CHAPTER 26 – MENTAL HEALTH: GENERAL

SUBCHAPTER 26A – RULES OF PROCEDURE

SECTION .0100 – RULEMAKING PROCEDURES

10A NCAC 26A .0101 AVAILABILITY OF THESE RULES

A copy of all rules adopted by the Commission for Mental Health Services and a copy of all rules adopted by the Department of Human Resources for the Division of mental health services shall be available for public inspection during regular office hours at the Raleigh office of the Division, each of the regional offices of the Division and each of the institutions of the Division.

History Note: *Authority G.S. 143B-147;*
Eff. February 1, 1976;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26A .0102 SCOPE

These rules apply to persons wishing to submit comments at rule-making hearings or request additional information regarding proposed or adopted rules.

History Note: *Authority G.S. 143B-10(j)(2); 143B-147; 150B-11;*
Eff. February 1, 1976;
Amended Eff. April 1, 1990; January 1, 1987; April 1, 1984;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26A .0103 PETITIONS

(a) Except for petitions regarding the addition, deletion, or rescheduling of controlled substances which are governed by 10A NCAC 26F .0117, any person wishing to submit a petition requesting the adoption, amendment, or repeal of a rule by the Commission or the Division Director shall address the petition to: A.P.A. Coordinator, Division of Mental Health, Developmental Disabilities and Substance Abuse Services, 3001 Mail Service Center, Raleigh, North Carolina 27699-3001.

(b) The petition shall contain the following information:

(1) either a draft of the proposed rule or a summary of its contents and the statutory authority for the Commission or the Division Director to promulgate the rule;
(2) reason for proposal;
(3) effect on existing rules;
(4) any data supporting the proposal;
(5) effect of the proposed rule on existing practices in the area involved, including cost factors;
(6) names and addresses, if known, of those most likely to be affected by the proposed rule; and
(7) name and address of the petitioner.

(c) The A.P.A. coordinator shall determine whether the rule comes under the statutory authority of the Commission or the Division Director or both and submit the petition to the appropriate body.

(d) The Commission or Division Director shall determine, based on a study of the facts stated in the petition, whether the public interest will be served by granting the petition. The Commission or Division Director shall consider all the contents of the petition, plus any additional information deemed relevant.

(e) The Commission or Division Director shall render a final decision on the petition within the time requirements of G.S. 150B-20. If the decision is to deny the petition, the petitioner shall be notified in writing and provided the reasons for the denial. Denial of the petition shall be considered a final agency decision as specified in G.S. 150B-20. If the decision is to approve the petition, rule-making proceedings shall be initiated in accordance with the rules in this Section.

History Note: *Authority G.S. 143B-10(j)(2); 143B-147; 150B-11; 150B-16;*
Eff. February 1, 1976;
Amended Eff. April 1, 1990; January 1, 1987; April 1, 1984;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26A .0104 NOTICE

(a) When a rule-making hearing is scheduled for either the Commission or the Division Director, in response to a petition or otherwise, the Division shall give notice of a public hearing. The notice shall meet the requirements of G.S. 150B-21.2.
(b) Persons desiring information in addition to that provided in a particular rule-making notice shall contact the Division's A.P.A. coordinator or other person specified in the hearing notice according to the directions in the notice.

History Note: *Authority G.S. 143B-10(j)(2); 143B-18; 143B-147; 150B-11; 150B-12;*
Eff. February 1, 1976;
Amended Eff. January 1, 1987; April 1, 1984;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26A .0105 HEARINGS
(a) Written Submissions.
(1) Any person may file a written submission containing data, comments, or arguments within the 30-day period that the hearing record is open for written comments. The deadline for written submissions shall be stated in the hearing notice.
(2) The written submission shall clearly state the proposed rule to which the comments are addressed. Written submissions shall be sent to the person and address specified in the hearing notice.
(b) Management of Hearing. The hearing officer shall have complete control of the hearing, including:
(1) the responsibility of having a record made of the hearing,
(2) extension of any time allotments,
(3) recognition of speakers,
(4) elimination of repetitious presentations, and
(5) general management of the hearing.
(c) Fair Opportunity to Present Views. The hearing officer shall insure that each person participating in the hearing is given a fair opportunity to present views, data, and comments.

History Note: *Authority G.S. 143B-10(j)(2); 143B-147; 150B-11; 150B-12;*
Eff. February 1, 1976;
Amended Eff. April 1, 1990; January 1, 1987; April 1, 1984;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26A .0106 JUSTIFICATION OF RULE-MAKING DECISION
(a) Any interested person, either prior to adoption of a rule or within 30 days thereafter, who desires a concise statement of the principal reasons for and against the adoption of a rule by the Commission or Division Director and the factors that led to overruling the considerations urged against its adoption may submit a request to: A.P.A. Coordinator, Division of Mental Health, Developmental Disabilities and Substance Abuse Services, 3001 Mail Service Center, Raleigh, North Carolina 27699-3001.
(b) For purposes of this Rule, an "interested person" shall be any person, group, or organization whose rights, duties, or privileges might be affected by the adoption of the rule.
(c) The request shall be made in writing, shall identify the rule or proposed rule involved, and shall contain a statement of the reasons of interest.

History Note: *Authority G.S. 143B-10(j)(2); 143B-147; 150B-11; 150B-12;*
Eff. February 1, 1976;
Amended Eff. January 1, 1987; April 1, 1984;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26A .0107 RECORD OF RULE-MAKING PROCEEDINGS
A record of all rule-making hearings shall be maintained by the office of the Division's A.P.A. coordinator. The record shall be available for public inspection during regular office hours and shall include:
(1) any petitions related to the hearing,
(2) the hearing notice,
(3) all written memoranda and information submitted,
(4) a transcript of the oral hearing,
(5) any statement of reasons issued to an interested person according to Rule .0105 of this Section, and

(6) a final draft of the rule.

The record shall be available for public inspection during regular office hours.

History Note: *Authority G.S. 143B-10(j)(2); 143B-147; 150B-11;*
Eff. February 1, 1976;
Amended Eff. August 1, 1990; April 1, 1990; January 1, 1987; April 1, 1984;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26A .0108 FEES

Except when a statute provides otherwise, the Division may charge a fee to cover the costs of meeting requests for information related to the rule-making hearing including material, duplicating, mailing, and allocable personnel costs.

History Note: *Authority G.S. 143B-147; 150B-11;*
Eff. February 1, 1976;
Amended Eff. April 1, 1984;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .0200 - CONTESTED CASES

10A NCAC 26A .0201 SCOPE

The procedures in this Section shall apply to all contested cases coming under the authority of the Director or the authority of the Commission.

History Note: *Authority G.S. 143B-10; 143B-147; 150B-22;*
Eff. January 1, 1980;
Amended Eff. April 1, 1990
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26A .0202 DEFINITIONS

As used in this Section, the following terms shall have the meaning specified:

(1) "Agency" is the Division of Mental Health, Developmental Disabilities and Substance Abuse Services (DMH/DD/SAS) or the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services.

(2) "Contested case" means any agency proceeding which is an opportunity for an administrative appeal and in which the legal rights, duties or privileges of a party are required by law to be determined. In particular, this includes appeals under the following statutes:
   (a) G.S. 122C-26 (exceptions to standards established by the Commission);
   (b) G.S. 122C-24 (appeal from denial or revocation of a license);
   (c) G.S. 122C-27 (determination of non-compliance with drug abuse standards); and
   (d) G.S. 122C-151.2 (appeal from certain divisional actions).

(3) "Hearing" means a contested case hearing as provided for in G.S. 150B-22 through G.S. 150B-37.

(4) "Hearing officer" is the person appointed by the Director to conduct a hearing in accordance with the provisions of this Section.

History Note: *Authority G.S. 143B-10; 143B-147; 150B-22;*
Eff. January 1, 1980;
Amended Eff. April 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26A .0203 DETERMINATION OF CONTESTED CASE HEARING

(a) Request for Determination.

(1) Persons may at any time request from the Director a determination of their legal rights, privileges, or duties. Requests shall specify whether a hearing is desired.

(2) Requests shall be in writing and shall be made only to the Director whether any hearing resulting from the request comes under the authority of the Director or the Commission.

(b) Determination by Director. If persons request a determination of their legal rights the Director shall promptly take the following actions:

(1) determine that all informal appeal procedures for resolving the issue have been exhausted unless such procedures would cause undue delay;

(2) determine whether the issue can be brought to a contested case hearing in accordance with Rule .0202(2) of this Section;

(3) determine whether the request lies within the purview of the Commission or the Director or should be directed to some other authority; or

(4) appoint a hearing officer.

(c) Notification of Requesting Person. The Director shall notify the person requesting a determination of the actions taken in accordance with (b) of this Rule with the following stipulations:

(1) If the requesting party is instructed to exhaust all informal appeal procedures, those procedures shall be delineated; or

(2) If a hearing is to be scheduled and a hearing officer appointed, the Director's notification shall indicate whether the hearing will be held under the authority of the Director or the Commission.

(d) Notification of Commission. If a hearing is to be scheduled as a result of a request for determination and that hearing falls under the authority of the Commission, the Director shall notify the Commission chairman and provide the name of the hearing officer.

History Note: *Authority G.S. 143B-10; 143B-147; 150B-22;*
Eff. January 1, 1980;
Amended Eff. April 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26A .0204 CROSS-REFERENCE TO DEPARTMENTAL RULES

History Note: *Authority G.S. 143B-10; 143B-147; 150B-22; 150B-34;*
Eff. January 1, 1980;
Amended Eff. April 1, 1990;
Pursuant to G.S. 150B-21.3A, rule expired July 1, 2015.

SECTION .0300 - DECLARATORY RULINGS

10A NCAC 26A .0301 SCOPE

The procedures in this Section shall apply to all requests for and issuance of declaratory rulings, whether arising under the authority of the Director or of the Commission.

History Note: *Authority G.S. 143B-10; 143B-147; 150B-17;*
Eff. January 1, 1980;
Amended Eff. April 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26A .0302 DEFINITIONS

(a) "Declaratory ruling" means a formal and binding interpretation as specified in G.S. 150B-4.

(b) "Petitioner" as used in this Section means the person requesting a declaratory ruling from the agency.

History Note: *Authority G.S. 143B-10; 143B-147; 150B-17;*
Eff. January 1, 1980;
Amended Eff. April 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26A .0303 AUTHORITY TO MAKE DECLARATORY RULINGS

The Director shall have the power to make all declaratory rulings, whether arising under the authority of the Director or of the Commission.

History Note: *Authority G.S. 143B-10; 143B-147; 150B-17;*

Eff. January 1, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26A .0304 PROCEDURES FOR REQUESTING DECLARATORY RULINGS

(a) All requests for declaratory rulings shall be by written petition and shall be submitted to: The Director, Division of Division of Mental Health, Developmental Disabilities and Substance Abuse Services, 3001 Mail Service Center, NC 27699-3001.

(b) All requests for a declaratory ruling shall include the following information:

(1) the name and address of the petitioner;
(2) the statute or rule to which the petition relates;
(3) a concise statement of the manner in which the petitioner is aggrieved by the rule or statute or its potential application to the petitioner; and
(4) the consequences of a failure to issue a declaratory ruling.

History Note: *Authority G.S. 143B-10; 143B-147; 150B-17;*
Eff. January 1, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26A .0305 ACTION ON REQUEST FOR DECLARATORY RULING

(a) Whenever the Director has good cause to believe that issuing a declaratory ruling is undesirable, the Director may decline to issue one. In such cases, the Director shall notify the petitioner in writing of the decision stating the reason for the denial of a declaratory ruling.

(b) The Director may decline to issue a declaratory ruling in the following specific circumstances:

(1) if the request for a declaratory ruling addresses a situation or fact similar to those specifically considered at the rule-making hearing and is found in the rule-making record;
(2) if the petitioner cannot show that the circumstances are so changed since adoption of the rule that such a ruling would be warranted; or
(3) if the circumstances stated in the request indicate that there is a factual dispute and a contested case hearing would be more appropriate.

(c) When issuing a declaratory ruling is deemed appropriate, the Director shall issue the ruling within 60 days of the receipt of the petition.

History Note: *Authority G.S. 143B-10; 143B-147; 150B-17;*
Eff. January 1, 1980;
Amended Eff. April 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26A .0306 PROCEDURES FOR ISSUING DECLARATORY RULINGS

(a) The declaratory ruling process may consist of written submissions, oral hearings or such other procedures as may be deemed appropriate by the Director in the particular case.

(b) The Director, at his discretion, may notify persons who might be affected by the declaratory ruling that they may submit written comments or make oral presentations at the scheduled hearing.

History Note: *Authority G.S. 143B-10; 143B-147; 150B-17;*
Eff. January 1, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26A .0307 RECORD OF DECLARATORY RULING PROCEEDINGS

A record of all declaratory ruling proceedings shall be maintained by the Division's publications officer and shall be available for public inspection during regular business hours. This record shall contain:

(1) the original request;
(2) all written memoranda and information submitted;
(3) any recording or transcript if an oral hearing is held; and
(4) a statement of the ruling or the reasons for refusing to issue a ruling.

History Note: *Authority G.S. 143B-10; 143B-147; 150B-17;*

Eff. January 1, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26A .0308 NOTIFICATION OF COMMISSION
The Director shall provide to the Commission Chairman a copy of all declaratory rulings issued.

History Note: *Authority G.S. 143B-10; 143B-147; 150B-17;*
Eff. January 1, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SUBCHAPTER 26B – CONFIDENTIALITY RULES

SECTION .0100 – GENERAL RULES

10A NCAC 26B .0101 PURPOSE AND SCOPE
(a) The purpose of the rules in this Subchapter is to set forth requirements for those who collect, store and disseminate information on individuals who are served by facilities, as defined in G.S. 122C-3. The rules shall be used in conjunction with the confidentiality requirements specified in G.S. 122C-51 through 122C-56. Area and State facilities shall comply with all Rules in this Subchapter; however, facilities, as defined in G.S. 122C-3, except Area and State facilities, shall comply only with Rules .0103(b)(7) and .0111 of this Subchapter.
(b) Area and State facilities governed by these Rules include offices of the Division; regional psychiatric hospitals, mental retardation centers and alcohol and drug abuse treatment centers; State special care centers; schools for emotionally disturbed children; area programs and their contract agencies; and other public and private agencies, institutions or programs which are operated by or contract with the Division for Mental Health, Developmental Disabilities or Substance Abuse Services. All employees, students, volunteers or other individuals who have access to or control over confidential information in these facilities or programs shall abide by these Rules. However, local hospitals that are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) which contract with an area facility or provide services for a State facility shall be excluded from these Rules and the confidentiality policies of that accredited hospital shall apply. In addition, education records generated by Alcohol and Drug Education Traffic Schools (ADETS) and Drug Education Schools (DES) are excluded from these Rules since the records maintained by such schools are considered public records.

History Note: *Authority G.S. 122C-52; 122C-55; 131E-67; 143B-147;*
Eff. July 1, 1979;
Amended Eff. November 2, 1992; February 1, 1991; February 1, 1986; July 15, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015;
Amended Eff. September 1, 2021.

10A NCAC 26B .0102 GENERAL PROVISIONS
(a) Area or state facilities or individuals with access to or control over confidential information shall take affirmative measures to safeguard such information.
(b) Confidential information may not be released or disclosed except in accordance with G.S. 122C-51 through 122C-56 and the rules in this Subchapter.
(c) Confidential information regarding substance abusers shall be released or disclosed in accordance with the federal regulations 42 C.F.R. Part 2, "Confidentiality of Alcohol and Drug Abuse Patient Records", which are adopted by reference pursuant to G.S. 150B-14(c), unless the rules in this Subchapter are more restrictive in which case the rules in this Subchapter shall be followed.
(d) Confidential information regarding infants and toddlers receiving early intervention services who have or who are at risk for atypical development, developmental delay or developmental disability shall be released or disclosed in accordance with the federal regulations 34 C.F.R. Part 300, Subpart E, Sections 300.560 through 300.575, which are adopted by reference pursuant to G.S. 150B-14(c), unless the rules in this Subchapter are more restrictive in which case the rules in this Subchapter shall be followed.
(e) Questions regarding interpretation of these Rules shall be directed to the Client Records Consultant in the Institution Management Support Section of the Division.

History Note: *Authority G.S. 122C-52; 131E-67; 143B-147; 150B-14;*
Eff. July 1, 1979;
Amended Eff. February 1, 1991; March 1, 1990; February 1, 1986; January 1, 1984;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0103 DEFINITIONS

(a) The following terms shall have the meanings specified in G.S. 122C-3, 122C-4 and 122C-53:

(1) "Area board",
(2) "Area facility",
(3) "Confidential information",
(4) "Guardian",
(5) "Internal client advocate",
(6) "Legally responsible person",
(7) "Next of kin",
(8) "Provider of support services",
(9) "Secretary", and
(10) "State facility".

(b) As used in this Subchapter, unless the context clearly requires otherwise, the following terms have the meanings specified:

(1) "Client Record" means any documentation made of confidential information. For the purpose of the rules in this Subchapter, this also includes confidential information generated on an individual who was not admitted but received a service from an area or state facility.
(2) "Clinical Staff Member" means a mental health, developmental disabilities or substance abuse professional who provides active treatment/habilitation to a client.
(3) "Confidential information" as defined in G.S. 122C-3 includes but is not limited to photographs, videotapes, audiotapes, client records, reimbursement records, verbal information relative to clients served, client information stored in automated files, and clinical staff member client files.
(4) "Delegated Employee" means anyone designated by the facility head to carry out the responsibilities established by the rules in this Subchapter.
(5) "Disclosure of Information" means the dissemination of confidential information without consent.
(6) "Division" means Division of Mental Health, Developmental Disabilities and Substance Abuse Services.
(7) "Legitimate role in the therapeutic services offered" means next of kin or other family member who, in the judgment of the responsible professional as defined in G.S. 122C-3, and after considering the opinion of the client, currently provides, or within the past 12 months preceding the current hospitalization, provided substantial time or resources in the care of the client.
(8) "Minor Client" means a person under 18 years of age who has not been married or who has not been emancipated by a decree issued by a court of competent jurisdiction or is not a member of the armed forces.
(9) "Parent" means the biological or adoptive mother or father of a minor. Whenever "parents" are legally separated or divorced or have never been married, the "parent" legally responsible for the minor shall be the "parent" granted custody or either parent when joint custody has been granted.
(10) "Person Standing in Loco Parentis" means one who has put himself in the place of a lawful parent by assuming the rights and obligations of a parent without formal adoption.
(11) "Release of Information" means the dissemination of confidential information with consent.
(12) "Signature" means signing by affixing one's own signature; or by making one's mark; or impressing some other sign or symbol on the paper by which the signature may be identified.

History Note: *Authority G.S. 122C-3; 122C-4; 122C-52; 122C-55; 131E-67; 143B-147;*
Eff. July 1, 1979;
Amended Eff. November 2, 1992; February 1, 1991; March 1, 1990; February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0104 LIABILITY OF PERSONS WITH ACCESS TO INFORMATION

(a) Individuals employed in area and state facilities and employees governed by the State Personnel Act, G.S. Chapter 126, are subject to suspension, dismissal or disciplinary action for failure to comply with the rules in this Subchapter.

(b) Individuals, other than employees but including students and volunteers, who are agents of the Department of Health and Human Services who have access to confidential information in an area or state facility who fail to comply with the rules in this Subchapter shall be denied access to confidential information by the facility.

History Note: *Authority G.S. 122C-52; 131E-67; 143B-147(a)(6);*
Eff. July 1, 1979;
Amended Eff. March 1, 1990; February 1, 1986; July 15, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0105 OWNERSHIP OF RECORDS

(a) All records, including those which contain confidential information which are generated in connection with the performance of any function of an area or state facility, are the property of the facility.

(b) Original client records may be removed from an area or state facility premises only under the following conditions:

(1) in accordance with a subpoena to produce document or object or other order of the court or when client records are needed for district court hearings held in accordance with Article 5 of Chapter 122C of the N.C. General Statutes;

(2) whenever client records are needed for treatment/habilitation or audit purposes, records may be transported within an area facility or between state facilities;

(3) in situations where the facility determines it is not feasible or practical to copy the client record or portions thereof, client records may be securely transported to a local health care provider, provided the record remains in the custody of a delegated employee;

(4) whenever a client expires at an area or state facility and an autopsy is to be conducted, the client record may be transported to the agency wherein the autopsy will be performed provided the agency complies with Rule .0108 of this Subchapter.

(c) Area facilities shall develop written policies and procedures regarding fees for the reproduction of client records.

(d) Except as otherwise provided in this Rule, state facilities shall charge uniform fees for the reproduction of client records which do not exceed the cost of reproduction, postage and handling. The uniform fee shall be five dollars ($5.00) for up to three pages and fifteen cents ($0.15) for each additional page. State facilities shall not charge for the reproduction of client records in the following types of situations:

(1) professional courtesy when records are requested by physicians, psychologists, hospital or other health care providers;

(2) third party payors when the state facility will derive direct financial benefits;

(3) providers of support services as defined in G.S. 122C-3;

(4) attorneys representing the Attorney General's office and Special Counsel;

(5) other situations determined by the state facility to be for good cause;

(6) when indigent clients request pertinent portions of their client records necessary for the purpose of establishing eligibility for SSI, SSADIB, Medicaid, or other legitimate aid; or

(7) whenever state facilities utilize private photocopy services wherein the photocopy service, rather than the state facility, bills the recipient of the information based on the usual and customary fee established by the copy service.

History Note: *Authority G.S. 122C-52; 122C-54; 122C-224.3; 122C-268; 122C-286; 131E-67; 143B-147;*
Eff. July 1, 1979;
Amended Eff. February 1, 1991; March 1, 1990; February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0106 ALTERATIONS IN THE CLIENT RECORD

A client or a client's legally responsible person may contest the accuracy, completeness or relevancy of information in the client record and may request alteration of such information. Alterations shall be made as follows:

(1) whenever a clinical staff member concurs that such alteration is justified, the area or state facility shall identify the contested portion of the record and allow the insertion of the alteration as an addendum to the contested portion of the client record; however, the original portion of the written record may not be deleted; or

(2) whenever a clinical staff member does not concur that such alteration is justified, the area or state facility shall identify the contested portion of the record and allow a statement relative to the contested portion to be added to the client record which shall be recorded on a separate form and not on the

original portion of the record which is being contested. Such statement shall be made a permanent part of the client's record and shall be released or disclosed along with the contested portion of the record.

History Note: *Authority G.S. 122C-52; 122C-53; 131E-67; 143B-147(a)(6);*
Eff. July 1, 1979;
Amended Eff. March 1, 1990; February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0107 SECURITY OF CONFIDENTIAL INFORMATION

(a) Each area or state facility that maintains records with confidential information shall provide a secure place for the storage of records and shall develop written policies and procedures regarding controlled access to those records.

(b) Each area or state facility shall ensure that only authorized employees or other individuals authorized by the facility director have access to the records.

(c) Each area or state facility director shall ensure that a clinical staff member is present in order to explain and protect the record when a client or a client's legally responsible person comes to the facility to review the client record. A delegated employee shall document such review in the client's record.

(d) Each area or state facility that maintains confidential information in an automated data processing system shall develop written policies and procedures regarding the provision of safeguards to ensure controlled access to such information.

History Note: *Authority G.S. 122C-52; 131E-67; 143B-147(a)(6);*
Eff. July 1, 1979;
Amended Eff. February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0108 ASSURANCE OF CONFIDENTIALITY

(a) The area or state facility director shall make known to all employees, students, volunteers and all other individuals with access to confidential information the provisions of the rules in this Subchapter and G.S. 122C-52 through 122C-56. The facility shall develop written policies and procedures in accordance with the rules of this Subchapter and applicable statutes and provide training to all individuals with access to confidential information.

(b) Such individuals shall indicate an understanding of the requirements governing confidentiality by signing a statement of understanding and compliance. Employees shall sign such statement upon employment and, again, whenever revisions are made in the requirements. Such statement shall contain the following information:

(1) date and signature of the individual and his title;
(2) name of area or state facility;
(3) statement of understanding;
(4) agreement to hold information confidential; and
(5) acknowledgement of civil penalties and disciplinary action for improper release or disclosure.

History Note: *Authority G.S. 122C-52; 131E-67; 143B-147;*
Eff. July 1, 1979;
Amended Eff. March 1, 1990; February 1, 1986; July 15, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0109 REVIEW OF DECISIONS

Clients, clients' legally responsible persons or employees may request a review of any decisions made under the rules in this Subchapter by the area or state facility director, or, if elsewhere within the Division, by the Division director.

History Note: *Authority G.S. 122C-52; 131E-67; 143B-147(a)(6);*
Eff. February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0110 INFORMATION RECEIVED FROM OTHER AGENCIES/INDIVIDUALS

Whenever an area or state facility receives confidential information from another facility, agency or individual, then such information shall be treated as any other confidential information generated by the area or state facility. Release or disclosure of such information shall be governed by the rules of this Subchapter.

History Note: *Authority G.S. 122C-52; 131E-67; 143B-147;*
Eff. February 1, 1986;
Amended Eff. March 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0111 INFORMATION PROVIDED TO FAMILY/OTHERS

Information shall be provided to the next of kin or other family member, who has a legitimate role in the therapeutic services offered, or other person designated by the client or his legally responsible person in accordance with G.S. 122C-55(j) through (l).

