

REQUEST FOR TECHNICAL CHANGE

AGENCY: Medical Care Commission

RULE CITATION: All Rules

DEADLINE FOR RECEIPT: December 11, 2020

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

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

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

Are any of the proposed rules stricter than those issued by the Commission under G.S. 131E-79 of the Hospital Licensing Act? See G.S. 131E-149(a).

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Ashley Snyder
Commission Counsel
Date submitted to agency: November 30, 2020

REQUEST FOR TECHNICAL CHANGE

AGENCY: Medical Care Commission

RULE CITATION: 10A NCAC 13C .0202

DEADLINE FOR RECEIPT: December 11, 2020

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

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

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

At line 8, please add a comma after "AAAHC."

In (b), line 11, please do not capitalize "Rules."

At line 22, are you referring to the application in Rule .0201 of this Section?

At lines 33-36, please consider deleting "as a preliminary step to avoid last minute difficulty with construction documents approval." Is this necessary? If it is purely informational, simply explaining the reason behind the option to submit early, it does not meet the definition of a "rule." 150B-2(8a)(c).

In (f)(2), under what circumstances does the Division approve construction documents and specifications? Is this covered by 10A NCAC 13C .1400?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Ashley Snyder
Commission Counsel
Date submitted to agency: November 30, 2020

1 10A NCAC 13C .0202 is readopted as published in 34:24 NCR 2375-2377 as follows:

2
3 **10A NCAC 13C .0202 REQUIREMENTS FOR ISSUANCE OF LICENSE**

4 (a) Upon application for a license from a facility never before licensed, a representative of the Department shall make
5 an inspection of that facility. Every building, institution, or establishment ~~for which a license that~~ has been issued a
6 license shall be inspected for compliance with the rules found in this Subchapter. An ambulatory surgery facility shall
7 be deemed to meet licensure requirements if the ambulatory surgery facility is accredited by The Joint ~~Commission~~
8 ~~(formerly known as "JCAHO"), Commission, AAAHC or AAAASF.~~ Accreditation ~~does~~ shall not exempt a facility
9 from statutory or rule requirements for licensure nor ~~does~~ shall it prohibit the Department from conducting inspections
10 as provided in this Rule to determine compliance with all requirements.

11 (b) If the applicant has been issued a Certificate of Need and is found to be in compliance with the Rules found in
12 this Subchapter, then the Department shall issue a license to expire on December 31 of each year.

13 (c) The Department shall be notified at the time of:

- 14 (1) any change of the owner or operator;
- 15 (2) any change of location;
- 16 (3) any change as to a lease; and
- 17 (4) any transfer, assignment, or other disposition or change of ownership or control of 20 percent or
18 more of the capital stock or voting rights thereunder of a corporation that is the operator or owner
19 of an ambulatory surgical facility, or any transfer, assignment, or other disposition of the stock or
20 voting rights thereunder of such corporation that results in the ownership or control of more than 20
21 percent of the stock or voting rights thereunder of such corporation by any person.

22 A new application shall be submitted to the Department in the event of such a change or changes.

23 (d) The Department shall not grant a license until the plans and specifications that are stated in Section .1400 of this
24 Subchapter, covering the construction of new buildings, additions, or material alterations to existing buildings are
25 approved by the Department.

26 (e) The facility design and construction shall be in accordance with the licensure rules for ambulatory surgical
27 facilities found in this Subchapter, the North Carolina State Building Code, and local municipal codes.

28 (f) Submission of Plans.

- 29 (1) ~~Before construction is begun, schematic plans and specifications and final plans and specifications~~
30 ~~covering construction of the new buildings, alterations, renovations, or additions to existing~~
31 ~~buildings shall be submitted to the Division for approval. When construction or remodeling of a~~
32 facility is planned, one copy of construction documents and specifications shall be submitted by the
33 owner or owner's appointed representative to the Department for review and approval. As a
34 preliminary step to avoid last minute difficulty with construction documents approval, schematic
35 design drawings and design development drawings may be submitted for approval prior to the
36 required submission of construction documents.

