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

AGENCY: N.C. Medical Board

RULE CITATION: All Rules

DEADLINE FOR RECEIPT: Friday, November 1, 2024

***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 Box 6 of the Submission for Permanent Rule Form for all three rules submitted, the agency has not checked the box certifying that "[t]he requirements listed in G.S. 150B-19.1(c)(1)-(5) were posted on the agency's Web site no later than the publication date of the notice in the N.C. Register.

If the agency did comply with G.S. 150B-19.1(c), please resubmit the form with the box checked, and please provide documentation showing compliance.

Also in Box 6, please fill in the date that the rules were adopted by the agency.

In Box 9 of all three rules, you've checked "Legislation enacted by the General Assembly" and cited "NCGS 150B-20(a)" as the relevant session law. First, that's not a session law. Second, that statute refers to procedures for processing a petition for rulemaking. If these rules were adopted pursuant to a rulemaking petition, you'll want to check the box labeled "Petition for rule-making". Otherwise, please specify the correct session law.

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: October 18, 2024

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

AGENCY: N.C. Medical Board

RULE CITATION: 21 NCAC 32N .0107

DEADLINE FOR RECEIPT: Friday, November 1, 2024

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

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

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

In (b), line 9, please define "good cause". To the extent that "good cause" has a different meaning please also define this term in (d), line 18.

In (c), line 13, upon a written request from whom?

In (c), lines 13-16, where is your statutory authority to withhold the response from a complainant?

In (d), line 20, you refer to the "respondent", yet elsewhere you refer to the "licensee". Is this intentional? If so, what is the significance of the change?

In (f), line 25, you don't need to highlight "For purposes of G.S. 90-14(1) an investigation. . . ." since it was not changed from what was published.

In (f), lines 27-29, I don't think you have statutory authority to exempt further investigation from the six-month requirement of G.S. 90-14(l). The statute gives you six months to investigate, and anything beyond that requires an explanation to the licensee. It doesn't give the Board the authority to impose an end-date for the six-month period and then continue to investigate without providing an explanation to the licensee.

In (f), line 29, delete both instances of the hyphen in "six-months".

I'm not sure that you have statutory authority for paragraph (g). The statute puts the burden on the Board to provide the licensee with the explanation, it doesn't say the licensee has to ask the Board. I do not think you can create a rule permitting the licensee to ask the Board to comply with its own statutory requirements after the Board fails to do so. The implication is that without the rule, the licensee is prohibited from making that request.

Brian Liebman
Commission Counsel
Date submitted to agency: October 18, 2024

Further, in (g), p.2, lines 1-2, to confirm, if the Board complies with 90-14(l) and sends the licensee a written explanation of the reasons for the extension, no estimate of completion will be sent, but if the licensee makes the request, then the Board will give an estimate?

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: October 18, 2024

21 NCAC 32N .0107 is amended with changes as published in 39:01 NCR 37 as follows:

21 NCAC 32N .0107 INVESTIGATIONS AND COMPLAINTS

(a) At the time of first oral or written communication from the Board or staff or agent of the Board to a licensee regarding a complaint or investigation, the Board shall provide the notices set forth in G.S. 90-14(i), except as provided in Paragraph (e) of this Rule.

(b) A licensee shall submit a written response to a complaint received by the Board within 45 days from the date of a written request by Board staff. The Board shall grant up to an additional 30 days for the response where the licensee demonstrates good cause for the extension of time. The response shall contain accurate and complete information. Where a licensee fails to respond in the time and manner provided herein, the Board may treat that as a failure to respond to a Board inquiry in a reasonable time and manner as required by G.S. 90-14(a)(14).

(c) The licensee's written response to a complaint submitted to the Board in accordance with Paragraph (b) of this Rule shall be provided to the complainant upon written request as permitted in G.S. 90-16(e1), except that the response shall not be provided where the Board determines that the complainant has misused the Board's complaint process or that the release of the response would be harmful to the physical or mental health of the complainant who was a patient of the responding licensee.

(d) A licensee shall submit to an interview within 30 days from the date of an oral or written request from Board staff. The Board may grant up to an additional 15 days for the interview where the licensee demonstrates good cause for the extension of time. The responses to the questions and requests for information, including documents, during the interview shall be complete and accurate. Where respondent fails to respond in the time and manner provided herein, the Board may treat that as a failure to respond to a Board inquiry in a reasonable time and manner as required by G.S. 90-14(a)(14).

(e) The licensee who is the subject of a Board inquiry may retain and consult with legal counsel of his or her choosing in responding to the inquiries as set out in G.S. 90-14(i).

