Fiscal Impact Analysis of
Permanent Rule Readoption with No Substantial Economic Impact

Agency Proposing Rule Change
North Carolina Medical Care Commission

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Impact Summary

Federal Government Entities:	No Impact
State Government entities:	No Impact
Local Government Entities:	No Impact
Small Business:	No Impact
Substantial Impact:	No Impact

Title of Rules Changes and Statutory Citations

10A NCAC 13B

Section .3500 – Governance and Management
- Governing Body 10A NCAC 13B .3501 (Amend)
- Required Facility Policies, Rules, and Regulations 10A NCAC 13B .3502 (Readopt)
- Functions 10A NCAC 13B .3503 (Readopt)

Section .3700 – Medical Staff
- General Provisions 10A NCAC 13B .3701 (Readopt)
- Establishment 10A NCAC 13B .3702 (Repeal)
- Appointment 10A NCAC 13B .3703 (Amend)
- Categories of Medical Staff Membership 10A NCAC 13B .3704 (Readopt)
- Medical Staff Bylaws, Rules and Regulations 10A NCAC 13B .3705 (Readopt)
- Organization and Responsibilities of the Medical Staff 10A NCAC 13B .3706 (Readopt)
- Medical Orders 10A NCAC 13B .3707 (Readopt)
- Medical Staff Responsibilities for Quality Improvement Review 10A NCAC 13B .3708 (Amend)

See proposed text of these rules in Appendix 1

Statutory Authority

N.C.G.S. 131E-79

Background and Purpose

The Medical Care Commission is proposing changes to eleven hospital licensure rules related to the responsibilities of the governing body and medical staff. Under authority of N.C.G.S. 150B-21-3A, Periodic review and expiration of existing rules, the Medical Care Commission, Rules Review Commission and the Joint Legislative Administrative Procedure Oversight Committee approved the

subchapter report with classifications for the rules located at 10A NCAC 13B—Rules for the Licensing of Hospitals on February 10, 2017, May 18, 2017, and July 22, 2017, respectively. Eight rules were determined as necessary with substantive change and therefore subject to readoptions as new rules (10A NCAC 13B .3502, .3503, .3701, 3702, .3704, .3705, .3706, and .3707).

Three rules are proposed for amendment (10A NCAC 13B .3501, .3703, and.3708).

There are 119 licensed Hospitals in North Carolina, each operated by a governing body with final decision-making authority regarding conduct of the facility, including granting clinical privileges to medical staff and defining the scope of services offered at the facility. The Commission believes that medical staff offer a unique perspective on the needs of the community served, and current state, federal, and Joint Commission rules require the governing body to consider input from the medical staff. However, the Commission is concerned about the effect of recent decisions by some governing body to discontinue or greatly reduce certain service lines, affecting access to care and continuity of care for residents. Access to care can be particularly challenging in some rural parts of the state where patients may be required to travel for miles to get to a hospital facility. Some of the major hospitals, such as UNC is working to help improve access to care by partnering with affiliate hospitals and hospital systems across the state. The rule readoptions presented in this fiscal analysis are intended to improve safety, quality and access to care by promoting improved communication between facilities and medical staff. Readoptions will also update language, provide clarity, remove ambiguity, address previous Rules Review objections, and implement several technical changes. Changes will also clarify authorities granted in federal regulations and allow reference to the statute where appropriate.

It is unknown whether the changes will result in different management decisions and therefore different patient outcomes, however, the changes are intended to ensure that medical staff are consulted and kept informed. The Commission believes that the proposed changes will establish a structure for information sharing that may increase medical staff awareness of their opportunity to make recommendations on proposed decisions and increase feedback on the potential impact of those changes on medical staff, patient, and health outcomes. Ultimate responsibility for the hospital from a corporate, legal, accreditation, licensure, and compliance standpoint will continue to reside with the governing body.

Rules Summary and Anticipated Fiscal Impact

Rule .3501 – Governing Body
The agency is proposing to amend this rule. This rule established criteria for the Governing Body. Changes clarify that the governing body is the entity responsible for ensuring charter objectives are attained and is the authority for decisions in the facility. This is and continues to be the standard.

Changes clarify that the local advisory board should contain members from the county where the facility is located. This is a current occurrence. Local advisory boards are established to advise facilities regarding community needs, ensure locals are involved in decision making, which will ultimately improve quality of care, safety and access to care. Local advisory boards are a current requirement for facilities that have out of state owners. There are three such facilities in North Carolina - Kindred Hospital, Frye Regional, and Martin General Hospital. Current healthcare administration research advocates for the use of patient advisory boards and community advisory boards but research is limited as to their impact on hospital leadership decision-making.