History Note: *Authority G.S. 122C-52; 122C-55; 131E-67; 143B-147;*
Eff. November 2, 1992;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .0200 – RELEASE OF CONFIDENTIAL INFORMATION WITH CONSENT

10A NCAC 26B .0201 CONSENT FOR RELEASE

Area or state facility employees may not release any confidential information until a Consent for Release form as described in Rules .0202 and .0203 of this Section has been obtained. Disclosure without authorization shall be in accordance with G.S. 122C-52 through 122C-56 and Section .0300 of this Subchapter.

History Note: *Authority G.S. 122C-52; 122C-53; 131E-67; 143B-147(a)(6);*
Eff. July 1, 1979;
Amended Eff. February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0202 CONSENT FOR RELEASE FORM

(a) When consent for release of information is obtained by an area or state facility covered by the rules in this Subchapter, a Consent for Release form containing the information set out in this Paragraph shall be utilized. The consent form shall contain the following information:

(1) client's name;
(2) name of facility releasing the information;
(3) name of individual or individuals, agency or agencies to whom information is being released;
(4) information to be released;
(5) purpose for the release;
(6) length of time consent is valid;
(7) a statement that the consent is subject to revocation at any time except to the extent that action has been taken in reliance on the consent;
(8) signature of the client or the client's legally responsible person; and
(9) date consent is signed.

(b) Unless revoked sooner by the client or the client's legally responsible person, a consent for release of information shall be valid for a period not to exceed one year except under the following conditions:

(1) a consent to continue established financial benefits shall be considered valid until cessation of benefits; or
(2) a consent for release of information to the Division, Division of Motor Vehicles, the Court and the Department of Correction for information needed in order to reinstate a client's driving privilege shall be considered valid until reinstatement of the client's driving privilege.

(c) A consent for release of information received from an individual or agency not covered by the rules in this Subchapter does not have to be on the form utilized by area or state facilities; however, the receiving area or state facility shall determine that the content of the consent form substantially conforms to the requirements set forth in this Rule.

(d) A clear and legible photocopy of a consent for release of information shall be considered to be as valid as the original.

(e) Confidential information relative to a client with HIV infection, AIDS or AIDS related conditions shall only be released in accordance with G.S. 130A-143. Whenever authorization is required for the release of this information, the

consent shall specify that the information to be released includes information relative to HIV infection, AIDS or AIDS related conditions.

History Note: *Authority G.S. 122C-52; 122C-53; 130A-143; 131E-67; 143B-147;*
Eff. July 1, 1979;
Amended Eff. July 1, 1993; February 1, 1991; March 1, 1990; February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0203 PERSONS WHO MAY SIGN CONSENT FOR RELEASE

The following persons may sign a consent for release of confidential information:

(1) a competent adult client;
(2) the client's legally responsible person;
(3) a minor client under the following conditions:
    (a) pursuant to G.S. 90-21.5 when seeking services for veneral disease and other diseases reportable under G.S. 130A-135, pregnancy, abuse of controlled substances or alcohol, or emotional disturbances;
    (b) when married or divorced;
    (c) when emancipated by a decree issued by a court of competent jurisdiction;
    (d) when a member of the armed forces; or
(4) personal representative of a deceased client if the estate is being settled or next of kin of a deceased client if the estate is not being settled.

History Note: *Authority G.S. 28A-13.3; 90-21.5; 122C-52; 122C-53; 131E-67; 143B-147;*
Eff. July 1, 1979;
Amended Eff. January 1, 1996; January 1, 1994; March 1, 1990; February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0204 VERIFICATION OF AUTHORIZATION IN CASES OF DOUBT

Whenever the validity of an authorization is in question, an area or state facility employee shall contact the client or the client's legally responsible person to confirm that the consent is valid. Such determination of validity of the consent shall be documented in the client record.

History Note: *Authority G.S. 122C-52; 122C-53; 131E-67; 143B-147(a)(6);*
Eff. July 1, 1979;
Amended Eff. February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0205 INFORMED CONSENT

Prior to obtaining a consent for release of confidential information, a delegated employee shall inform the client or his legally responsible person that the provision of services is not contingent upon such consent and of the need for such release. The client or legally responsible person shall give consent voluntarily.

History Note: *Authority G.S. 122C-52; 122C-53; 131E-67; 143B-147(a)(6);*
Eff. July 1, 1979;
Amended Eff. February 1, 1986; July 15, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0206 PERSONS DESIGNATED TO RELEASE CONFIDENTIAL INFORMATION

The area or state facility director shall be responsible for the release of confidential information but may delegate the authority for release to other persons under his supervision. The delegation shall be in writing.

History Note: *Authority G.S. 122C-52; 131E-67; 143B-147;*
Eff. July 1, 1979;
Amended Eff. March 1, 1990; February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0207 DOCUMENTATION OF RELEASE

Whenever confidential information is released with consent, a delegated employee shall ensure that the release is placed in the client record.

History Note: *Authority G.S. 122C-52; 122C-53; 131E-67; 143B-147(a)(6);*
Eff. July 1, 1979;
Amended Eff. January 1, 2005; February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0208 PROHIBITION AGAINST REDISCLOSURE

(a) Area or state facilities releasing confidential information shall inform the recipient that redisclosure of such information is prohibited without client consent.

(b) A stamp may be used to fulfill this requirement.

History Note: *Authority G.S. 122C-52; 131E-67; 143B-147(a)(6);*
Eff. July 1, 1979;
Amended Eff. February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0209 RELEASE TO HUMAN RIGHTS COMMITTEE MEMBERS

(a) Human Rights Committee members may have access to confidential information only upon written consent of the client or the client's legally responsible person.

(b) A delegated employee shall release confidential information upon written consent to Human Rights Committee members only when such members are engaged in fulfilling their function as set forth in 10A NCAC 28A .0207, and when involved in or being consulted in connection with the training or treatment of the client.

History Note: *Authority G.S. 122C-52; 122C-53; 122C-64; 131E-67; 143B-147(a)(6);*
Eff. July 15, 1980;
Amended Eff. February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0210 RELEASE TO AREA BOARD MEMBERS

Area board members may have access to confidential information only upon written consent of the client or the client's legally responsible person or pursuant to other exceptions to confidentiality as specified in G.S. 122C-53 through 122C-55. Area board members may have access to non-identifying client information.

History Note: *Authority G.S. 122C-52; 122C-53; 131E-67; 143B-147;*
Eff. February 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0211 RELEASE OF INFORMATION BY INTERNAL CLIENT ADVOCATES

Upon request by the Secretary, internal client advocates may disclose to the Secretary or his designee confidential information obtained while fulfilling monitoring and advocacy functions.

History Note: *Authority G.S. 122C-53; 131E-67; 143B-147;*
Eff. February 1, 1991;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .0300 – DISCLOSURE OF CONFIDENTIAL INFORMATION WITHOUT CONSENT

10A NCAC 26B .0301 NOTICE TO CLIENT

(a) Each area or state facility that maintains confidential information shall give written notice to the client or the legally responsible person at the time of admission that disclosure may be made of pertinent information without his expressed consent in accordance with G.S. 122C-52 through 122C-56. This notice shall be explained to the client or legally responsible person as soon as possible.

(b) The giving of notice to the client or legally responsible person shall be documented in the client record.

History Note: *Authority G.S. 122C-52; 131E-67; 143B-147;*
Eff. July 1, 1979;
Amended Eff. March 1, 1990; February 1, 1986; July 15, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0302 PERSONS DESIGNATED TO DISCLOSE CONFIDENTIAL INFORMATION
The area or state facility director shall be responsible for the disclosure of confidential information but may delegate the authority for disclosure to other persons under his supervision. Such delegation shall be in writing.

History Note: *Authority G.S. 122C-52; 131E-67; 143B-147;*
Eff. July 1, 1979;
Amended Eff. March 1, 1990; February 1, 1986; July 15, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26B .0303 DOCUMENTATION OF DISCLOSURE

History Note: *Authority G.S. 122C-52; 122C-55; 131E-67; 143B-147;*
Eff. July 1, 1979;
Amended Eff. March 1, 1990; February 1, 1986; July 15, 1980;
Repealed Eff. January 1, 2005.

10A NCAC 26B .0304 PROHIBITION AGAINST REDISCLOSURE
(a) Agencies disclosing confidential information pursuant to G.S. 122C-52 through G.S. 122C-56 shall inform the recipient that redisclosure of such information is prohibited without client consent.
(b) A stamp may be used to fulfill this requirement.

History Note: *Authority G.S. 122C-52; 131E-67; 143B-147(a)(6);*
Eff. January 1, 1984;
Amended Eff. February 1, 1986;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SUBCHAPTER 26C – OTHER GENERAL RULES

SECTION .0100 – DESIGNATION OF FACILITIES FOR THE CUSTODY AND TREATMENT OF INVOLUNTARY CLIENTS

10A NCAC 26C .0101 SCOPE
(a) The purpose of this Section is to establish procedures by which 24-hour facilities may be designated as facilities for the custody and treatment of involuntary clients, pursuant to G.S. 122C-252.
(b) This Section applies to all those state facilities, 24-hour facilities licensed under Chapter 122C of the General Statutes of North Carolina, and hospitals licensed under Chapter 131E of the General Statutes of North Carolina that wish to provide custody and treatment of those individuals involuntarily committed under Article 5, Parts 7 and 8 of Chapter 122C of the General Statutes.
(c) Facilities that are licensed in accordance with G.S. 122C requirements in the following categories may request a designation to care for and treat individuals under petitions of involuntary commitment:

(1) 10A NCAC 27G .3100 Nonhospital Medical Detoxification for Individuals who are Substance Abusers;
(2) 10A NCAC 27G .5000 Facility Based Crisis for Individuals of all Disability Groups; and
(3) 10A NCAC 27G .6000 Inpatient Hospital Treatment for Individuals who have Mental Illness or Substance Abuse Disorders.

(d) Clients affected include those persons who are mentally ill, individuals with mental retardation or developmental disabilities and accompanying behavior disorders, and substance abusers as defined in G.S. 122C-3 who require custody and treatment before a district court hearing or after commitment.

(e) Facilities designated as facilities for the custody and treatment of involuntary clients shall have adequate staffing and provide supervision to ensure the protection of the individual and the general public.

History Note: *Authority G.S. 122C-252;*
Temporary Rule Eff. January 1, 1986, for a Period of 32 Days to Expire on February 1, 1986;
Eff. February 1, 1986;
Amended Eff. March 1, 2009;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

10A NCAC 26C .0102 REQUEST FOR DESIGNATION

(a) A request for designation shall be made to the Division of Mental Health, Developmental Disabilities and Substance Abuse Services (DMH/DD/SAS).

(b) Each request shall include the following:

(1) name and address of applicant;
(2) type of facility to be designated and type of service for which designation is requested;
(3) staffing levels of the facility;
(4) location of the facility;
(5) name of the administrator;
(6) status of license; and
(7) name and principal business address of holder of license.

History Note: *Authority G.S. 122C-252;*
Temporary Rule Eff. January 1, 1986, for a Period of 32 Days to Expire on February 1, 1986;
Eff. February 1, 1986;
Amended Eff. March 1, 2009;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

10A NCAC 26C .0103 REVIEW PROCESS

(a) Upon receipt of the request, the DMH/DD/SAS shall review the following regarding the facility prior to granting designation:

(1) status of licensure by the Division of Health Service Regulation;
(2) status of accreditation by an accrediting body, such as the Council on Accreditation, the Council on Quality and Leadership, the Council on Accreditation of Rehabilitation Facilities, or The Joint Commission, and review of the most recent survey report;
(3) adequacy of treatment program provided clients;
(4) consistency of staff coverage with proposed services;
(5) existence and adequacy of staff capability to manage the more dangerous and violent involuntary client as well as procedures for transfer to a more secure facility, where applicable;
(6) existence and adequacy of security procedures, including elopement and suicide prevention procedures;
(7) existence and adequacy of seclusion and restraint capabilities, policies and procedures;
(8) adequacy of staff training as to North Carolina laws pertaining to the involuntary committed client; and
(9) existence and adequacy of clients' rights policies and procedures.

(b) The facility shall make information specified in Paragraph (a) of this Rule available to the DMH/DD/SAS and such other information relevant to the request process as the DMH/DD/SAS shall request.

History Note: *Authority G.S. 122C-252;*
Temporary Rule Eff. January 1, 1986, for a Period of 32 Days to Expire on February 1, 1986;
Eff. February 1, 1986;
Amended Eff. March 1, 2009; April 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

10A NCAC 26C .0104 DESIGNATION

(a) The DMH/DD/SAS shall designate as facilities for the custody and treatment of involuntary clients those facilities that demonstrate both treatment capability and the capability to assure the safety of the client and the general public.

(b) The DMH/DD/SAS shall notify the facility in writing of its designation status.

(c) The DMH/DD/SAS shall notify the Clerks of Superior Court in that region of those facilities designated with copies to be sent to the local management entities. For purposes of this Rule, local management entity shall have the same definition as set forth in G.S. 122C-3(20b).
(d) A list of designated facilities may be obtained from the DMH/DD/SAS at a cost to cover printing and postage or may be downloaded from the DMH/DD/SAS website at http://www.dhhs.state.nc.us/ivc.
(e) A facility granted designation shall notify the DMH/DD/SAS of any changes in operation concerning any of the information submitted with the original request within seven calendar days of the change.
(f) Designation may be terminated by the DMH/DD/SAS upon finding that the facility no longer meets the qualifications for designation and is no longer able to provide treatment.

History Note: *Authority G.S. 122C-252;*
Temporary Rule Eff. January 1, 1986, for a Period of 32 Days to Expire on February 1, 1986;
Eff. February 1, 1986;
Amended Eff. March 1, 2009;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

10A NCAC 26C .0105 APPEAL
Any facility denied designation or whose designation has been terminated under this Section may appeal pursuant to the contested case process set forth in G.S. 150B, Article 3.

History Note: *Authority G.S. 122C-252; 150B-23;*
Temporary Rule Eff. January 1, 1986, for a Period of 32 Days to Expire on February 1, 1986;
Eff. February 1, 1986;
Amended Eff. March 1, 2009; April 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

SECTION .0200 - RESEARCH

10A NCAC 26C .0201 MONITORING OF RESEARCH
All research carried out in any of the Division of mental health's facilities, or in connection with its program, shall be closely monitored for quality, the interest of clients' rights and welfare, confidentiality and optimal treatment.

History Note: *Authority G.S. 143B-147;*
Eff. February 1, 1976;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

10A NCAC 26C .0202 PROTOCOL
Before any investigation is launched involving the Division's clients, their records, or a mental health program's records, a written protocol of the planned study shall be submitted to the chief executive offices of the institution or area program. The protocol shall contain the following:

(1) identification of project and investigator;
(2) abstract, containing a short description;
(3) statement of objectives and rationale;
(4) description of methodology, including projected number of people and time involved;
(5) measures taken to protect subjects' interests, including, if necessary, informed consent;
(6) statement of interests of involved mental health programs; and
(7) plans for dissemination and disposition of findings.

History Note: *Authority G.S. 143B-147;*
Eff. February 1, 1976;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

10A NCAC 26C .0203 ADVICE OF RESEARCH COMMITTEE
The chief executive officer of the institution or area program before approving or rejecting a research project shall seek the advice of a research committee. The Committee may recommend acceptance, acceptance with revision, or rejection.

The recommendation shall carefully weigh the expected gain for future mental health clients against the possible risk for persons involved in the study.

History Note: *Authority G.S. 143B-147;*
Eff. February 1, 1976;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

10A NCAC 26C .0204 RESEARCH COMMITTEE

It shall be the policy of the Division of mental health services to have a sufficient number of research committees all over the state, so that each program has easy access to a committee. Each committee's procedures shall be recorded and written records kept in a specially designated file. The principal investigator and the research committee shall ensure that projects in progress are reviewed at least every three months or whenever a change in method is planned. Each research committee is charged with furthering as well as monitoring any project.

History Note: *Authority G.S. 143B-147;*
Eff. February 1, 1976;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

10A NCAC 26C .0205 YEARLY RESEARCH STATEMENT

The Division of mental health, through its head of research, shall receive once a year from each region a statement of all research projects which have been started, continued or terminated in that region. Each region's efforts shall be supported by a research consultant from the Division's office, who shall also be a member of each research committee in the region. The research consultants shall assist in the formulation of research plans, wherever this may become necessary.

History Note: *Authority G.S. 143B-147;*
Eff. February 1, 1976;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

SECTION .0300 - DEATH REPORTING

10A NCAC 26C .0301 SCOPE

(a) For purposes of this Section, facilities licensed in accordance with G.S. 122C, Article 2, state facilities operating in accordance with G.S. 122C Article 4, Part 5 and inpatient psychiatric units of hospitals licensed under G.S. 131E shall report client deaths to the Division of Health Service Regulation.

(b) Client deaths occurring in facilities not licensed in accordance with G.S. 122C, Article 2 or state facilities operating in accordance with G.S. 122C, Article 4, Part 5 shall be reported to the Division of Mental Health, Developmental Disabilities and Substance Abuse Services.

History Note: *Authority G.S. 122C-26; 122C-131;*
Temporary Adoption Eff. January 1, 2001;
Eff. August 1, 2002;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

10A NCAC 26C .0302 DEFINITIONS

In addition to the definitions contained in G.S. 122C-3 and 10A NCAC 27G .0103, the following definitions shall apply with respect to this Section:

(1) "Accident" means an unexpected, unnatural or irregular event contributing to a client's death and includes, but is not limited to, medication errors, falls, fractures, choking, elopement (escape, run away from or abscond), exposure, poisoning, drowning, burns or thermal injury, electrocution, misuse of equipment, motor vehicle accidents, and natural disasters.
(2) "Immediately" means at once, at or near the present time, without delay.
(3) "Violence" means physical force exerted for the purpose of violating, damaging, abusing or injuring.

History Note: *Authority G.S. 122C-26; 122C-131;*
Temporary Adoption Eff. January 1, 2001;
Eff. August 1, 2002;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

10A NCAC 26C .0303 REPORTING REQUIREMENTS

(a) Upon learning of the death of a client currently receiving services, a facility shall file a report in accordance with G.S. 122C-31 and these Rules. A facility shall be deemed to have learned of a death when any facility staff obtains information that the death occurred.

(b) A written notice containing the information listed under Paragraph (d) of this Rule shall be made immediately for deaths occurring within seven days of physical restraint or seclusion of a client.

(c) A written notice containing the information under Paragraph (d) of this Rule shall be made within three days of any death resulting from violence, accident, suicide or homicide.

(d) Written notice may be submitted in person, telefascimile or electronic mail. If the reporting facility does not have the capacity or capability to submit a written notice immediately, the information contained in the notice can be reported by telephone following the same time requirements under Subparagraph (b) and (c) of this Rule until such time the written notice can be submitted. The notice shall include at least the following information:

(1) Reporting facility: name, address, county, license number (if applicable); Medicare/Medicaid provider number (if applicable); facility director and telephone number; name and title of person preparing report; first person to learn of death and first staff to receive report of death; facility telephone number; and date and time report prepared;

(2) Client information: name, client record number, unit/ward (if applicable); Medicare/Medicaid number (if applicable); date of birth, age, height, weight, sex, race, competency, admitting diagnoses, primary or secondary mental illness, developmental disability or substance abuse diagnoses, primary/secondary physical illness/conditions diagnosed prior to death, date(s) of last two medical examinations (if known), date of most recent admission to a state-operated psychiatric, developmental disability or substance abuse facility (if known); and date of most recent admission to an acute care hospital for physical illness (if known);

(3) Circumstances of death: place and address where decedent died; date and time death was discovered; physical location decedent was found, cause of death (if known), whether or not decedent was restrained at the time of death or within seven days of death and if so, a description of the type of restraint and its usage; whether or not decedent was in seclusion at the time of death or within seven days of death and if so, a description of the seclusion episode(s); and a description of the events surrounding the death; and

(4) Other information: list of other authorities such as law enforcement or the County Department of Social Services that have been notified, have investigated or are in the process of investigating the death or events related to the death.

(e) The facility shall submit a written report, using a form pursuant to G.S. 122C-31(f). The facility shall provide, fully and accurately, all information sought on the form. If the facility is unable to obtain any information sought on the form, or if any such information is not yet available, the facility shall so explain on the form.

(f) In addition, the facility shall:

(1) notify the division specified in Rule .0301 of this Section, immediately whenever it has reason to believe that information provided may be erroneous, misleading, or otherwise unreliable;

(2) submit to the division specified in Rule .0301 of this Section, immediately after it becomes available, any information required by this Rule that was previously unavailable; and

(3) provide, upon request by the division specified in Rule .0301 of this Section, other information the facility obtains regarding the death, including, but not limited to, death certificates, autopsy reports, and reports by other authorities.

(g) With regard to any client death under circumstances described in G.S. 130A-383, a facility shall notify law enforcement authorities so the medical examiner of the county in which the body is found can be notified. Documentation of such notification shall be maintained by the facility and be made available for review by the division specified in Rule .0301 of this Section, upon request.

(h) In deaths not under the jurisdiction of the medical examiner, the facility shall notify the decedent's next-of-kin, or other individual authorized according to G.S. 130A-398, that an autopsy may be requested as designated in G.S. 130A-389.

(i) If the circumstances surrounding any client death reveal reason to believe that one or more disabled adults at the facility may be abused, neglected or exploited and in need of protective services, the facility shall initiate the procedures outlined in G.S. 108A, Article 6.

(j) If the circumstances surrounding any client death reveal reason to believe that one or more juveniles at the facility may be abused, neglected or exploited and in need of protective services, the facility shall initiate the procedures outlined in G.S. 7B, Article 3.

History Note: *Authority G.S. 122C-26; 122C-131;*
Temporary Adoption Eff. January 1, 2001;
Eff. August 1, 2002;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

SECTION .0400 - MISCELLANEOUS

10A NCAC 26C .0401 LIAISON WITH CITIZEN GROUPS

The Division shall consult and maintain liaison with citizen advocacy groups in the area of mental health services.

History Note: *Authority G.S. 143B-147;*
Eff. February 1, 1976;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

10A NCAC 26C .0402 STANDARDIZED FORMS AND PROCESSES

(a) Pursuant to G.S. 122C-112.1(a)(32) this Rule sets forth the standardized forms and processes to be used by local management entities (LMEs) and providers in support of LME system management functions. LMEs and providers shall use the standardized forms and processes provided by the Secretary for system management functions including:

(1) person-centered plan;
(2) screening/triage/referral interview;
(3) claims processing;
(4) contract;
(5) memorandum of agreement;
(6) quality improvement plan;
(7) strategic plan;
(8) local business plan;
(9) authorization of state funded services;
(10) endorsement of a provider of service; and
(11) letter of support for residential facilities.

(b) All standardized forms and processes shall be implemented on a statewide basis.
(c) No standardized form or process shall require more information than is necessary to comply with state or federal reporting requirements.
(d) A standardized form or process shall not be altered by a LME or provider.
(e) An LME shall not add any additional requirements upon providers that are not included in a standardized process.

History Note: *Authority G.S. 122C-112.1(a)(32); S.L. 2006-142, Section 4(m);*
Eff. May 1, 2008;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

SECTION .0500 – SUMMARY SUSPENSION AND REVOCATION

10A NCAC 26C .0501 SCOPE

This Section sets forth rules governing summary suspension and revocation of authorization to receive public funding for providing mental health, developmental disabilities and substance abuse services.

History Note: *Authority G.S. 122C-112.1; 143B-139.1; 150B-21.1;*
Temporary Adoption Eff. July 1, 2003;
Eff. July 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

10A NCAC 26C .0502 DEFINITIONS

As used in the rules in this Section, the following terms have the meanings specified:

(1) "Authorization to receive public funding for providing services" means approval from the Department to receive funding through one or more of the following mechanisms;
  (a) enrollment of a provider with Medicaid, as defined in 42 C.F.R. 440.90, 42 C.F.R. 440.130(D), and 42 C.F.R. 440.180 and SL 2002-164; or
  (b) compliance with contract or funding requirements for state or federal funds, as defined in 10A NCAC 27A, Sections .0100 through .0200.
(2) "Funding authority" means the state agency that is responsible for administering state or federal funds, or the area authority or county program that is responsible for administering local funds.
(3) "Provider" means any person or entity authorized to provide publicly funded services.
(4) "Services" means publicly funded mental health, developmental disabilities and substance abuse services.
(5) "Statutes or rules" mean the North Carolina General Statutes, North Carolina Administrative Code.
(6) "Substantial failure to comply" means evidence of one or more of the following:
  (a) the provider has not addressed issues that endanger the health, safety or welfare of clients receiving services;
  (b) the provider has been convicted of a crime specified in G.S. 122C-80;
  (c) the provider has not made available and assessable all sources of information necessary to complete the monitoring processes set out in G.S. 122C-112.1;
  (d) the provider has created or altered documents to avoid sanctions;
  (e) the provider has not submitted, revised or implemented a plan of correction in the specified timeframes; or
  (f) the provider has not removed the cause of a summary suspension in the specified timeframes.

