies, and procedures…." Moreover, how is this different from what is required in (b)? ***To amend the statement and delete "and" does not alter the intent of the regulation.***

Thank you for answering the first part of the question and making the change. I'm still curious what you think about the second part – is the requirement in (b) different than what is being required in (e)(2)?

Rule .3903

In (b), at what time must the patient be a minor for this provision to apply? At the time of treatment, or at discharge? ***The patient is defined as a minor during the inpatient and / or outpatient hospitalization. The age is determined on admission, during the course of the hospitalization, and point of discharge or disposition.***

I don't understand the response. For instance, if someone is a minor when admitted, but attains majority while hospitalized, how are the records characterized, and under which provision do they fall?

Moreover, if someone who was treated as a minor is readmitted later as an adult, but before age 30, do the medical records from the period of minority fall then fall under (a), rather than (b)?

Correct. Records for the stage of life defined as minor fall under (b)

I believe this is contradictory. I'm asking if a person's minor medical records become part of their adult records if the person is readmitted as an adult, but before the age of 30, thus requiring them to be preserved for another 11 years. My main point for asking these questions is to point out, at least in my mind, that there seems to be ambiguity in how medical records are classified and thus preserved when a patient has been admitted as both a minor and as an adult.

Rule .4305

In (a)(3), please remove the parenthetical and incorporate the material into the body of the Rule. ***Suggestion made in rule.*** *Also, I do not understand the contents of the parenthetical. Can you clarify which infants you're referring to?* ***Level III neonates are fragile or ill infants with a gestational age of 32 weeks to 36 weeks.***

I still am a little confused by the new language, and with this response. The new language in the Rule says (with changes redacted for clarity):

> Neonates or infants that are high-risk, small or approximately 32 and less than 36 completed weeks of gestational age but otherwise healthy, or sick with a moderate degree of illness that are admitted from within the hospital or transferred from another facility requiring intermediate care services for sick infants, but not requiring intensive care.

The text of the rule indicates that Level III neonates are healthy AND high risk, OR small, OR between 32-36 weeks, OR sick AND requiring intermediate care. Your response indicates that they are "fragile" (which I assume captures high risk and small) OR ill AND between 32 and 36 weeks. Can you clarify what the intent is here?

Rule .4801

In (c), G.S. 150B-21.6 requires that the agency "must specify in the rule both where copies of the material can be obtained and the cost on the date the rule is adopted of a copy of the material." Obviously, these rules are available online and at no cost, but please add a hyperlink and state that they are available at no cost. **Prior RRC staff counsel directed agencies to not use "and editions" in rule when referring by reference to other rules in the Code. Likewise, agencies were directed by RRC staff attorneys that it was not necessary to write in the rules the cost and where to find another rule referenced in the Code because the rule was already in the Code and online, the referenced rule was also in the Code and online, therefore that person would be able to find the referenced rule without cost online. Please advise on any change to this prior direction from RRC staff counsel.**

I suppose if you're referring to other provisions of the NCAC this is fine. No change necessary then.

Rule .4805

In (c), is the Medical Care Commission requiring these safety inspections or are these already required by Radiation Protection? In other words, is this necessary or are you repeating something that is already required? ***The rule is essential to promoting safe practices and standards in the delivery of radiation services.***

I don't think this is quite responsive to my question, which was whether the Rule is repeating a requirement that appears elsewhere in the Code.

In (c), lines 8-9, do you mean that the Division shall make available copies of the report to the public? Or that the Division shall be the entity to review the report?

The Division is responsible for identifying areas of noncompliance and writing the report for corrective action. Also, the Division is responsible for disclosing reports to the public.

The text of the Rule states:

Safety inspections of the imaging department, including equipment, shall be conducted by the North Carolina Division of ~~Environmental Health,~~ Health Service Regulation, Radiation Protection ~~Services~~ Section. Copies of the report shall be available for review by the Division.

As written, this is unclear. It sounds like the Division conducts an inspection, then someone, presumably Division staff, prepares a report, and then the report is available for review "by the Division." It is not clear from the text of the Rule that the Division is responsible for drafting the report, and the Rule says nothing about making the report public. Under what circumstances is the report made public? Is it posted on the Division's website? Is it available on request pursuant to Ch. 132 as a public record?

In (d)(1), please define "experienced." ***The state licensed Medicare certified regulated providers are knowledgeable of the regulations and daily operations. Experienced is hospital specific and defined by the hospital's medical staff bylaws and includes a combination of educations, and hands on exposure or skill over a specific period.***

Based on this answer, I will have to recommend objection to this rule on the basis of ambiguity. You're requiring a hospital to maintain a committee, stating who shall be on the committee, and setting a qualification for that role, but not defining the qualification and leaving it up to the hospital.

Rule .5406

In (a), line 6, what "established goals" are you referring to? ***Goals of care.***
This is not clear from the text. Consider revising for clarity.

Again in (a), line 6, who makes this determination? The attending physician? A utilization review board? The patient? ***The state licensed Medicare certified regulated providers are knowledgeable of the regulations and processes for assessing and implementing care to meet the needs of patients with an overarching goal of improvement to returning to an independent state of health with the least parameters of assistance. The team and decision-making are a comprehensive team approach addressing the needs of the rehab patient. The attending physician or physiatrist direct the comprehensive rehab program. This is an inclusive process of a multi-disciplinary team of health care providers which may include OT, PT, SLP, mental health professionals, psychologist, psychiatrist, etc.***
It isn't clear from the text of the rule who makes these determinations, and thus who bears the burden of complying with the Rule because the Rule is written in the passive tense. Please consider revising in the active tense.

In (a), line 7, what is an "appropriate setting"? ***Appropriate care setting is a place considered discharge appropriate to meet the needs of the reference patient. The overall goal to promote stabilization and improvement in the patient's condition.***
Again, this is not clear from the text of the Rule. Please clarify.

In (a), line 10, what are "referral sources"? ***Referral sources include persons, inpatient and / or outpatient dwellings to promote a smooth transition from the hospital setting to the home or other dwelling.***
Again, this is not clear from the text. Is this term defined elsewhere?

If you could, I'd appreciate responses by the end of the day on Friday.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission

Burgos, Alexander N

Subject: FW: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Wednesday, August 10, 2022 9:22 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Brian,
Received. Thank 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

Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Wednesday, July 27, 2022 8:58 AM
To: Rules, Oah <oah.rules@oah.nc.gov>
Cc: Liebman, Brian R <brian.liebman@oah.nc.gov>; Randolph, Kimberly <krandolph@ncdoj.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

We have been notified of the technical changes requested by Mr. Brian Liebman on June 3, 2022 pursuant to G.S. 150B-21.10 for the following rules: 10A NCAC 13B .3801, .3903, .4103, .4104, .4106, .4305, .4603, .4801, .4805, .5102, .5406, and .5408. In preparation for the August 18, 2022 RRC meeting, attached to this email you will find the amended text for rules 10A NCAC 13B .3801, .3903, .4305, .4805, and .5408 as requested in the Request for Technical Change document received, as well as the Agency's responses to the concerns raised in the "Request for Changes" document as seen in bold black font on the document. In addition, to accompany the Agency's responses to the "Request for Changes" attached is an additional document titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22" that addresses the statutory authority concerns and staff opinion issued by Mr. Liebman on June 7, 2022 for these rules.

Should you have any questions regarding the attachments, please feel free to contact me. ***Please note, I will be on annual leave August 3 through August 9.

Thank 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

Burgos, Alexander N

Subject: FW: Submission of Permanent Rule Technical Changes - 10A NCAC 13B
Attachments: 2022.06 - MCC - 13B Staff Opinion 2.0.doc

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Friday, August 5, 2022 3:18 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Hi Nadine,

Attached, please find my revised staff opinion with respect to statutory authority for all rules in this package. Please also be aware that I anticipate issuing several other staff opinions for individual rules early next week.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

Subject: FW: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Wednesday, July 27, 2022 10:48 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Thank 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: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Wednesday, July 27, 2022 10:43 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Hi Nadine,

Thank you. I will review this and get back to you soon. If I don't speak with you prior to your vacation, I hope you have a great week!

Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Wednesday, July 27, 2022 8:58 AM

To: Rules, Oah <oah.rules@oah.nc.gov>
Cc: Liebman, Brian R <brian.liebman@oah.nc.gov>; Randolph, Kimberly <krandolph@ncdoj.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

We have been notified of the technical changes requested by Mr. Brian Liebman on June 3, 2022 pursuant to G.S. 150B-21.10 for the following rules: 10A NCAC 13B .3801, .3903, .4103, .4104, .4106, .4305, .4603, .4801, .4805, .5102, .5406, and .5408. In preparation for the August 18, 2022 RRC meeting, attached to this email you will find the amended text for rules 10A NCAC 13B .3801, .3903, .4305, .4805, and .5408 as requested in the Request for Technical Change document received, as well as the Agency's responses to the concerns raised in the "Request for Changes" document as seen in bold black font on the document. In addition, to accompany the Agency's responses to the "Request for Changes" attached is an additional document titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22" that addresses the statutory authority concerns and staff opinion issued by Mr. Liebman on June 7, 2022 for these rules.

Should you have any questions regarding the attachments, please feel free to contact me. ***Please note, I will be on annual leave August 3 through August 9.

Thank 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

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .3801

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

***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:

In (a), line 6, what is a "centralized organizational structure" and what is a "decentralized organizational structure?" Is your regulated public familiar with these terms? ***The state licensed and Medicare certified, accreditation organizations, and regulated providers are knowledgeable of the regulations and daily operations and familiar with the terms, "centralized organizational structure" and "decentralized organizational structure. The organizational structures are hospital specific references in the use of the centralized or decentralized structure.***

In (a), generally, R. .3001 defines "nurse executive" as a "registered nurse who is the director of nursing services or a representative of decentralized nursing management staff." Given that definition, does a nurse executive have different duties between a centralized or decentralized organizational structure? ***Yes. This depends on the structure of the centralized or decentralized organization. The traditional Nurse Executive duties are often split between roles or delegated down which they still have oversight of nurse responsibilities. The Nurse Executive is still at the top of the organizational chart in both structures and responsible for nursing. In a decentralized organizational structure, there is a shared governance where the Nurse Executive delegates and empowers nursing staff at various levels in the decision-making process. In summary, one Nurse Executive should have the overall responsibility for nursing services. The hospital should have policies, procedures, o-charts, and position descriptions that define the overall delivery of nursing services. The difference resolves around the manner duties are carried out in a centralized as opposed to decentralized system. O-charts vary from hospital to hospital. We rely on the O-chart and position descriptions.***

In (c), line 11, what "required functions" are you referring to? ***The state licensed and Medicare certified, accreditation organizations, and regulated providers are knowledgeable of the regulations and daily operations which define the***

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

various functions warranting the development and implementation of policies and procedures for patient care.