A review of Kindred's website revealed that Kindred Hospital has an advisory board of physicians who care for patients within the patients' community. A similar internet search of Martin General Hospital did not reveal a specific reference to an advisory board; however, it did express a commitment to sharing information with employees, patients and the community, to include working with the community to

provide quality healthcare that fits their lifestyle.[1] They do endorse several national and regional organizations of this nature. For Kindred, the advisory board already has members from the county and thus the new requirement will have no additional impact. Martin General currently doesn't specifically identify an advisory board on it's website. There could potentially be a minimal cost regarding administrative staff time and space required to hold meetings. Generally, advisory boards don't include reimbursement. In addition, the Centers for Disease Control requires hospitals every three years to communicate with the community and conduct a community health assessment. A community health assessment gives organizations comprehensive information about the community's current health status, needs, and issues. In turn, this information can help with developing a community health improvement plan by justifying how and where resources should be allocated to best meet community needs.[2] Frye Regional completes the Community Needs Health Assessment in which it defines priorities for health improvement, creates a collaborative community environment to engage stakeholders, and an open and transparent process to listen and understand the health needs of the community served by Frye Regional medical center. It brings together all the care providers, citizens, government, schools, churches, not for profit organizations and business and industry around an effective plan of action. In state hospital facilities also have advisor boards. Community advisory boards advise on important outreach initiatives and provide a vital link between the facility and the community. Facilities with out of state owners already have advisory boards/committees with members from the county. This rule change will have minimal impact on communication and information sharing between the local community and the governing board and impose minimal additional costs. Local advisory boards' advice is nonbinding, and it is unknown whether any additional input will result in different decisions and outcomes.[3]

Rule .3502-- Required Policies, Rules, and Regulations & Rule .3705 – Medical Staff Bylaws, Rules, or Regulations

The agency is proposing to readopt these rules with substantive changes. Rule .3502 and .3705 includes a new requirement that facility policies, rules, and regulations shall not conflict with the medical staff bylaws, rules, and regulations. The governing body, medical staff, or facility administration may not unilaterally change the medical staff bylaws, rules and regulations except in emergency circumstances. In addition, the rules further specify the required content of the medical staff bylaws. The remainder of the changes clarify governing body responsibilities regarding facility policies, rules, and regulations. The rule was changed to clarify language regarding the governing body and to make technical changes.

By requiring the medical staff bylaws and facility bylaws to be congruent, these rules are possibly changing the process that medical staff and facility staff will use when developing their bylaws. The governing body and the medical staff will have to review and update their bylaws, rules, and regulations to ensure they are congruent, requiring an investment of time by both medical staff and governing body members. However, it is unclear whether this requirement is likely to result in more collaboration or more effective communication. Under current rules, both the governing body and the medical staff must have bylaws, and the governing body must review and approve medical staff bylaws. Given the existing approval process, the extent of any changes to medical staff bylaws, rules, and regulations resulting from this new requirement is unknown.

More detail was added to clarify what subjects the medical staff bylaws, rules, and regulations shall cover. The rule requires medical staff bylaws to include a process for selection/election or removal of medical staff officers and for the adoption and amendment of medical staff bylaws. The North Carolina Medical Society Model Medical Staff Bylaws document currently includes a process for

[1] https://www.kindredhealthcare.com/resources/blog-kindred-continuum/2012/03/29/medical-advisory-boards-help-kindred-improve-quality-of-patient-care

[2] https://www.cdc.gov/publichealthgateway/cha/index.html

[3] https://www.fryemedctr.com/community-health/community-health-needs-assessment

selection/election or removal of medical staff officers, and amendment of bylaws. However, this document only serves as an example and is not mandated for use, so it is unclear how many entities will need to update their bylaws, or how much staff time may need to be devoted to updating the bylaws. Remaining changes to these rules are primarily technical in nature and will not affect processes currently used by hospitals.

Rule .3503 – Functions

The agency is proposing to readopt this rule with substantive changes. This rule establishes functions for the governing body. Proposed changes would require the facility and medical staff to develop a policy for how it will make recommendations to the governing body regarding granting and defining the scope of clinical privileges. Because the agency has no authority to establish a process when the governing body does not concur with medical staff recommendations, that language was deleted.

Current rules also provide several means for maintaining communications with medical staff. The governing body may establish meetings with the executive committee of the medical staff or appoint individual medical staff members to the medical review committee (previously "governing body committees"). In addition, a provision was added that requires the governing body to have consultation with medical staff twice during the year regarding quality of care provided, and limitations placed on medical staff.

The agency is also further interpreting policies established by federal regulations, to include updating authorities delegated and not delegated to the state agency as they relate to the functions of the governing body. Finally, these changes also updated language to current terminology and include other technical and clarifying changes.

The governing body is currently required to consider recommendations of staff regarding appointments. Language was added to require facilities to establish a policy for making recommendations. This language was added in an attempt to address any potential information asymmetry problems. Comments were submitted to the Medical Care Commission regarding areas of concern include the ability for physician privileges to be eliminated without peer physicians on the hospital staff being involved. Having a policy in place for this process may increase awareness and engagement in the process.

This requirement to establish policy for making recommendations may have no effect on medical staff and patient outcomes, or it may have some effect of unknown magnitude. While organizational research generally agrees that communication is essential to informed decision making, it is unclear whether this requirement will result in the governing body receiving different information from the medical staff compared to current practices or how additional information may change decision-making. The ultimate authority for granting and defining the scope of clinical privileges resides with the governing body.

The facility and medical staff may incur staff time costs to develop their policy for making recommendations about clinical privileges, depending upon the existing process in the facility. The governing body is currently required to consider recommendations of staff regarding appointments. While the number of affected facilities is unknown, facilities may need to establish formal policies for the first time or revise existing policies to satisfy both parties. The time required is likely to be highly variable for each facility.