History Note: *Authority G.S. 122C-112.1; 143B-139.1; 150B-21.1;*
Temporary Adoption Eff. July 1, 2003;
Eff. July 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

10A NCAC 26C .0503 SUMMARY SUSPENSION

(a) The DMH/DD/SAS shall issue a written order of agency-wide, site-limited or service-specific summary suspension of state or federal mental health, developmental disabilities and substance abuse services funds and shall refer findings concerning licensed providers for investigation by the licensing agency, when it determines that a client's health, safety or welfare is in immediate jeopardy, as defined in 10A NCAC 27G .0602(5). Where funding is authorized by other public sources, the DMH/DD/SAS shall refer its findings to the funding authority and shall refer findings concerning licensed providers for investigation by the licensing agency, when it determines that a client's health, safety or welfare is in immediate jeopardy. The DMH/DD/SAS shall include its findings in the order or referral.

(b) An order of summary suspension shall be effective on the date specified in the order or on the date of the first attempt to deliver notification at the last known address of the provider, whichever is later.

(c) The order shall specify a date by which the provider shall remove the cause for the emergency action and authorization for funding shall resume.

(d) The provider may contest the order by requesting a contested case hearing pursuant to G.S. 150B. Requesting a contested hearing does not stay the order for summary suspension.

History Note: *Authority G.S. 122C-112.1; 143B-139.1; 150B-21.1;*
Temporary Adoption Eff. July 1, 2003;
Eff. July 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

10A NCAC 26C .0504 REVOCATION

(a) The DMH/DD/SAS shall revoke authorization to receive funding to provide services utilizing state or federal mental health, developmental disabilities and substance abuse services funds and make a recommendation to DMA to revoke enrollment for Medicaid, when it finds that there has been substantial failure to comply with statutes or pursuant to Rule .0502(5) of this Section. Where funding is authorized by other public sources, the DMH/DD/SAS shall refer its findings to the funding authority. Regardless of funding authority, the DMH/DD/SAS shall refer findings concerning licensed providers for investigation by the licensing agency when it determines there has been substantial failure to comply with statutes or rules. The DMH/DD/SAS shall include its findings in the revocation order, recommendation or referral.

(b) Before revoking authorization, making a recommendation to the Division of Medical Assistance (DMA) or making a referral to another funding authority or licensing agency, the DMH/DD/SAS shall provide written notice to the provider stating that continued failure to comply with statutes or rules will result in the revocation, recommendation and referral.
(c) The DMH/DD/SAS shall give the provider written notice of the revocation order, the recommendation to DMA or referral of findings to the funding authority or licensing agency, as applicable. The written notice shall include the reasons for the action, and the grievance/appeal process or contested case procedures pursuant to G.S. 150B.
(d) The revocation notice shall be effective on the date specified in the notice or on the date of the first attempt to deliver notification at the last known address of the provider, whichever is later.
(e) The DMH/DD/SAS shall provide to DMA or other funding authority a written notice of the revocation order and a recommendation to revoke Medicaid enrollment. The DMH/DD/SAS shall also provide a copy of the notice and recommendation to the licensing agency, as applicable.
(f) The provider may contest the order by requesting a contested case hearing pursuant to G.S. 150B. Requesting a contested case hearing does not stay the revocation order.

History Note: *Authority G. S. 122C-112.1; 143B-139.1; 150B-21.1;*
Temporary Adoption Eff. July 1, 2003;
Eff. July 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018.

SECTION .0600 – REMOVAL OF LOCAL MANAGEMENT ENTITY FUNCTIONS

10A NCAC 26C .0601 SCOPE
10A NCAC 26C .0602 DEFINITIONS
10A NCAC 26C .0603 NOTICE OF DEFICIENT PERFORMANCE
10A NCAC 26C .0604 PLAN OF CORRECTION REQUIREMENTS
10A NCAC 26C .0605 FOCUSED TECHNICAL ASSISTANCE
10A NCAC 26C .0606 REMOVAL OF LME FUNCTION

History Note: *Authority G.S. 122C-115.4(f)(3);*
Eff. May 1, 2008;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. May 1, 2018;
Repealed Eff. October 3, 2023 pursuant to G.S. 150B-21.7.

SECTION .0700 – COUNTY DISENGAGEMENT FROM A LOCAL MANAGEMENT ENTITY-MANAGED CARE ORGANIZATION

10A NCAC 26C .0701 SCOPE
10A NCAC 26C .0702 COUNTY REQUEST TO DISENGAGE FROM A LOCAL MANAGEMENT ENTITY-MANAGED CARE ORGANIZATIONSCOPE
10A NCAC 26C .0703 SECRETARY RESPONSE TO COUNTY REQUESTS TO DISENGAGE FROM A LOCAL MANAGEMENT ENTITY-MANAGED CARE ORGANIZATION

History Note: *Authority G.S. 122C-115;*
Eff. February 1, 2017;
Repealed Eff. October 3, 2023 pursuant to G.S. 150B-21.7.

SUBCHAPTER 26D - NORTH CAROLINA DEPARTMENT OF CORRECTION: STANDARDS FOR MENTAL HEALTH AND MENTAL RETARDATION

SECTION .0100 - SCOPE AND DEFINITIONS

10A NCAC 26D .0101 SCOPE

This Subchapter sets forth standards for the delivery of mental health and mental retardation services to inmates in the custody of the Department of Correction. These standards shall apply to such services provided to inmates by the Department or by any other provider of services on a contractual basis.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0102 REQUIRED SERVICES

(a) The Department shall provide or contract for mental health and mental retardation services.

(b) Such services, which address the needs of the client as assessed by a clinician, shall include, but need not be limited to:

(1) emergency;
(2) prevention;
(3) outpatient;
(4) residential; and
(5) inpatient.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0103 DEFINITIONS

For the rules contained in this Subchapter, the following definitions apply:

(1) "Administering medication" means direct application of a medication whether by injection, inhalation, ingestion, or any other means to the client.
(2) "Admission" means acceptance of an inmate for mental health and mental retardation services in accordance with Department procedures.
(3) "Area" means one of the six geographic catchment areas designated by the Department for administrative purposes.
(4) "Area program" means a public agency providing mental health, developmental disabilities and substance abuse services for a catchment area designated by the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services.
(5) "Chief of Mental Health Services" means the individual who is responsible for the development, provision and monitoring of mental health and mental retardation services in the Department's Division of Prisons. His duties include ensuring compliance with statutory and professional standards for services.
(6) "Client" means an inmate who is admitted to and is receiving mental health or mental retardation services.
(7) "Client care evaluation study" means evaluation of the quality of services by measuring actual services against specific criteria through collection of data, identification and justification of variations from criteria, analysis of unjustified variations, corrective action, and follow-up study.
(8) "Client record" means a written account of all mental health and mental retardation services provided to an inmate from the time of acceptance of the inmate as the client until termination of services. This information is documented on standard forms which are filed in a standard order in an identifiable folder.
(9) "Clinician" means a psychiatrist, physician, or psychologist.
(10) "Commission" means the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services, established under Part 4 of Article 3 of G.S. 143B.
(11) "Contract agency" means an entity with which the Department contracts for a service as defined in the standards exclusive of intermittent purchase of service for an individually identified client.
(12) "Department" means the Department of Correction.
(13) "DHR" means the Department of Health and Human Services.
(14) "DHR review team" means the staff delegated by the Department of Health and Human Services to monitor the implementation of standards in accordance with the provisions of G.S. 148-19(d).

(15) "Direct care staff" means staff who provide care, treatment, or habilitation services to the client on a continual and regularly scheduled basis.
(16) "Disability group" means two or more inmates who are either mentally ill or mentally retarded.
(17) "Discharge" means the termination of mental health or mental retardation services to the client.
(18) "Dispensing medication" means issuing for the client one or more unit doses of a medication in a suitable container with appropriate labeling.
(19) "Documentation" means provision of written, dated and authenticated evidence of the delivery of services to the client or compliance with standards.
(20) "Emergency service" means a service which is provided on a 24-hour, non-scheduled basis to inmates for immediate screening and assessment of presenting problems. Crisis intervention and referral to other services are provided as indicated.
(21) "Facility" means the physical area where mental health or mental retardation services are provided, including both buildings and grounds, under the auspices of the Department.
(22) "Habilitation" means education, training, care and specialized therapies undertaken to assist a mentally retarded client in achieving or maintaining progress in developmental skills.
(23) "Habilitation plan" means an individualized, written plan for the client who is mentally retarded which includes measurable, time-specific objectives based on evaluations, observations, and other assessment data. The plan is based on the strengths and needs of the client and identifies specific staff responsibilities for implementation of the plan.
(24) "Health professional" means a staff member trained in the delivery of medical or mental health services.
(25) "Inmate" means an incarcerated individual who remains in the custody of the Department.
(26) "Inpatient service" means a service provided on a 24-hour basis. Client care is provided under the clinical direction of a physician or doctoral level psychologist. The service provides continuous, close supervision for the client with moderate to severe mental health problems.
(27) "Legend drug" means a drug that must be dispensed with a prescription.
(28) Medication" means a substance in the official "United States Pharmacopoeia" or "National Formulary" intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or intended to affect the structure or any function of the body.
(29) "Mental health program director" means the individual who is responsible for the operation of mental health and mental retardation services for inmates.
(30) "Mental illness" means the term as defined in G.S. 122C-3.
(31) "Mental retardation" means the term as defined in G.S. 122C-3.
(32) "Nurse" means a person licensed to practice in the State of North Carolina either as a registered nurse or as a licensed practical nurse.
(33) "Officer in charge" means the correctional officer who has designated responsibility for the custody and safekeeping of inmates in the facility.
(34) "Outpatient service" means a service designed to meet the diagnostic and therapeutic needs of the client residing with the regular inmate population. Individual counseling, psychotherapy, extended testing and evaluation, and medication therapy are provided as needed.
(35) "Peer review" means the formal assessment by professional staff of the quality and efficiency of services ordered or performed by other professional staff.
(36) "Physician" means a medical doctor who is licensed to practice medicine in the State of North Carolina.
(37) "Prevention service" means a service provided to the prison population. Service activities include counseling, information, instruction, and technical assistance with the goals of preventing dysfunction and promoting well being.
(38) "Privileging" means a process by which each staff member's credentials, training and experience are examined and a determination made as to which treatment or habilitation modalities the staff member is qualified to provide.
(39) "Program evaluation" means the systematic documented assessment of program objectives to determine the effectiveness, efficiency, and scope of the system under investigation, to define its strengths and weaknesses and thereby to provide a basis for informed decision-making.
(40) "Protective device" means an intervention that provides support for a medically fragile client or enhances the safety of the client with self-injurious behavior. Such device may include geri-chairs or table top chairs to provide support and safety for the client with a major physical handicap; devices

such as seizure helmets or helmets and mittens for self-injurious behaviors; or a device such as soft ties used to prevent a medically ill client from removing intravenous tubes, indwelling catheters, cardiac monitor electrodes, or similar medical devices.

(41) "Psychiatric nurse" means an individual who is licensed to practice as a registered nurse in the State of North Carolina by the North Carolina Board of Nursing and who is a graduate of an accredited master's level program in psychiatric mental health nursing with two years of nursing experience, or has a master's degree in behavioral science with two years of supervised clinical experience, or has four years of experience in psychiatric mental health nursing.

(42) "Psychiatrist" means a physician who is licensed to practice medicine in the State of North Carolina and who has completed an accredited training program in psychiatry.

(43) "Psychologist" means an individual who is licensed as a practicing psychologist or a psychological associate in the State of North Carolina or one exempt from licensure requirements who meets the supervision requirements of the North Carolina Board of Examiners of Practicing Psychologists as specified in 21 NCAC 54 .2000.

(44) "Psychotherapy" means a form of treatment of mental illness or emotional disorder which is based primarily upon verbal interaction with the client. Treatment is provided by a trained professional for the purpose of removing or modifying existing symptoms, of attenuating or reversing disturbed patterns of behavior, and of promoting positive personality growth and development.

(45) "Psychotropic medication" means medication given with the primary intention of treating mental illness. These medications include, but are not limited to, antipsychotics, antidepressants, minor tranquilizers and lithium.

(46) "Qualified mental health professional" means any one of the following: psychiatrist; psychiatric nurse; psychologist; psychiatric social worker; an individual with a master's degree in a related human service field and two years of supervised clinical experience in mental health services; or an individual with a baccalaureate degree in a related human service field and four years of supervised clinical experience in mental health services.

(47) "Qualified mental retardation professional" means an individual who holds at least a baccalaureate degree in a discipline related to developmental disabilities and who has at least one year of experience in working with mentally retarded clients.

(48) "Qualified professional" means a qualified mental health professional or a qualified mental retardation professional.

(49) "Qualified record manager" means an individual who is a graduate of a curriculum accredited by the Committee on Allied Health Education and Accreditation of the American Medical Association and the Council on Education of the American Health Information Management Association and who is currently registered or accredited by the American Health Information Management Association.

(50) "Quality assurance" means a process for objectively and systematically monitoring and evaluating the quality, appropriateness, and effectiveness of mental health and mental retardation services provided and the degree to which those services meet the identified needs and intended goals for the client.

(51) "Release" means the completion of an inmate's active sentence and return to the community.

(52) "Research" means inquiry involving a trial or special observation made under conditions determined by the investigator to confirm or disprove a hypothesis, or to explicate some principle or effect.

(53) "Residential service" means a service provided in a designated treatment setting where 24-hour supervision is an integral part of the care, treatment, habilitation or rehabilitation provided to the client.

(54) "Responsible clinician" means the psychologist, psychiatrist, or physician designated as responsible for the client's treatment. This may include a clinician designated as on-call for the facility.

(55) "Restraint" means limitation of the client's freedom of movement with the intent of controlling behavior by mechanical devices which include, but are not limited to, cuffs, ankle straps, or sheets. For purposes of these Rules, restraint is a therapeutic modality and does not include protective devices used for medical conditions or to assist a non-ambulatory client to maintain a normative body position, or devices used for security purposes.

(56) "Seclusion" means isolating the client in a separate locked room or a room from which he cannot exit for the purpose of controlling the client's behavior. For purposes of these Rules, seclusion is a therapeutic modality and does not include segregation for administrative purposes.

(57) "Service" means an activity or interaction intended to benefit an individual who is in need of assistance, care, habilitation, intervention, rehabilitation or treatment.

(58) "Service delivery site" means any area, correctional institution, residential unit, or inpatient unit operated by the Department where mental health and mental retardation services are provided.

(59) "Social worker" means an individual who holds a master's degree in social work from an accredited school of social work and has two years of clinical social work experience in a mental health setting or who is a clinical social worker certified by the North Carolina Certification Board for Social Work.

(60) "Standards" means minimum standards for the delivery of mental health and mental retardation services to clients, prescribed by the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services and codified in 10A NCAC 26D .0100 through .1600.

(61) "State facility" means a facility operated by the Division of Mental Health, Developmental Disabilities and Substance Abuse Services and which provides mental health, mental retardation or substance abuse services.

(62) "Support service" means a service provided to enhance the client's progress in his primary treatment or habilitation program.

(63) "Testing services" means the administration and interpretation of the results of standardized instruments for the assessment, diagnosis or evaluation of psychological or developmental disorders.

(64) "Treatment" means the process of providing for the physical, emotional, psychological, and social needs of the client through services.

(65) "Treatment plan" means an individualized, written plan of treatment for a mentally ill client. The plan contains time-specific goals and strategies for implementing the goals, and identifies direct care staff responsible for the provision of treatment services to the client.

(66) "Waiver" means a situation in which the Commission determines that a specific prison site is not required to comply with a specific standard. A waiver is granted according to the provisions of 10A NCAC 27G .0800.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .0200 - ORGANIZATIONAL RESPONSIBILITIES

10A NCAC 26D .0201 COORDINATION AND DELIVERY OF SERVICES

The Department shall develop and implement a plan to ensure coordination in the delivery of all mental health and mental retardation services.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0202 ORGANIZATIONAL CHART

The organizational chart of the Department shall clearly articulate the channels of responsibility in implementing and ensuring the coordination of mental health and mental retardation services.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0203 DISTRIBUTION OF STANDARDS

The Department shall distribute to all service delivery sites adequate copies of the rules of this Subchapter and any subsequent revisions to these Rules as they occur.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0204 COMPLIANCE WITH RULES

(a) The Department shall conduct an annual internal evaluation of compliance with Commission standards in each service delivery site.
(b) The evaluation report shall be made available to the DHHS review team.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0205 GRIEVANCE RULE
The Department shall develop and implement a rule which identifies procedures for review and disposition of grievances regarding mental health and mental retardation services.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .0300 - REQUIRED STAFF

10A NCAC 26D .0301 PSYCHIATRIST
Each service delivery site shall employ, or contract for, the services of a psychiatrist to ensure the client's accessibility to services which require the judgment and expertise of a psychiatrist.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0302 PSYCHOLOGIST
Each service delivery site shall employ, or contract for, the services of a psychologist to ensure the client's accessibility to services which require the judgment and expertise of a psychologist.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0303 REGISTERED NURSE
Each service delivery site shall employ, or contract for, a registered nurse to ensure that the client is given the nursing care that requires the judgment and specialized skills of a registered nurse.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0304 SOCIAL WORKER
Unless exempted by the Chief of Mental Health Services based on size and mission of the facility, each service delivery site shall employ, or contract for, social work staff to ensure the client's accessibility to services which require the knowledge and expertise of a social worker.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0305 SUPPORT STAFF
Each service delivery site shall have support staff to ensure the delivery of mental health and mental retardation services to clients. This includes, but need not be limited to, clerical staff.

History Note: *Authority G.S. 148-19(d);*

Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .0400 - ORGANIZATIONAL RELATIONS

10A NCAC 26D .0401 COORDINATION OF SERVICES

The Department shall develop and implement procedures to facilitate cooperative working relationships between the staff of mental health and mental retardation services, custody personnel, and other service staff to facilitate the provision of services for inmates who are mentally ill or mentally retarded.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0402 INFORMATION AND OUTREACH SERVICES

The Department shall provide, to correctional staff, information designed to promote awareness of mental health and mental retardation services available to inmates within the Department.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0403 AGREEMENT WITH THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Department shall have a written agreement with the Department of Health and Human Services regarding mutual responsibilities for mental health and mental retardation services to inmates under Department supervision.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .0500 - QUALITY ASSURANCE

10A NCAC 26D .0501 SCOPE

(a) Quality assurance shall be a continuing responsibility of the Department and each service delivery site that offers mental health and mental retardation services.
(b) Quality assurance activities shall include, but need not be limited to:
(1) clinical and professional supervision and privileging;
(2) client care evaluation studies;
(3) record review;
(4) utilization and peer review;
(5) employee education and training;
(6) program evaluation; and
(7) evidence of corrective action.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0502 QUALITY ASSURANCE PLAN

(a) The Department shall establish and implement a written quality assurance plan for mental health and mental retardation services that describes how quality assurance activities will be carried out.
(b) Quality assurance activities shall include, but need not be limited to, the following:
(1) an objective and systematic process for monitoring and evaluating the quality and appropriateness of client care, incorporating a review of significant incidents, which may include but need not be limited to, suicides, sudden deaths, and major assaults;

(2) a written plan of professional and clinical supervision describing such activities and how they shall be carried out;
(3) the establishment and implementation of program evaluation activities;
(4) the strategies for improving client care; and
(5) evidence of corrective action.

(c) The plan shall be reviewed annually, and may be revised at any time by the Department.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0503 QUALITY ASSURANCE COMMITTEE

(a) The Department shall have a quality assurance committee which shall be comprised of:
(1) representation from mental health and mental retardation service areas;
(2) a qualified record manager;
(3) a nurse;
(4) a psychologist;
(5) a psychiatrist; and
(6) a social worker.

(b) The purpose, scope and organization of the quality assurance committee shall be specified in the quality assurance plan, which shall include, but need not be limited to the following:
(1) the committee shall meet at least monthly;
(2) a member shall not review his own client's treatment or habilitation record; and
(3) minutes of meetings shall be recorded and shall include, but need not be limited to:
(A) date, time, attendees and absentees; and
(B) a summary of the business which was conducted.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0504 CLIENT CARE EVALUATION STUDIES

The quality assurance committee shall ensure that at least one client care evaluation study of issues, relevant to the improvement of services to clients, is completed during each fiscal year.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0505 CLIENT RECORD REVIEW

The quality assurance committee shall establish, implement and document the criteria, procedure and methodology for client record reviews for completeness and adequacy, as delineated in Section .0700 of these Rules.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0506 SUPERVISION OF MENTAL HEALTH AND MENTAL RETARDATION STAFF

(a) The Department shall implement a written plan of supervision for staff who are not qualified mental health or mental retardation professionals, as defined in Rule .0103 of this Subchapter, and who provide mental health or mental retardation services.

(b) The Department shall ensure that:
(1) each mental health staff member who provides services, and who is not qualified in that service area, shall have an individual contract of supervision with a qualified mental health professional; and
(2) each mental retardation staff member shall be supervised by, or have access to, the professional supervision of a qualified mental retardation professional.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0507 PRIVILEGING OF ALL PROFESSIONAL STAFF

(a) The Department shall ensure that the qualifications of each mental health and mental retardation professional are examined, and a determination is made as to treatment or habilitation privileges granted and supervision needed.

(b) Delineation of privileges shall be based on documented verification of the individual's competence, training, experience and licensure.

(c) The privileging process shall be reviewed and approved by the Department's quality assurance committee.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0508 EMPLOYEE EDUCATION AND TRAINING

(a) The Department shall:

(1) provide or secure orientation programs and annual continuing education and training for employees to enhance their competencies and knowledge needed to administer, manage, and deliver quality mental health and mental retardation services; and

(2) assure the maintenance of an ongoing record of all education and training activities provided or secured for employees.

(b) The education and training activities shall:

(1) address, at a minimum, the needs identified by the quality assurance process and related committees; and

(2) as deemed necessary by the Department, be provided at no expense to staff.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0509 PROGRAM EVALUATION ACTIVITIES

(a) The Department shall implement program evaluation activities.

(b) These activities shall reflect the evaluation of program quality, effectiveness and efficiency in such areas as the:

(1) impact of the program in reducing readmissions;

(2) availability and accessibility of services;

(3) impact of services upon the clients within the service area;

(4) patterns of use of service; and

(5) cost of the program operation.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0510 QUALITY ASSURANCE ANNUAL REPORT

(a) The Department shall make available, to the DHHS review team, a written annual report summarizing the activities and recommendations of the quality assurance committee.

(b) This report shall include, at a minimum, the following functional areas:

(1) client care evaluation studies;

(2) client record reviews;

(3) utilization and peer reviews;

(4) clinical supervision;

(5) employee education and training activities; and

(6) the results of program evaluation.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .0600 - FACILITIES MANAGEMENT

10A NCAC 26D .0601 SCOPE

The rules in this Section apply to each service delivery site within the Department and to any other provider of services on a contractual basis.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0602 BUILDINGS AND GROUNDS

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule expired July 1, 2015.

10A NCAC 26D .0603 SPACE REQUIREMENTS

(a) Space shall be provided to facilitate the delivery of mental health and mental retardation services.
(b) Each client in an inpatient mental health unit shall be housed in a single cell.
(c) Each client in a residential treatment program shall have a minimum of 50 square feet of living space; e.g., if two clients are housed in the living space, the minimum shall be 100 square feet.
(d) Each service delivery site shall have private space for interviews and conferences with clients.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0604 ADDITIONAL REQUIREMENTS FOR RESIDENTIAL/INPATIENT UNITS

(a) Each residential and inpatient unit providing mental health or mental retardation services shall have indoor space for group activities and gatherings.
(b) The space in which therapeutic and habilitative activities are routinely conducted shall be separate from sleeping areas.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .0700 - CLIENT RECORDS

10A NCAC 26D .0701 SCOPE

(a) The rules in this Section apply to each service delivery site and to any other provider of services on a contractual basis, unless otherwise specified in this Section.
(b) This Section applies to the management of client information which is generated by a service delivery site during the period of time that treatment or habilitation services are rendered to clients.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0702 STANDARD CLIENT RECORD

(a) The Department shall develop and maintain a standard client record for each client who receives mental health or mental retardation treatment or habilitation services.

(b) The same forms and filing format shall be utilized within each disability.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0703 RECORD REQUIREMENTS

(a) A written client record shall be maintained for each client, and shall contain, at a minimum, the following identifying information:

(1) name;
(2) record number;
(3) date of birth;
(4) race, sex, and marital status;
(5) admission date; and
(6) discharge date.

(b) Active outpatient client records shall be kept in the outpatient health record and filed at the client's assigned unit.

(c) Each inpatient program shall maintain active inpatient records which shall be kept separate from the outpatient records.

(d) The outpatient record shall be transferred to the inpatient unit.

(e) Information required in other rules in this Subchapter, including but not limited to, prescribing and administering medication, and seclusion and restraint shall be documented in the client record.

(f) All client record entries shall include the date of entry and authentication by the individual making the entry.

(g) The time of service shall be recorded, based upon the nature of the service or incident, such as, shift notes, medication administration, and accidents and injuries.

(h) All client record entries shall be legible and made in permanent ink or typewritten.

(i) Alterations in client records, which are necessary in order to correct recording errors or inaccuracies, shall:

(1) be made by the individual who recorded the entry;
(2) have a single, thin line drawn through the error or inaccurate entry with the original entry still legible;
(3) show the corrected entry legibly recorded above or near the original entry;
(4) show the type of documentation error or inaccuracy whenever the reason for the alteration is unclear; and
(5) include the date of correction and initials of recorder.

