

RRC STAFF OPINION

PERIODIC REVIEW AND EXPIRATION OF EXISTING RULES REPORT

PLEASE NOTE: THIS COMMUNICATION IS EITHER THE RECOMMENDATION OF AN RRC STAFF ATTORNEY AS TO AN ACTION THAT THE ATTORNEY BELIEVES THE COMMISSION SHOULD TAKE ON THE CITED REPORT AT ITS NEXT MEETING OR AN OPINION OF THAT ATTORNEY AS TO SOME MATTER CONCERNING THAT REPORT. THE AGENCY AND MEMBERS OF THE PUBLIC ARE INVITED TO SUBMIT THEIR OWN COMMENTS AND RECOMMENDATIONS TO THE COMMISSION IN ACCORDANCE WITH THE RULES OF THE RRC FOUND IN 26 NCAC 05.

AGENCY: NC Medical Care Commission

REPORT: 10A NCAC 13B

RECOMMENDED ACTION:

- X Find the comments for Rules 10A NCAC 13B .3303, .4103, .4801, and .4805 have merit and change the classification of those Rules to “Necessary with Substantive Public Interest.”**

COMMENT:

It is Staff’s opinion that the comments received by the agency in relation to Rules 10A NCAC 13B .3303, .4103, .4801, and .4805 fall within the definition of “public comment.” Staff also believes that the comments regarding these Rules have merit as they address a specific portion of the Rule and relate to a standard of review set forth in G.S. 150B-21.9. Specifically, it is Staff’s opinion that the comments relate to the clarity of the Rules. Each of the responses by the agency indicates that the agency recognizes that updates are needed.

It is Staff’s opinion that the classifications for Rules 10A NCAC 13B .3303, .4103, .4801, and .4805 should be changed to “Necessary with Substantive Public Interest,” thereby subjecting these Rules to readoption pursuant to G.S. 150B-21.3A.

Included in the following pages are the comments received, agency responses, and pertinent Rules.

Public Comment regarding Rule 10A 13B .3303

B) clarify wording. For the address/phone number.

Agency Response to Public Comment regarding Rule 10A 13B .3303

The Agency determined this rule was necessary without substantive public interest.

This comment does not indicate the rule language is ambiguous or unclear. The comment is helpful, but is not necessary to change the determination of the rule. A technical change will be needed to this rule by the Agency to update the address and phone number following the periodic review process and is noted.

The Agency will not change the determination of this rule.

10A NCAC 13B .3303 PROCEDURE

(a) The facility shall develop and implement procedures to inform each patient of his rights. Copies of the facilities' Patient's Bill of Rights shall be made available through one of the following ways:

- (1) prominent displays in appropriate locations in addition to copies available upon request; or
- (2) provision of a copy to each patient or responsible party upon admission or as soon after admission as is feasible.

(b) The address and telephone number of the section in the Department responsible for the enforcement of the provisions of this part shall be posted.

(c) The facility shall adopt procedures to ensure effective and fair investigation of violations of patients' rights and to ensure their enforcement. These procedures shall ensure that:

- (1) a system is established to identify formal written complaints;
- (2) formal written complaints are recorded and investigated;
- (3) investigation and resolution of formal complaints shall be conducted; and
- (4) disciplinary and education procedures shall be developed for members of the hospital and medical staff who are noncompliant with facility policies.

(d) The Division shall investigate or refer to appropriate State agencies all complaints within the jurisdiction of the rules in this Subchapter.

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

Public Comment regarding Rule 10A NCAC 13B .4103

Any of any facility' doesn't make sense

Agency Response to Public Comment regarding Rule 10A NCAC 13B .4103

The Agency determined this rule was necessary without substantive public interest.

The wording in the rule “Any of any” is a typographical error that has been in the rule since 1996. A technical change will be needed to be made to this rule by the Agency after the periodic review process pursuant to G.S.150B-21.5(a)(5) to update and is noted.

The Agency will not change the determination of this rule.