Changes also require facilities to formulate short and long range plans as defined in their bylaws, policies, rules, and regulations. Facilities currently have short and long range plans. It is unclear how timeframes are chosen. Medical staff are currently required to participate in strategic planning as described in their bylaws. Changes will require facilities to formulate long range plans according to their bylaws, policies,

rules or regulations. It is likely that some facilities currently meet the requirement, but it is unknown to what extent. Strategic plans improve the ability to manage and control resources, which are critical to the organization's survival. This is especially true in rural hospitals that are struggling to maintain operations. Strategic planning offers a proactive way to foresee and prepare for the future and increase operational efficiency. If facilities do not currently have short and long range plans defined in their bylaws, policies, rules, and regulations, there will likely be some marginal staff time costs involved in revising the timeframe of the plans, but the agency expects the costs to be minimal. The MCC is also further interpreting policies established by federal regulations, to include updating authorities delegated and not delegated to the state agency as they relate to the functions of the governing body. These changes also updated language to current terminology.

As the governing body is the final authority regarding what happens in a facility, there is no authority to establish a process when the governing body does not concur with medical staff recommendations. That language was deleted.

This rule amendment also includes changes made to the language around the reporting of "unusual incidents." The term "unusual incidents" was removed, and replaced with "allegations of abuse and neglect of patients." Abuse and neglect are currently reported and investigated. Improving the definition of the intent of this rule helps to provide clarity as to the expectations for reporting.

In addition, detail regarding conflict of interest was removed and language was added requiring governing body members to execute a conflict of interest statement. General Statute 131E-14.2 address conflicts of interest in public hospitals. Pursuant to the Internal Revenue Manual,[4] 26 CFR § 53 addresses the prohibition on self-dealing in private hospitals. These provisions makes it unnecessary to discuss self dealings regarding the governing body in rule, so this language has been removed. These changes have no fiscal impact.

Rule .3701 – General Provisions & Rule .3704 – Categories of Medical Staff Membership
The agency is proposing to readopt these rules with substantive changes. Rule .3701 establishes general provision for medical staff. The rule is changed to interpret language in the federal regulation regarding medical staff. Changes clarify that medical staff are self-governed, responsible for working in collaboration with facility administration, and accountable to the governing body. Federal regulation requires medical staff to make recommendations to the governing body regarding medical staff appointments[5]. The governing body has approval authority for medical staff bylaws, rules, and other medical staff regulations. This rule change does not require any additional actions by the facility or staff.

Rule .3704 also establishes categories of medical staff membership, expand who is eligible to vote and hold medical staff office positions and informs facilities that they are to determine medical staff office positions in their bylaws, rules, and regulations. This is a current requirement in the Conditions of Participation (COP) and is a current practice. Together the rules grant the medical staff the authority to determine the organization and office positions of the medical staff. While we believe the changes will improve the communication process by better informing medical staff and facilities regarding responsibilities, it will be difficult to quantify its effectiveness.

The requirement for taking minutes was relocated from .3704 and .3706 to this rule to eliminate redundancy and clarifying language was added to identify what the minutes should reflect and the retention schedule. This was done to eliminate ambiguity. As minutes are currently taken at Medical

[4] https://www.irs.gov/irm/part7/irm_07-027-030
[5] See 42 CFR 482.22

Staff meetings, (following Parliamentary procedures of Roberts Rules of Order) there is not expected to be a change in procedure or cost related to additional time spent.
This rule also includes several technical changes. Language regarding staff appointments, review, file retention, and minutes was relocated to Rule.3703. Relocating this information to .3703 grouped similar guidance together. The changes will result in zero to minimal fiscal impact.

Rule .3703 – Appointment
The agency is proposing to amend this rule that establishes staff appointment requirements.

In accordance with G.S. 131E-85 and 42 CFR 482.12, the rule identifies the governing body as the final decision maker regarding appointment of staff and clinical privileges. Changes also clarify what appointment of staff means and requires facilities and medical staff to develop a policy for making recommendations to grant, deny, renew, modify, suspend, or terminate medical staff membership and clinical privileges to the governing body.

Although current state and federal requirements direct the governing body to consider the recommendations of the medical staff regarding appointments, the proposed rules expand the scope of topics on which the governing body must consult with the medical staff. Medical staff will make recommendations to the governing body regarding appointment or reappointment which specifies the approval or denial of clinical privileges and the scope of privileges, excluding qualified providers from medical service lines; or limiting facility access to medical staff. In addition, the rules require medical staff appointments to be reviewed once every two years.

The intent of these rule changes is to increase communication between the governing body and medical staff regarding quality of care issues. This requirement may increase the frequency of communication between the governing body and medical staff. However, the magnitude of the impact on medical staff and patient outcomes is unknown. While organizational research generally agrees that communication is essential to informed decision making, it is unclear whether this requirement will result in the governing body receiving different information from the medical staff compared to current practices, or how additional information may change decision-making. The ultimate authority for decisions related to staffing and service lines resides with the governing body.

Other amendments remove ambiguity, clarify rule language and make technical changes. They also include relocating certain existing requirements from other sections of rule.

The requirement for medical staff and others granted clinical privileges to hold a current license was relocated and is a current requirement in federal and state regulation. Regulations also address medical staff and access to the facility's medical resources which is a normal part of facility protocol. The remaining requirements that were added to e, f, and g were relocated from existing rules.

