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

A pharmacy that has dispensed controlled substances for inpatient administration to individuals residing in a licensed nursing home shall be responsible for either returning unused controlled substances to its stock, or disposing of and destroying any unused controlled substances in accordance with 21 CFR 1317.05(a) or (c), and other applicable federal regulations governing U.S. Drug Enforcement Administration (DEA) registrant collection, disposal, and destruction of unused controlled substances in licensed nursing homes, including 21 U.S.C. 822(g), 21 CFR 1317.10, 21 CFR 1317.15, 21 CFR 1317.80, 21 CFR 1304.22, and 21 CFR Part 1317 Subpart C. 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 with the original manufacturer's labelling legible. 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 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. Pharmacies that are authorized by the DEA as collectors may install, manage, and maintain collection receptacles at nursing homes for the purpose of collection, disposal, and destruction of unused controlled substances from nursing homes, in accordance with 21 CFR 1317.05(c), 21 CFR 1317.40, and other applicable federal regulations governing the use of collection receptacles by authorized pharmacy collectors in nursing homes, including 21 CFR 1301.51, 21 CFR 1316.02, 21 CFR 1317.05(c)(2)(iv), 21 CFR 1317.60, 21 CFR 1317.75, and 21 CFR 1317.80. 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 30, 2024;
Temporary Amendment Eff. January 2, 2025;
Amended Eff. November 1, 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.