

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

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Raleigh, NC 27699-2701

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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

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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
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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: 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
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Burgos, Alexander N

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To: Liebman, Brian R
Cc: Randolph, Kimberly; Burgos, Alexander N
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Thank you.

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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

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Brian

Brian Liebman
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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
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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](#)

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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: 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
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brian.liebman@oah.nc.gov

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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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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

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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

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brian.liebman@oah.nc.gov

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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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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
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brian.liebman@oah.nc.gov

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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

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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

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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](#)

Office: 919-855-3811

Fax: 919-733-2757

nadine.pfeiffer@dhhs.nc.gov

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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

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state official.

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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](http://www.ncdhhs.gov)

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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

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Burgos, Alexander N

Subject: FW: Submission of Permanent Rule Technical Changes - 10A NCAC 13B
Attachments: 10A NCAC 13B .3801.docx; 10A NCAC 13B .3903.docx; 10A NCAC 13B .4305.docx; 10A NCAC 13B .4805.docx; 10A NCAC 13B .5408.docx; Request for Changes 13B response 7-26-22.docx; Response to RRC Staff Attorney for Hospital Rules 7-25-22.pdf

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](http://www.ncdhhs.gov)

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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 ($\frac{1}{25}$ 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."

Request for Changes Pursuant to
N.C. Gen. Stat. § 150B-21.10

Staff reviewed these Rules to ensure that each Rule is within the agency's statutory authority, reasonably necessary, clear and unambiguous, and adopted in accordance with Part 2 of the North Carolina Administrative Procedure Act. Following review, staff has issued this document that may request changes pursuant to G.S. 150B-21.10 from your agency or ask clarifying questions.

If the request includes questions, please contact the reviewing attorney to discuss.

In order to properly submit rewritten rules, please refer to the following Rules in the NC Administrative Code:

- Rule 26 NCAC 02C .0108 – The Rule addresses general formatting.
- Rule 26 NCAC 02C .0404 – The Rule addresses changing the introductory statement.
- Rule 26 NCAC 02C .0405 – The Rule addresses properly formatting changes made after publication in the NC Register.

Note the following general instructions:

1. You must submit the revised rule via email to oah.rules@oah.nc.gov. The electronic copy must be saved as the official rule name (XX NCAC XXXX).
2. For rules longer than one page, insert a page number.
3. Use line numbers; if the rule spans more than one page, have the line numbers reset at one for each page.
4. Do not use track changes. Make all changes using manual strikethroughs, underlines and highlighting.
5. You cannot change just one part of a word. For example:
 - Wrong: “~~a~~Association”
 - Right: “~~association~~ Association”
6. Treat punctuation as part of a word. For example:
 - Wrong: “day;, and”
 - Right: “~~day,~~ day, and”
7. Formatting instructions and examples may be found at:
www.ncoah.com/rules/examples.html

If you have any questions regarding proper formatting of edits after reviewing the rules and examples, please contact the reviewing attorney.

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.

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.

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.

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.

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.

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.

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.

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***

Brian Lieberman

Commission Counsel

Date submitted to agency: June 3, 2022

***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.

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.

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.

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.***

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

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.

See rule revision for clarity.

*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.

I think item (d) is clear

clearly defines the assembled nursing committee as assigned the task of evaluating nursing services. Please advise.

*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)?

Text deleted. Redundant.

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?

Revised text in (a) & (b) for clarity

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.

Revised text in (a) & (b) for clarity

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?

The primary focus is to address the care needs of neonates less than full term at 40 weeks. It is more common to have health concerns in babies born at a gestational age of less than full term at 40 weeks. The intent was to include varying degrees of health within the gestational age groupings. Another option is to include weights of neonates.

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. Yes

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?

(c) deleted in Rule

*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.

(d)(1) text clarified, added approved by the medical staff

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?

Lines 6-15 of the rule text revised for clarity

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.*

1 10A NCAC 13B .4805 is readopted with changes as published in 36:12 NCR 1029-1032 as follows:

2
3 **10A NCAC 13B .4805 SAFETY**

4 (a) The facility shall require that all imaging equipment is operated under the supervision of a physician and by
5 qualified personnel.

6 (b) The facility shall require that **proper** caution is exercised to protect all persons from exposure to radiation.

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

10 (d) The governing authority shall appoint a radiation safety committee. The committee shall ~~include but is not limited~~
11 ~~to~~ include:

12 (1) a physician experienced in the handling of radio-active isotopes and their therapeutic use; and

13 (2) other representatives of the medical staff.

14 (e) All radio-active isotopes, whether for diagnostic, therapeutic, or research purposes shall be received, handled, and
15 disposed of in accordance with the requirements of the North Carolina Department of ~~Environment and Natural~~
16 ~~Resources, Health and Human Services, Division of Environmental Health, Health Service Regulation, Radiation~~
17 ~~Protection Services Section. Section set forth in 10A NCAC 15, hereby incorporated by reference including~~
18 ~~subsequent amendments. Copies of regulations are available from the North Carolina Department of Environment,~~
19 ~~Health, and Natural Resources, Division of Radiation Protection, 3825 Barrett Drive, Raleigh, NC 27609 at a cost of~~
20 ~~six dollars (\$6.00) each.~~

21
22 *History Note: Authority G.S. 131E-75(b); 131E-79;*

23 *Eff. January 1, ~~1996~~. 1996;*

24 *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: 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

E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law N.C.G.S. Chapter 132 and may be disclosed to third parties.

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

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Raleigh, NC 27699-2701

Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized State official. Unauthorized disclosure of juvenile, health, legally privileged, or otherwise confidential information, including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this email in error, please notify the sender immediately and delete all records of this email.

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

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.

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.

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.

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.

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.

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.

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***

Brian Lieberman

Commission Counsel

Date submitted to agency: June 3, 2022

***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.

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.

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.

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.***

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 ($\frac{1}{25}$ 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.*

1 10A NCAC 13B .4805 is readopted with changes as published in 36:12 NCR 1029-1032 as follows:

2
3 **10A NCAC 13B .4805 SAFETY**

4 (a) The facility shall require that all imaging equipment is operated under the supervision of a physician and by
5 qualified personnel.

6 (b) The facility shall require that **proper** caution is exercised to protect all persons from exposure to radiation.

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

10 (d) The governing authority shall appoint a radiation safety committee. The committee shall ~~include but is not limited~~
11 ~~to~~ include:

12 (1) a physician experienced in the handling of radio-active isotopes and their therapeutic use; and

13 (2) other representatives of the medical staff.

14 (e) All radio-active isotopes, whether for diagnostic, therapeutic, or research purposes shall be received, handled, and
15 disposed of in accordance with the requirements of the North Carolina Department of ~~Environment and Natural~~
16 ~~Resources, Health and Human Services, Division of Environmental Health, Health Service Regulation, Radiation~~
17 ~~Protection Services Section. Section set forth in 10A NCAC 15, hereby incorporated by reference including~~
18 ~~subsequent amendments. Copies of regulations are available from the North Carolina Department of Environment,~~
19 ~~Health, and Natural Resources, Division of Radiation Protection, 3825 Barrett Drive, Raleigh, NC 27609 at a cost of~~
20 ~~six dollars (\$6.00) each.~~

21
22 *History Note: Authority G.S. 131E-75(b); 131E-79;*

23 *Eff. January 1, ~~1996~~. 1996;*

24 *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: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B
Attachments: 10A NCAC 13B .3801.docx; 10A NCAC 13B .3903.docx; 10A NCAC 13B .4805.docx; 10A NCAC 13B .5406.docx; RRC Additional questions 8-9-22.docx

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Tuesday, July 8, 2025 11:04 AM
To: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: FW: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Looks like you weren't copied on this one. I think there are others, stand by.

Brian Liebman
Codifier of Rules
Office of Administrative Hearings
(984)236-1941
brian.liebman@oah.nc.gov

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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](#)

Office: 919-855-3811
Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

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Raleigh, NC 27699-2701

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

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~~, as required in Paragraph (c) of this Rule.

(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 and procedures related to the delivery of nursing care;~~

~~(3)~~(2) planning for and the evaluation of the delivery of nursing care delivery system;

~~(4)~~(3) establishment of a mechanism to validate qualifications, knowledge, and skills of nursing personnel;

~~(5)~~(4) provision of orientation and educational opportunities related to expected nursing ~~performance~~, performance and maintenance of records pertaining thereto;

~~(6)~~(5) implementation of a system for performance evaluation;

~~(7)~~(6) 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)~~(7) 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)~~(8) 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, records that were created when the patient was an adult, whether original, computer media, or microfilm, digital archived 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, that were created when the patient was a minor, whether original, computer media, or digital archived, until the patient's 30th birthday. If a minor patient is readmitted as an adult, the manager of the medical records shall maintain medical records according to Paragraph (a) of this Rule.

(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;

1

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 approved by the medical staff 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.

1 10A NCAC 13B .5406 is readopted with changes as published in 36:12 NCR 1029-1032 as follows:

2
3 **10A NCAC 13B .5406 DISCHARGE CRITERIA FOR INPATIENT REHABILITATION FACILITIES**
4 **OR UNITS**

5 (a) Discharge planning shall be an integral part of the patient's treatment plan and shall begin upon admission to the
6 facility. After ~~established~~ goals ~~of care~~ have been reached, or a determination ~~by the interdisciplinary care team~~ has
7 been made that care in a less intensive setting ~~would be appropriate, to return to the setting from which was admitted,~~
8 or that further progress is unlikely, the patient shall be discharged to ~~an appropriate setting, another inpatient or~~
9 ~~residential health care facility that can address the patient's needs including skilled nursing homes, assisted living~~
10 ~~facilities, nursing homes, or other hospitals.~~ Other reasons for discharge may include an inability or unwillingness of
11 patient or family to cooperate with the planned therapeutic program or medical complications that preclude a further
12 intensive rehabilitative effort. The facility shall involve the patient, family, staff ~~members~~ ~~members~~, and ~~referral~~
13 ~~sources~~ community-based services to include, but not limited to, home health services, hospice or palliative care,
14 respiratory services, rehabilitation services to include occupational therapy, physical therapy, and speech therapy, end
15 stage renal disease, nutritional, medical equipment and supplies, transportation services, meal services, and household
16 services such as housekeeping in discharge planning.

17 (b) The case manager shall facilitate the discharge or transfer process in coordination with the facility social worker.

18 (c) If a patient is being referred to another facility for further care, ~~appropriate~~ documentation of the patient's current
19 status shall be forwarded with the patient. A ~~formal~~ discharge summary shall be forwarded within 48 hours following
20 discharge and shall include the reasons for referral, the diagnosis, functional limitations, services provided, the results
21 of services, referral action ~~recommendations~~ recommendations, and activities and procedures used by the patient to
22 maintain and improve functioning.

23
24 *History Note: Authority G.S. 131E-75(b); 131E-79;*

25 *Eff. March 1, ~~1996~~. 1996;*

26 *Readopted Eff. September 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

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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](#)

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nadine.pfeiffer@dhhs.nc.gov

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

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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](#)

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

809 Ruggles Drive, Edgerton Building
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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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Fax: 919-733-2757
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
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: 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](#)

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

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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

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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

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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](#)

Office: 919-855-3811
Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

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

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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

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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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Burgos, Alexander N

From: Liebman, Brian R
Sent: Tuesday, July 8, 2025 11:10 AM
To: Burgos, Alexander N
Subject: FW: Historical documents for Hospital rules
Attachments: RRC minutes 7-13-95.pdf; RRC Objections 7-13-95.pdf; RRC minutes 1-18-96.pdf; RRC rules-objections 1-96.pdf; RRC rules-objections 7-95.pdf; RRC rules-objections2 7-95.pdf; RRC rules-objections3 7-95.pdf

Brian Liebman
Codifier of Rules
Office of Administrative Hearings
(984)236-1941
brian.liebman@oah.nc.gov

E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law N.C.G.S. Chapter 132 and may be disclosed to third parties.

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.

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Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
[NC Department of Health and Human Services](#)

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AGENDA
RULES REVIEW COMMISSION
January 18, 1996
10:00 a.m.

Methodist Building
1307 Glenwood avenue
Raleigh, North Carolina
(Assembly Room)

- I. Remarks by Commission Chairman
- II. Approval of minutes of last meeting
- III. Follow Up Matters
 - A. 10/3L .1402 - DHR/Medical Care Commission - o - 11/16/95
 - B. 15A/7B .0101, .0201, .0204, .0206, .0207, .0210, .0211, .0212, .0213, .0215, .0401, .0402, and .0501 - DEHNR/Coastal Resources Commission - o - 12/21/95
 - C. 21/17 .0201 - N C Board of Dietetics/Nutrition - o - 12/21/95
 - D. 21/32N .0002 - N C Medical Board - o - 8/10/95
- IV. Review of rules (Log Report #112)
- V. Next meeting: February 15, 1996

12/27/95

RULES REVIEW COMMISSION

January 18, 1996

MINUTES

The Rules Review Commission met at 9:30 a.m. on January 18, 1996, in the Conference Room of the Methodist Building, 1307 Glenwood Avenue, Raleigh, North Carolina. Commissioners in attendance were Chairman Jennie J. Hayman, Vernice B. Howard, Philip O. Redwine, Ed Shelton, Bill Graham, Marvea D. Francis.

Staff members present were: Joe DeLuca, Staff Director; Bobby Bryan, Rules Review Specialist; Glenda Gruber, Administrative Assistant; and Sandy Webster.

The following people attended:

Mary Ann Stone	N C Hearing Aid Dealers and Fitters Board
Mike Mangum	Administration
Bob Rhinehardt	Administration
Jerrie Lattimore	Revenue/Motor Fuels
Curtis Venable	Attorney
Marc Lodge	DHR/DMH/DD/SAS
Bill Hottel	DHR/DMA
Mike Eddinger	DHR/DFS
Ray Martinez	Insurance
Linda Lloyd	Insurance
Kris Horton	DEHNR/DCM
Charles Swindell	Insurance
Emily Lee	Transportation
George Hearn	Attorney
Bernard Cox	Insurance
Dedra Alston	DEHNR
Rodney Finger	Insurance
Portia Rochelle	DHR/DMA
Ray Bedsaul	N C Assn of Hearing Care
Ellie Sprenkel	Insurance
Bill Stevens	Insurance
Jill Cramer	Labor/OSHA
Sharnese Ransome	DHR/DSS
Jeanne Marlowe	DHR/Child Development
W R Hoke	Opticians, Electrical Contractors
Willard Barnes	Board of Opticians
Nancy Guy	DHR/Child Development
E. Ann Christian	Substance Abuse

APPROVAL OF MINUTES

Chairman Hayman asked for any discussion, comments, or corrections concerning the minutes of the December 21, 1995

meeting. There being none, the minutes were approved as read.

FOLLOW-UP MATTERS

10 NCAC 3L .1402 - DHR/Medical Care Commission - The rewritten rule submitted by the agency was approved by the Commission

15A NCAC 7B .0101, .0201, .0204, .0206, .0207, .0210, .0211, .0212, .0213, .0215, .0401, .0402, and .0501 - DEHNR/Coastal Resources Commission - The agency requested that the rules be returned to them to be filed over the Rules Review Commission's objections. The rules were returned to the agency.

21 NCAC 17 .0201 - N C Board of Dietetics/Nutrition - The Board responded that their meeting was scheduled for January 19 and this rule would be revised at that time.

21 NCAC 32N .0002 - N C Medical Board - The rule was returned to the agency for failure to comply with the Administrative Procedures Act.

LOG OF FILINGS

Chairman Hayman presided over the review of the log. The rules this month represent a large portion of the mass of filings immediately preceding the December 1, 1995 effective date of the APA changes. The Commission approved the following motion: All rule approvals by the Rules Review Commission are contingent on:

(1) staff's being satisfied that all technical changes have been made; (2) that all rewrites have actually been submitted as represented by the agency and that they do, in fact, respond to the Rules Review Commission's objection. In the event of any disagreement the rules shall be held over until the next meeting and the agencies may address the Rules Review Commission concerning any disputed rules; and (3) that in the case of repeals the corresponding new or replacement rules or amendments have been approved. All rules were approved with the following exceptions:

1 NCAC 5A .0002 - Department of Administration - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5A .0012 - Department of Administration - The Commission objected to the original rule due to lack of statutory authority and ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .0201 - Department of Administration - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .0207 - Department of Administration - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .0307 - Department of Administration - The Commission objected to the original rule due to lack of statutory authority and ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .0314 - Department of Administration - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

1 NCAC 5B .0401 - Department of Administration - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

1 NCAC 5B .0402 - Department of Administration - The Commission objected to the original rule due to lack of statutory authority and ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .0502 - Department of Administration - The Commission objected to the original rule due to lack of statutory authority and ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .0701 - Department of Administration - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .0802 - Department of Administration - The Commission objected to the repeal due to ambiguity and approved the rewritten amended rule submitted by the agency.

1 NCAC 5B .0902 - Department of Administration - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .0904 - Department of Administration - The Commission objected to the original rule due to lack of statutory authority and ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .0905 - Department of Administration - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .1301 - Department of Administration - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .1302 - Department of Administration - The Commission objected to the original rule due to lack of statutory authority and approved the repeal submitted by the agency.

1 NCAC 5B .1402 - Department of Administration - The Commission objected to the original rule due to lack of statutory authority and ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .1505 - Department of Administration - The Commission objected to the original rule due to lack of statutory authority and ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .1506 - Department of Administration - The Commission objected to the original rule due to lack of statutory authority and ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .1509 - Department of Administration - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .1513 - Department of Administration - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .1516 - Department of Administration - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .1518 - Department of Administration - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .1601 - Department of Administration - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .1602 - Department of Administration - The Commission objected to the original rule due to lack of statutory authority and ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .1603 - Department of Administration - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .1701 - Department of Administration - The Commission objected to the original rule due to lack of necessity and approved the repeal submitted by the agency.

1 NCAC 5B .1702 - Department of Administration - The Commission objected to the original rule due to lack of necessity and approved the repeal submitted by the agency.

1 NCAC 5B .1804 - Department of Administration - The Commission objected to the original rule due to lack of statutory authority and ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5B .1903 - Department of Administration - The Commission objected to the original rule due to lack of statutory authority and ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5C .0201 - Department of Administration - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5C .0204 - Department of Administration - The Commission objected to the original rule due to lack of statutory authority and ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5C .0303 - Department of Administration - The Commission objected to the original rule due to lack of statutory authority and necessity and approved the repeal submitted by the agency.

1 NCAC 5C .0304 - Department of Administration - The Commission objected to the original rule due to lack of necessity and approved the repeal submitted by the agency.

1 NCAC 5C .0508 - Department of Administration - The Commission objected to the original rule due to lack of statutory authority and lack of necessity and approved the repeal submitted by the agency.

1 NCAC 5D .0203 - Department of Administration - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

1 NCAC 5D .0205 - Department of Administration - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

1 NCAC 5D .0206 - Department of Administration - This rule was withdrawn by the agency.

1 NCAC 5D .0208 - Department of Administration - This rule was withdrawn by the agency. w/p

1 NCAC 5D .0210 - Department of Administration - The Commission objected to the original rule due to ambiguity and lack of necessity and approved the repeal submitted by the agency.

10 NCAC 3C .5401 - DHR/Medical Care Commission - The Commission objected to this rule due to lack of statutory authority. 0

10 NCAC 3C .5402 - DHR/Medical Care Commission - The Commission objected to this rule due to lack of statutory authority. 0

10 NCAC 3C .5405 - DHR/Medical Care Commission - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 3C .5407 - DHR/Medical Care Commission - The Commission objected to this rule due to lack of statutory authority. 0

10 NCAC 3C .5408 - DHR/Medical Care Commission - The Commission objected to this rule due to lack of statutory authority and ambiguity. 0

10 NCAC 3C .5409 - DHR/Medical Care Commission - The Commission objected to this rule due to lack of statutory authority. 0

10 NCAC 3C .5412 - DHR/Medical Care Commission - The Commission objected to this rule due to lack of statutory authority. 0

10 NCAC 3C .5413 - DHR/Medical Care Commission - The Commission objected to this rule due to lack of statutory authority. 0

10 NCAC 3T .0202 - DHR/Medical Care Commission - The Commission objected to this rule due to lack of statutory authority. 0

10 NCAC 3T .0601 - DHR/Medical Care Commission - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 3T .0605 - DHR/Medical Care Commission - The Commission objected to this rule due to lack of statutory authority. 0

10 NCAC 3T .0801 - DHR/Medical Care Commission - The Commission objected to the original rule due to ambiguity and to the rewritten rule for the same reason.

D

10 NCAC 3T .0901 - DHR/Medical Care Commission - The Commission objected to this rule due to ambiguity.

6

10 NCAC 14C .1010 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

R/W

10 NCAC 14C .1013 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

R/W

10 NCAC 14C .1015 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and ambiguity and approved the rewritten rule submitted by the agency.

R/W

10 NCAC 14C .1133 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14C .1134 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14C .1136 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

10 NCAC 14C .1137 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14C .1148 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency contingent upon receiving a technical change. It was later determined that the technical change was not necessary.

10 NCAC 14C .1150 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

10 NCAC 14C .1152 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

10 NCAC 14C .1153 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

10 NCAC 14C .1154 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency. p/w

10 NCAC 14C .1155 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

10 NCAC 14C .1158 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

10 NCAC 14C .1159 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

10 NCAC 14C .1160 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

10 NCAC 14D .0006 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

10 NCAC 14V .0103 - DHR/CMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .0208 - DHR/CMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .0301 - DHR/CMH/DD/SAS - The Commission objected to the original rule due to ambiguity and lack of necessity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .0303 - DHR/CMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .0402 - DHR/CMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .0403 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

10 NCAC 14V .0404 - DHR/CMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .0502 - DHR/CMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and

ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .0504 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency. *R/w*

10 NCAC 14V .0505 - DHR/CMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .0603 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

10 NCAC 14V .0604 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .0605 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

10 NCAC 14V .0707 - DHR/CMH/DD/SAS - The Commission objected to the rule due to lack of statutory authority. *0*

10 NCAC 14V .0709 - DHR/CMH/DD/SAS - The Commission objected to this rule due to lack of necessity.

10 NCAC 14V .0802 - DHR/DMH/DD/SAS - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency. *R/w*

10 NCAC 14V .0803 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .0804 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .0805 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .1403 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .2304 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .2306 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency. *R/w*

10 NCAC 14V .2403 - DHR/DMH/DD/SAS - The agency submitted a rewritten rule to clarify in the appropriate place a problem raised in the next rule. The rewritten rule was approved by the Commission.

10 NCAC 14V .2404 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .3402 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .3603 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .3702 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .3803 - DHR/DMH/DD/SAS - The Commission objected to both the original rule and a rewritten rule due to lack of statutory authority. *O*

10 NCAC 14V .3902 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to lack of statutory authority and ambiguity and approved the rewritten rule submitted by the agency. *R/w*

10 NCAC 14V .3903 - DHR/DMH/DD/SAS - The Commission objected to this rule due to lack of statutory authority. *O*

10 NCAC 14V .4102 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency. *R/w*

10 NCAC 14V .5302 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .5503 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .5702 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .5801 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

R/W

10 NCAC 14V .5803 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 14V .6002 - DHR/DMH/DD/SAS - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 19C Rules³ - DHR/Division of Services for the Blind/Commission for the Blind - These rules were withdrawn by the agency.

W/D

10 NCAC 20B Rules³ - DHR/Division of Vocational Rehabilitation Services - These rules were withdrawn by the agency.

W/D

10 NCAC 39D .0304 - DHR/Social Services Commission - The Commission extended the period of review on this rule.

EPR

10 NCAC 46D .0106 - DHR/Social Services Commission - The Commission objected to this rule due to lack of statutory authority.

D

10 NCAC 46D .0107 - DHR/Social Services Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 46D .0202 - DHR/Social Services Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 46E .0108 - DHR/Social Services Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 46H .0104 - DHR/Social Services Commission - The Commission objected to the original rule and to the rewritten rule due to ambiguity and lack of necessity.

10 NCAC 46H .0105 - DHR/Social Services Commission - The Commission objected to this rule due to ambiguity and lack of necessity.

10 NCAC 50D Rules - DHR/DMA - The Commission extended the period of review on these rules.

EPR

11 NCAC 6A .0201 - Department of Insurance - This rule was withdrawn by the agency.

W/D

11 NCAC 6A .0217 - Department of Insurance - This rule was withdrawn by the agency. WD

11 NCAC 6A .0225 - Department of Insurance - This rule was withdrawn by the agency.

11 NCAC 6A .0226 - Department of Insurance - This rule was withdrawn by the agency.

11 NCAC 6A .0235 - Department of Insurance - This rule was withdrawn by the agency.

11 NCAC 6A .0236 - Department of Insurance - This rule was withdrawn by the agency.

11 NCAC 6A .0304 - Department of Insurance - This rule was withdrawn by the agency.

11 NCAC 6A .0501 - Department of Insurance - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency. R/W

11 NCAC 6A .0701 - Department of Insurance - This rule was withdrawn by the agency. WD

11 NCAC 6A .0702 - Department of Insurance - This rule was withdrawn by the agency.

11 NCAC 6A .0703 - Department of Insurance - This rule was withdrawn by the agency.

11 NCAC 6A .0704 - Department of Insurance - This rule was withdrawn by the agency.

11 NCAC 6A .0705 - Department of Insurance - This rule was withdrawn by the agency.

11 NCAC 11B .0141 - Department of Insurance - This rule was withdrawn by the agency.

11 NCAC 11B .0602 - Department of Insurance - This rule was withdrawn by the agency.

11 NCAC 11B .0617 - Department of Insurance - This rule was withdrawn by the agency.

11 NCAC 11C .0112 - Department of Insurance - This rule was withdrawn by the agency.

11 NCAC 12 .0824 - Department of Insurance - The commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency. R/W

11 NCAC 12 .0839 - Department of Insurance - The commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency. *rw*

11 NCAC 12 .1707 - Department of Insurance - The commission objected to the original rule due to lack of statutory authority and necessity and approved the rewritten rule submitted by the agency.

11 NCAC 13 .0317 - Department of Insurance - This rule was withdrawn by the agency. *wd*

11 NCAC 14 .0705 - Department of Insurance - This rule was withdrawn by the agency.

12 NCAC 7D .0204 - Justice/N C Private Protective Services Board - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency. *rw*

15A NCAC 7H .0208 - DEHNR/Coastal Resources Commission - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

15A NCAC 7H .2205 - DEHNR/Coastal Resources Commission - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

15A NCAC 7K .0103 - DEHNR/Coastal Resources Commission - The Commission objected to this rule due to ambiguity. *0*

17 NCAC 9K .0201 - Department of Revenue - This rule was withdrawn by the agency. *wd*

19A NCAC 3D .0553 - Transportation/Division of Motor Vehicles - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency. *rw*

21 NCAC 8F .0103 - N C State Board of Certified Public Accountant Examiners - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

21 NCAC 8G .0404 - N C State Board of Certified Public Accountant Examiners - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

21 NCAC 18B .0902 - N C State Board of Examiners of Electrical Contractors - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

21 NCAC 22F .0020 - N C State Hearing Aid Dealers and Fitters Board - The Commission extended the period of review on this rule.

EPR

21 NCAC 22I .0008 - N C State Hearing Aid Dealers and Fitters Board - The Commission extended the period of review on this rule.

21 NCAC 22I .0009 - N C State Hearing Aid Dealers and Fitters Board - The Commission extended the period of review on this rule.

21 NCAC 22L Rules - N C State Hearing Aid Dealers and Fitters Board - The Commission extended the period of review on these rules.

21 NCAC 26 .0307 - N C Board of Landscape Architects - The Commission objected to this rule due to lack of statutory authority and ambiguity.

O

21 NCAC 40 .0314 - N C State Board of Opticians - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

RW

21 NCAC 48A .0001 - N C Board of Physical Therapy Examiners - The Commission objected to the original rule due to lack of necessity and approved the repeal submitted by the agency.

21 NCAC 48A .0010 - N C Board of Physical Therapy Examiners - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

21 NCAC 56 .1301 - N C State Board of Registration for Professional Engineers and Land Surveyors - The Commission objected to this rule due to lack of statutory authority.

O

21 NCAC 65 Rules - N C State Therapeutic Recreation Certification Board - The Commission voted to return these rules to the agency for failure to comply with OAH filing requirements.

FTC

21 NCAC 68 .0504 - N C Substance Abuse Professional Certification Board - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

RW

21 NCAC 68 .0507 - N C Substance Abuse Professional Certification Board - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

COMMISSION PROCEDURES AND OTHER MATTERS

Ms. Gruber had no budget report for this month. Mr. DeLuca asked permission to attend the NASS winter meeting in Washington, D.C. and it was granted.

The next meeting of the RRC is tentatively scheduled for February 15, 1996 at 10:00 a.m.

The meeting adjourned at 12:25 p.m.

Respectfully submitted,

Sandy Webster

1/22/96

RULES REVIEW COMMISSION

July 13, 1995

MINUTES

The Rules Review Commission met at 10:00 a.m. on July 13, 1995, in the Conference Room of the Methodist Building, 1307 Glenwood Avenue, Raleigh, North Carolina. Commissioners in attendance were Chairman Jennie J. Hayman, Laurence Colbert, Philip O. Redwine, Charles H. Henry, Brent E. Wood, and Marvea D. Francis.

Staff members present were: Joe DeLuca, Staff Director; Bobby Bryan, Rules Review Specialist; Glenda Gruber, Administrative Assistant; and Sandy Webster.

The following people attended:

Mary Cissy Majebi	N C Acupuncturists
Roberta Weathers	DEHNR
Malinda Maitlan	DHR/DCD
Anna Carter	DHR/DCD
Jeanne Marlowe	DHR/DCD
Howard Kramer	Board of Nursing
Virginia Gibbons	Wildlife Resources
Robin Smith	Attorney General
Juliann Tenney	Acupuncture Licensing Board
Francis M. Neils	DEHNR
Steve Fussell	Real Estate Commission
Thomas Allen	DEHNR/DEM/AQS
Portia Rochelle	DHR
Dedra Alston	DEHNR
Delores Stanley	Office of State Personnel
Eula E. Reid	Office of State Personnel
Jim Wellons	Attorney General
Scott Perry	Attorney General

APPROVAL OF MINUTES

Chairman Hayman asked for any discussion, comments, or corrections concerning the minutes of the June 14, 1995 meeting. There being none, the minutes were approved as read.

FOLLOW-UP MATTERS

15A NCAC 19A .0202 - DEHNR/Commission for Health Services - The rewritten rule submitted by the agency was approved by the Commission.

23 NCAC 2C .0604 - N C State Board of Community Colleges - The rewritten rule submitted by the agency was approved by the Commission.

LOG OF FILINGS

Chairman Hayman presided over the review of the log and all rules were approved with the following exceptions:

10 NCAC 3C .3001 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .3108 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3C .3205 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3C .3302 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3C .3502 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .3602 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .3603 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .3607 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3C .3608 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3C .3704 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3C .3902 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .3904 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .4003 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3C .4102 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .4104 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .4203 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .4303 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .4307 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .4401 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .4502 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .4512 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3C .4702 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .4703 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .4704 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority and ambiguity.

10 NCAC 3C .4705 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .4801 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .4905 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .5002 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .5201 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3C .5202 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority and ambiguity.

10 NCAC 3C .5205 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3C .5302 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3C .5309 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .5315 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .5318 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .5319 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .5322 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .5323 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .5324 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .5325 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .5326 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .5403 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .5405 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .5407 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .5501 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .5502 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .5507 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of necessity.

10 NCAC 3C .5508 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .5512 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .5513 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3C .6102 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority and ambiguity.

10 NCAC 3C .6208 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3H .2001 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .2201 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .2202 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .2203 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .2206 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .2209 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3H .2212 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .2301 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .2302 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .2308 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .2401 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .2501 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority and ambiguity.

10 NCAC 3H .2505 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .2506 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority and ambiguity.

10 NCAC 3H .2601 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .2604 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3H .2605 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .2606 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .2607 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .2701 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority and ambiguity.

10 NCAC 3H .2801 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .2802 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .3002 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .3003 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .3004 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority and ambiguity.

10 NCAC 3H .3005 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .3011 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3H .3012 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3H .3013 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority and ambiguity.

10 NCAC 3H .3015 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .3016 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .3021 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .3027 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .3031 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority.

10 NCAC 3H .3103 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3H .3201 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3H .3401 - DHR/N C Medical Care Commission - The Commission objected to this rule due to lack of statutory authority and ambiguity.