Rule .3706 – Organization and Responsibilities of the Medical Staff
The agency is proposing to readopt this rule with substantive changes. This rule established organization and responsibilities of the medical staff. The rule is being changed to reference the federal requirement that medical staff have bylaws that describe the organization of the medical staff.[6] This is a current practice.

The requirement to keep minutes of proceedings was relocated to .3701 (General Provision) to eliminate redundancy. The functions listed as those performed by medical staff are a current requirement in the federal regulations as a condition of participation in the Medicare and Medicaid programs. Changes were

[6] See 42 CFR 482.22

made to combine similar items, and add medical review and peer review as identified in the federal regulations. Surgical case reviews and medical care evaluation reviews was deleted as a result of adding medical review and peer review which are more encompassing.

Medical staff are currently required to make recommendation regarding granting of privileges to staff. The rule was changed to include recommendations for discipline or corrective action. The rule also, identified what meetings require minutes. It is unlikely that there is any fiscal impact associated with this rule change, as the rule generally incorporates federal requirements that are currently being done. A potential cost could result from a change in which meetings require someone to record minutes, versus what meetings are currently appropriate for minutes. However, any cost will likely be minor.

Rule .3707 – Medical Orders
This rule is being readopted with technical changes to reflect more current terminology but does not require any changes in current practices. This rule addresses guidelines for medical orders. The electronic health record did not exist at the time this rule was last amended, thus the requirement relating to the patient chart, computer or data processing system was removed and replaced with a reference to the medical record. Two additional technical changes/clarifications were made to replace hospital policies with facility polices, rules, and regulations and to replace rules with bylaws, rules, or regulations. All changes are technical in nature and do not have cost implications.

Rule .3708 – Medical Staff Responsibilities for Quality Improvement Review
The agency is proposing to amend this rule to clarify rule language and meeting requirements for medical staff. This rule established medical staff responsibilities for quality improvement review. The rule is being amended to change the requirements for quarterly meetings to having a policy to schedule meetings. Medical staff, together with the governing body, may choose to change the frequency of quality improvement meetings.

Other amendments clarify rule language and make technical changes. Medical staff are currently required to have a plan for review of services. Plans must currently be approved by the facility administration and ultimately the governing body. The governing body has the final authority. Meeting minutes are a current requirement, but language was added to clarify what the minutes should reflect and to impose a retention schedule as identified by the facility and medical staff. The only possible cost will involve the time required for facilities and medical staff to establish a policy for maintaining the minutes as well as the additional time required if additional details are added to the minutes. With the change, facilities will be required to retain minutes as determined by the facility. It is expected that any costs will be minimal.

Impact Summary

Taken together, the total impact of these rule amendments on access and quality of care is unknown. There may be no change, or, the rule provisions could increase communication between the medical staff and the governing body and may inform management decision-making - particularly the requirements to establish a formal policy for medical staff to make recommendations to the governing body, and for twice annual consultations on quality of care matters, medical staff membership, and medical staff access to facility resources. However, any effect on medical staff and patient outcomes depends upon three unknown factors: the extent to which these new provisions differ from current practices, whether governing bodies are likely to receive more or different information from the medical staff compared to current practices, and how any additional information may change final management decisions. The governing body retains final decision-making authority regarding conduct of the facility.

Similarly, hospitals may incur administrative costs to implement these changes dependent upon each facility's current practices. Although, resource requirements cannot be quantified, any changes to current

processes or an increase in the frequency of communication may require additional staff time from hospital leadership and staff across the state's 119 licensed facilities. It is unknown to what extent hospitals may be affected.

It is highly unlikely that there will be a State government impact. Changes may improve the communication process and transparency, but it is almost impossible to determine what impact those changes may have on facilities. The changes won't add any additional tasks or responsibilities to State staff. State staff will continue to provide oversight of hospitals, which is a part of their current responsibilities.

Appendix 1

10A NCAC 13B .3501 is proposed for amendment as follows:

SECTION .3500 - GOVERNANCE AND MANAGEMENT

10A NCAC 13B .3501 GOVERNING BODY

(a) The governing body, ~~owner~~ owner, or the person or persons designated by the owner as the governing ~~authority~~ body shall be responsible for ~~seeing~~ ensuring that the objectives specified in the ~~charter (or resolution if publicly owned)~~ facility's governing documents are attained.

(b) The governing body shall be the final authority ~~in the facility~~ ~~to which~~ ~~the administrator,~~ for decisions for which the facility administration, the medical staff, and the facility personnel ~~and all auxiliary organizations~~ are directly or indirectly ~~responsible.~~ responsible within the facility.

(c) A local advisory board shall be established if the facility is owned ~~or controlled~~ by an organization or persons outside of North Carolina. A local advisory board shall include members from the county where the facility is located. The local advisory board will provide non-binding advice to the governing body.

History Note: *Authority G.S. 131E-75; 131E-79;*
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.