(f) For purposes of G.S. 90-14(l) an investigation [~~shall be deemed~~] is complete when the Board's Chief Investigative Officer, or his or her designee, approves an investigative report for submission to the Board's Disciplinary Committee. Once approved, subsequent consideration of the report by the Disciplinary Committee and any follow-up investigation requested by the Disciplinary Committee shall not be considered part of the six-month period contained in G.S. 90-14(l). If an investigation is extended beyond six-months, then within six-months of beginning an investigation [~~An e-mail from~~] Board staff [~~explaining the reasons for extending an investigation that is sent~~] shall provide written notification pursuant to G.S. 90-14(l) by sending an email to the licensee or the licensee's attorney at his or her last known email address as provided to the Board explaining the reasons for the extending the investigation. [~~shall be deemed compliant with the written notification requirement contained in G.S. 90-14(l) so long as the email is sent within the six-month period.~~]

(g) Should a licensee not receive a written explanation of the circumstances or reasons for extending an investigation within the applicable six-month period, the licensee, or his or her attorney, may request a written explanation from the Board as to the reasons why the investigation has not yet been completed. The Board shall respond to the request

within 15 days from the date of receipt of the request. In the response the Board shall provide the reasons for extending the investigation along with an estimate as to when the investigation may be completed.

History Note: *Authority G.S. 90-5.1(a)(3); 90-14(a)(14); ~~90-14(i);~~ 90-14(a)(i) and (l); 90-16(e1);*
Eff. February 1, 2012;
Pursuant to G.S. 150B-21.3A rule is necessary without substantive public interest Eff. March 1, 2016.
Amended Eff. December 1, 2024.

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

AGENCY: N.C. Medical Board

RULE CITATION: 21 NCAC 32M .0110

DEADLINE FOR RECEIPT: Friday, November 1, 2024

***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:

I am not sure you have statutory authority to allow nurse practitioners to issue DNRs or determine or pronounce death. First, I think specific statutes within Ch. 90 require that both tasks be completed by physicians. Second, to the extent that the Board can allow nurse practitioners to issue DNRs or declare a person dead, I do not think that this rule complies with the requirements of G.S. 90-8.2.

First, with respect to Do Not Resuscitate orders, G.S. 90-21.17(b) states that a "physician" may order a portable DNR or MOST for a patient. G.S. 90-21.17(c) goes on to describe the forms for a DNR and a MOST, and explicitly draws a distinction when contemplating who can sign each form. According to 90-21.17(c), the "official DNR form shall include fields for . . . the name, address, and telephone number of the ***physician****; the signature of the* ***physician****. . . ." Meanwhile, the "official MOST form shall include fields for . . . the name, telephone number, and signature of the* ***physician, physician assistant, or nurse practitioner*** *authorizing the order. . . ." Thus, it appears that the GA acknowledged the possibility of nurse practitioners issuing such orders, and explicitly decided to limit them to signing the MOST form rather than the DNR form.*

Second, with respect to the ability to determine and pronounce death, G.S. 90-323 explicitly states that "the determination that a person is dead shall be made by a ***physician*** *licensed to practice medicine applying ordinary and accepted standards of medical practice."*

While G.S. 90-8.2(a), 90-18(c)(14) and 90-18.2 speak to the performance of "medical acts" by a nurse practitioner, that term is undefined in either your statutes or rules. However, G.S. 90-18.2 defines the "limitations on nurse practitioners," and appears to restrict a nurse practitioner to writing prescriptions (paragraph (b)), compounding and dispensing drugs (paragraph (c)), and ordering medications, tests, and treatments (paragraph (d)). Thus, it appears the specific statutes governing DNRs/MOSTs and

Brian Liebman
Commission Counsel
Date submitted to agency: October 18, 2024

the pronouncement of death control over the general statute permitting the practice of nurse practitioners.

Second, as discussed above, G.S. 90-8.2 requires both the Medical Board and the Board of Nursing to adopt rules that "govern the performance of medical acts" by the nurse practitioner. G.S. 90-18(c)(14) states that it is not the unlicensed practice of medicine for a nurse to perform "acts otherwise constituting medical practice . . . when performed in accordance with rules and regulations . . . ." Finally, G.S. 90-18.2(b), (c), and (d) all speak to the development of specific rules and regulations for each task.