(2) ~~The Division shall review the plans and notify the licensee that said buildings, alterations, additions, or changes are approved or disapproved. If plans are disapproved the Division shall give the applicant notice of deficiencies identified by the Division. Approval of construction documents and specifications shall be obtained from the Department prior to licensure. Approval of construction documents and specifications shall expire one year after the date of approval unless a building permit for the construction has been obtained prior to the expiration date of the approval of construction documents and specifications.~~

(3) The plans shall include a plot plan showing the size and shape of the entire site and the location of all existing and proposed facilities.

(4) ~~Plans shall be submitted in duplicate. The Division shall distribute a copy to the Department of Insurance for review of the North Carolina State Building Code requirements if required by the North Carolina State Building Code which is hereby incorporated by reference, including all subsequent amendments. Copies of the Code may be accessed electronically free of charge at: http://www.ecodes.biz/ecodes_support/Free_Resources/2012NorthCarolina/12NorthCarolina_main.html.~~

(g) To qualify for licensure or license renewal, each facility shall provide to the Division, with its application, an attestation statement in a form provided by the Division verifying compliance with the requirements defined in Rule .0301(d) of this Subchapter.

History Note: Authority G.S. 131E-91; 131E-147; 131E-149; S.L. 2013-382, s. 13.1; Eff. October 14, 1978; Amended Eff. April 1, 2003; Temporary Amendment Eff. May 1, 2014; Amended Eff. November 1, 2014. 2014; Readopted Eff. January 1, 2021.

REQUEST FOR TECHNICAL CHANGE

AGENCY: Medical Care Commission

RULE CITATION: 10A NCAC 13C .0203

DEADLINE FOR RECEIPT: December 11, 2020

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

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

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

Why is this Rule necessary given G.S. 131E-148?

G.S. 131E-148 also says a license can be amended or recalled. Were those options intentionally left out of this Rule?

Do 150B-3 and 150B-23 grant authority for this Rule? Do they need to be listed in your history note or are the cross-references in (b) and (c) sufficient?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Ashley Snyder
Commission Counsel
Date submitted to agency: November 30, 2020

1 10A NCAC 13C .0203 is amended as published in 34:24 NCR 2375-2377 as follows:

2
3 **10A NCAC 13C .0203 SUSPENSION OR REVOCATION: AMBULATORY SURGICAL FACILITY**

4 (a) The license may be suspended or revoked at any time for noncompliance with the ~~regulations~~ rules of the
5 Department.

6 (b) Suspension or revocation of the license shall be covered by the rules regarding contested cases as found in ~~40~~
7 ~~NCAC 3B .0200.~~ G.S. 150B-23.

8 (c) Notwithstanding ~~Subsection~~ Paragraph (a) and (b) of this Rule, the Department may summarily suspend the license
9 pursuant to ~~General Statute~~ G.S. 150B-3(c).

10
11 *History Note: Authority G.S. 131E-148; 131E-149; 143B-165; 150B-3(c); 150B-23;*

12 *Eff. October 14, 1978;*

13 *Amended Eff. November 1, 1989;*

14 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December*
15 *23, ~~2017~~, 2017;*

16 *Amended Eff. January 1, 2021.*

REQUEST FOR TECHNICAL CHANGE

AGENCY: Medical Care Commission

RULE CITATION: 10A NCAC 13C .0301

DEADLINE FOR RECEIPT: December 11, 2020

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

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

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

In (a)(3), what are you requiring by stating the facility's manual shall be "designed to ensure professional and safe care for the patients?" Is there any standard by which this is measured? Is it up to the facility?