10A NCAC 13B .3502 is proposed for readoption with substantive changes as follows:

10A NCAC 13B .3502 REQUIRED FACILITY BYLAWS, POLICIES, RULES, AND REGULATIONS

(a) The governing body shall adopt written bylaws, 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 bylaws, 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 authority delegated to the chief executive officer and to the medical staff. No assignment, referral, or delegation of authority by the governing body shall relieve the governing body of its responsibility for the conduct of the facility. The governing body shall retain the right to rescind any such delegation;

(5) require ~~Board~~ governing body approval of the bylaws of any auxiliary organizations established by the ~~hospital;~~ facility;

(6) require the governing body to review and approve the bylaws of the medical ~~staff organization;~~ staff;

(7) establish ~~a procedure~~ procedures for processing and evaluating the applications for medical staff membership and for the granting of clinical privileges;

(8) establish a procedure for implementing, disseminating, and enforcing a Patient's Bill of Rights as set forth in Rule .3302 of this Subchapter and in compliance with G.S. 131E-117; and

(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;

(B) the development of procedures for periodic reexamination of the relationship of the ~~board~~ governing 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:

(1) a financial assistance policy as defined in G.S. 131E-214.14(b)(3);

(2) how a patient may obtain an estimate of the charges for the statewide 100 most frequently reported Diagnostic Related Groups (DRGs), where applicable, 20 most common outpatient imaging procedures, and 20 most common outpatient surgical procedures. The policy shall require that the

information be provided to the patient in writing, either electronically or by mail, within three business days;

(3) how a patient or patient's representative may dispute a bill;

(4) issuance of a refund within 45 days of the patient receiving notice of the overpayment when a patient has overpaid the amount due to the ~~hospital;~~ facility;

(5) providing written notification to the patient or patient's representative at least 30 days prior to submitting a delinquent bill to a collections agency;

(6) providing the patient or patient's representative with the facility's charity care and financial assistance policies, if the facility is required to file a Schedule H, federal form 990;

(7) the requirement that a collections agency, entity, or other assignee obtain written consent from the facility prior to initiating litigation against the patient or patient's representative;

(8) a policy for handling debts arising from the provision of care by the ~~hospital~~ facility involving the doctrine of necessaries, in accordance with G.S. 131E-91(d)(5); and

(9) a policy for handling debts arising from the provision of care by the ~~hospital~~ facility to a minor, in accordance with G.S. 131E-91(d)(6).

(c) The governing body shall ensure that the bylaws, rules, and regulations of the medical staff and the bylaws, rules, policies, and regulations of the facility shall not be in conflict.

~~(c)~~(d) The written policies, rules, and regulations shall be reviewed every three years, revised as necessary, and dated to indicate when last reviewed or revised.

~~(d)~~(e) To qualify for licensure or license renewal, each facility must provide to the Division, upon application, an attestation statement in a form provided by the Division verifying compliance with the requirements of this Rule.

~~(e)~~(f) On an annual basis, on the license renewal application provided by the Division, the facility shall provide to the Division the direct website address to the facility's financial assistance policy. This ~~Rule~~ requirement applies only to facilities required to file a Schedule H, federal form 990.

History Note: *Authority G.S. 131E-79; 131E-91; 131E-214.8; 131E-214.13(f); 131E-214.14; ~~S.L. 2013-382, s. 10.1; S.L. 2013-382, s. 13.1;~~*
Eff. January 1, 1996;
Temporary Amendment Eff. May 1, 2014;
Amended Eff. November 1, ~~2014.~~ 2014;
Readopted Eff. July 1, 2020.

10A NCAC 13B .3503 is proposed for readoption with substantive changes as follows:

10A NCAC 13B .3503 FUNCTIONS

(a) The governing body shall:

(1) provide management, physical ~~resources~~ 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 by the facility's license;

(2) require ~~management~~ facility administration to establish a quality control mechanism ~~which~~ that includes ~~as an integral part~~ a risk management component and an infection control program;

(3) formulate short-range and long-range plans ~~for the development of the facility;~~ as defined in the facility bylaws, policies, rules, and regulations;

(4) conform to all applicable ~~federal,~~ State and federal laws, rules, and regulations, and applicable local ~~laws and regulations;~~ ordinances;

(5) provide for the control and use of the physical and financial resources of the facility;

(6) review the annual audit, ~~budget~~ budget, and periodic reports of the financial operations of the facility;

(7) consider the ~~advice~~ recommendation of the medical staff in granting and defining the scope of clinical privileges to ~~individuals. When the governing body does not concur in the medical staff recommendation regarding the clinical privileges of an individual, there shall be a review of the recommendation by a joint committee of the medical staff and governing body before a final decision is reached by the governing body;~~ individuals in accordance with medical staff bylaws requirements for making such recommendations and the facility bylaws established by the governing body for the review and final determination of such recommendations;

(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 in accordance with the facility bylaws established by the governing body, after an application has been submitted;

(9) review and approve the medical staff bylaws, ~~rules~~ rules, and ~~regulations body;~~ regulations;

(10) delegate to the medical staff the authority ~~to~~ to:

(A) evaluate the professional competence of medical staff members and applicants for ~~staff privileges~~ medical staff membership and clinical privileges; and

(B) ~~hold the medical staff responsible for recommending~~ recommend to the governing body initial medical staff appointments, ~~reappointments~~ reappointments, and assignments or curtailments of privileges;

(11) require that resources be made available to address the emotional and spiritual needs of patients either directly or through referral or arrangement with community agencies;

(12) maintain ~~effective~~ communication with the medical staff which ~~shall~~ may be ~~established,~~ established through:

~~(a)~~(A) meetings with the ~~Executive Committee~~ executive committee of the ~~Medical Staff;~~ medical staff;