(j) Each page of the client record shall include the client's name and number.

(k) Client records shall include only those symbols and abbreviations contained in an abbreviation list approved by the Department.

(l) Notations in a client's record shall not identify another client by name.

(m) Each service delivery site shall designate, in writing, those individuals authorized to have access to client records and who may make entries in the record.

(n) Any additional information regarding the following shall be included in the client record:

(1) diagnostic tests, assessments, evaluation, consultations, referrals, support services or medical services provided;
(2) known allergies or hypersensitivities;
(3) major events, accidents or medical emergencies, involving the client;
(4) consent for, and documentation of, release of information;
(5) documentation of applied behavior modification, which includes at risk or other intrusive interventions, including authorization, duration, summaries of observation and justification;
(6) conferences or involvements with the client's family, significant others, or involved agencies or service providers;
(7) documentation of attendance in outpatient service; and
(8) results of any standardized and non-standardized evaluations, such as social, developmental, medical, psychological, vocational or educational.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0704 CONFIDENTIALITY OF CLIENT RECORD

(a) All information contained in the client record shall be considered privileged and confidential, with the exception of matters of public record, as set forth in 5 NCAC 02D .0600.

(b) The Department shall ensure confidentiality of client records during their use, transportation, and storage.

(c) The Department shall ensure that information contained in client records is released upon the written authorization of the client, in accordance with other Department Rules, or as set forth in the provisions of G.S. 122C-55(c).

(d) Employees governed by the State Personnel Act, G.S. 126, are subject to suspension, dismissal or disciplinary action for failure to comply with the rules in this Subchapter.

(e) The Department shall inform all employees, students, volunteers, and all other individuals with access to confidential information, the provisions of the rules in this Subchapter. Such individuals with access to confidential information shall sign a statement of understanding and compliance.

(f) Records shall be protected against loss, tampering, or use by unauthorized persons.

(g) Records shall be readily accessible to authorized users at all times.

(h) When consent for release of information is obtained, a time-limited consent, not to exceed one year, shall be utilized.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0705 DIAGNOSTIC CODING

The Department shall code diagnoses for clients using the following diagnostic systems:

(1) Mental illness or mental retardation shall be diagnosed according to the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition - Revised (DSM-IV-R).

(2) Physical disorders shall be diagnosed according to Interational Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM).

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0706 CLIENT RECORD AVAILABILITY

The Department shall ensure that client records are available to professional staff for a minimum of three years following the inmate's release. This shall apply to previous incarcerations.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .0800 - SERVICE ELIGIBILITY

10A NCAC 26D .0801 SCOPE

The rules in this Section apply to each service delivery site within the Department and to any other provider of services on a contractual basis.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0802 SERVICE CRITERIA

The Department shall ensure the development of service criteria for mental health and mental retardation services. These criteria shall be communicated to inmates and staff.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0803 SCREENING
The Department shall develop a systematic means of screening each inmate referred for services to determine his need for services, and designate staff qualified to make screening determinations.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0804 WAITING LISTS
The Department shall establish criteria for prioritizing service delivery and use of waiting lists for mental health and mental retardation services.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0805 INFORMATION REGARDING AVAILABILITY TO SERVICES
The Department shall ensure that each inmate is informed how to access mental health and mental retardation services.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .0900 - TREATMENT AND HABILITATION

10A NCAC 26D .0901 SCOPE
(a) The rules in this Section apply to each service delivery site within the Department and to any other provider of services on a contractual basis.
(b) The process of treatment or habilitation shall incorporate activities and procedures that address the client's assets and needs from the point of initial contact, through active treatment or habilitation, and after discharge from treatment.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0902 ADMISSION ASSESSMENT
(a) An admission note shall be completed within 24 hours of admission which includes, but need not be limited to:
(1) reason for admission;
(2) present condition of the client reported in objective, behavioral terms, and when possible, a description of the client's condition by others;
(3) diagnostic impression, including a provisional or admitting diagnosis;
(4) determination of and request for additional referrals or special diagnostic tests, assessments or evaluations, if needed; and
(5) a preliminary individual treatment or habilitation plan.
(b) If clinically indicated, a social, educational, medical, criminal, vocational, developmental, and psychiatric history shall be completed within 30 days after admission.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0903 EVALUATION AND DIAGNOSIS
Each service delivery site shall document, for each client, any routine diagnostic tests, assessments and evaluations, or medical examinations, as well as time frames for their completion.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0904 TREATMENT OR HABILITATION PLAN

(a) Each service delivery site shall develop an individualized treatment or habilitation plan for each client based upon:
- (1) an evaluation of his condition, assets and needs; and
- (2) information gathered during the admission assessment process.

(b) The treatment or habilitation plan shall be documented in the client record as follows and shall:
- (1) provide a systematic approach to the treatment or habilitation of the client;
- (2) substantiate the appropriateness of treatment or habilitation goals;
- (3) designate clinical responsibility for the development and implementation of the plan;
- (4) include at least the diagnosis to ensure consistency;
- (5) include time-specific measurable goals; and
- (6) provide a summary of client, and if appropriate, family strengths and weaknesses.

(c) The plan shall be reviewed at least annually; and when medically or clinically indicated, the plan shall be revised accordingly.

(d) The client shall have the opportunity to participate in the development and implementation of the treatment and habilitation plan.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0905 PROGRESS NOTES

(a) Progress notes shall be recorded at least on a weekly basis in residential and inpatient services and following each scheduled appointment in outpatient services.

(b) Progress notes shall reflect the client's progress or lack of progress:
- (1) in meeting goals;
- (2) in staff interventions;
- (3) regarding information which may have a significant impact on the client's condition; and
- (4) when indicating reviews of relevant laboratory reports and actions taken.

History Note: *Authority G. S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0906 TRANSFER OR DISCHARGE SUMMARY

(a) Whenever a client is transferred to a different level of service, a written transfer note by the referring unit shall accompany the client summarizing the client's condition at the time of transfer, and any recommendations for continued care.

(b) A qualified professional in the receiving unit shall evaluate the client to determine the need for continued treatment or habilitation.

(c) At the time of discharge, a discharge summary shall be completed and shall include:
- (1) the reason for admission;
- (2) course and progress of the client in relation to the goals and strategies in the individual treatment or habilitation plan;
- (3) condition of the client at discharge;
- (4) recommendations and arrangements for further services or treatment; and
- (5) final diagnosis.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0907 TREATMENT AND HABILITATION COORDINATION

(a) Coordination shall be maintained among all staff members contributing to the evaluation, planning, and treatment and habilitation efforts for each client.
(b) Each service delivery site, utilizing shifts or relief staff, shall develop mechanisms to ensure adequate communication among staff regarding clients.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .0908 RELEASE PLANNING IN RESIDENTIAL AND INPATIENT SERVICES
(a) When release of a client can be anticipated and the need for continued treatment has been identified, each client shall have a written individualized aftercare plan.
(b) The aftercare plan shall:
(1) be formulated by qualified professionals;
(2) inform the client of how and where to receive treatment or habilitation services;
(3) identify continuing treatment or habilitation needs; addressing issues, such as food, housing, and employment;
(4) indicate the need and the plan, if applicable, to involuntarily commit (inpatient or outpatient);
(5) involve the respective area program or state facility, when indicated;
(6) address the procurement and availability of medication prescribed for mental health problems for the released client, regardless of his ability to pay;
(7) address the use and coordination of generic resources in the community, which may be through Employment Security Services, Vocational Rehabilitation Services, community colleges, and YMCA; and
(8) be provided to the client.
(c) The Department shall designate a qualified professional to assist the client in establishing contact with the respective area program or state-operated facility.
(d) The designee shall be responsible for providing information to the area program or state-operated facility to ensure continuity of treatment upon the client's release.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .1000 - CLINICAL SERVICES

10A NCAC 26D .1001 SCOPE
(a) The rules in this Section apply to each service delivery site, and to any other provider of services on a contractual basis that incorporates clinical services in their activities.
(b) The provision of clinical services shall be provided by qualified mental health professionals as an essential component of the treatment or habilitation process, to include but not limited to:
(1) individual and group counseling;
(2) psychotherapy services;
(3) testing services; and
(4) specialized therapies of various kinds.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .1002 COUNSELING AND PSYCHOTHERAPY SERVICES
Individual, group and family counseling, and psychotherapy shall be provided by, or under the direct supervision of, qualified professionals who have received training in these treatment or habilitation modalities.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .1003 SPECIALIZED THERAPIES

The following shall be provided by, or under the direct supervision of, staff licensed or registered to perform these activities:

(1) medical care;
(2) physical, occupational, or language and communication therapy; and
(3) nursing care.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .1004 TESTING SERVICES

Individuals, who are privileged to utilize the particular testing instrument being administered, shall perform testing on each client, who is referred by a clinician, in the areas of:

(1) psychology;
(2) development;
(3) education; and
(4) intelligence.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .1100 - MEDICATION SERVICES

10A NCAC 26D .1101 SCOPE

(a) The rules in this Section apply to each service delivery site and to any other provider of services on a contractual basis that provide medication services.

(b) Any client who is placed on medication for problems associated with mental health and mental retardation disabilities and needs shall receive, at least, medication services that include, but need not be limited to:

(1) prescribing;
(2) dispensing;
(3) administration;
(4) storage;
(5) control; and
(6) provision of education.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .1102 DISPENSING OF MEDICATION

(a) Medication shall be dispensed, by a pharmacist or physician, in a properly labeled container in accordance with state and federal law.

(b) The medication container shall protect medication from light and moisture, and shall be in compliance with the Poison Prevention Packaging Act.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .1103 ADMINISTRATION OF MEDICATION

(a) Medication shall be administered in accordance with state and federal law.

(b) Prescription medication shall be administered in service delivery sites only on the order of an authorized prescriber.

(c) Non-prescription medications and standing orders shall be administered only on the written approval of a physician or person authorized to prescribe legend drugs.
(d) Only properly dispensed medication shall be administered.
(e) Medication shall be administered in inpatient psychiatric services only by a physician, physician assistant, or nurse.
(f) In other service delivery sites, medication may be either:
(1) administered by program or correctional staff who have received training by the Department; or
(2) self-administered by any client who has received instructions, from either the program's physician or designee, about:
(A) each medication;
(B) dosage;
(C) time of administration; and
(D) side effects and contraindications.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .1104 INVOLUNTARY ADMINISTRATION OF PSYCHOTROPIC MEDICATION
(a) Psychotropic medication may be administered to any non-consenting client who has a mental illness and is receiving inpatient mental health treatment if any one or more of the following conditions exist:
(1) failure to treat the client's illness or injury would pose an imminent substantial threat of injury or death to the client or those around him; or
(2) there is evidence that the client's condition is worsening and, if not treated, is likely to produce acute exacerbation of a chronic condition that would endanger the safety or life of the client or others; and:
(A) the evidence of substantial and prolonged deterioration is corroborated by medical history; and
(B) the source of the history is documented in the client's record.
(b) Medication refusal shall mean a client has refused to take medication within 30 minutes of the initial offer. A client who accepts medication within 30 minutes of the initial offer shall not be considered to have refused medication.
(c) Medication Refusal:
(1) All incidents of medication refusal shall be:
(A) reported as promptly as possible to the psychiatrist who is treating the client; and
(B) documented on progress notes and the medication chart by staff responsible for administering the medication.
(2) The administering staff shall attempt to determine the reason for refusal by questioning the client and encouraging him to accept the medication. Such shall be documented in the client's record.
(3) A member of the treatment team shall discuss the reasons for refusal directly with the client and attempt to resolve those concerns that are the source of the refusal before a forced medication order is written.
(d) Initial Emergency Situation:
(1) In an initial emergency situation the physician:
(A) may initiate procedures and write an order for administering emergency forced medication for a period not to exceed 72 hours; and
(B) shall document in the client's record the pertinent circumstances and rationale for the psychotropic medication.
(2) Psychotropic medication may be administered if the physician determines that the condition set forth in Paragraph (a) of this Rule exists and:
(A) the medication is a generally accepted treatment for the client's condition;
(B) there is a substantial likelihood that the treatment will effectively reduce the signs and symptoms of the client's illness; and
(C) the proposed medication is the least intrusive of the possible treatments.
In all cases, the medication shall not exceed the dosage expected to accomplish the treatment and the client shall be monitored for adverse reactions and side effects.
(3) Continuation of emergency situation:

(A) If needed, two subsequent emergency periods of 72 hours may be authorized only after the attending psychiatrist has received the written or verbal concurrence from another psychiatrist not currently involved in the client's treatment.

(B) If the client continues to refuse medication after it is determined that psychotropic medication is still warranted, procedures for administering medication in a non-emergency situation shall be implemented.

(e) Non-Emergency Situations:

(1) If a client refuses psychotropic medication in a non-emergency situation, the attending physician shall:

(A) make every effort to determine the cause of the refusal;

(B) inform the client of indications for psychotropic medication, including benefits and risk, and the advantages and disadvantages of alternate courses of treatment; and

(C) request his or her consent.

(2) The treatment team may also assist in efforts to explain the advantages of medication to the client.

(3) The client's record shall contain documentation that efforts have been made to determine the cause of refusal and advantages of medication.

(4) The physician shall initiate a referral to the Involuntary Medication Committee if the client continues to refuse medication. The Committee shall:

(A) determine whether either of the conditions as set forth in Paragraph (a) of this Rule exists before authorizing an involuntary medication order; and

(B) apply the criteria set forth in Subparagraphs (d)(1) and (2) of this Rule in making its determination.

(C) If neither of the conditions set forth in Paragraph (a) of this Rule exists, the client shall not be involuntarily medicated.

(f) Involuntary Medication Committee:

(1) The members of the Involuntary Medication Committee shall be appointed by the Chief of Psychiatry and shall consist of a psychiatrist, a psychologist, and a mental health nurse who is a Registered Nurse.

(A) If the psychiatrist who issued the involuntary medication order is the individual who normally sits on the committee, another psychiatrist shall serve in that capacity.

(B) Other prison staff who have pertinent information that may be useful to the committee in making its determination shall be required by the committee to attend the hearing.

(2) In conducting the hearing, the committee chairman, appointed by the Chief of Psychiatry, shall ensure that the client:

(A) has received written and verbal notice of the time, date, place, and purpose of the hearing;

(B) is informed of his or her right to hear evidence providing the basis for the involuntary medication, the right to call witnesses on his or her behalf; and the right to request that the Client Representative attend the hearing as set forth in Subparagraph (g)(2) of this Rule;

(C) attends the hearing unless his or her clinical condition is such that his or her attendance is not feasible. In this case, the Committee shall:

(i) state the reasons for determining that the presence of the client is not feasible;

(ii) allow the client to be interviewed in his or her room by the client representative and one or more members of the Committee; and

(iii) allow the client representative an opportunity to present facts relevant to whether an involuntary medication order should be issued;

(D) shall be allowed a reasonable number of witnesses, to be determined by the committee chairman, or:

(i) written statements may be considered in lieu of direct testimony; and

(ii) specific client witnesses may be excluded from direct testimony if the unit superintendent or designee determines a justifiable security risk would occur if they were brought to the hearing site; and

(E) be given the opportunity to question any staff who present evidence that supports the need to involuntarily medicate.

(3) After the committee has received all relevant information, the committee shall:

(A) consider the facts and arrive at a majority decision;

(B) ensure that the authorization to involuntarily medicate shall not exceed 30 days;

(C) prepare and file in the client's record a written summary of the evidence presented and the rationale for the decision; and

(D) consult an attorney from the Attorney General's Office, assigned to represent the Department, concerning the legal propriety of forcibly administering medication in a given case.

(4) If, after the initial 30 day period, involuntary medication is still deemed necessary, the psychiatrist may again present the case to the Involuntary Medication Committee, which:

(A) shall conduct a review of the record and the reasons presented in support of continuing involuntary medication; and

(B) may then authorize the administration of involuntary medication for 90 additional days. Subsequent 90-day periods may be authorized only after similar reviews.

(g) Client Representative:

(1) If a client is recommended for forced medication on a non-emergency basis, the Chief of Psychiatry or his or her designee shall appoint a member of the treatment staff to serve as a Client Representative, whose role shall include:

(A) assisting the client in verbalizing the reasons for his or her refusal of psychotropic medications in meetings with his or her treatment team;

(B) providing this information to the Involuntary Medication Committee; and

(C) preparing a summary of the reasons for the refusal and documenting it in the client's record.

(2) The Client Representative shall appear before the Involuntary Medication Committee whenever he feels that it is in the best interest of the client or at the client's request.

(3) When reviewing a case involving the involuntary administration of medication, the Involuntary Medication Committee shall consider oral or written comments from the Client Representative.

(h) If physical force is actually employed, documentation of all actions relating to the forceful administration of medication shall be included in the client's record and reported to the Unit Superintendent on a "Use of Force Report" (DC-422).

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Readopted Eff. March 1, 2019.

10A NCAC 26D .1105 PSYCHOTROPIC MEDICATION EDUCATION

(a) To ensure the client's understanding of psychotropic medication, individual or group medication education shall be provided to each client:

(1) who is to begin receiving, or is to be maintained on, psychotropic medication; and

(2) by the prescribing physician or other person approved by the physician;

(b) Medical education that has been provided to a client shall be documented in the client's record.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Readopted Eff. March 1, 2019.

SECTION .1200 - PROTECTIONS REGARDING CERTAIN PROCEDURES

10A NCAC 26D .1201 SCOPE

The rules in this Section specify protections regarding the use of certain specified procedures, in order to promote dignity and humane care for any client receiving mental health and mental retardation services.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .1202 USE OF SECLUSION

(a) Seclusion shall be used only under one of the following conditions:

(1) on an emergency basis when it is necessary to prevent immediate harm to the client or to others; or

(2) on a non-emergency basis if that seclusion will resolve the precipitating crisis.

(b) Emergency seclusion shall last no longer than is necessary to control the client.

(c) Seclusion shall not exceed seven days without the review and approval of an internal committee in accordance with Paragraph (e) of this Rule.

(d) Observations or reviews of any client in seclusion shall be made as follows:

(1) any client placed in seclusion shall be observed no less frequently than every 30 minutes;

(2) a clinician may extend this interval up to 60 minutes if such an observation would not affect the health, safety, or welfare of the client;

(3) documentation for extending the observation shall be placed in the client's record;

(4) observations by a clinician shall be made at least daily or, if the clinician is not present at the facility, observations by a health professional shall be reported by telephone to a clinician; and

(5) reviews by an internal committee shall be made in accordance with Paragraph (e) of this Rule.

(e) Committee review:

(1) If it appears that seclusion may be indicated for a period to exceed seven days:

(A) an internal committee consisting of a clinician, a nurse or member of the medical staff, and a member of the administrative staff shall review the use of seclusion and interview the client; and

(B) continued use shall not exceed the initial 7 days without the approval of this committee.

(2) Following its initial review, the committee shall review the case at intervals not to exceed 30 days.

(f) If a client is placed in seclusion, his or her client record shall contain the following documentation:

(1) the rationale and authorization for the use of seclusion, including placement in seclusion pending review by the responsible clinician;

(2) a record of the observation of the client as required in Subparagraph (d)(1) of this Rule;

(3) each review by the responsible clinician as required in Subparagraph (d)(4) of this Rule, including a description of the client's behavior and all significant changes that may have occurred; and

(4) each review by the internal committee as required in Paragraph (e) of this Rule.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Readopted Eff. March 1, 2019.

10A NCAC 26D .1203 USE OF RESTRAINT

(a) Restraint shall be used only under the following circumstances:

(1) after less restrictive measures, such as counseling and seclusion, have been attempted or if clinically determined to be inappropriate or inadequate to avoid injury to self or others; and

(2) either:

(A) upon the order of a clinician to control a client who has attempted, threatened, or accomplished harm to himself or others; or

(B) upon the authorization of the officer-in-charge on an emergency basis if believed necessary to prevent immediate harm to the client or to others.

(3) In determining if restraint is indicated, a clinician shall consider whether the client:

(A) has inflicted an injury to himself or to others and, if so, the nature and extent of such injury; or

(B) threatens, through words or gestures, to inflict injury to himself or others and the nature of the threat.

(b) When a client exhibits behavior indicating the use of restraints and under the conditions of Paragraph (a) of this Rule, the following procedures shall be followed:

(1) If, in the judgment of any staff member, immediate restraint is necessary to protect the client or others, the client shall be referred immediately to a clinician for observation and treatment.

(2) If there is insufficient time to make the referral or if a clinician is not immediately available:

(A) the staff in charge may employ emergency use of restraint;

(B) the client shall be reviewed within four hours of the initial restraint, and a restraint may be ordered by a clinician pursuant to Paragraph (a) of this Rule. This may be accomplished by:

(i) telephone contact between the senior health professional at the facility and the clinician; and

(ii) if such review cannot be obtained, the client shall be released from restraint.

(C) a restraint order shall not exceed four hours. At the expiration of the restraint order, the client shall be released from restraint unless a new order is issued; and

(D) a subsequent order for continuing restraint shall be based on:

(i) the client's present condition and behavior; and

(ii) reasons other than the original reasons for restraint, unless the order indicates the original reasons are considered applicable at the time of the subsequent order.

(c) If the client is restrained and subject to injury by another client, a professional staff member shall remain continuously present with the client. Observations and interventions shall be documented in the client record.

(d) All orders for continuation of restraint shall be reviewed and documented in intervals not to exceed four hours thereafter, either by personal examination or telephone communication between health professionals and the responsible clinician.

(e) All orders of restraint issued or approved by a clinician shall include written authorization to correctional staff or health professionals to release the client when he or she is no longer dangerous to him or herself or to others.

(f) The responsible clinician shall be notified upon release of a client from restraint.

(g) Observations or reviews of all clients in restraint shall be made as follows:

(1) observations no less frequently than every 30 minutes;

(2) observations every four hours by the responsible clinician either personally or through reports from health professionals; and

(3) reviews by an internal committee in accordance with Paragraph (h) of this Rule.

(h) Committee review: An internal committee consisting of three members of the Department's clinical and administrative staff, including at least one psychologist and one psychiatrist shall review cases in which restraints were used beyond four hours. The incident will be reviewed and include consideration of the following:

(1) the use of appropriate procedures in the decision to restrain;

(2) sufficient indications for the use of restraint; and

(3) release of the client from restraint as soon as clinically indicated based upon consideration of the factors listed in Paragraphs (a) and (b) of this Rule.

(i) When a client is placed in restraint, the client record shall contain documentation of the following:

(1) the rationale and authorization for the use of restraint, including placement in restraint pending review by the responsible clinician;

(2) a record of the observations of the client as required by Paragraph (g) of this Rule.

(3) each review by the responsible clinician as required by this Rule, including a description of the client and all significant changes that have occurred; and

(4) each review by the internal committee as required in Paragraph (h) of this Rule.

History Note: *Authority G. S. 148-19(d);*
Eff. January 4, 1994;
Readopted Eff. March 1, 2019.

10A NCAC 26D .1204 PROTECTIVE DEVICES

Whenever protective devices are used for any client, the Chief of Psychiatry shall:

(1) ensure that the:

(a) necessity for the protective device has been assessed and approved by a mental health professional;

(b) device is applied by a person who has been trained in the use of protective devices;

(c) client who is using protective devices which limits his or her freedom of movement is observed every two hours; and

(d) client is given the opportunity for toileting and exercising as needed.

(2) document the use of protective devices in the client's medical record.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Readopted Eff. March 1, 2019.

10A NCAC 26D .1205 VOLUNTARY REFERRALS AND TRANSFERS

(a) Non-emergency referrals shall be forwarded to the mental health or mental retardation professional designated to receive such referrals at the service delivery site to which the client is assigned.

(b) If the mental health or mental retardation professional determines that the client is in need of services provided at a residential or inpatient unit, the client shall be given:

(1) written notice of the reasons for the referral;

(2) the expected benefits of the treatment to be received; and
(3) his rights as described in Rule .1207 of this Section.

(c) If the client agrees to a voluntary transfer to the specified residential or inpatient unit, he will be asked to give written consent, with witness by a member of the staff.

(d) If the client refuses to sign the form, yet verbally agrees, this fact must be documented by two witnesses prior to initiating the transfer to the mental health unit.

(e) The referring mental health or mental retardation professional shall complete the necessary referral forms and arrange for the client's transfer.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .1206 INVOLUNTARY REFERRALS AND TRANSFERS

(a) Involuntary referrals and transfers to residential or inpatient units shall occur only if the attending clinician determines that:

(1) a client requires treatment services not available at his or her current service delivery site; and
(2) a transfer over the client's objections is required.

(b) Non-emergency involuntary referrals:

(1) If a qualified professional determines that the following conditions exist:
    (A) a diagnosable mental disorder; and
    (B) determination is made that outpatient services are not effective treatment for the client; and
(2) the professional has given the client a written notice of a referral for transfer and has explained to the client his or her rights in accordance with Rule .1207 of this Section; then
(3) the following steps shall be taken if the client does not voluntarily consent to the referral and transfer:
    (A) the client shall be informed of the time, date and place of a hearing;
    (B) the Chief of Psychiatry or his or her designee shall contact the hearing officer to arrange a hearing; and
    (C) a client advisor shall be appointed and a hearing conducted in accordance with the procedures specified in this Rule.