In (d), who is evaluating the quality and efficiency of nursing services? Under what framework? ***The state licensed and Medicare certified, accreditation organizations, and regulated providers are knowledgeable of the regulations and daily operations. Hospitals define parameters for staffing related to patient care acuity and needs to ensure the delivery of safe and quality care. Staffing is patient care directed.***

In (e)(2), would it change the meaning to say "…standards, ~~and~~ policies, and procedures…." Moreover, how is this different from what is required in (b)? ***To amend the statement and delete "and" does not alter the intent of the regulation.***

In (e)(3), is not repetitive to say "the ***delivery*** *of nursing care* ***delivery*** *system"?* ***Yes. There is no concern deleting the second "delivery" as recommended.***

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

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .3903

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

***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:

In (a), line 4, should it state "the manager of the medical records service…."? **Suggestion made in rule**

In (b), at what time must the patient be a minor for this provision to apply? At the time of treatment, or at discharge? ***The patient is defined as a minor during the inpatient and / or outpatient hospitalization. The age is determined on admission, during the course of the hospitalization, and point of discharge or disposition.***

I assume that if someone is discharged, and then subsequently readmitted, the 11-year clock re-starts, correct? ***Correct.***

Moreover, if someone who was treated as a minor is readmitted later as an adult, but before age 30, do the medical records from the period of minority fall then fall under (a), rather than (b)? ***Correct. Records for the stage of life defined as minor fall under (b)***

In (f), lines 20-21, I'm a little confused by the construction here. Is it personnel authorized by (1) State laws, (2) HIPAA, and (3) regulations (which I assume are federal regulations, per our usual construction of that term), or personnel authorized by (1) State laws and (2) HIPAA regulations (which I imagine would be part of the CFR)? If the latter, I think a reference to the precise portions of the CFR would be appropriate here. ***Only personnel authorized by State laws and Health Insurance Portability and Accountability Act (HIPPA) regulations shall have access to medical records. Added 42 CFR 482 to rule text with refer by reference language, where to access regulation and cost.***

Where is your statutory authority for (g)? ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

In (g), line 24, what is the facility "jurisdiction"? What are the bounds here? ***(g), line 24 revised for clarity. Medical records are the property of the hospital, ~~they shall not be removed from the facility jurisdiction~~ and shall remain the property of the hospital, except through a court order.***

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

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .4103

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

***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:

What are you relying upon for authority for (a)? Which statute are you implementing? 131E-79 only grants rulemaking authority for rules "necessary to implement this Article. ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***
"

For (b) and (c), what are you relying upon as your authority to require certain hospital equipment? I see you have this authority over ambulances in Article 7. Where is your authority over equipment at facilities? ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

In (b), line 8, what does "emergency services under the rules of this Section" refer to? What limit are you trying to set? ***The licensed hospital's governing body and medical staff define the emergency services to be provided within the capability and scope of acute care services provided to meet the needs of the community. Hospitals have the option of advertising services as a dedicated emergency department or providing emergency services per their definitions. All must have the capability to render services to a pregnant patient and / or deliver babies.***

In (c), I take it you are still governing "facilities," correct? ***Yes***

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

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .4104

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

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:

> *Where is your statutory authority for Paragraphs (a), (c), and (d)?* ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

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

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .4104

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

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:

> *Where is your statutory authority for Paragraphs (a), (c), and (d)?* ***Duplicate comment, this rule was addressed on previous page by RRC counsel.***

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

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .4106

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

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:

> *Where is your statutory authority for this Rule?* ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

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

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .4305

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

***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:

Where is your statutory authority for this Rule? ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

In (a)(1), line 7, consider "infants who are small for gestational age or neonates who are large for gestational age ~~neonates~~" if this is what you mean. ***Replaced wording as suggested.***

In (a)(2), line 9, capitalize "Level" to remain consistent with the rest of the Rule. ***Suggestion made in rule***

In (a)(3), please remove the parenthetical and incorporate the material into the body of the Rule. ***Suggestion made in rule.*** *Also, I do not understand the contents of the parenthetical. Can you clarify which infants you're referring to?* ***Level III neonates are fragile or ill infants with a gestational age of 32 weeks to 36 weeks.***

In (a)(4), line 18, add the oxford comma following "unstable." ***Suggestion made in rule***

In (a)(4), line 19, what does "approximately under 32 weeks" mean? ***Replaced with neonates ~~approximately~~ under 32 weeks of gestational age***

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

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .4603

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

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:

> *Where is your statutory authority for this Rule?* ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

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

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .4801

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

***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:

Where is your statutory authority for this Rule? ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

In (c), G.S. 150B-21.6 requires that the agency "must specify in the rule both where copies of the material can be obtained and the cost on the date the rule is adopted of a copy of the material." Obviously, these rules are available online and at no cost, but please add a hyperlink and state that they are available at no cost. **Prior RRC staff counsel directed agencies to not use "and editions" in rule when referring by reference to other rules in the Code. Likewise, agencies were directed by RRC staff attorneys that it was not necessary to write in the rules the cost and where to find another rule referenced in the Code because the rule was already in the Code and online, the referenced rule was also in the Code and online, therefore that person would be able to find the referenced rule without cost online. Please advise on any change to this prior direction from RRC staff counsel.**

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

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .4805

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

***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:

Where is your statutory authority for this Rule? ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

In (b), line 6, please define or delete "proper". ***Suggestion made in rule for deletion.***

In (c), is the Medical Care Commission requiring these safety inspections or are these already required by Radiation Protection? In other words, is this necessary or are you repeating something that is already required? ***The rule is essential to promoting safe practices and standards in the delivery of radiation services.***

In (c), lines 8-9, do you mean that the Division shall make available copies of the report to the public? Or that the Division shall be the entity to review the report?
The Division is responsible for identifying areas of noncompliance and writing the report for corrective action. Also, the Division is responsible for disclosing reports to the public.

In (d)(1), please define "experienced." ***The state licensed Medicare certified regulated providers are knowledgeable of the regulations and daily operations. Experienced is hospital specific and defined by the hospital's medical staff bylaws and includes a combination of educations, and hands on exposure or skill over a specific period.***

In (e), G.S. 150B-21.6 requires that the agency "must specify in the rule both where copies of the material can be obtained and the cost on the date the rule is adopted of a copy of the material." Obviously, these rules are available online and at no cost, but please add a hyperlink and state that they are available at no cost. **Prior RRC staff counsel directed agencies and page 21 of the Rules Style Guide state "*If incorporating material by reference that will affect a set of rules, please do note the agency only needs to incorporate the material using this method one time. The agency does not have to repeatedly incorporate the same material***

within the same rule or set of rules." **The rules in 10A NCAC 15 are already incorporated by reference in Rule 13B .4801. Please advise on any change to this prior direction from RRC staff counsel and the Rules Style Guide.**

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

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .5102

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

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:

> *Where is your statutory authority for this Rule?* ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

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

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .5105

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

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:

> *Where is your statutory authority for this Rule?* ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

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

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .5406

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

***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:

Where is your statutory authority for this Rule? ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

In (a), line 6, what "established goals" are you referring to? ***Goals of care.***

Again in (a), line 6, who makes this determination? The attending physician? A utilization review board? The patient? ***The state licensed Medicare certified regulated providers are knowledgeable of the regulations and processes for assessing and implementing care to meet the needs of patients with an overarching goal of improvement to returning to an independent state of health with the least parameters of assistance. The team and decision-making are a comprehensive team approach addressing the needs of the rehab patient. The attending physician or physiatrist direct the comprehensive rehab program. This is an inclusive process of a multi-disciplinary team of health care providers which may include OT, PT, SLP, mental health professionals, psychologist, psychiatrist, etc.***

In (a), line 7, what is an "appropriate setting"? ***Appropriate care setting is a place considered discharge appropriate to meet the needs of the reference patient. The overall goal to promote stabilization and improvement in the patient's condition.***

In (a), line 10, what are "referral sources"? ***Referral sources include persons, inpatient and / or outpatient dwellings to promote a smooth transition from the hospital setting to the home or other dwelling.***

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

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

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

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

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .5408

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

***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:

Where is your statutory authority for this Rule? ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

More specifically, where is your statutory authority to set supervision requirements, with the exception of physicians supervising care as provided in 131E-76(3)? Is this already governed by occupational licensing boards? ***Removed Subparagraph (a)(4), and text in new Subparagraph (a)(5).***

Where is your authority to set staff qualification requirements? ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

What does (b) require? How is this measured? How do you determine whether the requirements in (b) have been met? ***The state licensed Medicare certified regulated providers are knowledgeable of the regulations and processes for assessing, implementing, and ongoing evaluation of a comprehensive plan of care to meet the needs of the patient centered and directed goals. The multi-disciplinary team is responsible for an ongoing assessment and evaluation of the rehab patient to obtain goals. Examples of rehab measures may include but are not limited to ability to button clothing without assistance, ability to walk with a cane as opposed to a walker, or the ability to increase steps.***

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

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

Agency Response to
Hospital Rules Statutory Authority Opinion
by Brian Lieberman

The Medical Care Commission ("MCC") was created by the General Assembly in 1973. Pursuant to N.C. Gen. Stat. § 143B-165:

> (6) The Commission has the duty to adopt rules and regulations and ***standards*** with respect to the different types of hospitals to be licensed under the provisions of Article 13A of Chapter 131 of the General Statutes of North Carolina.

N.C. Gen. Stat. § 143B-165(6)***(emphasis added).***

Chapter 131, Article 13A, the Hospital Licensing Act (Attachment A) was repealed and replaced with Chapter 131E, Article 5, the Hospital Licensure Act. The North Carolina General Statutes Annotated for Chapter 131 (Attachment B) includes as *Cross References* "[a]s to health care facilities and services, see now Chapter 131E." Although, the reference to Article 13A was not changed in N.C. Gen. Stat. § 143B-165(6), the General Assembly did not remove the duty of the MCC to promulgate standards for hospital. The Hospital Licensing Act and the Hospital Licensure Act are in reference to facilities that provide medical and nursing care to two or more individuals in excess of 24 hours. Both are in reference to the same type of facility, a hospital. *See* N.C. Gen. Stat. § 131E-76(3).

The purpose of Article 5 of Chapter 131E, the Hospital Licensure Act (the "Hospital Licensure Act") is to "establish hospital licensing requirements which promote public health, safety and welfare ***and*** to provide for the development, ***establishment and enforcement of basic standards for the care and treatment of patients in hospitals***." *See* N.C. Gen. Stat. § 131E-75 (***emphasis added***).

Article 5.

Hospital Licensure Act.

Part 1. Article Title and Definitions.

§ 131E-75. Title; purpose.

(a) This Article shall be known as the "Hospital Licensure Act."

(b) The purpose of this article is to establish hospital licensing requirements which promote public health, safety and welfare and to provide for the development, establishment and enforcement of basic standards for the care and treatment of patients in hospitals.

N.C. Gen. Stat. § 131E-75.

The Hospital Licensure Act requires and expressly authorizes the MCC to promulgate rules necessary to carry out the Article. Pursuant to N.C. Gen. Stat. § 131E-79(a) & (b), the Commission is mandated to promulgate rules to carry out the Article and the North Carolina Department of

Health and Human Services ("Department" or "Agency") is then charged with enforcing these rules, including the rules that establish basic standards of safe care for patients. *See* N.C. Gen. Stat. §§ 131E-75(b) and -79(a) & (b).