10 NCAC 3H .3404 - DHR/N C Medical Care Commission - The Commission objected to this rule due to ambiguity.

10 NCAC 3U .0705 - DHR/Child Day Care Commission - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 3U .1403 - DHR/Child Day Care Commission - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 3U .1717 - DHR/Child Day Care Commission - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 26H .0302 - DHR/Division of Medical Assistance - The Commission objected to the original rule due to lack of statutory authority and ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 26H .0304 - DHR/Division of Medical Assistance - The Commission objected to the original rule due to lack of statutory authority and ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 26H .0305 - DHR/Division of Medical Assistance - The Commission objected to the original rule due to lack of statutory authority and ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 26H .0308 - DHR/Division of Medical Assistance - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

12 NCAC 9B .0202 - Justice/Criminal Justice Education and Training Standards Commission - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

12 NCAC 9B .0206 - Justice/Criminal Justice Education and Training Standards Commission - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

12 NCAC 9D .0104 - Justice/Criminal Justice Education and Training Standards Commission - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

12 NCAC 9D .0105 - Justice/Criminal Justice Education and Training Standards Commission - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

15A NCAC 2B .0202 - DEHNR/Environmental Management Commission - Commissioner Colbert made a motion to extend the period of review on this rule. It failed for lack of a second. The motion was then made to object to the original rule due to lack of statutory authority and approve the rewritten rule submitted by the agency contingent upon receiving it today. The rule was subsequently received.

15A NCAC 2B .0211 - DEHNR/Environmental Management Commission - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

21 NCAC 8M .0102 - N C State Board of CPA Examiners - The Commission objected to this rule due to ambiguity.

21 NCAC 8M .0104 - N C State Board of CPA Examiners - The Commission objected to the original rule due to lack of statutory authority and ambiguity and approved the rewritten rule submitted by the agency.

21 NCAC 8N .0307 - N C State Board of CPA Examiners - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

21 NCAC 37 .0502 - N C State Board of Examiners of Nursing Home Administrators - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

21 NCAC 37 .0914 - N C State Board of Examiners of Nursing Home Administrators - This rule was withdrawn by the agency.

24 NCAC 5 .0414 - State Health Plan Alliance Purchasing Board - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency contingent upon them making a technical change to remove the word "unless the agreement" by July 21.

24 NCAC 5 .0419 - State Health Plan Alliance Purchasing Board - This rule was withdrawn by the agency.

25 NCAC 1C .0405 - State Personnel Commission - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

25 NCAC 1C .0407 - State Personnel Commission - The Commission objected to the original rule due to lack of statutory authority and approved the rewritten rule submitted by the agency.

25 NCAC 1D .2001 - State Personnel Commission - The Commission objected to the original rule due to lack of necessity and approved the repeal submitted by the agency.

25 NCAC 1K .0312 - State Personnel Commission - The Commission objected to the original rule due to ambiguity and approved the rewritten rule submitted by the agency.

10 NCAC 3C and 3H repeals - DHR/Medical Care Commission - The Commission objected to the repeals based on a lack of statutory authority, ambiguity and lack of necessity.

COMMISSION PROCEDURES AND OTHER MATTERS

Ms. Gruber reported that we had purchased a new fax machine and computer hardware for the fiscal year ending June 30 and that we had begun a new accounting system as of July 1. Mr. DeLuca reported that there had been a change in the expansion budget and that the APA portion had been removed from the bill.

The next meeting of the RRC is tentatively scheduled for August 10, 1995 at 10:00 a.m.

The meeting adjourned at 12:35 p.m.

Respectfully submitted,

Sandy Webster

7/13/95

**HOSPITAL RULES WITH OBJECTIONS BASED ON
LACK OF STATUTORY AUTHORITY**

10 N.C.A.C. 3C .3001

10 N.C.A.C. 3C .3902

10 N.C.A.C. 3C .4102

10 N.C.A.C. 3C .4104

10 N.C.A.C. 3C .4203

10 N.C.A.C. 3C .4303

10 N.C.A.C. 3C .4307

10 N.C.A.C. 3C .4401

10 N.C.A.C. 3C .4502

10 N.C.A.C. 3C .4702

10 N.C.A.C. 3C .4705

10 N.C.A.C. 3C .4801

10 N.C.A.C. 3C .5002

10 N.C.A.C. 3C .5202

RULES REVIEW COMMISSION OBJECTIONS

RRC objects to these rules on the ground that the Medical Care Commission ("MCC") lacks the requisite statutory authority to adopt rules governing staff qualifications. This objection manifests itself in three different situations. RRC contends that:

- (1) the MCC lacks the authority to specify that only certain licensed persons can perform certain functions, even if the limitations merely reiterate requirements of the relevant occupational licensing laws.
 - Therefore, RRC objects to the hospital rule that specifies that a *registered* nurse shall supervise nursing care in special care units. See 10 N.C.A.C. 3C .4203.
- (2) the MCC lacks the authority to set standards of education and experience for certain licensed staff members that exceed minimum occupational licensing requirements.
 - Therefore, RRC objects to the hospital rule that specifies that the director of Level I and II emergency services shall be a physician *with experience in emergency care*. See 10 N.C.A.C. 3C .4104.
- (3) the MCC lacks the authority to set standards of education, experience, registration, or certification for unlicensed staff members.
 - Therefore, RRC objects to the hospital rule that specifies that a hospital must retain the services of a *registered record administrator or an accredited records technician* on either a full-time or part-time basis. See 10 N.C.A.C. 3R .3902.

**THE ADMINISTRATIVE PROCEDURE ACT:
STANDARD OF REVIEW BY RULES REVIEW COMMISSION.**

§ 150B-21.9. Standards and timetable for review by Commission.

(a) Standards. - The Commission must determine whether a rule meets all of the following criteria:

(1) **It is within the authority delegated to the agency by the General Assembly.**

(2) It is clear and unambiguous.

(3) It is reasonably necessary to fulfill a duty delegated to the agency by the General Assembly.

North Carolina Medical Care Commission

§ 143B-165. North Carolina Medical Care Commission - creation, powers and duties.

There is hereby created the North Carolina Medical Care Commission of the Department of Human Resources **with the power and duty to promulgate rules and regulations to be followed in the construction and maintenance of public and private hospitals**, medical centers, and related facilities with the power and duty to adopt, amend and rescind rules and regulations under and not inconsistent with the laws of the State necessary to carry out the provisions and purposes of this Article.

(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 [now Article 5 of chapter 131E] of the General Statutes of North Carolina [the Hospital Licensure Act].

(10) The Commission shall have **the power and duty to promulgate rules and regulations for the operation of nursing homes**, as defined by G.S. 130-9(e) [now G.S. 131E-101(6)].

THE HOSPITAL LICENSURE ACT

§ 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.

§ 131E-76. Definitions.

(3) "Hospital" means any facility which has an organized medical staff and which is designed, used, and operated to provide health care, diagnostic and therapeutic services, and continuous nursing care primarily to inpatients where such care and services are rendered under the supervision and direction of physicians licensed under Chapter 90 of the General Statutes, Article 1, to two or more persons over a period in excess of 24 hours. The term includes facilities for the diagnosis and treatment of disorders within the scope of specific health specialties. The term does not include private mental facilities licensed under Article 2 of Chapter 122C of the General Statutes, nursing homes licensed under G.S. 131E-102, and domiciliary homes licensed under G.S. 131D-2.

§ 131E-79. Rules and enforcement.

(a) The Commission shall promulgate rules necessary to implement this Article.

NURSING HOME LICENSURE ACT

§ 131E-100. Title; purpose.

(a) This Part shall be known as the "Nursing Home Licensure Act."

(b) The purpose of the Nursing Home Licensure Act is to establish authority and duty for the Department to inspect and license private nursing homes.

§ 131E-101. Definitions.

(6) "Nursing home" means a facility, however named, which is advertised, announced, or maintained for the express or implied purpose of providing nursing or convalescent care for three or more persons unrelated to the licensee. A "nursing home" is a home for chronic or convalescent patients, who, on admission, are not as a rule, acutely ill and who do not usually require special facilities such as an operating room, X-ray facilities, laboratory facilities, and obstetrical facilities. A "nursing home" provides care for persons who have remedial ailments or other ailments, for which medical and nursing care are indicated; who, however, are not sick enough to require general hospital care. Nursing care is their primary need, but they will require continuing medical supervision.

§ 131E-104. Rules and enforcement.

(a) The Commission is authorized to adopt, amend, and repeal all rules necessary for the implementation of this Part.

NURSING HOME PATIENTS' BILL OF RIGHTS.

§ 131E-115. Legislative intent.

It is the intent of the General Assembly to promote the interests and well-being of the patients in nursing homes and homes for the aged and disabled licensed pursuant to G.S. 131E-102, and patients in a nursing home operated by a hospital which is licensed under Article 5 of G.S. Chapter 131E. It is the intent of the General Assembly that every patient's civil and religious liberties, including the right to independent personal decisions and knowledge of available choices, shall not be infringed and that the facility shall encourage and assist the patient in the fullest possible exercise of these rights.

§ 131E-116. Definitions.

(2) "Facility" means a nursing home and a home for the aged or disabled licensed pursuant to G.S. 131E-102, and also means a nursing home operated by a hospital which is licensed under Article 5 of G.S. Chapter 131E [the Hospital Licensure Act].

§ 131E-117. Declaration of patient's rights.

All facilities shall treat their patients in accordance with the provisions of this Part. **Every patient shall have the following rights:**

(2) **To receive care, treatment and services which are adequate, appropriate, and in compliance with relevant federal and State statutes and rules;**

§ 131E-131. Rule-making authority; enforcement.

The Commission shall adopt rules necessary for the implementation of this Part. . . .

THE ADMINISTRATIVE PROCEDURE ACT:
STATUTORY RESTRICTIONS ON WHAT CAN BE ADOPTED AS A RULE

§ 150B-19. Restrictions on what can be adopted as a rule.

An agency may not adopt a rule that does one or more of the following:

(1) Implements or interprets a law unless that law or another law specifically authorizes the agency to do so.

(2) **Enlarges the scope of a profession, occupation, or field of endeavor for which an occupational license is required.**

(3) Imposes criminal liability or a civil penalty for an act or omission, including the violation of a rule, unless a law specifically authorizes the agency to do so or a law declares that violation of the rule is a criminal offense or is grounds for a civil penalty.

(4) Repeats the content of a law, a rule, or a federal regulation.

(5) Establishes a reasonable fee or other reasonable charge for providing a service in fulfillment of a duty unless a law specifically authorizes the agency to do so or the fee or other charge is for one of the following:

- a. A service to a State, federal, or local governmental unit.
- b. A copy of part or all of a State publication or other document, the cost of mailing a document, or both.
- c. A transcript of a public hearing.
- d. A conference, workshop, or course.
- e. Data processing services.

(6) Allows the agency to waive or modify a requirement set in a rule unless a rule establishes specific guidelines the agency must follow in determining whether to waive or modify the requirement.

CASE LAW

In its next assignment of error, CUCA contends that the Commission erred when it determined that it did not have the authority to determine the constitutionality of N.C.G.S. § 62-158. (footnote omitted). CUCA argues that the Commission has this authority pursuant to N.C.G.S. § 62-60, which provides:

For the purpose of conducting hearings, making decisions and issuing orders, and in formal investigations where a record is made of testimony under oath, the Commission shall be deemed to exercise functions judicial in nature and shall have all the powers and jurisdiction of a court of general jurisdiction as to all subjects over which the Commission has or may hereafter be given jurisdiction by law.

N.C.G.S. § 62-60 (1989). CUCA takes the position that this statute gives the Commission the authority to determine the constitutionality of the legislation at issue. We disagree.

We addressed this question in a similar context in *Great American Insurance Co. v. Gold*, 254 N.C. 168, 118 S.E.2d 792 (1961), overruled on other grounds by *Smith v. State*, 289 N.C. 303, 222 S.E.2d 412 (1976), where an insurance company sought a declaratory judgment in order to have the Fireman's Pension Fund created by the legislature declared unconstitutional. In that case, the Court asked the following pertinent question and answered it:

Quaere: Does a quasi-judicial board of the executive branch of government have jurisdiction to pass upon the constitutionality of a statute? **Administrative boards have only such authority as is properly conferred upon them by the Legislature. The question of constitutionality of a statute is for the judicial branch.**

Id. at 173, 118 S.E.2d at 796; see also *In re Appeals of Timber Cos.*, 98 N.C. App. 412, 415, 391 S.E.2d 503, 505 (1990) ("Property Tax Commission is without authority to rule on the constitutionality of [statute]"); *Johnston v. Gaston County*, 71 N.C. App. 707, 713, 323 S.E.2d 381, 384 (1984) ("constitutional claims will not be acted upon by administrative tribunals").

Utilities Commission vs. Carolina Utility Customers Association, Inc., 336 N.C. 657, 446 S.E.2d 332 (1994).

**CODA:
STANDARD OF REVIEW**

The Commission must determine whether a rule:

- (1) is within the authority
- (2) delegated to the agency
- (3) by the General Assembly.

N. C. Gen. Stat. § 150B-21.9

1 10 NCAC 3C .5301 is proposed to be adopted as follows as published in the NCR, Vol. 10, Issue 14 Page 1232.

2
3 SECTION .5300 NURSING AND ADULT CARE HOME BEDS

4
5 .5301 THE LICENSURE OF NURSING AND ADULT CARE HOME BEDS IN A HOSPITAL

6
7 When a facility has nursing facility beds or adult care home beds, the beds shall be provided under the hospital's license
8 as provided in Rule .3101 of this Subchapter. The nursing facility beds and the adult care home beds shall be subject to
9 the rules in 10 NCAC Subchapter 3H, with the exception that the following rules shall not apply: 10 NCAC 3H .2001 (5);
10 .2101 - .2108; .2201; .2208; .2209; .2211; .2212; .2302; .2401; .2402; .2503; .2504; .2602; .2607; .2701; and .2901. With
11 these exceptions, the rules in 10 NCAC Subchapter 3H are incorporated by reference with all subsequent amendments.
12 Referenced rules are available from the N.C. Division of Facility Services, 701 Barbour Drive, Raleigh, North Carolina
13 27626-0530 at a cost of \$6.00 per copy.

14
15 History Note: Statutory Authority G.S. 131E-79;

16 Eff. March 1, 1996.

RRC STAFF RECOMMENDATION

AGENCY: DHR/N C Medical Care Commission

RULE CITATION: 10 NCAC 3C .5401

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited to require occupational licenses, or any other qualifications, in order to perform certain functions. That is going to be the effect of the provisions in (5) - (16).

Joseph J. DeLuca, Jr.
Staff Director

1 10 NCAC 3C .5401 is proposed to be adopted as follows as published in the NCR, Vol. 10, Issue 14 Pages 1232-1233:

2
3 SECTION .5400

4 COMPREHENSIVE INPATIENT REHABILITATION

5
6 .5401 DEFINITIONS

7 The following definitions shall apply to inpatient rehabilitation facilities or units only:

8 (1) "Case management" means the coordination of services, for a given patient, between disciplines so that the patient
9 may reach optimal rehabilitation through the judicious use of resources.

10 (2) "Comprehensive, inpatient rehabilitation program" means a program for the treatment of persons with functional
11 limitations or chronic disabling conditions who have the potential to achieve a significant improvement in
12 activities of daily living. A comprehensive, rehabilitation program utilize a coordinated and integrated,
13 interdisciplinary approach, directed by a physician, to assess patient needs and to provide treatment and evaluation
14 of physical, psycho-social and cognitive deficits.

15 (3) "Inpatient rehabilitation facility or unit" means a free-standing facility or a unit (unit pertains to contiguous dedicated
16 beds and spaces) within an existing licensed health service facility approved in accordance with N.C. Gen. Stat.
17 131E, Article 9 to establish inpatient, rehabilitation beds and to provide a comprehensive, inpatient rehabilitation
18 program.

19 (4) "Medical consultations" means consultations which the rehabilitation physician or the attending physician determine
20 are necessary to meet the acute medical needs of the patient and do not include routine medical needs.

21 (5) "Occupational therapist" means any individual licensed in the State of North Carolina as an occupational therapist in
22 accordance with the provisions of N.C. Gen. Stat. 90, Article 18D.

23 (6) "Occupational therapist assistant" means any individual licensed in the State of North Carolina as an occupational
24 therapist assistant in accordance with the provisions of N.C. Gen. Stat. 90, Article 18D.

25 (7) "Psychologist" means a person licensed as a practicing psychologist in accordance with N.C. Gen. Stat. 90, Article
26 18A.

27 (8) "Physiatrist" means a licensed physician who has completed a physical medicine and rehabilitation residency
28 training program approved by the Accrediting Council of Graduate Medical Education or the American
29 Osteopathic Association.

30 (9) "Physical therapist" means any person licensed in the State of North Carolina as a physical therapist in accordance
31 with the provisions of N.C. Gen. Stat. 90, Article 18B.

32 (10) "Physical therapist assistant" means any person licensed in the State of North Carolina as a physical therapist
33 assistant in accordance with the provisions of N.C. Gen. Stat. 90-270.24, Article 18B.

34 (11) "Recreational therapist" means a person certified by the State of North Carolina Therapeutic Recreational
35 Certification Board.

175

1 (12) "Rehabilitation nurse" means a registered nurse licensed in North Carolina, with training, either academic or on-
2 the-job, in physical rehabilitation nursing and at least one year experience in physical rehabilitation nursing.

3 (13) "Rehabilitation aide" means an unlicensed assistant who works under the supervision of a registered nurse, licensed
4 physical therapist or occupational therapist in accordance with the appropriate occupational licensure laws
5 governing his or her supervisor and consistent with staffing requirements as set forth in rule .5508 of this Section.
6 The rehabilitation aide shall be listed on the North Carolina Nurse Aide Registry and have received additional staff
7 training as listed in rule .5509 of this Section.

8 (14) "Rehabilitation physician" means a physiatrist or a physician who is qualified, based on education, training and
9 experience regardless of specialty, of providing medical care to rehabilitation patients.

10 (15) "Social worker" means a person certified by the North Carolina Certification Board for Social Work in accordance
11 with N.C. Gen. Stat. 90B-3.

12 (16) "Speech and language pathologist" means any person licensed in the State of North Carolina as a speech and
13 language pathologist in accordance with the provisions of N.C. Gen. Stat. 90, Article 22.

14
15 History Note: Statutory Authority G.S. 131E-79:

16 Eff. March 1, 1996.
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RRC STAFF RECOMMENDATION

AGENCY: DHR/N C Medical Care Commission

RULE CITATION: 10 NCAC 3C .5402

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited for the provision in
(b) requiring a rehabilitation physician.

Joseph J. DeLuca, Jr.
Staff Director

1 10 NCAC 3C .5402 is proposed to be adopted as follows as published in the NCR, Vol. 10, Issue 14 Page 1233:

2
3 **.5402 PHYSICIAN REQUIREMENTS FOR INPATIENT REHABILITATION FACILITIES OR UNITS**

4 (a) In a rehabilitation facility or unit, a physician shall participate in the provision and management of rehabilitation
5 services and in the provision of medical services.

6 (b) In a rehabilitation facility or unit, a rehabilitation physician shall be responsible for a patient's interdisciplinary
7 treatment plan. Each patient's interdisciplinary treatment plan shall be developed and implemented under the supervision
8 of a rehabilitation physician.

9 (c) The rehabilitation physician shall participate in the preliminary assessment within 48 hours of admission, prepare a
10 plan of care and direct the necessary frequency of contact based on the medical and rehabilitation needs of the patient.
11 The frequency shall be appropriate to justify the need for comprehensive inpatient rehabilitation care.

12 (d) An inpatient rehabilitation facility or unit's contract or agreements with a rehabilitation physician shall require that
13 the rehabilitation physician shall participate in individual case conferences or care planning sessions and shall review and
14 sign discharge summaries and records. When patients are to be discharged to another health care facility, the discharging
15 facility shall ensure that the patient has been provided with a discharge plan which incorporates post discharge continuity
16 of care and services. When patients are to be discharged to a residential setting, the facility shall ensure that the patient
17 has been provided with a discharge plan that incorporates the utilization of community resources when available and
18 when included in the patient's plan of care.

19 (e) The intensity of physician medical services and the frequency of regular contacts for medical care for the patient shall
20 be determined by the patient's pathophysiologic needs.

21 (f) Where the attending physician of a patient in an inpatient rehabilitation facility or unit orders medical consultations
22 for the patient, such consultations should be provided by qualified physicians within 48 hours of the physician's order. In
23 order to achieve this result, the contracts or agreements between inpatient rehabilitation facilities or units and medical
24 consultants shall require that such consultants render the requested medical consultation within 48 hours.

25 (g) An inpatient rehabilitation facility or unit shall have a written procedure for setting the qualifications of the
26 physicians, rendering physical rehabilitation services in the facility or unit.

27
28 History Note: Statutory Authority G.S. 131E-79;

29 Eff. March 1, 1996.

178

1 10 NCAC 3C .5403 is proposed to be adopted as follows as published in the NCR, Vol. 10, Issue 14 Page 1233:

3 **.5403 ADMISSION CRITERIA FOR INPATIENT REHABILITATION FACILITIES OR UNITS**

4 (a) The facility shall have written criteria for admission to the inpatient rehabilitation facility or unit. A description of
5 programs or services for screening the suitability of a given patient for placement shall be available to staff and referral
6 sources.

7 (b) For patients found unsuitable for admission to the inpatient rehabilitation facility or unit, there shall be
8 documentation of the reasons.

9 (c) Within 48 hours of admission, a preliminary assessment shall be completed by members of the interdisciplinary team
10 to insure the appropriateness of placement and to identify the immediate needs of the patients.

11 (d) Patients admitted to an inpatient rehabilitation facility or unit must be able to tolerate a minimum of three hours of
12 rehabilitation therapy, five days a week, including at least two of the following rehabilitation services: physical therapy,
13 occupational therapy or speech therapy.

14 (e) Patients admitted to an inpatient rehabilitation facility or unit must be medically stable, have a prognosis indicating a
15 progressively improved medical condition and have the potential for increased independence.

16
17 History Note: Statutory Authority G.S. 131E-79;

18 Eff. March 1, 1996
19)

179

1 10 NCAC 3C .5404 is proposed to be adopted as follows as published in the NCR, Vol. 10, Issue 14, Page 1233:

3 .5404 COMPREHENSIVE INPATIENT REHABILITATION EVALUATION

4 (a) A comprehensive, inpatient rehabilitation evaluation is required for each patient admitted to an inpatient
5 rehabilitation facility or unit. At a minimum this evaluation shall include the reason for referral, a summary of the
6 patient's clinical condition, functional strengths and limitations, and indications for specific services. This evaluation
7 shall be completed within three days.

8 (b) Each patient shall be evaluated by the interdisciplinary team to determine the need for any of the following services:
9 medical, dietary, occupational therapy, physical therapy, prosthetics and orthotics, psychological assessment and therapy,
10 therapeutic recreation, rehabilitation medicine, rehabilitation nursing, therapeutic counseling or social work, vocational
11 rehabilitation evaluation and speech-language pathology.

12
13 History Note: Statutory Authority G.S. 131E-79;

14 Eff. March 1, 1996.

188

RRC STAFF RECOMMENDATION

AGENCY: DHR/N C Medical Care Commission

RULE CITATION: 10 NCAC 3C .5405

RECOMMENDATION:

Object, based on

Lack of
Statutory
authority

X Unclear,
ambiguous

Unnecessary

COMMENT: Paragraph (d) (line 19) requires that each patient have a case manager. The last sentence (line 22) states who that case manager may be. However it is not clear whether the director of nursing or social worker is acting as the case manager or whether there is another meaning to "accept the coordination responsibility for the patients" (line 23). If it means something other than being a case manager, then it is not clear if the rule requiring a case manger is being complied with.

Joseph J. DeLuca, Jr.
Staff Director

1 10 NCAC 3C .5405 is proposed to be adopted as follows as published in the NCR, Vol. 10, Issue 14, Pages 1233 - 1234:

2
3 **.5405 COMPREHENSIVE INPATIENT REHABILITATION INTERDISCIPLINARY**

4 **TREAT/PLAN**

5 (a) The interdisciplinary treatment team shall develop an individual treatment plan for each patient within seven days
6 after admission. The plan shall include evaluation findings and information about the following:

- 7 (1) prior level of function;
8 (2) current functional limitations;
9 (3) specific service needs;
10 (4) treatment, supports and adaptations to be provided;
11 (5) specified treatment goals;
12 (6) disciplines responsible for implementation of separate parts of the plan; and
13 (7) anticipated time frames for the accomplishment of specified long-term and short-term goals.

14 (b) The treatment plan shall be reviewed by the interdisciplinary team at least every other week. All members of the
15 interdisciplinary team, or a representative of their discipline, shall attend each meeting. Documentation of each review
16 shall include progress toward defined goals and identification of any changes in the treatment plan.

17 (c) The treatment plan shall include provisions for all of the services identified as needed for the patient in the
18 comprehensive inpatient rehabilitation evaluation completed in accordance with rule .5404 of this Subchapter.

19 (d) Each patient shall have a designated case manager who is responsible for the coordination of the patient's
20 individualized treatment plan. The case manager is responsible for promoting the program's responsiveness to the needs
21 of the patient and shall participate in all team conferences concerning the patient's progress toward the accomplishment of
22 specified goals. Any of the professional staff involved in the patient's care may be the designated case manager for one or
23 more cases, or the director of nursing or social worker may accept the coordination responsibility for the patients.

24
25 History Note: Statutory Authority G.S. 131E-79;

26 Eff. March 1, 1996.

182

1 10 NCAC 3C .5406 is proposed to be adopted as follows as published in the NCR, Vol. 10, Issue 14, Page 1234:

2
3 **.5406 DISCHARGE CRITERIA FOR INPATIENT REHABILITATION FACILITIES OR UNITS**

4 (a) Discharge planning shall be an integral part of the patient's treatment plan and shall begin upon admission to the
5 facility. After established goals have been reached, or a determination has been made that care in a less intensive setting
6 would be appropriate, or that further progress is unlikely, the patient shall be discharged to an appropriate setting. Other
7 reasons for discharge may include an inability or unwillingness of patient or family to cooperate with the planned
8 therapeutic program or medical complications that preclude a further intensive rehabilitative effort. The facility shall
9 involve the patient, family, staff members and referral sources in discharge planning.

10 (b) The case manager shall facilitate the discharge or transfer process in coordination with the facility social worker.

11 (c) If a patient is being referred to another facility for further care, appropriate documentation of the patient's current
12 status shall be forwarded with the patient. A formal discharge summary shall be forwarded within 48 hours following
13 discharge and shall include the reasons for referral, the diagnosis, functional limitations, services provided, the results of
14 services, referral action recommendations and activities and procedures used by the patient to maintain and improve
15 functioning.

16
17 *History Note: Statutory Authority G.S. 131E-79;*

18 *Eff. March 1, 1996.*

RRC STAFF RECOMMENDATION

AGENCY: DHR/N C Medical Care Commission

RULE CITATION: 10 NCAC 3C .5407

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: The meaning of "qualified" in (a) (line 4) is unclear. If it means meeting MCC mandated qualifications that is not clear and there is no authority cited for setting such qualifications. If it means that the facility shall set the qualifications, that is not clear.

Joseph J. DeLuca, Jr.
Staff Director

1 10 NCAC 3C .5407 is proposed to be adopted as follows as published in the NCR, Vol. 10, Issue 14, Page 1234:

2
3 **.5407 COMPREHENSIVE REHABILITATION PERSONNEL ADMINISTRATION**

4 (a) The facility shall have qualified staff members, consultants and contract personnel to provide services to the patients
5 admitted to the inpatient rehabilitation facility or unit.

6 (b) Personnel shall be employed or provided by contractual agreement in sufficient types and numbers to meet the needs
7 of all patients admitted for comprehensive rehabilitation.

8 (c) Written agreements shall be maintained by the facility when services are provided by contract on an ongoing basis.

9
10 History Note: Statutory Authority G.S. 131E-79;

11 Eff. March 1, 1996.

RRC STAFF RECOMMENDATION

AGENCY: DHR/N C Medical Care Commission

RULE CITATION: 10 NCAC 3C .5408

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

X Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority to set staff qualifications as set out in this rule and .5401.

This rule is confusing in that (a)(1) tells the facility to "identify the nursing skills necessary...and assign staff qualified...." (lines 5-7) to be a rehabilitation nurse. However the definitional rule, .5401, specifies the qualifications for a rehabilitation nurse.

Joseph J. DeLuca, Jr.
Staff Director

186

1 10 NCAC 3C .5408 is proposed to be adopted as follows as published in the NCR, Vol. 10, Issue 14, Pages 1234 - 1234:

2
3 **.5408 COMPREHENSIVE INPATIENT REHABILITATION PROGRAM STAFFING REQUIREMENTS**

4 (a) The staff of the inpatient rehabilitation facility or unit shall include at a minimum:

5 (1) the inpatient rehabilitation facility or unit shall be supervised by a rehabilitation nurse. The facility shall
6 identify the nursing skills necessary to meet the needs of the rehabilitation patients in the unit and assign staff
7 qualified to meet those needs;

8 (2) the minimum nursing hours per patient in the rehabilitation unit shall be 5.5 nursing hours per patient day. At
9 no time shall direct care nursing staff be less than two full-time equivalents, one of which must be a registered
10 nurse;

11 (3) the inpatient rehabilitation unit shall employ or provide by contractual agreements sufficient therapist to
12 provide a minimum of three hours of specific (physical, occupational or speech) or combined rehabilitation
13 therapy services per patient day;

14 (4) physical therapy assistants and occupational therapy assistants shall be supervised on-site by physical therapists
15 or occupational therapists;

16 (5) rehabilitation aides shall have documented training appropriate to the activities to be performed and the
17 occupational licensure laws of his or her supervisor. The overall responsibility for the on-going supervision
18 and evaluation of the rehabilitation aide remains with the registered nurse as identified in Subparagraph (a)(1)
19 of this Rule. Supervision by the physical therapist or by the occupational therapist is limited to that time when
20 the therapist is on-site and directing the rehabilitation activities of the aide; and

21 (6) hours of service by the rehabilitation aide are counted toward the required nursing hours when the aide is
22 working under the supervision of the nurse. Hours of service by the rehabilitation aide are counted toward
23 therapy hours during that time the aide works under the immediate, on-site supervision of the physical therapist
24 or occupational therapist. Hours of service shall not be dually counted for both services. Hours of service by
25 rehabilitation aides in performing nurse-aide duties in areas of the facility other than the rehabilitation unit
26 shall not be counted toward the 5.5 hour minimum nursing requirement described for the rehabilitation unit.

27 (b) Additional personnel shall be provided as required to meet the needs of the patient, as defined in the comprehensive
28 inpatient rehabilitation evaluation.

29
30 History Note: Statutory Authority G.S. 131E-79;

31 Eff. March 1, 1996.

187

RRC STAFF RECOMMENDATION

AGENCY: DHR/N C Medical Care Commission

RULE CITATION: 10 NCAC 3C .5409

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited to set staff training qualifications.

It is my opinion that the agency may require a facility to train its employees in various ways. But this rule merely sets a requirement (or qualification) that a person have certain training or possess certain knowledge. If the person has not had the training or does not possess the knowledge (in other words lacks the qualifications) then the facility must provide it.

Joseph J. DeLuca, Jr.
Staff Director

1 10 NCAC 3C .5409 is proposed to be adopted as follows as published in the NCR, Vol. 10, Issue 14, Page 1235:

2
3 .5409 STAFF TRAINING FOR INPATIENT REHABILITATION FACILITIES OR UNIT

4 Prior to the provision of care, all rehabilitation personnel, excluding physicians, assigned to the rehabilitation unit shall
5 be provided training or shall provide documentation of training that includes at a minimum the following:

- 6 (1) active and passive range of motion;
7 (2) assistance with ambulation;
8 (3) transfers;
9 (4) maximizing functional independence;
10 (5) the psycho-social needs of the rehabilitation patient;
11 (6) the increased safety risks of rehabilitation training (including falls and the use of restraints);
12 (7) proper body mechanics;
13 (8) nutrition, including dysphagia and restorative eating;
14 (9) communication with the aphasic and hearing impaired patient;
15 (10) behavior modification;
16 (11) bowel and bladder training; and
17 (12) skin care.

18
19 History Note: Statutory Authority G.S. 131E-79;

20 Eff. March 1, 1996.

1 10 NCAC 3C .5410 is proposed to be adopted as follows as published in the NCR, Vol. 10, Issue 14, Page 1235:
2

3 **.5410 EQUIPMENT REQUIREMENTS/COMPREHENSIVE INPATIENT REHABILITATION PROGRAMS**

4 (a) The facility shall provide each discipline with the necessary equipment and treatment methods to achieve the short
5 and long-term goals specified in the comprehensive inpatient rehabilitation interdisciplinary treatment plans for patients
6 admitted to these facilities or units.

7 (b) Each patient's needs for a standard wheelchair or a specially designed wheelchair or additional devices to allow safe
8 and independent mobility within the facility shall be met.

9 (c) Special physical therapy and occupational therapy equipment for use in fabricating positioning devices for beds and
10 wheelchairs shall be provided including splints, casts, cushions, wedges and bolsters.