(c) Emergency involuntary referrals:

(1) Such referrals shall be implemented only:
    (A) if a client has a diagnosable mental disorder; and either:
        (i) presents a substantial risk of harm to himself or others, as manifested by recent overt acts or expressed threats of violence; or
        (ii) is so unable to care for his or her own personal health and safety as to create a substantial risk of harm to himself; and
    (B) the Chief of Psychiatry has made a determination that outpatient services are not effective treatment for the client's condition.
(2) Such referrals shall be made by the mental health staff, the unit physician, nurse, or officer in charge after consultation with the designated mental health staff of the receiving unit.
(3) The officer in charge shall authorize a transfer only under the following conditions and if the officer determines:
    (A) the emergency referral criteria have been met; and
    (B) efforts to contact the referring mental health professional have failed.

(d) A client who is transferred because he or she meets the criteria of an emergency involuntary referral shall be afforded a hearing at the receiving unit within 10 days of admission. This hearing will follow the same procedures as those required by Paragraph (b) of this Rule.

(e) Client advisors:

(1) Each client referred for a hearing shall have an advisor appointed to assist him or her in preparing for the hearing.
(2) Each area administrator or institution head shall be responsible for appointing advisors for all units within his or her jurisdiction.
(3) Client advisors shall be free to advise the client independently and to act solely in his or her behalf, and shall not be subject to any harassment, discipline, or coercion in connection with such advice for the client.

(4) Ex parte attempts to influence the decision of the hearing officer shall be prohibited.

(f) Hearing officers: The Chief of Psychiatry shall recommend and the Director of the Division of Prisons shall appoint persons to serve as hearing officers who shall:

(1) be qualified professionals who are neutral and independent;
(2) have the authority to refuse to transfer an client if they determine that such a transfer is not justified.
(3) ensure and document that an client advisor has been assigned;
(4) conduct a hearing that follows the procedures specified in this Rule in a fair and impartial manner; and
(5) determine from evidence presented whether the criteria for emergency or non-emergency referrals have been met.

(g) Hearing procedures:

(1) The hearing shall be conducted no sooner than 48 hours after the time the client is given written notice that he or she is being considered for a referral to a residential or inpatient unit; however, the client has the right to waive the 48-hour notice.
(2) The hearing officer shall determine the time, place, and site of the hearing.
(3) The hearing officer shall consider all relevant and non- repetitive evidence justifying or disputing the involuntary transfer and that:
    (A) the client has a diagnosable mental disorder;
    (B) the client requires services that are not currently available on an outpatient basis; and
    (C) the unit to which the client is to be transferred is better able to provide the needed treatment or habilitation services than is the currently assigned housing unit.
(4) A copy of the referral form, as well as other relevant written documents, shall be entered as evidence.
(5) All written documents or verbal information are to be considered confidential, in accordance with applicable law and Department policy.
(6) The client shall not have direct access to his or her client record; however, the client advisor may:
    (A) review the client's record presented at the hearing; and
    (B) consult with the client about its use at the hearing and any other matters which could be relevant at the hearing, including the questioning of all witnesses.
(7) The client who is being considered for transfer or his or her advisor may question any witnesses for the State, including mental health or mental retardation professionals.
(8) The client may also present witnesses in his or her own behalf with limitations that include:
    (A) a reasonable number of witnesses will be allowed at the discretion of the Hearing Officer;
    (B) testimony may be received by conference telephone call if the hearing is conducted away from the client's assigned unit;
    (C) written statements may be entered in lieu of direct testimony; and
    (D) specific client witnesses may be excluded from direct testimony if a justifiable security risk, including threats of harm or inmate escape, as determined by a unit superintendent, or designee, would occur were they brought to the hearing site.
(9) The hearing officer shall:
    (A) document the results of the hearing, summarizing the evidence presented and the rationale for his or her decision;
    (B) communicate the results of the hearing to the client and staff; and
    (C) ensure that a copy of relevant documents is placed in the client record.
(10) The decision to transfer involuntarily shall be valid throughout the duration of the stay at any residential or inpatient unit. There shall be a review of the need for continued treatment or habilitation every 30 days.
(11) A client may be transferred to another like unit without a rehearing; however, if he or she is discharged from residential or inpatient services, a rehearing shall be required prior to readmission to that level of service.
(12) At the request of the client, his or her case shall be reviewed by a Hearing Officer within 90 days after the initial hearing to determine whether the assignment to the residential or inpatient unit will be extended or terminated. Subsequent reviews by a Hearing Officer shall take place each 180 days if requested by the client.

(h) The receiving unit shall be responsible for notifying the client of his or her right to inform his or her family of the transfer, and such notice shall be provided within 24 hours of the admission to the receiving unit.

History Note: *Authority G.S. 148-19(d);*

Eff. January 4, 1994;
Readopted Eff. March 1, 2019.

10A NCAC 26D .1207 TRANSFER TO RESIDENTIAL OR INPATIENT UNITS

All inmates who are considered for transfer to a residential or inpatient unit shall have rights which include, but need not be limited to:

(1) written notice that transfer to a residential or inpatient mental health facility is being considered, including a statement of the reasons for the referral or transfer;
(2) a hearing, sufficiently after notice is given, to prepare objections, if any;
(3) opportunity to:
  (a) testify in person;
  (b) present documented evidence; and
  (c) present and question witnesses called by the State, except upon a finding not arbitrarily made, of good cause, for not permitting such presentation, confrontation, or cross-examination;
(4) a neutral and independent decision-maker who has the authority to refuse admission;
(5) a written statement by the decision-maker as to reasons for his decision to refer and transfer, with which two psychiatrists or psychologists concur;
(6) qualified and independent assistance from an advisor, not necessarily an attorney, to assist the inmate in preparing his objections;
(7) periodic review of the continuing need for treatment; and
(8) effective and timely notice of all of the above rights.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .1300 - RESEARCH PRACTICES

10A NCAC 26D .1301 SCOPE

(a) The rules in this Section apply to research activity or treatment involving direct contact with a client.
(b) An activity or treatment procedure shall be considered research when it:
(l) involves a clinical practice that is not conventional; or
(2) is a type of procedure that serves the purpose of research only, and does not include treatment designed primarily to benefit the client.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .1302 RESEARCH REVIEW BOARD

(a) Research that involves a client shall be reviewed and approved by a research review board established by the Department.
(b) The research review board shall approve, require modification, or disapprove proposed research projects subject to the approval of the Department.
(c) Individuals who are not directly associated with research projects under consideration shall comprise a majority of the review board.
(d) Each proposed research project shall be presented to a research review board as a written protocol containing the following information:
(1) identification of the project and the investigator;
(2) abstract, containing a short description of the project;
(3) statement of objectives and rationale; and
(4) description of methodology, including informed consent if necessary.
(e) Prior to the initiation of each research project, a research review board shall:
(1) conduct an initial review of the project;
(2) state the frequency with which it will review the project after it has been initiated; and
(3) hold a review prior to any major changes being made in research procedures.

(f) Written minutes of each research board's meeting shall be maintained and contain documentation that:

(1) risks to the client were minimal and reasonable for the benefits to be accrued;
(2) client participation was voluntary;
(3) unnecessary intrusion on the client was eliminated;
(4) informed consent was obtained; and
(5) compliance with confidentiality requirements as contained in Rule .0704 of these Rules.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .1303 CONDITIONS OF CLIENT PARTICIPATION

(a) Informed written consent shall be obtained from each client in a research project as follows:

(1) documentation that the client has been informed of any potential dangers that may exist, and that he understands the conditions of participation; and
(2) notice of the client's right to terminate participation at any time without prejudicing the treatment he is receiving.

(b) A copy of the dated, signed consent form shall be kept on file.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .1400 - EMERGENCY SERVICES

10A NCAC 26D .1401 SCOPE

(a) The Department shall ensure that emergency mental health and mental retardation services are available to all inmates.

(b) Emergency services provide:

(1) immediate assessment and intervention; and
(2) referral for continuing care after emergency treatment, for inmates experiencing acute emotional or behavioral problems.

(c) Emergency services consist of a variety of services which may include, but need not be limited to:

(1) crisis intervention;
(2) telephone crisis services; and
(3) medical and psychiatric back-up.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .1402 TRAINING OF STAFF

The Department shall ensure that staff who:

(1) supervise inmates have been trained to access and refer to emergency services; and
(2) provide emergency services are properly trained.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .1500 - PREVENTION SERVICES

10A NCAC 26D .1501 SCOPE

The Department shall develop a process to identify inmates who are:

(1) at risk for developing mental disorders; and

(2) provide counseling, education, instruction and protective living arrangements to enhance their ability to cope in the prison environment.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SECTION .1600 - INPATIENT SERVICES FOR INMATES WHO ARE MENTALLY ILL

10A NCAC 26D .1601 SCOPE

(a) Inpatient units for clients who are mentally ill shall provide close supervision by a qualified mental health professional on a 24-hour basis.
(b) The inpatient unit shall be designed to serve any client who requires continuous treatment for moderate or severe mental illness.
(c) Client care shall be provided under the supervision of a psychiatrist or doctoral level psychologist.
(d) Individuals who, in addition to mental illness, have other disorders such as mental retardation or substance abuse, shall be eligible for admission.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .1602 HOURS OF OPERATION

The inpatient unit shall provide services seven days per week, 12 months per year.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

10A NCAC 26D .1603 REQUIRED SERVICES

(a) Services provided on an inpatient unit shall include, but need not be limited to:
(1) psychiatry;
(2) psychology;
(3) nursing;
(4) social work;
(5) rehabilitation; and
(6) recreational.
(b) Multi-disciplinary treatment teams shall be developed to oversee the delivery of such services.

History Note: *Authority G.S. 148-19(d);*
Eff. January 4, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 20, 2015.

SUBCHAPTER 26E - MANUFACTURERS: DISTRIBUTORS: DISPENSERS AND RESEARCHERS OF CONTROLLED SUBSTANCES

SECTION .0100 - REGISTRATION OF MANUFACTURERS: DISTRIBUTORS: AND DISPENSERS OF CONTROLLED SUBSTANCES

10A NCAC 26E .0101 SCOPE

Procedures governing the registration of manufacturers, distributors and dispensers of controlled substances pursuant to General Statutes 90-101 to 90-103 are set forth generally by those sections and specifically by the rules of this Section.

History Note: *Authority G.S. 90-100; 143B-210(9);*

Eff. June 30, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0102 DEFINITIONS

As used in this Section, the following terms shall have the meanings specified:

(1) The term "act" means the North Carolina Controlled Substances Act (G.S. Chapter 90, Article 5).

(2) The term "Commission" means the same as defined in G.S 90-87

(3) The term "basic class" means as to controlled substances listed in Schedules I, II and VI:

(a) each of the opiates including its isomers; esters; ethers; salts; and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation listed in Schedule I of the North Carolina Controlled Substances Act;

(b) each of the opium derivatives including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation listed in Schedule I of the North Carolina Controlled Substances Act;

(c) each of the hallucinogenic substances including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation listed in Schedule I of the North Carolina Controlled Substances Act;

(d) each of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

(i) opium including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, deodorized opium and tincture of opium;

(ii) apomorphine;

(iii) ethylmorphine;

(iv) hydrocodone;

(v) hydromorphone;

(vi) metopon;

(vii) morphine;

(viii) oxycodone;

(ix) oxymorphone;

(x) thebaine;

(xi) mixed alkaloids of opium listed in Schedule I of the North Carolina Controlled Substances Act;

(xii) cocaine; and

(xiii) ecgonine;

(e) each of the opiates including its isomers; esters; ethers; salts; and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation listed in Schedule II of the North Carolina Controlled Substances Act; and

(f) methamphetamine including its salts, isomers and salts of isomers when contained in any injectable liquid.

(4) The term "commercial detection service" means the same as defined in G.S. 90-102.1.

(5) The term "DEA" means the Federal Drug Enforcement Administration.

(6) The term "Director" means the Director of the Division of Mental Health, Developmental Disabilities and Substance Abuse Services, Department of Health and Human Services.

(7) The term "dog handler" means the same as defined in G.S. 90-102.1. For purposes of this definition person means an individual.

(8) The term "drug detection dog" means the same as defined in G.S. 90-102.1.

(9) The term "hearing" means any hearing held pursuant to this part of the granting, denial, revocation or suspension of a registration pursuant to G.S. 90-102 and 90-103.

(10) The term "individual practitioner" means same as defined in G.S. 90-87

(11) The term "person" means the same as defined in G.S. 90-87.

(12) The terms "register" and "registration" refer only to registration required and permitted by G.S. 90-102.

(13) The term "registrant" means any person who is registered pursuant to G.S. 90-102.
(14) The term "office-based opioid treatment" means any controlled substance listed in Schedules III-V dispensed for the maintenance or detoxification treatment of opioid addiction or for the detoxification treatment of opioid dependence.
(15) Any term not defined in this Section shall have the definition set forth in G.S. 90-87.

History Note: *Authority G.S. 90-100; 90-102.1; 143B-147(a)(5);*
Eff. June 30, 1978;
Amended Eff. February 1, 2005; July 1, 2004; May 1, 1990; May 15, 1979; September 30, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0103 ADDITIONAL INFORMATION
Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the director.

History Note: *Authority G.S. 90-100; 143B-210(9);*
Eff. June 30, 1978;
Amended Eff. May 15, 1979;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0104 PERSONS REQUIRED TO REGISTER
(a**)** Any person who manufactures, distributes or dispenses any controlled substance or uses any controlled substance for the purpose of the initial and maintenance training of drug detection dogs or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance or use of any controlled substance for the purpose of the initial and maintenance training of drug detection dogs in this state shall obtain annually a registration unless exempted by law or pursuant to Rules .0109-.0111 of this Section.
(b) Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)
(c) Any person applying for registration or re-registration shall file, annually, an application for registration with the Department of Health and Human Services and submit the required nonrefundable fee with the application. Categories of applicants and the annual fee for each category are as follows:

	CATEGORY	FEE
(1)	Clinic	125.00
(2)	Hospital	300.00
(3)	Nursing Home	100.00
(4)	Teaching Institution	100.00
(5)	Researcher	125.00
(6)	Analytical Laboratory	100.00
(7)	Distributor	500.00
(8)	Manufacturer	600.00
(9)	Office-Based Opioid Treatment	0.00
(10)	Dog Handler	125.00

(d) For any person applying for registration at least six months or less prior to the end of the fiscal year, the required annual fee submitted with the application shall be reduced by one-half of the above listed fee for each category.

History Note: *Authority G.S. 90-100; 90-101; 90-102.1; 143B-210(9);*
Eff. June 30, 1978;
Amended Eff. February 23, 2005; January 1, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0105 SEPARATE REGISTRATION FOR INDEPENDENT ACTIVITIES

(a) The following groups of activities are deemed to be independent of each other:

(1) manufacturing controlled substances;
(2) distributing controlled substances;
(3) dispensing controlled substances listed in Schedules II through V;
(4) conducting research [other than research described in Subparagraph (6) of this Paragraph] with controlled substances listed in Schedules II through V;
(5) conducting instructional activities with controlled substances listed in Schedule II through V;
(6) conducting research with narcotic drugs listed in Schedules II through V for the purpose of continuing the dependence on such drugs of a narcotic drug dependent person in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program pursuant to a notice of claims investigational exemption for a new drug approved by the Food and Drug Administration;
(7) conducting research and instructional activities with controlled substances listed in Schedules I and VI;
(8) conducting chemical analysis with controlled substances listed in any schedule;
(9) dispensing of controlled substances in Schedules III-V for opioid treatment; and
(10) possessing or training with controlled substances for the purpose of providing a commercial detection service.

(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities except as provided in this Paragraph. Any person when registered to engage in the group activities described in each Subparagraph of this Paragraph shall be authorized to engage in the coincident activities described in that Subparagraph without obtaining a registration to engage in such coincident activities provided that unless specifically exempted, the person complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities as follows:

(1) A person registered to manufacture any controlled substance or basic class of controlled substance shall be authorized to distribute that substance or class but no other substance or class which the person is not registered to manufacture.
(2) A person registered to manufacture any controlled substance listed in Schedules II through V shall be authorized to conduct chemical analysis and preclinical research (including quality control analysis) with narcotic and nonnarcotic controlled substances listed in those Schedules the person authorized to manufacture.
(3) A person registered or authorized to conduct research with a basic class of controlled substances listed in Schedules I and VI shall be authorized to manufacture such class if and to the extent that such manufacture is set forth in the research protocol filed with the Drug Enforcement Administration and to distribute such class to other persons registered or authorized to conduct research with such class or registered or authorized to conduct chemical analysis with controlled substances.
(4) A person registered or authorized to conduct chemical analysis with controlled substances shall be authorized to manufacture such substances for analytical or instructional purposes, to distribute such substances to other persons registered or authorized to conduct chemical analysis or instructional activities or research with such substances and to persons exempted from registration pursuant to Rule .0111 of this Section and to conduct instructional activities with controlled substances.
(5) A person registered or authorized to conduct research [other than research described in Paragraph (a)(6) of this Rule] with controlled substances listed in Schedules II through V shall be authorized to conduct chemical analysis with controlled substances listed in those schedules in which the person is authorized to conduct research, to manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration and to distribute such substances to other persons registered or authorized to conduct chemical analysis, instructional activities or research with such substances and to persons exempted from registration pursuant to Rule .0111 of this Section and to conduct instructional activities with controlled substances.
(6) A person registered to dispense controlled substances listed in Schedules II through V shall be authorized to conduct research [other than research described in Paragraph (a)(6) of this Rule] and to conduct instructional activities with those substances.

(c) A single registration to engage in any group of independent activities may include one or more controlled substances listed in the Schedules authorized in that group of independent activities. A person registered to conduct research with

controlled substances listed in Schedules I and VI may conduct research with any substance listed in Schedules I and VI for which the person has filed and approved a research protocol from the Drug Enforcement Administration.

History Note: *Authority G.S. 90-100; 90-101; 90-102.1; 143B-210(9);*
Eff. June 30, 1978;
Amended Eff. February 1, 2005; July 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0106 TRAINING AND QUALIFICATION REQUIREMENTS FOR DOG HANDLERS

(a) An individual applying for registration as a dog handler shall demonstrate competence in the field of drug detection dog training and handling. The applicant shall demonstrate competence by achieving certification as a drug detection dog handler from an approved canine certification association pursuant to G.S. 90-102.1 and as set forth in Rule .0107 of this Section.

(b) The applicant shall submit proof to the Department of Health and Human Services (DHHS) of a Drug Enforcement Administration registration or pending application.

(c) The applicant shall submit documentation to DHHS verifying current certification as a drug detection dog handler from an approved canine certification association as set forth in Rule .0107 of this Section

(d) The applicant shall submit to DHHS five letters of reference showing the applicant is of good moral character and temperate habits in accordance with G.S. 90-102.1.

(e) Pursuant to G.S. 90-102.1, the Department of Justice may provide a criminal record check to the DHHS for an individual who applies for a new or renewal registration. The applicant shall comply with the criminal record check including the use of his or her fingerprints and shall incur any costs associated with the criminal record check.

History Note: *Authority G.S. 90-102.1; S.L. 2003-398;*
Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0107 APPROVAL OF CANINE CERTIFICATION ASSOCIATIONS BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

(a) The Department of Health and Human Services shall approve a canine certification association that requests approval and meets the requirements as set forth in this Rule.

(b) Each canine certification association shall utilize certification standards that require the dog handler to demonstrate competence in the following areas:

(1) basic canine obedience;
(2) canine safety;
(3) drug detection; and
(4) legal aspects of searches and controlled substances identification.

(c) The canine certification association shall make available to DHHS the certification procedures and standards it plans to employ.

(d) The certification procedures and standards shall certify the dog handler and drug detection dog as a team.

(e) The canine certification association shall submit documentation to DHHS showing the following:

(1) the certification procedures and standards it utilizes are accepted as valid by a court of law; and
(2) the dog handler/drug detection dog teams that have obtained certifications from that association are accepted as valid by a court of law.

(f) The DHHS shall review the certification procedures and standards to verify the association's compliance with the requirements as set forth in this Rule.

(g) The approval of a canine certification association by the DHHS shall be valid for three years. Canine certification associations that want to maintain approval shall request renewal from DHHS prior to the end of the three year period.

(h) The DHHS shall maintain a list of approved canine certification associations.

History Note: *Authority G.S. 90-102.1; S.L. 2003-398;*
Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0108 SEPARATE REGISTRATION FOR SEPARATE LOCATIONS

(a) A separate registration is required for each principal place of business or professional practice at any one general physical location where controlled substances are manufactured, distributed or dispensed by a person.

(b) The following location shall be deemed not to be a place where controlled substances are manufactured, distributed or dispensed by a person: an office used by agents of a registrant where sales of controlled substances are solicited, made or supervised but which neither contains such substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders.

History Note: *Authority G.S. 90-100; 90-101; 143B-147(a)(5);*
Eff. June 30, 1978;
Amended Eff. May 1, 1990;
Recodified from 10A NCAC 26E .0106 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0109 EXEMPTION OF AGENTS AND EMPLOYEES: AGENTS OF MANUFACTURERS

The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities if such agent or employee is acting in the usual course of his business or employment.

History Note: *Authority G.S. 90-100; 90-101; 143B-210(9);*
Eff. June 30, 1978;
Amended Eff. September 30, 1978;
Recodified from 10A NCAC 26E .0107 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0110 EXEMPTION OF INDIVIDUAL PRACTITIONERS

(a) The requirement of registration is waived for all physicians, dentists, podiatrists, pharmacists, optometrists and veterinarians practicing as individual practitioners and licensed in North Carolina by their respective boards to the extent authorized by their boards; except as noted in G.S. 90-101(a1).

(b) An individual practitioner (other than an intern, resident or foreign trained physician on the staff of a Veterans Administration facility or physician who is an agent or employee of the Health Bureau of the Canal Zone Government) who is an agent or employee of another practitioner registered to dispense controlled substances may, when acting in the usual course of employment, administer and dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which the individual practices under the registration of the employer or principal practitioner in lieu of being registered.

(c) An individual practitioner who is an intern, resident or foreign-trained physician or physician on the staff of a Veterans Administration facility or physician who is an agent or employee of the Health Bureau of the Canal Zone Government may dispense, administer and prescribe controlled substances under the registration of the hospital or other registered institution in which the individual is employed in lieu of being registered, provided that:

(1) such dispensing, administering or prescribing is done in the usual course of professional practice;
(2) such individual practitioner is authorized or permitted to do so by the jurisdiction in which the individual is practicing;
(3) the hospital or other institution by whom the individual is employed has verified that the individual practitioner is so permitted to dispense, administer or prescribe drugs within the jurisdiction;
(4) such individual practitioner is acting only within the scope of employment in the hospital or institution;
(5) the hospital or other institution authorizes the intern, resident or foreign-trained physician to dispense or prescribe under the hospital registration and designates a specific internal code number for each intern, resident or foreign physician so authorized. The code number shall consist of numbers, letters or a combination thereof and shall be a suffix to the institution's Drug Enforcement Administration registration number preceded by a hyphen (e.g., AP0123456-10 or AP0123456-A12); and
(6) current list of internal codes and the corresponding individual practitioner is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner.

(d) An individual on the staff of a teaching or research institution may handle controlled substances under the registration of the institution in which the individual is employed in lieu of being registered, provided that:

(1) the institution authorizes the staff member to handle under the institution registration and designates a specific internal code number for each staff member so authorized. The code number shall consist of numbers, letters or a combination thereof and shall be a suffix to the institution's Drug Enforcement Administration registration number preceded by a hyphen (e.g., AP0123456-10 or AP0123456-A12); and

(2) a current list of internal codes and the corresponding staff members are kept by the institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the individual staff member.

History Note: *Authority G.S. 90-100; 90-101; 143B-210(9);*
Eff. June 30, 1978;
Amended Eff. July 1, 2004; September 30, 1978;
Recodified from 10A NCAC 26E .0108 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0111 EXEMPTION OF LAW ENFORCEMENT OFFICIALS

(a) The requirement of registration is waived for the following persons in the circumstances described in this Rule:

(1) any person employed by the following agencies who is lawfully engaged in the enforcement of any North Carolina or federal law relating to controlled substances, drugs or customs and is duly authorized to possess controlled substances in the course of his official duties: the Department of Health and Human Services, the North Carolina Department of Justice, the North Carolina Board of Pharmacy, the Drug Enforcement Administration, the United States Bureau of Customs and the United States Food and Administration;

(2) any dog handler who is employed or under contract to a North Carolina law enforcement agency and any other person specified in G.S. 90-101(c)(5);

(3) any person employed by any political subdivision of the State who is engaged in the enforcement of any state or local law relating to controlled substances and who is duly authorized to possess controlled substances in the course of his official duties; or

(4) any official of the United States Army, Navy, Marine Corps, Air Force, Coast Guard or Public Health Service who is authorized to prescribe, dispense or administer but not to procure or purchase controlled substances in the course of his official duties. Such officials shall follow procedures set forth in Section .0400 of this Subchapter regarding prescriptions but shall state the branch of service or agency (e.g., United States Army or Public Health Service) and the service identification number of the issuing official in lieu of the registration number required on prescription forms. The service identification number of a Public Health Service officer is his social security number.

(b) Any official exempted by this Rule may, when acting in the course of his official duties, possess any controlled substance and distribute any such substance to any other official who is also exempted by this Section and acting in the course of his official duties.