> **§ 131E-79. Rules and enforcement.**
> (a) The Commission shall promulgate rules necessary to implement this Article.
> (b) The Department shall enforce this Article and the rules of the Commission.

N.C. Gen. Stat. § 131E-79.

The Department is charged with the responsibility of determining if an initial license should be issued to a hospital and determining if the license should be renewed on an annual basis. *See* N.C. Gen. Stat. § 131E-77(a) & (d).

> **§ 131E-77. Licensure requirement.**
> (a) No person or governmental unit shall establish or operate a hospital in this state without a license. An infirmary is not required to obtain a license under this Part.
> (b) The Commission shall prescribe by rule that any licensee or prospective applicant seeking to make specified types of alteration or addition to its facilities or to construct new facilities shall submit plans and specifications before commencement to the Department for preliminary inspection and approval or recommendations with respect to compliance with the applicable rules under this Part.
> (c) An applicant for licensing under this Part shall provide information related to as requested by the Department. The required information shall be submitted by the applicant on forms provided by the Department and established by rule.
> (d) Upon receipt of an application for a license, the Department shall issue a license if it finds that the applicant complies with the provisions of this Article and the rules of the Commission. The Department ***shall renew*** each license in accordance with the rules of the Commission…

N.C. Gen. Stat. § 131E-77(a) & (d)***(emphasis added).***

In issuing and renewing licenses, the Department is required to assess if a hospital is meeting the "requirements which promote public health, safety and welfare to provide for the development, establishment and enforcement of basic standards for the care and treatment of patients" including "information related to hospital operations as requested by the Department." *See* N.C. Gen. Stat. §§ 131E-75(b) and -77(d).

The licensing of a hospital encompasses ongoing regulation beyond that of the initial license. *See* N.C. Gen. Stat. § 131E-77(a). After the Department issues an initial license, the Department has "the authority to deny, suspend, revoke, annul, withdraw, recall, cancel, or amend a license…" after issuance. *See* N.C. Gen. Stat. § 131E-78(a). The Department inspects the hospital to validate continuing compliance with providing the basic standards of care and treatment of patients. *See* N.C. Gen. Stat. § 131E-80(a) & (d). To aid in this process, the Department has the

authority to inspect hospital records involving admission, discharge, medication, and treatment. *See* N.C. Gen. Stat. § 131E-80(d). When the hospital is in compliance with this Part and the rules, the Department issues a renewal license. N.C. Gen. Stat. § 131E-77(d).

Therefore, the regulated hospitals must be informed of the operational standards related to the health, safety, and basic standards of care and treatment of the patients, that the Department will survey during complaint and compliance inspections, to maintain its license and avoid adverse action on the license. *See* N.C. Gen. Stat. § 131E-80(d). For example, Rule 10A NCAC 13B .4103 outlines exactly what the Department will be reviewing for facilities providing emergency services to ensure all patients receive fair, timely, and consistent treatment, including medical direction, in an emergency.

In turn, the Department must establish, through rules, the operational minimum standards related to the health, safety and basic standards of care and treatment of patients it will use during complaint and compliance inspections, in order for regulated hospitals to ensure compliance. For example, when a patient goes to the hospital for imaging services, they have some assurance that the employee is qualified, supervised by a physician, the equipment is safe, and the radiation exposure is handled appropriately. *See* Rule 10 NCAC 13B .4805. In both examples, Rules 10A NCAC 13B .4103 and 10A NCAC 13B .4805, the Agency has set the standard, informed the hospitals of the standards and will conduct inspections for compliance according to the standards in order to protect the public's health, safety, and welfare.

The Supreme Court has said, since early times, that to require proficiency and skill in the business mentioned is, an exercise of the police power "for the protection of the public against incompetents and impostors." *State. v. Call,* 121 N.C. 643, 28 S.E. 517 (1897). It is upon the same principles "that the Legislature has required a license of physicians, surgeons, osteopaths, chiropractors, chiropodists, dentists, opticians, barbers, and others[.]" *Roach v Durham*, 204 N.C. 587, 591, 169 S.E. 149, 151 (1993) (citations and quotation marks omitted). The Legislature has determined that the same is true for hospitals. The MCC is responsible for developing the hospital rules for licensing and safety standards similar to the other agencies created by the General Assembly for the various other licenses issued in North Carolina. *Igram v. N.C. State Bd. Of Plumbing, Heating and Fire Sprinkler, Contrs.*, 269 N.C. App. 476, 839 S.E.2d 74 (2020).

The requirement for express authority does not equate to a requirement for the Legislature to specify, subject by subject, each area of rule promulgation to an agency. The General Assembly has not specifically enumerated every area of rule promulgation with any of the agencies creating rules for licensing. Instead, the General Assembly expressly authorizes the agencies to promulgate rules.

The Dental Examiners, for example, have authority to create rules to govern the practice of dentistry in N.C. Gen. Stat. § 90-48. Based on this authority, Rules 21 NCAC 16P .0101-.0105 is used to regulate communications concerning dental services and advertising which are not specified topics for rules addressed in the Article. Similarly, Rule 21 NCAC 16T .010 requires a record retention period of 10 years even though the Legislature did not specifically instruct the Dental Examiners to set a period for record retention.

The Board of Chiropractic Examiners has authority to create rules necessary to carry out and enforce the provisions of the Chapter 90, Article 8. *See* N.C. Gen. Stat. § 90-142. This express authority has resulted in the creation of rules such as 21 NCAC 10 .0208 Acupuncture and 21 NCAC 10 .0305 Prepaid Treatment Plans. The words "acupuncture" and "prepaid treatment plans" are not in Chapter 90, Article 8; instead, the Legislature gave express authority for creation of these rules for protection of the public under the practice of medicine and allied occupations.

The same is true here; the Legislature gave express authority for the creation of rules for protection of the public in hospitals and medical facilities. A hospital license is a representation to the public that the hospital will adhere to basic standards for the care and treatment of patients established by the MCC and enforced by the Department, which promote public health, safety, and welfare. *See* N.C. Gen. Stat. §§ 131E-75(b) and -79(a) & (b). A renewed license is a representation to the public that the hospital continues to adhere to the basic standards for the care and treatment of patients that promote public health, safety, and welfare. *Id.*

The hospital rules listed below are necessary for the protection of the health, safety, and welfare of patients in hospitals in North Carolina and provide minimum standards for the care and treatment of patients. The MCC respectfully requests the Rules Review Commission find that these rules are within the authority delegated to the MCC by the General Assembly.

10A NCAC 13B .3801	Nurse Executive
10A NCAC 13B .3903	Preservation of Medical Records
10A NCAC 13B .4103	Provision of Emergency Services
10A NCAC 13B .4104	Medical Director
10A NCAC 13B .4106	Policies and Procedures
10A NCAC 13B .4305	Organization of Neonatal Services
10A NCAC 13B .4603	Surgical and Anesthesia Staff
10A NCAC 13B .4801	Organization
10A NCAC 13B .4805	Safety
10A NCAC 13B .5102	Policies and Procedures
10A NCAC 13B .5105	Sterile Supply Services
10A NCAC 13B .5406	Discharge Criteria For Inpatient Rehabilitation Facilities or Units
10A NCAC 13B .5408	Comprehensive Inpatient Rehabilitation Program Staffing Requirements
10A NCAC 13B .5411	Repealed

A

THE NORTH CAROLINA MEDICAL CARE COMMISSION

CHAPTER 131. GENERAL STATUTES OF NORTH CAROLINA

ARTICLE 13A

HOSPITAL LICENSING ACT

Sec. 131-126.1. *Definitions.*—As used in this article. (a) "Hospital" means an institution devoted primarily to the rendering of medical, surgical, obstetrical, or nursing care, which maintains and operates facilities for the diagnosis, treatment or care of two or more nonrelated individuals suffering for illness, injury or deformity, or where obstetrical or other medical or nursing care is rendered over a period exceeding twenty-four hours.

The term "hospital" for clarification purposes, includes, but not by way of limitation, an institution that receives patients and renders for them diagnostic, medical, surgical and nursing care; and "hospital" means also an allied institution that provides for patients diagnostic, medical, surgical and nursing care in branches of medicine such as obstetric, pediatric, orthopedic, and eye, ear, nose and throat and cardiac services, and in the diagnosis and treatment of mental and neurological ailments, and in the diagnosis and treatment and care of chronic diseases and transmissible diseases.

The term "hospital" as used in this article does not apply to a welfare institution, the primary purpose of which is to provide domiciliary and/or custodial care to its residents, and it does not apply to an infirmary which such institution may maintain to provide medical and nursing care for its residents.

Further to distinguish a "hospital" from a "welfare institution," as the term is used in this article, the latter means orphanages; penal and correctional institutions; home for the county or city poor, aged, and infirm; nursing homes for the mentally and physically infirm; homes for the aged; and convalescent and rest homes; and homes for pregnant women who require public assistance and/or custodial care or obstetrical and nursing care in such home, or nursing care prior to or subsequent to delivery in a "hospital."

(b) "Person" means any individual, firm, partnership, corporation, company, association, or joint stock association; and includes any trustee, receiver, assignee or other similar representative thereof.

(c) "Governmental unit" means the state, or any county, municipal or other political subdivision or any department, division, board or other agency of any of the foregoing.

(d) "Commission" means the North Carolina Medical Care Commission as established by chapter 1096 of the Session Laws of 1945, as amended, and as the same may be hereafter amended.

Sec. 131-126.2 *Purpose.*—The purpose of this article is to provide for the development, establishment and enforcement of basic standards (1) for the care and treatment of individuals in hospitals and (2) for the construction, maintenance and operation of such hospitals, which, in the light of existing knowledge, will ensure safe and adequate treatment of such individuals in hospitals, provided, that nothing in this article shall be construed as repealing any of the provisions of article 27 of chapter 130 of the General Statutes of North Carolina.

Sec. 131-126.3. *Licensure.*—After July 1st, 1947, no person or governmental unit, acting severally or jointly with any other person or governmental unit shall establish, conduct or maintain a hospital in this state without a license. None of the provisions of Chapter 104C of the General Statutes shall apply to X-ray facilities in or as a part of any hospital or medical facility which is, or will upon its completion become, subject to the provisions of law relating to the licensing thereof by the North Carolina Medical Care Commission pursuant to this Article.

Sec. 131-126.4. *Application for license.*—Licenses shall be obtained from the Commission. Applications shall be upon such forms and shall contain such information as the said Commission may reasonably require, which may include affirmative evidence of ability to comply with such reasonable standards, rules and regulations as may be lawfully prescribed hereunder.

Sec. 131-126.5. *Issuance and renewal of license.*—Upon receipt of an application for license, the Commission shall issue a license if it finds that the applicant and hospital facilities comply with the provisions of this article and the regulations of the said Commission. Each such license, unless sooner suspended or revoked, shall be renewable annually without charge upon filing of the license, and approval by the Commission, of an annual report upon such uniform dates and containing such information in such form as the Commission shall prescribe by regulation. Each license shall be issued only for the premises and persons or governmental units named in the application and shall not be transferable or assignable except with the written approval of the Commission. Licenses shall be posted in a conspicuous place on the licensed premises as prescribed by regulation of the said Commission.

