

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](#)

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From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Saturday, June 4, 2022 11:27 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Subject: RE: NC Medical Care Commission Request for Changes - June 2022 RRC

Hi Nadine,

Just wanted to confirm you received these? I know it was late on Friday, and I do apologize for not getting these to you sooner, it's been yet another heavy month for us here.

As always, let me know if you have any questions or concerns.

Brian

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

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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
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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
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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, June 9, 2022 2:56 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: Historical documents for Hospital rules

Hi Brian,

As a follow-up to this afternoon's conference call, please see the attached documents I received from the prior Codifier on the rule filings for the hospital permanent rules prior to the rules becoming effective January 1, 1996. These documents include the RRC objections and RRC meeting minutes. Please note, the rules were recodified in 2003. Prior to recodification, the hospital rules Subchapter was 10 NCAC 13C but the rule numbers were the same as they are today.

I also have 3 documents (RRC rules-objections 7-95, RRC rules-objections2 7-95, & RRC rules-objections3 7-95) that look like it was all the rules that were submitted to RRC that became effective 1/1/96. From review of this document, it seems as the rules Joe DeLuca, staff attorney, did not object to are just the rules with maybe some highlights on them and the ones with an objection have the objection following the text of the rule.

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

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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

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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](#)

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Burgos, Alexander N

Subject: FW: [External] Hospital Rules

From: Randolph, Kimberly <Krandolph@ncdoj.gov>

Sent: Wednesday, June 8, 2022 11:19 AM

To: Liebman, Brian R <brian.liebman@oah.nc.gov>

Cc: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgon, Bethany A <bburgon@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: Re: [External] Hospital Rules

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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
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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
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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
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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](#)

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From: Pfeiffer, Nadine

Sent: Monday, August 2, 2021 4:48 PM

To: Reeder, Amanda J <amanda.reeder@oah.nc.gov>; May, Amber Cronk <amber.may@oah.nc.gov>

Subject: Pre-review comments response - 10A NCAC 13B Phase 4 readoption rules

Hello!

You can't get enough of me today, can you? We got a pre-review back that Ashley did on our Phase 4 Hospital rules in 10A NCAC 13B on 6/16/21. One of you lucky ladies will most likely get these when we file for permanent rule for the June '22 meeting (or maybe you will pawn them off to one of your new staff whenever they get hired), but in any case, here are our responses to the pre-review comments for those rules.

Nadine Pfeiffer

Rules Review Manager

Division of Health Service Regulation

[NC Department of Health and Human Services](#)



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Burgos, Alexander N

From: Snyder, Ashley B
Sent: Tuesday, June 7, 2022 9:41 AM
To: Pfeiffer, Nadine
Cc: Burgos, Alexander N
Subject: RE: Reviewed rules for June meeting
Attachments: 10A NCAC 13B - ABS.docx

Nadine,

I was curious if I missed something in the pre-review so I pulled my notes. See attached. I asked numerous questions about significant statutory authority concerns in the pre-review. Brian's change requests line up with the same questions raised in the pre-review. These questions should come as no surprise.

Ashley Snyder

Codifier of Rules
Office of Administrative Hearings
(984) 236-1941

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Monday, June 6, 2022 8:10 AM
To: Snyder, Ashley B <ashley.snyder@oah.nc.gov>
Subject: RE: Reviewed rules for June meeting

Good Morning Ashley,

Thank you for getting back with me. Yes, I did receive the technical changes from Brian, however they were received after business hours on Friday (like 6:18pm) and I had left for the day. You are correct, I as the rule coordinator cannot answer any of the technical change questions the staff attorneys pose. Those are handled by the subject matter experts in our Sections that implement the rules. What I do when I get the technical changes is send the document over to them to answer and then I make all the rule changes they want made (I automatically do any "easy" things like changing a word here and there or punctuation changes etc). My folks have no idea how to make changes to the rule text after the NOT is filed so it is easier if I just do it for them, so yes, all of this takes time and a lot of back and forth. I am glad you impressed upon your staff the time it does take agencies to accomplish all of this and the amount of people that are sometimes involved. Thank you!

As for the technical changes I received late Friday evening for the hospital rules, I am disappointed that for 12 of the 14 (1 was a repeal) rules there were questions on the statutory authority for those rules after we had sent those rules for a pre-review and you were the attorney who sent us back the comments on the pre-review and this was not mentioned for all these rules. It would have been nice to know in advance of these issues, which to me, could be a game stopper. Also, to give us a five business day deadline to get the changes back to your agency, instead of the usual 10 business days, when we have to involve DOJ at this point, feels punitive. Our staff subject matter experts have other duties besides rulemaking. They are oftentimes in the field conducting health and safety surveys of facilities for the residents of NC. It is not as easy as one would think to get the answers needed to the technical changes in the typical 10 business days, and now we are asked to do it in five. Yes, I am aware we could ask to extend the period of review for these rules and other rules in the future if we cannot make the deadline for submission of technical changes; however, there will be some rules like CON rules that this will not be possible since the rules will have to become effective the 1st day of the month after the RRC meeting or it will affect the applicants for CONs.

I am truly sorry that there was a large amount of rule filings for this month, but there will be many months like that and have been in the past. Just like for us rulemaking coordinators. When agencies have met the permanent rule submission deadline or submitted earlier than the deadline, I do not feel it is a fair practice to place a shortened technical change submission deadline on agencies because of OAH's workload. Please give this some thought.

Thank you.

Nadine Pfeiffer

Rules Review Manager

Division of Health Service Regulation

[NC Department of Health and Human Services](#)

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From: Snyder, Ashley B <ashley.snyder@oah.nc.gov>

Sent: Saturday, June 4, 2022 7:57 AM

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

Subject: RE: Reviewed rules for June meeting

Good morning, Nadine,

We do have these rules and they are assigned to Brian. As a former rulemaking coordinator, I understand your concern and frustration. It can be difficult to turnaround tech change requests in a short timeline. I actually took a minute to explain that to our staff attorneys on Thursday – rulemaking coordinators often have to take drafts to other staffers, their boss, etc. so they need time to respond to the changes and circulate them within their agency.

From our point of view, please understand we have had heavy filings months in a row resulting in a high volume of rules for the staff attorneys to review this month in addition to numerous follow-up matters. I can assure you our staff attorneys have been working overtime to complete their review as quickly as possible. We are also working on hiring our 4th staff attorney position. I will reach out to Brian and ask him to give you an update.

Thank you for contacting me about this. I always appreciate feedback.

Ashley Snyder

Codifier of Rules

Office of Administrative Hearings

(984) 236-1941

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

Sent: Friday, June 3, 2022 4:26 PM

To: Snyder, Ashley B <ashley.snyder@oah.nc.gov>

Subject: Reviewed rules for June meeting

Hi Ashley,

I am just checking to see that you all did receive my Submission for Permanent Rule from the Medical Care Commission for 14 readoption rules for 10A NCAC 13B. I submitted the rules on May 16, 2022 and did not get a bounce back from my

email. I have not received any correspondence from your agency on these rules, not an acknowledgement of the receipt, nor any technical change requests. This is highly unusual. In all the years I have worked on rules, there has never been this long of delay in receiving any type of communication from OAH. Typically I would have gotten technical change requests by the beginning of this week at the latest, since they are due to your office next Friday. Have you all received them? I am getting quite worried.

Thank you.

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

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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

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.

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.

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**