(c) Any official exempted by this Rule may procure any controlled substance in the course of an inspection in accordance with .0503(a)(4) of this Subchapter or in the course of any criminal investigation involving the person from whom the substance was procured.

History Note: *Authority G.S. 90-100; 90-101; 90-102.1; 143B-147(a)(5);*
Eff. June 30, 1978;
Amended Eff. February 1, 2005; May 1, 1990;
Recodified from 10A NCAC 26E .0109 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0112 TIME FOR APPLICATION FOR REGISTRATION: EXPIRATION DATE

(a) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and certificate of registration is issued by the director to such persons. However, a person already

registered under federal law shall be allowed to continue to engage in the activity for which federal registration is allowed during the time his application is being processed and until such application is denied.

(b) Any person who is registered may apply to be re-registered not more than 60 days before the expiration date of the registration.

(c) All registrations shall expire annually on the anniversary of their date of inception as hereafter set out. For the purposes of these registrations, the state shall be divided into a Northern, Central, and Southern Region. The counties which are included in each of these regions are specified in Paragraph (d) of this Rule. The date of expiration for each registration shall be determined by the region of the state in which the registrant is located. The registrations from the Northern Region shall expire on October 31 of each year. The registrations from the Central Region shall expire on December 31 of each year. The registrations from the Southern Region shall expire on July 31 of each year. If the registrant registers within the three months preceding the expiration date for his region, the registration which he receives shall not expire until the expiration date of the following year. However, for the registration year of 1989 all renewal registrations shall be handled in accordance with Paragraph (e) of this Rule.

(d) The counties of the State of North Carolina are divided into three regions as follows:

(1) The Northern Region shall include the following counties: Alamance; Alleghany; Ashe; Bertie; Camden; Caswell; Chowan; Currituck; Dare; Durham; Edgecombe; Forsyth; Franklin; Gates; Granville; Guilford; Halifax; Hertford; Martin; Nash; Northampton; Orange; Pasquotank; Perquimans; Person; Rockingham; Stokes; Surry; Tyrrell; Vance; Warren; Washington; Watauga; Wilkes; and Yadkin.

(2) The Central Region shall include the following counties: Alexander; Avery; Beaufort; Buncombe; Burke; Caldwell; Carteret; Catawba; Chatham; Cherokee; Clay; Craven; Davidson; Davie; Graham; Greene; Haywood; Hyde; Iredell; Jackson; Johnston; Jones; Lenoir; Macon; Madison; McDowell; Mitchell; Pamlico; Pitt; Randolph; Rowan; Swain; Wake; Wayne; Wilson; and Yancey.

(3) The Southern Region shall include the following counties: Anson; Bladen; Brunswick; Cabarrus; Cleveland; Columbus; Cumberland; Duplin; Gaston; Harnett; Henderson; Hoke; Lee; Lincoln; Mecklenburg; Montgomery; Moore; New Hanover; Onslow; Pender; Polk; Richmond; Robeson; Rutherford; Sampson; Scotland; Stanly; Transylvania; and Union.

(e) All renewal registrations applied for on October 31, 1989 shall be granted in accordance with the following specifications:

(1) The renewal registrations received from the Northern Region shall be granted for the period of October 31, 1989 until October 31, 1990.

(2) The renewal registrations received from the Central Region shall be extended until December 31, 1989 at which time they will be granted for the period of December 31, 1989 until December 31, 1990.

(3) The renewal registrations received from the Southern Region shall be granted for the period of October 31, 1989 until July 31, 1990.

History Note: *Authority G.S. 90-100;*
Eff. June 30, 1978;
Amended Eff. May 1, 1990; July 1, 1989; May 15, 1979;
Recodified from 10A NCAC 26E .0110 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0113 APPLICATION FORMS: CONTENTS: SIGNATURE

(a) Any person required to be registered and who is not registered and applying for registration:

(1) to manufacture or distribute controlled substances, shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 225;

(2) to dispense controlled substances listed in Schedules II through V, shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 224;

(3) to conduct instructional activities with controlled substances listed in Schedules II through V, shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 224;

(4) to conduct research with controlled substances listed in Schedules II through V other than research described in .0105(a)(6) of this Subchapter, shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 225 with evidence of federal registration to conduct research with such controlled substances;

(5) to conduct research with narcotic drugs listed in Schedules II through V, as described in .0105(a)(6) of this Subchapter, shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 225 with evidence of federal registration to conduct research with narcotic drugs;

(6) to conduct research with controlled substances listed in Schedules I and VI, shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 225 with evidence of federal registration to conduct research with such controlled substances;

(7) to conduct instructional activities with controlled substances listed in Schedules I and VI, shall apply as a researcher on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 225 with evidence of federal registration to conduct instructional activities with controlled substances; to conduct chemical analysis with controlled substances listed in any schedule, shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 225;

(8) to conduct chemical analysis with controlled substances listed in any schedule, shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services From 25;

(9) to dispense controlled substances in Schedule III-V for opioid treatment, shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 224; and

(10) to provide a commercial detection service, shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 225.

(b) Any person registered and who is applying for re-registration:

(1) to manufacture or distribute controlled substances, shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 227;

(2) to dispense controlled substances in Schedules II through V, shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 226;

(3) to conduct instructional activities with controlled substances listed in Schedules II through VI, shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 226;

(4) to conduct research with controlled substances listed in Schedules II through V other than research described in Rule .0105(a)(6) of this Subchapter, shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 227;

(5) to conduct research with narcotic drugs listed in Schedules II through V, as described in Rule .0105(a)(6) of this Subchapter, shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 227;

(6) to continue to conduct research with controlled substances listed in Schedules I and VI under one or more approved research protocols, shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 227;

(7) to continue to conduct instructional activities with controlled substances listed in Schedules I and VI under one or more approved federal instructional statements, shall apply as a researcher on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 227;

(8) to conduct chemical analysis with controlled substances listed in any schedule, shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 227;

(9) to dispense controlled substances in Schedule III-V in opioid treatment , shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 226; and

(10) to provide a commercial detection service, shall apply on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 227.

(c) Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Forms 224 and 225 may be obtained by writing to the Director. Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Forms 226 and 227 will be mailed as applicable to each registered person approximately 60 days before the expiration date of registration; if any registered person does not receive such forms within 45 days before the expiration date of registration, the registered person must give notice of such fact and request such forms by writing to the Director.

(d) Each application for registration to handle any basic class of controlled substance listed in Schedules I (except to conduct chemical analysis with such classes) and VI and each application for registration to manufacture a basic class of controlled substances listed in Schedule II or to conduct research with any narcotic controlled substance listed in Schedule II shall include the Federal Drug Enforcement Administration code number for each class or substance to be covered by such registration.

(e) Each application shall include all information called for by these Rules unless the item is not applicable, in which case this fact shall be indicated.
(f) An applicant may authorize one or more individuals who would not otherwise be authorized to do so to sign applications for the applicant by filing with the director a power of attorney for each such individual. The power of attorney shall be signed by a person who is authorized to sign applications under this Paragraph and shall contain the signature of the individual being authorized to sign applications. The power of attorney shall be valid until revoked by the applicant.

History Note: *Authority G.S. 90-100; 90-102; 143B-147(a)(5);*
Eff. June 30, 1978;
Amended Eff. February 1, 2005; May 1, 1990; May 15, 1979; September 30, 1978;
Recodified from 10A NCAC 26E .0111 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0114 FILING OF APPLICATION: JOINT FILINGS
(a) All applications for registration shall be submitted for filing to the Director.
(b) Any person required to obtain more than one registration may submit all applications in one package. Each application must be complete and shall not refer to any accompanying application for required information.

History Note: *Authority G.S. 90-100; 143B-147(a)(5);*
Eff. June 30, 1978;
Amended Eff. May 1, 1990; May 15, 1979;
Recodified from 10A NCAC 26E .0112 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0115 ACCEPTANCE FOR FILING: DEFECTIVE APPLICATIONS
(a) Applications submitted for filing are dated upon receipt. If found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will not generally be accepted for filing. In the case of minor defects as to completeness, the director may accept the application for filing with a request to the applicant for additional information. A defective application will be returned to the applicant within 10 days following its receipt with a statement of the reason for not accepting the application for filing. A defective application may be corrected and resubmitted for filing at any time; the director shall accept for filing any application upon resubmission by the applicant whether complete or not.
(b) Accepting an application for filing does not preclude any subsequent request for additional information pursuant to .0114 of this Subchapter and has no bearing on whether the application will be accepted except as provided in General Statutes 90-102(c) and (d).

History Note: *Authority G.S. 90-100; 143B-210(9);*
Eff. June 30, 1978;
Amended Eff. May 15, 1979; September 30, 1978;
Recodified from 10A NCAC 26E .0113 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0116 ADDITIONAL INFORMATION
The director may require an applicant other than one registered under federal law to submit such documents or written statements of facts relevant to the application as he deems necessary to determine whether the application should be accepted. The failure of the applicant to provide such documents or statements within 60 days after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or statements for consideration by the director granting or denying the application.

History Note: *Authority G.S. 90-100; 143B-147(a)(5);*
Eff. June 30, 1978;
Amended Eff. May 1, 1990; May 15, 1979; September 30, 1978;

Recodified from 10A NCAC 26E .0114 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0117 AMENDMENTS TO AND WITHDRAWAL OF APPLICATIONS

(a) An application may be amended or withdrawn without permission of the director at any time before the date on which the applicant receives an order to show cause pursuant to .0119 of this Section or before the date on which a notice of hearing on the application is published pursuant to Rule .0117 of this Section, whichever is sooner.

(b) After an application has been accepted for filing, the failure by the applicant to respond to official correspondence regarding the application when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.

History Note: *Authority G.S. 90-100; 143B-147(a)(5);*
Eff. June 30, 1978;
Amended Eff. May 15, 1979; September 30, 1978;
Recodified from 10A NCAC 26E .0115 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0118 ADMINISTRATION REVIEW GENERALLY

The director may inspect or cause to be inspected the establishment of an applicant or registrant pursuant to Section .0500 of this Subchapter. The director shall review the application for registration and any other information concerning the applicant or registrant in order to determine whether the applicable standards of G.S. 90-102 have been met by the applicant.

History Note: *Authority G.S. 90-104; 143B-210(9);*
Eff. June 30, 1978;
Amended Eff. May 15, 1979;
Recodified from 10A NCAC 26E .0116 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10 NCAC 26E .0119 CERTIFICATE OF REGISTRATION: DENIAL OF REGISTRATION

(a) The director shall issue a certificate of registration (Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 223) to an applicant if the issuance of registration or re-registration is required under the applicable provisions of G.S. 90-102. Before denying any application, the director shall issue an order to show cause pursuant to Rule .0121 of this Section and shall hold a hearing on the application pursuant to Rule .0122 of this Section.

(b) The certificate of registration (Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 223) shall contain the name, address and registration number of the registrant, the activity authorized by the registration, the schedules or Drug Enforcement Administration controlled substances code number of the controlled substances which the registrant is authorized to handle and the expiration date of the registration.

(c) The registrant shall maintain the certificate of registration at the registered location in a readily retrievable manner and shall permit inspection of the certificate by an official, agent or employee of the Department of Health and Human Services or any federal or state agency engaged in enforcement of laws relating to controlled substances.

History Note: *Authority G.S. 90-100; 90-103; 143B-147(a)(5);*
Eff. June 30, 1978;
Amended Eff. May 1, 1990; May 15, 1979; September 30, 1978;
Recodified from 10A NCAC 26E .0117 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0120 SUSPENSION OR REVOCATION OF REGISTRATION

(a) The Commission may suspend any registration pursuant to G.S. 90-103(a) and (d). Where the Commission suspends a registration under G.S. 90-103(d), the hearing on such suspension must be held no later than 60 days after the original date of suspension.

(b) The Commission may revoke any registration pursuant to G.S. 90-103(a).
(c) Before revoking or suspending any registration, the Commission shall issue an order to show cause pursuant to Rule .0121 of this Section. Notwithstanding the requirements of this Section, however, the Commission may suspend any registration pending a final order pursuant to Rule .0119 of this Section.
(d) Upon service of the order of the Commission suspending or revoking registration, the registrant shall immediately deliver his certificate of registration and any order forms in his possession to the Raleigh office of the Director. Also upon service of the order of the Commission revoking registration, the registrant shall, as instructed by the Commission:

(1) deliver all controlled substances in his possession to the Raleigh office of the Director.
(2) place all controlled substances in his possession under seal as described in G.S. 90-103(e).

(e) In the event that revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new certificate of registration for all substances not affected by such revocation or suspension. The registrant shall deliver the old certificate of registration to the Raleigh office of the Director. Also, the registrant shall, as instructed by the Commission:

(1) deliver to the Raleigh office of the Director all of the particular controlled substance or substances affected by the revocation or suspension which are in his possession, or
(2) place all of such substances under seal as described in G.S. 90-103(e).

History Note: *Authority G.S. 90-100; 90-103; 143B-147(a)(5);*
Eff. June 30, 1978;
Amended Eff. May 1, 1990; May 15, 1979;
Recodified from 10A NCAC 26E .0118 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0121 SUSPENSION OF REGISTRATION PENDING FINAL ORDER

(a) The Commission may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended in any case where it finds that there is an imminent danger to the public health or safety. If the Commission so suspends, it shall serve with the order to show cause pursuant to Rule .0121 of this Section an order of immediate suspension which shall contain a statement of its findings regarding the danger to public health or safety.
(b) Upon service of the order of immediate suspension, the registrant shall promptly return his certificate of registration and any order forms in his possession to the Raleigh office of Director. Upon service of the order of the Director immediately suspending registration, the registrant shall, as instructed by the Commission:

(1) deliver all affected controlled substances in his possession to the Raleigh office of the Director, or
(2) place all such substances under seal as described in G.S. 90-103(3).

(c) Any suspension shall continue in effect until the conclusion of all proceedings upon the revocation or suspension including any judicial review thereof, unless sooner withdrawn by the Commission or dissolved by a court of competent jurisdiction. Any registrant whose registration is suspended under this Section may request a hearing on the revocation or suspension of his registration at a time earlier than specified in the order to show cause pursuant to Rule .0121 of this Section, which request shall be granted by the director who shall fix a date for such hearing as early as reasonably possible.

History Note: *Authority G.S. 90-100; 90-103; 143B-147(a)(5); 150B-3(c);*
Eff. June 30, 1978;
Amended Eff. May 1, 1990; May 15, 1979; September 30, 1978;
Recodified from 10A NCAC 26E .0119 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0122 EXTENSION OF REGISTRATION PENDING FINAL ORDER

In the event that an applicant for registration (who is operating under a registration previously granted and not revoked or suspended) has applied for registration at least 45 days before the date on which the existing registration is due to expire and the director has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the director so issues his order. The director may extend any other existing registration under the circumstances contemplated in this Rule even though the registrant failed to apply for registration at least 45 days before expiration of

the existing registration, with or without request by the registrant, if the director finds that such extension is not inconsistent with the public health and safety.

History Note: *Authority G.S. 90-100; 90-103; 143B-210(9);*
Eff. June 30, 1978;
Amended Eff. May 15, 1979; September 30, 1978;
Recodified from 10A NCAC 26E .0120 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0123 ORDER TO SHOW CAUSE

(a) If, upon examination of the application for registration from any applicant and other information gathered by the director regarding the applicant, the director is unable to make the determinations required by the applicable provisions of G.S. 90-102 to register the applicant, the Commission shall serve upon the applicant an order to show cause why the registration should not be denied.

(b) If, upon information gathered by the Commission regarding any registrant, the director determines that the registration of such registrant is subject to suspension or revocation pursuant to G.S. 90-103, the Commission shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before the director at a time and place stated in the order which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation or suspension of registration and a summary of the matters of fact and law asserted.

(d) When authorized by the Commission, any agent of the Department of Health and Human Services may serve the order to show cause.

(e) All show cause hearings shall be conducted according to the Administrative Procedure Act, G.S. 150B, Article 3.

History Note: *Authority G.S. 90-100; 90-103; 143B-147(a)(5);*
Eff. June 30, 1978;
Amended Eff. May 1, 1990; May 15, 1979;
Recodified from 10A NCAC 26E .0121 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0124 HEARINGS GENERALLY

In a case where the Commission shall hold a hearing on any registration or application, the hearing officer shall follow the requirements of the Administrative Procedure Act, Chapter 150B, Article 3.

History Note: *Authority G.S. 90-100; 90-102; 90-103; 143B-147(a)(5);*
Eff. June 30, 1978;
Amended Eff. May 1, 1990; May 15, 1979
Recodified from 10A NCAC 26E .0122 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0125 MODIFICATION IN REGISTRATION

Any registrant may apply to modify his registration to authorize the handling of additional controlled substances by submitting a letter of request to the director. The letter shall contain the registrant's name, address, registration number and the substances and schedules to be added to his registration. If the registrant is seeking to handle additional controlled substances listed in Schedules I and VI for the purpose of research or instructional activities, he shall attach evidence of federal registration to conduct research with such controlled substances. The request for modification shall be handled in the same manner as an application for registration. If the modification and registration is approved, the director shall issue a new certificate of registration (Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 223) to the registrant, who shall maintain it with the old certificate of registration until expiration.

History Note: *Authority G.S. 90-100; 143B-147(a)(5);*

Eff. June 30, 1978;
Amended Eff. May 1, 1990; May 15, 1979;
Recodified from 10A NCAC 26E .0123 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0126 TERMINATION OF REGISTRATION

The registration of any person shall terminate if and when such person dies, ceases legal existence, discontinues business or professional practice or changes his name or address as shown on the certificate of registration. Any registrant who ceases legal existence, discontinues business or professional practice or changes his name or address as shown on the certificate of registration shall notify the director promptly of such fact. In the event of a change in name or address, the person may apply for a new certificate of registration in advance of the effective date of such change by filing an application. The application shall be handled in the same manner as an application for registration.

History Note: *Authority G.S. 90-100; 143B-210(9);*
Eff. June 30, 1978;
Amended Eff. May 15, 1979;
Recodified from 10A NCAC 26E .0124 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0127 TRANSFER OF REGISTRATION

No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the director may specifically designate and then only pursuant to his written consent.

History Note: *Authority G.S. 90-100; 143B-210(9);*
Eff. June 30, 1978;
Amended Eff. May 15, 1979;
Recodified from 10A NCAC 26E .0125 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0128 EXEMPTION FROM REGISTRATION

(a) The requirement of registration is waived for homes for the aged and infirm and for agents and employees of homes for aged and infirm so long as such agents or employees are acting in the usual course of their business or employment.
(b) The requirement of registration is waived for community based residential programs that have nine or fewer beds for individuals who are mentally ill, mentally retarded or developmentally disabled and for agents and employees of community based residential programs that have nine or fewer beds for individuals who are mentally ill, mentally retarded or developmentally disabled so long as such agents or employees are acting in the course of their business or employment.

History Note: *Authority G.S. 90-100; 90-101(d); 143B-147;*
Eff. June 30, 1978;
Amended Eff. May 1, 1990; August 1, 1985;
Recodified from 10A NCAC 26E .0126 Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0129 SECURITY REQUIREMENTS GENERALLY

(a) Any person who manufactures, distributes, dispenses, or conducts research with any controlled substance shall comply with Part 1301 of Title 21 of the Code of Federal Regulations, which sets forth security requirements.
(b) This compliance shall be deemed in compliance with G.S. 90-100, G.S. 90-101(a) and G.S. 90-102(a), Article 5.

History Note: *Authority G.S. 90-100; 143B-147;*
Eff. July 1, 1994;
Recodified from 10A NCAC 26E .0127 Eff. February 1, 2005;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

SECTION .0200 - LABELING AND PACKAGING CONTROLLED SUBSTANCES: RECORDS OF REGISTRANTS

10A NCAC 26E .0201 LABELING AND PACKAGING REQUIREMENTS GENERALLY

Compliance with the labeling and packaging of controlled substance requirements of federal law, including the requirements presented in Part 1302 and Sections 1306.14 and 1306.24 of Title 21 of the Code of Federal Regulations, shall be deemed compliance under General Statute 90-106(f) with the addition that a physician dispensing any controlled substance shall affix to the package a label showing the date, the physician's name and address, the name of the patient, the name of the controlled substance and directions for use and cautionary statements, if any, which the physician feels necessary or which are required by law.

History Note: *Authority G.S. 90-100; 90-104; 143B-210(9);*
Eff. June 30, 1978;
Amended Eff. September 30, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0202 RECORD AND INVENTORY REQUIREMENTS GENERALLY

Compliance with the record and inventory requirements of federal law, including the requirements presented in Part 1304 of the Code of Federal Regulations, shall be deemed compliance under G.S. 90-104.

History Note: *Authority G.S. 90-104;*
Eff. June 30, 1978;
Amended Eff. May 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

SECTION .0300 - PRESCRIPTIONS

10A NCAC 26E .0301 PRESCRIPTION REQUIREMENTS GENERALLY

Compliance with the prescription requirements of the federal law, including the requirements presented in Part 1306 of Title 21 of the Code of Federal Regulations, shall be deemed compliance under General Statute Chapter 90, Article 5.

History Note: *Authority G.S. 90-100; 90-106; 143B-147;*
Eff. June 30, 1978;
Amended Eff. August 1, 1987; July 1, 1982;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0302 NONPRESCRIPTION REQUIREMENTS GENERALLY

Compliance with the requirements for dispensing without prescriptions, of the federal law, including the requirements presented in Part 1306 of Title 21 of the Code of Federal Regulations shall be deemed compliance under General Statute Chapter 90, Article 5.

History Note: *Authority G.S. 90-106;*
Eff. June 30, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0303 USE OF CONTROLLED SUBSTANCES IN SCHEDULE VI

(a) Pursuant to General Statute 90-113.3 the Department of Health and Human Services is authorized to engage in research in the misuse and abuse of Schedule VI controlled substances. The Department of Health and Human Services is also authorized to enter into contracts with other public agencies, institutions of higher education and private

organizations or individuals for the purpose of research on the misuse and abuse of Schedule VI controlled substances. Other than through the authority of the Department of Health and Human Services or proper evidence of federal registration to conduct research in accordance with General Statutes 90-102(c) and (d), no other person is authorized to use Schedule VI controlled substances.

(b) Practitioners licensed pursuant to Chapter 90, Article 5, may dispense Tetrahydrocannabinol (THC) as an antiemetic agent in cancer chemotherapy. Compliance with the dispensing requirements of the federal law including the requirements presented in Part 1306 of Title 21 of the Code of Federal Regulations relating to Tetrahydrocannabinol (THC) shall be deemed compliance under General Statute 90, Article 5.

History Note: *Authority G.S. 90-113.3;*
Eff. June 30, 1978;
Amended Eff. September 15, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0304 HOSPITALS HAVING 24-HOUR PHARMACY SERVICE

In those hospitals having 24-hour outpatient pharmacy service, all controlled substances dispensed to outpatients including emergency department patients must be dispensed by a pharmacist.

History Note: *Authority G.S. 90-100; 143B-147(a)(5);*
Eff. June 30, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0305 HOSPITALS NOT HAVING 24-HOUR PHARMACY SERVICE

In those hospitals not having 24-hour outpatient pharmacy services or those hospitals having no outpatient pharmacy services, controlled substances dispensed to emergency department patients when the pharmacy service is closed shall follow this procedure:

(1) All controlled substances shall be dispensed to a bona fide patient, or his agent, of the emergency room pursuant to the written or verbal order of a licensed practitioner who is registered with the Federal Drug Enforcement Administration to prescribe or dispense controlled substances.

(2) The pharmacist designated by the hospital shall be responsible for developing and supervising a system of control and accountability of all controlled substances administered in or dispensed from the emergency department.

(3) The hospital's emergency department committee (or like group or person responsible for policy in that department) in conjunction with the hospital pharmacy shall develop an emergency department formulary or controlled substances list of those controlled substances which may be dispensed from the emergency department for patients receiving care in that department. This formulary or controlled substances list shall consist of controlled substances of the nature and type to meet the immediate need of emergency department patients, and quantities in each container shall be limited to not more than a 24-hour supply.

(4) Such controlled substances shall be prepackaged in suitable safety closure containers and shall be appropriately prelabeled (including necessary auxiliary labels) by the pharmacy so as to provide for all label information necessary for use as well as other information required by law.

(5) At the time of delivery of the controlled substance, the physician, or physician assistant or a registered nurse under his direction shall appropriately complete the label and initial it.

(6) A suitable and perpetual record of dispensing of these controlled substances shall be maintained in the emergency department. The pharmacist shall verify the correctness of this record at least once a week.

(7) The dispenser shall sign the record of dispensing that is maintained in the emergency department to verify the controlled substance ordered.

(8) When the controlled substances are delivered, the appropriately labeled, prepackaged container of the controlled substance shall be checked for correctness and given to the patient by the physician or by a person authorized to prescribe or dispense controlled substances pursuant to G.S. 90-18.1 or by a registered nurse or physician assistant under the supervision of the ordering physician.

History Note: *Authority G.S. 90-100; 143B-147(a)(5);*

Eff. June 30, 1978;
Amended Eff. May 1, 1990; January 14, 1981; September 15, 1980; September 30, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0306 SUPPLYING OF METHADONE IN TREATMENT PROGRAMS BY RN

(a) Methadone or other medications approved for use in narcotic addiction treatment by the Food and Drug Administration, and under the North Carolina Controlled Substances Act, may be supplied to a bona fide patient of a methadone treatment program.