Sec. 131-126.6. *Denial or revocation of license; hearings and review.*—The Commission shall have the authority to deny, suspend or revoke a license in any case where it finds that there has been a substantial failure to comply with the provisions of this article or the rules, regulations or minimum standards promulgated under this article.

Such denial, suspension, or revocation shall be effected by mailing to the applicant or licensee by registered mail, or by personal service of, a notice setting forth the particular reasons for such action. Such denial, suspension, or revocation shall become effective thirty days after the mailing or

B

General Statutes of North Carolina

ANNOTATED

2021 EDITION

CHAPTER 131.
PUBLIC HOSPITALS.

§§ 131-1 through 131-188: Repealed by Session Laws 1983, c. 775, s. 1.

Cross References.

As to health care facilities and services, see now Chapter 131E.

Editor's Note.

Session Laws 1983, c. 775, s. 3, provides: "Sec. 3. Notwithstanding the foregoing, any unit of government, or units of government acting jointly, that as of December 31, 1983, is operating a hospital or hospitals pursuant to Articles 2 or 2A of Chapter 131 of the General Statutes may continue to operate pursuant to the provisions of those Articles as they existed on December 31, 1983, to the extent that those Articles are inconsistent with this Chapter. However, a unit of government that has been operating a hospital pursuant to those Articles may choose to continue operations under the provisions of one of the Parts of Article 2 of this Chapter by adopting an appropriate resolution and by satisfying all other requirements of the relevant Part of Article 2 of this Chapter."

Session Laws 1989, c. 283, effective June 12, 1989, amends G.S. 131-7. Session Laws 1989, c. 283, ss. 1 and 2 provide:

"Section 1. G.S. 131-7, as it applies to hospitals continuing to operate under Article 2, Chapter 131 of the North Carolina General Statutes pursuant to Section 3, Chapter 775 of the 1983 Session Laws, is amended by rewriting the first sentence to read: 'Should a majority of the qualified voters upon the question be in favor of establishing such county, township, or town hospital, the governing body shall proceed at once to appoint seven trustees chosen from the citizens at large with reference to their fitness for such office, all residents of the county, township or town, who shall constitute a board of trustees for such public hospital.'

"Sec. 2. G.S. 131-7 is amended by deleting the phrase 'No practicing physician may serve as a trustee.', and substituting 'One practicing physician may serve as a trustee'."

Session Laws 1999-377, s. 1, effective August 4, 1999, amends G.S. 131-4 as it applies to hospitals continuing to operate under Article 2, Chapter 131 of the North Carolina General Statutes pursuant to Section 3, Chapter 775 of the 1983 Session Laws, by adding a new subdivision to read:

"(4) Extension of Tax Levy. Prior to or following the expiration of the tax levy specified in subdivision (3) of this section, a new petition may be presented to the governing body of any county in which a township is located, signed by 200 resident freeholders of such township asking that an annual tax continue to be levied for the maintenance, operation, and improvement of the public hospital, after the expiration of the tax levy specified in subdivision (3). The procedure for submitting the petition and holding an election on the issue of continuing the tax levy shall be the same as the procedure for the petition and election for establishment of the initial tax levy, provided that the requirement that 150 of the 200 petitioners not be residents of the city, town, or village where the hospital is to be located shall not apply. The tax to be levied under such new election shall not exceed one twenty-fifth of one cent (1/25 of 1 cent) on the dollar ($1.00) for a period of time not exceeding 30 years and shall be for the issue of county or township bonds to provide funds for the maintenance and improvement of the public hospital."

Session Laws 1999-377, s. 2, amends G.S. 131-5 by adding a sentence providing that the procedure for submission of the issue of continuation of the tax levy is to be the same as set forth previously in G.S. 131-5, so long as the tax is not to exceed one twenty-fifth of one cent on the dollar, and by providing the statement to be used on ballots when the issue is submitted.

Session Laws 1999-377, s. 3, provides that all hospitals which continue to operate under Article 2 of Chapter 131, of the General Statutes pursuant to Section 3 of Chapter 775 of the 1983 Session Laws, shall, in addition to the powers granted in that article have the powers set forth in G.S. 131E-7(a)(1), (3), (5), (6), 131E-7(b), 131E-7(c), 131E-7.1, 131E-11, 131E-23(1), (2), (5), (6), (7), (8), (10), (11), (12), (13), (14), (15), (16), (17), (18), (19), (23), (24), (25), (26), (27), (28), (30), (31), (32), (33), (34), 131E-26, and 131E-27.

Session Laws 1999-377, s. 4, provides that any hospital continuing to operate under Article 2 of Chapter 131, pursuant to Section 3 of Chapter 775 of the 1983 Session Laws, shall be considered a "public hospital" within the meaning of G.S. 159-39 and a "unit of local government" within the meaning of G.S. 160A-20.

Session Laws 2018-81, s. 2(a), (b), provides: "(a) All hospitals that continue to operate under Article 2 of Chapter 131 of the General Statutes pursuant to Section 3 of Chapter 775 of the 1983 Session Laws may, in addition to the powers and authorities set forth in said Article

2 of Chapter 131 of the General Statutes, exercise each of the powers, authorities, and exemptions set forth in the following provisions of Chapter 131E of the General Statutes, singly or in combination:

"(1) G.S. 131E-7(a)(1), (3), (5), and (6).
"(2) G.S. 131E-7(b).
"(3) G.S. 131E-7(c).
"(4) G.S. 131E-7(f).
"(5) G.S. 131E-7.1.
"(6) G.S. 131E-8.
"(7) G.S. 131E-10.
"(8) G.S. 131E-11.
"(9) G.S. 131E-13.
"(10) G.S. 131E-14.1.
"(11) G.S. 131E-23(a)(1) through (38).
"(12) G.S. 131E-23(b).
"(13) G.S. 131E-23(d).
"(14) G.S. 131E-26.
"(15) G.S. 131E-27.
"(16) G.S. 131E-32.
"(17) G.S. 131E-47.1.

"(b) This act amends and adds to the powers and authorities previously conveyed by Section 3 of S.L. 1999-377 to hospitals that continue to operate under Article 2 of Chapter 131 of the General Statutes. This act is not intended to alter or amend the remaining provisions of S.L. 1999-377."

10A NCAC 13B .3801 is readopted with changes as published in 36:12 NCR 1029-1032 as follows:

SECTION .3800 - NURSING SERVICES

10A NCAC 13B .3801 NURSE EXECUTIVE

(a) Whether the facility utilizes a centralized or decentralized organizational structure, a nurse executive shall be responsible for the coordination of nursing organizational functions.

(b) A nurse executive shall develop facility wide patient care programs, ~~policies~~ policies, and procedures that describe how the nursing care needs of patients are assessed, ~~met~~ met, and evaluated.

(c) The nurse executive shall develop and adopt, subject to the approval of the facility, a set of administrative policies and procedures to establish a framework to accomplish required functions.

(d) There shall be scheduled ~~meetings,~~ meetings ~~at least~~ every 60 ~~days,~~ days of the members of the nursing staff to evaluate the quality and efficiency of nursing services. Minutes of these meetings shall be maintained.

(e) The nurse executive shall be responsible for:

(1) the development of a written organizational plan which describes the levels of accountability and responsibility within the nursing organization;

(2) identification of ~~standards and policies~~ standards, policies, and procedures related to the delivery of nursing care;

(3) planning for and the evaluation of the delivery of nursing care ~~delivery~~ system;

(4) establishment of a mechanism to validate qualifications, knowledge, and skills of nursing personnel;

(5) provision of orientation and educational opportunities related to expected nursing ~~performance,~~ performance and maintenance of records pertaining thereto;

(6) implementation of a system for performance evaluation;

(7) provision of nursing care services in conformance with ~~the North Carolina Nursing Practice Act;~~ G.S. 90-171.20(7) and G.S. 90-171.20(8);

(8) assignment of nursing staff to clinical or managerial responsibilities based upon educational preparation, in conformance with licensing laws and an assessment of current competence; and

(9) staffing nursing units with ~~sufficient~~ personnel in accordance with a written ~~plan.~~ plan of care to meet the needs of the patients.

History Note: *Authority G.S. 131E-75(b); 131E-79;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. September 1, 2022.

10A NCAC 13B .3903 is readopted with changes as published in 36:12 NCR 1029-1032 as follows:

10A NCAC 13B .3903 PRESERVATION OF MEDICAL RECORDS

(a) The manager of the medical records service shall maintain medical records, whether original, computer media, or microfilm, for ~~a minimum of~~ 11 years following the discharge of an adult patient.

(b) The manager of medical records shall maintain medical records of a patient who is a minor until the patient's 30th birthday.

(c) If a hospital discontinues operation, its management shall make known to the Division where its records are stored. Records shall be stored in a business offering retrieval services for ~~at least~~ 11 years after the closure ~~date.~~ date or according to Paragraph (b) of this Rule if the patient was a minor.

~~(d) The hospital shall give public notice prior to destruction of its records, to permit former patients or representatives of former patients to claim the record of the former patient. Public notice shall be in at least two forms: written notice to the former patient or their representative and display of an advertisement in a newspaper of general circulation in the area of the facility.~~

~~(e)~~(d) The manager of medical records may authorize the ~~microfilming~~ digital archiving of medical records. ~~Microfilming~~ Digital archiving may be done on or off the premises. If done off the premises, the facility shall provide for the confidentiality and safekeeping of the records. The original of ~~microfilmed~~ digital archived medical records shall not be destroyed until the medical records department has had an opportunity to review the ~~processed film~~ digital record for content.

~~(f)~~(e) Nothing in this Section shall be construed to prohibit the use of automation in the medical records service, provided that all of the provisions in this Rule are met and the information is readily available for use in patient care.

~~(g)~~(f) Only personnel authorized by ~~state~~ State laws and the Health Insurance Portability and Accountability Act (HIPAA) ~~regulations~~ found in 42 CFR 482, which is incorporated by reference including subsequent amendments and editions, shall have access to medical records. This regulation may be obtained free of charge at https://www.govinfo.gov/help/cfr. Where the written authorization of a patient is required for the release or disclosure of health information, the written authorization of the patient or authorized representative shall be maintained in the original record as authority for the release or disclosure.

~~(h)~~(g) Medical records are the property of the hospital, and ~~they shall not be removed from the facility jurisdiction~~ shall remain the property of the hospital, except through a court order. Copies shall be made available for authorized purposes such as insurance claims and physician review.

History Note: *Authority G.S. ~~90-21.20B;~~ 131E-75(b); 131E-79; 131E-97;*
Eff. January 1, 1996;
Amended Eff. July 1, ~~2009.~~ 2009;
Readopted Eff. September 1, 2022.