11 (d) Physical therapy devices shall be provided, including a mat, table, parallel
12 bars, sliding boards, and special adaptive bathroom equipment.

13
14 History Note: Statutory Authority G.S. 131E-79:

15 Eff. March 1, 1996.
16

10 NCAC 3C .5411 is proposed to be adopted as follows as published in the NCR, Vol. 10, Issue 14, Pages 1235 - 1237:

.5411 PHYSICAL FACILITY REQUIREMENTS/INPATIENT REHABILITATION FACILITIES OR UNIT

(a) The inpatient rehabilitation facility or unit shall be in a designated area and shall be used for the specific purpose of providing a comprehensive inpatient rehabilitation program.

(b) The floor area of a single bedroom shall be sufficient for the patient or the staff to easily transfer the patient from the bed to a wheelchair and to maneuver a 180 degree turn with a wheelchair on at least one-side of the bed.

(c) The floor area of a multi-bed bedroom shall be sufficient for the patient or the staff to easily transfer the patient from the bed to a wheelchair and to maneuver a 180 degree turn with a wheelchair between beds.

(d) Each patient room shall meet the following requirements:

(1) maximum room capacity of no more than four patients;

(2) operable windows;

(3) a nurse call system designed to meet the special needs of rehabilitation patients;

(4) in single and two-bed rooms with private toilet room, the lavatory may be located in the toilet room;

(5) a wardrobe or closet for each patient which is wheelchair accessible and arranged to allow the patient to access the contents;

(6) a chest of drawers or built-in drawer storage with mirror above, which is wheelchair accessible; and

(7) a bedside table for toilet articles and personal belongings.

(e) Space for emergency equipment such as resuscitation carts shall be provided and shall be under direct control of the nursing staff, in proximity to the nurse's station and out of traffic.

(f) Patients' bathing facilities shall meet the following specifications:

(1) there shall be at least one shower stall or one bathtub for each 15 beds not individually served. Each tub or shower shall be in an individual room or privacy enclosure which provides space for the private use of the bathing fixture, for drying and dressing and for a wheelchair and an assisting attendant.

(2) showers in central bathing facilities shall be at least five feet square without curbs and designed to permit use by a wheelchair patient.

(3) at least one five-foot-by-seven-foot shower shall be provided which can accommodate a stretcher and an assisting attendant.

(g) Patients' toilet rooms and lavatories shall meet the following specifications:

(1) the size of toilet room shall permit a wheelchair, a staff person and appropriate wheel-to-water closet transfers.

(2) A lavatory in the room shall permit wheelchair access.

(3) Lavatories serving patients shall:

(A) allow wheelchairs to extend under the lavatory; and

(B) have water supply spout mounted so that its discharge point is a minimum of five inches above the rim of the fixture; and

(4) Lavatories used by patients and by staff shall be equipped with blade-operated supply valves.

1 (h) The space provided for physical therapy, occupational therapy and speech therapy by all inpatient rehabilitation
2 facilities or units may be shared but shall, at a minimum, include:

- 3 (1) office space for staff;
4 (2) office space for speech therapy evaluation and treatment;
5 (3) waiting space;
6 (4) training bathroom which includes toilet, lavatory and bathtub;
7 (5) gymnasium or exercise area;
8 (6) work area such as tables or counters suitable for wheelchair access;
9 (7) treatment areas with available privacy curtains or screens;
10 (8) an activities of daily living training kitchen with sink, cooking top (secured when not supervised by staff),
11 refrigerator and counter surface for meal preparation;
12 (9) storage for clean linens, supplies and equipment;
13 (10) janitor's closet accessible to the therapy area with floor receptor or service sink and storage space for housekeeping
14 supplies and equipment (one closet or space may serve more than one area of the inpatient rehabilitation facility
15 or unit); and
16 (11) hand washing facilities

17 (i) For social work and psychological services the following shall be provided:

- 18 (1) office space for staff;
19 (2) office space for private interviewing and counseling for all family members; and
20 (3) work space for testing, evaluation and counseling.

21 (j) If prosthetics and orthotics services are provided, the following space shall be made available as necessary:

- 22 (1) work space for technician; and
23 (2) space for evaluation and fittings (with provisions for privacy).

24 (k) If vocational therapy services are provided, the following space shall be made available as necessary:

- 25 (1) office space for staff;
26 (2) work space for vocational services activities such as prevocational and vocational evaluation;
27 (3) training space;
28 (4) storage for equipment; and
29 (5) counseling and placement space.

30 (l) Recreational therapy space requirements shall include the following:

- 31 (1) activities space;
32 (2) storage for equipment and supplies;
33 (3) office space for staff; and
34 (4) access to male and female toilets.

35 (m) The following space shall be provided for patient's dining, recreation and day areas:

- 1 (1) sufficient room for wheelchair movement and wheelchair dining seating;
2 (2) if food service is cafeteria type, adequate width for wheelchair maneuvers, queue space within the dining area
3 (and not in a corridor) and a serving counter low enough to view food;
4 (3) total space for inpatients, a minimum of 25 square feet per bed;
5 (4) for outpatients participating in a day program or partial day program, 20 square feet when dining is a part of
6 the program and 10 square feet when dining is not a part of the program; and
7 (5) storage for recreational equipment and supplies, tables and chairs.
8 (6) the patient dining, recreation and day area spaces shall be provided with windows that have glazing of an area not
9 less than eight percent of the floor area of the space, and at least one-half of the required window area must be
10 operable.
11 (n) A laundry shall be available and accessible for patients.

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13 History Note: Statutory Authority G.S. 131E-79;
14 Eff. March 1, 1996.
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RRC STAFF RECOMMENDATION

AGENCY: DHR/N C Medical Care Commission

RULE CITATION: 10 NCAC 3C .5412

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited for the provision in
(4) to set staff qualifications for the medical director
(line 15).

Joseph J. DeLuca, Jr.
Staff Director

1 10 NCAC 3C .5412 is proposed to be adopted as follows as published in the NCR, Vol. 10, Issue 14, Page 1237:

2
3 **.5412 ADDITIONAL REQUIREMENTS FOR TRAUMATIC BRAIN INJURY PATIENTS**

4 Inpatient rehabilitation facilities providing services to persons with traumatic brain injuries shall meet the requirements in
5 this Rule in addition to those identified in this Section.

6 (1) Direct-care nursing personnel staffing ratios established in rule .5408 of this Section shall not be applied to nursing
7 services for traumatic brain injury patients in the inpatient, rehabilitation facility or unit. The minimum nursing
8 hours per traumatic brain injury patient in the unit shall be 6.5 nursing hours per patient day. At no time shall
9 direct care nursing staff be less than two full-time equivalents, one of which shall be a registered nurse.

10 (2) The inpatient rehabilitation facility or unit shall employ or provide by contractual agreements physical, occupational
11 or speech therapists in order to provide a minimum of 4.5 hours of specific or combined rehabilitation therapy
12 services per traumatic brain injury patient day.

13 (3) The facility shall provide special facility or special equipment needs for patients with traumatic brain injury,
14 including specially designed wheelchairs, tilt tables and standing tables.

15 (4) The medical director of an inpatient traumatic brain injury program shall have two years management in a brain
16 injury program, one of which may be in a clinical fellowship program and board eligibility or certification in the
17 medical specialty of the physician's training.

18 (5) The facility shall provide the consulting services of a neuropsychologist.

19 (6) The facility shall provide continuing education in the care and treatment of brain injury patients for all staff.

20 (7) The size of the brain injury program shall be adequate to support a comprehensive, dedicated ongoing brain injury
21 program.

22
23 History Note: Statutory Authority G.S. 131E-79;

24 Eff. March 1, 1996.

195

RRC STAFF RECOMMENDATION

AGENCY: DHR/N C Medical Care Commission

RULE CITATION: 10 NCAC 3C .5413

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited for the provision in
(4) to set staff qualifications for the medical director
(line 15).

Joseph J. DeLuca, Jr.
Staff Director

1 10 NCAC 3C .5413 is proposed to be adopted as follows as published in the NCR, Vol. 10, Issue 14, page 1237:

2
3 **.5413 ADDITIONAL REQUIREMENTS FOR SPINAL CORD INJURY PATIENTS**

4 Inpatient rehabilitation facilities providing services to persons with spinal cord injuries shall meet the requirements in this
5 Rule in addition to those identified in this Section.

6 (1) Direct-care nursing personnel staffing ratios established in rule .5408 of this Section shall not be applied to nursing
7 services for spinal cord injury patients in the inpatient rehabilitation facility or unit. The minimum nursing hours
8 per spinal cord injury patient in the unit shall be 6.0 nursing hours per patient day. At no time shall direct care
9 nursing staff be less than two full-time equivalents, one of which shall be a registered nurse.

10 (2) The inpatient rehabilitation facility or unit shall employ or provide by contractual agreements physical, occupational
11 or speech therapists in order to provide a minimum of 4.0 hours of specific or combined rehabilitation therapy
12 services per spinal cord injury patient day.

13 (3) The facility shall provide special facility or special equipment needs of patients with spinal cord injury, including
14 specially designed wheelchairs, tilt tables and standing tables.

15 (4) The medical director of an inpatient spinal cord injury program shall have either two years experience in the medical
16 care of persons with spinal cord injuries or six months minimum in a spinal cord injury fellowship.

17 (5) The facility shall provide continuing education in the care and treatment of spinal cord injury patients for all staff.

18 (6) The facility shall provide specific staff training and education in the care and treatment of spinal cord injury.

19 (7) The size of the spinal cord injury program shall be adequate to support a comprehensive, dedicated ongoing spinal
20 cord injury program.

21
22 History Note: Statutory Authority G.S. 131E-79;

23 Eff. March 1, 1996.
24

1 10 NCAC 3C .5414 is proposed to be adopted as follows as published in the NCR, Vol 10, Issue 14, Pages 1237 - 1238:

2
3 **.5414 DEEMED STATUS FOR INPATIENT REHABILITATION FACILITIES OR UNIT**

4 (a) If an inpatient rehabilitation facility or unit with a comprehensive inpatient rehabilitation program is surveyed and
5 accredited by the Joint Commission for the Accreditation of Health Care Organizations (JCAHO) or the Commission on
6 Accreditation of Rehabilitation Facilities (CARF) and has been approved by the Department in accordance with N.C.
7 General Statute 131E, Article 9, the Department deems the facility to be in compliance with rules .5401 through .5413 of
8 this Section.

9 (b) Deemed status shall be provided only if the inpatient rehabilitation facility or unit provides copies of survey reports to
10 the Department. The JCAHO report shall show that the facility or unit was surveyed for rehabilitation services. The
11 CARF report shall show that the facility or unit was surveyed for comprehensive rehabilitation services. The facility or
12 unit shall sign an agreement (Memorandum of Understanding) with the Department specifying these terms.

13 (c) The inpatient rehabilitation facility or unit shall be subject to inspections or complaint investigations by
14 representatives of the Department at any time. If the facility or unit is found not to be in compliance with the rules listed
15 in Paragraph (a) of this Rule, the facility shall submit a plan of correction and be subject to a follow-up visit to ensure
16 compliance.

17 (d) If the inpatient rehabilitation facility or unit loses or does not renew its accreditation, the facility or unit shall notify
18 the Division in writing within 30 days.

19
20 History Note: Statutory Authority G.S. 131E-79;

21 Eff. March 1, 1996.

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .3001

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority to require licensure, registration, or certification for the following defined occupations: (3), (7), (12), (13), (27), (28), (29), (34), (36).

There are other terms which, when used in context, may require definitions.

Joseph J. DeLuca, Jr.
Staff Director

SECTION .3000 GENERAL INFORMATION

.3001 DEFINITIONS

The following definitions shall apply throughout this section, unless the text clearly indicates to the contrary:

- (1) "Appropriate" means suitable or fitting; conforming to standards of care as established by professional organizations.
- ~~(2) "Approved" means acceptable to the authority having jurisdiction.~~
- ~~(3) "Advanced Practice Nurse" means a registered nurse with a graduate degree or advanced formal education in a clinical nursing specialty who is credentialed by the Board of Nursing or the Board of Medical Examiners. This includes but is not limited to the Certified Registered Nurse Anesthetist (CRNA) and Certified Nurse Practitioner.~~
- (4) (2) "Authority having jurisdiction" means the Division of Facility Services.
- (5) (3) "Certified Dietary Manager" or "CDM" means an individual who is certified by the Certifying Board of the Dietary Managers and meets the standards and qualification as referenced in the "Dietary Manager Training Program Requirements." These standards include any subsequent amendments and editions of the referenced manual. Copies of the "Dietary Manager Training Program Requirements" may be purchased for \$15.00 dollars from the Dietary Managers Association, One Pierce Place, Suite 1220W, Itasca, Illinois 60143.
- (6) (4) "Competence" means having the predetermined requisite abilities or qualities to perform specific functions.
- (7) (5) "Comprehensive" means covering completely, inclusive.
- (8) (6) "Continuous" means ongoing or uninterrupted, 24 hours per day.
- (9) (7) "CRNA" means a Certified Registered Nurse Anesthetist as credentialed by the Council on Certification of Nurse Anesthetists, ~~Board of Nursing, or the Board of Medical Examiners and recognized by the Board of Nursing in 21 NCAC 36.0226.~~
- (10) (8) "Credentialed" means that the individual having a given title or position has been credited with the right to exercise official power, responsibilities to provide specific patient care and treatment services, within defined limits, based primarily upon the individual's license, education, training, experience, competence, and judgment.
- (11) (9) "Department" means the Department of Human Resources.
- (12) (10) "Departmentalized medical staff" means the divisions within the medical staff which separate specialties such as medicine, surgery, pediatrics, orthopedics.
- (13) (11) "Dietetics" means the integration and application of principles derived from the science of nutrition, biochemistry, physiology, food and management and from behavioral and social sciences to achieve and maintain optimal nutritional status.
- (14) (12) "Dietitian" means an individual who is licensed according to N.C. Gen. Stat. 90, Article 25, or is registered by the Commission on Dietetic Registration (CDR) of the American Dietetic Association (ADA) according to the standards and qualifications as referenced in the second edition of the "Accreditation/Approval Manual for Dietetic Education Programs", "The Registration Eligibility Application for Dietitians" and the "Continuing Professional Education" and subsequent amendments or editions of the reference material. Copies of the "Accreditation/Approval Manual for Dietetic Education Programs" may be purchased for \$21.95 plus \$3.00 minimum shipping and handling from ADA Sales Order Department, P.O. Box 97215, Chicago, IL 60678-7215.
- (15) (13) "Dietetic Technician Registered" or "DTR" means an individual who is registered by the Commission on Dietetic Registration (CDR) of the American Dietetic Association (ADA) according to the standards and qualifications as referenced in the second edition of the "Accreditation/Approval Manual for Dietetic Education Programs". The Registration Eligibility Application for Dietetic Technicians" and the "Continuing

Professional Education". Standards include any subsequent amendments and editions of the referenced material. Copies of the "Accreditation/Approval Manual for Dietetic Education Programs" may be purchased for \$21.95 plus \$3.00 minimum for shipping and handling from the ADA Sales Order Department, P.O. Box 97215, Chicago, IL 60678-7215.

- (14) "Direct Supervision" means under the immediate management of a supervisor or other person of authority.
- (15) "Division" means the Division of Facility Services.
- (16) "Easily accessible" means the ability to enter, approach, communicate with or pass to and from, or to make use of without interference of physical barriers.
- (17) "Facility" means a hospital as defined in N.C. Gen. Stat. 131E-76.
- (18) "Free standing facility" means a facility that is physically separated from the primary hospital building or separated by a three hour fire containment wall.
- (19) "Full-time equivalent" means the method used to designate employee status for budget purposes; for accounting purposes this equals 2080 hours.
- (20) "Governing body" means the authority as defined in N.C. Gen. Stat. 131E-76.
- (21) "Imaging" means a reproduction or representation of a body or body part for diagnostic purposes by radiologic intervention that may include conventional fluoroscopic exam, magnetic resonance, nuclear or radio-isotope scan.
- ~~(24) "Informed consent" means consent to health care treatment as defined in N.C. Gen. Stat. 90-21.13.~~
- (22) "Invasive procedure" means a procedure involving puncture or incision of the skin, insertion of an instrument or foreign material into the body (excluding venipuncture and intravenous therapy).
- (23) "LDRP" (labor, delivery, recovery, post-partum) means a specific single occupancy obstetrical use room not counted as a licensed bed.
- (24) "License" means formal permission to provide services as granted by the State.
- (25) "Mission statement" means a written statement of the philosophy and beliefs of the organization or hospital as approved by the governing authority body.
- (26) "Neonate" means the newborn from birth to 1 month.
- (27) "NP" means a Nurse Practitioner as defined in N. C. Gen. Stat. 90-6; 90-18(14); and 90-18.2.
- (28) "Nurse executive" means a registered nurse who is the director of nursing services or a representative of decentralized nursing management staff.
- (29) "Nurse midwife" means a Certified Nurse Midwife as defined in N. C. Gen. Stat. 90, Article 10.
- (30) "Nursing facility" means that portion of a hospital that is approved to provide skilled nursing care.
- (31) "Nutrition therapy" ranges from intervention and counseling on diet modification to administration of specialized nutrition therapies as determined necessary to manage a condition or treat illness or injury. Specialized nutrition therapies include supplementation with medical foods, enteral and parenteral nutrition. Nutrition therapy integrates information from the nutrition assessment with information on food and other sources of nutrients and meal preparation consistent with cultural background and socioeconomic status.
- (32) "Observation bed" means a bed used for a limited time, generally for no more than 24-72 hours, to evaluate and determine the condition and disposition of a patient and is not considered a part of the hospital's licensed bed capacity.
- ~~(36) "PA" means a Physician Assistant as certified by the North Carolina Board of Medical Examiners.~~
- (33) "Patient" means any person admitted to the hospital for receiving diagnostic or medical services or nursing care at a hospital.
- (34) "Pharmacist" means a person licensed according to G.S. 90, Article 4A, by the N.C. board of Pharmacy to practice pharmacy.

(38)(35) "Physical Rehabilitation Services" means any combination of physical, occupational, speech therapy or vocational rehabilitation that meets the needs of the patient's patients served.

(36) "Physician" means a person licensed according to G.S. 90, Article 1, by the N.C. Board of Medical Examiners to practice medicine.

(39)(37) "Provisional license" means a hospital license recognizing significantly less than full compliance with the licensure rules.

(40)(38) "Qualification" means the conditions that must be complied with have been met (as the attainment of a privilege)

(41)(39) "Qualified" means having complied with the specific predetermined conditions for employment or the performance of a function.

~~(42) "Reasonable" means not extreme, sensible.~~

(43)(40) "Reference" means to use in consultation to obtain information.

~~(44) "Sound" means free from defect or damage; reliable.~~

(45)(41) "Special Care Unit" means a designated unit or area of a hospital with a concentration of qualified professional staff and support services that provide intensive or extraordinary care on a 24-hour basis to critically ill patients; these units may include but are not limited to Cardiac Care, Medical or Surgical Intensive Care Unit, Cardiothoracic Intensive Care Unit, Burn Intensive Care Unit, Neurologic Intensive Care Unit or Pediatric Intensive Care Unit.

(46)(42) "Substantial" means ample to satisfy and nourish; real or true; being that specified to a large degree or in the main.

(47)(43) "Substantially" means firmly, with strength or to a substantial degree.

(48)(44) "Unit" means a designated area of the hospital for the delivery of patient care services.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

SECTION .3100 PROCEDURE

.3101 GENERAL REQUIREMENTS

- (a) An application for licensure shall be submitted to the Division prior to a license being issued or patients admitted.
- (b) An existing facility shall not sell, lease or subdivide a portion of its bed capacity without the approval of the Division.
- (c) Application forms may be obtained by contacting the Division.
- (d) The Division shall be notified in writing prior to the occurrence of any of the following:
 - (1) addition or deletion of a licensable service;
 - (2) increase or decrease in bed capacity;
 - (3) change of chief executive officer;
 - (4) change of mailing address;
 - (5) ownership change; or
 - (6) name change.
- (e) Each application shall contain the following information:
 - (1) legal identity of applicant;
 - (2) name or names under which the hospital or services are presented to the public;
 - (3) name of chief executive officer;
 - (4) ownership disclosure;
 - (5) bed complement;
 - (6) bed utilization;
 - (7) accreditation data;
 - (8) physical plant inspection data; and
 - (9) service data.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~February 1, 1995~~ September 1, 1995.

.3102 PLAN APPROVAL

(a) The facility design and construction shall be in accordance with the construction standards of the Division, the North Carolina Building Code, and local municipal codes.

(b) Submission of Plans

- (1) Before construction is begun, plans ~~color marked as required by the Division~~ and specifications covering construction of the new buildings, alterations or additions to existing buildings, or any change in facilities shall be submitted to the Division for approval.
- (2) The Division will review the plans and notify the licensee that said buildings, alterations, additions, or changes are approved or disapproved if plans are disapproved the Division shall give the applicant notice of deficiencies identified by the Division.
- (3) In order to avoid unnecessary expense in changing final plans, a preliminary step, proposed plans in schematic form shall be reviewed by the Division.
- (4) The plans shall include a plot plan showing the size and shape of the entire site and the location of all existing and proposed facilities.
- (5) Plans shall be submitted in triplicate in order that the Division may distribute a copy to the Department of Insurance for review of State Building Code requirements and to the Department Environmental Health Natural Resources for review under state sanitation requirements.

(c) Location

- (1) The site for new construction or expansion shall be approved by the Division.
- (2) Hospitals shall be so located that they are free from undue noise from railroads, freight yards, main traffic arteries, schools and children's playgrounds.
- (3) The site shall not be exposed to smoke, foul odors, or dust from nearby industrial plants.
- (4) The area of the site shall be sufficient to permit future expansion and to provide adequate parking facilities.
- (5) The site shall be easily accessible.
- (6) Available paved roads, adequate water, sewage and power lines shall be taken into consideration in selecting the site.

(d) The bed capacity and services provided in a facility shall be in compliance with N.C. Gen. Stat. 131E, Article 9 regarding Certificate of Need. A facility shall be licensed for no more beds than the number for which required physical space and other required facilities are available. Neonatal Level II and III beds are considered beds for licensure purposes, but Level I (bassinets for newborns) are not considered part of licensed bed capacity.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ ~~September 1, 1995~~

.3103 CLASSIFICATION OF MEDICAL FACILITIES

(a) The classification of "hospital" shall be restricted to facilities that provide as their primary functions diagnostic services and medical and nursing care in the treatment of acute stages of illness. On the basis of specialized facilities and services available, the Division shall license each such hospital according to the following medical types:

- (1) general acute care hospital;
- (2) rehabilitation hospital;
- (3) designated primary care hospital; or
- (4) federally certified primary care hospital.

(b) All other inpatient medical facilities accepting patients requiring skilled nursing services but which are not operated as a part of any hospital within the above meaning shall be considered to be operating as a nursing home and, therefore, are not subject to hospital licensure.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .3104 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1773 as follows:

.3104 LENGTH OF LICENSE

Licenses shall remain in effect for an indefinite period of time, unless the following occurs:

- (a) Division imposes an administrative sanction which specifies license expiration;
- (b) change of ownership;
- (c) closure;
- (d) change of site;
- (e) failure to comply with Rule .3105 of this Section.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995

10 NCAC .3105 is adopted as published in the N.C. Register Volume 21, Issue 9, pages 1773-1774 as follows:

.3105 STATISTICAL INFORMATION

Utilization data shall be submitted annually upon request by the Division. Forms for collection of this data will be forward to each facility by the Division.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

.3106 LICENSURE SURVEYS

(a) Prior to the initial issuance of a license to operate a facility, the Division shall conduct a survey to determine compliance with rules promulgated pursuant to N. C. Gen. Stat. 131E-79.

(b) The Division may conduct an investigation of a specific complaint in any facility.

(c) Facilities that are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) shall choose one of the following options:

(1) Accredited hospitals may agree to provide the Division with:

(A) JCAHO Accreditation Certificate;

(B) JCAHO Statement of Construction;

(C) JCAHO Reports and Recommendations;

(D) JCAHO Interim Self-Survey Reports; and

(E) permission to participate in any regular survey conducted by the JCAHO.

If a review of the information listed in Subparagraphs (c)(1)(A) - (c)(1)(D) indicates non-compliance with licensure rules contained in this Subchapter, then the Division may conduct surveys or partial surveys with special emphasis on deficiencies noted. If a review indicates compliance with licensure regulations contained in this Subchapter, the Division will not conduct a licensure survey except as provided in (b), (c)(1)(E), and (d) of this Rule.

(2) Accredited hospitals which do not agree to provide the Division with JCAHO reports found in (c)(1) of this Rule shall be surveyed at least once every three years.

(d) The Division reserves the right to conduct any validation survey in facilities that choose the option under (c)(1) of this Rule.

(e) The Division shall survey non-accredited facilities at least once every three years.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

.3107 DENIAL, AMENDMENT OR REVOCATION OF LICENSE

(a) The Department may deny any licensure application upon becoming aware that the applicant is not in compliance with any applicable provision of the Certificate of Need law located in N. C. Gen. Stat. 131E, Article 9 and the rules adopted under that law.

(b) The Department may amend a license by reducing it from a full license to a provisional license whenever the Department finds that:

- (1) the licensee has failed to comply with the provisions of N. C. Gen. Stat. 131E, Article 5 and the rules promulgated under that article;
- (2) there is a probability that the licensee can remedy the licensure deficiencies within a length of time not to exceed the expiration date on the license; and
- (3) there is a probability that the licensee will be able thereafter to remain in compliance with the hospital licensure rules for the foreseeable future.

(c) The Department shall also amend a license to provisional status by specifically prohibiting a licensee from providing certain services, for which it has been found to be out of compliance with N. C. Gen. Stat. 131E, Articles 5 or 9. In all cases the Department shall give the licensee written notice of the amendment of the license. This notice shall be given by registered or certified mail or by personal service and shall set forth:

- (1) the length of the provisional license;
- (2) the factual allegations;
- (3) the statutes and rules alleged to be violated; and
- (4) notice of the facility's right to a contested case hearing on the amendment of the license.

(d) The provisional license shall be effective immediately upon its receipt by the licensee and shall be posted in a prominent location, accessible to public view, within the licensed premises in lieu of the full license. The provisional license shall remain in effect until:

- (1) the Department restores the licensee to full licensure status;
- (2) the Department revokes the licensee's license; or
- (3) the end of the licensee's licensure period.

If a licensee has a provisional license at the time that the licensee submits a renewal application, the license, if renewed, shall also be a provisional license unless the Department determines that the licensee can be returned to full licensure status. A decision to issue a provisional license is stayed during the pendency of an administrative appeal and the licensee may continue to display its full license during the appeal.

(d) The Department shall revoke a license whenever:

(1) The Department finds that:

- (A) the licensee has failed to comply with the provisions of N. C. Gen. Stat. 131E, Article 5 and the rules promulgated under that article; and
- (B) it is not probable that the licensee can remedy the licensure deficiencies within a length of time acceptable to the Department; or

(2) The Department finds that:

- (A) The licensee has failed to comply with the provisions of N. C. Gen. Stat. 131E, Article 5; and
- (B) although the licensee may be able to remedy the deficiencies within a reasonable time, it is not probable that the licensee will be able to remain in compliance with hospital licensure rules for the foreseeable future; or

(3) The Department finds that the licensee has failed to comply with any of the provisions of N. C. Gen. Stat. 131E, Article 5 and the rules promulgated thereunder that endangers the health, safety or welfare of the patients in the facility.

The issuance of a provisional license is not a procedural prerequisite to the revocation of a license pursuant to Subparagraphs (d)(1), (2) or (3) of this rule.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .3108

RECOMMENDATION:

Object, based on

Lack of
Statutory
authority

X Unclear,
ambiguous

Unnecessary

COMMENT: In (a) the rule provides that the department may suspend the admission of new patients when warranted "under the provisions of G.S. 131E-78. There are no such provisions in that statute. That statute refers to administrative hearings to revoke licenses (or other actions against the hospital's license).

If they mean that they have the authority to suspend admissions (on any specific basis?) pending the completion of any adverse action against the licensee, then the rule needs to express that more clearly (and also the grounds for such suspension).

Joseph J. DeLuca, Jr.
Staff Director

11 A

.3108 SUSPENSION OF ADMISSIONS

(a) The Department may suspend the admission of any new patient to any facility when warranted under the provisions of N. C. Gen. Stat. 131E-78.

(b) The Department shall notify the facility by registered or certified mail or by personal service of the decision to suspend admissions. Such notice will include:

- (1) the period of the suspension;
- (2) factual allegations;
- (3) citation of statutes and rules alleged to be violated; and
- (4) notice of the facility's right to a contested case hearing.

(c) The suspension shall be effective when the notice is served or on the date specified in the notice of suspension, whichever is later. The suspension shall remain effective for the period specified in the notice or until the facility demonstrates to the Department that conditions are no longer detrimental to the health and safety of the patient.

(d) The facility shall not admit new patients during the effective period of the suspension.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

CASE NOTES

A board of trustees is not within the contemplation of subdivision (5), which defines a medical review committee. *Shelton v. Morehead Mem. Hosp.*, 76 N.C. App. 253, 332 S.E.2d 499 (1985), modified on other grounds, 318 N.C. 76, 347 S.E.2d 824 (1986).

A board of trustees of a hospital is not a medical review committee, even though the board may review personnel

recommendations of the medical review committees and has ultimate decision-making authority upon these recommendations by virtue both of the hospital's bylaws and § 131E-85. *Shelton v. Morehead Mem. Hosp.*, 318 N.C. 76, 347 S.E.2d 824 (1986).

Quoted in *Cohn v. Wilkes Gen. Hosp.*, 127 F.R.D. 117 (W.D.N.C. 1989).

Part A. Hospital Licensure.

§ 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 hospital operations 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.

(e) The Department shall issue the license to the operator of the hospital who shall not transfer or assign it except with the written approval of the Department.

(f) The operator shall post the license on the licensed premises in an area accessible to the public. (1947, c. 933, s. 6; 1949, c. 920, ss. 3, 4; 1963, c. 66; 1973, c. 476, s. 152; c. 1090, s. 1; 1975, c. 718, s. 2; 1983, c. 775, s. 1.)

§ 131E-78. Adverse action on a license.

(a) The Department shall have the authority to deny, suspend, revoke, annul, withdraw, recall, cancel, or amend a license in any case when it finds a substantial failure to comply with the provisions of this Part or any rule promulgated under this Part.

(b) The Department shall conduct a hearing in accordance with Chapter 150B of the General Statutes, the Administrative Procedure Act, when:

(1) The Department denies an application and the applicant requests a hearing; or

(2) The Department initiates proceedings under subsection (a).

(c) Any applicant or operator who is dissatisfied with the decision of the Department as a result of the hearing provided in this section

10 NCAC .3109 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1775 as follows:

.3109 PROCEDURE FOR APPEAL

A facility may appeal any decision of the Department to deny, revoke or amend a license or any decision to suspend admissions by making such an appeal in accordance with N. C. Gen. Stat. 150B.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

.3110 ITEMIZED CHARGES

(a) The facility shall either present an itemized list of charges to all discharged patients upon request or the facility shall include on patients' bills, which are not itemized, notification of the right to request an itemized bill within 30 days of receipt of the non-itemized bill.

(b) If requested, the facility shall present an itemized list of charges to each patient, or his ~~the~~ patient's responsible party.