(b) Methadone may be supplied by either a registered nurse or a licensed practical nurse employed by that program, provided the methadone is supplied pursuant to the order of the program's medical director, who is a licensed physician registered with the Federal Drug Enforcement Administration to dispense controlled substances in the applicable schedule.

(c) The program's medical director shall countersign or sign in the medical record of the program all orders for methadone or other medications approved for use in narcotic addiction treatment by the Food and Drug Administration and under the North Carolina Controlled Substances Act within 72 hours of the initiation of the order.

(d) For purposes of this Rule, supplying shall not include prescribing or compounding.

History Note: *Authority G.S. 90-100; 143B-147(a)(5);*
Eff. June 30, 1978;
Amended Eff. May 1, 1990;
Amended Eff. August 1, 2002;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0307 PREPRINTED PRESCRIPTION BLANKS PROHIBITED

The preprinting of or use of preprinted prescription blanks with the name of Schedule II through V Controlled Substances shall be prohibited.

History Note: *Authority G.S. 90-100; 143B-147;*
Eff. April 1, 1983;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0308 USE OF SYNTHETIC CANNABINOIDS IN SCHEDULE II

Practitioners licensed pursuant to Chapter 90, Article 5, may dispense the following synthetic cannabinoids only as an antiemetic agent in cancer chemotherapy:

(1) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatine capsule in a U.S. Food and Drug Administration approved drug product; and
(2) Nabilone.

History Note: *Authority G.S. 90-90; 90-100; 90-101(h); 143B-147;*
Eff. December 1, 1986;
Amended Eff. December 1, 1987;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

SECTION .0400 - MISCELLANEOUS

10A NCAC 26E .0401 DEFINITIONS

As used in this Section, the following terms shall have the meanings specified:

(1) The term "act" means the North Carolina Controlled Substances Act (G.S. 90, Article 5).
(2) Any term not defined in this Rule shall have the definition set forth in G.S. 90-87 and Rule .0102 of this Subchapter.

History Note: *Authority G.S. 90-100; 143B-147;*

Eff. June 30, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0402 APPLICATION OF OTHER STATE LAW AND FEDERAL LAW

Nothing in Sections .0100 through .0500 of this Subchapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under federal laws or obligations under international treaties, conventions or protocols or under other law of the state, nor shall compliance with such parts be construed as compliance with federal or state laws expressly provided in such other laws.

History Note: *Authority G.S. 90-100; 143B-147;*
Eff. June 30, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0403 DISTRIBUTION TO SUPPLIER

Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he obtained it or to the manufacturer of the substance, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address and registration number, if known, of the supplier or manufacturer. In the case of returning a controlled substance listed in Schedule I, II or VI, a Federal Drug Enforcement Order Form shall be used and be maintained as the written record of the transaction. Any person not required to register pursuant to G.S. 90-101 shall be exempt from maintaining the records required by this Rule.

History Note: *Authority G.S. 90-100; 143B-147;*
Eff. June 30, 1978;
Amended Eff. September 30, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0404 DISCONTINUANCE OR TRANSFER OF BUSINESS

Any registrant desiring to discontinue or transfer business activities altogether or with respect to controlled substances shall return his certificate of registration to the director for cancellation.

History Note: *Authority G.S. 90-100; 143B-210(9);*
Eff. June 30, 1978;
Amended Eff. May 15, 1979;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0405 PROCEDURE FOR DISPOSING OF CONTROLLED SUBSTANCES

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance (e.g., upon discontinuance or transfer of business) shall be in compliance with the State requirements as long as the requirements prescribed in Part 1307 of Title 21 of the Code of Federal Regulations, as amended, are met.
(b) Any pharmacy, as defined in G.S. 90-87, licensed by the North Carolina Board of Pharmacy and not subject to registration by the Department, as defined in G.S. 122C-3, shall comply with State requirements set forth in 21 NCAC 46 .3001(c).

History Note: *Authority G.S. 90-100; 143B-147;*
Eff. June 30, 1978;
Amended Eff. July 1, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0406 DISPOSAL OF UNUSED CONTROLLED SUBSTANCES FROM NURSING HOME

Controlled substances dispensed for inpatient administration to individuals residing in a licensed nursing home, which, for any reason, are unused, shall be returned to the pharmacy from which they were received. The pharmacy that receives these controlled substances shall return them to its stock or dispose of and destroy them in accordance with 21 CFR 1317.05(a). The pharmacy shall keep a record of the disposal and destruction of unused controlled substances available for a minimum of two years. This record of disposal and destruction shall be kept on the Division of Mental Health, Developmental Disabilities, and Substance Use Services (Division) form entitled "Record of Controlled Substances Destroyed pursuant to Rule 10A NCAC 26E .0406". This form is available upon request at Drug Control Unit 3008 Mail Service Center Raleigh, NC 27699-3008 or nccsareg@dhhs.nc.gov. Controlled substances returned to stock must be in a hermetically sealed container or in a pure uncontaminated condition and be identifiable. A pharmacy may outsource destruction of the unused controlled substances to a reverse distributor in accordance with 21 CFR 1317.05(a)(2), provided the pharmacy must first verify the reverse distributor is registered with the federal Drug Enforcement Agency (DEA) as a reverse distributor and maintains compliance with all applicable federal and State laws and regulations governing reverse distributors and destruction of unused controlled substances per 21 CFR 1317.15. Compliance with this Rule is subject to audit by the Division Director or their designated representative.

History Note: *Authority G.S. 90-100; 143B-147;*
Eff. June 30, 1978;
Amended Eff. September 15, 1980; May 15, 1979;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Emergency Amendment Eff. September 25, 2024;
Temporary Amendment Eff. January 2, 2025.

10A NCAC 26E .0407 DISPOSAL BY REGISTRANTS AND PRACTITIONERS: SCHEDULES II-V

The destruction of a controlled substance in Schedules II, III, IV and V by a registrant or practitioner or by his authorized agent shall be witnessed by the director or his designated representative or a state or federal official authorized to enforce the Federal Controlled Substances Act or the North Carolina Controlled Substances Act except when a dose/doses of any controlled substance is accidentally contaminated at a nursing station or adjacent area, the controlled substance may be destroyed at the pharmacy or nursing station by a practitioner, a registered nurse or a licensed practical nurse; provided a record of destruction is made on a controlled substance disposition record showing the date, time, quantity, manner of destruction, and type of controlled substance, and the initials or signatures of persons destroying and witnessing the destruction. The destruction shall be in accordance with the procedures outlined by the director and a record of this destruction shall be kept available by the registrant or practitioner for a minimum of two years.

History Note: *Authority G.S. 90-100; 143B-147;*
Eff. June 30, 1978;
Amended Eff. July 1, 1982; September 14, 1981; May 15, 1979; September 30, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0408 SPECIAL CONTROLLED SUBSTANCES EMERGENCY KIT

(a) A (special) controlled substances emergency kit shall be permitted in those skilled nursing facilities, intermediate care facilities and combination facilities which are licensed with the Department of Health and Human Services:
(b) The controlled substances emergency kit shall contain not more than seven controlled drug entities (Schedules II-V) as determined by the medical staff of the facility with the approval of the pharmaceutical services committee.
(c) Controlled substances for emergency use shall be obtained through purchase orders from the licensed pharmacist who regularly provides medications to the facility and its patients. When Schedule II drugs are purchased, federal Drug Enforcement Administration order forms must be used.
(d) Controlled substances for emergency use shall be provided in a single unit-dose form.
(e) A facility shall be permitted to possess not more than five doses of each controlled drug entity for each 50 licensed beds or fraction thereof. The five doses of each drug entity may be of the same or differing concentrations.
(f) The controlled emergency drug supply shall be used to meet the urgent needs of patients, consistent with good medical practice. The need for such use shall be documented in the patient's medical record consistent with applicable state and federal statutes and regulations.
(g) The controlled substance emergency kit shall be securely locked and stored with access limited to authorized personnel.

(h) Only those persons designated by the director of the facility shall have access to the controlled substances emergency kit.
(i) The pharmacist-supplier of the controlled drugs for emergency use shall have primary responsibility for the proper control and accountability of such drugs in the facility.
(j) No person, individual, practitioner or facility shall be permitted to perform by virtue of these regulations any act otherwise prohibited by law.
(k) Nothing in these regulations shall compel any licensed pharmacist to provide controlled drugs for emergency use to any facility against his professional judgment.
(l) Requirements contained in North Carolina Board of Pharmacy rule 21 NCAC 46 .1414(i) relating to emergency kits generally shall apply.
(m) Exceptions to these regulations shall not be made unless otherwise provided by law.
(n) Each registrant desiring to maintain a controlled substance emergency kit must be registered with the Federal Drug Enforcement Administration or receive an exemption from registration by that agency.

History Note: *Authority G.S. 90-100; 143B-147;*
Eff. June 30, 1978;
Amended Eff. September 30, 1978;
Temporary Amendment Eff. June 15, 1999;
Temporary Amendment Expired February 28, 2000;
Codifier determined that findings did not meet criteria for temporary rule on May 22, 2000;
Temporary Amendment Eff. May 30, 2000;
Amended Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0409 DISPOSAL OF UNUSED PORTIONS OF INJECTABLE: SCHEDULES II-V
Both the amount of the injectable Schedules II-V controlled substance administered to the patient and the amount destroyed shall be recorded on the controlled substances disposition document or the patient's medical record with initials of individual administering and destroying the injectable controlled substance. Other procedures of documenting this information shall be submitted to the director for approval before implementation.

History Note: *Authority G.S. 90-100; 143B-147;*
Eff. June 30, 1978;
Amended Eff. May 15, 1979; September 30, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0410 RECORD OF ALL CONTROLLED SUBSTANCES DISPENSED
Practitioners shall maintain a readily retrievable record of all controlled substances dispensed whether or not the practitioner charges the patient for the controlled substance.

History Note: *Authority G.S. 90-100; 143B-147;*
Eff. September 15, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

SECTION .0500 - ADMINISTRATIVE FUNCTIONS: PRACTICES AND PROCEDURES

10A NCAC 26E .0501 SCOPE
Procedures regarding administrative inspections pursuant to General Statutes 90-101(f) and 90-107 are governed generally by those sections and specifically by the rules of this Section.

History Note: *Authority G.S. 90-101; 90-107;*
Eff. June 30, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0502 DEFINITIONS

As used in this Section, the following terms shall have the meanings specified:

(1) The term "act" means the North Carolina Controlled Substances Act (General Statute Chapter 90, Article 5);

(2) The term "commission" means the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services;

(3) The term "controlled premises" means places where original or other records or documents required under the act are kept or required to be kept; and places, including factories, warehouses or other establishments and conveyances where persons registered under the act or exempted from registration under the act may lawfully hold, manufacture or distribute, dispense, administer or otherwise dispose of controlled substances;

(4) The term "director" means the Director of the Division of Mental Health, Developmental Disabilities and Substance Abuse Services;

(5) The term "inspector" means an officer or employee of the Department of Health and Human Services authorized by the director to make inspections under the act;

(6) The terms "register" and "registration" refer to registration required; and

(7) Any term not defined in this Rule shall have the definition set forth in General Statute 90-87.

History Note: *Authority G.S. 90-100; 143B-210(9);*
Eff. June 30, 1978;
Amended Eff. August 1, 1990; May 15, 1979;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0503 AUTHORITY TO MAKE INSPECTIONS

(a) In carrying out his functions under the act, the director through his inspectors, is authorized in accordance with General Statutes 90-101(f) and 90-107 to enter controlled premises and conduct administrative inspections thereof for the purpose of:

(1) inspecting, copying and verifying the correctness of records, reports or other documents required to be kept or made under the act and the regulations promulgated under the act, including but not limited to inventory and other records required to be kept pursuant to Section .0200 of this Subchapter, prescription and distribution records required to be kept pursuant to Section .0300 of this Subchapter, shipping records identifying the name of each carrier used and the date and quantity of each shipment and storage records identifying the names of each warehouse used and the date and quantity of each storage;

(2) inspecting within reasonable limits and in a reasonable manner all pertinent equipment, finished and unfinished, controlled substances and other substances or materials, containers and labeling found at the controlled premises relating to this act;

(3) making a physical inventory of all controlled substances on hand at the premises;

(4) collecting samples of controlled substances or precursors; (In the event any samples are collected during an inspection, the inspector shall issue a receipt for such samples on Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 84 to the owner, operator or agent in charge of the premises.)

(5) checking of records and information on distribution of controlled substances by the registrant as they relate to total distribution of the registrant (i.e., has the distribution in controlled substances increased markedly within the past year, and if so, why); and

(6) except as provided in Section .0500 of this Subchapter, all other things therein (including records, files, papers, processes, controls and facilities) appropriate for verification of the records, reports, documents referred to above or otherwise bearing on the provisions of the act and the regulations thereunder.

(b) All inspections shall be conducted during regular business hours and shall be completed in a reasonable manner.

(c) All inspections shall be conducted in accordance with applicable provisions of the Constitution of the United States and the State of North Carolina. In any event, the owner (or operator) of the premises, as the case may be, shall be given reasonable notice of the time, place, purpose and identity of the person or persons conducting the inspection.

History Note: *Authority G.S. 90-101; 90-107;*

Eff. June 30, 1978;
Amended Eff. August 1, 1990; May 15, 1979;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0504 EXCLUSION FROM INSPECTION

Unless the owner, operator or agent in charge of the controlled premises so consents in writing, no inspection authorized by these regulations shall extend to:

(1) financial data,
(2) sales data other than shipping date, or
(3) pricing data.

History Note: *Authority G.S. 90-101; 90-107;*
Eff. June 30, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0505 ENTRY

An inspection shall be carried out by an inspector. Any such inspector, upon:

(1) stating his purpose;
(2) presenting to the owner, operator or agent in charge of the premises to be inspected appropriate credentials; and
(3) receiving informed consent, shall have the right to enter such premises and conduct inspections at reasonable times and in a reasonable manner.

If entry to inspect premises is denied an inspector by a registrant or an applicant for registration, a written notice of inspection as described in Rule .0506 of this Section shall be obtained and executed.

History Note: *Authority G.S. 90-101; 90-107;*
Eff. June 30, 1978;
Amended Eff. May 15, 1979; September 30, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0506 NOTICE OF INSPECTION

The notice of inspection (Commission for Mental Health, Developmental Disabilities and Substance Abuse Services Form 82) shall contain:

(1) the name and title of the owner, operator or agent in charge of the controlled premises;
(2) the controlled premises name;
(3) the address of the controlled premises to be inspected;
(4) the date and time of the inspection;
(5) a statement that a notice of inspection is given; and
(6) the signature of the inspector.

History Note: *Authority G.S. 90-101;*
Eff. June 30, 1978;
Amended Eff. August 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

SECTION .0600 - CONTROLLED SUBSTANCES REPORTING SYSTEM

10A NCAC 26E .0601 SCOPE

The rules of this Section as well as the provisions of Chapter 90, Article 5E shall govern requirements for the controlled substances reporting system as set forth in G.S. 90-113.70.

History Note: *Authority G.S. 90-113.70; 90-113.76;*

Temporary Adoption Eff. January 1, 2007;
Eff. April 1, 2007;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0602 DEFINITIONS

(a) As used in this Section, the following terms shall have the meanings as specified:

(1) "Controlled substance reporting system (CSRS)" means the reporting system as set forth in Article 5E of Chapter 90.

(2) "ASAP" means the American Society for Automation in Pharmacy.

(3) "DEA" means the Drug Enforcement Administration responsible for enforcing the controlled substances laws and regulations of the United States.

(4) "Delegate Account Holder" means a person designated to review records of the CSRS with the written approval of the Master Account Holder.

(5) "DHHS" means North Carolina Department of Health and Human Services.

(6) "Dispense" means the same as defined in G.S. 90-87.

(7) "Dispenser" means the same as defined in G.S. 90-113.72 and 90-113.73(f).

(8) "Good faith" means an attempt to report the information required by G.S. 90-113.73(b) that was unsuccessful due to a temporary electrical or technological failure impacting the transmission of data to the CSRS.

(9) "Master Account Holder" means a practitioner, as defined in G.S. 90-87, who has current DEA registration.

(A) "Zero Reporting" means the following: instances when a dispenser who, except as provided in G.S. 90-113.73(c) and (d), fails to comply with the reporting provisions of 90-113.73; or

(B) instances when a dispenser does not dispense any Schedule II – IV controlled substances during the previous business day.

(10) "Pharmacist-patient Relationship" means a consensual relationship in which an individual seeks pharmaceutical care from a pharmacist, and the pharmacist affirmatively acts to provide pharmaceutical care, or agrees to do so.

(11) "Prescriber-patient Relationship" means a consensual relationship in which an individual seeks medical care from a prescriber, and the prescriber affirmatively acts to provide medical care, or agrees to do so.

(12) "Data Errors Notification" means a written notification from DHHS to a dispenser of failure to report data as required by G.S. 90-113.73 and of errors related to the submission of that data. Errors occur when information required per Rule 10A NCAC 26E .0604(a) is omitted, incomplete, or submitted late.

(b) Any term not defined in this Section shall have the same definitions as set forth in G.S. 90-87 and 90-113.72.

History Note: *Authority G.S. 90-113.76;*
Temporary Adoption Eff. January 1, 2007;
Eff. April 1, 2007;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. November 1, 2022.

10A NCAC 26E .0603 REQUIREMENTS FOR TRANSMISSION OF DATA

(a) Each dispenser shall transmit to the Department the data as set forth in G.S. 90-113.73. The data shall be transmitted in the ASAP Telecommunication Format for Controlled Substances, published by the American Society for Automation in Pharmacy that is in use in the majority of states operating a controlled substance reporting system.

(b) The dispenser shall transmit the data electronically unless the Department approves a request for submission on paper as set forth in Paragraphs (e) and (f) of this Rule.

(c) The dispenser's electronic transfer data equipment including hardware, software and internet connections shall be in compliance with the Health Insurance Portability and Accountability Act as set forth in 45 CFR, Part 164.

(d) Each electronic transmission shall meet data protection requirements as follows:

(1) Data shall be at least 128B encryption in transmission and at rest; or

(2) Data shall be transmitted via secure file transfer protocol. Once received, data at rest shall be encrypted.

(e) The data may be submitted on paper if the dispenser submits a written request to the Department and receives prior approval.
(f) The Department shall consider the following in granting approval of the request:
(1) The dispenser does not have a computerized record keeping system; or
(2) The dispenser is unable to conform to the submission format required by the database administrator without incurring expenses over three thousand dollars ($3,000).
(g) The dispenser shall report the data pursuant to the requirements of G.S. 90-113.73(a).

History Note: *Authority G.S. 90-113.70; 90-113.73; 90-113.76;*
Temporary Adoption Eff. January 1, 2007;
Eff. April 1, 2007;
Amended Eff. January 1, 2012;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26E .0604 REPORTING REQUIREMENTS
(a) Each dispenser shall report the following information to the Controlled Substances Reporting System in accordance with the time frames provided in G.S. 90-113.73:
(1) the dispenser's DEA number;
(2) the name of the patient for whom the controlled substance is being dispensed as well as the patient's:
(A) full address including apartment number where applicable, city, state, and zip code;
(B) telephone number; and
(C) date of birth;
(3) the date the prescription was written;
(4) the date the prescription was filled;
(5) the prescription number;
(6) whether the prescription is new or a refill;
(7) the metric quantity of the drug dispensed;
(8) the estimated days of supply of the dispensed drug, if provided to the dispenser;
(9) the national drug code of the dispensed drug;
(10) the prescriber's DEA number;
(11) the prescriber's national provider identification number, for any prescriber that has one provided, however, a pharmacy shall not be subject to a civil penalty under G.S. 90-113.73(e) for failure to report the prescriber's national provider identification number when it is not received by the pharmacy; and
(12) the method of payment for the prescription.
(b) DHHS shall notify the dispenser of failure to report data as required by G.S. 90-113.73 and any reporting errors related to that submission, in writing, within ten business days of detecting the error.
(c) The dispenser shall correct the error(s) and resubmit the required information, via his or her dispensation software, within ten calendar days of the date of the written notification.

History Note: *Authority G.S. 90-113.73;*
Eff. November 1, 2022.

10A NCAC 26E .0605 PENALTIES
(a) DHHS shall consider the following factors in determining the amount of each civil penalty assessed against a person who violates Chapter 90, Article 5E:
(1) whether the violation involved an improper attempt to obtain or release information from the CSRS;
(2) whether the person succeeded in improperly obtaining or releasing information from the CSRS;
(3) whether the person committed the violation intentionally, knowingly, or negligently;
(4) the frequency of the violations the person has committed; and
(5) the number of violations the person has committed.
(b) DHHS shall consider these additional factors in determining the amount of civil penalty assessed against a pharmacy that employs dispensers who fail to report information in accordance with G.S. 90-113.73(e):
(1) whether it is a first, second, third, or subsequent violation within a calendar year;
(2) whether it is a continuing violation;

(3) whether the pharmacy has acted in good faith in attempting to report the required information.

History Note: *Authority G.S. 90-113.73; 90-113.75;*
Eff. November 1, 2022.

SUBCHAPTER 26F – CONTROLLED SUBSTANCES

SECTION .0100 - SCHEDULES OF CONTROLLED SUBSTANCES

10A NCAC 26F .0101 DEFINITIONS

As used in this Section, the following terms shall have the meanings specified:

(1) The term "act" means the North Carolina Controlled Substances Act (G.S. Chapter 90, Article 5).

(2) The term "basic class" means, as to controlled substances listed in Schedules I, II and VI:

(a) Each of the opiates, including its isomers, esters, ethers, salts and salts of isomers, esters, ethers and salts is possible within the specific chemical designation listed in Schedule I of the North Carolina Controlled Substances Act;

(b) Each of the opium derivatives, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation listed in Schedule I of the North Carolina Controlled Substances Act;

(c) Each of the hallucinogenic substances, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation listed in Schedule I of the North Carolina Controlled Substances Act;

(d) Each of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

(i) opium, including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, deodorized opium and tincture of opium;
(ii) apomorphine;
(iii) codeine;
(iv) etorphine hydrochloride;
(v) ethylmorphine;
(vi) hydrocodone;
(vii) hydromorphine;
(viii) metopon;
(ix) morphine;
(x) oxycodone;
(xi) oxymorphone;
(xii) thebaine;
(xiii) mixed alkaloids of opium listed in Schedule I of the North Carolina Controlled Substances Act;
(xiv) cocaine; and
(xv) ecgonine;

(e) Each of the opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters and ethers, and salts is possible within the specific chemical designation, listed in Schedule II of the North Carolina Controlled Substances Act;

(f) Methamphetamine, its salts, isomers and salts of its isomers;

(g) Amphetamine, its salts, optical isomers and salts of its optical isomers;

(h) Phenmetrazine and its salts;

(i) Methylphenidate;

(j) Each of the substances having a depressant effect on the central nervous system, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of

isomers is possible within the specific chemical designation listed in Rule .0205 of this Section.

(3) The term "hearing" means any hearing held pursuant to this part for the addition, deletion or rescheduling of any substances within Schedules I through VI of the North Carolina Controlled Substances Act.

(4) The term "isomer" means, except as used in Paragraph .0202(d) of this Section, the optical isomer. As used in Paragraph .0202(d) of this Section, the term "isomer" means the optical, position or geometric isomer.

(5) The term "interested person" means any person affected by any decision issuable pursuant to General Statute 90-88.

(6) The term "proceeding" means all actions taken for the addition, deletion, or rescheduling of any substance within Schedules I through VI of the North Carolina Controlled Substances Act, issued pursuant to General Statute 90-88, commencing with the publication by the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services of the proposed addition, deletion or rescheduling.

(7) The term anabolic steroid means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids) that promotes muscle growth, and includes:

(a) Boldenone;
(b) Chlorotestosterone (4-chlortestosterone);
(c) Clostebol;
(d) Dehydrochlormethyltestosterone;
(e) Dihydrotestosterone (4-dihydrotestosterone);
(f) Drostanolone;
(g) Ethylestrenol;
(h) Fluoxymesterone;
(i) Formebulone (formebolone);
(j) Mesterolone;
(k) Methandienone;
(l) Methandranone;
(m) Methandriol;
(n) Methandrostenolone;
(o) Methenolone;
(p) Methyltestosterone;
(q) Mibolerone;
(r) Nandrolone;
(s) Norethandrolone;
(t) Oxandrolone;
(u) Oxymesterone;
(v) Oxymetnolone;
(w) Stanolone;
(x) Stanozolol;
(y) Testolactone;
(z) Testosterone;
(aa) Trenbolone; and
(bb) Any salt, ester, or isomer of a drug or substance described or listed in this Paragraph, if that salt, ester, or isomer promotes muscle growth. Except such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for such administration. If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this Paragraph.

(8) Any term not defined in this Rule shall have the definition set forth in General Statute 90-87.

History Note: *Authority G.S. 90-88;*
Eff. June 30, 1978;

Amended Eff. September 1, 1998; August 1, 1991; May 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26F .0102 SCHEDULE I

(a) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated and as specified in G.S. 90-89. Each drug or substance has been assigned the Drug Enforcement Administration controlled substances code number set forth in the Code of Federal Regulations, Title 21, Section 1308.11.