In (d)(6), does your regulated public understand what is required by their obligation to "file a Schedule H, federal form 990?" I take it this is a requirement from the federal government, correct?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Ashley Snyder
Commission Counsel
Date submitted to agency: November 30, 2020

1 10A NCAC 13C .0301 is readopted as published in 34:24 NCR 2375-2377 as follows:

2
3 **SECTION .0300 – GOVERNING AUTHORITY MANAGEMENT**

4
5 **10A NCAC 13C .0301 GOVERNING AUTHORITY**

6 (a) The facility's governing authority shall adopt bylaws or other operating policies and procedures to assure that:

- 7 (1) a named individual is identified who is responsible for the overall operation and maintenance of the
8 facility. The governing authority shall have methods in place for the oversight of the individual's
9 performance;
- 10 (2) ~~at least~~ annual meetings of the governing authority ~~are~~ shall be conducted if the governing authority
11 consists of two or more individuals. Minutes shall be maintained of such meetings;
- 12 (3) a policy and procedure manual is created that is designed to ensure professional and safe care for
13 the patients. The manual shall be reviewed annually and revised ~~when necessary~~, in accordance
14 with facility policy. The manual shall include provisions for administration and use of the facility,
15 compliance, personnel quality assurance, procurement of outside services and consultations, patient
16 care ~~policies~~ policies, and services offered; and
- 17 (4) annual reviews and evaluations of the facility's policies, management, and operation are conducted.

18 (b) When services such as dietary, laundry, or therapy services are purchased from others, the governing authority
19 shall be responsible ~~to assure~~ for assuring the supplier meets the same local and ~~state~~ State standards the facility would
20 have to meet if it were providing those services ~~itself~~ using its own staff.

21 (c) The governing authority shall provide for the selection and appointment of the professional staff and the granting
22 of clinical privileges and shall be responsible for the professional conduct of these persons.

23 (d) The governing authority shall establish written policies and procedures to assure billing and collection practices
24 in accordance with G.S. 131E-91. These policies and procedures shall include:

- 25 (1) a financial assistance policy as defined in G.S. 131E-214.14(b)(3);
- 26 (2) how a patient may obtain an estimate of the charges for the statewide 20 most common outpatient
27 imaging procedures and 20 most common outpatient surgical procedures based on the primary
28 Current Procedure Terminology Code (CPT). The policy shall require that the information be
29 provided to the patient in writing, either electronically or by mail, within three business days;
- 30 (3) how a patient or patient's representative may dispute a bill;
- 31 (4) issuance of a refund within 45 days of the patient receiving notice of the overpayment when a patient
32 has overpaid the amount due to the facility;
- 33 (5) providing written notification to the patient or patient's representative, ~~at least~~ 30 days prior to
34 submitting a delinquent bill to a collections agency;
- 35 (6) providing the patient or patient's representative with the facility's charity care and financial
36 assistance policies, if the facility is required to file a Schedule H, federal form 990;

- 1 (7) the requirement that a collections agency, entity, or other assignee obtain written consent from the
- 2 facility prior to initiating litigation against the patient or patient's representative;
- 3 (8) a policy for handling debts arising from the provision of care by the ambulatory surgical facility
- 4 involving the doctrine of necessities, in accordance with G.S. 131E-91(d)(5); and
- 5 (9) a policy for handling debts arising from the provision of care by the ambulatory surgical facility to
- 6 a minor, in accordance with G.S. 131E-91(d)(6).

7

8 *History Note:* Authority G.S. 131E-91; 131E-147.1; 131E-149; 131E-214.13(f); 131E-214.14; ~~S.L. 2013-382, s.~~

9 ~~10.1; S.L. 2013-382, s. 13.1;~~

10 *Eff. October 14, 1978;*

11 *Amended Eff. November 1, 1989; November 1, 1985; December 24, 1979;*

12 *Temporary Amendment Eff. May 1, 2014;*

13 *Amended Eff. November 1, ~~2014.~~ 2014.*

14 *Readopted Eff. January 1, 2021.*

REQUEST FOR TECHNICAL CHANGE

AGENCY: Medical Care Commission

RULE CITATION: 10A NCAC 13C .0501

DEADLINE FOR RECEIPT: December 11, 2020

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

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

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

At line 6, please use commas to separate items in a list. Here, please consider: "Only a physician, dentist, qualified anesthetist, or qualified anesthesiologist..."