Here, the Board is permitting a nurse practitioner to issue a DNR or pronounce death "so long as all applicable requirements are met and doing so is permitted by and consistent with practice-site-specific policies and procedures". Setting aside issues of ambiguity (see below), this language essentially delegates the two boards' responsibility to develop rules governing the performance of these acts to the "practice site". This does not appear permissible under any of the statutes cited by the Board in the History Note for this Rule.

Moreover, this appears to be an incorporation by reference of another body's policies and procedures—the Board is saying a violation of a practice site's policies and procedures constitutes a violation of the Board's rule—without specifying what it is incorporating. G.S. 150B-21.6 governs incorporation by reference, and requires not only that the material being incorporated be a "rule" adopted by an agency, or a "code, standard, or regulation adopted by another agency, the federal government, or a generally recognized organization or association." It does not appear to me that the policies of any particular clinic, office, or hospital cross this threshold, and in any event, you haven't complied with any of the other procedural requirements of G.S. 150B-21.6 (i.e. stating whether the incorporation applies to subsequent editions or amendments).

In (2)(c), line 20, what are the "appliable requirements"? Failing to state what "applicable requirements" govern the performance of these duties is impermissibly ambiguous under G.S. 150B-21.9(a)(2).

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: October 18, 2024

21 NCAC 32M .0110 is amended as published in 39:01 NCR 36 as follows:

21 NCAC 32M .0110 QUALITY ASSURANCE STANDARDS FOR A COLLABORATIVE PRACTICE AGREEMENT

The following are the quality assurance standards for a collaborative practice agreement:

(1) Availability: The primary or back-up supervising physician(s) and the nurse practitioner shall be continuously available to each other for consultation by direct communication or telecommunication.

(2) Collaborative Practice Agreement:

(a) shall be agreed upon, signed, and dated by both the primary supervising physician and the nurse practitioner, and maintained in each practice site;

(b) shall be reviewed at least yearly. This review shall be acknowledged by a dated signature sheet, signed by both the primary supervising physician and the nurse practitioner, appended to the collaborative practice agreement, and available for inspection by either Board;

(c) shall include the drugs, devices, medical treatments, tests, and procedures that may be prescribed, ordered, and performed by the nurse practitioner consistent with Rule .0109 of this Subchapter~~; and~~ and may include issuing do not resuscitate orders as outlined in G.S. 90-21.17(b) and determining and pronouncing death pursuant to G.S. 90-323 so long as all applicable requirements are met and doing so is permitted by and consistent with practice-site-specific policies and procedures; and

(d) shall include a pre-determined plan for emergency services.

(3) The nurse practitioner shall demonstrate the ability to perform medical acts as outlined in the collaborative practice agreement upon request by members or agents of either Board.

(4) Quality Improvement Process:

(a) The primary supervising physician and the nurse practitioner shall develop a process for the ongoing review of the care provided in each practice site, including a written plan for evaluating the quality of care provided for one or more frequently encountered clinical problems.

(b) This plan shall include a description of the clinical problem(s), an evaluation of the current treatment interventions, and if needed, a plan for improving outcomes within an identified time frame.

(c) The quality improvement process shall include scheduled meetings between the primary supervising physician and the nurse practitioner for a minimum of every six months. Documentation for each meeting shall:

(i) identify clinical problems discussed, including progress toward improving outcomes as stated in Sub-Item (4)(b) of this Rule, and recommendations, if any, for changes in treatment plan(s);

(ii) be signed and dated by those who attended; and

(iii) be available for review by either Board for the previous five calendar years and be retained by both the nurse practitioner and primary supervising physician.

(5) Nurse Practitioner-Physician Consultation. The following requirements establish the minimum standards for consultation between the nurse practitioner and primary supervising physician(s):

(a) During the first six months of a collaborative practice agreement between a nurse practitioner and the primary supervising physician, there shall be monthly meetings to discuss practice-relevant clinical issues and quality improvement measures.

(b) Documentation of the meetings shall:

(i) identify clinical issues discussed and actions taken;

(ii) be signed and dated by those who attended; and

(iii) be available for review by either Board for the previous five calendar years and be retained by both the nurse practitioner and primary supervising physician.

History Note *Authority G.S. 90-5.1(a)(3); 90-8.1; 90-8.2; 90-18(c)(14); 90-18.2; 90-171.23(b)(14);*
Eff. January 1, 1991;
Amended Eff. August 1, 2004; May 1, 1999; January 1, 1996; March 1, 1994;
Recodified from Rule .0109 Eff. August 1, 2004;
Amended Eff. December 1, 2009;
Pursuant to G.S. 150B-21.3A rule is necessary without substantive public interest Eff. March 1, 2016;
Amended Eff. December 1, 2024; June 1, 2021.

