10A NCAC 13B .3302 is proposed for readoption with substantive changes as follows:

10A NCAC 13B .3302 MINIMUM PROVISIONS OF PATIENT'S BILL OF RIGHTS

This Rule does not apply to patients in licensed nursing facility beds since these individuals are granted rights pursuant to G.S. 131E-117. A patient in a facility subject to this Rule has the following rights:

(1) A patient has the right to respectful care given by competent personnel.

(2) A patient has the right, upon request, to be given the name of his attending physician, the names of all other physicians directly participating in his or her care, and the names and functions of other health care persons having direct contact with the patient.

(3) A patient has the right to privacy concerning his or her own medical care program. Case discussion, consultation, examination, and treatment are considered confidential and shall be conducted discreetly.

~~(4) A patient has the right to have all records pertaining to his medical care treated as confidential except as otherwise provided by law or third party contractual arrangements.~~

~~(5)~~(4) A patient has the right to know what facility rules and regulations apply to his or her conduct as a patient.

~~(6)~~(5) A patient has the right to expect emergency procedures to be implemented without ~~unnecessary~~ delay.

~~(7)~~(6) A patient has the right to ~~good~~ quality care and ~~high~~ professional standards that are ~~continually~~ maintained and reviewed.

~~(8)~~(7) A patient has the right to full information in laymen's terms, concerning his diagnosis, treatment and prognosis, including information about alternative treatments and possible complications. When it is not possible or medically advisable to give such information to the patient, the information shall be given on his or her behalf to the patient's designee.

~~(9)~~ (8) Except for emergencies, a physician must obtain ~~necessary~~ informed consent prior to the start of any procedure or ~~treatment, or both.~~ treatment.

~~(10)~~ (9) A patient has the right to be advised when a physician is considering the patient as a part of a medical care research program or donor program. Informed consent ~~must~~ shall be obtained prior to ~~actual~~ participation in such a ~~program and the~~ program. The patient or legally responsible ~~party, may, at any time,~~ party may refuse to continue in any ~~such~~ program ~~to which~~ that he or she has previously given informed consent. An Institutional Review Board (IRB) may waive or alter the informed consent requirement if it reviews and approves a research study in ~~accord~~ accordance with federal regulations for the protection of human research subjects including U.S. Department of Health and Human Services (HHS) regulations under 45 CFR Part 46 and U.S. Food and Drug Administration (FDA) regulations under 21 CFR Parts 50 and 56. For any research study proposed for conduct under an FDA "Exception from Informed Consent Requirements for Emergency Research" or an HHS "Emergency Research Consent Waiver" ~~in which~~ that waives informed consent ~~is waived~~ but

community consultation and public disclosure about the research are required, any facility proposing to be engaged in the research study shall also ~~must~~ verify that the proposed research study has been registered with the North Carolina Medical Care Commission. When the IRB ~~reviewing the research study~~ has authorized the start of the community consultation process required ~~by the federal regulations~~ for emergency research, but before the beginning of that process, notice of the proposed research study ~~by the facility~~ shall be provided to the North Carolina Medical Care Commission. The notice shall include:

(a) the title of the research study;

(b) a description of the research study, including a description of the population to be enrolled;

(c) a description of the planned community consultation process, including ~~currently~~ proposed meeting dates and times;

(d) ~~an explanation of the way that people choosing not to participate in~~ instructions for opting out of the research ~~study may opt out;~~ study; and

(e) contact information including mailing address and phone number for the IRB and the principal investigator.

The Medical Care Commission may publish all or part of the above information in the North Carolina Register, and may require the institution proposing to conduct the research study to attend a public meeting convened by a Medical Care Commission member in the community where the proposed research study is to take place to present and discuss the study or the community consultation process proposed.

~~(11)~~ (10)A patient has the right to refuse any drugs, treatment or procedure offered by the facility, to the extent permitted by law, and a physician shall inform the patient of his or her right to refuse any drugs, treatment or procedures and of the medical consequences of the patient's refusal of any drugs, treatment or procedure.

~~(12)~~ (11)A patient has the right to assistance in obtaining consultation with another physician at the patient's request and expense.

~~(13)~~ (12)A patient has the right to medical and nursing services without discrimination based upon race, color, religion, sex, sexual orientation, gender identity, national origin or source of payment.

~~(14)~~ (13)A patient who does not speak English shall have ~~access, when possible,~~ access to an interpreter.

~~(15)~~ (14)~~A facility shall provide a patient, or patient designee, upon request, access to all information contained in the patient's medical records.~~ A patient or his or her designee has the right to have all records pertaining to his or her medical care treated as confidential except as otherwise provided by law or third party contractual arrangements. A patient's access to medical records may be restricted by the patient's attending physician. If the physician restricts the patient's access to information in the patient's medical record, the physician shall record the reasons on the patient's medical record. Access shall be restricted only for sound medical reason. A patient's designee may have access to

the information in the patient's medical records even if the attending physician restricts the patient's access to those records.

~~(16)~~ (15)A patient has the right not to be awakened by hospital staff unless it is medically necessary.

~~(17)~~ (16)The patient has the right to be free from duplication of medical and nursing procedures as determined by the attending physician.

~~(18)~~ (17)The patient has the right to medical and nursing treatment that avoids unnecessary physical and mental discomfort.

~~(19)~~ (18)When medically permissible, a patient may be transferred to another facility only after he or his next of kin or other legally responsible representative has received complete information and an explanation concerning the needs for and alternatives to such a transfer. The facility ~~to which~~ that the patient is to be transferred must first have accepted the patient for transfer.

~~(20)~~ (19)The patient has the right to examine and receive a detailed explanation of his bill.

~~(21)~~ (20)The patient has a right to full information and counseling on the availability of known financial resources for his health care.

~~(22)~~ (21)A patient has the right to be informed upon discharge of his or her continuing health care requirements following discharge and the means for meeting them.

~~(23)~~ (22)A patient shall not be denied the right of access to an individual or agency who is authorized to act on his or her behalf to assert or protect the rights set out in this Section.

~~(24)~~ (23)A patient has the right to be informed of his rights at the earliest possible time in the course of his or her hospitalization.

~~(25)~~ (24)A patient has the right to designate visitors who shall receive the same visitation privileges as the patient's immediate family members, regardless of whether the visitors are legally related to the patient.

History Note: *Authority G.S. 131E-75; 131E-79; 143B-165;*
RRC Objection due to ambiguity Eff. July 13, 1995;
Eff. January 1, 1996;
Temporary Amendment Eff. April 1, 2005;
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Readopted Eff. April 1, 2020.