10A NCAC 13B .4305 is readopted with changes as published in 36:12 NCR 1029-1032 as follows:

10A NCAC 13B .4305 ORGANIZATION OF NEONATAL SERVICES

(a) The governing body shall approve the scope of all neonatal services and the facility shall classify its capability in providing a range of neonatal services using the following criteria:

(1) LEVEL I: Full-term and pre-term neonates that are stable without complications. This may ~~include,~~ include infants who are small for gestational age or neonates who are large for gestational ~~age neonates.~~ age.

(2) LEVEL II: Neonates or infants that are stable without complications but require special care and frequent feedings; infants of any weight who no longer require ~~Level~~ LEVEL III or LEVEL IV neonatal services, but who still require more nursing hours than normal infant. This may include infants who require close observation in a licensed acute care ~~bed~~ bed.

(3) LEVEL III: Neonates or infants that are high-risk, small ~~(or~~ or approximately 32 and less than 36 completed weeks of gestational ~~age)~~ age but otherwise healthy, or sick with a moderate degree of illness that are admitted from within the hospital or transferred from another facility requiring intermediate care services for sick infants, but not requiring intensive care. The beds in this level may serve as a "step-down" unit from Level IV. Level III neonates or infants require less constant nursing care, but care does not exclude respiratory support.

(4) LEVEL IV (Neonatal Intensive Care Services): High-risk, medically ~~unstable~~ unstable, or critically ill neonates ~~approximately~~ under 32 weeks of gestational age, or infants, requiring constant nursing care or supervision ~~not limited to~~ that includes continuous cardiopulmonary or respiratory support, complicated surgical procedures, or other intensive supportive interventions.

(b) The facility shall provide for the availability of equipment, supplies, and clinical support services.

(c) The medical and nursing staff shall develop and approve policies and procedures for the provision of all neonatal services.

History Note: *Authority G.S. 131E-75(b); 131E-79;*
Eff. January 1, 1996;
Temporary Amendment Eff. March 15, 2002;
Amended Eff. April 1, ~~2003.~~ 2003;
Readopted Eff. September 1, 2022.

10A NCAC 13B .4805 is readopted with changes as published in 36:12 NCR 1029-1032 as follows:

10A NCAC 13B .4805 SAFETY

(a) The facility shall require that all imaging equipment is operated under the supervision of a physician and by qualified personnel.

(b) The facility shall require that ~~proper~~ caution is exercised to protect all persons from exposure to radiation.

(c) Safety inspections of the imaging department, including equipment, shall be conducted by the North Carolina Division of ~~Environmental Health,~~ Health Service Regulation, Radiation Protection ~~Services~~ Section. Copies of the report shall be available for review by the Division.

(d) The governing authority shall appoint a radiation safety committee. The committee shall ~~include but is not limited to:~~ include:

(1) a physician experienced in the handling of radio-active isotopes and their therapeutic use; and

(2) other representatives of the medical staff.

(e) All radio-active isotopes, whether for diagnostic, therapeutic, or research purposes shall be received, handled, and disposed of in accordance with the requirements of the North Carolina Department of ~~Environment and Natural Resources,~~ Health and Human Services, Division of ~~Environmental Health,~~ Health Service Regulation, Radiation Protection ~~Services Section.~~ Section set forth in 10A NCAC 15, hereby incorporated by reference including subsequent amendments. ~~Copies of regulations are available from the North Carolina Department of Environment, Health, and Natural Resources, Division of Radiation Protection, 3825 Barrett Drive, Raleigh, NC 27609 at a cost of six dollars ($6.00) each.~~

History Note: *Authority G.S. 131E-75(b); 131E-79;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. September 1, 2022.

10A NCAC 13B .5408 is readopted with changes as published in 36:12 NCR 1029-1032 as follows:

10A NCAC 13B .5408 COMPREHENSIVE INPATIENT REHABILITATION PROGRAM STAFFING REQUIREMENTS

(a) The staff of the inpatient rehabilitation facility or unit shall ~~include at a minimum:~~ include:

(1) the inpatient rehabilitation facility or unit shall be supervised by a rehabilitation ~~nurse.~~ nurse as defined in Rule .5401 of this Section. The facility shall ~~identify the nursing skills necessary to meet the needs of the rehabilitation patients in the unit and~~ assign staff qualified to meet ~~those needs;~~ the needs of the patient;

(2) the minimum nursing hours per patient in the rehabilitation unit shall be 5.5 nursing hours per patient day. At no time shall direct care nursing staff be less than two full-time equivalents, one of which must be a registered nurse;

(3) the inpatient rehabilitation unit shall employ or provide by contractual agreements ~~sufficient~~ therapist to provide ~~a minimum of~~ three hours of specific (physical, occupational or speech) or combined rehabilitation therapy services per patient day;

~~(4) physical therapy assistants and occupational therapy assistants shall be supervised on site by physical therapists or occupational therapists;~~

~~(5)~~(4) rehabilitation aides shall have documented training appropriate to the activities to be performed and the occupational licensure laws of his or her supervisor. ~~The overall responsibility for the on-going supervision and evaluation of the rehabilitation aide remains with the registered nurse as identified in Subparagraph (a)(1) of this Rule.~~ Supervision by the physical therapist or by the occupational therapist is limited to that time when the therapist is on-site and directing the rehabilitation activities of the aide; and

~~(6)~~(5) hours of service by the rehabilitation aide are counted toward the required nursing hours when the aide is working under the supervision of the nurse. Hours of service by the rehabilitation aide are counted toward therapy hours during that time the aide works under the immediate, on-site supervision of the physical therapist or occupational therapist. Hours of service shall not be dually counted for both services. Hours of service by rehabilitation aides in performing nurse-aide duties in areas of the facility other than the rehabilitation unit shall not be counted toward the 5.5 hour minimum nursing requirement described for the rehabilitation unit.

(b) Additional personnel shall be provided as required to meet the needs of the patient, as defined in the comprehensive inpatient rehabilitation evaluation.

History Note: *Authority G.S. 131E-75(b);131E-79;*
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, ~~1996.~~ 1996;
Readopted Eff. July 1, 2022.

Burgos, Alexander N

Subject: FW: Technical changes - MCC 10A NCAC 13B rules

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Thursday, July 7, 2022 10:38 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Technical changes - MCC 10A NCAC 13B rules

Nadine,

First, I think we both forgot to copy Alex on this correspondence, so I am adding him here so he can post this chain on our website.

Continuing to August is fine, and I will let the Commission know that MCC is a no action item for this month's meeting.

As for the due date, I'll expect your responses by close of business on 8/2. If you don't think you'll be able to make that deadline, then let me know, and we'll adjust from there.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Thursday, July 7, 2022 10:34 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: RE: Technical changes - MCC 10A NCAC 13B rules

Thank you Brian. Yes, we do want to continue this matter to the August RRC meeting.

Also, thank you for the deadline date and time for sending you responses for the August meeting. Just for your planning purposes, I am on vacation August 3-9 and will be out of state. With that in mind, we will shoot for sending you our revisions/responses before I am on leave.

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

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2701 Mail Service Center
Raleigh, NC 27699-2701

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Thursday, July 7, 2022 9:30 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Subject: RE: Technical changes - MCC 10A NCAC 13B rules

Hi Nadine,

Yes, I received your email on Tuesday. I apparently did not hit send on this email yesterday morning. I'm sorry about that.

Pursuant to G.S. 150B-21.13, when RRC extends the period for review, as it did at the June 2022 meeting, RRC must approve or object to the rules "[w]ithin 70 days after extending the period for review." So, to answer your questions:

a) No, you do not need to request a second extension. If you want to go to the August meeting, I will let RRC know at this month's meeting, and we'll simply put you back on the agenda for August.
b) Yes, this is the only extension that RRC can grant, as the statutory language requires RRC to approve or object within 70 days.
c) With respect to a timetable for August, given the potential complexity, I would want your revisions/responses back with sufficient lead time for me to review and respond or amend my staff opinion. The August meeting is scheduled for Thursday, 8/18, so let's set that deadline for 9 AM on Monday, 8/8. That way, if we should have a busy month, I'll have time to devote to reviewing your responses.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Thursday, July 7, 2022 9:07 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: FW: Technical changes - MCC 10A NCAC 13B rules

Good Morning Brian,
Just checking that you received this email I sent to you on Tuesday since I have not heard back from you. I have issues with sending email to someone else and was hoping this wasn't also happening with emails to 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

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Raleigh, NC 27699-2701

From: Pfeiffer, Nadine
Sent: Tuesday, July 5, 2022 4:37 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: Technical changes - MCC 10A NCAC 13B rules

Hi Brian,
Because I have not experienced this situation before, I have a couple questions regarding the technical change request for the Medical Care Commission rules in 10A NCAC 13B originally sent to me on June 3, 2022:

a) We received one approval from the RRC to extend the period of review for these rules following the June meeting. If we need additional time to work on the concerns identified in the technical change request, do we submit a second request for the July meeting?
b) If a) is correct, am I correct that this is the last extension and the rules will put on the agenda for the August meeting for consideration by the RRC?
c) If the period of review is extended to the August RRC meeting for these rules, what is the last day you will accept revised rules and responses to the technical change concerns?

Thank you.

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

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nadine.pfeiffer@dhhs.nc.gov

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Burgos, Alexander N

Subject: FW: NC Medical Care Commission Request for Changes - June 2022 RRC

From: Snyder, Ashley B <ashley.snyder@oah.nc.gov>
Sent: Wednesday, June 15, 2022 12:23 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Liebman, Brian R <brian.liebman@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: NC Medical Care Commission Request for Changes - June 2022 RRC

Thank you, Nadine. It looks like Alex was not copied on the email chain. I have added him here so he will see this and post.

Ashley Snyder
Codifier of Rules
Office of Administrative Hearings
(984) 236-1941

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Wednesday, June 15, 2022 11:54 AM
To: Snyder, Ashley B <ashley.snyder@oah.nc.gov>
Subject: FW: NC Medical Care Commission Request for Changes - June 2022 RRC

These emails have not been posted on your website for agency communication.

Nadine Pfeiffer
Rules Review Manager
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NC Department of Health and Human Services

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Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

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Raleigh, NC 27699-2701

From: Pfeiffer, Nadine
Sent: Monday, June 6, 2022 7:39 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: RE: NC Medical Care Commission Request for Changes - June 2022 RRC

Good Morning Brian,
Yes, I did receive your email on Friday after I had left the office for the weekend and I am just able to respond to it now. I will communicate your concerns with legal and other relevant Division staff. Due to the unusually short due date timeframe requested by your agency of five business days, we hope to be in a position to respond accordingly.

Nadine Pfeiffer

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

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nadine.pfeiffer@dhhs.nc.gov

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From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Saturday, June 4, 2022 11:27 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Subject: RE: NC Medical Care Commission Request for Changes - June 2022 RRC

Hi Nadine,

Just wanted to confirm you received these? I know it was late on Friday, and I do apologize for not getting these to you sooner, it's been yet another heavy month for us here.

As always, let me know if you have any questions or concerns.

Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Liebman, Brian R
Sent: Friday, June 3, 2022 6:18 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: NC Medical Care Commission Request for Changes - June 2022 RRC

Hi Nadine,

I'm the attorney who reviewed the Rules submitted by the Board for the June 2022 RRC meeting. The RRC will formally review these Rules at its meeting on Thursday, June 16, 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 to me via email, no later than 5 p.m. on Friday, June 10, 2022. You'll note I had statutory authority questions for all rules contained in this packet. If you want to discuss, I'm available at your convenience next week.