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Ashley Snyder
Commission Counsel
Date submitted to agency: November 30, 2020

1 10A NCAC 13C .0501 is readopted as published in 34:24 NCR 2375-2377 as follows:

2
3 **SECTION .0500 - ANESTHESIA SERVICES**
4

5 **10A NCAC 13C .0501 PROVIDING ANESTHESIA SERVICES**

6 Only a physician, ~~dentist~~ dentist, or qualified anesthetist or qualified anesthesiologist as defined in Rule .0103 of this
7 Subchapter, shall administer anesthetic ~~agents (general and regional)~~ agents. Podiatrists shall administer only local
8 anesthesia. The governing authority shall establish written policies and procedures concerning the provision of
9 anesthesia services, including the designation of those persons authorized to administer ~~anesthetics~~ anesthetics in
10 accordance with State law.
11

12 *History Note: Authority G.S. 131E-149;*

13 *Eff. October 14, ~~1978~~ 1978;*

14 *Readopted Eff. January 1, 2021.*

REQUEST FOR TECHNICAL CHANGE

AGENCY: Medical Care Commission

RULE CITATION: 10A NCAC 13C .0702

DEADLINE FOR RECEIPT: December 11, 2020

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

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

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

At line 4, please simply refer to "rules" instead of "rules and regulations." "Regulations" are issued by federal agencies, whereas "rules" are adopted by State agencies.

At line 6, is it necessary to say "at least?" Rules always set minimum requirements.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Ashley Snyder
Commission Counsel
Date submitted to agency: November 30, 2020

1 10A NCAC 13C .0702 is amended as published in 34:24 NCR 2375-2377 as follows:

2
3 **10A NCAC 13C .0702 REGULATIONS FOR PERFORMED SERVICES**

4 Radiation protection shall be provided in accordance with the rules and regulations adopted by the Radiation
5 Protection Commission found in ~~10 NCAC 3G, and the recommendations of the National Council on Radiation~~
6 ~~Protection and Measurements.~~ 10A NCAC 15. Records shall be kept of at least annual checks and calibration of all
7 ionizing radiation therapy equipment used in the facility.

8
9 *History Note: Authority G.S. 131E-149;*

10 *Eff. October 14, 1978;*

11 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December*
12 *23, ~~2017.~~ 2017.*

13 *Amended Eff. January 1, 2021.*

REQUEST FOR TECHNICAL CHANGE

AGENCY: Medical Care Commission

RULE CITATION: 10A NCAC 13C .0902

DEADLINE FOR RECEIPT: December 11, 2020

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

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

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

What are you requiring in (a)? Are you requiring any specific ratio of nurses to patients or other similar minimum requirement? Under what circumstances would the Commission determine staffing levels do not meet the nursing needs of patients?

In (b), who determines whether nursing personnel are "assigned to duties consistent with their training and experience." Is this left to the discretion of the governing authority?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Ashley Snyder
Commission Counsel
Date submitted to agency: November 30, 2020

1 10A NCAC 13C .0902 is readopted as published in 34:24 NCR 2375-2377 as follows:

2
3 **10A NCAC 13C .0902 NURSING PERSONNEL**

4 (a) ~~An adequate number of licensed~~ Licensed and ancillary nursing personnel shall be on duty to assure that staffing
5 levels meet the ~~total~~ nursing needs of patients ~~based on the number of patients~~ in the facility and their individual
6 nursing care needs.

7 (b) At least one registered nurse shall be in the facility during the hours ~~it is in~~ of operation. Nursing personnel shall
8 be assigned to duties consistent with their training and experience.

9
10 *History Note: Authority G.S. 131E-149;*

11 *Eff. October 14, 1978; 1978;*

12 *Readopted Eff. January 1, 2021.*