(c) The itemized listing shall include, at a minimum, those charges incurred in the following service areas:

- (1) room rates;
- (2) laboratory;
- (3) radiology and nuclear medicine;
- (4) surgery;
- (5) anesthesiology;
- (6) pharmacy;
- (7) emergency services;
- (8) outpatient services;
- (9) specialized care;
- (10) extended care;
- (11) prosthetic and orthopedic appliances; and
- (12) other professional services.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

SECTION .3200 GENERAL HOSPITAL REQUIREMENTS

.3201 HOSPITAL REQUIREMENTS

A facility shall have all of the following:

- (1) an organized governing body;
- (2) a chief executive officer;
- (3) an organized medical staff;
- (4) an organized nursing staff;
- (5) continuous medical services;
- (6) continuous nursing services;
- (7) permanent on-site facilities for the care of patients 24 hours a day;
- (8) a hospital-wide infection control program;
- (9) minimum on-site clinical provisions as follows:
 - (a) appropriately equipped inpatient care areas;
 - (b) nursing care units;
 - (c) diagnostic and treatment areas to include on-site laboratory and imaging facilities with the capacity to provide immediate response to patient emergencies;
 - (d) pharmaceutical services in compliance with the Pharmacy Laws of North Carolina;
 - (e) facilities to assure the sterilization of equipment and supplies;
 - (f) medical records services;
 - (g) provision for social work services;
 - (h) current reference sources to meet staff needs; and
 - (i) nutrition services.
- (10) minimum supportive capabilities or facilities as follows:
 - (a) nutrition and dietetic services;
 - (b) scheduled general and preventive maintenance services for building, services and biomedical equipment;
 - (c) capability for obtaining police and fire protection, emergency transportation, grounds-keeping, and snow removal;
 - (d) personnel recruitment, training and continuing education;
 - (e) business management capability;
 - (f) short and long-range planning capability;
 - (g) financial plan to assure ~~provide~~ continuity of operation under both normal and emergency conditions;
 - (h) ~~comprehensive policies and standards for assuring the safety of patients, employees, and visitors and for protection against malpractice and negligence~~ provision for patient, employee, and visitor safety; and
 - (i) ~~comprehensive policies assuring that for~~ preventive and corrective maintenance is performed including procedures to be followed in the event of a breakdown of essential equipment.
- (11) facilities must comply with construction rules in Sections .6000-.6200 of this Subchapter.
- (12) a risk management program as follows:
 - (a) a specific staff member shall be assigned responsibility for development and administration of the program;
 - (b) a written policy statement evidencing a current commitment to the risk management program together with written procedures, policies and educational programs applicable to a risk management program which are reviewed at least every three years and updated as necessary;
 - (c) established lines of communication between the risk management program and other functions relating to quality of patient care, safety, and professional staff

- performance; and
 - (d) a written report of the activities of the risk management program shall be annually submitted to the governing body.
- (13) a quality assessment and improvement program which provides:
- (a) continuous assessment and evaluation of patient care and related services in all services and departments;
 - (b) a designated individual to coordinate the quality assessment and improvement program who will assist in the establishment of quality assessment and improvement plans and reporting methods for each service and department;
 - (c) a committee made up of representatives of the medical and nursing staff, administration, and other services or departments as defined by the hospital to coordinate the program, meet at least quarterly and maintain minutes of the meetings and committee activities; and
 - (d) for each service and department as defined by the hospital to be involved in the continuous assessment, monitoring and evaluation of patient care and related services.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

individual, upon the same terms and conditions as this aid and financial assistance is granted to municipalities and subdivisions of government.

(g) The Department may make available to any eligible hospital, clinic, or other medical facility operated by the State any unallocated federal sums or balances remaining after all grants-in-aid for local approvable projects made by the Department have been completed, disbursed or encumbered. (1945, c. 1096; 1947, c. 933, ss. 3, 5; 1949, c. 592; 1951, c. 1183, s. 1; 1971, c. 134; 1973, c. 476, s. 152; c. 1090, s. 1; 1979, c. 504, ss. 8, 14; 1983, c. 775, s. 1.)

Legal Periodicals. — For article, "The Obligation of North Carolina Municipalities and Hospital Authorities to Provide Uncompensated Hospital Care to the Medically Indigent," see 20 Wake Forest L. Rev. 317 (1984).

§§ 131E-71 through 131E-74: Reserved for future codification purposes.

ARTICLE 5.

Hospital Licensure Act.

§ 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. (1947, c. 933, s. 6; 1983, c. 775, s. 1.)

Editor's Note. — Session Laws 1991, c. 521, s. 1 provides: "The Department of Human Resources, Office of Rural Health and Resource Development, shall participate in the Health Care Financing Administrator's Essential Access Community Hospital (EACH) Program."

Legal Periodicals. — For article, "The Obligation of North Carolina Municipalities and Hospital Authorities to Provide Uncompensated Hospital Care to the Medically Indigent," see 20 Wake Forest L. Rev. 317 (1984).

§ 131E-76. Definitions.

As used in this article, unless otherwise specified:

- (1) "Commission" means the North Carolina Medical Care Commission.
- (2) "Governing body" means the Board of Trustees, Board of Directors, partnership, corporation, association, person or group of persons who maintain and control the hospital. The governing body may or may not be the owner of the properties in which the hospital services are provided.
- (3) "Hospital" means any facility which has an organized medical staff and which is designed, used, and operated to provide health care, diagnostic and therapeutic services, and continuous nursing care primarily to inpatients where such care and services are rendered under the supervision and direction of physicians licensed under Chapter 90 of

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the General Statutes, Article 1, to two or more persons over a period in excess of 24 hours. The term includes facilities for the diagnosis and treatment of disorders within the scope of specific health specialties. The term does not include private mental facilities licensed under Article 2 of Chapter 122C of the General Statutes, nursing homes licensed under G.S. 131E-102, and domiciliary homes licensed under G.S. 131D-2.

- (4) "Infirmity" means a unit of a school, or similar educational institution, which has the primary purpose to provide limited short-term health and nursing services to its students.
- (5) "Medical review committee" means a committee of a State or local professional society, of a medical staff of a licensed hospital or a committee of a peer review corporation or organization which is formed for the purpose of evaluating the quality, cost of, or necessity for hospitalization or health care, including medical staff credentialing.
- (6) "Primary care hospital" means a hospital which has been designated as a primary care hospital by the North Carolina Department of Human Resources, Office of Rural Health and Resource Development. To be designated as a primary care hospital under this subdivision, the hospital must be located in a rural community, provide primary care inpatient services that do not include inpatient surgery, and provide outpatient services which may include outpatient surgery. A primary care hospital shall have a maximum annual average daily census of 15 patients and may have psychiatric and long-term care distinct part units. A primary care hospital must be part of a rural hospital network.
- (7) "Rural hospital network" means an alliance of members that shall include at least one primary care hospital and one other hospital. To qualify as a rural hospital network, the members must submit a comprehensive, written memorandum of understanding to the Department of Human Resources for the Department's approval. The memorandum of understanding must include provisions for patient referral and transfer, a plan for network-wide emergency services, and a plan for sharing patient information and services between hospital members including medical staff credentialing, risk management, quality assurance, and peer review. (1947, c. 933, s. 6; 1949, c. 920, s. 1; 1955, c. 369; 1961, c. 51, s. 1; 1973, c. 476, s. 152; 1983, c. 775, s. 1; 1985, c. 589, s. 41; 1993, c. 321, s. 245.)

Editor's Note. — Session Laws 1993, c. 321, s. 322 is a severability clause.

Effect of Amendments. — The 1993 amendment, effective July 1, 1993, added subdivisions (6) and (7).

Legal Periodicals. — For comment, "Civil Procedure — Discovery of Medical

Records in a Corporate Negligence Action," see 10 Campbell L. Rev. 193 (1987).

For survey on the medical review committee privilege, see 67 N.C.L. Rev. 79 (1988).

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CASE NOTES

A board of trustees is not within the contemplation of subdivision (5), which defines a medical review committee. *Shelton v. Morehead Mem. Hosp.*, 76 N.C. App. 253, 332 S.E.2d 499 (1985), modified on other grounds, 318 N.C. 76, 347 S.E.2d 824 (1986).

A board of trustees of a hospital is not a medical review committee, even though the board may review personnel

recommendations of the medical review committees and has ultimate decision-making authority upon these recommendations by virtue both of the hospital's bylaws and § 131E-85. *Shelton v. Morehead Mem. Hosp.*, 318 N.C. 76, 347 S.E.2d 824 (1986).

Quoted in *Cohn v. Wilkes Gen. Hosp.*, 127 F.R.D. 117 (W.D.N.C. 1989).

Part A. Hospital Licensure.

§ 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 hospital operations 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.

(e) The Department shall issue the license to the operator of the hospital who shall not transfer or assign it except with the written approval of the Department.

(f) The operator shall post the license on the licensed premises in an area accessible to the public. (1947, c. 933, s. 6; 1949, c. 920, ss. 3, 4; 1963, c. 66; 1973, c. 476, s. 152; c. 1090, s. 1; 1975, c. 718, s. 2; 1983, c. 775, s. 1.)

§ 131E-78. Adverse action on a license.

(a) The Department shall have the authority to deny, suspend, revoke, annul, withdraw, recall, cancel, or amend a license in any case when it finds a substantial failure to comply with the provisions of this Part or any rule promulgated under this Part.

(b) The Department shall conduct a hearing in accordance with Chapter 150B of the General Statutes, the Administrative Procedure Act, when:

(1) The Department denies an application and the applicant requests a hearing; or

(2) The Department initiates proceedings under subsection (a).

(c) Any applicant or operator who is dissatisfied with the decision of the Department as a result of the hearing provided in this section

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and after a written copy of the decision is served, may request a judicial review under Chapter 150B of the General Statutes, the Administrative Procedure Act. (1947, c. 933, s. 6; 1973, c. 476, s. 152; c. 1090, s. 1; 1981, c. 614, ss. 16, 17; 1983, c. 775, s. 1; 1987, c. 827, s. 1.)

§ 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. (1947, c. 933, s. 6; 1973, c. 476, s. 152; 1983, c. 775, s. 1.)

§ 131E-79.1. Counseling patients regarding prescriptions.

(a) Any hospital or other health care facility licensed pursuant to this Chapter or Chapter 122C of the General Statutes, health maintenance organization, local health department, community health center, medical office, or facility operated by a health care provider licensed under Chapter 90 of the General Statutes, providing patient counseling by a physician, a registered nurse, or any other appropriately trained health care professional shall be deemed in compliance with the rules adopted by the North Carolina Board of Pharmacy regarding patient counseling.

(b) As used in this section, "patient counseling" means the effective communication of information to the patient or representative in order to improve therapeutic outcomes by maximizing proper use of prescription medications and devices. (1993, c. 529, s. 7.7.)

Editor's Note. — Session Laws 1993, c. 529, s. 7.9 makes this section effective July 1, 1994.

Session Laws 1993, c. 529, s. 8.1 is a severability clause.

§ 131E-80. Inspections.

(a) The Department shall make or cause to be made inspections as it may deem necessary. Any hospital licensed under this Part shall at all times be subject to inspections by the Department according to the rules of the Commission.

(b) The Department may delegate to any state officer or agency the authority to inspect hospitals. The Department may revoke this delegated authority at its discretion and make its own inspections.

(c) Authorized representatives of the Department shall have at all times the right of proper entry upon any and all parts of the premises of any place in which entry is necessary to carry out the provisions of this Part or the rules adopted by the Commission; and it shall be unlawful for any person to resist a proper entry by such authorized representative upon any premises other than a private dwelling. However, no representative shall, by this entry onto the premises, endanger the health or well being of any patient being treated in the hospital.

(d) (Effective October 1, 1994 — See editor's note) To enable the Department to determine compliance with this Part and the rules promulgated under the authority of this Part and to investi-

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gate complaints made against a hospital licensed under this Part, while maintaining the confidentiality of the complainant, the Department shall have the authority to review any writing or other record in any recording medium which pertains to the admission, discharge, medication, treatment, medical condition, or history of persons who are or have been patients of the hospital licensed under this Part and the personnel records of those individuals employed by the licensed hospital. The examinations of these records is permitted notwithstanding the provisions of G.S. 8-53, "Communications between physician and patient," or any other provision of law relating to the confidentiality of communications between physician and patient. Proceedings of medical review committees are exempt from the provisions of this section. The hospital, its employees, and any person interviewed during these inspections shall be immune from liability for damages resulting from the disclosure of any information to the Department. Any confidential or privileged information received from review of records or interviews shall be kept confidential by the Department and not disclosed without written authorization of the patient, employee or legal representative, or unless disclosure is ordered by a court of competent jurisdiction. The Department shall institute appropriate policies and procedures to ensure that this information shall not be disclosed without authorization or court order. The Department shall not disclose the name of anyone who has furnished information concerning a hospital without the consent of that person. Any officer, administrator, or employee of the Department who willfully discloses confidential or privileged information without appropriate authorization or court order shall be guilty of a Class 3 misdemeanor and upon conviction shall only be fined in the discretion of the court but not in excess of five hundred dollars (\$500.00). Neither the names of persons furnishing information nor any confidential or privileged information obtained from records or interviews shall be considered "public records" within the meaning of G.S. 132-1, "Public Records" defined.

(e) Information received by the Commission and the Department through filed reports, license applications, or inspections that are required or authorized by the provisions of this Part, may be disclosed publicly except where this disclosure would violate the confidential relationship existing between physician and patient. However, no such public disclosure shall identify the patient involved without permission of the patient or court order. (1947, c. 933, s. 6; 1973, c. 476, s. 152; c. 1090, s. 1; 1981, c. 586, s. 3; 1983, c. 775, s. 1; 1993, c. 539, s. 957; 1994, Ex. Sess., c. 24, s. 14(c).)

Editor's Note. — Session Laws 1993, c. 539, which amended this section, in s. 1359, as amended by Session Laws 1994, Extra Session, c. 24, s. 14(c), provides: "This act becomes effective October 1, 1994, and applies to offenses occurring on or after that date. Prosecutions for offenses committed before the effective date of this act are not abated or affected by this act, and the statutes that would

be applicable but for this act remain applicable to those prosecutions."

Effect of Amendments. — The 1993 amendment, effective October 1, 1994, and applicable to offenses occurring on or after that date, inserted "Class 3" preceding "misdemeanor" and inserted "only" following "shall" in the next-to-last sentence of subsection (d).

§ 131E-81. (Effective October 1, 1994 — See editor's note) Penalties.

(a) Any person establishing, conducting, managing, or operating any hospital without a license shall be guilty of a Class 3 misdemeanor, and upon conviction shall only be liable for a fine of not more than fifty dollars (\$50.00) for the first offense and not more than five hundred dollars (\$500.00) for each subsequent offense. Each day of a continuing violation after conviction shall be considered a separate offense.

(b) Except as otherwise provided in this Part, any person who willfully violates any provision of this Part or who willfully fails to perform any act required, or who willfully performs any act prohibited by this Part, shall be guilty of a Class 1 misdemeanor. However, any person who willfully violates any rule adopted by the Commission under this Part or who willfully fails to perform any act required by, or who willfully does any act prohibited by, these rules shall be guilty of a Class 3 misdemeanor. (1947, c. 933, s. 6; 1983, c. 775, s. 1; 1993, c. 539, s. 958; 1994, Ex. Sess., c. 24, s. 14(c).)

Editor's Note. — Session Laws 1993, c. 539, which amended this section, in s. 1359, as amended by Session Laws 1994, Extra Session, c. 24, s. 14(c), provides: "This act becomes effective October 1, 1994, and applies to offenses occurring on or after that date. Prosecutions for offenses committed before the effective date of this act are not abated or affected by this act, and the statutes that would be applicable but for this act remain applicable to those prosecutions."

Effect of Amendments. — The 1993 amendment, effective October 1, 1994, and applicable to offenses occurring on or after that date, inserted "Class 3" pre-

ceding "misdemeanor" and "only" following "shall" in the first sentence of subsection (a), substituted "Class 1 misdemeanor" for "misdemeanor and upon conviction thereof shall be punished by a fine or by imprisonment for a period not to exceed two years or by both such fine and imprisonment in the discretion of the court" in the first sentence of subsection (b), and substituted "Class 3 misdemeanor" for "misdemeanor and upon conviction shall be punished by a fine not to exceed fifty dollars (\$50.00) or by imprisonment for a period not to exceed 30 days" in the last sentence of subsection (b).

§ 131E-82. Injunction.

(a) Notwithstanding the existence or pursuit of any other remedy, the Department may, in the manner provided by law, maintain an action in the name of the State for injunction or other process against any person or governmental unit to restrain or prevent the establishment, conduct, management or operation of a hospital without a license.

(b) If any person shall hinder the proper performance of duty of the Secretary or a representative in carrying out the provisions of this Part, the Secretary may institute an action in the superior court of the county in which the hindrance occurred for injunctive relief against the continued hindrance, irrespective of all other remedies at law.

(c) Actions under this section shall be in accordance with Article 37 of Chapter 1 of the General Statutes, and Rule 65 of the Rules of Civil Procedure. (1947, c. 933, s. 6; 1973, c. 476, s. 152; 1983, c. 775, s. 1.)

§§ 131E-83, 131E-84: Reserved for future codification purposes.

Part B. Hospital Privileges.

§ 131E-85. Hospital privileges and procedures.

(a) The granting or denial of privileges to practice in hospitals to physicians licensed under Chapter 90 of the General Statutes, Article 1, dentists and podiatrists and the scope and delineation of such privileges shall be determined by the governing body of the hospital on a non-discriminatory basis. Such determinations shall be based upon the applicant's education, training, experience, demonstrated competence and ability, and judgment and character of the applicant, and the reasonable objectives and regulations of the hospital, including, but not limited to appropriate utilization of hospital facilities, in which privileges are sought. Nothing in this Part shall be deemed to mandate hospitals to grant or deny to any such individuals or others privileges to practice in hospitals, or to offer or provide any type of care.

(b) The procedures to be followed by a licensed hospital in considering applications of dentists and podiatrists for privileges to practice in such hospitals shall be similar to those applicable to applications of physicians licensed under Chapter 90 of the General Statutes, Article 1. Such procedures shall be available upon request.

(c) In addition to the granting or denial of privileges, the governing body of each hospital may suspend, revoke, or modify privileges.

(d) All applicants or individuals who have privileges shall comply with all applicable medical staff bylaws, rules and regulations, including the policies and procedures governing the qualifications of applicants and the scope and delineation of privileges.

(e) The Department shall not issue or renew a license under this Article unless the applicant has demonstrated that the procedures followed in determining hospital privileges are in accordance with this Part and rules of the Department. (1981, c. 659, s. 10; 1983, c. 775, s. 1; 1987, c. 859, s. 18; 1989, c. 446.)

CASE NOTES

Reasonableness of Qualifications Is Only Question Before Court. — The court is charged with the narrow responsibility of assuring that the qualifications imposed by the board are reasonably related to the operation of the hospital and fairly administered. In short, so long as staff selections are administered with fairness, geared by a rationale compatible with hospital responsibility, and unencumbered with irrelevant considerations, a court should not interfere. *Cameron v. New Hanover Mem. Hosp.*, 58 N.C. App. 414, 293 S.E.2d 901, cert. denied, 307 N.C. 127, 297 S.E.2d 399 (1982), decided under former §§ 131-126.11A, 131-126.11B.

No court should substitute its eval-

uation for that of the hospital board. It is the board, not the court, which is charged with the responsibility of providing a competent staff of doctors. *Cameron v. New Hanover Mem. Hosp.*, 58 N.C. App. 414, 293 S.E.2d 901, cert. denied, 307 N.C. 127, 297 S.E.2d 399 (1982), decided under former §§ 131-126.11A, 131-126.11B.

A hospital's governing body has statutory authority to make decisions concerning the scope and range of privileges that will be extended to physicians and others at the hospital. *Cohn v. Wilkes Gen. Hosp.*, 767 F. Supp. 111 (W.D. N.C.), aff'd, 953 F.2d 154 (4th Cir. 1991), cert. denied, — U.S. —, 112 S. Ct. 3057, 120 L. Ed. 2d 922 (1992).

Patient's Freedom of Choice Is Subject to Hospital's Staff Privilege Standards. — The right to enjoy hospital staff privileges is not absolute; it is subject to the standards set by the hospital's governing body. This is implicit in the language of § 90-202.12, especially in view of the policy of this State as currently stated by this section. Section 90-202.12 does not require a hospital to grant staff privileges regardless of the standards set by its board of trustees which are reasonably related to the operation of the hospital. Generally, the protection offered by § 90-202.12 is for patients to have the freedom to choose a qualified "provider of care or service." *Cameron v. New Hanover Mem. Hosp.*, 58 N.C. App. 414, 293 S.E.2d 901, cert. denied, 307 N.C. 127, 297 S.E.2d 399 (1982), decided under former §§ 131-126.11A, 131-126.11B.

Medical Practitioner's Right to Have Application for Staff Privileges Considered by Hospital. — A medical practitioner is not granted the right to have his application for staff privileges considered by a hospital if the hospital's governing board has made a decision to deny further staff privilege requests which is reasonably related to the operation of the hospital, is consistent with its responsibility as a community hospital, and is administered fairly; however, if the defendant hospital's actions are determined to be unreasonable or irrational, the plaintiff is entitled under this section to have his application for staff privileges reviewed and a decision, granting or denying him staff privileges, based on the other criteria provided in this section. *Claycomb v. HCA-Raleigh Community Hosp.*, 76 N.C. App. 382, 333 S.E.2d 333 (1985), cert. denied, 315 N.C. 586, 341 S.E.2d 23 (1986), decided under former § 131-126.11A.

Hospital Board's Discretion Regarding Chiropractors. — The legislature did not intend to take away the discretion afforded hospital boards to make decisions regarding health care providers not included in subsection (a) of

this section, such as chiropractics. *Cohn v. Wilkes Regional Medical Ctr.*, 113 N.C. App. 275, 437 S.E.2d 889 (1994).

A board of trustees of a hospital is not a medical review committee, even though the board may review personnel recommendations of the medical review committees and has ultimate decision-making authority upon these recommendations by virtue both of the hospital's bylaws and this section. *Shelton v. Morehead Mem. Hosp.*, 318 N.C. 76, 347 S.E.2d 824 (1986).

Hearing under Subsection (a). — Subsection (a) of this section does not require a hearing if hospital's decision to limit the number of physicians using its equipment is based upon the reasonable objectives required by the statute. *Coastal Neuro-Psychiatric Assocs. v. Onslow Mem. Hosp.*, 795 F.2d 340 (4th Cir. 1986).

Waiver of Irregularities. — A doctor's letter to the chairman of the county hospital authority stating that she was formally withdrawing her application for permanent medical staff privileges and a hearing in relation to the loss of those privileges was effective as a waiver of any procedural irregularities that might have existed in connection with the revoking and failing to renew of her staff privileges. *Paine v. Brunswick County Hosp. Auth.*, 470 F. Supp. 28 (E.D.N.C. 1978), decided under former § 131-22.

Immunity of Hospital from Federal Antitrust Liability. — In restricting privileges to its inhouse radiologists, county hospital complied with this section. If it engaged in anticompetitive activity, it did so under a law passed to promote greater hospital self-governance. The hospital was therefore immune from federal antitrust liability. *Coastal Neuro-Psychiatric Assocs. v. Onslow Mem. Hosp.*, 795 F.2d 340 (4th Cir. 1986).

Cited in *Cooper v. Forsyth County Hosp. Auth.*, 789 F.2d 278 (4th Cir. 1986).

§ 131E-86. Limited privileges.

(a) It shall be unlawful for an individual who is not licensed under Chapter 90 of the General Statutes, Article 1, to admit a patient to a hospital without written proof in accordance with the policy of the governing body of the hospital that a physician licensed under Chapter 90 of the General Statutes, Article 1, who is a member of the medical staff will be responsible for the performance of a basic medical appraisal and for the medical needs of the pa-

tient. The governing body of a hospital may waive this requirement for a dentist licensed under Chapter 90 of the General Statutes, Article 2, to the extent authorized by this statute, who has successfully completed a postgraduate program in oral and maxillofacial surgery accredited by the American Dental Association.

(b) The governing body of each hospital shall not grant privileges that exceed the scope of a license. (1983, c. 775, s. 1.)

§ 131E-87. Reports of disciplinary action; immunity from liability.

The chief administrative officer of each licensed hospital in the State shall report to the appropriate occupational licensing board the details, as prescribed by the board, of any revocation, suspension, or limitation of privileges of a health care provider to practice in that hospital. Each hospital shall also report to the board its medical staff resignations. Any person making a report required by this section shall be immune from any resulting criminal prosecution or civil liability unless the person knew the report was false or acted in reckless disregard of whether the report was false. (1983, c. 775, s. 1; 1987, c. 859, s. 16.)

§§ 131E-88, 131E-89: Reserved for future codification purposes.

Part C. Discharge from Hospital.

§ 131E-90. (Effective October 1, 1994 — See editor's note) Authority of administrator; refusal to leave after discharge.

The case of a patient who refuses or fails to leave the hospital upon discharge by the attending physician shall be reviewed by two physicians licensed to practice medicine in this State, one of whom may be the attending physician. If in the opinion of the physicians, the patient should be discharged as cured or as no longer needing treatment or for the reason that treatment cannot benefit the patient's case or for other good and sufficient reasons, the patient's refusal to leave shall constitute a trespass. The patient shall be guilty of a Class 3 misdemeanor. (1965, c. 258; 1983, c. 775, s. 1; 1993, c. 539, s. 959; 1994, Ex. Sess., c. 24, s. 14(c).)

Editor's Note. — Session Laws 1993, c. 539, which amended this section, in s. 1359, as amended by Session Laws 1994, Extra Session, c. 24, s. 14(c), provides: "This act becomes effective October 1, 1994, and applies to offenses occurring on or after that date. Prosecutions for offenses committed before the effective date of this act are not abated or affected by this act, and the statutes that would be applicable but for this act remain applicable to those prosecutions."

Effect of Amendments. — The 1993 amendment, effective October 1, 1994, and applicable to offenses occurring on or after that date, substituted "Class 3 misdemeanor" for "misdemeanor, and upon conviction shall be punished by a fine not to exceed fifty dollars (\$50.00) or imprisoned not more than 30 days" in the last sentence.

Legal Periodicals. — For survey on the medical review committee privilege, see 67 N.C.L. Rev. 179 (1988).

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.3202 ADMISSION AND DISCHARGE

- (a) Facility management shall provide written admission and discharge, and referral policies.
- (b) There shall be on the premises at all times an employee authorized to receive patients and to make ~~administrative decisions on~~ **arrangements** for their disposition.
- (c) A patient shall be admitted only under the care of a member of the medical staff meeting the provisions of ~~rule .4302 of this Subchapter~~ **Section .3700 of this Subchapter**.
- (d) Facility management shall ~~ensure that~~ **take appropriate** precautions ~~are taken to ensure to~~ **protect** the safety and legal rights of all patients and employees.
- (e) Facility management shall ~~ensure that~~ **maintain** a complete and permanent record ~~is maintained for~~ **of** all outpatients and inpatients including the date and time of admission and discharge. Effort shall be made to verify the full and true name, address, date of birth, nearest of kin, provisional diagnosis, condition on admission and discharge, referring physicians, attending physician or service.
- (f) Facility staff shall provide at the time of admission an identification bracelet, band, or other suitable device for positive identification of each patient.
- (g) No mentally competent adult shall be detained by the facility against his will, ~~except as authorized by law.~~ **nor shall a child be detained against the will of a parent or legal guardian.** ~~This restriction shall not apply to persuasion of the patient in his own interest to consider the possible consequences of his action, nor to the temporary detention of a mentally disturbed patient for the protection of himself and others, pending prompt legal disposition as may be provided for in N. C. Gen. Stat. 122C. Documentation of the commitment process shall be retained for all involuntary commitments in accordance with the provisions of Section .4503 of this Subchapter.~~

History Note: Statutory Authority G.S. 131E-79;
Eff. May 1, 1995 **September 1, 1995.**

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10 NCAC .3203 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1777 as follows with changes:

.3203 DISCHARGE PLANNING

(a) ~~Facility management shall ensure that discharge planning is~~ Discharge planning shall be an integral part of in-patient hospitalization.

(b) Facility management shall have written policies and procedures governing discharge planning. These shall include but need not be limited to the following:

- (1) appropriate screening to determine the need for discharge planning;
- (2) methods to facilitate the provision of follow-up care;
- (3) information to be given to the patient or his family or other persons involved in caring for the patient on matters such as the patient's condition; his health care needs; the amount of activity he should engage in; any necessary medical regimens including drugs, nutrition therapy, appointments or other forms of therapy; sources of additional help from other agencies; and procedures to follow in case of complications; and
- (4) procedures for assisting the patient and his family in gaining information regarding financial assistance in paying bills incurred as a result of the hospitalization, including how to receive assistance from the various federal and State government programs.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .3204 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1777 as follows with changes:

.3204 TRANSFER AGREEMENT

(a) Any facility which does not provide hospital based nursing facility service shall maintain written agreements with institutions offering this kind of care. Such agreements shall provide for the transfer and admission of patients who no longer require the services of the hospital but do require nursing facility services.

(b) A patient shall not be transferred to another medical care facility unless prior arrangements for admission have been made. Clinical records of sufficient content to ~~insure~~ **provide** continuity of care shall accompany the patient.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995**

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .3205

RECOMMENDATION:

Object, based on

Lack of
Statutory
authority

X Unclear,
ambiguous

Unnecessary

COMMENT: It is unclear who constitutes a "responsible party."

Joseph J. DeLuca, Jr.
Staff Director

10 NCAC .3205 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1777 as follows:

.3205 DISCHARGE OF MINOR OR INCOMPETENT

Any individual who cannot legally consent to his own care shall be discharged only to the custody of parents, legal guardian, person standing in loco parentis, or another responsible party unless otherwise directed by the parent or guardian or court of competent jurisdiction. If the parent or guardian directs that discharge be made otherwise, he shall so state in writing, and the statement shall become a part of the permanent medical record of the patient.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .3301 is adopted as published in the N.C. Register Volume 21, Issue 9, pages 1777-1778 as follows:

SECTION .3300 PATIENT'S BILL OF RIGHTS

.3301 PRINCIPLE

It is the purpose of these requirements to promote the interests and well-being of the patients in facilities subject to this Subchapter even in those instances where the interests of the patients may be in opposition to the interests of the facility. The facility has the right to expect the patient to fulfill patient responsibilities as may be stated in the facilities' policies affecting patient care and conduct.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .3302

RECOMMENDATION:

Object, based on

Lack of
Statutory
authority

X Unclear,
ambiguous

Unnecessary

COMMENT: The requirement in (d) to maintain the confidentiality of records (and presumably that would include verbal communication of the contents of those records) would seem to conflict with the requirement in (h) to tell third persons about the patient's condition. The problem could be corrected by allowing it to be communicated to the patient's designee, as set out in (o). That paragraph (o) probably makes (h) unnecessary.

In (q) it is unclear what constitutes "needless" and from whose point of view. This would be especially true in a teaching hospital where every second or third person is asking or checking the same item over again.

Joseph J. DeLuca, Jr.
Staff Director

.3302 MINIMUM PROVISIONS OF PATIENT'S BILL OF RIGHTS

- (a) A patient has the right to respectful care given by competent personnel.
- (b) A patient has the right, upon request, to be given the name of his attending physician, the names of all other physicians directly participating in his care, and the names and functions of other health care persons having direct contact with the patient.
- (c) A patient has the right to every consideration of his privacy concerning his own medical care program. Case discussion, consultation, examination, and treatment are considered confidential and should be conducted discreetly.
- (d) A patient has the right to have all records pertaining to his medical care treated as confidential except as otherwise provided by law or third party contractual arrangements.
- (e) A patient has the right to know what facility rules and regulations apply to his conduct as a patient.
- (f) The patient has the right to expect emergency procedures to be implemented without unnecessary delay.
- (g) The patient has the right to good quality care and high professional standards that are continually maintained and reviewed.
- (h) The patient has the right to full information in laymen's terms, concerning his diagnosis, treatment and prognosis, including information about alternative treatments and possible complications. When it is not possible or medically advisable to give such information to the patient, the information shall be given on his behalf to the patient's next of kin or other appropriate person.
- (i) Except for emergencies, the physician must obtain the necessary informed consent prior to the start of any procedure or treatment, or both.
- (j) A patient has the right to be advised when a physician is considering the patient as a part of a medical care research program or donor program. Informed consent must be obtained prior to actual participation in such program and the patient or legally responsible party, may, at any time, refuse to continue in any such program to which he has previously given informed consent.
- (k) A patient has the right to refuse any drugs, treatment or procedure offered by the facility, to the extent permitted by law, and a physician shall inform the patient of his right to refuse any drugs, treatment or procedures and of the medical consequences of the patient's refusal of any drugs, treatment or procedure.
- (l) A patient has the right to assistance in obtaining consultation with another physician at the patient's request and expense.
- (m) A patient has the right to medical and nursing services without discrimination based upon race, color, religion, sex, sexual preference, national origin or source of payment.
- (n) A patient who does not speak English shall have access, when possible, to an interpreter.
- (o) The facility shall provide the patient, or patient designee, upon request, access to all information contained in his medical records, unless access is specifically restricted by the attending physician. If the physician restricts the patients' access to information in his medical record, the physician shall record the reasons on the patient's medical record. Access shall be restricted only for sound medical reason.
- (p) ~~The resting patient has the right to expect management techniques to be implemented within the facility considering effective use of the time of the patient and to avoid the personal discomfort of the patient.~~ A patient has the right not to be awakened by hospital staff unless it is medically necessary.
- (q) The patient has the right to be free from needless duplication of medical and nursing procedures.
- (r) The patient has the right to medical and nursing treatment that avoids unnecessary physical and mental discomfort.
- (s) When medically permissible, a patient may be transferred to another facility only after he or his next of kin or other legally responsible representative has received complete

information and an explanation concerning the needs for and alternatives to such a transfer. The facility to which the patient is to be transferred must first have accepted the patient for transfer.

(+) (t) The patient has the right to examine and receive a detailed explanation of his bill.

(+) (u) The patient has a right to full information and counseling on the availability of known financial resources for his health care.

(+) (v) A patient has the right to expect that the facility will provide a mechanism whereby he is informed upon discharge of his continuing health care requirements following discharge and the means for meeting them.