In the meantime, do not hesitate to reach out via email with any questions or concerns.

Thanks,

Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

From: Liebman, Brian R
Sent: Friday, June 10, 2022 1:53 PM
To: Pfeiffer, Nadine
Cc: Burgos, Alexander N
Subject: RE: Historical documents for Hospital rules

Thank you, Nadine. I'll review these and see if there are any other rules subject to objection that we need to work on.

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Thursday, June 9, 2022 2:56 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: Historical documents for Hospital rules

Hi Brian,
As a follow-up to this afternoon's conference call, please see the attached documents I received from the prior Codifier on the rule filings for the hospital permanent rules prior to the rules becoming effective January 1, 1996. These documents include the RRC objections and RRC meeting minutes. Please note, the rules were recodified in 2003. Prior to recodification, the hospital rules Subchapter was 10 NCAC 13C but the rule numbers were the same as they are today.

I also have 3 documents (RRC rules-objections 7-95, RRC rules-objections2 7-95, & RRC rules-objections3 7-95) that look like it was all the rules that were submitted to RRC that became effective 1/1/96. From review of this document, it seems as the rules Joe DeLuca, staff attorney, did not object to are just the rules with maybe some highlights on them and the ones with an objection have the objection following the text of the rule.

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

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Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

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Raleigh, NC 27699-2701

Burgos, Alexander N

Subject: FW: Request to extend the period of review - 10A NCAC 13B rules

---

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Friday, June 10, 2022 11:00 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Request to extend the period of review - 10A NCAC 13B rules

Hi Nadine,

Thanks for sending me the request. I will recommend that RRC grant your request for an extension at next week's meeting.

Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Friday, June 10, 2022 10:26 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: Request to extend the period of review - 10A NCAC 13B rules

Brian,
On behalf of the N.C. Medical Care Commission, this is a request to extend the period of review for the hospital rules in 10A NCAC 13B to the July 21, 2022 Rules Review Commission meeting to address technical change requests issued by you on June 2, 2022. It is not unlikely the N.C. Medical Care Commission will need to seek a second extension of time; however, we work as quickly as possible to address the technical change concerns. Please let me know if this extension is approved.

Thank 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

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Raleigh, NC 27699-2701

Burgos, Alexander N

Subject: FW: [External] Hospital Rules

From: Randolph, Kimberly <Krandolph@ncdoj.gov>
Sent: Wednesday, June 8, 2022 11:19 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgon, Bethany A <bburgon@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: Re: [External] Hospital Rules

Thanks Brian. I will send out a conf call number.

Sent from my iPhone

Burgos, Alexander N

Subject: FW: [External] Hospital Rules

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Wednesday, June 8, 2022 10:27 AM
To: Randolph, Kimberly <krandolph@ncdoj.gov>
Cc: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgon, Bethany A <bburgon@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: [External] Hospital Rules

Hi Kim,

Thanks for the information. I'll take a look at 143B-165 and let you know my thoughts. As for the meeting, 1:00 tomorrow would be great. Look forward to speaking with you all.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

Subject: FW: [External] Hospital Rules

From: Randolph, Kimberly <Krandolph@ncdoj.gov>
Sent: Wednesday, June 8, 2022 8:10 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgon, Bethany A <bburgon@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: [External] Hospital Rules

Hi Brian,

Just FYI - I was able to confirm that Article 5, in N.C. Gen. Stat. § 131E, did replace Article 13A when it was repealed, even though that reference has not been updated in N.C. Gen. Stat. § 143B-165(6).

Additionally, I just noticed I inadvertently proposed 10 for a call tomorrow when I intended to propose 1:00, since you indicated you preferred the afternoon. We are available at 1:00 tomorrow if that works for you. I will be happy to set up a conference call number for tomorrow at 1:00, if that time works. Thanks!

Kim Randolph
Assistant Attorney General
(919) 716-0270 Direct

Burgos, Alexander N

Subject: FW: [External] Hospital Rules

From: Randolph, Kimberly <Krandolph@ncdoj.gov>
Sent: Tuesday, June 7, 2022 2:21 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgon, Bethany A <bburgon@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: [External] Hospital Rules

Hi Brian,

That you for your quick response! After we looked at these again, we noticed that N.C. Gen. Stat. § 143B-165 was not listed. We believe we need to add that to our history note. When reading N.C. Gen. Stat. § 143B-165, in conjunction with N.C. Gen. Stat. § 131E-75(b) and the specific authority of N.C. Gen. Stat. § 131E-79, will that provide the authority you are looking for these rules? Will be glad to hear your thoughts.

Would 10 on Thursday work for a call? Thanks again!

Kim Randolph
Assistant Attorney General
(919) 716-0270 Direct

Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

From: Liebman, Brian R
Sent: Tuesday, June 7, 2022 12:48 PM
To: Randolph, Kimberly
Cc: Pfeiffer, Nadine; Burgon, Bethany A; Burgos, Alexander N
Subject: RE: [External] Hospital Rules
Attachments: 2022.06 - MCC - 13B Staff Opinion.doc

Hi Kim,

I hope you are well also! Thanks for reaching out.

I have received the pre-review responses you sent to Ashley, and I have had an opportunity to review them today. It appears to me that these statutory authority issues were raised during the pre-review, and the agency's position is that the policy statute within Article 5—G.S. 131E-75(b)—provides sufficient statutory authority for each of these rules. Unfortunately, I do not believe that this statute, in light of the entirety of the Hospital Licensure Act, is sufficient authority to adopt the Rules currently before RRC. As such, I am issuing the attached staff opinion recommending that RRC object to these rules for lack of statutory authority, with the caveat that it may be revised or withdrawn depending on further argument MCC may make in response to my request for changes, or further review on my part.

While I can't meet on Wednesday, I can definitely speak with you on Thursday. I'd prefer the afternoon, but I can do anytime after 9:30 a.m. I look forward to speaking with you.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Randolph, Kimberly <Krandolph@ncdoj.gov>
Sent: Tuesday, June 7, 2022 12:07 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgon, Bethany A <bburgon@ncdoj.gov>
Subject: [External] Hospital Rules
Importance: High

Hey Brian,

Hope you are well.

I understand you received our 8-2-2021 response to pre-review comments today. Will you please let me know if you need any additional information in response to your comments, after you have had a chance to review our response?

If you need additional information, can we set up a time to talk on Wed at 9:00 or 2:00 or anytime Thursday? Thank you.

Kim Randolph
Assistant Attorney General
Health Service Section
(919) 716-0270 - Direct
(919) 716-6756 - Fax
krandolph@ncdoj.gov
P.O. Box 629 Raleigh, NC 27602-0629
ncdoj.gov

Please note messages to or from this address may be public records.

Burgos, Alexander N

Subject: FW: Pre-review comments response - 10A NCAC 13B Phase 4 readoption rules

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From: Snyder, Ashley B
Sent: Tuesday, June 7, 2022 10:38 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Subject: RE: Pre-review comments response - 10A NCAC 13B Phase 4 readoption rules

Thank you, Nadine. I am not sure if Amber or Amanda provided a copy of your responses to Brian, though I do know they left folders of pre-review materials. I provided him a copy of what you just sent.

Ashley Snyder
Codifier of Rules
Office of Administrative Hearings
(984) 236-1941

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Tuesday, June 7, 2022 10:14 AM
To: Snyder, Ashley B <ashley.snyder@oah.nc.gov>
Subject: FW: Pre-review comments response - 10A NCAC 13B Phase 4 readoption rules

Hi Ashley,
Thank you for taking the time to look through your files for the pre-review comments on our 13B rules. We take all the pre-review comments we receive extremely seriously and we do make changes to our rules accordingly and also send responses back to your office so the staff attorneys will have them when they review the permanent rules. When we received your pre-review comments, we discussed the statutory authority concerns with attorneys at DOJ and made revisions to the history notes based on their counsel to us. I sent our pre-review responses to Amanda and Amber on 8/2/21 that included explanations for the concerns asked in your pre-review. (see email below). I sent this to the two of them because you had already been named Codifier and no longer was in the staff attorney role. I know both of these ladies are no longer employed by your agency; however, was this document forwarded to Brian for his consideration when he reviewed our rules?

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

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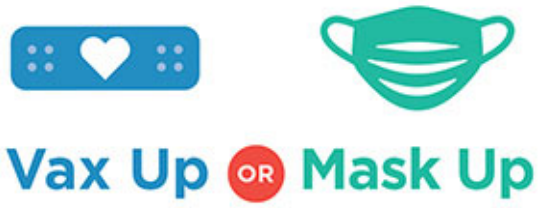
From: Pfeiffer, Nadine
Sent: Monday, August 2, 2021 4:48 PM

To: Reeder, Amanda J <amanda.reeder@oah.nc.gov>; May, Amber Cronk <amber.may@oah.nc.gov>
Subject: Pre-review comments response - 10A NCAC 13B Phase 4 readoption rules

Hello!
You can't get enough of me today, can you? We got a pre-review back that Ashley did on our Phase 4 Hospital rules in 10A NCAC 13B on 6/16/21. One of you lucky ladies will most likely get these when we file for permanent rule for the June '22 meeting (or maybe you will pawn them off to one of your new staff whenever they get hired), but in any case, here are our responses to the pre-review comments for those rules.

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



Find a vaccine location, get questions answered and more at YourSpotYourShot.nc.gov.

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nadine.pfeiffer@dhhs.nc.gov

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Burgos, Alexander N

From: Snyder, Ashley B
Sent: Tuesday, June 7, 2022 9:41 AM
To: Pfeiffer, Nadine
Cc: Burgos, Alexander N
Subject: RE: Reviewed rules for June meeting
Attachments: 10A NCAC 13B - ABS.docx

Nadine,

I was curious if I missed something in the pre-review so I pulled my notes. See attached. I asked numerous questions about significant statutory authority concerns in the pre-review. Brian's change requests line up with the same questions raised in the pre-review. These questions should come as no surprise.

Ashley Snyder
Codifier of Rules
Office of Administrative Hearings
(984) 236-1941

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Monday, June 6, 2022 8:10 AM
To: Snyder, Ashley B <ashley.snyder@oah.nc.gov>
Subject: RE: Reviewed rules for June meeting

Good Morning Ashley,
Thank you for getting back with me. Yes, I did receive the technical changes from Brian, however they were received after business hours on Friday (like 6:18pm) and I had left for the day. You are correct, I as the rule coordinator cannot answer any of the technical change questions the staff attorneys pose. Those are handled by the subject matter experts in our Sections that implement the rules. What I do when I get the technical changes is send the document over to them to answer and then I make all the rule changes they want made (I automatically do any "easy" things like changing a word here and there or punctuation changes etc). My folks have no idea how to make changes to the rule text after the NOT is filed so it is easier if I just do it for them, so yes, all of this takes time and a lot of back and forth. I am glad you impressed upon your staff the time it does take agencies to accomplish all of this and the amount of people that are sometimes involved. Thank you!