~~(b)~~(B) service by the president of the medical staff as a member of the governing body with or without a vote;

~~(c)~~(C) appointment of individual medical staff members to ~~governing body committees; or~~ the medical review committee; or

~~(d)~~(D) a joint conference ~~committee;~~ committee that will be a committee of the governing body and the medical staff composed of equal representatives of each of the governing body, the chairman of the board or designee, the medical staff, and the chief of the medical staff or designee, respectively;

(13) require the medical staff to establish controls that are designed to provide that standards of ethical professional practices are met;

(14) provide ~~the necessary~~ administrative staff support to facilitate utilization review and infection control within the ~~facility and~~ facility, to support quality ~~control,~~ control and any other medical staff functions required by this Subchapter or by the facility bylaws;

(15) meet the following disclosure requirements:

~~(a)~~(A) provide data required by the Division;

~~(b)~~(B) disclose the facility's average daily inpatient charge upon request of the Division; and

~~(c)~~(C) disclose the identity of persons owning ~~5.0~~ five percent or more of the facility as well as the facility's officers and members of the governing body upon request;

(16) establish a procedure for reporting the occurrence and disposition of ~~any unusual incidents.~~ allegations of abuse or neglect of patients and incidents involving quality of care or physical environment at the facility. These procedures shall require that:

~~(a)~~(A) incident reports are analyzed and ~~summarized;~~ summarized by a designated party; and

~~(b)~~(B) corrective action is taken ~~as indicated by~~ based upon the analysis of incident reports;

(17) in a facility with one or more units, or portions of units, however described, utilized for psychiatric or substance abuse treatment, adopt policies implementing the provisions of G.S. 122C, Article 3, and Article 5, Parts, 2, 3, 4, 5, 7, and 8;

(18) develop arrangements for the provision of extended care and other long-term healthcare services. Such services shall be provided in the facility or by outside resources through a transfer agreement or referrals;

(19) provide and implement a written plan for the care or for the referral, or ~~for~~ both, of patients who require mental health or substance abuse services while in the ~~hospital;~~ facility;

(20) develop a conflict of interest policy which shall apply to all governing body members and ~~corporate officers.~~ facility administration. All governing body members shall execute a conflict of interest ~~statement;~~ statement; and

~~(21) prohibit members of the governing body from engaging in the following forms of self-dealing:~~

~~(a) the sale, exchange or leasing of property or services between the facility and a governing board member, his employer or an organization substantially controlled by him on a basis less favorable to the facility than that on which such property or service is made available to the general public;~~

~~(b) furnishing of goods, services or facilities by a facility to a governing board member, unless such furnishing is made on a basis not more favorable than that on which such goods, services, or facilities are made available to the general public or employees of the facility; or~~

~~(c) any transfer to or use by or for the benefit of a governing board member of the income or assets of a facility, except by purchase for fair market value; and~~

~~(22) prohibit the lease, sale, or exclusive use of any facility buildings or facilities receiving a license in accordance with this Subchapter to any entity which provides medical or other health services to the facility's patients, unless there is full, complete disclosure to and approval from the Division.~~

(21) conduct direct consultations with the medical staff at least twice during the year.

(b) For the purposes of this Rule, "direct consultations" means the governing body, or a subcommittee of the 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 telecommunications system permitting immediate, synchronous communication.

(c) The direct consultations shall consist of discussions of matters related to the quality of medical care provided to the hospital's patients, including quality matters arising out of the following:

(1) the scope and complexity of services offered by the facility;

(2) specific clinical populations served by the facility;

(3) limitations on medical staff membership other than peer review or corrective action in individual cases;

(4) circumstances relating to medical staff access to a facility resource; or

(5) any issues of patient safety and quality of care that a hospital's quality assessment and performance improvement program might identify as needing the attention of the governing body in consultation with the medical staff.

(d) For the purposes of this Rule, "specific clinical populations" includes those individuals who may be treated at the facility by the medical staff in place at the time of the consultation.

History Note: *Authority G.S. 131E-14.2; 131E-79; 42 CFR 482.12; 42 CFR 482.22;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. July 1, 2020.

10A NCAC 13B .3701 is proposed for readoption with substantive changes as follows:

SECTION .3700 - MEDICAL STAFF

10A NCAC 13B .3701 GENERAL PROVISIONS

a) The facility shall have a self-governed medical staff ~~organized in accordance with the facility's by-laws which~~ that shall be accountable to the governing body ~~and which shall have responsibility~~ for the quality of ~~professional services~~ care provided by individuals with medical staff membership and clinical ~~privileges.~~ privileges to provide medical services in the facility. Facility policy shall provide that individuals with clinical privileges shall perform only services within the scope of individual privileges granted.

b) Minutes required by the rules of this Section shall reflect all transactions, conclusions, and recommendations of meetings. Minutes shall be prepared and retained in accordance with a policy established by the facility and medical staff, and available for inspection by members of the medical staff and governing body, respectively, unless such minutes include confidential peer review information that is not accessible to others in accordance with applicable law, or as otherwise protected by law.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. July 1, 2020.

10A NCAC 13B .3702 is proposed for readoption as a repeal as follows:

10A NCAC 13B .3702 ESTABLISHMENT

History Note: *Authority G.S. 131E-79;*
Eff. January 1, ~~1996.~~ 1996;
Repealed Eff. July 1, 2020.