(+) (w) A patient cannot be denied the right of access to an individual or agency who is authorized to act on his behalf to assert or protect the rights set out in this section.

(+) (x) A patient has the right to be informed of his rights at the earliest possible time in the course of his hospitalization.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

.3303 PROCEDURE

(a) Facility management shall develop and implement procedures to inform each patient of his rights. Copies of the facilities' Patient's Bill of Rights shall be made available through one of the following ways:

(1) prominent displays in appropriate locations in addition to copies available upon request;
or

(2) provision of a copy to each patient or responsible party upon admission or as soon after admission as is feasible.

(b) The address and telephone number of the section in the Department responsible for the enforcement of the provisions of this part shall be posted.

(c) Facility management shall adopt procedures to ensure effective and fair investigation of violations of patients' rights and to ensure their enforcement. These procedures shall ensure that:

(1) a system is established to identify formal written complaints;

(2) formal written complaints are recorded and investigated;

(3) investigation and resolution of formal complaints shall be conducted; and

(4) disciplinary and education procedures shall be developed for members of the hospital and medical staff who consistently cause patient relationship problems. ~~are non-compliant with facility policies.~~

(d) The Division shall investigate or refer to appropriate State agencies all complaints within the jurisdiction of the rules in this Subchapter.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .3401 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1779 as follows:

**SECTION .3400 SUPPLEMENTAL RULES FOR THE LICENSURE OF
DESIGNATED PRIMARY CARE HOSPITALS AND FEDERALLY
CERTIFIED PRIMARY CARE HOSPITALS**

.3401 SUPPLEMENTAL RULES

The rules of this Section pertain only to designated Primary Care Hospitals or Federally Certified Primary Care Hospitals. The general requirements of this Subchapter shall apply to such facilities except where they are specifically waived or modified by the rules of this Section.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995

.3402 DEFINITIONS

The following definitions shall apply throughout this Section, unless text otherwise clearly indicates to the contrary:

- (1) "Available" means provided directly by the facility or by written agreement with a qualified provider of the service within one hour.
- (2) "Designated Primary Care Hospital" means a facility designated by the North Carolina Office of Rural Health and Resource Development in accordance with N. C. Gen. Stat. 131E-76(6).
- (3) "Federally Certified Primary Care Hospital" means a hospital which has been designated and certified as a Federally Certified Rural Primary Care Hospital under the Essential Access Community Hospital Program administered through the North Carolina Office of Rural Health and Resource Development in accordance with P.L. 101-239 and P.L. 101-508.
- (4) "Primary Care Inpatient Services" means that the hospital provides acute care inpatient services appropriate to the level of service at the facility up to a maximum annual average daily census of 15 patients per day. In addition, the facility may also provide long term care in "swing bed" or distinct part status and psychiatric distinct part beds.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995

10 NCAC .3403 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1779 as follows:

.3403 LICENSURE APPLICATION

An application from a facility seeking to be licensed under the rules of this Section must be accompanied by written certification from the North Carolina Office of Rural Health and Resource Development that the facility is a Designated Primary Care Hospital or a Federally Certified Primary Care Hospital.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .3404 is adopted as published in the N.C. Register Volume 21, Issue 9, pages 1779-1780 as follows:

.3404 FEDERALLY CERTIFIED PRIMARY CARE HOSPITAL

(a) The requirements of 10 NCAC 3C .3500 through .5206 shall be waived for a facility which the North Carolina Office of Rural Health and Resource Development certified as a designated Federally Certified Primary Care Hospital, and Rule .6227 (f) and (g) of that Subchapter shall not apply to such facilities which do not provide emergency room service or maintain any life support systems.

(b) The Division reserves the right to conduct any validation survey or investigation of a specific complaint in facilities which choose to be licensed as a Federally Certified Primary Care Hospital.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

.3405 DESIGNATED PRIMARY CARE HOSPITALS

The requirements of 10 NCAC 3C shall apply to Designated Primary Care Hospitals with the following modifications:

- (1) Autopsy facilities required in rule .4907 of this Subchapter are not required for a Designated Primary Care Hospital, provided that the facility has in effect a written agreement with another facility meeting rule .4907 of this Subchapter for providing autopsy services.
- (2) Radiological services required in Section .4800 of this Subchapter are not required for Designated Primary Care Hospitals provided that the facility has radiological equipment on site and a written agreement with another licensed facility meeting the requirements of Section .4800 of this Subchapter which makes radiological service available.
- (3) Emergency services required in Section .4100 of this Subchapter are not required for Designated Primary Care Hospitals. Medical staff of a Designated Primary Care Hospital shall assure that ~~participate in training~~ facility personnel ~~in are capable of~~ initiating life-saving measures at a first-aid level of response for any patient or person in need of such services. This shall include:
 - (a) Establishing protocols or agreements with any facility providing emergency services;
 - (b) Initiating basic cardio-respiratory resuscitation according to the American Red Cross or American Heart Association standards;
 - (c) Availability of ~~inter-venious~~ ~~intravenous~~ fluids and supplies required to establish ~~inter-venious~~ ~~intravenous~~ access; and
 - (d) Availability of first-line emergency drugs as specified by the medical staff.
- (4) Anesthesia services required in Section .4600 of this Subchapter are not required in Designated Primary Care Hospitals not offering outpatient surgery services.
- (5) Food services required in Section .4700 of this Subchapter shall be provided for inpatients of Designated Primary Care Hospitals either directly or made available through contractual arrangements.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ ~~September 1, 1995~~.

SECTION .3500 GOVERNANCE AND MANAGEMENT

.3501 GOVERNING BODY

(a) The governing body, owner or the person or persons designated by the owner as the governing authority shall be responsible for seeing that the objectives specified in the charter (or resolution if publicly owned) are attained.

(b) The governing body shall be the final authority in the facility to which the administrator, the medical staff, the personnel and all auxiliary organizations are directly or indirectly responsible.

(c) A local advisory board shall be established if the facility is owned or controlled by an organization or persons outside of North Carolina.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .3502

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited for DFS to either require a business entity to enact bylaws or to specify what goes into state required corporate bylaws. That is governed, for a corporation, by other N.C. corporate (profit or not-for-profit) law.

Joseph J. DeLuca, Jr.
Staff Director

30A

.3502 BYLAWS

(a) The governing body shall adopt bylaws in accordance with all requirements contained in this subchapter and in accordance with the community responsibility of the facility. As a minimum, the bylaws shall do the following:

- (1) state the general and specific goals of the facility;
 - (2) describe the powers and duties of the governing body officers and committees and the responsibilities of the chief executive officer;
 - (3) state the qualifications for governing body membership, the procedures for selecting members, and the terms of service for members, officers and committee chairmen;
 - (4) describe the authority delegated to the chief executive officer and to the medical staff. No assignment, referral, or delegation of authority by the governing body shall relieve the governing body of its responsibility for the conduct of the facility. The governing body shall retain the right to rescind any such delegation;
 - (5) require Board approval of the bylaws of any auxiliary organizations established by the hospital;
 - (6) require the governing body to review and approve the bylaws of the medical staff organization;
 - (7) establish a procedure for processing and evaluating the applications for medical staff membership and for the granting of clinical privileges;
 - (8) establish a procedure for implementing, disseminating, and enforcing a Patient's Bill of Rights in compliance with N. C. Gen. Stat. 131E-117; and as described in Section .3302 of this Subchapter and in compliance with N.C. Gen Stat. 131E-117 where applicable;
 - (9) require the governing body to institute procedures to ~~ensure~~ provide for:
 - (A) orientation of newly elected board members to specific board functions and procedures;
 - (B) the development of procedures for periodic reexamination of the relationship of the board to the total facility community; and
 - (C) the recording of minutes of all governing body and executive committee meetings and the dissemination of those minutes, or summaries thereof, on a regular basis to all members of the governing body.
- (b) The bylaws shall be reviewed at least every three years, revised as necessary, and dated to indicate when last reviewed or revised.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995

.3503 FUNCTIONS

The governing body, ~~with technical assistance and advice from the facility staff, shall~~ be responsible for the following:

- (1) provide management, physical resources and personnel required to meet the needs of the patients for which it is licensed;
- (2) require management to establish a quality control mechanism which includes as an integral part a risk management component and an infection control program;
- (3) formulate short-range and long-range plans for the development of the facility;
- (4) conform to all applicable federal, State and local laws and regulations;
- (5) provide for the control and use of the physical and financial resources of the facility;
- (6) review the annual audit, budget and periodic reports of the financial operations of the facility;
- (7) ~~utilize~~ **consider** the advice of the medical staff in granting and defining the scope of clinical privileges to individuals. When the governing body does not concur in the medical staff recommendation regarding the clinical privileges of an individual, there shall be a review of the recommendation by a joint committee of the medical staff and governing body before a final decision is reached by the governing body;
- (8) require that applicants be informed of the disposition of their application for medical staff membership or clinical privileges, or both, within an established period of time after their application has been submitted;
- (9) review and approve the medical staff bylaws, rules and regulations body;
- (10) delegate to the medical staff the authority to evaluate the professional competence of staff members and applicants for staff privileges and hold the medical staff responsible for recommending initial staff appointments, reappointments and assignments or curtailments of privileges;
- (11) require that resources be made available to address the emotional and spiritual needs of patients either directly or through referral or arrangement with community agencies;
- (12) maintain effective communication with the medical staff which shall be established, through:
 - (A) meetings with the Executive Committee of the Medical Staff;
 - (B) service by the president of the medical staff as a member of the governing body with or without a vote;
 - (C) appointment of individual medical staff members to governing body committees;
~~and or~~
 - (D) a joint conference committee.
- (13) require the medical staff to establish controls that are designed to ~~ensure~~ **provide that** standards of ethical professional practices ~~are met~~;
- (14) ~~ensure that the medical staff is provided with~~ **provide** the necessary staff support to facilitate utilization review and infection control within the facility and to support quality control, any other medical staff functions required by this subchapter or by the facility bylaws;
- (15) ~~ensure that meet~~ the following public disclosure requirements ~~are being met~~:
 - (A) ~~provide~~ data required by the North Carolina Medical Data Base Commission and the Division;
 - (B) ~~disclose the facilities' facility's~~ average daily inpatient charge upon request ~~of the Division~~; and
 - (C) ~~public disclosure~~ **disclose** of the ~~identity of~~ persons owning 5.0 percent or more of the facility as well as the ~~facilities facility's~~ officers and members of the governing body ~~upon request~~.
- (16) establish a procedure for reporting the occurrence and disposition of any unusual incidents; ~~which will assure that~~ **These procedures shall require that:**

- (A) incident reports are analyzed and summarized; and
- (B) corrective action is taken as indicated by the analysis of incident reports;
- (17) in a facility with one or more units, or portions of units, however described, utilized for psychiatric or substance abuse treatment adopt policies implementing the provisions of N. C. Gen. Stat. 122C, Article 3, and Article 5, Parts, 2, 3, 4, 5, 7, and 8;
- (18) develop arrangements for the provision of extended care and other long-term healthcare services. Such services shall be provided in the facility or by outside resources through a transfer agreement or referrals;
- (19) provide and implement a written plan for the care or for the referral, or for both, of patients who require mental health or substance abuse services while in the hospital;
- (20) develop a conflict of interest policy which shall apply to all governing body members and corporate officers. All governing body members shall execute a conflict of interest statement;
- (21) ~~ensure~~ ~~prohibit~~ members of the governing body ~~shall not engage from engaging~~ in the following forms of self-dealing:
 - (A) the sale, exchange or leasing of property ~~of~~ or services between the facility and a governing board member, his employer or an organization substantially controlled by him on a basis less favorable to the facility than that on which such property or service is made available to the general public;
 - (B) furnishing of goods, services or facilities by a facility to a governing board member, unless such furnishing is made on a basis not more favorable than that on which such goods, services, or facilities are made available to the general public or employees of the facility; or
 - (C) any transfer to or use by or for the benefit of a governing board member of the income or assets of a facility, except by purchase for fair market value; and
- (22) prohibit the lease, sale, or exclusive use of any facility buildings or facilities receiving a license in accordance with this subchapter to any entity which provides medical or other health services to the facility's patients, unless there is full, complete disclosure to and approval from the Division.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ ~~September 1, 1995~~.

10 NCAC .3601 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1782 as follows:

SECTION .3600 MANAGEMENT AND ADMINISTRATION OF OPERATIONS

.3601 CHIEF EXECUTIVE OFFICER

The governing body shall designate a chief executive officer whose qualifications, authority, responsibilities and duties shall be defined in a written statement adopted by the governing body.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .3602

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited for the agency to dictate how a business entity (the hospital) should manage its internal affairs, i.e. who is responsible for those functions.

Even if they have the authority, it would seem that that would be limited to requiring the hospital to deal with each item and perhaps designate who is to handle it.

Joseph J. DeLuca, Jr.
Staff Director

.3602 RESPONSIBILITIES

- (a) The chief executive officer shall be the designated representative of the governing body.
- (b) The chief executive officer shall:
 - (1) designate an individual to act for him in his absence;
 - (2) manage the facility commensurate with the authority conferred on him by the governing body and consonant with its expressed aims and policies;
 - (3) attend meetings of the governing body and appropriate meetings of the medical staff;
 - (4) ~~implementation of~~ **implement** policies adopted by the governing body for the operation of the facility;
 - (5) organize the administrative functions of the facility, delegate duties and establish formal means of accountability on the part of subordinates;
 - (6) establish such facility departments as are indicated, provide for departmental and interdepartmental meetings and attend or be represented at such meetings, and appoint hospital departmental representatives to medical staff committees where appropriate or when requested to do so by the medical staff;
 - (7) appoint the heads of administrative departments;
 - (8) report to the governing body and to the medical staff on the overall activities of the facility as well as on appropriate federal, State and local developments that affect health care in the facility;
 - (9) review the annual audit of the financial operations of the facility and acting upon recommendations therein;
 - (10) provide fiscal planning and financial management of the facility including the provision of annual budgets and periodic financial status reports to the governing board;
 - (11) develop in cooperation with the departmental heads and other appropriate staff, an overall organizational plan for the facility which will coordinate the functions, services and departments of the facility, when possible; and
 - (12) ~~ensure~~ **require** that the agreements with service providers, such as laundry, laboratory and imaging, specifically indicate that compliance will be maintained with applicable State rules as would apply to the same services if provided directly by the facility.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995**.

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .3603

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority for requiring the C.E.O. to set these personnel policies. They do have the authority to require the hospital facility in general, or the governing body in particular to develop these policies.

Joseph J. DeLuca, Jr.
Staff Director

10 NCAC .3603 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1783 as follows with changes:

.3603 PERSONNEL POLICIES AND PRACTICES

The chief executive officer shall ~~ensure that~~ **develop, establish and maintain** personnel policies and practices which support sound patient care ~~are established and maintained~~. The policies shall be in writing and made available to all employees, and they shall be reviewed periodically but no less often than once every three years. The date of the most recent review shall be indicated on the written policies. A procedure shall be established for notifying employees of changes in the established personnel policies.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995**

10 NCAC .3604 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1783 as follows with changes:

.3604 JOB DESCRIPTIONS

Facility management shall ~~ensure that~~ develop and make available to the employee a written job description for each type of job in the facility, including the chief executive officer and heads of departments, ~~is developed and made available to the employee.~~

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

.3605 PERSONNEL RECORDS

(a) Facility management shall maintain accurate and complete personnel records for each facility employee during his ~~the~~ term of employment and for two years thereafter. The chief executive officer may designate an individual to carry out this assignment.

(b) Personnel records shall ~~be maintained under such conditions as may be required by state or federal law and shall~~ contain at least the following:

- (1) information regarding the employee's education, training and experience ~~and clinical competence~~, including, if applicable, professional licensure status and license number, sufficient to verify the employee's qualifications for the job for which he is employed. Such information shall be kept current. Applicants for positions requiring a licensed person shall be hired only after obtaining verification of their licenses from the appropriate board;
- (2) current information relative to periodic work performance evaluations;
- (3) records of such pre-employment health examinations and of subsequent health services rendered to the employees as are necessary to ~~ensure~~ ~~determine~~ that all facility employees are physically able to perform their ~~the essential~~ duties of their positions; and
- (4) reports verifying that reasonable precautions have been taken to ~~ensure the absence of~~ ~~protect against~~ detectable active communicable diseases as defined by the North Carolina Department of Environment, Health and Natural Resources.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995

10 NCAC .3606 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1783 as follows:

.3606 EDUCATION PROGRAMS

Facility management shall provide new employee orientation and continuing education programs for all employees to maintain the skills necessary for the performance of their duties and learn new developments in health care. Records shall be maintained of all orientation and educational programs, and of the participants.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .3607

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

X Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited to set personnel qualifications.

It is also unclear what constitutes "medically acceptable criteria."

Joseph J. DeLuca, Jr.
Staff Director

39A

10 NCAC .3607 is adopted as published in the N.C. Register Volume 21, Issue 9, pages 1783-1784 as follows:

.3607 PERSONNEL HEALTH REQUIREMENTS

Employees shall have pre-employment medical examinations and interim examinations in accordance with medically acceptable criteria.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .3608

RECOMMENDATION:

Object, based on

Lack of
Statutory
authority

X Unclear,
ambiguous

Unnecessary

COMMENT: There is no indication what constitutes "adequate" insurance or "appropriate" coverage. The definition of "appropriate" in .3001 refers to persons.

Joseph J. DeLuca, Jr.
Staff Director

40A

10 NCAC .3608 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1784 as follows:

.3608 INSURANCE

The governing board shall have in place an insurance program which provides for the protection of the physical and financial resources of the facility. There shall be appropriate coverage of the building and equipment and adequate comprehensive liability insurance or an equivalent self-insurance plan covering members of the governing board and appropriate medical and administrative personnel.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .3609 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1784 as follows:

.3609 AUDIT OF FINANCIAL OPERATIONS

An audit of the financial operations of the facility shall be performed by a public accountant at least once a year.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .3701 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1784 as follows with changes:

SECTION .3700 MEDICAL STAFF

.3701 GENERAL PROVISIONS

The facility shall have an organized medical staff which shall be accountable to the governing body and which shall have responsibility for the quality of professional services provided by individuals with clinical privileges. ~~Facility management shall have a mechanism to ensure that individuals~~ Facility policy shall provide that individuals with clinical privileges shall perform only provide services within the scope of individual privileges granted.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .3702 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1784 as follows:

.3702 COMPOSITION

The medical staff shall be established in accordance with the by-laws, rules and regulations of the medical staff and with the by-laws of the facility. The governing body of the facility, after considering the recommendations of the medical staff, may grant clinical privileges to other qualified, licensed practitioners in accordance with their training, experience, and demonstrated competence and judgment in accordance with the medical staff by-laws.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

.3703 APPOINTMENT AND REAPPOINTMENT

(a) Formal appointment for membership and granting of clinical privileges shall follow established procedures set forth in the by-laws, rules and regulations of the medical staff. These procedures shall require the following:

- (1) a signed application for membership, specifying age, year and school of graduation, date of licensure, statement of postgraduate or special training and experience with a statement of the scope of the clinical privileges sought by the applicant;
- (2) verification by the hospital of the qualifications of the applicant as stated in the application, including evidence of continuing education;
- (3) written notice to the applicant from the medical staff and the governing body, regarding appointment or reappointment which specifies the approval or denial of clinical privileges and the scope of the privileges granted; and
- (4) members of the medical staff and others granted clinical privileges in the facility shall hold current licenses to practice in North Carolina.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .3704

RECOMMENDATION:

Object, based on

Lack of
Statutory
authority

X Unclear,
ambiguous

Unnecessary

COMMENT: It is unclear in other rules whether, where action is required to be taken by the "medical staff" if it is the entire medical staff as set out in this rule, the active medical staff, or some other subgroup determined by the hospital, the staff, or DFS.

Joseph J. DeLuca, Jr.
Staff Director

10 NCAC .3704 is adopted as published in the N.C. Register Volume 21, Issue 9, pages 1784-1785 as follows:

.3704 STATUS

(a) Every facility shall have an active medical staff to deliver medical services within the facility. The active medical staff shall be responsible for its own organization and administration. Every member of the active medical staff shall be eligible to vote at staff meetings and to hold office.

(b) The medical staff shall determine categories for membership which shall be identified and defined in the medical staff bylaws. Examples are:

- (1) active medical staff;
- (2) associate medical staff;
- (3) courtesy medical staff;
- (4) temporary medical staff;
- (5) consulting medical staff;
- (6) honorary medical staff; or
- (7) other staff classifications.

(b) Medical staff appointments shall be reviewed at least once every two years by the governing board.

(c) Facility management shall maintain an individual file for each medical staff member. Representatives of the Department shall have access to these files in accordance with N. C. Gen. Stat. 131E-80.

(d) Minutes of all actions taken by the medical staff and the governing board concerning the privileges granted shall be maintained.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .3705 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1785 as follows:

.3705 MEDICAL STAFF BYLAWS, RULES AND REGULATIONS

(a) The medical staff shall develop and adopt, subject to the approval of the governing body, a set of bylaws, rules and regulations, to establish a framework for self governance of medical staff activities and accountability to the governing body.

(b) The medical staff bylaws, rules and regulations shall provide for at least the following:

- (1) organizational structure;
- (2) qualifications for staff membership;
- (3) procedures for admission, retention, assignment, and reduction or withdrawal of privileges;
- (4) procedures for fair hearing and appellate review mechanisms for denial of staff appointments, reappointments, suspension, or revocation of clinical privileges;
- (5) composition, functions and attendance of standing committees;
- (6) policies for completion of medical records and procedures for disciplinary actions;
- (7) formal liaison between the medical staff and the governing body;
- (8) methods developed to formally verify that each medical staff member on appointment or reappointment agrees to abide by current medical staff bylaws and facility bylaws; and
- (9) procedures for members of medical staff participation in quality assurance functions.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

.3706 ORGANIZATION AND RESPONSIBILITIES OF THE MEDICAL STAFF

(a) The medical staff shall be organized to accomplish its required functions and provide for the election or appointment of its officers.

(b) There shall be an executive committee, or its equivalent, which represents the medical staff, which has responsibility for the effectiveness of all medical activities of the staff, and which acts for the medical staff.

(c) All minutes of proceedings of medical staff committees shall be recorded and available for inspections by members of the medical staff and the governing body.

(d) The following reviews and functions shall be performed by the medical staff:

- (1) credentialing review;
- (2) surgical case review;
- (3) medical records review;
- (4) medical care evaluation review;
- (5) drug utilization review;
- (6) radiation safety review;
- (7) blood usage review; and
- (8) bylaws review.

(e) There shall be medical staff and departmental meetings for the purpose of reviewing the performance of the medical staff, departments or services, and reports and recommendations of medical staff and multi-disciplinary committees. The medical staff shall ensure that minutes are taken at each meeting and retained in accordance with the policy of the facility. These minutes shall reflect the transactions, conclusions and recommendations of the meetings.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

.3707 MEDICAL ORDERS

(a) No medication or treatment shall be administered or discontinued except in response to the order of a member of the medical staff in accordance with established rules and regulations.

(b) Such orders shall be dated and recorded directly in the patient chart or in a computer or data processing system which provides a hard copy printout of the order for the patient chart. A method shall be established to safeguard against fraudulent recordings.

(c) All orders for medication or treatment shall be authenticated at the time of recording by the ordering member of the medical staff except as specified in Paragraph (e) of this rule. Authentication must be accomplished by signature, initials, computer entry or code or other methods not inconsistent with the laws, rules and regulations of any other applicable jurisdictions.

(d) The names of drugs shall be recorded in full and not abbreviated except where approved by the medical staff.

(e) Verbal orders shall be taken and transcribed in the patient's medical record by personnel qualified according to medical staff bylaws and rules. ~~The transcription of medical orders shall be described in the medical staff by laws and departmental policy.~~ The order shall include the date, time, and full signature of the person taking the order and shall be countersigned by a physician within 24 hours. Authentication must be accomplished by signature, initials, computer entry code, or other methods not inconsistent with the laws, rules and regulations of any other applicable jurisdictions.

(f) The medical staff shall establish a written policy in conjunction with the pharmacy committee or its equivalent for all medications not specifically prescribed as to time or number of doses to be automatically stopped after a reasonable time limit, but no more than 14 days. The prescriber shall be notified according to established policies and procedures at least 24 hours before an order is automatically stopped.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .3708 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1786 as follows with changes:

.3708 MEDICAL STAFF RESPONSIBILITIES FOR QUALITY IMPROVEMENT REVIEW

(a) The medical staff shall have in effect a system to review medical services rendered, to assess quality, to provide a process for improving performance when indicated and to monitor the outcome.

(b) The medical staff shall establish criteria for the evaluation of the quality of medical care.

(c) Facility management shall have a written plan approved by the medical staff, administration and governing body which generates reports to permit identification of patient care problems. The plan shall establish a system to use this data to document and identify interventions.

(d) The medical staff shall ~~ensure that there is~~ **establish and maintain** a continuous review process of the care rendered to both inpatients and outpatients in every medical department of the facility. At least quarterly, the medical staff shall have a meeting to ~~review~~ **examine** the ~~review~~ process and results. The review process shall include both practitioners and allied health professionals from the facility staff.

(e) Minutes shall be taken at all meetings reviewing quality improvement, and these minutes shall be made available to the medical staff on a regular basis in accordance with established policy. These minutes shall be retained as determined by the facility.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995.**

SECTION .3800 NURSING SERVICES

.3801 NURSE EXECUTIVE

(a) ~~If 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 and procedures that describe how the nursing care needs of patients are assessed, ~~evaluated and met~~ ~~met and evaluated.~~

(c) The nurse executive shall develop and adopt, subject to the approval of facility management, a set of administrative policies and procedures to establish a framework to accomplish required functions.

(d) There shall be scheduled meetings at least every 60 days of the members of the nursing management 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 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; 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;~~
- (8) ~~assignment of nursing staff to clinical and 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.~~

~~-(f) The nurse executive shall ensure that nursing care services are provided in conformance with the North Carolina Nursing Practice Act.~~

~~-(g) The nurse executive shall ensure that each member of the nursing staff is assigned clinical and or managerial responsibilities based upon educational preparation, in conformance with licensing laws and an assessment of current competence. Orientation and continuing education records shall be maintained.~~

~~-(h) Nurse executives shall ensure that staffing is based on a patient classification system which reflects the number of nursing personnel required for each patient unit.~~

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ ~~September 1, 1995.~~

10 NCAC .3802 is adopted as published in the N.C. Register Volume 21, Issue 9, pages 1786-1787 as follows:

.3802 NURSING STAFF

(a) Licensed nurses and other nursing personnel shall be qualified by training, education, experience and demonstrated abilities to provide nursing care within their scope of practice.

(b) Staffing schedules which reflect personnel assignment by date and service unit shall be kept on file for at least three years by hospital management.

(c) Facility management shall establish policies for the provision of services for all contractual agreement personnel that include at a minimum the following:

- (1) verification of licensure or certification by the appropriate occupational board;
- (2) delivery and documentation of care;
- (3) participation on interdisciplinary care planning activities; and
- (4) supervision of contractual agreement personnel.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995

.3803 NURSING POLICIES AND PROCEDURES

(a) ~~A nurse executive shall ensure that nursing care policies and procedures are available to the nursing staff in each nursing care unit and service area.~~ Nursing policies and procedures shall be available to the nursing staff in each nursing care unit and service area and shall include the following:

- (1) method of noting diagnostic and therapeutic orders;
- (2) method of assigning nursing care of patients;
- (3) infection control measures;
- (4) patient safety measures; and
- (5) method of implementing orders for medication or treatment.

(b) Each unit shall have relevant clinical reference materials available. The following shall be provided to each unit:

- (1) a facility formulary or comparable drug reference;
- (2) a policy and procedure manual; and
- (3) a medical dictionary.

(c) Facility management shall provide a program of inservice education which shall be maintained and documented for all nursing service personnel. Annual inservices shall include infection control measures, cardiopulmonary resuscitation and fire and safety.

(d) Nursing care policies and procedures shall be reviewed at least every three years by the nursing staff and facility management and revised as necessary. They shall include the date to indicate the time of the most recent review or revision.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .3804 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1787 as follows with changes:

.3804 PATIENT CARE

- (a) Each patient's need for nursing care related to his or her admission shall be determined by a registered nurse. Patient needs shall be reassessed when warranted by the patient's condition.
- (b) Each patient's nursing care shall be based upon patient assessed needs and shall be coordinated with the therapies of other disciplines.
- (c) The patient's medical record shall include documentation of:
 - (1) the initial assessment and reassessments of patient clinical status;
 - (2) patient care needs;
 - (3) interventions identified performed to meet the patient's nursing care needs;
 - (4) implementation of physician's orders;
 - (5) the nursing care provided; and
 - (6) the patient's response to, and the outcomes of, the care provided.
- (d) Each plan of care shall be initiated within 24 hours of admission. The plan of care shall become a part of the clinical record.
- (e) The nursing care plan shall be readily available to all physicians and facility personnel involved with the care of the patient.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .3901 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1787 as follows with changes:

SECTION .3900 MEDICAL RECORD SERVICES

.3901 ORGANIZATION

(a) Facility management shall establish a medical record service. It shall be directed, staffed and equipped to ~~ensure the accurate processing, indexing and filing of~~ accurately process, index, and file all medical records. Orientation, on-the-job training and in-service programs for medical records personnel shall be provided.

(b) The medical record service shall be equipped to enable its personnel to maintain medical records so that they are readily accessible and secure from unauthorized use.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .3902

RECOMMENDATION:

Object, based on

- X Lack of
Statutory
authority
- Unclear,
ambiguous
- Unnecessary

COMMENT: There is no authority cited to set standards for
medical records personnel.

Joseph J. DeLuca, Jr.
Staff Director

10 NCAC .3902 is adopted as published in the N.C. Register Volume 21, Issue 9, pages 1787-1788 as follows:

.3902 MANAGER

(a) The medical records service shall be directed and supervised by a qualified medical records manager. If the manager is not a registered record administrator or an accredited records technician, the facility shall retain a person with those qualifications on a part-time or consulting basis.

(b) The manager of the medical record service shall advise, administer, supervise and perform work involved in the development, analysis, maintenance and use of medical records and reports.

(c) Where the manager is employed on a part-time or consulting basis, he or she shall organize the department, train the regular personnel and make periodic visits to the facility. The manager shall evaluate the records and the operation of the service and document the visits by written reports. A written contract specifying his or her duties and responsibilities shall be kept on file and made available for inspection by the Division's surveyor.

(d) The manager of the medical record service shall maintain a system of identification and filing to facilitate the prompt location of medical record of any patient.

(e) The manager of the medical records service shall ensure that medical records are stored in such a manner as to provide protection from loss, damage, and unauthorized access.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

.3903 PRESERVATION OF MEDICAL RECORDS

(a) The manager of medical records service shall ~~ensure that~~ **maintain** medical records, whether original, computer media, or microfilm, ~~be kept on file~~ for a minimum of 11 years following the discharge of an adult patient.

(b) The manager of medical records shall ~~ensure that if the patient is a minor~~ **maintain medical records of a patient who is a minor**, ~~records shall be kept on file until the patient's his 19th 30th birthday, and, then, for 11 years.~~

(c) If a hospital discontinues operation, its management shall make known to the Division where its records are stored. Records are to be stored in a business offering retrieval services for at least 11 years after the closure date.

(d) Prior to destruction, public notice shall be made to permit former patients or their representatives to claim their own records. 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) The manager of medical records may authorize the microfilming of medical records. Microfilming may be done on or off the premises. If done off the premises, the facility shall ~~take precautions to ensure~~ **provide for** the confidentiality and safekeeping of the records. The original of microfilmed medical records shall not be destroyed until the medical records department has had an opportunity to review the processed film for content.

(f) 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 subsection are met and the information is readily available for use in patient care.

(g) All medical records are confidential. Only authorized personnel shall have access to the records. The written authorization of the patient shall be maintained in the original record as authority for release of medical information outside the facility.

(h) Medical records are the property of the hospital, and they shall not be removed from the facility jurisdiction except through a court order. Copies shall be made available for authorized purposes such as insurance claims and physician review.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995.**

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .3904

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: The authority cited for the fee, 90-411, specifies that section applies only to copies of records for personal injury liability claims. So there is no authority cited for the agency to limit the fee.

Joseph J. DeLuca, Jr.
Staff Director

57A

10 NCAC .3904 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1788 as follows with changes:

.3904 PATIENT ACCESS

The manager of medical records shall ~~ensure that~~ **provide** patients or patient designees, when requested, ~~are given~~ access to or a copy of their medical records, or both. Upon the death of a patient, the executor of the decedent's estate, or in the absence of an executor, the next of kin responsible for the disposition of the remains, shall have access to all medical records of the deceased patient. The patient or the patient's next of kin may be charged for the cost of reproducing copies in accordance with N. C. Gen. Stat. 90-411.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995.**

§ 90-401.1. Direct solicitation prohibited.