(b) The Commission for MH/DD/SAS may add, delete, or reschedule substances within Schedules I-VI as specified in G.S. 90-88.

(c) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds the following substance within Schedule I for Stimulants:

(1) 2, 5 - Dimethoxy-4-(n)- propylthiophenethylamine; and
(2) N-Benzylpiperazine.

(d) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds the following substance within Schedule I for Hallucinogenic substances:

(1) Alpha-Methyltryptamine;
(2) 5-Methoxy-N, N-diisopropyltryptamine;
(3) methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate, (FUB-AMB, MMB-FUBINACA, AMB-FUBINACA) DEA controlled substances code number 7021;
(4) methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate (Other names: MMB-CHMICA; AMB-CHMICA) DEA controlled substances code number 7044;
(5) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (Other name: 5F-AB-PINACA) DEA controlled substances code number 7025;
(6) Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (Other names: NM2201; CBL2201) DEA controlled substances code number 7221;
(7) 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboxamide (Other name: 5F-CUMYL-P7AICA) DEA controlled substances code number 7085;
(8) 1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (Other names: 4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL BINACA; CUMYL-4CN-BINACA; SGT-78) DEA controlled substances code number 7089;
(9) N-ethylpentylone (Other names: ephylone, 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)pentan-1-one) DEA controlled substances code number 7543; and
(10) 1-(4-methoxyphenyl)-N-methylpropan-2-amine (other names: para-methoxymethamphetamine, PMMA) DEA controlled substances code number 1245.

(e) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds the following substance within Schedule I for Opiates:

(1) para-Methoxybutyryl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide) DEA controlled substances code number 9837;
(2) Cyclopentyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide)DEA controlled substances code number 9847;
(3) Isobutyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide) DEA controlled substances code number 9827;
(4) para-Chloroisobutyrvl fentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide) DEA controlled substances code number 9826;
(5) Crotonyl fentanyl ((E)-N-(1-phenethylpiperidin-4-yl)-N-phenylbut-2-enamide) DEA controlled substances code number 9844;
(6) Phenyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylbenzamide; also known as benzoyl fentanyl) DEA controlled substances code number 9841;
(7) para-Methylfentanyl (N-(4-methylphenyl)-N-(1-phenethylpiperidin-4-yl)propionamide; also known as 4-methylfentanyl) DEA controlled substances code number 9817;
(8) ortho-Methyl methoxyacetyl fentanyl (2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide; also known as 2-methyl methoxyacetyl fentanyl) DEA controlled substances code number 9820;

(9) ortho-Methyl acetylfentanyl (N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide; also known as 2-methyl acetylfentanyl) DEA controlled substances code number 9848;
(10) Thiofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylthiophene-2-carboxamide; also known as 2-thiofuranyl fentanyl; thiophene fentanyl) DEA controlled substances code number 9839;
(11) beta-Methyl fentanyl (N-phenyl-N-(1-(2-phenylpropyl)piperidin-4-yl)propionamide; also known as β-methyl fentanyl) DEA controlled substances code number 9856;
(12) beta'-Phenyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N,3-diphenylpropanamide; also known as β'-phenyl fentanyl; 3-phenylpropanoyl fentanyl) DEA controlled substances code number 9842;
(13) 2'-Fluoro ortho-fluorofentanyl (N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide; also known as 2'-fluoro 2-fluorofentanyl) DEA controlled substances code number 9855;
(14) 4′-Methyl acetyl fentanyl (N-(1-(4-methylphenethyl)piperidin-4-yl)-N-phenylacetamide) DEA controlled substances code number 9819;
(15) ortho-Fluorobutyryl fentanyl (N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide; also known as 2-fluorobutyryl fentanyl) DEA controlled substances code number 9846;
(16) Fentanyl carbamate (ethyl (1-phenethylpiperidin-4-yl)(phenyl)carbamate) DEA controlled substances code number 9851;
(17) ortho-Fluoroacryl fentanyl (N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)acrylamide) DEA controlled substances code number 9852;
(18) para-Fluoro furanyl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide) DEA controlled substances code number 9854; and
(19) ortho-Fluoroisobutyryl fentanyl (N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide) DEA controlled substances code number 9853.

History Note: *Authority G.S. 90-88; 90-89; 143B-147;*
Eff. June 30, 1978;
Amended Eff. November 1, 2005; July 1, 1995; November 1, 1994; April 1, 1994; January 1, 1994;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. December 1, 2021.

10A NCAC 26F .0103 SCHEDULE II

(a) Schedule II shall consist of the drugs and other substances by whatever official name, common or usual name, chemical name, or brand name designated and as specified in G.S. 90-90. Each drug or substance has been assigned the Drug Enforcement Administration controlled substances code number set forth in the Code of Federal Regulations, Title 21, Section 1308.12.

(b) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds Lisdexamfetamine, its salts, isomers, and salts of its isomers to Schedule II for Stimulants.

(c) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds Tapendatol, its esters, ethers, salts, isomers and salts of its isomers, esters and ethers to Schedule II for Opiates.

(d) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds fentanyl immediate precursor chemical, N-phenyl-N-(piperidin-4-yl) propionamide (norfentanyl), DEA controlled substances code number 8366, its esters, ethers, salts, isomers and salts of its isomers, esters and ethers, to Schedule II for Opiates.

(e) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds Oliceridine (N-[(3-methoxythiophen-2-yl)methyl]({2-[(9R)-9-(pyridin-2-yl)-6-oxaspiro[4.5]decan-9-yl]ethyl})amine), DEA controlled substances code number 9245, its esters, ethers, salts, isomers and salts of its isomers, esters and ethers, to Schedule II for Opiates.

History Note: *Authority G.S. 90-88; 90-90; 143B-147;*
Eff. June 30, 1978;
Amended Eff. January 1, 1994; April 1, 1993; August 1, 1991; August 1, 1989;
Temporary Amendment Eff. May 13, 1997;
Amended Eff. February 1, 2010; June 1, 2009; August 1, 2002; July 1, 1998;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. December 1, 2021.

10A NCAC 26F .0104 SCHEDULE III

(a) Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated and as specified in G.S. 90-91. Each drug or substitute has been assigned the Drug Enforcement Administration controlled substances code number set forth in the Code of Federal Regulations, Title 21, Section 1308.13.

(b) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds Embutramide to Schedule III for Depressants.

(c) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds Buprenorphine to Schedule III for Narcotic Drugs.

(d) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds for anabolic steroids, including their salts, esters and ethers:

(1) Boldione (androsta-1,4-diene-3,17-dione);
(2) Desoxymethyltestosterone (17[alpha]-methyl-5[alpha]-androst- 2-en-17[beta]-ol) (a.k.a., madol); and
(3) 19-nor-4,9(10)- androstadienedione (estra-4,9(10)-diene- 3,17-dione).

History Note: *Authority G.S. 90-88; 90-91; 143B-147;*
Eff. June 30, 1978;
Amended Eff. July 1, 2011; June 1, 2009; August 1, 2002; August 1, 1991; December 1, 1987; August 1, 1987; July 1, 1982;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26F .0105 SCHEDULE IV

(a) Schedule IV shall consist of the drugs and other substances by whatever official name, common or usual name, chemical name, or brand name designated and listed in either G.S. 90-92 or this Rule. Each drug or substance has been assigned the Drug Enforcement Administration (DEA) controlled substances code number set forth in the Code of Federal Regulations, Title 21, Section 1308.l4.

(b) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds the following substances within Schedule IV for Depressants:

(1) Dichloralphenazone - DEA controlled substances code number 2467;
(2) Zopiclone - DEA controlled substances code number 2784;
(3) Fosporopol - DEA controlled substances code number 2138;
(4) Carisoprodol - DEA controlled substances code number 8192;
(5) Lemborexant - DEA controlled substances code number 2245; and
(6) Remimazolam - DEA controlled substances code number 2846.

(c) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds the following substances within Schedule IV for Stimulants: Serdexmethylphenidate – DEA controlled substances code number 1729.

History Note: *Authority G.S. 90-88; 90-92; 143B-147;*
Eff. June 30, 1978;
Amended Eff. July 1, 1993; January 1, 1989; December 1, 1987; August 1, 1987;
Temporary Amendment Eff. May 28, 1998;
Temporary Amendment Expired March 12, 1999;
Amended Eff. August 1, 2000;
Temporary Amendment Eff. January 1, 2002; February 15, 2001;
Amended Eff. July 1, 2012; July 1, 2011; November 1, 2005; April 1, 2003; August 1, 2002;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. December 1, 2021.

10A NCAC 26F .0106 SCHEDULE V

(a) Schedule V shall consist of the drugs and other substances by whatever official name, common or usual name, chemical name, or brand name designated and listed in either G.S. 90-93 or this Rule. Each drug or substance is set forth in this Rule with its corresponding Drug Enforcement Administration (DEA) controlled substances code number set forth in the Code of Federal Regulations, Title 21, Section 1308.l5.

(b) Narcotic drugs containing non-narcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited

quantities as set forth in this Paragraph, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:

(1) not more than 200 milligrams of codeine per 100 milliliters or per 100 grams,
(2) not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams,
(3) not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams,
(4) not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit,
(5) not more than 100 milligrams of opium per 100 milliliters or per 100 grams,
(6) not more than 0.5 milligrams of difenoxin and not less than 25 micrograms atropine sulfate per dosage unit.

(c) Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers: Pyrovalerone - DEA controlled substances code number 1485.

(d) Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

(1) Lacosamide – DEA controlled substances code number 2746;
(2) Ezogabine – DEA controlled substances number 2779;
(3) Cenobamate – DEA controlled substances number 2720; and
(4) Lasmiditan – DEA controlled substances number 2790.

History Note: *Authority G.S. 90-88; 90-93; 143B-147;*
Eff. June 30, 1978;
Amended Eff. July 1, 2012; February 1, 2010; April 1, 1992; August 1, 1988; December 1, 1987; April 1, 1983;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. December 1, 2021; March 1, 2021; January 1, 2019.

10A NCAC 26F .0107 SCHEDULE VI

(a) Schedule VI shall consist of the drugs and other substances by whatever official name, common or usual name, chemical name or brand name designated listed in this Rule. Each drug or substance has been assigned the Drug Enforcement Administration code number set forth opposite it:

Tetrahydrocannabinols	7370

(b) Synthetic equivalents of the substances contained in the plant or in the resinous extractives of cannabis, and/or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity such as the following:

1 cis or trans tetrahydrocannabinol and their optical isomers.
6 cis or trans tetrahydrocannabinol and their optical isomers.
3, 4 cis or trans tetrahydrocannabinol and its optical isomers.

(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation, designations of atomic position are covered.)

Marijuana	7360

History Note: *Authority G.S. 90-88(a);*
Eff. June 30, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26F .0108 APPLICATION FOR EXCLUSION OF NONNARCOTIC SUBSTANCE

(a) Any person seeking to have any nonnarcotic substance which may, under the Federal Food, Drug and Cosmetic Act (21 USC 301), as amended, be lawfully sold over the counter without a prescription, excluded from any schedule, pursuant to General Statute Chapter 90-88(e) may apply to the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services.

(b) An application for an exclusion under this Section shall contain the following information:

(1) the name and address of the applicant,

(2) the name and the substance for which exclusion is sought, and

(3) the complete quantitative composition of the substance.

(c) The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services may reject an application for filing, giving the reason therefor, if any of the requirements prescribed in Paragraph (b) of this Rule is lacking or is not set forth so as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of Paragraph (b) of this Rule. If accepted for filing, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall publish general notice in three newspapers of statewide circulation qualified for legal advertising in accordance with Rule 4 of the North Carolina Rules of Civil Procedure that it will make a determination on the application at its next regularly scheduled meeting. The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall permit any interested person to file written comments or objections to the proposal and shall designate in the notice the time during which such filings may be made.

(d) After consideration of the application and any comments on or objections to its proposed decision at its next regularly scheduled meeting, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall issue and publish in three newspapers of statewide circulation qualified for legal advertising in accordance with Rule 4 of the North Carolina Rules of Civil Procedure its final order on the application. This order shall specify the date on which it shall take effect, which shall not be less than 30 days from the date of publication unless the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services finds that conditions of public health or safety necessitate an earlier effective date in which event the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall specify in the order its findings as to such conditions.

(e) In the event a nonnarcotic substance no longer meets the criteria in G.S. 90-88(e), the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services may at any time revoke any exclusion granted pursuant to G.S. 90-88(e) by following the procedures set forth in Paragraphs (c) and (d) of this Rule for handling an application for an exclusion which has been accepted for filing.

History Note: *Authority G.S. 90-88;*
Eff. June 30, 1978;
Amended Eff. May 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26F .0109 EXCLUDED SUBSTANCES

Those drugs which were excluded by the Drug Enforcement Administration on April 1, 1973, under Section 201(g)(1) of Federal Controlled Substances Act [21 USC 811(g)(1)], as amended, have been excluded by the Drug Commission from all schedules pursuant to General Statute Chapter 90-88(e).

History Note: *Authority G.S. 90-88;*
Eff. June 30, 1978;
Amended Eff. September 30, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26F .0110 APPLICATION FOR EXEMPT CHEMICAL PREPARATIONS

(a) Any person seeking to have any preparation or mixture containing controlled substances and one or more noncontrolled substances exempted from the application of all or any part of the act pursuant to General Statute Chapter 90-88(g) may apply to the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services.

(b) An application for an exemption under this Rule shall contain the following information:

(1) the name, address and registration number, if any, of the applicant;

(2) the name, address and registration number, if any, of the manufacturer or importer of the preparation or mixture, if not the applicant;

(3) the exact trade name or other designation of the preparation or mixture;

(4) the complete quantitative composition of all the preparation or mixture (including all active ingredients and noncontrolled substances);

(5) the form of the immediate container in which the preparation or mixture will be distributed with sufficient descriptive detail to identify the preparation or mixture (e.g., bottle, packet, vial, soft plastic pillow, agar gel plate, etc.);
(6) the dimensions or capacity of the immediate container of the preparation or mixture;
(7) the label and labeling, as defined in Rule .0201 of Subchapter 26E of this Chapter and of G.S. 90-106, the North Carolina Controlled Substances Act, as amended, of the immediate container and the commercial containers, if any, of the preparation or mixture;
(8) a brief statement of the facts which the applicant believes justify the granting of an exemption under this Paragraph including information on the use to which the preparation or mixture will be put;
(9) the date of application; and
(10) which of the information submitted on the application, if any, is deemed by the applicant to be a trade secret or otherwise confidential and entitled to protection under any law restricting public disclosure of information.

(c) The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services may require the applicant to submit such documents or written statements of fact relevant to the application as it deems necessary to determine whether the application should be granted.

(d) Within a reasonable period of time after the receipt of an application for an exemption under this Rule, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall notify the applicant of its acceptance or nonacceptance of his application and, if not accepted, the reason therefor. The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services need not accept an application for filing if any of the requirements prescribed in Paragraph (b) of this Rule or requested pursuant to Paragraph (c) of this Rule is lacking or is not set forth as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of Paragraphs (b) and (c) of this Rule. If the application is accepted, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall issue and publish in three newspapers of statewide circulation qualified for legal advertising in accordance with Rule 4 of the North Carolina Rules of Civil Procedure its final order on the application. This order shall specify the date on which it shall take effect which shall not be less than 30 days from the date of publication unless the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services finds that conditions of public health or safety necessitate an earlier effective date in which event the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall specify in the order its findings as to such conditions.

(e) In the event a preparation or mixture containing controlled substance no longer meets the criteria in G.S. 90-88(e) for being excluded, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services may at any time revoke or modify any exemption granted pursuant to this Section by following the procedure set forth in Paragraph (d) of this Rule for handling an application for exemption.

History Note: *Authority G.S. 90-88;*
Eff. June 30, 1978;
Amended Eff. May 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26F .0111 EXEMPT CHEMICAL PREPARATIONS

Those drugs which were exempted by the Drug Enforcement Administration on April 1, 1973, under Sections 302, 303, 305, 306, 307, 308, 309, 1002, 1003, 1004 of the Federal Controlled Substances Act (21 USC 822-3, 825-9, 952-4) as amended, have been exempted by the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services to the same extent described in 21 CFR 308.24(b) through (h) pursuant to G.S. 90-88(g).

History Note: *Authority G.S. 90-88;*
Eff. June 30, 1978;
Amended Eff. May 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26F .0112 APPLICATION FOR EXCEPTION OF A STIMULANT OR DEPRESSANT

(a) Any person seeking to have any compound, mixture or preparation containing any depressant or stimulant substance listed in Paragraph .0204(b) or (c) or in Rule .0205 or in .0206 of this Section excepted from the application of all or any

part of the act, pursuant to G.S. 90-91(i) and 90-92(b), may apply to the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services.

(b) An application for an exception under this Rule shall contain the following information:

(1) the complete quantitative composition of the dosage form,
(2) description of the unit dosage form together with complete labeling,
(3) a summary of the pharmacology of the product including animal investigations and clinical evaluations and studies with emphasis on the psychic or physiological dependence liability, (This must be done for each of the active ingredients separately and for the combination product.)
(4) details of dynergisms and antagonisms among ingredients,
(5) deterrent effects of the noncontrolled ingredients,
(6) complete copies of all literature in support of claims,
(7) reported instances of abuse,
(8) reported and anticipated adverse effects,
(9) number of dosage units produced for the past two years.

(c) The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services may reject an application for filing, giving the reason therefor, if any of the requirements prescribed in Paragraph (b) of this Rule is lacking or is not set forth so as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of Paragraph (b) of this Rule. If accepted for filing, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall publish general notice in three newspapers of statewide circulation qualified for legal advertising in accordance with Rule 4 of the North Carolina Rules of Civil Procedure that it will make a determination on the application at its next regularly scheduled meeting. The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall permit any interested person to file written comments on or objections to the proposal and shall designate in the notice the time during which such filings may be made.

(d) After consideration of the application and any comments on or objections to its proposed decision at its next regularly scheduled meeting, the Director shall issue and publish its final order on the application in three newspapers of statewide circulation qualified for legal advertising in accordance with Rule 4 of the North Carolina Rules of Civil Procedure. This order shall specify the date on which it shall take effect which shall not be less than 30 days from the date of publication unless the Director finds that conditions of public health or safety necessitate an earlier effective date in which event the Director shall specify in the order its findings as to such conditions.

(e) The Director may at any time revoke any exception granted pursuant to G.S. 90-91 or G.S. 90-92(b) by following the procedures set forth in Paragraphs (c) and (d) of this Rule for handling an application for an exception which has been accepted for filing.

History Note: *Authority G.S. 90-88;*
Eff. June 30, 1978;
Amended Eff. May 1, 1990; May 15, 1979;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26F .0113 EXCEPTED COMPOUNDS

Those drugs which were excepted by the Drug Enforcement Administration April 1, 1973, under Section 202(d) of the Federal Controlled Substances Act [21 USC 812(d)] as amended have been excepted by the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services from application of G.S. 90-104, 90-105 and 90-106. Any deviation from the quantitative composition of any of the listed drugs shall require a petition for exception in order for that drug to be excepted.

History Note: *Authority G.S. 90-88;*
Eff. June 30, 1978;
Amended Eff. May 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26F .0114 HEARINGS GENERALLY

In any case where the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall hold a hearing on the addition, deletion or rescheduling of substances within Schedules I through VI of the North Carolina Controlled Substances Act pursuant to G.S. 90-88, the procedures for such hearings and accompanying

proceedings shall be governed generally by the rulemaking procedures set forth in G.S. 150B and specifically by G.S. 90-88 and by these rules and regulations, Departmental rules.

History Note: *Authority G.S. 90-88;*
Eff. June 30, 1978;
Amended Eff. May 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26F .0115 PURPOSE OF HEARING

The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the addition, deletion or rescheduling with Schedules I through VI of the North Carolina Controlled Substances Act.

History Note: *Authority G.S. 90-88;*
Eff. June 30, 1978;
Amended Eff. May 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26F .0116 WAIVER OR MODIFICATION OF RULES

The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services may modify or waive any rule in this part by notice in advance of the hearing with the consent of the parties to the hearing if it determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

History Note: *Authority G.S. 90-88; 150B-25;*
Eff. June 30, 1978;
Amended Eff. May 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26F .0117 ADDITION: DELETION OR RESCHEDULING OF A SUBSTANCE

(a) Any interested person may submit a petition to initiate proceedings for the addition, deletion or rescheduling of any substances within Schedules I through VI of the North Carolina Controlled Substances Act pursuant to the provisions of G.S. 90-88.

(b) Petitions shall be submitted in quintuplicate to the Commission for Mental Health, Mental Retardation and Substance Abuse Services in the following form:

_____
Date

(The Commission Address)

Dear Sir: The undersigned _____ hereby petitions the commission to initiate proceedings for the addition (deletion or rescheduling) of a substance within Schedules I through VI of the North Carolina Controlled Substances Act pursuant to G.S. 90-88.

Attached hereto and constituting a part of this petition are the following:

(1) the proposed substance in the form proposed by the petitioner; (If the petitioner seeks the deletion or rescheduling of an existing controlled substance, the existing controlled substance together with a reference to this Section in the latest commission publication of Schedules I through VI where it appears should be included.)

(2) a statement of the grounds which the petitioner relies upon for the addition (deletion or rescheduling) of the substance. (Such grounds shall include a reasonably concise statement of the facts relied upon by the petitioner including a summary of any relevant medical or scientific evidence known to the petitioner.)

All notices to be sent regarding this petition should be addressed to:

_____
Name

_____
Street Address

_____
City and State

Respectfully yours,

_____
Signature of Petitioner

(c) The commission may reject a petition for filing if any of the requirements in Paragraph (b) of this Rule is lacking or is not set forth so as to be readily understood. If petitioner desires, he may amend the petition to meet the requirements of Paragraph (b) of this Rule.

(d) When the commission holds a hearing pursuant to G.S. 90-88(a), it shall publish in newspapers of statewide circulation qualified for legal advertising in accordance with Rule 4 of the North Carolina Rules of Civil Procedure general notice of any proposed addition, deletion or rescheduling of a substance pursuant to G.S. 90-88. Such published notice shall include a statement of the time, place and nature of the hearings on the proposal. Such hearings may not be commenced until after the expiration of at least 10 days from the date the general notice is published in accordance with this Rule. Such published notice shall include a reference to the legal authority under which the substance change is proposed, a statement of the proposed change and in the discretion of the commission a summary of the subjects and issues involved. In addition, notice of the proposed change and the date and place of the public hearing shall be sent by the commission to each registrant under the act.

(e) The commission may permit any interested persons to file written comments on or objections to the proposal and shall designate in the notice of proposed change the time during which such filings may be made.

(f) The commission shall before adding, deleting or rescheduling any substance and after gathering the necessary data make a scientific and medical evaluation as to whether such drug or other substances should be so controlled, transferred or removed as a controlled substance.

(g) The commission in making its determination whether to add, delete or reschedule a substance within Schedules I through VI of the North Carolina Controlled Substances Act must in accordance with G.S. 90-88(a) consider the following:

(1) the actual or relative potential for abuse;
(2) the scientific evidence of its pharmacological effect, if known;
(3) the state of current scientific knowledge regarding the substance;
(4) the history and current pattern of abuse;
(5) the scope, duration and significance of abuse;
(6) the risk to the public health;
(7) the potential of the substance to produce psychic or physiological dependence liability; and
(8) whether the substance is an immediate precursor of a substance already controlled under the North Carolina Controlled Substances Act.

History Note: *Authority G.S. 90-88;*
Eff. June 30, 1978;
Amended Eff. April 1, 1982;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26F .0118 BURDEN OF PROOF

At any hearing the proponent for the addition, deletion or rescheduling of any substance within Schedules I through VI of the North Carolina Controlled Substances Act shall have the burden of proof.

History Note: *Authority G.S. 90-88;*
Eff. June 30, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26F .0119 TIME AND PLACE OF HEARING

The hearing will commence at the place and time designated in the notice published in accordance with .0117(d) of this Subchapter, but, thereafter, it may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

History Note: *Authority G.S. 90-88; 150B-33;*
Eff. June 30, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26F .0120 FINAL ORDER

As soon as practicable after the hearing has been concluded, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall cause to be published its decision in the form of an order. This order shall specify the date on which it shall take effect which shall not be less than 30 days from the date of publication unless the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services finds that conditions of public health or safety necessitate an earlier effective date in which event the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall specify in the order its findings as to such conditions.

History Note: *Authority G.S. 90-88;*
Eff. June 30, 1978;
Amended Eff. May 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26F .0121 MEETING REQUIRED

Pursuant to G.S. 90-88(d), any time a substance is added, deleted or rescheduled as a controlled substance, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall meet within 180 days and either agree or object to the change. In either case the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall adopt an order setting forth its decisions and the reasons therefor.

History Note: *Authority G.S. 90-88(d);*
Eff. June 30, 1978;
Amended Eff. May 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

10A NCAC 26F .0122 HEARING PROCEDURE

If the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services objects thereby precipitating a hearing under G.S. 90-88(d), the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall follow generally the procedures set forth in Rules .0114 through .0120 of this Subchapter.

History Note: *Authority G.S. 90-88(d);*
Eff. June 30, 1978;
Amended Eff. May 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.