As for the technical changes I received late Friday evening for the hospital rules, I am disappointed that for 12 of the 14 (1 was a repeal) rules there were questions on the statutory authority for those rules after we had sent those rules for a pre-review and you were the attorney who sent us back the comments on the pre-review and this was not mentioned for all these rules. It would have been nice to know in advance of these issues, which to me, could be a game stopper. Also, to give us a five business day deadline to get the changes back to your agency, instead of the usual 10 business days, when we have to involve DOJ at this point, feels punitive. Our staff subject matter experts have other duties besides rulemaking. They are oftentimes in the field conducting health and safety surveys of facilities for the residents of NC. It is not as easy as one would think to get the answers needed to the technical changes in the typical 10 business days, and now we are asked to do it in five. Yes, I am aware we could ask to extend the period of review for these rules and other rules in the future if we cannot make the deadline for submission of technical changes; however, there will be some rules like CON rules that this will not be possible since the rules will have to become effective the 1st day of the month after the RRC meeting or it will affect the applicants for CONs.

I am truly sorry that there was a large amount of rule filings for this month, but there will be many months like that and have been in the past. Just like for us rulemaking coordinators. When agencies have met the permanent rule submission deadline or submitted earlier than the deadline, I do not feel it is a fair practice to place a shortened technical change submission deadline on agencies because of OAH's workload. Please give this some thought.

Thank you.

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

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nadine.pfeiffer@dhhs.nc.gov

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From: Snyder, Ashley B <ashley.snyder@oah.nc.gov>
Sent: Saturday, June 4, 2022 7:57 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Subject: RE: Reviewed rules for June meeting

Good morning, Nadine,

We do have these rules and they are assigned to Brian. As a former rulemaking coordinator, I understand your concern and frustration. It can be difficult to turnaround tech change requests in a short timeline. I actually took a minute to explain that to our staff attorneys on Thursday – rulemaking coordinators often have to take drafts to other staffers, their boss, etc. so they need time to respond to the changes and circulate them within their agency.

From our point of view, please understand we have had heavy filings months in a row resulting in a high volume of rules for the staff attorneys to review this month in addition to numerous follow-up matters. I can assure you our staff attorneys have been working overtime to complete their review as quickly as possible. We are also working on hiring our 4th staff attorney position. I will reach out to Brian and ask him to give you an update.

Thank you for contacting me about this. I always appreciate feedback.

Ashley Snyder
Codifier of Rules
Office of Administrative Hearings
(984) 236-1941

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Friday, June 3, 2022 4:26 PM
To: Snyder, Ashley B <ashley.snyder@oah.nc.gov>
Subject: Reviewed rules for June meeting

Hi Ashley,
I am just checking to see that you all did receive my Submission for Permanent Rule from the Medical Care Commission for 14 readoption rules for 10A NCAC 13B. I submitted the rules on May 16, 2022 and did not get a bounce back from my

email. I have not received any correspondence from your agency on these rules, not an acknowledgement of the receipt, nor any technical change requests. This is highly unusual. In all the years I have worked on rules, there has never been this long of delay in receiving any type of communication from OAH. Typically I would have gotten technical change requests by the beginning of this week at the latest, since they are due to your office next Friday. Have you all received them? I am getting quite worried.

Thank you.

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

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

Medical Care Commission – 10A NCAC 13B

Pre-Review

Ashley Snyder

General Notes:

- As a reminder, pre-reviews are conducted voluntarily by RRC staff counsel. Staff counsel may still issue technical corrections or staff opinions upon filing the rules for review by the Rules Review Commission.
- I see you cited G.S. 131E-70 for all of these rules. That is a grant of general rulemaking authority to implement G.S. 131E, Article 5. That statute does not grant authority for anything the agency wants to do, for example, implementation of requirements not mentioned in G.S. 131E, Article 5. You will see questions about this in multiple rules. Please think about what statute you are implementing. What language in 131E, Article 5 are you relying upon for the rule? RRC has historically interpreted statutory authority narrowly. Please keep this in mind as you review.

.3801:

- What authority are you relying upon for this Rule? I see you have cited 131E-79, which provides authority to "promulgate rules necessary to implement this Article," but which statute or statutes within this Article are you implementing? G.S. 131E-77(c) allows you to require the provision of information related to hospital operations. Where is your authority to govern operations instead of just request information related to operations?
- In (a), what is a "centralized organizational structure" and what is a "decentralized organizational structure?" Is your regulated public familiar with these terms?
- Do nurse executives work in centralized organizational structures? Please review the definition of "nurse executive" in 13B .3001.
- In (b), please add a comma after "policies."
- In (c), what "required functions" are you referring to?
- In (d), please delete the commas after "meetings" and "days."
- In (d), is it up to the facility to determine how nursing staff evaluates nursing services?
- Is (e)(2) the same as (b)? Is there some overlap with (e)(9) as well? If so, please avoid repetition.
- In (e)(5), please delete the comma.

.3903:

- Are you relying upon 131E-80(d) as your authority? If so, please add that statute to your history note.

- What are you relying upon as statutory authority for (d)?
- In (g), please capitalize "State" if you are only referring to North Carolina.
- In (g), consider adding "(HIPPA)" after the name of the Act.
- In (h), what is considered an "authorized purpose?" What is not? How is this determination made?
- Why is G.S. 90-21.20B listed in your history note? Does that statute grant authority to the Medical Care Commission? I do not think it does.

.4103:

- What are you relying upon for authority for (a)? Which statute are you implementing? 131E-79 only grants rulemaking authority for rules "necessary to implement this Article."
- If you keep (a), please delete or define "appropriate." For example, which medical screening policies are appropriate vs. not appropriate? What does this Rule require?
- For (b) and (c), what are you relying upon as your authority to require certain hospital equipment? I see you have this authority over ambulances in Article 7. Where is your authority over equipment at facilities?
- In (c), I take it you are still governing "facilities," correct?
- In (c), if the rules 10A NCAC 13P were promulgated by the Medical Care Commission, you do not need to incorporate them by reference because they are your rules! Simply refer to them. Incorporation lets your regulated public know "We're enforcing this other document now and making it part of our rules." You're already enforcing 13P, so a cross-reference is all you need.

.4104:

- Where is your statutory authority for Paragraphs (a), (c), and (d)?
- For Paragraph (b), are you relying upon 131E-85? If so, please add that to your history note.

.4106:

- Where is your statutory authority for this Rule?
- In (11), please capitalize "State" if you are only referring to North Carolina.

.4305:

- Where is your statutory authority for this Rule?
- In (a)(1), consider "This may include infants who are small…"

.4603:

- To the extent this Rule governs hospital privileges, please add 131E-85 to your history note. Does that statute provide authority for this entire Rule? For example, what authority are you relying upon for (b)(5)?
- Is (b) the list of processes required in (a)? If so, please make that clear. Consider combining (a) and (b) so you just have one paragraph followed by a list.
- In (b)(2), please delete or define "qualified physician" and "immediately."
- In (b)(4), delete or define "qualified." Are you just requiring a registered nurse or are you requiring additional qualifications?

.4801:

- Does this Rule govern hospital privileges as well? If so, please add 131E-85 to your history note. If not, what is your statutory authority for this Rule?
- In (a), please change "must" to "shall."
- In (b), what are you getting at here? Is it that radio-therapy services shall be conducted under supervision of a radiologist or other experienced physician as described in (a)? If so, consider: "Radio-therapy shall be considered an imaging service" or "Radio-therapy is a type of imaging service."
- In (c), define "qualified personnel."

.4805:

- Why is (a) necessary? It repeats .4801(a).
- Why is (b) necessary? It repeats .4801(c).
- For (c), is the Medical Care Commission requiring these safety inspections or are these already required by Radiation Protection? In other words, is this necessary or are you repeating something that is already required?
- In (d), do you need to say "but is not limited to?" Does it make the rule clearer to retain this language or is "shall include" sufficient?
- In (d)(1), define "experienced." What experience is required?
- Where is your statutory authority for this Rule?

.5102 and .5105:

- Where is your statutory authority for these Rules?

.5406:

- Where is your statutory authority for this Rule? Are you relying upon G.S. 131E-80(d) or 131E-90?

- In (a), what "established goals" are you referring to?
- At line 6, a determination by who? Does this refer to the two physicians mentioned in 131E-90? Please clarify.

.5408:

- Overall, what are you relying upon for authority? What statute or statutes are you implementing?
- Throughout this Rule, where is your statutory authority to set supervision requirements, with the exception of physicians supervising care as provided in 131E-76(3)? Is this already governed by occupational licensing boards?
- What are you requiring in (a)(1)? Are you requiring a rehabilitation nurse as defined in .5401?
- Where is your authority to set staff qualification requirements?
- What does (b) require? How is this measured? How do you determine whether the requirements in (b) have been met?

.5411:

- What are you relying upon for authority for Paragraph (a)?
- In (b), please delete "the rules outlined in" and simply refer to "Sections .6000 and .6100." "Section" refers to an entire division of rules - .0100, .0200, etc. Here you have a reference to a section and an individual rule, .6105. I think you intended to refer to all of .6100, but please confirm.

Burgos, Alexander N

From: Liebman, Brian R
Sent: Friday, June 3, 2022 6:18 PM
To: Pfeiffer, Nadine
Cc: Burgos, Alexander N
Subject: NC Medical Care Commission Request for Changes - June 2022 RRC
Attachments: 06.2022 - Medical Care Commission 13B Request for Changes.docx

Hi Nadine,

I'm the attorney who reviewed the Rules submitted by the Board for the June 2022 RRC meeting. The RRC will formally review these Rules at its meeting on Thursday, June 16, 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 to me via email, no later than 5 p.m. on Friday, June 10, 2022. You'll note I had statutory authority questions for all rules contained in this packet. If you want to discuss, I'm available at your convenience next week.

In the meantime, do not hesitate to reach out via email with any questions or concerns.

Thanks,

Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Medical Care Commission – 10A NCAC 13B

Pre-Review

Ashley Snyder

General Notes:

- As a reminder, pre-reviews are conducted voluntarily by RRC staff counsel. Staff counsel may still issue technical corrections or staff opinions upon filing the rules for review by the Rules Review Commission.
- I see you cited G.S. 131E-70 for all of these rules. That is a grant of general rulemaking authority to implement G.S. 131E, Article 5. That statute does not grant authority for anything the agency wants to do, for example, implementation of requirements not mentioned in G.S. 131E, Article 5. You will see questions about this in multiple rules. Please think about what statute you are implementing. What language in 131E, Article 5 are you relying upon for the rule? **G.S. 131E-75(b)** RRC has historically interpreted statutory authority narrowly. Please keep this in mind as you review.