10A NCAC 13B .3703 is proposed for amendment as follows:

10A NCAC 13B .3703 APPOINTMENT

(a) The governing body may grant, deny, renew, modify, suspend, or terminate medical staff membership and clinical privileges after consideration of the recommendation made by the medical staff in accordance with the bylaws established by the medical staff and approved by the governing body for making such recommendations, and the facility bylaws established by the governing body for review and final determination of such recommendations.

(b) ~~Formal appointment~~ Review of an applicant for medical staff membership and the granting of clinical privileges shall follow procedures set forth in the ~~by-laws, rules or~~ bylaws, rules, and regulations of the medical staff. These procedures shall require the following:

(1) a signed application for medical staff membership, specifying ~~age,~~ date of birth, 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.

~~(4) members of the medical staff and others granted clinical privileges in the facility shall hold current 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.

(d) Medical staff appointments shall be reviewed at least once every two years by the medical staff in accordance with the bylaws established by the medical staff and approved by the governing body, and shall be followed with recommendations made to the governing body for review and a final determination.

(e) The facility shall maintain a file containing performance information for each medical staff member. Representatives of the Division shall have access to these files in accordance with, and subject to the limitations and restrictions set forth in, G.S. 131E-80; however, to the extent that the same includes confidential medical review information, such information shall be reviewable and confidential in accordance with G.S. 131E-80(d) and other applicable law.

(f) Minutes shall be taken and maintained of all meetings of the medical staff and governing body that concern the granting, denying, renewing, modifying, suspending or terminating of clinical privileges.

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

10A NCAC 13B .3704 is proposed for readoption with substantive changes as follows:

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

(a) The medical staff shall be established in accordance with the bylaws of the facility and organized in accordance with the bylaws, rules, and regulations of the medical staff. The governing body of the facility, after considering the recommendations of the medical staff, may grant medical staff membership and clinical privileges to qualified, licensed practitioners in accordance with their training, experience, and demonstrated competence and judgment in accordance with the medical staff bylaws, rules, and regulations.

~~(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 organization and administration of the medical staff. Every member~~ facility and to administer medical staff functions. The members of the active medical staff shall be eligible to vote at medical staff meetings and to hold ~~office.~~ medical staff office positions as determined by the medical staff bylaws, rules, and regulations and shall be responsible for 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.

~~(b)~~(c) The active medical staff may establish other categories for membership in the medical staff. These categories for membership shall be identified and defined in the medical staff ~~bylaws, rules or regulations adopted by the active medical staff.~~ bylaws. Examples of ~~these other~~ membership categories ~~for membership are:~~ include:

(1) active medical staff;

~~(1)~~ (2) associate medical staff;

~~(2)~~ (3) courtesy medical staff;

~~(3)~~ (4) temporary medical staff;

~~(4)~~ (5) consulting medical staff;

~~(5)~~ (6) honorary medical staff; or

~~(6)~~ (7) other staff classifications.

The medical staff ~~bylaws, rules or regulations may grant limited or full~~ bylaws shall describe the authority, duties, privileges, and voting rights ~~to any one or more of these other~~ for each membership ~~categories.~~ category consistent with applicable law, rules, and regulations and requirements of facility accrediting bodies.

~~(c) Medical staff appointments shall be reviewed at least once every two years by the governing board.~~

~~(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.~~

~~(e) Minutes of all actions taken by the medical staff and the governing board concerning clinical privileges shall be maintained by the medical staff and the governing board, respectively.~~

History Note: *Authority G.S. 131E-79;*
Eff. January 1, ~~1996.~~ 1996;

Readopted Eff. July 1, 2020.

10A NCAC 13B .3705 is proposed for readoption with substantive changes as follows:

10A NCAC 13B .3705 MEDICAL STAFF BYLAWS, ~~RULES~~ RULES, ~~OR~~ AND REGULATIONS

(a) The active medical staff shall develop and adopt, subject to the approval of the governing body, a set of bylaws, ~~rules or~~ rules, and ~~regulations,~~ regulations to establish a framework for ~~self-governance~~ self-governance of medical staff activities and accountability to the governing body.

(b) The medical staff bylaws, ~~rules~~ rules, and regulations shall provide for ~~at least~~ the following:

(1) organizational structure;

(2) qualifications for medical staff membership;

(3) procedures for ~~admission, retention, assignment, and reduction or withdrawal of~~ granting or renewing, denying, modifying, suspending, and revoking clinical privileges;

(4) procedures for disciplinary or corrective actions;

~~(4)~~ (5) procedures for fair hearing and appellate review mechanisms for ~~denial of staff appointments, reappointments, suspension, or revocation of~~ denying, modifying, suspending, and revoking clinical privileges;

~~(5)~~ (6) composition, functions and attendance of standing committees;

~~(6)~~ (7) policies for completion of medical ~~records and procedures for disciplinary actions;~~ records;

~~(7)~~ (8) formal liaison between the medical staff and the governing body;

~~(8)~~ (9) methods developed to formally verify that each medical staff member on appointment or reappointment agrees to abide by current medical staff ~~bylaws~~ bylaws, rules, and regulations, and the facility ~~bylaws; and~~ bylaws, rules, policies, and regulations;

~~(9)~~ (10) procedures for ~~members of medical staff~~ participation in quality assurance ~~functions.~~ functions by medical staff members;

(11) the process for the selection and election and removal of medical staff officers; and

(12) procedures for the proposal, adoption, and amendment, and approval of medical staff bylaws, rules, and regulations.