It shall be unlawful for a health care provider or the provider's employee or agent to initiate direct personal contact or telephone contact with any injured, diseased, or infirmed person, or with any other person residing in the injured, diseased, or infirmed person's household, for a period of 90 days following the injury or the onset of the disease or infirmity, if the purpose of initiating the contact, in whole or in part, is to attempt to induce or persuade the injured, diseased, or infirmed person to become a patient of the health care provider. This section shall not be construed to prohibit a health care provider's use of posted letters, brochures, or information packages to solicit injured, diseased, or infirmed persons, so long as such use does not entail direct personal contact with the person. (1993 (Reg. Sess., 1994), c. 689, s. 3.)

Editor's Note. — Session Laws 1993 (Reg. Sess., 1994), c. 689, s. 6, made this section effective October 1, 1994. Session Laws 1993 (Reg. Sess., 1994), c. 689, s. 5, is a severability clause.

§ 90-402. Sanctions.

Violation of the provisions of this Article shall be grounds for the offending health care provider's licensing board to suspend or revoke the health care provider's license, to refuse to renew the health care provider's license, or to take any other disciplinary action authorized by law. (1991 (Reg. Sess., 1992), c. 858, s. 1; 1993 (Reg. Sess., 1994), c. 689, s. 4.)

Editor's Note. — Session Laws 1993 (Reg. Sess., 1994), c. 689, s. 5, is a severability clause. (Reg. Sess., 1994) amendment, effective October 1, 1994, substituted "the provisions of this Article" for "G.S. 90-401."

Effect of Amendments. — The 1993

ARTICLE 29.*Medical Records.***§ 90-411. Record copy fee.**

A health care provider may charge a reasonable fee to cover the costs incurred in searching, handling, copying, and mailing medical records to the patient or the patient's designated representative. The maximum fee shall be fifty cents (50) per page, provided that the health care provider may impose a minimum fee of up to ten dollars (\$10.00), inclusive of copying costs. If requested by the patient or the patient's designated representative, nothing herein shall limit a reasonable professional fee charged by a physician for the review and preparation of a narrative summary of the patient's medical record. This section shall only apply with respect to liability claims for personal injury, except that charges for medical records and reports related to claims under Article 1 of Chapter 97 of the General Statutes shall be governed by the fees established by the North Carolina Industrial Commission pursuant to G.S. 97-26.4. (1993, c. 529, s. 4.3; 1993 (Reg. Sess., 1994), c. 679, s. 5.5.)

10 NCAC .3905 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1788-1789 as follows with changes:

.3905 PATIENT MEDICAL RECORDS

(a) Hospital management shall ~~ensure that~~ **maintain** medical records ~~are maintained~~ for every ~~each~~ patient treated or examined in the facility.

(b) The medical record or medical record system shall provide data for each episode of care and treatment rendered by the facility.

(c) Where the medical record does not combine all episodes of inpatient, outpatient and emergency care, the medical records system shall:

(1) assemble, upon request of the physician, any or all divergently located components of the medical record when a patient is admitted to the facility or appears for outpatient or clinic services; or

(2) require placing copies of pertinent portions of each inpatient's medical record, such as the discharge resume, the operative note and the pathology report in the outpatient or combined outpatient emergency unit record file as directed by the medical staff.

(d) The manager of medical records shall ~~ensure~~ **provide that**:

(1) each patient's medical record is complete, readily accessible and available to the professional staff concerned with the care and treatment of the patient;

(2) all significant clinical information pertaining to a patient is incorporated in his medical record;

(3) all entries in the record are dated and authenticated by the person making the entry;

(4) symbols and abbreviations are used only when they have been approved by the medical staff and when there exists a legend to explain them;

(5) verbal orders include the date and signature of the person recording them. They shall be given and authenticated in accordance with the provisions of rule .3707(e) of this Subchapter; and

(6) records of patients discharged are completed within 30 days following discharge or disciplinary action is initiated as defined in the medical staff bylaws.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ **September 1, 1995.**

.3906 CONTENTS

(a) The medical record shall contain sufficient information to justify the diagnosis, verify the treatment and document the course of treatment and results accurately.

(b) All in-patient records shall include the following information:

- (1) identification data (name, address, age, sex) and, when the identification data is not obtainable, the reason for such;
- (2) date and time of admission and discharge;
- (3) medical history:
 - (A) chief complaint;
 - (B) details of the present illness;
 - (C) relevant past, social, and family histories; and
 - (D) reports of relevant physical examinations;
- (5) diagnostic and therapeutic orders;
- (6) reports of procedures, tests and their results;
- (7) provisional or admitting diagnosis;
- (8) evidence of appropriate informed consent; ~~or a written statement explaining why consent was not obtained;~~
- (9) clinical observations, including results of therapy;
- (10) record of medication and treatment administration;
- (11) progress notes of all disciplines;
- (12) conclusions at termination of hospitalization or evaluation and treatment;
- (13) all relevant diagnosis established by the time of discharge;
- (14) consultation reports;
- (15) surgical record, including anesthesia record, pre-operative diagnosis, surgeon's operative report and post-operative orders and any instructions given to the patient or family; and
- (16) autopsy findings, if performed.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ ~~September 1, 1995.~~

10 NCAC .3907 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1789 as follows with changes:

.3907 MEDICAL RECORDS REVIEW

The medical staff shall review ~~medical~~ records periodically for completeness and shall:

- (1) establish requirements regarding completion of medical records, including a system for disciplinary actions for those who do not complete records in a timely manner; and
- (2) make recommendations to the medical records department ~~to ensure that the recorded~~ regarding clinical information is sufficient for ~~the purpose of~~ medical care evaluation.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ ~~September 1, 1995~~.

10 NCAC .4001 is adopted as published in the N.C. Register Volume 21, Issue 9, pages 1789-1790 as follows with changes:

SECTION .4000 OUTPATIENT SERVICES

.4001 ORGANIZATION

(a) Facility management shall ~~assure that~~ ~~establish and maintain the type and scope of~~ outpatient care services ~~is established~~ in accordance with the facility's written mission statement.

(b) The relationship of outpatient services to other divisions within the facility, including channels of responsibility and authority, shall be documented and made available for review by facility management.

(c) Facility management shall vest the direction of outpatient services in one or more individuals whose qualifications, authority and duties are defined in writing.

(d) The facility management shall ~~ensure~~ ~~establish and maintain procedures for~~ the review and evaluation of outpatient services.

(e) Each medical staff member shall have privileges delineated in accordance with criteria established by the medical staff by-laws.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ ~~September 1, 1995~~.

10 NCAC .4002 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1790 as follows with changes:

.4002 STAFFING

- (a) The director of outpatient services shall ~~ensure~~ **require** that ambulatory care services are staffed with sufficient personnel in accordance with a written plan.
- (b) The responsibility for the delivery of outpatient services by the professional staff shall be clearly defined and documented by the director of ambulatory care services.
- (c) Facility management shall provide education programs specifically related to outpatient care for the staff and document the extent of participation in education and training programs.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995**

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .4003

RECOMMENDATION:

Object, based on

Lack of
Statutory
authority

X Unclear,
ambiguous

Unnecessary

COMMENT: It is unclear who is to review these policies and procedures.

Joseph J. DeLuca, Jr.
Staff Director

63A

10 NCAC .4003 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1790 as follows:

.4003 POLICIES AND PROCEDURES

(a) The provision of outpatient services shall be guided by written policies and procedures which are current and approved by the medical staff. The policies and procedures shall be reviewed at least every 3 years.

(b) The policies shall include the following:

- (1) patient access to outpatient services;
- (2) the process of obtaining informed consent;
- (3) the location, storage and procurement of medications, supplies and equipment; and
- (4) the mechanism to be used to contact patients for necessary follow-up.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .4004 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1790 as follows with changes:

.4004 OUTPATIENT SURGICAL AND ANESTHESIA SERVICES

(a) When surgical or anesthesia services are provided in an outpatient setting, the facility shall ~~ensure~~ ~~require~~ that the medical staff approve all types of surgical procedures to be offered. The facility shall maintain and make available a current listing of approved outpatient procedures.

(b) The facility shall define the scope of anesthesia services that may be provided, the locations where such anesthesia services may be administered and who shall provide anesthesia services.

(c) The facility shall ~~ensure~~ ~~require~~ that ~~requirements~~ ~~standards~~ for informed consent, history and physical examination, preoperative studies, administration of anesthesia, medical records and discharge criteria meet the same standards of care as apply for inpatient surgery unless otherwise specified by the medical staff.

(d) The facility shall ~~ensure that provisions be made~~ ~~provide~~ for back-up service by other departments in the case of emergencies or complications.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ ~~September 1, 1995~~.

10 NCAC .4005 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1790 as follows with changes:

.4005 MEDICAL RECORDS

(a) The manager of outpatient services shall ~~ensure~~ **require** that a record of outpatient care and services ~~is developed~~ for each patient and ~~is~~ maintained either in the ambulatory care services or medical records department.

(b) Facility management shall ~~develop~~ **ensure** that a system of identification and filing ~~as developed, to prepare for which will ensure~~ safe storage and prompt retrieval ~~of records~~ upon subsequent inpatient or outpatient visits.

(c) Facility management shall ~~ensure that~~ **establish** medical records procedures ~~which~~ include provisions for maintaining the confidentiality of patient information and for the release of information to authorized individuals.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995.**

bb

10 NCAC .4101 is adopted as published in the N.C. Register Volume 21, Issue 9, pages 1790-1791 as follows with changes:

SECTION .4100 EMERGENCY SERVICES

.4101 EMERGENCY RESPONSE CAPABILITY REQUIRED

The medical staff of each facility shall ~~ensure~~ **require** that facility personnel are capable of initiating life-saving measures at a first-aid level of response for any patient or person in need of such services. This shall include:

- (1) initiating basic cardio-respiratory resuscitation according to American Red Cross or American Heart Association standards;
- (2) availability of first-line emergency drugs as specified by the medical staff;
- (3) availability of IV fluids and supplies required to establish IV access; and
- (4) establishing protocols or agreements for the transfer of patients to a facility for a higher level of care when these services are not available on site.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995.**

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .4102

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited for regulating the
qualification of emergency services physicians.

Joseph J. DeLuca, Jr.
Staff Director

67A

.4102 CLASSIFICATION OF OPTIONAL EMERGENCY SERVICES

(a) Facility management of any facility providing emergency services shall classify its capability in providing such services according to the following criteria:

(1) Level I:

- (A) the facility shall have a comprehensive, 24-hour-per-day emergency service with at least one physician experienced in emergency care on duty in the emergency care area;
- (B) the facility shall have in-hospital physician coverage by members of the medical staff or by senior-level residents for at least medical, surgical, orthopedic, obstetric, gynecologic, pediatric and anesthesia services;
- (C) services of other medical and surgical specialists shall be available; and
- (D) the facility shall provide prompt access to labs, radiology, operating suites, critical care and obstetric units and other services as defined by the governing body.

(2) Level II:

- (A) the facility shall have 24-hour per day emergency service with at least one physician experienced in emergency care on duty in the emergency care area; and
- (B) the facility shall have consultation available within 30 minutes by members of the medical staff or by senior level residents to meet the needs of the patient. Consultation by phone is acceptable.

(3) Level III:

The facility shall have emergency service available 24 hours per day with at least one physician available to the emergency care area within 30 minutes through a medical staff call roster.

- (b) Facilities seeking trauma center designation shall comply with N.C. Gen. Stat. 131E-162.
- (c) The location of the emergency access area shall be identified by clearly visible signs.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995

.4103 PROVISION OF EMERGENCY SERVICES

(a) Facility management of any facility providing emergency services shall ensure ~~establish and maintain policies requiring that~~ appropriate medical screening, treatment and transfer services for any individual who presents to the facility emergency department and on whose behalf a ~~request for treatment is made shall be provided~~ treatment is requested regardless of that person's ability to pay for medical services ~~and without delay to inquire about the individual's method of payment.~~

~~(b) Facility management shall ensure that the facility shall not delay provision of the medical screening examination or treatment required in order to inquire about the individual's method of payment status.~~

(e) ~~(b)~~ Any facility providing emergency services under this section shall install, operate and maintain, on a 24-hour per day basis, an emergency two-way radio licensed by the Federal Communications Commission in the Public Safety Radio Service capable of establishing voice radio communication with ambulance units transporting patients to said facility or having any written procedure or agreement for handling emergency services with the local ambulance service, rescue squad or other trained medical personnel.

~~(d)~~ ~~(c)~~ All communication equipment shall be in compliance with current rules established by North Carolina Rules for Basic Life Support/Ambulance Service (10 NCAC 3D .1100) adopted by reference with all subsequent amendments. Referenced rules are available at no charge from the Office of Emergency Medical Service, P.O. Box 29530, Raleigh, N.C. 27626-0530.

History Note: Statutory Authority G.S. 131E-79;
Eff. May 1, 1995 ~~September 1, 1995.~~

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .4104

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited for regulating the
director of emergency services qualifications, as set out in
(c) and (d).

Joseph J. DeLuca, Jr.
Staff Director

69A

10 NCAC .4104 is adopted as published in the N.C. Register Volume 21, Issue 9, pages 1791-1792 as follows:

.4104 MEDICAL DIRECTOR

(a) The governing body shall establish the qualifications, duties, and authority of the director of emergency services. Appointments shall be recommended by the medical staff and approved by the governing body.

(b) The medical staff credentials committee shall approve the mechanism for emergency privileges for physicians employed for brief periods of time such as evenings, weekends or holidays.

(c) Level I and II emergency services shall be directed and supervised by a physician with experience in emergency care.

(d) Level III services shall be directed and supervised by a physician with experience in emergency care or through a multi-disciplinary medical staff committee. The chairman of this committee shall serve as director of emergency medical services.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .4105 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1792 as follows:

.4105 NURSING

(a) Level I and Level II emergency services shall have one or more registered nurses assigned and on duty within the emergency service area at all times.

(b) A Level III emergency service shall have a registered nurse available on at least an on-call, in-house basis at all times.

(c) All emergency services nursing personnel shall have documented orientation, training and continuing education in the reception and care of emergency patients.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .4106 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1792 as follows:

.4106 POLICIES AND PROCEDURES

Each emergency department shall establish written policies and procedures which specify the scope and conduct of patient care to be provided in the emergency areas. They shall include the following:

- (1) the location, storage, and procurement of medications, blood, supplies, equipment and the procedures to be followed in the event of equipment failure;
- (2) the initial management of patients with burns, hand injuries, head injuries, fractures, multiple injuries, poisoning, animal bites, gunshot or stab wounds and other acute problems;
- (3) the provision of care to an unemancipated minor not accompanied by a parent or guardian, or to an unaccompanied unconscious patient;
- (4) management of alleged or suspected child, elder or adult abuse;
- (5) the management of pediatric emergencies;
- (6) the initial management of patients with actual or suspected exposure to radiation;
- (7) management of alleged or suspected rape victims;
- (8) the reporting of individuals dead on arrival to the proper authorities;
- (9) the use of standing orders;
- (10) tetanus and rabies prevention or prophylaxis; and
- (11) the dispensing of medications in accordance with state and federal laws.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .4107 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1792 as follows with changes:

.4107 EMERGENCY RECORDS

(a) Facility management shall ~~ensure~~ **require** all levels of emergency departments ~~to~~ maintain a continuous control register on each patient seen for services which shall include at least the name, age, sex, date, time, and means of arrival, nature of complaint, disposition, and time of discharge.

(b) Facility management shall ~~ensure that~~ maintain a record ~~shall be maintained~~ for each patient seeking emergency care. This shall include:

- (1) patient identification, time and means of arrival;
- (2) pertinent history and physical findings and patient vital signs;
- (3) diagnostic and therapeutic orders;
- (4) clinical observations including results of treatment;
- (5) reports of procedures, tests and results;
- (6) diagnostic impression; and
- (7) discharge or transfer summary of treatment including final disposition, the patient's condition, and any instructions given to the patient and or family for follow-up care.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995**.

10 NCAC .4108 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1792 as follows with changes:

.4108 OBSERVATION BEDS

When observation beds are used, facility management shall ~~ensure that there shall be~~ **implement** written policies and procedures that address the type of patient use, the mechanism for providing appropriate clinical monitoring, the length of time services may be provided in this setting and documentation requirements.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995.**

10 NCAC .4109 is adopted as published in the N.C. Register Volume 21, Issue 9, pages 1792-1793 as follows with changes:

.4109 TRANSFER

(a) Facility management shall ~~ensure that the facility has established~~ **establish and implement** protocols for stabilization and transportation of emergency patients.

(b) A facility with specialized capabilities, such as burn units, shock-trauma units and neonatal intensive care units, shall not refuse to accept an appropriate transfer for those services if the hospital has the capacity to treat the individual.

(c) ~~Hospital~~ **Facility** management shall ~~ensure that a patient shall not be transferred~~ **not transfer a patient** until the receiving organization has consented to accept the patient and the patient is sufficiently stable for transport.

(d) If the patient or the person acting on the patient's behalf refuses transfer, the facility staff shall:

(1) explain to the individual or his representative the risks and benefits of transfer; and

(2) shall request the patient's or his representative's refusal of transfer in writing.

(e) Facility management shall ~~ensure~~ **forward at the time of transfer** that a copy of all medical records related to the emergency condition for which the individual has presented ~~shall be made available at the time of the transfer, and shall accompany the patient to the receiving facility.~~

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ **September 1, 1995.**

10 NCAC .4110 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1793 as follows with changes:

.4110 DISASTER AND MASS CASUALTY PROGRAM

- (a) Facility management shall describe:
 - (1) the level of emergency services available during an external disaster;
 - (2) the emergency department's ~~place~~ **role** in the facility's external disaster plan;
 - (3) procedures to be followed in the event of an internal disaster; and
 - (4) the facility's connection to other community services such as fire, police and the American Red Cross.
- (b) The medical staff and governing body shall approve the plan, review it and revise it if needed, annually.
- (c) The plan shall:
 - (1) provide for prompt medical attention for all emergency patients as their needs may dictate;
 - (2) include protocols for handling non-emergency cases;
 - (3) establish medical staff coverage procedures or methods;
 - (4) specify drugs, solutions and equipment to be continuously available;
 - (5) provide for the evacuation and transfer for all inpatients as ~~there~~ **their** needs may indicate in the event of an internal disaster; and
 - (6) include mutual support agreements with area providers.
- (d) Schedules, names and telephone numbers of all physicians and others on emergency duty shall be maintained by the facility.
- (e) Names and telephone numbers of those to be contacted in the event of an internal disaster shall be maintained by the facility.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995**

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SECTION .4200 SPECIAL CARE UNITS

.4201 ORGANIZATION

- (a) The governing body shall approve the type and scope of special care units.
- (b) Facility management shall ~~assure that~~ **document** the relationship of the special care units to the other departments within the hospital, including channels of responsibility and authority; ~~be documented and available for review.~~
- (c) Facility management shall ~~ensure that there are~~ **provide** necessary equipment and supplies for delivery of nursing care specific to the unit population for each special care unit.
- (d) Facility management shall ~~ensure that the facility has~~ **provide** sufficient emergency drugs and equipment to meet anticipated needs as determined by the medical staff .
- (e) The governing body shall delegate to the medical and nursing staff the responsibility to develop policies and procedures concerning the scope and provision of safe care in each unit.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995.**

10 NCAC .4202 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1793 as follows with changes:

.4202 MEDICAL STAFF

(a) The governing body shall ~~ensure~~ ~~provide~~ that each special care unit or group of similar units be directed by qualified members of the medical staff whose clinical and administrative privileges have been approved by the governing board.

(b) The governing body shall designate the director to be responsible for making decisions in consultation with the physician responsible for the patient, for the disposition of a patient when patient load exceeds optimal operation capacity.

(c) The governing body shall ~~ensure~~ ~~require~~ that the medical staff provide medical staff coverage sufficient to meet the specific needs of the patients on a 24-hour basis.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ ~~September 1, 1995~~.

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .4203

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited to regulate special
care units personnel.

Joseph J. DeLuca, Jr.
Staff Director

78A

10 NCAC .4203 is adopted as published in the N.C. Register Volume 21, Issue 9, pages 1793-1794 as follows with changes:

.4203 NURSING STAFF

~~Facility management shall ensure that~~ The supervision of nursing care for each special care unit shall be provided by a qualified registered nurse- ~~and shall include the following:~~ The supervisor shall ensure the following:

- (1) unit-specific orientation and competency evaluation for each staff member;
- (2) a staffing plan based upon the needs of the patient population which is implemented to ensure a sufficient number of qualified Registered Nurses are on duty when patients are in the unit;
- (3) assessment, planning, implementation and evaluation of nursing care which is documented according to policy; and
- (4) delivery of nursing care in accordance with the North Carolina Nurse Practice Act.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

.4204 POLICIES AND PROCEDURES

(a) Facility management ~~shall assure that in conjunction with the medical and nursing staff shall develop~~ written policies and procedures which guide the provision of care. ~~be developed by the medical and nursing staff. Facility management shall ensure that~~ These policies and procedures ~~shall be~~ are approved by the medical staff and ~~that they~~ include:

- (1) patient admission and discharge criteria;
- (2) notification of appropriate medical staff for changes in the condition of the patient;
- (3) use of standing orders and emergency protocols;
- (4) designation of staff members authorized to perform special procedures and special circumstances requiring such authorization;
- (5) patient care procedures, including medication administration;
- (6) infection control;
- (7) pertinent safety practices;
- (8) use of equipment and procedures to be followed in the even of equipment failure;
- (9) regulations governing visitors and traffic control; and
- (10) role of special care unit in internal and external disaster plans.

(b) The governing body shall review, update and approve regularly, but at least every three years, its policies and procedures.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

SECTION .4300 MATERNAL - NEONATAL SERVICES

.4301 ORGANIZATION MATERNAL SERVICES

(a) The governing body shall approve the scope of obstetric services offered based upon the level of patient need, qualifications of the credentialed staff, and resources of the facility.

(b) The following capabilities and minimum services shall be made available when obstetric services are provided:

- (1) identification of high-risk mothers and fetuses;
- (2) continuous electronic fetal monitoring;
- (3) cesarean delivery capability within 30 minutes of decision;
- (4) blood or fresh frozen plasma for transfusion;
- (5) anesthesia on a 24-hour or on-call basis;
- (6) radiology and ultrasound examination;
- (7) stabilization of unexpectedly small or sick neonates before transfer;
- (8) neonatal resuscitation;
- (9) laboratory services on a 24-hour or on-call basis;
- (10) consultation and transfer agreements;
- (11) assessment and care for the neonates; and
- (12) nursery or other appropriate space for care of the neonates.

(c) In a facility without intensive care nursery services, the facility management shall establish procedures and maintain a plan for the stabilization and transportation of sick newborns to a regional neonatal unit, and maintain the essential equipment necessary for transport.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995

10 NCAC .4302 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1794 as follows with changes:

.4302 MEDICAL DIRECTOR STAFF MATERNAL SERVICES

(a) The medical staff shall ~~ensure~~ **require** that each birth is ~~be~~ attended by a physician or certified nurse midwife who has documented evidence of current competence and appropriate privileges.

(b) ~~At all times~~ **Medical** staff with obstetrical privileges shall be available ~~in the facility to provide services~~ within 30 minutes ~~at all times to to provide services~~ and attend deliveries. An on-call schedule shall be available to the Division for review.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995.**

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .4303

RECOMMENDATION:

Object, based on

- X Lack of
Statutory
authority
- Unclear,
ambiguous
- Unnecessary

COMMENT: There is no authority cited to regulate maternal
obstetric services personnel.

Joseph J. DeLuca, Jr.
Staff Director

82A

10 NCAC .4303 is adopted as published in the N.C. Register Volume 21, Issue 9, pages 1794-1795 as follows with changes:

.4303 NURSING SERVICES MATERNAL SERVICES

(a) The nurse executive or the decentralized nursing management staff shall designate a registered nurse who has education, training, and experience in obstetrical care as supervisor of obstetrical services.

(b) A registered nurse shall be ~~assigned responsibility~~ **responsible** for providing the type and amount of nursing care needed by each patient. A staffing plan shall be available to the Division for review.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995.**

.4304 POLICIES AND PROCEDURES MATERNAL SERVICES

(a) The provision of patient care shall be guided by written policies and procedures developed by the medical and nursing staff and approved by the medical staff.

(b) Written policies shall relate to at least the following:

(1) a system for informing the physician ~~or certified nurse midwife~~ responsible for a patient of the following:

(A) the patient's admission;

(B) the onset of labor; and

(C) pertinent information about progress of labor or changes in patient's condition.

(2) emergency response protocols for patients who demonstrate evidence of maternal, fetal or neonatal distress;

(3) a program to prevent isoimmunization of RH-negative mothers;

(4) administration of oxytocic agents when used for induction or stimulation of labor;

(5) the use and administration of analgesics and anesthetics;

(6) administration of magnesium sulfate when and for the treatment preeclampsia.

(7) ~~explicit directions as to~~ the location and storage of medications, supplies, and special equipment;

(8) the method of identification for the neonates;

(9) assessment and care of the neonates;

(10) provision of resuscitation, stabilization, and preparation for the transport of sick ~~newborns~~ ~~neonates~~ at any hour; and

(11) an infection control plan.

(c) Accurate and complete medical records shall be provided for each obstetric patient.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ ~~September 1, 1995~~.

10 NCAC .4305 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1795 as follows with changes:

.4305 ORGANIZATION OF NEONATAL SERVICES

(a) The governing body shall approve the scope of all neonatal services and the facility management shall classify its capability in providing a range of neonatal services using the following criteria:

- (1) LEVEL I or Neonate Nursery: neonates ~~or infants~~ that are stable without complications; may include premature, small for gestational age or large for gestational age neonates;
- (2) LEVEL II: Ill neonates or infants requiring less constant nursing care but does not exclude respiratory support; may serve as "step-down" unit from LEVEL III; and
- (3) LEVEL III: Medically unstable or critically ill neonates ~~or infants~~ requiring constant nursing care or supervision involving complicated surgical procedures, continual respiratory or other intensive interventions.

(b) Facility management shall ~~ensure~~ ~~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: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ ~~September 1, 1995~~

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .4307

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited to regulate maternal
obstetric services personnel, as set out in (a) and (b).

Joseph J. DeLuca, Jr.
Staff Director

86A

10 NCAC .4307 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1795 as follows with changes:

.4307 NURSING STAFF OF NEONATAL SERVICES

(a) The nurse executive or the decentralized nursing management staff shall designate a registered nurse who has training and experience in the care of neonates as supervisor of neonatal services.

(b) A registered nurse shall be ~~assigned responsibility~~ **responsible** for providing the type and amount of nursing care needed by each patient. A staffing plan shall be available to the Division for review.

(c) The nursing staff shall provide educational opportunities for parents of neonates on routine care and procedures needed by the neonate.

(d) The nursing staff shall provide opportunities for parental participation in care of the neonate to facilitate bonding and family adjustment to the neonate's needs.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995**

.4308 POLICIES AND PROCEDURES OF NEONATAL SERVICES

(a) The provision of neonatal care at all levels shall be guided by written policies and procedures ~~developed and approved by the medical and nursing staffs.~~

(b) The policies and procedures shall include but are not limited to:

- (1) emergency resuscitation and stabilization of the neonate;
- (2) equipment for routine and emergency care of the neonate;
- (3) continuous oxygen supply and means of administration including ventilators;
- (4) administration of medications;
- (5) insertion and care of invasive lines;
- (6) prevention of infectious diseases or processes ~~transmission~~; and
- (7) family involvement in care of the neonate.

(c) The medical and nursing staff shall review, update and approve ~~regularly, but at least its~~ policies and procedures every three years ~~its policies and procedures.~~

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .4401

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited to regulate
respiratory care services or personnel.

Joseph J. DeLuca, Jr.
Staff Director

88A

10 NCAC .4402 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1796 as follows with changes:

.4402 STAFFING

- (a) Staffing numbers shall be determined by the types and complexities of the services offered.
- (b) The director of the service shall ~~ensure~~ **provide for** the availability of trained respiratory technicians, Certified Respiratory Therapy Technicians, registry eligible or Registered Respiratory Therapist needed for the scope of services offered.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995.**

.4403 POLICIES AND PROCEDURES

Facility management shall establish ~~and maintain~~ written policies and procedures for the services offered. These shall include but are not limited to:

- (a) scope of services and treatment offered;
- (b) medication administration;
- (c) cleaning, assembly and storage of equipment;
- (d) safety;
- (e) infection control;
- (f) documentation of delivered care or treatments; and
- (g) care and supervision of all ventilated patients.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ ~~September 1, 1995.~~

10 NCAC .4501 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1796 as follows:

SECTION .4500 PHARMACY SERVICES AND MEDICATION ADMINISTRATION

.4501 PROVISION OF SERVICE

The facility shall provide for pharmaceutical services which are administered in accordance with the pharmacy laws of North Carolina including but not limited to N. C. Gen. Stat. 90 and 106.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .4502

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited to regulate pharmacy
services personnel, as set out in (a).

Joseph J. DeLuca, Jr.
Staff Director

92A

10 NCAC .4502 is adopted as published in the N.C. Register Volume 21, Issue 9, pages 1796-1797 as follows with changes:

.4502 PHARMACIST

(a) The pharmacy service shall be directed by a pharmacist licensed by the State of North Carolina. If a facility has a limited service as defined by the N.C. Board of Pharmacy, a part-time director of pharmacy shall have responsibility for control and dispensing of drugs.

(b) The director of pharmacy shall be responsible to the chief executive officer or his designee for developing, supervising, and coordinating all the activities of pharmacy services throughout the facility.

(c) The director of pharmacy shall ~~ensure~~ **require** that the pharmacists are trained in the specialized functions of facility pharmacy.

(d) The dispensing of drugs in the absence of a pharmacist shall be members who are under the direct supervision of staff approved by the pharmacy committee and who are responsible for following policies established by the pharmacy committee.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995.**

10 NCAC .4503 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1797 as follows:

.4503 STAFF

The director of pharmacy shall be assisted by additional pharmacists and such other personnel as the activities of the pharmacy may require to meet the pharmaceutical needs of the patients served.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

.4504 PHARMACY COMMITTEE

(a) A pharmacy committee or its equivalent, to include physicians, ~~registered~~ nurses, pharmacists and the administrator or designee shall be established.

(b) The committee shall meet at least quarterly, record its proceedings and report to the medical staff. It shall assist in the formulation of broad professional policies regarding the evaluation appraisal, selection, procurement, storage, distribution, use and safety procedures, and all other matters relating to drugs in the facility. This should include a mechanism to review and evaluate adverse drug reactions and drug usage evaluations, offering appropriate recommendations, actions, and follow-up if necessary. The committee shall:

- (1) serve as an advisory group to the medical staff and the pharmacy director on matters pertaining to drug selection;
- (2) develop an ongoing mechanism to review a formulary or drug list for use in the hospital;
- (3) recommend and develop policies regarding the use and control of investigational drugs and research in the use of U.S. Food and Drug Administration approved drugs;
- (4) evaluate clinical data concerning new drugs or preparations requested for use in the facility;
- (5) make recommendations concerning drugs to be stocked on the nursing units and by other services;
- (6) establish mechanisms which will prevent formulary duplication;
- (7) establish policies and procedures that address therapeutic drug substitution;
- (8) establish a policy ~~to ensure that~~ ~~describing~~ the duration of drug therapy or number of doses ~~is established~~ for all medication orders; and
- (9) make recommendations regarding medication administration policies and procedures.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ ~~September 1, 1995~~.

10 NCAC .4505 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1797 as follows:

.4505 PHARMACY FACILITIES

Facility management shall provide equipment and supplies for the pharmaceutical service to carry out its professional and administrative functions and to ensure patient safety through the proper storage and dispensing of drugs. Space and equipment shall be provided for the storage, safeguarding, preparation and dispensing of drugs.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .4506 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1797 as follows with changes:

.4506 SUPPLIES

~~The director of pharmacy shall ensure that a supply of drugs and pharmaceutical devices adequate to meet the needs of the patients and the medical staff is maintained.~~ The director of pharmacy shall maintain an inventory of drugs and pharmaceutical devices to meet the needs of the patients as described in the facility's formulary.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .4507 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1797 as follows with changes:

.4507 STORAGE

- (a) All drugs and related pharmaceutical supplies located throughout the facility shall be under the control of the pharmacy service.
- (b) All areas where drugs and related pharmaceutical supplies are stored shall be monitored at least monthly by the pharmacy service.
- (c) The director of pharmacy shall ~~ensure~~ **require** that corresponding records are maintained of drug inventory variances and the corrective action taken.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995.**

10 NCAC .4508 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1797 as follows:

.4508 SPACE

Adequate space shall be provided for all pharmacy operations and drugs shall be stored in a satisfactory location provided with proper lighting, ventilation and temperature controls, as specified by the U. S. Food & Drug Administration, Dockets Management Branch, FDS, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857; at a cost dependent on the material requested and the U.S. Pharmacopoeia, US Pharmacopoeia, 12601 Twinbrook Parkway, Rockville, Maryland 20852 (1-800-227-8772), at a cost of \$450.00 plus \$12.00 shipping and handling.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995

10 NCAC .4509 is adopted as published in the N.C. Register Volume 21, Issue 9, pages 1797-1798 as follows with changes:

.4509 SECURITY

(a) The director of pharmacy shall ~~ensure~~ **require** that all drugs and related pharmaceutical supplies be stored in a lockable environment except when under the direct supervision of personnel authorized by the pharmacy committee to handle drugs.