10A NCAC 13B .4103 PROVISION OF EMERGENCY SERVICES

(a) **Any of any facility** providing emergency services shall establish and maintain policies requiring appropriate medical screening, treatment and transfer services for any individual who presents to the facility emergency department and on whose behalf treatment is requested regardless of that person's ability to pay for medical services and without delay to inquire about the individual's method of payment.

(b) Any facility providing emergency services under this Section shall install, operate and maintain, on a 24-hour per day basis, an emergency two-way radio licensed by the Federal Communications Commission in the Public Safety Radio Service capable of establishing voice radio communication with ambulance units transporting patients to said facility or having any written procedure or agreement for handling emergency services with the local ambulance service, rescue squad or other trained medical personnel.

(c) All communication equipment shall be in compliance with current rules established by North Carolina Rules for Basic Life Support/Ambulance Service (10 NCAC 3D .1100) adopted by reference with all subsequent amendments. Referenced rules are available at no charge from the Office of Emergency Medical Services, 2707 Mail Service Center, Raleigh, N.C. 27699-2707.

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

Public Comment regarding 10A NCAC 13B .4801

(c) Need to update language regarding NCHENR. Radiation Protection Section is now under the Division of Health Service Regulation. Regulations are now available online.

Agency Response to Public Comment regarding 10A NCAC 13B .4801

The Agency determined this rule was necessary without substantive public interest.

This comment about updating the Section name and regulations does not indicate the rule language is ambiguous or unclear. The comment is helpful, but it is not necessary to change the determination of the rule. To update this, a rule technical change revision will be needed to following the periodic review and is noted.

The Agency will not change the determination of this rule.

10A NCAC 13B .4801 ORGANIZATION

(a) Imaging services shall be under the supervision of a full-time radiologist, consulting radiologist, or a physician experienced in the particular imaging modality and the physician in charge must have the credentials required by facility policies.

(b) Activities of the imaging service may include radio-therapy.

(c) All imaging equipment shall be operated under professional supervision by qualified personnel trained in the use of imaging equipment and knowledgeable of all applicable safety precautions required by the North Carolina Department of Environment and Natural Resources, Division of Environmental Health Radiation Protection Section. Copies of regulations are available from the N.C. Department of Environment and Natural Resources, Radiation Protection Section, 3825 Barrett Drive, Raleigh, NC 27609 at a cost of sixteen dollars (\$16.00) each.

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

*RRC objection due to lack of statutory authority and ambiguity Eff. July 13, 1995;
Eff. January 1, 1996.*

Public Comment regarding Rule 10A NCAC 13B .4805

(c) Need to update language regarding NCHENR. Radiation Protection Section is now under the Division of Health Service Regulation. (e) Need to update language regarding NCHENR. Radiation Protection Section is now under the Division of Health Service Regulation.

Agency Response to Public Comment regarding Rule 10A NCAC 13B .4805

The Agency determined this rule was necessary without substantive public interest.

This comment about updating the Section name does not indicate the rule language is ambiguous or unclear. The comment is helpful, but it is not necessary to change the determination of the rule. To update this, a rule technical change revision will be needed to following the periodic review and is noted.

The Agency will not change the determination of this rule.

10A NCAC 13B .4805 SAFETY

(a) The facility shall require that all imaging equipment is operated under the supervision of a physician and by qualified personnel.

(b) The facility shall require that proper caution is exercised to protect all persons from exposure to radiation.

(c) Safety inspections of the imaging department, including equipment, shall be conducted by the North Carolina Division of Environmental Health, Radiation Protection Services Section. Copies of the report shall be available for review by the Division.

(d) The governing authority shall appoint a radiation safety committee. The committee shall include but is not limited to:

- (1) a physician experienced in the handling of radio-active isotopes and their therapeutic use; and
- (2) other representatives of the medical staff.

(e) All radio-active isotopes, whether for diagnostic, therapeutic, or research purposes shall be received, handled, and disposed of in accordance with the requirements of the North Carolina Department of Environment and Natural Resources, Division of Environmental Health, Radiation Protection Services Section. Copies of regulations are available from the North Carolina Department of Environment, Health, and Natural Resources, Division of Radiation Protection, 3825 Barrett Drive, Raleigh, NC 27609 at a cost of six dollars (\$6.00) each.

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