.3801:

- What authority are you relying upon for this Rule? **G.S. 131E-75(b)** I see you have cited 131E-79, which provides authority to "promulgate rules necessary to implement this Article," but which statute or statutes within this Article are you implementing? **G.S. 131E-75(b)** G.S. 131E-77(c) allows you to require the provision of information related to hospital operations. Where is your authority to govern operations instead of just request information related to operations? **G.S. 131E-75(b)**
- In (a), what is a "centralized organizational structure" and what is a "decentralized organizational structure?" Is your regulated public familiar with these terms? **The state licensed and Medicare certified, accreditation organizations, and regulated providers are knowledgeable of the regulations and daily operations and familiar with the terms, "centralized organizational structure" and "decentralized organizational structure. The organizational structures are hospital specific references the use of the centralized or decentralized structure.**
- Do nurse executives work in centralized organizational structures? **Yes.** Please review the definition of "nurse executive" in 13B .3001. **The definition of nurse executive expanded as common nomenclature as hospitals transitioned to centralized organizational structures.**
- In (b), please add a comma after "policies." **Done**
- In (c), what "required functions" are you referring to? **The state licensed and Medicare certified, accreditation organizations, and regulated providers are knowledgeable of the regulations and daily operations which define the various functions warranting the development and implementation of policies and procedures for patient care.**

- In (d), please delete the commas after "meetings" and "days." **Done**
- In (d), is it up to the facility to determine how nursing staff evaluates nursing services? **Yes. The state licensed and Medicare certified, accreditation organizations, and regulated providers are knowledgeable of the regulations and daily operations. Hospitals define parameters for staffing related to patient care acuity and needs to ensure the delivery of safe and quality care. Staffing is patient care directed.**
- Is (e)(2) the same as (b)? **No** Is there some overlap with (e)(9) as well? **Yes. Staffing is correlated to the policies and procedure implemented to direct the delivery of the patient care.** If so, please avoid repetition.
- In (e)(5), please delete the comma. **Done**

.3903:

- Are you relying upon 131E-80(d) as your authority? **G.S. 131E-75(b)** If so, please add that statute to your history note. **Done**
- What are you relying upon as statutory authority for (d)? **G.S. 131E-75(b)**
- In (g), please capitalize "State" if you are only referring to North Carolina. **Done**
- In (g), consider adding "(HIPPA)" after the name of the Act. **Done**
- In (h), what is considered an "authorized purpose?" What is not? How is this determination made? **The state licensed and Medicare certified regulated providers are knowledgeable of the regulations and daily operations on the disclosure of medical records in accordance with HIPAA regulations. Hospitals must have defined policies and procedures for implementation that clearly defines those authorized and not authorized. Pursuant to Medicare regulations § 482.24(b)(3) …. Information from or copies of medical records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Additional examples of authorized purposes include court orders, subpoenas, continuation of medical care, case reviews. Individuals have the right to access their personal medical records at any time and disclose as they deem appropriate.**
- Why is G.S. 90-21.20B listed in your history note? Does that statute grant authority to the Medical Care Commission? I do not think it does. **G.S. 90-21.20B removed.**

.4103:

- What are you relying upon for authority for (a)? **G.S.131E-75(b)** Which statute are you implementing? **G.S.131E-75(b)** 131E-79 only grants rulemaking authority for rules "necessary to implement this Article."
- If you keep (a), please delete or define "appropriate." For example, which medical screening policies are appropriate vs. not appropriate? What does this Rule require? **"appropriate" deleted**
- For (b) and (c), what are you relying upon as your authority to require certain hospital equipment? **Article 5 Hospital Licensure Act § 131E-75. Title: purpose This is the**

basic for safe care to promote public health, safety, and welfare and to provide for the development, establishment, and enforcement of basic standards for the care and treatment of patients in hospitals. I see you have this authority over ambulances in Article 7. Where is your authority over equipment at facilities? **The definition of hospital under Article 5 131E-76 includes the provision of diagnostic and therapeutic care. This article covers our ability to ensure safe equipment. The provision of safe care includes assurances equipment is safe and operational.**

- In (c), I take it you are still governing "facilities," correct? **Yes**
- In (c), if the rules 10A NCAC 13P were promulgated by the Medical Care Commission, you do not need to incorporate them by reference because they are your rules! Simply refer to them. Incorporation lets your regulated public know "We're enforcing this other document now and making it part of our rules." You're already enforcing 13P, so a cross-reference is all you need. **Cross reference done.**

.4104:

- Where is your statutory authority for Paragraphs (a), (c), and (d)? **G.S. 131E-75(b) The agency has no statutory authority for regulating the qualifications of the director of emergency services.**
- For Paragraph (b), are you relying upon 131E-85? If so, please add that to your history note. **131E-85(a) added to history note.**

.4106:

- Where is your statutory authority for this Rule? **G.S.131E-75(b)**
- In (11), please capitalize "State" if you are only referring to North Carolina. **Done**

.4305:

- Where is your statutory authority for this Rule? **G.S.131E-75(b)**
- In (a)(1), consider "This may include infants who are small…" **Replaced with "include infants who are small"**

.4603:

- To the extent this Rule governs hospital privileges, please add 131E-85 to your history note. **Done** Does that statute provide authority for this entire Rule? For example, what authority are you relying upon for (b)(5)? **G.S. 131e-75(b)**

- Is (b) the list of processes required in (a)? If so, please make that clear. Consider combining (a) and (b) so you just have one paragraph followed by a list. **Done**
- In (b)(2), please delete or define "qualified physician" and "immediately." **Done**
- In (b)(4), delete or define "qualified." Are you just requiring a registered nurse or are you requiring additional qualifications? **Done**

.4801:

- Does this Rule govern hospital privileges as well? If so, please add 131E-85 to your history note. If not, what is your statutory authority for this Rule? **G.S.131E-75(b)**
- In (a), please change "must" to "shall." **Done**
- In (b), what are you getting at here? Is it that radio-therapy services shall be conducted under supervision of a radiologist or other experienced physician as described in (a)? If so, consider: "Radio-therapy shall be considered an imaging service" or "Radio-therapy is a type of imaging service." **Replaced with "Radio-therapy is a type of imaging service."**
- In (c), define "qualified personnel." **"Qualified" deleted**

.4805:

- Why is (a) necessary? It repeats .4801(a). **The state licensed Medicare certified regulated providers are knowledgeable of the regulations and daily operations. Although, the regulation may seem duplicative, .4801 lays out the organizational structure. The organizational structures are hospital specific. The intent of the regulation is to ensure a designated person is assigned the responsibility of ensuring the use of safe equipment and ongoing preventative maintenance. The regulation is essential.**
- Why is (b) necessary? It repeats .4801(c). **The state licensed Medicare certified regulated providers are knowledgeable of the regulations and daily operations. The intent of the regulations is to ensure systems are in place for individual staff safety. The regulation is essential to promote safety. It is noted, the monitoring of staff safety is often overlooked.**
- For (c), is the Medical Care Commission requiring these safety inspections or are these already required by Radiation Protection? In other words, is this necessary or are you repeating something that is already required?
- In (d), do you need to say "but is not limited to?" **No** Does it make the rule clearer to retain this language or is "shall include" sufficient? **Shall include is sufficient. Remove "but is not limited to" and replace with…The committee shall include:**

- In (d)(1), define "experienced." What experience is required? **The state licensed Medicare certified regulated providers are knowledgeable of the regulations and daily operations. Experienced is hospital specific and defined by the hospital's**

medical staff bylaws and includes a combination of educations, and hands on exposure or skill over a specific period.

- Where is your statutory authority for this Rule? **131E-75(b)**

.5102 and .5105:

- Where is your statutory authority for these Rules? **131E-75(b)**

.5406:

- Where is your statutory authority for this Rule? Are you relying upon G.S. 131E-80(d) or 131E-90? **G.S.131E-75(b)**
- In (a), what "established goals" are you referring to? **Goals of care.**
- At line 6, a determination by who? Does this refer to the two physicians mentioned in 131E-90? Please clarify. **Yes. The state licensed Medicare certified regulated providers are knowledgeable of the regulations and processes for assessing and implementing care to meet the needs of patients with an overarching goal of improvement to returning to an independent state of health with the least parameters of assistance. The team and decision-making are a comprehensive team approach addressing the needs of the rehab patient. The attending physician or physiatrist direct the comprehensive rehab program. This is an inclusive process of a multi-disciplinary team of health care providers which may include OT, PT, SLP, mental health professionals, psychologist, psychiatrist, etc.**

.5408:

- Overall, what are you relying upon for authority? What statute or statutes are you implementing? **G.S.131E-75(b)**
- Throughout this Rule, where is your statutory authority to set supervision requirements, with the exception of physicians supervising care as provided in 131E-76(3)? Is this already governed by occupational licensing boards? **G.S. 131E-75(b)**
- What are you requiring in (a)(1)? Are you requiring a rehabilitation nurse as defined in .5401? **Yes**
  Where is your authority to set staff qualification requirements? **The agency has no statutory authority to set staff qualification requirements.**
- What does (b) require? How is this measured? How do you determine whether the requirements in (b) have been met? **The state licensed Medicare certified regulated providers are knowledgeable of the regulations and processes for assessing, implementing, and ongoing evaluation of a comprehensive plan of care to meet the needs of the patient centered and directed goals. The multi-disciplinary team is responsible for an ongoing assessment and evaluation of the rehab patient to obtain**

goals. Examples of rehab measures may include but are not limited to ability to button clothing without assistance, ability to walk with a cane as opposed to a walker, or the ability to increase steps.

.5411:

- What are you relying upon for authority for Paragraph (a)?
- In (b), please delete "the rules outlined in" and simply refer to "Sections .6000 and .6100." "Section" refers to an entire division of rules - .0100, .0200, etc. Here you have a reference to a section and an individual rule, .6105. I think you intended to refer to all of .6100, but please confirm. **.5411 Repealed**

Burgos, Alexander N

From: Liebman, Brian R
Sent: Wednesday, August 31, 2022 5:05 PM
To: Pfeiffer, Nadine; Burgos, Alexander N
Subject: Re: 10A NCAC 13F/13G Requests for Changes - September 2022 RRC

Hi Nadine,

I will review and let you know. I did copy the 13F change requests for 13G (adding and subtracting as necessary, naturally) as they were largely the same. I was trying to work quickly and may have left some extraneous change requests in there. If so, I'll send an updated version to you later tonight. Apologies for the confusion.

Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Wednesday, August 31, 2022 4:58 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: RE: 10A NCAC 13F/13G Requests for Changes - September 2022 RRC

Thank you Brian, we will respond as quickly as we can.

A couple things on the document however. The last three rules listed in the document are duplicates of what you had already written. We believe the duplicate changes requested for Rule 10A NCAC 13F .1006 were supposed to be for Rule 10A NCAC 13G .1006 and will treat them a such. As for the remaining duplicate changes requested for 10A NCAC 13F and .1010, we will discard those requests.

If any of this is not correct, please let me know.

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

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Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

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From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Wednesday, August 31, 2022 3:55 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: 10A NCAC 13F/13G Requests for Changes - September 2022 RRC

Hi Nadine,
I'm the attorney who reviewed the Rules submitted by MCC for the September 2022 RRC meeting. The RRC will formally review these Rules at its meeting on Thursday, September 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 5 p.m. on Friday, September 9, 2022.
In the meantime, please do not hesitate to reach out via email with any questions or concerns.
Thanks,
Brian
Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov