AGENCY: Medical Care Commission

RULE CITATION: 10A NCAC 13B .3501

DEADLINE FOR RECEIPT: Friday, June 12, 2020

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

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

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

In (a), what are the "governing documents"? Previously, this Rule said "charter." Is this still accurate? Could you say something like "governing documents, such as the charter or resolution if publicly owned,..."?

In (b), what is meant by "final authority"? Do you mean that they have the final decision making power here?

In (b), do you need "directly or indirectly"?

In (c), what is a "local advisory board"? Here, do you mean "A local advisory board shall be established to provide non-binding advice to the governing body if the facility is owned..." What are they to provide advice on? Also, what is your authority for this? Are you relying upon G.S. 131E-75? If so, is the local advisory board to provide advice regarding the "public health, safety, and welfare" of their community?

1	10A NCAC 13E	3.3501 is amended as published in 34:12 NCR 1104-1110 as follows:
2		
3		SECTION .3500 - GOVERNANCE AND MANAGEMENT
4		
5	10A NCAC 13I	3.3501 GOVERNING BODY
6	(a) The govern	ng body, owner owner, or the person or persons designated by the owner as the governing authority
7	<u>body</u> shall be re	esponsible for seeing ensuring that the objectives specified in the charter (or resolution if publicly
8	owned) <u>facility'</u>	s governing documents are attained.
9	(b) The govern	ng body shall be the final authority in the facility to which the administrator, for decisions for which
10	the facility adm	nistration, the medical staff, and the facility personnel and all auxiliary organizations are directly or
11	indirectly respon	nsible. responsible within the facility.
12	(c) A local adv	isory board shall be established if the facility is owned or controlled by an organization or persons
13	outside of North	Carolina. A local advisory board shall include members from the county where the facility is located.
14	The local advise	ry board will provide non-binding advice to the governing body.
15		
16	History Note:	Authority G.S. <u>131E-75;</u> 131E-79;
17		Eff. January 1, 1996;
18		Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22,
19		2017. <u>2017:</u>
20		<u>Amended Eff. July 1, 2020.</u>

AGENCY: Medical Care Commission

RULE CITATION: 10A NCAC 13B .3502

DEADLINE FOR RECEIPT: Friday, June 12, 2020

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

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

In (a), what is the "community responsibility of the facility"?

In (a)(1), is the "purpose of the facility" the same as the "objectives" as set forth in .3501(a)? Please use consistent language where you can.

In (a)(9)(B), by "the total facility community" do you mean "the facility"? I just want to be sure that I understand.

In (a)(9)(C), what is a "regular basis"?

In (f), by "this requirement", do you mean "this Paragraph"?

24

25

10A NCAC 13B .3502 is readopted as published in 34:12 NCR 1104-1110 as follows:

3 10A NCAC 13B .3502 REQUIRED <u>FACILITY BYLAWS</u>, POLICIES, RULES, AND REGULATIONS

(a) The governing body shall adopt written <u>bylaws</u>, policies, rules, and regulations in accordance with all requirements
 contained in this Subchapter and in accordance with the community responsibility of the facility. The written <u>bylaws</u>,

- 6 policies, rules, and regulations shall:
- (1) state the purpose 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 artherity delegated to the shief accuration officer and to the medical staff. Note:
- (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;
- 16 (5) require Board governing body approval of the bylaws of any auxiliary organizations established by
 17 the hospital; facility:
- 18 (6) require the governing body to review and approve the bylaws of the medical staff organization; staff;
- 19(7)establish a procedure procedures for processing and evaluating the applications for medical staff20membership and for the granting of clinical privileges;
- (8) establish a procedure for implementing, disseminating, and enforcing a Patient's Bill of Rights as
 set forth in Rule .3302 of this Subchapter and in compliance with G.S. 131E-117; and
- 23 (9) require the governing body to institute procedures to provide for:
 - (A) orientation of newly elected board governing body members to specific board functions and procedures;
- 26(B)the development of procedures for periodic reexamination of the relationship of the board27governing body 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 governing body shall assure provide written policies and procedures to assure billing and collection practices
 in accordance with G.S. 131E-91. These policies and procedures shall include:
- 33 (1) a financial assistance policy as defined in G.S. 131E-214.14(b)(3);
- 34(2)how a patient may obtain an estimate of the charges for the statewide 100 most frequently reported35Diagnostic Related Groups (DRGs), where applicable, 20 most common outpatient imaging36procedures, and 20 most common outpatient surgical procedures. The policy shall require that the

12/16/19

1		information be provided to the patient in writing, either electronically or by mail, within three
2		business days;
3	(3)	how a patient or patient's representative may dispute a bill;
4	(4)	issuance of a refund within 45 days of the patient receiving notice of the overpayment when a patient
5		has overpaid the amount due to the hospital; facility;
6	(5)	providing written notification to the patient or patient's representative at least 30 days prior to
7		submitting a delinquent bill to a collections agency;
8	(6)	providing the patient or patient's representative with the facility's charity care and financial
9		assistance policies, if the facility is required to file a Schedule H, federal form 990;
10	(7)	the requirement that a collections agency, entity, or other assignee obtain written consent from the
11		facility prior to initiating litigation against the patient or patient's representative;
12	(8)	a policy for handling debts arising from the provision of care by the hospital facility involving the
13		doctrine of necessaries, in accordance with G.S. 131E-91(d)(5); and
14	(9)	a policy for handling debts arising from the provision of care by the hospital facility to a minor, in
15		accordance with G.S. 131E-91(d)(6).
16	(c) The governin	g body shall ensure that the bylaws, rules, and regulations of the medical staff and the bylaws, rules,
17	policies, and regu	alations of the facility shall not be in conflict.
18	(c)(d) The writte	n policies, rules, and regulations shall be reviewed every three years, revised as necessary, and dated
19	to indicate when	last reviewed or revised.
20	(d)(e) To qualify	y for licensure or license renewal, each facility must provide to the Division, upon application, an
21	attestation statem	ent in a form provided by the Division verifying compliance with the requirements of this Rule.
22	(e)(f) On an annu	al basis, on the license renewal application provided by the Division, the facility shall provide to the
23	Division the direct	ct website address to the facility's financial assistance policy. This Rule requirement applies only to
24	facilities required	to file a Schedule H, federal form 990.
25		
26	History Note:	Authority G.S. 131E-79; 131E-91; <u>131E-214.8;</u> 131E-214.13(f); 131E-214.14; <u>S.L. 2013 382, s.</u>
27		10.1; S.L. 2013-382, s. 13.1;
28		Eff. January 1, 1996;
29		Temporary Amendment Eff. May 1, 2014;
30		Amended Eff. November 1, 2014. <u>2014:</u>
31		Readopted Eff. July 1, 2020.

1 10A NCAC 13B .3503 is readopted as published in 34:12 NCR 1104-1110 as follows:

2 3 10A NCAC 13B .3503 **FUNCTIONS** 4 (a) The governing body shall: 5 (1)provide management, physical resources, and personnel determined by the governing body to be required to meet the needs of the patients for which it is licensed; treatment as authorized 6 7 by the facility's license; 8 (2)require management facility administration to establish a quality control mechanism which that 9 includes as an integral part a risk management component and an infection control program; 10 formulate short-range and long-range plans for the development of the facility; as defined in the (3) 11 facility bylaws, policies, rules, and regulations; 12 (4)conform to all applicable federal, State and federal laws, rules, and regulations, and applicable local 13 laws and regulations; ordinances; 14 (5) provide for the control and use of the physical and financial resources of the facility; 15 (6)review the annual audit, budget budget, and periodic reports of the financial operations of the 16 facility; 17 (7)consider the advice recommendation of the medical staff in granting and defining the scope of 18 clinical privileges to individuals. When the governing body does not concur in the medical staff 19 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 20 21 decision is reached by the governing body; individuals in accordance with medical staff bylaws 22 requirements for making such recommendations and the facility bylaws established by the 23 governing body for the review and final determination of such recommendations; 24 (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 privileges 25 26 in accordance with the facility bylaws established by the governing body, after an application has 27 been submitted; 28 (9) review and approve the medical staff bylaws, rules rules, and regulations body; regulations; 29 (10)delegate to the medical staff the authority to to: 30 (A) evaluate the professional competence of medical staff members and applicants for staff 31 privileges medical staff membership and clinical privileges; and hold the medical staff responsible for recommending recommend to the governing body 32 (B) 33 initial medical staff appointments, reappointments reappointments, and assignments or 34 curtailments of privileges; 35 (11)require that resources be made available to address the emotional and spiritual needs of patients 36 either directly or through referral or arrangement with community agencies;

1	(10)	
1	(12)	maintain effective communication with the medical staff which shall may be established, established
2		through:
3		(a)(A) meetings with the Executive Committee executive committee of the Medical Staff; medical
4		<u>staff;</u>
5		(b)(B) service by the president of the medical staff as a member of the governing body with or
6		without a vote;
7		(c)(C) appointment of individual medical staff members to governing body committees; or the
8		medical review committee; or
9		(d)(D) a joint conference committee; committee that will be a committee of the governing body
10		and the medical staff composed of equal representatives of each of the governing body, the
11		chairman of the board or designee, the medical staff, and the chief of the medical staff or
12		designee, respectively;
13	(13)	require the medical staff to establish controls that are designed to provide that standards of ethical
14		professional practices are met;
15	(14)	provide the necessary administrative staff support to facilitate utilization review and infection
16		control within the facility and facility, to support quality control, control and any other medical staff
17		functions required by this Subchapter or by the facility bylaws;
18	(15)	meet the following disclosure requirements:
19		(a)(A) provide data required by the Division;
20		(b)(B) disclose the facility's average daily inpatient charge upon request of the Division; and
21		(c) disclose the identity of persons owning 5.0 five percent or more of the facility as well as
22		the facility's officers and members of the governing body upon request;
23	(16)	establish a procedure for reporting the occurrence and disposition of any unusual incidents.
24		allegations of abuse or neglect of patients and incidents involving quality of care or physical
25		environment at the facility. These procedures shall require that:
26		(a)(A) incident reports are analyzed and summarized; summarized by a designated party; and
27		(b)(B) corrective action is taken as indicated by based upon the analysis of incident reports;
28	(17)	in a facility with one or more units, or portions of units, however described, utilized for psychiatric
29	(17)	or substance abuse treatment, adopt policies implementing the provisions of G.S. 122C, Article 3,
30		and Article 5, Parts, 2, 3, 4, 5, 7, and 8;
31	(18)	develop arrangements for the provision of extended care and other long-term healthcare services.
	(10)	
32		Such services shall be provided in the facility or by outside resources through a transfer agreement
33	(10)	or referrals;
34	(19)	provide and implement a written plan for the care or for the referral, or for both, of patients who
35		require mental health or substance abuse services while in the hospital; facility;

1	(20)	develop a conflict of interest policy which shall apply to all governing body members and corporate
2		officers. facility administration. All governing body members shall execute a conflict of interest
3		statement; statement; and
4	(21)	prohibit members of the governing body from engaging in the following forms of self dealing:
5		(a) the sale, exchange or leasing of property or services between the facility and a governing
6		board member, his employer or an organization substantially controlled by him on a basis
7		less favorable to the facility than that on which such property or service is made available
8		to the general public;
9		(b) furnishing of goods, services or facilities by a facility to a governing board member, unless
10		such furnishing is made on a basis not more favorable than that on which such goods,
11		services, or facilities are made available to the general public or employees of the facility;
12		or
13		(c) any transfer to or use by or for the benefit of a governing board member of the income or
14		assets of a facility, except by purchase for fair market value; and
15	(22)	prohibit the lease, sale, or exclusive use of any facility buildings or facilities receiving a license in
16		accordance with this Subchapter to any entity which provides medical or other health services to the
17		facility's patients, unless there is full, complete disclosure to and approval from the Division.
18	<u>(21)</u>	conduct direct consultations with the medical staff at least twice during the year.
19	(b) For the pu	rposes of this Rule, "direct consultations" means the governing body, or a subcommittee of the
20	governing body	, meets with the leader(s) of the medical staff(s), or his or her designee(s) either face-to-face or via a
21	telecommunicat	ions system permitting immediate, synchronous communication.
22	(c) The direct c	consultations shall consist of discussions of matters related to the quality of medical care provided to
23	the hospital's pa	tients, including quality matters arising out of the following:
24	(1)	the scope and complexity of services offered by the facility;
25	(2)	specific clinical populations served by the facility;
26	<u>(3)</u>	limitations on medical staff membership other than peer review or corrective action in individual
27		<u>cases;</u>
28	<u>(4)</u>	circumstances relating to medical staff access to a facility resource; or
29	(5)	any issues of patient safety and quality of care that a hospital's quality assessment and performance
30		improvement program might identify as needing the attention of the governing body in consultation
31		with the medical staff.
32	(d) For the purp	oses of this Rule, "specific clinical populations" includes those individuals who may be treated at the
33	facility by the m	nedical staff in place at the time of the consultation.
34		
35	History Note:	Authority G.S. <u>131E-14.2;</u> 131E-79; <u>42 CFR 482.12; 42 CFR 482.22;</u>
36		Eff. January 1, 1996. <u>1996:</u>
37		<u>Readopted Eff. July 1, 2020.</u>

AGENCY: Medical Care Commission

RULE CITATION: 10A NCAC 13B .3701

DEADLINE FOR RECEIPT: Friday, June 12, 2020

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

In (b), what is meant by "applicable law, or as otherwise protected by law"? What is the applicable law? Also, is "or as otherwise protected by law" necessary? Would this not be captured by "applicable law"?

1	10A NCAC 13B .3701 is readopted as published in 34:12 NCR 1104-1110 as follows:
2	
3	SECTION .3700 - MEDICAL STAFF
4	
5	10A NCAC 13B .3701 GENERAL PROVISIONS
6	a) The facility shall have a self-governed medical staff organized in accordance with the facility's by laws which that
7	shall be accountable to the governing body and which shall have responsibility for the quality of professional services
8	care provided by individuals with medical staff membership and clinical privileges. privileges to provide medical
9	services in the facility. Facility policy shall provide that individuals with clinical privileges shall perform only services
10	within the scope of individual privileges granted.
11	b) Minutes required by the rules of this Section shall reflect all transactions, conclusions, and recommendations of
12	meetings. Minutes shall be prepared and retained in accordance with a policy established by the facility and medical
13	staff, and available for inspection by members of the medical staff and governing body, respectively, unless such
14	minutes include confidential peer review information that is not accessible to others in accordance with applicable
15	law, or as otherwise protected by law.
16	
17	History Note: Authority G.S. 131E-79;
18	Eff. January 1, 1996. <u>1996;</u>
19	<u>Readopted Eff. July 1, 2020.</u>

1	10A NCAC 13H	3.3702 is repealed through readoption as published in 34:12 NCR 1104-1110 as follows:
2		
3	10A NCAC 13	B.3702 ESTABLISHMENT
4		
5	History Note:	Authority G.S. 131E-79;
6		Eff. January 1, 1996. <u>1996;</u>
7		<u>Repealed Eff. July 1, 2020.</u>

10A NCAC 13B .3703 is amended as published in 34:12 NCR 1104-1110 as follows:

3 10A NCAC 13B .3703 APPOINTMENT

4 (a) The governing body may grant, deny, renew, modify, suspend, or terminate medical staff membership and clinical

5 privileges after consideration of the recommendation made by the medical staff in accordance with the bylaws

6 established by the medical staff and approved by the governing body for making such recommendations, and the

7 <u>facility bylaws established by the governing body for review and final determination of such recommendations.</u>

8 (b) Formal appointment Review of an applicant for medical staff membership and the granting of clinical privileges

9 shall follow procedures set forth in the by laws, rules or bylaws, rules, and regulations of the medical staff. These

10 procedures shall require the following:

- (1) a signed application for <u>medical staff</u> membership, specifying age, <u>date of birth</u>, year and school of
 graduation, date of licensure, statement of postgraduate or special training and experience with
 experience, and a statement of the scope of the clinical privileges sought by the applicant;
- (2) verification by the hospital facility of the applicant's qualifications of the applicant as stated in the
 application, including evidence of any required continuing education; and
- (3) written notice to the applicant from the medical staff and the governing body, body regarding
 appointment or reappointment reappointment, which specifies the approval or denial of clinical
 privileges and the scope of the privileges granted; and if granted.
- 19 (4) members of the medical staff and others granted clinical privileges in the facility shall hold current
 20 licenses to practice in North Carolina.

(c) Members of the medical staff and others granted clinical privileges in the facility shall hold current licenses to
 practice in North Carolina.

23 (d) Medical staff appointments shall be reviewed at least once every two years by the medical staff in accordance

24 with the bylaws established by the medical staff and approved by the governing body, and shall be followed with 25 recommendations made to the governing body for review and a final determination.

26 (e) The facility shall maintain a file containing performance information for each medical staff member.

27 Representatives of the Division shall have access to these files in accordance with, and subject to the limitations and

28 restrictions set forth in, G.S. 131E-80; however, to the extent that the same includes confidential medical review

29 information, such information shall be reviewable and confidential in accordance with G.S. 131E-80(d) and other

30 <u>applicable law.</u>

31 (f) Minutes shall be taken and maintained of all meetings of the medical staff and governing body that concern the

32 granting, denying, renewing, modifying, suspending or terminating of clinical privileges.

33 34

35

History Note: Authority G.S. 131E-79; <u>42 CFR 482.12(a)(10); 42 CFR 482.22(a)(1);</u>

Eff. January 1, 1996;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22,
 2017. 2017:

Amended Eff. July 1, 2020;

1

AGENCY: Medical Care Commission

RULE CITATION: 10A NCAC 13B .3704

DEADLINE FOR RECEIPT: Friday, June 12, 2020

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

In (a), do you mean "medical staff" as defined by .3001? If so, wouldn't G.S. 131E-85 be applicable? That statute uses more qualifications than are contained on lines 8-9. Could you instead say something like "in accordance with G.S. 131E-85"?

In (c), would it be appropriate to specifically cross-reference .3705? If so, I note that here you say "medical staff bylaws" and in .3705 you say "bylaws, rules, and regulations."

5

10A NCAC 13B .3704 is readopted as published in 34:12 NCR 1104-1110 as follows:

3 10A NCAC 13B .3704 STATUS ESTABLISHMENT AND CATEGORIES OF MEDICAL STAFF 4 MEMBERSHIP

(a) The medical staff shall be established in accordance with the bylaws of the facility and organized in accordance

6 with the bylaws, rules, and regulations of the medical staff. The governing body of the facility, after considering the 7 recommendations of the medical staff, may grant medical staff membership and clinical privileges to qualified, 8 licensed practitioners in accordance with their training, experience, and demonstrated competence and judgment in 9 accordance with the medical staff bylaws, rules, and regulations. 10 (a)(b) Every facility shall have an active medical staff staff, as defined by the medical staff bylaws, rules, and regulations, to deliver medical services within the facility. The active medical staff shall be responsible for the 11 organization and administration of the medical staff. Every member facility and to administer medical staff functions. 12 13 The members of the active medical staff shall be eligible to vote at medical staff meetings and to hold office. medical 14 staff office positions as determined by the medical staff bylaws, rules, and regulations and shall be responsible for 15 recommendations made to the governing body regarding the organization and administration of the medical staff. Medical staff office positions shall be determined in the medical staff bylaws, rules, and regulations. 16 17 (b)(c) The active medical staff may establish other categories for membership in the medical staff. These categories 18 for membership shall be identified and defined in the medical staff bylaws, rules or regulations adopted by the active 19 medical staff. bylaws. Examples of these other membership categories for membership are: include: 20 (1) active medical staff; 21 (1) (2) associate medical staff; 22 (2) (3) courtesy medical staff; 23 (3) (4) temporary medical staff; 24 (4) (5) consulting medical staff; 25 (5) (6) honorary medical staff; or 26 (6) (7) other staff classifications. 27 The medical staff bylaws, rules or regulations may grant limited or full bylaws shall describe the authority, duties, 28 privileges, and voting rights to any one or more of these other for each membership categories. category consistent 29 with applicable law, rules, and regulations and requirements of facility accrediting bodies. 30 (c) Medical staff appointments shall be reviewed at least once every two years by the governing board. 31 (d) The facility shall maintain an individual file for each medical staff member. Representatives of the Department shall have access to these files in accordance with G.S. 131E 80. 32 33 (c) Minutes of all actions taken by the medical staff and the governing board concerning clinical privileges shall be 34 maintained by the medical staff and the governing board, respectively. 35 36 Authority G.S. 131E-79; *History Note:* 37 Eff. January 1, 1996. 1996;

Readopted Eff. July 1, 2020.

1

AGENCY: Medical Care Commission

RULE CITATION: 10A NCAC 13B .3705

DEADLINE FOR RECEIPT: Friday, June 12, 2020

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

(a) Says "active medical staff", but (c) and (d) say "medical staff." Was this intentional? Maybe it was, but please be consistent where you can.

1	10A NCAC 13B	.3705 is readopted as published in 34:12 NCR 1104-1110 as follows:
2		
3	10A NCAC 13B	3.3705 MEDICAL STAFF BYLAWS, RULES <u>RULES</u> , OR <u>AND</u> REGULATIONS
4	(a) The active n	nedical staff shall develop and adopt, subject to the approval of the governing body, a set of bylaws,
5	rules or <u>rules, ar</u>	nd regulations, regulations to establish a framework for self governance self-governance of medical
6	staff activities ar	nd accountability to the governing body.
7	(b) The medical	staff bylaws, rules <u>rules</u> , and regulations shall provide for at least the following:
8	(1)	organizational structure;
9	(2)	qualifications for medical staff membership;
10	(3)	procedures for admission, retention, assignment, and reduction or withdrawal of granting or
11		renewing, denying, modifying, suspending, and revoking clinical privileges;
12	<u>(4)</u>	procedures for disciplinary or corrective actions;
13	(4) <u>(5)</u>	procedures for fair hearing and appellate review mechanisms for denial of staff appointments,
14		reappointments, suspension, or revocation of denying, modifying, suspending, and revoking clinical
15		privileges;
16	(5) <u>(6)</u>	composition, functions and attendance of standing committees;
17	(6) <u>(7)</u>	policies for completion of medical records and procedures for disciplinary actions; records;
18	(7) <u>(8)</u>	formal liaison between the medical staff and the governing body;
19	(8) <u>(9)</u>	methods developed to formally verify that each medical staff member on appointment or
20		reappointment agrees to abide by current medical staff bylaws bylaws, rules, and regulations, and
21		the facility bylaws; and bylaws, rules, policies, and regulations;
22	(9) <u>(10)</u>	procedures for members of medical staff participation in quality assurance functions. functions by
23		medical staff members;
24	<u>(11)</u>	the process for the selection and election and removal of medical staff officers; and
25	(12)	procedures for the proposal, adoption, and amendment, and approval of medical staff bylaws, rules,
26		and regulations.
27		nedical staff, the governing body, nor the facility administration may unilaterally amend the medical
28	-	es, and regulations.
29		medical staff, the governing body, nor the facility administration may waive any provision of the
30	-	laws, rules, and regulations, except in an emergency circumstance. For purposes of this Rule, an
31		umstance" means a situation of urgency that justifies immediate action and when there is not sufficient
32		he applicable provisions and procedures of the medical staff bylaws. Examples of an emergency
33	circumstance include an immediate threat to the life or health of an individual or the public, a natural disaster, or a	
34	judicial or regulatory order. The duration of a waiver permitted by this Rule will be only so long as the emergency	
35	circumstance exi	ists.
36		
37	History Note:	Authority G.S. 131E-79;

 1
 Eff. January 1, 1996. 1996;

 2
 Readopted Eff. July 1, 2020.

AGENCY: Medical Care Commission

RULE CITATION: 10A NCAC 13B .3706

DEADLINE FOR RECEIPT: Friday, June 12, 2020

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

In (b), what is meant by "or its equivalent"? Is this needed just because not all facilities will call it an "executive committee"? I'm not sure a change is needed, I just want to be sure that I understand.

In (b), is the "executive committee" the same as the "medical review committee" in Part 5 of the Act? I'm thinking not, but want to be sure.

In (c), are these to be preformed by just the executive committee or the "medical staff" as a whole?

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10A NCAC 13B .3706 is readopted as published in 34:12 NCR 1104-1110 as follows:

- 10A NCAC 13B .3706 ORGANIZATION AND RESPONSIBILITIES OF THE MEDICAL STAFF
- 4 (a) The medical staff shall be organized to accomplish its required functions as established by the governing body
- 5 <u>and medical staff bylaws, rules, and regulations</u> and provide for the election or appointment of its <u>own</u> officers.
- 6 (b) There shall be an executive committee, or its equivalent, which represents the medical staff, which that has
- 7 responsibility for the effectiveness of all medical activities of the staff, and which that acts for the medical staff.
- 8 (c) All minutes of proceedings of medical staff committees shall be recorded and available for inspections by members
- 9 of the medical staff and the governing body.
- 10 (d) (c) The following reviews and functions shall be performed by the medical staff:
- 11 (1) credentialing review;
- 12 (2) surgical case review;
- 13 (3) (2) medical records review;
- 14 (4) medical care evaluation review;
- 15 (5) (3) drug utilization review;
- 16 (6) (4) radiation safety review;
- 17 (7) (5) blood usage review; and
- 18 (8) (6) bylaws review. review;
- 19 <u>(7)</u> medical review;
- 20 (8) peer review; and

21 (9) recommendations for discipline or corrective action of medical staff members.

(e) (d) 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 prepared for each meeting and retained in accordance with the policy of the facility. These minutes shall reflect the transactions, conclusions and recommendations of the meetings, medical staff, departmental, and committee meeting.

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

- 29 Eff. January 1, 1996. <u>1996;</u>
- 30 <u>Readopted Eff. July 1, 2020.</u>

AGENCY: Medical Care Commission

RULE CITATION: 10A NCAC 13B .3707

DEADLINE FOR RECEIPT: Friday, June 12, 2020

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

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

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

In (d), approved by medical staff how? In the bylaws?

10A NCAC 13B .3707 is readopted as published in 34:12 NCR 1104-1110 as follows:

3 10A NCAC 13B .3707 MEDICAL ORDERS

- 4 (a) No medication or treatment shall be administered or discontinued except in response to the order of a member of
- 5 the medical staff in accordance with established rules policies, rules, and regulations established by the facility and
- 6 <u>medical staff</u> and as provided in Paragraph (f) below. of this Rule.
- 7 (b) Such orders shall be dated and recorded directly in the patient chart or in a computer or data processing system

8 which provides a hard copy printout of the order for the patient chart. medical record. A method shall be established

- 9 to safeguard against fraudulent recordings.
- 10 (c) All orders for medication or treatment shall be authenticated according to hospital policies. medical staff and

11 <u>facility policies, rules, or regulations.</u> The order shall be taken by personnel qualified by medical staff rules <u>bylaws</u>,

- 12 rules, and regulations, and shall include the date, time, and name of persons who gave the order, and the full signature
- 13 of the person taking the order.
- 14 (d) The names of drugs shall be recorded in full and not abbreviated except where approved by the medical staff.

15 (e) The medical staff shall establish a written policy in conjunction with the pharmacy committee or its equivalent

16 for all medications not specifically prescribed as to time or number of doses to be automatically stopped after a

17 reasonable time limit, but no more than 14 days. The prescriber shall be notified according to established policies and

18 procedures at least 24 hours before an order is automatically stopped.

(f) For patients who are under the continuing care of an out-of-state physician but are temporarily located in North Carolina, a hospital facility may process the out-of-state physician's prescriptions or orders for diagnostic or therapeutic studies which maintain and support the patient's continued program of care, where the authenticity and currency of the prescriptions or orders can be verified by the physician who prescribed or ordered the treatment requested by the patient, and where the hospital facility verifies that the out-of-state physician is licensed to prescribe or order the treatment.

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26 *History Note:* Authority G.S. 131E-75; 131E-79; 143B-165;

- 27 *Eff. January 1, 1996;*
- 28 Amended Eff. April 1, 2005; August 1, 1998. <u>1998;</u>
- 29 <u>Readopted Eff. July 1, 2020.</u>

10A NCAC 13B .3708 is amended as published in 34:12 NCR 1104-1110 as follows:

3 10A NCAC 13B.3708 MEDICAL STAFF RESPONSIBILITIES FOR QUALITY IMPROVEMENT 4 REVIEW

5 (a) The medical staff shall have in effect a system to review medical services rendered, care provided at the facility

6 by members of the medical staff, to assess quality, to provide a process for improving performance when indicated

7 <u>quality improvement</u>, and to monitor the <u>outcome</u>. <u>outcome of quality improvement activities</u>.

8 (b) The medical staff shall establish criteria for the evaluation of the quality of medical care.

9 (c) The facility shall have a written plan approved by the medical staff, administration and governing body which that

10 generates reports to permit identification of patient care problems. The plan shall establish problems and that

11 <u>establishes</u> a system to use this data to document and identify interventions. <u>The plan shall be approved by the medical</u>

12 staff, facility administration, and the governing body.

13 (d) The medical staff shall establish and <u>a policy to</u> maintain a continuous review process of the care rendered to both

14 inpatients and outpatients provided by members of the medical staff to all patients in every medical department of the

15 facility. At least quarterly, the The medical staff shall have a meeting policy to schedule meetings to examine the

16 review process and results. The review process shall include both practitioners and allied health professionals from

17 the facility medical staff.

18 (e) Minutes shall be taken at prepared for all meetings reviewing quality improvement, and these minutes shall be

19 made available to the medical staff on a regular basis in accordance with established policy. These minutes shall be

- 20 retained as determined by the facility. improvement and shall reflect all of the transactions, conclusions, and
- 21 recommendations of the meeting.
- 22

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

Eff. January 1, 1996;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22,

2017. <u>2017;</u>

27 <u>Amended Eff. July 1, 2020.</u>