(b) Controlled substances and other drugs the facility deems subject to abuse shall be stored as outlined in the U.S. Controlled Substance Act, CFR 1301.41 and the N.C. Controlled Substances Act, N. C. Gen. Stat. 90, Article 5. These rules are available from the Regulatory Section of the N.C. Division of Mental health, Development Disabilities & Substance Abuse Services, 325 N. Salisbury St., Raleigh, N.C. 27603 (919/715-0652) without charge to current registrants.

(c) All keys and other locking devices to the pharmacy and controlled substances throughout the facility shall be under the control of the director of pharmacy and the ~~hospital~~ **facility** management.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ **September 1, 1995**

10 NCAC .4510 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1798 as follows with changes:

.4510 RECORDS

(a) The director of pharmacy shall ~~ensure~~ provide that all drug transactions of the pharmacy shall be recorded as described in policies approved by the pharmacy committee.

(b) The director of pharmacy shall establish and maintain a system of records and bookkeeping in accordance with the policies of the facility in order to maintain adequate control over the requisitioning and dispensing of all drugs and pharmaceutical supplies and over patient billing for all drugs and pharmaceutical supplies.

(c) The director of pharmacy shall ~~ensure that maintain~~ records for all drugs purchased, ordered, dispensed, distributed, returned and disposed of in accordance with the pharmacy laws of North Carolina ~~dispensed from the pharmacy shall be maintained in the pharmacy. Records of drugs administered to patients shall be maintained in the medical record of the patient.~~

(d) Verbal orders for drugs shall be subject to medical staff policies.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

.4511 MEDICATION ADMINISTRATION

(a) A facility shall ~~have~~ establish and maintain policies and procedures governing the administration of medications which shall be enforced and implemented by administration and staff. Policies and procedures shall include, but shall not necessarily be limited to:

- (1) accountability of controlled substances as defined by the N. C. Gen Stat. 90, Article 5; and
- (2) dispensing and administering behavior modifying drugs, and psychotherapeutic agents; insulin; intravenous fluids and medications; cardiovascular drugs; antibiotics; and cytotoxic and related agents.

(b) ~~Nursing staff are responsible for ensuring that a~~ All medications or drugs and treatments are ~~shall be~~ administered and discontinued in accordance with signed medical staff physician's orders which are recorded in the patient's medical record.

(c) ~~The governing body shall ensure that the facility's bylaws and operational policies clearly describe~~ The categories of staff that are privileged to administer medications shall be delineated by the operational policies of the facility. These policies shall be in agreement with current rules of North Carolina Occupational Boards for each category of staff.

(d) Medications shall be scheduled and administered according to the established policies of the facility.

(e) Variances to the medication administration policy shall be reviewed and evaluated by the nurse executive or her designee.

(f) The person administering medications shall identify each patient in accordance with the facility's policies and procedures prior to administering any medication.

(g) Medication administered to a patient shall be recorded in the patient's medication administration record immediately after administration in accordance with the facility's policies and procedures.

(h) Omission of medication and the reason for the omission shall be indicated in the patient's medical record.

(i) The person administering medications which are ordered to be given as needed (PRN) shall justify the need for the same in the patient's medical record.

(j) Medication administration records shall provide identification of the drug and strength of drug, quantity of drug administered, route administered, name and title of person administering the medication, and time and date of administration.

(k) Self-administration of medications shall be permitted only if prescribed by the medical staff. Directions must be printed on the container.

(l) The administration of one patient's medications to another patient is prohibited except in the case of an emergency. In the event of such as emergency, steps shall be taken by a pharmacist to ensure that the borrowed medications shall be replaced and so documented.

(m) Verbal orders shall be countersigned in accordance with rule .3707(e) of this Subchapter.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .4512

RECOMMENDATION:

Object, based on

Lack of
Statutory
authority

X Unclear,
ambiguous

Unnecessary

COMMENT: In (a) the meaning of "unfavorable" is unclear.

Joseph J. DeLuca, Jr.
Staff Director

102A

.4512 MEDICATIONS DISPENSED

(a) The pharmacy shall dispense only those drugs which are listed in one or more of the references listed in paragraph (b) of this rule or as provided in paragraph (c) of this rule. Any drug unfavorably evaluated in any of these references shall be used only in accordance with standards established by the facility's pharmacy committee.

(b) References:

- (1) United States Pharmacopoeia.;
- (2) National Drug Formulary;
- (3) Evaluations of Drug Interactions by the American Pharmaceutical Association;
- (4) American Hospital Formulary Service; and
- (5) Other references approved by the Pharmacy Committee.

(c) Any drug approved for use as an investigational drug or otherwise by the U.S. Food and Drug Administration but not listed in paragraph (b) of this rule may be used in accordance with standards established by the facility's pharmacy committee, or its equivalent and approved by the U.S. Food and Drug Administration, Dockets Management Branch, FDS, Room 4062, 5600 Fishers Lane, Rockfield, Maryland 20857, at a cost dependent on the material requested.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995

10 NCAC .4513 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1799 as follows:

.4513 DRUG DISTRIBUTION SYSTEMS

(a) The pharmacy committee shall develop written policies and procedures pertaining to the intra-facility drug distribution system. In developing such policies the committee shall utilize representatives of other disciplines within the facility, including nursing services.

(b) The label of each patient's individual medication container shall bear all information required by the Pharmacy Laws of North Carolina.

(c) The pharmacist, with the advice and guidance of the pharmacy committee or its equivalent, shall be responsible for specifications as to quality, quantity and source of supplies of all drugs.

(d) There shall be a formulary or list of drugs accepted for use in the facility which shall be developed and amended as necessary by the pharmacy committee.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .4514 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1799 as follows with changes:

.4514 EMERGENCY PHARMACEUTICAL SERVICES

~~Provision shall be made~~ The director of pharmacy shall be responsible for emergency pharmaceutical services as currently described in the Pharmacy Laws of North Carolina.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .4515 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1799 as follows with changes:

.4515 DISPOSITION

~~The director of pharmacy shall ensure that~~ Drugs, and pharmaceutical devices throughout the facility which are outdated, visibly deteriorated, unlabeled, inadequately labeled, recalled, discontinued or obsolete shall be identified by a pharmacist and shall be disposed of in compliance with applicable state and federal laws and regulations.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .4516 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1799 as follows:

.4516 COMMERCIAL PHARMACEUTICAL SERVICE

A facility using an outside pharmacist or pharmaceutical service must have a contract with that pharmacist or service. As part of the contract, the pharmacist or service shall be required to maintain at least the standards for operation of the pharmaceutical services outlined in this Subchapter.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995

SECTION .4600 SURGICAL AND ANESTHESIA SERVICES

.4601 ORGANIZATION

- (a) The governing body shall approve the types of surgery and types of anesthesia services to be available throughout the hospital consistent with identified needs and resources.
- (b) Facility management shall ~~assure~~ **require** that surgical or anesthesia procedures are performed only when the necessary equipment and personnel are available.
- (c) A facility that provides surgical or obstetric services shall provide anesthesia services on a 24-hour basis.
- (d) ~~The Facility management shall ensure that~~ requirements and standards identified in this section apply when any patient, in any setting, receives for any purpose, by any route:
 - (1) general, spinal or other major regional anesthesia; or
 - (2) sedation or analgesia that may result in the loss of protective reflexes; or
 - (3) surgery or other invasive procedure while receiving such anesthesia.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995**

10 NCAC .4602 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1800 as follows with changes:

.4602 DIRECTOR OF SURGICAL SERVICES

(a) ~~Facility management shall assure that each~~ Each department or service providing surgical services shall be directed by members of the medical staff whose clinical and administrative privileges have been approved by the governing body.

(b) The medical staff shall ensure ~~establish and maintain~~ a system for monitoring and evaluating the quality and appropriateness of the care and treatment of surgical patients, and for monitoring the clinical performance of all individuals with clinical privileges.

(c) In facilities where there is no anesthesiologist on staff the facility management shall:

- (1) with review of the medical staff, establish a consultation agreement with a board-certified or board-eligible anesthesiologist for the purpose of establishing policies and procedures ~~for anesthesia safety and policies~~ that relate to the ~~safe~~ administration of anesthesia in all departments or services of the facility;
- (2) assume the responsibility for establishing general policies for anesthesia services; and
- (3) establish a line of communication and supervision for staff.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .4603 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1800 as follows with changes:

.4603 SURGICAL AND ANESTHESIA STAFF

(a) Facility management shall develop processes ~~to ensure~~ **which require** that each individual provides only those services for which proof of licensure and competency can be demonstrated.

(b) Facility management shall ~~ensure~~ **require that:**

- (1) when anesthesia is administered, a qualified physician is immediately available in the facility to provide care in the event of a medical emergency;
- (2) a roster of practitioners with a delineation of current surgical and anesthesia privileges is available and maintained for the service.
- (3) an on-call schedule of surgeons with privileges to be available at all times for emergency surgery and for post-operative clinical management is maintained;
- (4) the operating room is supervised by a qualified registered nurse or doctor of medicine or osteopathy; and
- (5) an operating room register which shall include date of the operation, name and patient identification number, names of surgeons and surgical assistants, name of anesthetists, type of anesthesia given, pre- and post-operative diagnosis, type and duration of surgical procedure, and the presence or absence of complications in surgery is maintained.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995.**

10 NCAC .4604 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1800 as follows with changes:

.4604 DIRECTION OF ANESTHESIA SERVICES

(a) Facility management shall ensure that anesthesia care be organized, directed and integrated with other related services or departments of the facility.

(b) The department of anesthesia shall ~~be responsible for ensuring that all anesthetics are administered as established in the medical staff rules require that all anesthetics are administered according to procedures established in medical staff rules.~~ In facilities where there is no department of anesthesia, the medical staff shall assume the responsibility for establishing general policies and for supervising the administration of anesthetics.

(c) Facility management shall ~~ensure~~ provide that anesthesia services be directed by a member, or members, of the medical staff whose responsibilities shall be approved by the governing body and shall include:

- (1) establishment of criteria and procedures for the evaluation of the quality of all anesthesia care rendered;
- (2) review of clinical privileges for all licensed practitioners whose primary clinical activity is the provision of anesthesia services; and
- (3) establishment of written policies and procedures for anesthesia services.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

.4605 POLICIES AND PROCEDURES

(a) The director of surgical services shall develop policies and procedures for surgical and anesthesia services which shall be available to the medical, surgical, anesthesia staff and nursing personnel.

(b) Facility management shall ~~ensure~~ **require** that policies on anesthesia procedures include the delineation of pre-anesthesia and post-anesthesia responsibilities.

(c) Facility management shall ~~ensure~~ **require** that the policies listed below are followed and that each surgical patient's record contain the following documentation:

- (1) a complete history and physical documented in the ~~chart~~ **record** of every patient prior to surgery, including clinical indications for the surgical procedure;
 - (2) ~~an written evidence of informed consent, in the patient's chart record before surgery;~~
~~If prior written consent was not obtained, the record shall contain a written explanation of why prior written consent was not obtained;~~
 - (3) an evaluation of the patient and anesthesia planned, documented according to medical staff bylaws by an individual qualified to administer anesthesia services. Re-evaluation of the patient immediately prior to the induction of anesthesia shall be performed prior to surgery;
 - (4) an operative report describing techniques, findings, tissue removed or altered, and pre and post-surgical diagnosis. This report must be written or dictated following surgery and signed by the surgeon in compliance with medical staff rules;
 - (5) an intraoperative anesthesia record including the dosage of all drugs and agents used, the duration of anesthesia, and the type and amount of all fluids or blood and blood products administered shall be documented;
 - (6) evaluation and documentation of the postoperative status of the patient on admission to and discharge from the post-anesthesia recovery area; and
 - ~~(7) procedure to follow in the event that informed consent cannot be obtained.~~
- (d) The director of anesthesia services shall establish ~~and apply~~ criteria for discharge ~~to determine the readiness of the patient for discharge and:~~
- ~~(1) The facility management shall ensure require that a physician or CRNA with appropriate clinical privileges be responsible for the decision to discharge a patient from a post-anesthesia recovery area.~~
 - ~~(2) With respect to outpatients, the hospital shall insure that a post-anesthesia evaluation be performed in accordance with policies and procedures approved by the medical staff.~~
- (e) Facility management shall establish regulations governing visitors and traffic control.

History Note: Statutory Authority G.S. 131E-79;

Eff. May 1, 1995 ~~September 1, 1995.~~

10 NCAC .4701 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1801 as follows:

SECTION .4700 NUTRITION AND DIETETIC SERVICES

.4701 PROVISION OF SERVICES

The nutrition and dietetic services shall be organized, directed, staffed and integrated with other facility departments to provide optimal nutritional therapy and quality food service to patients. Nutrition therapy shall apply the principles of the science of nutrition and be administered in accordance with the law and rules including but not limited to N. C. Gen. Stat. 90, Article 25.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .4702

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited to regulate nutrition and dietetic services personnel, as set out in (a) and (b).

Joseph J. DeLuca, Jr.
Staff Director

113A

.4702 ORGANIZATION

(a) The nutrition and dietetic services shall be under the full-time direction of a person who is trained or experienced in food services administration and therapeutic diets. The director shall be one of the following:

(1) A qualified dietitian;

~~(2) An individual who possesses at least the following minimum qualifications:~~

(2) (A) Bachelor's degree in Foods and Nutrition or Food Service Management;

(3) (B) Dietetic Technician Registered (DTR); or

(4) (C) Certified Dietary Manager (CDM); or

(5)(3) An individual who is enrolled in a program to complete the above minimum qualifications.

(b) The nutrition and dietetic services of the facility shall have at least one dietitian either full-time, part-time, or as consultant. The qualifications of the dietitian shall be included in the personnel files. If the director of nutrition and dietetic services is not a registered dietitian, there shall be an established method of communication between the director and the dietitian which ensures that the dietitian supervises the nutritional aspects of patient care and ensures that quality nutritional care is provided to patients. Dietitians or qualified designees shall attend and participate in meetings relevant to patient nutritional care, including but not limited to patient care conferences and discharge planning.

(c) When a dietitian serves only in a consultant capacity, the facility management shall ~~have establish and maintain~~ a written contract with the individual ~~which shall clearly define defining~~ the responsibilities ~~which includes the of the dietician including requirements for~~ submission of written reports to the hospital administrator and the director of the nutrition and dietetic services describing the extent and quality of the services provided. Frequency of visits of the consultant dietitian shall be defined in the contract. The consultant dietitian shall provide, on site, no less than eight hours of service every two weeks to provide the nutritional aspects of patient care including but not limited to the following:

(1) approval of regular and modified menus, including standardized recipes;

(2) performance of nutritional assessments;

(3) development of nutrition care plans;

(4) provision of nutrition therapy;

(5) participation in development of policies and procedures; and

(6) monitoring and evaluation of the effectiveness and appropriateness of nutrition and dietetic services.

(d) Facility management shall ~~ensure that there are~~ ~~establish and maintain~~ written policies and procedures to govern all nutrition and dietetic service activities. These policies shall be developed by the nutrition and dietetic services in cooperation with personnel from other departments or services which are involved with nutrition and dietetic services and they shall be reviewed at least every three years, revised as necessary, and dated to indicate the time of last review. Administrative policies and procedures concerning food procurement, preparation, and service shall be written by the director of the nutrition and dietetic services. Nutritional care policies and procedures shall be written by the qualified dietitian. The nutrition and dietetic service policies and procedures shall include, but not be limited to the following:

(1) provision of food and nutrition therapy prescriptions/orders;

(2) development, approval and provision of regular and modified menus, including standardized recipes;

(3) food purchasing, storage, inventory, preparation and service;

(4) identification system designed to ensure that each patient receives appropriate diet as ordered;

(5) ancillary dietetic services, as appropriate, including food storage and kitchens on patient care units, formula supply, cafeterias, vending operations and ice making;

- (6) preparation, storage, distribution, and administration of enteral nutrition programs;
- (7) assessment and monitoring of patients receiving enteral and total parenteral nutrition;
- (8) personal hygiene and health of dietetic personnel;
- (9) infection control measures to minimize the possibility of contamination and transfer of infection, including establishment of monitoring procedure to ensure that personnel are free from communicable infections and open skin lesions; and
- (10) pertinent safety practices, including control of electrical, flammable, mechanical, and radiation hazards.

(e) Nutrition and dietetic services shall be provided by qualified personnel under supervision to meet needs of patients. The director of the nutrition and dietetic services shall ensure ~~require~~ that personnel assigned to the department perform all functions necessary to meet the nutritional needs of patients. The director or qualified designee shall attend and participate in meetings, including that of department heads, and function as an integral member of the facility.

(f) A facility which has a contract with an outside food management service, shall require as a part of the contract that the company complies with all applicable requirements and standards outlined in Section .4700 of this Subchapter for such service. The contract shall be available for review by the Division.

History Note: Statutory Authority G.S. 131E-79;
Eff. May 1, 1995 ~~September 1, 1995.~~

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .4703

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited for the Medical Care Commission to specify the minimum sanitation rating or other sanitation requirements. That seems to be within the authority of the Commission for Health Services.

Joseph J. DeLuca, Jr.
Staff Director

.4703 SANITATION AND SAFETY

(a) The nutrition and dietetic service shall maintain a Grade A sanitation rating and comply with current laws and rules for sanitation as promulgated by the Commission for Health Services. The facilities and equipment of the nutrition and dietetic services shall be in compliance with applicable sanitation and safety laws and rules. 15A NCAC 18A .1300 incorporated by reference including subsequent amendments and additions. Copies of 15A NCAC 18A .1300 may be obtained at no charge from the Environmental Health Section, Health Division, N.C. Department of Environment, Health and Natural Resources, P.O. Box 27687, Raleigh, NC 27611-7687.

(b) Sufficient space and equipment shall be provided for the nutrition and dietetic services to accomplish the following:

- (1) store food and nonfood supplies under sanitary and secure conditions;
- (2) store food separately from nonfood supplies. When storage facilities are limited, paper products may be stored with food supplies;
- (3) prepare and distribute food, including therapeutic diets;
- (4) clean and sanitize utensils and dishes apart from food preparation areas; and
- (5) allow personnel to perform their duties.

(c) Cleaning schedules and instructions for cleaning all equipment and work and storage areas shall be posted and followed in the nutrition and dietetic services area and accessible to all nutrition and dietetics staff. Procedures for cleaning all equipment and work areas shall be followed consistently and documented to safeguard the health of the patient.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

Part 3. Sanitation of Scallops, Shellfish and Crustacea.

§ 130A-230. Commission to adopt rules; enforcement of rules.

For the protection of the public health, the Commission shall adopt rules establishing sanitation requirements for the harvesting, processing and handling of scallops, shellfish and crustacea of in-State origin. The rules of the Commission may also regulate scallops, shellfish and crustacea shipped into North Carolina. The Department is authorized to enforce the rules and may issue and revoke permits according to the rules. (1965, c. 783, s. 1; 1967, c. 1005, s. 1; 1973, c. 476, s. 128; 1983, c. 891, s. 2.)

§ 130A-231. Agreements between the State Health Director and the Division of Marine Fisheries.

Nothing in this Part is intended to limit the authority of the Division of Marine Fisheries of the Department to regulate aspects of the harvesting, processing and handling of scallops, shellfish and crustacea relating to conservation of the fisheries resources of the State. The State Health Director and the Division of Marine Fisheries are authorized to enter into agreements respecting the duties and responsibilities of each agency as to the harvesting, processing and handling of scallops, shellfish and crustacea. (1965, c. 783, s. 1; 1967, c. 1005, s. 1; 1973, c. 476, s. 128; c. 1262, s. 86; 1977, c. 771, s. 4; 1983, c. 891, s. 2; 1989, c. 727, s. 142.)

§§ 130A-232 through 130A-234: Reserved for future codification purposes.

Part 4. Institutions and Schools.

§ 130A-235. Regulation of sanitation in institutions.

For protection of the public health, the Commission shall adopt rules to establish sanitation requirements for all institutions and facilities at which individuals are provided room or board and for which a license to operate is required to be obtained or a certificate for payment is obtained from the Department of Human Resources. The rules shall also apply to facilities that provide room and board to individuals but are exempt from licensure under G.S. 131D-10.4(1). No other State agency may adopt rules to establish sanitation requirements for these institutions and facilities. The Department of Human Resources shall issue a license to operate or a certificate for payment to such an institution or facility only upon compliance with all applicable sanitation rules of the Commission, and the Department of Human Resources may suspend or revoke a license or a certificate for payment for violation of these rules. In adopting rules pursuant to this section, the Commission shall define categories of standards to which such institutions and facilities

shall be subject and shall establish criteria for the placement of any such institution or facility into one of the categories. This section shall not apply to State institutions and facilities subject to inspection under G.S. 130A-5(10). (1945, c. 829, s. 1; 1957, c. 1357, s. 1; 1973, c. 476, s. 128; 1983, c. 891, s. 2; 1987, c. 543, s. 1; 1989, c. 727, s. 143.)

OPINIONS OF ATTORNEY GENERAL

Foster Homes. — Former § 130-170 authorized the Commission to adopt rules and regulations governing the sanitation of family foster homes. See opinion of Attorney General to Miss Lela Moore Hall, Director of Social Services, New Hanover County, 45 N.C.A.G. 138 (1975).

§ 130A-236. Regulation of sanitation in schools.

For the protection of the public health, the Commission shall adopt rules to establish sanitation requirements for public, private and religious schools. The rules shall address, but not be limited to, the cleanliness of floors, walls, ceilings, storage spaces and other areas; adequacy of lighting, ventilation, water supply, toilet and lavatory facilities; sewage collection, treatment and disposal facilities; and solid waste disposal. The Department shall inspect schools at least annually. The Department shall submit written inspection reports of public schools to the Department of Public Education and written inspection reports of private and religious schools to the Department of Administration. (1973, c. 1239, s. 1; 1983, c. 891, s. 2.)

§ 130A-237. Inspections, reports, corrective action.

A principal or administrative head of a public, private or religious school shall inspect the facility every month to monitor the level of sanitation and to assure compliance with the sanitation rules. A principal or administrative head shall immediately take action to correct conditions which do not satisfy the sanitation rules. Sample inspection report forms may be obtained from the Department upon request. (1973, c. 1239, s. 2; 1983, c. 891, s. 2.)

Part 5. Migrant Housing.

§§ 130A-238 through 130A-246: Repealed by Session Laws 1989, c. 91, s. 1, effective January 1, 1990.

Cross References. — For the Migrant Housing Act, see § 95-222 et seq.

Editor's Note. — Session Laws 1989, c. 91, which repealed this Part, in s. 5 provided in part: "If funds are appropriated for the 1989-90 fiscal year to implement the provisions of Sections 1, 2, and 3 of this act, Sections 1, 2, and 3 of this

act shall become effective January 1, 1990. This act shall not be construed to obligate the General Assembly to make any appropriation to implement the provisions of this act."

Repealed §§ 130A-245 and 130A-246 had been reserved for future codification purposes.

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .4704

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited for the Medical Care Commission to specify the minimum sanitation rating or other sanitation requirements. That seems to be within the authority of the Commission for Health Services.

Joseph J. DeLuca, Jr.
Staff Director

116C

10 NCAC .4704 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1803 as follows:

.4704 DISTRIBUTION OF FOOD

Foods being displayed or transported shall be protected from contamination and spoilage in clean containers, and cabinets, or serving carts. The food temperatures at the serving time shall be within the following acceptable ranges:

- (1) Hot liquids - 150 degrees (minimum)
- (2) Hot Cereal - 150 degrees (minimum)
- (3) Soups - 130 degrees (minimum)
- (4) Hot foods - 110 degrees (minimum)
- (5) Cold liquids - 50 degrees (maximum)
- (6) Cold foods - 65 degrees (maximum)

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .4705

RECOMMENDATION:

Object, based on

- X Lack of
Statutory
authority
- Unclear,
ambiguous
- Unnecessary

COMMENT: There is no authority cited to regulate nutrition and dietetic services personnel.

Joseph J. DeLuca, Jr.
Staff Director

117A

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .4801

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited to regulate diagnostic imaging services personnel.

Joseph J. DeLuca, Jr.
Staff Director

118A

10 NCAC .4801 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1803 as follows:

SECTION .4800 DIAGNOSTIC IMAGING

.4801 ORGANIZATION

(a) Imaging services shall be under the supervision of a full-time radiologist, consulting radiologist, or a physician experienced in the particular imaging modality and the physician in charge must have the credentials required by facility policies.

(b) Activities of the imaging service may include radio-therapy.

(c) All imaging equipment shall be operated under professional supervision by qualified personnel trained in the use of imaging equipment and knowledgeable of safety precautions required by the North Carolina Department of Environment, Health and Natural Resources, Division of Radiation Protection. Copies of regulations are available from the N.C. Department of Environment Health and Natural Resources, Division of Radiation Protection, P.O. Box 27687, Raleigh, NC 27611-7687 at a cost of \$16.00 each.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .4802 is adopted as published in the N.C. Register Volume 21, Issue 9, pages 1803-1804 as follows:

.4802 RECORDS

- (a) A documented record on each imaging examination shall be included in the patient's medical record.
- (b) Imaging reports shall be signed by the physician interpreting the study.
- (c) Copies of current reports made by private physicists or governing authority surveying the radiographic facilities shall be available to the Division.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995

10 NCAC .4803 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1804 as follows:

.4803 STAFFING

(a) The staffing of the imaging department shall be determined by the radiologist in charge or by another person designated by hospital management.

(b) There shall be a minimum of one radiologic technologist available to the department on at least an on-call basis.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .4804 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1804 as follows:

.4804 MONITORING RADIATION EXPOSURE OF PERSONNEL

- (a) Facility management shall establish procedures for the monitoring of personnel and shall maintain a record for each individual working in the area of radiation where there is a reasonable probability of receiving one-fourth of the maximum permissible dose.
- (b) Records documenting the monitoring of personnel receiving radiation exposure through the use of film badges or dosimeters must also be maintained by facility management. Readings from badges or dosimeters shall be recorded on at least a monthly basis.
- (c) Upon termination of employment, each employee shall be provided with a summary of his exposure record.
- (d) Permanent records of radiological exposure on all monitored personnel shall be maintained for review by the Division.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .4805 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1804 as follows with changes:

.4805 SAFETY

- (a) Facility management shall ~~ensure~~ **require** that all imaging equipment is operated under the supervision of a physician and by qualified personnel.
- (b) Facility management shall ~~ensure~~ **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 Radiation Protection Services. 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:
 - (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, Health, and Natural Resources, Division of Radiation Protection. Copies of regulations are available from the North Carolina Department of Environment, Health, and Natural Resources, Division of Radiation Protection, P.O. Box 27687, Raleigh, NC 27611-7687 at a cost of \$6.00 each.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995.**

10 NCAC .4806 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1804 as follows with changes:

.4806 NUCLEAR MEDICINE SERVICES

When nuclear medicine services are offered, ~~the governing board~~ facility management shall ~~adopt establish and maintain~~ written policies and procedures for the provision of those services which ~~will ensure~~ shall provide for the safety of patients and staff, management of radioactive isotopes and the maintenance of equipment according to the manufacturers' recommendations.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .4901 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1804 as follows with changes:

SECTION .4900 LABORATORY SERVICES AND PATHOLOGY

.4901 ORGANIZATION

The laboratory shall be under the supervision of a clinical pathologist or physician designated by the governing ~~board~~ **body**, who has special training in clinical laboratory diagnosis.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995.**

10 NCAC .4902 is adopted as published in the N.C. Register Volume 21, Issue 9, pages 1804-1805 as follows:

.4902 RECORDS

- (a) All requests for laboratory services shall be documented.
- (b) All reports of laboratory services performed, including autopsy, shall be placed in the patient's medical record.
- (c) Records of proficiency testing appropriate to the scope of services offered shall be available to the Division for review.
- (d) Records of equipment calibration and quality controls as recommended by the manufacturer shall be maintained and be available to the Division for review.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .4903 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1805 as follows with changes:

.4903 STAFFING

The clinical pathologist or his appointed designee, shall ~~ensure~~ **require** that:

- (1) procedures and tests conducted are within the scope of the laboratory as approved by the hospital;
- (2) at least one qualified medical technologist is available at all times; and
- (3) qualified staff are available to carry out the functions of the laboratory.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ **September 1, 1995.**

10 NCAC .4904 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1805 as follows with changes:

.4904 TESTS

(a) Laboratory tests to be performed on a patient at the time of admission (if any) shall be established by the medical staff and be approved by the governing board of the hospital. In the event the medical staff and governing board elect not to establish routine laboratory tests for new admissions, the request for such tests shall be left to the discretion of the admitting physician attending medical staff members.

(b) Serological tests for patients admitted shall be optional with the hospital. However, there shall be adequate records indicating that obstetrical patients have had a serological test during their current pregnancy.

(c) When laboratories outside of the facility are used, such laboratories must shall be approved by the governing board and medical staff of the facility. In case of such usage, a legible copy of the laboratory report must be included in the patient record.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .4905

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority to incorporate the CHS rules
by reference.

Joseph J. DeLuca, Jr.
Staff Director

128A

10 NCAC .4905 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1805 as follows with changes:

.4905 TISSUE REMOVAL AND DISPOSAL

(a) The medical staff shall ~~adopt~~ **establish and maintain** written policies for pathological examination of tissue and specimens removed during surgery.

(b) Pathological waste disposal ~~must~~ **shall** comply with the rules Governing the Sanitation of Hospitals, Nursing and Rest Homes, Sanitariums, Sanatoriums, and Educational and Other Institutions, contained in 15A NCAC 18A .1300 which is hereby incorporated by reference including subsequent amendments and editions. Copies of 15A NCAC 18A .1300 may be obtained at no charge from the Environmental Health Section, Health Division, North Carolina Department of Environment, Health and Natural Resources, P.O. Box 27687, Raleigh, NC 27611-7687.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995.**

10 NCAC .4906 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1805 as follows:

.4906 BLOOD BANK

(a) Facilities which provide for procurement, storage and transfusion of blood shall meet the standards of the American Association of Blood Banks as outlined in the most current edition of Standards of Blood Banks and Transfusion Services available from the American Association of Blood Banks, 8101 Glenbrook Road, Bethesda, Maryland 20814-2749 at a cost of \$33.50 per copy.

(b) The governing body shall approve the pathologist or physician as physician-in-charge of the blood bank service.

(c) Records shall be kept on file indicating the receipt and disposition of all blood handled. Care shall be taken to ascertain that blood administered has not exceeded its expiration date, and meets all criteria for safe administration.

(d) The facility shall make arrangements to secure on short notice all necessary supplies of blood, typed and cross-matched as required, for emergencies.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .4907 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1805 as follows with changes:

.4907 MORGUE AND AUTOPSY FACILITIES

(a) Morgue and autopsy services shall be provided either on site or by written agreement with a facility that provides those services.

(b) Procedures for the transport and storage of deceased patients shall be ~~adopted~~ **established and maintained** by facility management.

(c) Procedures for post mortem cleaning of patients with diagnosed contagious diseases shall be ~~adopted~~ **established and maintained** by the facility management.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995.**

10 NCAC .5001 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1805 as follows:

SECTION .5000 PHYSICAL REHABILITATION SERVICES

.5001 ORGANIZATION

Facility management shall designate an individual responsible for the administration and supervision of each rehabilitation service.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .5002

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited for regulating
physical rehab services personnel.

Joseph J. DeLuca, Jr.
Staff Director

132A

10 NCAC .5002 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1806 as follows with changes:

.5002 DELIVERY OF CARE

(a) A member of the medical staff shall be responsible for the general medical care of the in-patient.

(b) The delivery of all rehabilitation services shall be provided by practitioners credentialed or licensed in their respective fields.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995

10 NCAC .5003 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1806 as follows with changes:

.5003 POLICIES AND PROCEDURES

Facility management shall establish ~~and maintain~~ written policies and procedures that include but are not limited to:

- (1) provision for assessment and evaluation of the services performed;
- (2) safety measures;
- (3) infection control measures; and
- (4) procedures for referral to other facilities for services not available on site.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .5004 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1806 as follows:

.5004 PATIENT RECORDS

The patient record shall contain documentation of physical rehabilitation services utilized that include but is not limited to:

- (1) diagnosis to support the services requested;
- (2) assessment of patient's rehabilitative status;
- (3) re-assessment and progress of patient's rehabilitative status;
- (4) individualized plan of care and goals of rehabilitation; and
- (5) discharge plan.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .5005 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1806 as follows:

.5005 CARDIAC REHABILITATION PROGRAM

When a facility elects to provide an outpatient cardiac rehabilitation program, the program shall be subject to rules 10 NCAC 3S, Section .0300-.1000 adopted by reference with all subsequent amendments. Referenced rules are available from the North Carolina Department of Human Resources, Division of Facility Services, Medical Facilities Licensure Section, 701 Barbour Drive, Raleigh, NC 27603 at a cost of \$3.00 each.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

SECTION .5100 INFECTION CONTROL

.5101 ORGANIZATION

(a) The governing body shall establish ~~and maintain~~ an infection control program that includes all patient care and patient care support services and departments for the surveillance, prevention and control of infection.

