

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.