(c) Neither the medical staff, the governing body, nor the facility administration may unilaterally amend the medical staff bylaws, rules, and regulations.

(d) Neither the medical staff, the governing body, nor the facility administration may waive any provision of the medical staff bylaws, rules, and regulations, except in an emergency circumstance. For purposes of this Rule, an "emergency circumstance" means a situation of urgency that justifies immediate action and when there is not sufficient time to follow the applicable provisions and procedures of the medical staff bylaws. Examples of an emergency circumstance include an immediate threat to the life or health of an individual or the public, a natural disaster, or a judicial or regulatory order. The duration of a waiver permitted by this Rule will be only so long as the emergency circumstance exists.

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

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

Readopted Eff. July 1, 2020.

10A NCAC 13B .3706 is proposed for readoption with substantive changes as follows:

10A NCAC 13B .3706 ORGANIZATION AND RESPONSIBILITIES OF THE MEDICAL STAFF

(a) The medical staff shall be organized to accomplish its required functions as established by the governing body and medical staff bylaws, rules, and regulations and provide for the election or appointment of its own officers.

(b) There shall be an executive committee, or its equivalent, which represents the medical staff, ~~which~~ that has responsibility for the effectiveness of all medical activities of the staff, and ~~which~~ that acts for the medical staff.

~~(c) All minutes of proceedings of medical staff committees shall be recorded and available for inspections by members of the medical staff and the governing body.~~

~~(d)~~ (c) The following ~~reviews and~~ functions shall be performed by the medical staff:

(1) credentialing review;

~~(2) surgical case review;~~

~~(3)~~ (2) medical records review;

~~(4) medical care evaluation review;~~

~~(5)~~ (3) drug utilization review;

~~(6)~~ (4) radiation safety review;

~~(7)~~ (5) blood usage review; ~~and~~

~~(8)~~ (6) bylaws ~~review.~~ review;

(7) medical review;

(8) peer review; and

(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.

History Note: *Authority G.S. 131E-79;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. July 1, 2020.

10A NCAC 13B .3707 is proposed for readoption with substantive changes as follows:

10A NCAC 13B .3707 MEDICAL ORDERS

(a) No medication or treatment shall be administered or discontinued except in response to the order of a member of the medical staff in accordance with ~~established rules~~ policies, rules, and regulations established by the facility and medical staff and as provided in Paragraph (f) ~~below.~~ of this Rule.

(b) Such orders shall be dated and recorded directly in the patient ~~chart or in a computer or data processing system which provides a hard copy printout of the order for the patient chart.~~ medical record. A method shall be established to safeguard against fraudulent recordings.

(c) All orders for medication or treatment shall be authenticated according to ~~hospital policies.~~ medical staff and facility policies, rules, or regulations. The order shall be taken by personnel qualified by medical staff ~~rules~~ bylaws, rules, and regulations, and shall include the date, time, and name of persons who gave the order, and the full signature of the person taking the order.

(d) The names of drugs shall be recorded in full and not abbreviated except where approved by the medical staff.

(e) The medical staff shall establish a written policy in conjunction with the pharmacy committee or its equivalent for all medications not specifically prescribed as to time or number of doses to be automatically stopped after a reasonable time limit, but no more than 14 days. The prescriber shall be notified according to established policies and procedures at least 24 hours before an order is automatically stopped.

(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.

History Note: *Authority G.S. 131E-75; 131E-79; ~~143B-165;~~*
Eff. January 1, 1996;
Amended Eff. April 1, 2005; August 1, ~~1998.~~ 1998;
Readopted Eff. July 1, 2020.

10A NCAC 13B .3708 is proposed for amendment as follows:

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

(a) The medical staff shall have in effect a system to review ~~medical services rendered,~~ care provided at the facility by members of the medical staff, to assess quality, to provide a process for ~~improving performance when indicated~~ quality improvement, and to monitor the ~~outcome.~~ outcome of quality improvement activities.

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

(c) The facility shall have a written plan ~~approved by the medical staff, administration and governing body which~~ that generates reports to permit identification of patient care ~~problems. The plan shall establish~~ problems and that establishes a system to use this data to document and identify interventions. The plan shall be approved by the medical staff, facility administration, and the governing body.

(d) The medical staff shall establish ~~and~~ a policy to maintain a ~~continuous~~ review process of the care ~~rendered to both inpatients and outpatients~~ provided by members of the medical staff to all patients in every medical department of the facility. ~~At least quarterly, the~~ The medical staff shall have a ~~meeting~~ policy to schedule meetings to examine the review process and results. The review process shall include both practitioners and allied health professionals from the ~~facility~~ medical staff.

(e) Minutes shall be ~~taken at~~ prepared for all meetings reviewing quality ~~improvement, and these minutes shall be made available to the medical staff on a regular basis in accordance with established policy. These minutes shall be retained as determined by the facility.~~ improvement and shall reflect all of the transactions, conclusions, and recommendations of the meeting.

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.~~ 2017;
Amended Eff. July 1, 2020.