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

AGENCY: N.C. Medical Board

RULE CITATION: 21 NCAC 32S .0213

DEADLINE FOR RECEIPT: Friday, November 1, 2024

***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:

I am not sure you have statutory authority to allow physician assistants to issue DNRs or determine or pronounce death. First, I think specific statutes within Ch. 90 require that both tasks be completed by physicians. Second, to the extent that the Board can allow physician assistants to issue DNRs or declare a person dead, I do not think that this rule complies with the requirements of G.S. 90-8.2.

First, with respect to Do Not Resuscitate orders, G.S. 90-21.17(b) states that a "physician" may order a portable DNR or MOST for a patient. G.S. 90-21.17(c) goes on to describe the forms for a DNR and a MOST, and explicitly draws a distinction when contemplating who can sign each form. According to 90-21.17(c), the "official DNR form shall include fields for . . . the name, address, and telephone number of the ***physician****; the signature of the* ***physician****. . . ." Meanwhile, the "official MOST form shall include fields for . . . the name, telephone number, and signature of the* ***physician, physician assistant, or nurse practitioner*** *authorizing the order. . . ." Thus, it appears that the GA acknowledged the possibility of physician assistants issuing such orders, and explicitly decided to limit them to signing the MOST form rather than the DNR form.*

Second, with respect to the ability to determine and pronounce death, G.S. 90-323 explicitly states that "the determination that a person is dead shall be made by a ***physician*** *licensed to practice medicine applying ordinary and accepted standards of medical practice."*

While G.S. 90-8.2(a), 90-18(c)(13) and 90-18.1 speak to the performance of "medical acts" by a physician assistant, that term is undefined in either your statutes or rules. However, G.S. 90-18.1 defines the "limitations on physician assistants," and appears to restrict a PA to writing prescriptions (paragraph (b)), compounding and dispensing drugs (paragraph (c)), and ordering medications, tests, and treatments (paragraph (d)).

Brian Liebman
Commission Counsel
Date submitted to agency: October 18, 2024

Second, as discussed above, G.S. 90-18(c)(13) and 90-18.1 require the Medical Board to adopt rules that "govern the performance of medical acts" by the PA. G.S. 90-18(c)(13) states that it is not the unlicensed practice of medicine for a PA to perform "medical acts, tasks, and functions . . . at the direction or under the supervision of a physician in accordance with rules adopted by the Board." Finally, G.S. 90-18.1(b), (c), and (d) all speak to the development of specific rules and regulations for each task.

Here, the Board is permitting a PA to issue a DNR or pronounce death "so long as all applicable requirements are met and doing so is permitted by and consistent with practice-site-specific policies and procedures". Setting aside issues of ambiguity (see below), this language essentially delegates the board's responsibility to develop rules governing the performance of these acts to the "practice site". This does not appear permissible under any of the statutes cited by the Board in the History Note for this Rule.

Moreover, this appears to be an incorporation by reference of another body's policies and procedures—the Board is saying a violation of a practice site's policies and procedures constitutes a violation of the Board's rule—without specifying what it is incorporating. G.S. 150B-21.6 governs incorporation by reference, and requires not only that the material being incorporated be a "rule" adopted by an agency, or a "code, standard, or regulation adopted by another agency, the federal government, or a generally recognized organization or association." It does not appear to me that the policies of any particular clinic, office, or hospital cross this threshold, and in any event, you haven't complied with any of the other procedural requirements of G.S. 150B-21.6 (i.e. stating whether the incorporation applies to subsequent editions or amendments).

In light of this, what is the Board's position on why they have statutory authority for this amendment?

In (a), line 5, what are the "rules adopted by the Board"? Consider a specific citation to the applicable rules.

In (c)(2), line 11, who determines that the delegation is "appropriate to the skills of the supervising physician"? Under what guidelines is that determination made? Moreover, what does it mean that the delegation is appropriate to the skills of the supervising physician? Shouldn't the delegation be appropriate to the skills of the PA?

In (c)(2), line 12, who determines the PA's "level of competence"? What does the term "competence" mean in this context?

In (c)(2), line 14, what are the "appliable requirements"? Failing to state what "applicable requirements" govern the performance of these duties is impermissibly ambiguous under G.S. 150B-21.9(a)(2).

Brian Liebman
Commission Counsel
Date submitted to agency: October 18, 2024

In (d), lines 19-20, the physician assistant shall maintain whose written prescribing instructions at each site?

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: October 18, 2024