(b) The infection control committee shall include representatives of the medical staff, nursing staff, administration and the person directly responsible for the surveillance program activities.

(c) The infection control committee shall assume responsibility for the infection control program.

(d) Facility management shall designate a person to manage the infection control, prevention and surveillance program.

(e) The infection control committee shall involve facility departments and services as needed to maintain the infection control program.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

.5102 POLICY AND PROCEDURES

(a) Each facility department or service shall establish ~~and maintain~~ written infection control policies and procedures. These shall include but are not limited to:

- (1) the role and scope of the service or department in the infection control program;
- (2) the role and scope of surveillance activities in the infection control program;
- (3) the methodology used to collect and analyze data, maintain a surveillance program on nosocomial infection, and the control and prevention of infection;
- (4) the specific precautions to be used to prevent the transmission of infection and isolation methods to be utilized;
- (5) the method of sterilization and storage of equipment and supplies, including the reprocessing of disposable items;
- (6) the cleaning of patient care areas and equipment;
- (7) the cleaning of non-patient care areas; and
- (8) exposure control plans.

(b) The infection control committee shall approve all infection control policies and procedures. The committee shall review all policies and procedures at least every three years and indicate the last date of review.

(c) The infection control committee shall meet at least quarterly and maintain minutes of meetings.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ ~~September 1, 1995~~.

10 NCAC .5103 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1807 as follows with changes:

.5103 LAUNDRY SERVICE

Facility management shall provide, directly or by contract, a laundry service or department that achieves provides the following:

- (1) 24 hour a day availability of clean linen for patient care needs; and
- (2) delivery of clean linen and removal of soiled linen in a manner that reduces the spread of infection.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .5104 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1807 as follows with changes:

.5104 ENVIRONMENTAL SERVICES

Facility management shall ~~ensure~~ **require** that environmental services (housekeeping) ~~achieve~~ **provide** the following:

- (1) 24 hour a day availability of personnel or supplies and equipment for the cleaning of patient rooms, patient care equipment, and the cleaning of spills;
- (2) a routine cleaning schedule for all areas of the facility to assist in the prevention and spread of disease; and
- (3) removal and appropriate disposal of waste materials including biologicals.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ **September 1, 1995.**

10 NCAC .5105 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1807 as follows with changes:

.5105 STERILE SUPPLY SERVICES

Facility management shall ~~ensure that services achieve~~ **provide for** the following:

- (1) decontamination and sterilization of equipment and supplies;
- (2) monitoring of sterilizing equipment on a routine schedule;
- (3) ~~establishment of~~ policies and procedures for the ~~reuse use~~ of disposable items; and
- (4) ~~establishment of~~ policies and procedures addressing shelf life of stored sterile items.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ **September 1, 1995.**

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .5201

RECOMMENDATION:

Object, based on

Lack of
Statutory
authority

X Unclear,
ambiguous

Unnecessary

COMMENT: It is unclear whether there is a difference
between the "services" covered in this rule and the licensed
program in .5205.

Joseph J. DeLuca, Jr.
Staff Director

141A

10 NCAC .5201 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1807 as follows:

SECTION .5200 PSYCHIATRIC SERVICES

.5201 PSYCHIATRIC OR SUBSTANCE ABUSE SERVICES: APPLICABILITY OF RULES

The rules contained in 10 NCAC 3C .5200 shall apply to all psychiatric and substance abuse services provided.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .5202

RECOMMENDATION:

Object, based on

Lack of
Statutory
authority

X Unclear,
ambiguous

Unnecessary

COMMENT: The definition of psychiatric and substance abuse services may not be clear.

Joseph J. DeLuca, Jr.
Staff Director

142A

.5202 DEFINITIONS APPLICABLE TO PSYCHIATRIC OR SUBSTANCE ABUSE SERVICES

(a) "Certified counselor" means an alcoholism, drug abuse or substance abuse counselor who is certified by the North Carolina Substance Abuse Professional Certification Board.

(b) "Certified substance abuse counselor/supervisor" means an individual who is a "certified counselor" as defined in 10 NCAC 3C .5202(a) and is designated by the North Carolina Substance Abuse Professional Certification Board as a qualified substance abuse supervisor.

(c) "Clinical/professional supervision" means regularly scheduled assistance by a qualified mental health, professional or a qualified substance abuse professional to a staff member who is providing direct, therapeutic intervention to a client or clients. The purpose of clinical supervision is to ensure that each client receives appropriate treatment or habilitation which is consistent with accepted standards of practice and the needs of the client.

(d) "Detoxification service" means a service provided in a unit or department whose primary purpose is to treat substance abuse through detoxification.

(e) "Direct care staff" means an individual who provides active direct care, treatment, or rehabilitation or habilitation services to clients on a continuous and regularly scheduled basis.

(f) "Psychiatric nurse" means an individual who is licensed to practice as a registered nurse in North Carolina by the North Carolina Board of Nursing and ~~who is has~~

(1) a graduate ~~degree from~~ of an accredited master's level program in psychiatric mental health nursing with two years of experience; or ~~has~~

(2) a master's degree in behavioral science with two years of supervised clinical experience in psychiatric mental health nursing; or ~~has~~

(3) a baccalaureate degree in behavioral science with four years of supervised clinical experience in psychiatric mental health nursing;

~~four years of supervised clinical experience in psychiatric mental health nursing.~~

(g) "Psychiatric service" means a service provided in a unit or department who primary purpose is to treat mental illness.

(h) "Psychiatric social worker" means an individual who holds a master's degree in social work from an accredited school of social work and has two years of clinical social work experience.

(i) "Psychiatrist" means an individual who is licensed to practice medicine in North Carolina and who has completed an accredited training program in psychiatry.

(j) "Psychologist" means an individual licensed to practice psychology in North Carolina by the North Carolina State Board of Examiners of Practicing Psychologists.

(k) "Qualified mental health professional" means any one of the following: psychiatrist, psychiatric nurse, practicing psychologist, psychiatric social worker, an individual with at least a masters degree in a related human service field and two years of supervised clinical experience in mental health services or an individual with a baccalaureate degree in a related human service field and four years of supervised clinical experience in mental health services.

(l) "Qualified substance abuse professional" means an individual who is:

(1) certified by the North Carolina Substance Abuse Professional Certification Board;

(2) certified by the National Consortium of Chemical Dependency Nurses, Inc; or

(3) ~~certified by the National Nurses Society on Addictions; or~~

(4) a graduate of a college or university with a baccalaureate or advanced degree in a human service related field with documentation of at least two years of supervised experience in the profession of alcoholism and drug abuse counseling.

(m) "Restraint" means the limitation of one's freedom of movement and includes the following:

(1) mechanical restraint which means restraint of a client with the intent of controlling behavior with mechanical devices which include, but are not limited to, cuff, ankle straps, sheets or restraining shirts; or

(2) physical restraint which means restraint of a client until calm. As used in these rules, the term physical restraint does not apply to the use of professionally recognized methods for

therapeutic holds of brief duration (five minutes or less).

(n) "Restrictive facility" means a facility so designated by the Division of Facility Services which uses mechanical ~~restraint or seclusion~~ ~~is proposed to be adopted as follows: restraint or seclusion~~ in accordance with N.C. Gen. Stat. 122C-60 in order to restrain a client's freedom of movement.

(o) "Seclusion" means isolating a client in a separate locked room for the purpose of controlling a client's behavior.

(p) "Substance abuse service" means service provided in a unit or department whose primary purpose is to treat substance abuse.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

.5203 STAFFING FOR PSYCHIATRIC OR SUBSTANCE ABUSE SERVICES

(a) General Requirements:

- (1) A physician shall be present in the facility or on call 24 hours per day. The medical appraisal and medical treatment of each patient shall be the responsibility of a physician.
- (2) Each facility shall determine its overall staffing requirements based upon the age categories (child, adolescent, adult, elderly), clinical characteristics, treatment requirements and numbers of patients.
- (3) There shall be a sufficient number of appropriately qualified clinical and support staff to assess and address the clinical needs of the patients.
- (4) Staff members shall have training or experience in the provision of care in each of the age categories assigned for treatment.

(b) Psychiatric Services:

- (1) Staff coverage for psychiatric services shall include at least one each of the following: psychiatrist, psychiatric nurse, psychologist, and psychiatric social worker.
- (2) A qualified mental health professional shall be available by telephone or page and able to reach the facility within 30 minutes on a 24 hour basis.
- (3) Each clinical or direct care staff member who is not a qualified mental health professional shall receive professional supervision from a qualified mental health professional.
- (4) When detoxification services are provided, there shall be liaison and consultation with a qualified substance abuse professional prior to the discharge of a client.

(c) Substance Abuse Services:

- (1) At least one registered nurse shall be on duty during each shift.
- (2) Certified substance abuse counselors or qualified substance abuse professionals shall be employed at the ratio of one staff member for each ten inpatients or fraction thereof. In documented instances of bona fide shortages of certified persons, uncertified individuals expecting to become certified may be employed for a maximum of 38 months without qualifications.
- (3) The facility shall have a minimum of two staff members providing care, treatment and services directly to patients on duty at all times and maintain a shift ratio of one staff member for each 20 or less inpatients with the following exceptions:
 - (A) When there are minor inpatients there shall be staff available on the ratio of one staff member for each 5 minor inpatients or fraction thereof during each shift from 7:00 a.m. - 11:00 p.m.
 - (B) When detox services are offered there shall be no less than one staff member for each nine inpatients or fraction thereof on each shift.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

.5204 PSYCHIATRIC OR SUBSTANCE ABUSE SERVICES RECORD REQUIREMENTS

(a) In addition to the general record keeping requirements of 10 NCAC 3C .3906, specialized assessment and treatment plans for individuals undergoing psychiatric or substance abuse treatment are as follows:

- (1) Within 24 hours following admission each individual shall have a completed admission assessment. The initial assessment shall include the reason for admission, admitting diagnosis, mental status including suicide potential, diagnostic tests or evaluations, and a determination of the need for additional information to include the potential for the physical abuse of self or others and a family assessment when a minor is involved.
- (2) Within 72 hours following admission, a preliminary individual treatment plan shall be completed and implemented; and
- (3) Within ~~ten~~ **five** days following admission, a comprehensive individual treatment plan shall be developed and implemented. For outpatient programs the plan shall be developed and implemented within 30 days of admission to treatment.

(b) Individual treatment plans for psychiatric and substance abuse patients shall be developed in partnership with the patient or individual acting on behalf of the patient. Clinical responsibility for the development and implementation of the plan shall be clearly designated. Minimum components of the comprehensive treatment plan shall include diagnosis and time specific short and long term measurable goals, strategies for reaching goals, and staff responsibility for plan implementation. The plan shall be revised as medically or clinically indicated.

(c) Progress notes shall be entered in each individual's record. Included is information which may have a significant impact on the individual's condition or expected outcome such as family conferences or major events related to the patient. Patient status shall be documented each shift for any inpatient psychiatric or substance abuse services, and on a per visit basis for outpatient psychiatric and substance abuse services.

(d) For each individual to whom substance abuse services are provided, a written plan for aftercare services shall be developed which minimally includes:

- (1) plan for delivering aftercare services, including the aftercare services which are provided; and
- (2) provision for agreements with individuals or organizations if aftercare services are not provided directly by the facility.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ **September 1, 1995**

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .5205

RECOMMENDATION:

Object, based on

Lack of
Statutory
authority

X Unclear,
ambiguous

Unnecessary

COMMENT: It is unclear whether the licensed program referred to in this rule and the "services" referred to in .5201 are the same.

Joseph J. DeLuca, Jr.
Staff Director

146A

10 NCAC .5205 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1809 as follows:

.5205 SECLUSION

At least one seclusion room shall be provided in all hospitals licensed to provide a psychiatric program, a substance abuse program or both.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .5206 is adopted as published in the N.C. Register Volume 21, Issue 9, pages 1809-1810 as follows with changes:

.5206 COMPLIANCE WITH STATUTORY REQUIREMENTS

(a) Facilities providing psychiatric or substance abuse services shall develop procedures to ensure ~~protect~~ the rights of psychiatric and substance abuse patients in accordance with North Carolina statutes addressing the rights of psychiatric and substance abuse patients. Statutes addressing such rights are as follows:

- (1) G.S. 122C-51. Declaration of policy on clients' rights;
- (2) G.S. 122C-52. Right to confidentiality;
- (3) G.S. 122C-53. Exceptions; client;
- (4) G.S. 122C-54. Exceptions; abuse reports and court proceedings;
- (5) G.S. 122C-55. Exceptions; care and treatment;
- (6) G.S. 122C-56. Exceptions; research and planning;
- (7) G.S. 122C-57. Right to treatment and consent to treatment;
- (8) G.S. 122C-58. Civil rights and civil remedies;
- (9) G.S. 122C-59. Use of corporal punishment;
- (10) G.S. 122C-60. Use of physical restraints or seclusion;
- (11) G.S. 122C-61. Treatment rights in 24-hour facilities;
- (12) G.S. 122C-62. Additional rights in 24-hour facilities;
- (13) G.S. 122C-65. Offenses relating to clients; and
- (14) G.S. 122C-66. Protection from abuse and exploitation; reporting.

(b) Facilities providing psychiatric or substance abuse services shall develop procedures to protect confidentiality of information regarding communicable disease and conditions in compliance with N.C. Gen. Stat. 130A-143.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .5207 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1810 as follows:

.5207 PSYCHIATRIC OR SUBSTANCE ABUSE OUTPATIENT SERVICES

Partial hospitalization, outpatient and day treatment facilities shall be subject to rules 10 NCAC 14L Section .0300, 10 NCAC 14N Section .0700, and 10 NCAC 14N Section .0900 respectively and adopted by reference with all subsequent amendments. Referenced rules are available from the N.C. Division of Mental Health, Developmental Disabilities, and Substance Abuse Services, Quality Improvement Section, 325 North Salisbury Street, Raleigh, NC 27603-5906 at a cost of \$5.75 per copy.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .5301 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1810 as follows:

**SECTION .5300 SUPPLEMENTAL RULES FOR THE LICENSURE OF THE
NURSING FACILITY BEDS; DOMICILIARY BEDS IN A HOSPITAL**

.5301 SUPPLEMENTAL RULES

When a facility offers nursing facility services or domiciliary care services, the services shall be included under one hospital license as provided in rule .3101 of this Subchapter. The nursing facility care and domiciliary care unit shall meet the supplemental requirements of this Section in addition to all other applicable rules in this Subchapter.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .5302

RECOMMENDATION:

Object, based on

Lack of
Statutory
authority

X Unclear,
ambiguous

Unnecessary

COMMENT: The meaning of "sexual harassment" in (1)(b) and "humiliation" and "harassment" in (1)(d) are unclear.

In (17) it is unclear if the adjective "criminal" applies only to "taking" or to any or all of the remaining listed acts. It is unclear to me what constitutes "exploitation," of property criminal or otherwise.

Joseph J. DeLuca, Jr.
Staff Director

15bA

.5302 DEFINITIONS

The following definitions shall apply throughout this Section:

- (1) "Abuse" means the willful infliction of physical pain, injury, mental anguish or unreasonable confinement which may cause or result in temporary or permanent mental or physical injury, pain, harm or death. Abuse includes, but is not limited to, the following:
 - (a) Verbal abuse - any use of oral, written or gestured language which a reasonable person would view as disparaging and derogatory terms to a patient regardless of his or her age, ability to comprehend or disability;
 - (b) Sexual abuse - sexual harassment, sexual coercion or sexual assault of a patient;
 - (c) Physical abuse - hitting, slapping, kicking or corporal punishment of a patient;
 - (d) Mental abuse - language or treatment which would be viewed by a reasonable person as involving humiliation, harassment, threats of punishment or deprivation of a patient;
 - (e) Unreasonable confinement - the separation of a patient from other persons, or from his or her room, against the patient's will or the will of the patient's legal representative. Unreasonable confinement does not include emergency or short-term monitored separation used as therapeutic intervention to reduce agitation until a plan of care is developed to meet the patient's needs.
- (2) "Accident" means something occurring by chance or without intention which has caused physical or mental harm to a patient, resident or employee.
- (3) "Administer" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion or other means.
- (4) "Administrator" means the person who has authority for and is responsible to the governing board for the overall operation of a nursing facility or domiciliary care facility.
- (5) "Brain injury long term care" is defined as an inter-disciplinary, intensive maintenance program for patients who have incurred brain damage caused by external physical trauma and who have completed a primary course of rehabilitative treatment and have reached a point of no gain or progress for more than three consecutive months. Services are provided through a medically supervised interdisciplinary process and are directed toward maintaining the individual at the optimal level of physical, cognitive and behavioral functioning.
- (6) "Combination facility" means any facility with nursing facility beds (nursing home beds) which is licensed to provide more than one level of care.
- (7) "Convalescent care" means care given for the purpose of assisting the patient or resident to regain health or strength.
- (8) "Director of Nursing" means the registered nurse who has authority and direct responsibility for all nursing services and nursing care on the nursing facility.
- (9) "Dispense" means preparing and packaging a prescription drug or device in a container and labeling the container with information required by state and federal law. Filling or refilling drug containers with prescription drugs for subsequent use by a patient is "dispensing". Providing quantities of unit dose prescription drugs for subsequent administration is "dispensing".
- (10) "Drug" or "medication" means substances:
 - (a) recognized in the official United States Pharmacopoeia, official National Formulary, or any supplement to any of them;
 - (b) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;
 - (c) intended to affect the structure or any function of the body of man or other animals, i.e., substances other than food; and
 - (d) intended for use as a component of any article specified in (a), (b), or (c) of this

- Subparagraph; but does not include devices or their components, parts, or accessories.
- (11) "Duly licensed" means holding a current and valid license as required under the General Statutes of North Carolina.
 - (12) "Existing facility" means a licensed facility.
 - (13) "Exit conference" means the conference held at the end of a survey, inspection or investigation, but prior to finalizing the same, between the department's representatives who conducted the survey, inspection or investigation and a facility's representative(s).
 - (14) "Incident" means an intentional or unintentional action, occurrence or event which is likely to cause or lead to physical or mental harm to a patient resident or employee.
 - (15) "Licensed Practical Nurse" means a nurse who is duly licensed as a practical nurse under N. C. Gen. Stat. 90, Article 9A.
 - (16) "Licensee" means the person, firm, partnership, association, corporation or organization to whom a license has been issued.
 - (17) "Misappropriation of property" means the criminal taking, use, exploitation of, destruction of, or damage to, a patient's belongings or money. The Department must prove the misappropriation of property by a preponderance of the evidence. Conviction of the criminal act is not a prerequisite to placing a finding concerning the misappropriation of property on the North Carolina Nurse Aide Registry.
 - (18) "Neglect" means a failure through a lack of attention, carelessness, or omission, to provide timely and consistent services, treatment or care to a patient or patients which are necessary to obtain or maintain the patient's or patients' health, safety or comfort.
 - (19) "New facility" means a proposed facility, a proposed addition to an existing facility or a proposed remodeled portion of an existing facility. If it is determined by the department that more than one half of an existing facility is remodeled, the entire existing facility shall be considered a new facility.
 - (20) "Nurse Aide" means any individual providing nursing-related services to patients in a facility, who is not a licensed health professional, a registered dietitian or someone who volunteers to provide such services without pay, and who is listed on the North Carolina Nurse Aide registry.
 - (21) "Nurse Aide Trainee" means an individual who has not completed an approved nurse aide training course and competency evaluation but is performing tasks for which they have been found proficient by an instructor. These tasks shall be performed under the direct supervision of a registered nurse. The term does not apply to volunteers.
 - (22) "On duty" means personnel who are awake, dressed, responsive to patient needs and physically present in the facility performing assigned duties.
 - (23) "Patient" means any person admitted for care to a nursing facility.
 - (24) "Physician" means a person licensed under N. C. Gen. Stat. 90, Article 1 to practice medicine in North Carolina.
 - (25) "Registered Nurse" means a nurse who is duly licensed as a registered nurse under N. C. Gen. Stat. 90, Article 9A.
 - (26) "Resident" means any person admitted for care to a domiciliary home.
 - (27) "Restorative nursing care" means the plan and delivery of care to attain and maintain the patient's pre-illness level of function.
 - (28) "Sitter" means an individual employed to provide companionship and social interaction to a particular resident or patient, usually on a private duty basis.
 - (29) "Ventilator dependence" is defined as physiological dependency by a patient on the use of a ventilator for more than eight hours a day.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .5303 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1812 as follows:

.5303 INSPECTIONS

(a) Any facility with beds licensed by the Department under Section .5300 of this Subchapter may be inspected by one or more authorized representative of the Division at any time. Generally, inspections will be conducted between the hours of 8:00 a.m. and 6:00 p.m., Monday through Friday. However, complaint investigations shall be conducted at the most appropriate time for investigating the complaint.

(b) At the time of inspection, the authorized representative of the Division shall make his presence known to the administrator or other person in charge who shall cooperate with such representative and facilitate the inspection.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .5304 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1812 as follows:

.5304 ADMISSIONS

(a) No patient or resident shall be admitted except under the orders of a North Carolina licensed physician.

(b) The nursing facility shall acquire prior to or at the time of admission orders from the attending physician for the immediate care of the patient or resident.

(c) Within 48 hours of admission, the facility shall acquire medical information which shall include current medical findings, diagnosis, rehabilitation potential, a summary of the facility stay if the patient or resident is being transferred from a facility, and orders for the ongoing care of the patient or resident.

(d) If a patient is admitted from somewhere other than a facility, a physical examination shall be performed either within five days prior to admission or within 48 hours following admission.

(e) Facilities offering nursing facility or domiciliary home care as a new service must prepare a plan of admission which, at a minimum, ensures availability of staff time and plans for individual patient assessments, initiation of health care or nursing care plans, and implementation of physician and nursing treatment plans. This plan shall be available for inspection during the initial licensure survey prior to issuance of a license.

(f) Only persons who are 18 years of age or older shall be admitted to domiciliary home beds.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

.5305 POLICIES AND PROCEDURES

The governing board shall ensure the development of written policies and procedures which shall be available to and implemented by staff. These policies and procedures shall cover at least the following areas:

- (1) admissions and transfers;
- (2) discharges with physician orders and patients or residents leaving against physician advice;
- (3) nutrition and dietetic services;
- (4) gratuities and solicitation policies which at a minimum shall provide that no owner, operator, agent or employee of a facility nor any member of his family shall accept a gratuity directly or indirectly from a patient or resident in the facility or solicit for any type of contribution;
- (5) housekeeping;
- (6) infection control which include, but not limited to, requirements for sterile, aseptic and isolation techniques; and communicable disease screening including, at a minimum annual tuberculosis screening for all staff and inpatients of the facility;
- (7) screening and reporting communicable disease to the local health department;
- (8) orientation of all facility personnel;
- (9) patient or resident care plans, treatment and other health care or nursing care, including but not limited to all policies and procedures required by rules contained in this Subchapter;
- (10) patients' or residents' rights;
- (11) physical evaluation for residents and patients at least annually;
- (12) physician services and utilization of the individual's private physician;
- (13) procurement of supplies and equipment to meet individual patient care needs;
- (14) protection of patients from abuse and neglect;
- (15) rehabilitation services;
- (16) release of medical record information; and
- (17) maintenance of patient medical or health care records including charging or record keeping.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .5306 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1813 as follows:

.5306 GENERAL

The governing board shall ensure that policies and procedures are available and implemented for assessing each patient's or resident's health care needs and for planning to meet identified health care needs. There shall be a system for evaluating the effectiveness of the nursing care assessment, planning and implementation (delivery of care processes) for each patient or resident.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995

10 NCAC .5307 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1813 as follows:

.5307 ASSESSMENT AND PLANNING

Each patient's and resident's condition shall be assessed on a regular, periodic basis, at least quarterly, with appropriate notation and updating of the health plan of care. Health care planning for each patient and resident shall be an on-going interdisciplinary process and shall include, but not be limited to, the following:

- (1) data which is systematically and continuously collected about the patient's or resident's health status; and which shall be recorded so as to be accessible to all staff involved in the patient's or resident's care;
- (2) current problems or needs shall be identified and prioritized from a completed assessment; and
- (3) a current plan of care developed in conjunction with the patient or resident or legal guardian that includes measurable time-related goals and approaches, or measures to be employed by various disciplines in order to achieve the identified goals.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .5308 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1813 as follows:

.5308 IMPLEMENTATION OF HEALTH PLAN

All parts of the plan of care shall be assigned to specific disciplines or staff as indicated in the plan of care to ensure that health care and rehabilitative services are performed daily and documented for those patients and residents who require such services.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995

RRC STAFF RECOMMENDATION

AGENCY: DHR/Medical Care Commission

RULE CITATION: 10 NCAC 3C .5309

RECOMMENDATION:

Object, based on

X Lack of
Statutory
authority

Unclear,
ambiguous

Unnecessary

COMMENT: There is no authority cited for regulating
personnel working with hospital provided nursing facility
beds or domiciliary beds.

Joseph J. DeLuca, Jr.
Staff Director

158A

.5309 NURSING/HEALTH CARE ADMINISTRATION AND SUPERVISION

- (a) A hospital nursing facility or unit shall have a director of nursing service who shall be responsible for the overall organization and management of all nursing services. The director of nursing service shall be currently licensed to practice as a registered nurse by the North Carolina Board of Nursing in accordance with N. C. Gen. Stat. 90, Article 9A.
- (b) A facility or unit shall not be licensed unless it has a director of nursing or acting director or nursing.
- (c) The director of nursing shall not serve as administrator or assistant administrator.
- (d) A facility with shall provide a full-time director of nursing on duty at least eight hours per day, five days a week.
- (e) The director of nursing shall cause the following to be accomplished:
 - (1) establish and implement of nursing policies and procedures which shall include, but shall not be limited to the following:
 - (A) daily charting of any unusual occurrences or acute episodes related to patient care, and progress notes written monthly reporting each patient's performance in accordance with identified goals and objectives and each patient's progress toward rehabilitative nursing goals;
 - (B) assurance of the delivery of nursing services in accordance with physicians' orders, nursing care plans and the facility's policies and procedures;
 - (C) notification of emergency physicians or on-call physicians;
 - (D) infection control to prevent cross-infection among patients and staff;
 - (E) reporting of deaths;
 - (F) emergency reporting of fire, patient and staff accidents or incidents, or other emergency situations;
 - (G) use of protective devices or restraints to ensure that each patient or resident is restrained in accordance with physician orders and the facility's policies, and that the restrained patient or resident is appropriately evaluated and released at a minimum of every two hours;
 - (H) special skin care and decubiti care;
 - (I) bowel and bladder training;
 - (J) maintenance of proper body alignment and restorative nursing care;
 - (K) supervising and assisting patients with feeding;
 - (L) intake and output observation and reporting for those patients whose condition warrants monitoring of their fluid balance. This will include those patients on intravenous fluids or tube feedings, and patients with kidney failure and temperatures elevated to 102 degrees Fahrenheit or above;
 - (M) catheter care; and
 - (N) procedures used in caring for patients in the facility;
 - (2) develop written job descriptions for nursing personnel;
 - (3) periodic assessment of the nursing department and identification of personnel requirements as they relate to patient care needs and reporting same to the administrator;
 - (4) orientation plan and continuing inservice education program for nursing employees and documentation of staff attendance and subject matter covered during inservice education programs;
 - (5) provide appropriate reference materials for the nursing department, which includes a Physician's Desk Reference or comparable drug reference, policy and procedure manual, and medical dictionary for each nursing station; and

- (6) establish of operational procedures to ensure that appropriate supplies and equipment are available to nursing staff as determined by individual patient care needs.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

.5310 NURSE STAFFING REQUIREMENTS

(a) A hospital nursing facility or unit shall provide licensed nursing personnel sufficient to accomplished the following:

- (1) patient needs assessment;
- (2) patient care planning; and
- (3) supervisory functions in accordance with the level of patient or resident care advertised or offered by the facility.

The facility also shall provide additional nursing personnel sufficient to ensure that the activities of daily living, personal grooming, restorative nursing actions and other health care needs identified in each patient's or resident's plan of care are met.

(b) A multi-storied facility shall provide at least one person on duty on each patient care floor at all times.

(c) Daily direct patient care nursing staff, licensed and unlicensed, shall equal or exceed 2.1 nursing hours per patient. (nursing hours per patient day or NHPPD or NH/PD.)

(d) At least one licensed nurse shall be on duty for direct patient care at all times.

(e) A registered nurse shall be on duty for at least eight consecutive hours a day, seven days a week. The Director of Nursing may be counted as meeting the requirements for both the director of nursing and patient and resident care staffing for facilities of a total census of 60 beds or less.

(f) Nursing support personnel, including ward clerks, secretaries, nurse educators and persons primarily in administrative management positions and not actively involved in direct patient care shall not be counted toward compliance with minimum daily requirements for direct care staffing.

(g) A facility shall not employ or contract, as a nurse aide, any individual not listed on the North Carolina Nurse Aide Registry, unless the individual is enrolled full-time in a nurse aide training and competency evaluation program approved by the Department; or the individual can prove that he or she has recently successfully completed a training and competency evaluation program approved by the Department and has not yet been included in the registry. Facilities must follow up to ensure that such individuals actually become registered.

(h) The facility shall maintain an accurate record of qualifications and in-service training for each nurse aide employed by the facility. The facility shall provide, to the Department upon request, verification of employment of any nurse aide employed by the facility in the previous 12 months.

History Note: Statutory Authority G.S. 131E-79;

Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .5311 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1815 as follows:

.5311 DOMICILIARY HOME PERSONNEL REQUIREMENTS

(a) The administrator shall designate a person to be in charge of the domiciliary home residents at all times.

(b) If domiciliary home beds are located in a separate building or a separate level of the same building, there shall be a person on duty in the domiciliary home areas at all times.

(c) A facility shall provide sufficient staff to ensure that activities of daily living, personal grooming, and assistance with eating are provided to each resident. Medication administration as indicated by each resident's condition or physician's orders shall be carried out as identified in each resident's plan of care.

(d) Domiciliary home facilities (Home for the Aged beds) licensed as a part of a combination facility shall comply with the staffing requirements of 10 NCAC 42D .1407 as adopted by the Social Services Commission for freestanding domiciliary homes and any subsequent amendments thereto.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

.5312 REHABILITATIVE NURSING AND DECUBITUS CARE

Each patient or resident shall be given care coordinated by the registered nurse to prevent contractures, deformities, and decubiti, including but not limited to:

- (1) changing positions of bedfast and chairfast patients or residents every two hours and administering simple preventive care. Documentation of such care and outcome must be included in routine summaries or progress notes;
- (2) maintaining proper alignment and joint movement to prevent contractures and deformities. Documentation of such care must be included in routine summaries or progress notes;
- (3) implementing an individualized bowel and bladder training program except for patients or residents whose records document that such training is not effective. A monthly summary for patients and quarterly summaries for domiciliary residents shall be written relative to each patient's or resident's performance in the bowel and bladder training program;
- (4) providing adequate nutrition and hydration; and
- (5) such other services as are necessary to meet the needs of the patient.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

10 NCAC .5313 is adopted as published in the N.C. Register Volume 21, Issue 9, page 1815 as follows:

.5313 MEDICATION ADMINISTRATION

(a) The administration of medication in nursing facility units shall comply with rule .4511(a) of this Subchapter.

(b) Verbal and telephone orders shall be countersigned by a physician within five days of issuance.

History Note: Statutory Authority G.S. 131E-79;
Eff. ~~May 1, 1995~~ September 1, 1995.

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 <bbugon@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: Re: [External] Hospital Rules

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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

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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

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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

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Hi Brian,

Thank 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

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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
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(984)236-1948
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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

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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
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Burgos, Alexander N

Subject: FW: Pre-review comments response - 10A NCAC 13B Phase 4 readoption rules

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

809 Ruggles Drive, Edgerton Building

2701 Mail Service Center

Raleigh, NC 27699-2701

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](#)



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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](#)

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: 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](#)

Office: 919-855-3811

Fax: 919-733-2757

nadine.pfeiffer@dhhs.nc.gov

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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

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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 psychiatrist 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

Subject: FW: NC Medical Care Commission Request for Changes - June 2022 RRC

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From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
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](#)

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: 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

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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

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