

1 21 NCAC 46 .1317 is amended **with changes** as published in 35:22 NCR 2440 as follows:

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3 **21 NCAC 46 .1317 DEFINITIONS**

4 ~~The definitions of various terms~~ Terms used in this Chapter ~~and are found in~~ G.S. 90, Article 4A, are defined ~~and~~ as
5 follows, unless otherwise defined in G.S. 90, Article 4A: ~~follows:~~

- 6 (1) ~~Ambulation assistance equipment.~~ Assistance Equipment. Devices that aid in walking, excluding
7 canes, crutches, and walkers.
- 8 (2) ~~Approved school or college of pharmacy.~~ School or College of Pharmacy. A school or college of
9 pharmacy accredited by the American Council on Pharmaceutical Education. ~~Education, or a~~
10 ~~foreign school with a professional pharmacy degree program of at least five years approved by the~~
11 ~~Board pursuant to G.S. 90-85.13.~~
- 12 ~~(3) Auxiliary Drug Inventory. A secure, segregated, supplementary source for drugs to be used solely~~
13 ~~for the purpose of providing adequate drug availability when the pharmacy is closed or the~~
14 ~~pharmacist is unavailable.~~
- 15 ~~(4) Board. As defined in G.S. 90-85.3(b).~~
- 16 ~~(5) Certified technician. A technician who has passed a pharmacy technician certification board exam,~~
17 ~~or its equivalent, that has been approved by the Board according to the rules in this Chapter.~~
- 18 ~~(6) Consultant Pharmacist. A licensed pharmacist who, in collaboration with the supervising~~
19 ~~physician and nurse practitioner or assistant to the physician, develops a retrospective drug~~
20 ~~utilization review program that:~~
- 21 ~~(a) reviews the appropriateness of the choice of medication(s) for the patient and the patient's~~
22 ~~therapeutic regimen, including choice of medication, dose, frequency, and route of~~
23 ~~administration;~~
- 24 ~~(b) identifies and resolves therapeutic duplication in the patient's medication regimen; and~~
- 25 ~~(c) considers patient specific medication contraindications.~~
- 26 ~~The consultant pharmacist holds himself available for consultation in person, by telephone, or by~~
27 ~~other means of direct communication at all times when drugs are dispensed.~~
- 28 ~~(7)~~(3) Diagnostic equipment. Equipment used to record physiological information while a person goes
29 about normal daily living or while asleep in order to document a disease process. Early pregnancy
30 tests (EPTs), thermometers, glucose meters, and cholesterol equipment are not included as
31 diagnostic equipment.
- 32 ~~(8)~~(4) Drug regimen review or drug use review. ~~Pharmaceutical care assessment. An onsite~~ A review of
33 a patient's ~~or resident's~~ record by a licensed pharmacist that involves interpretation and evaluation
34 of the drug therapy and other pharmaceutical care services to achieve intended medication
35 outcomes and minimize negative effects of drug therapy.

- 1 ~~(9)~~ Duplicate as used in G.S. 90-85.24. Any license, permit, or registration issued or reissued by the
2 Board that is identical to a previously issued license, permit, or registration, including a permit
3 reissued due to a change in pharmacist manager.
- 4 ~~(10)~~ Emergency Drugs. Those drugs whose prompt use and immediate availability are generally
5 regarded by physicians as essential in the proper treatment of unforeseen adverse changes in a
6 patient's health or well-being.
- 7 ~~(11)~~(5) Employee. A person who is or would be considered an employee under the North Carolina
8 Workers' Compensation Act. This definition applies to locations both within and outside of this
9 State holding pharmacy or device and medical equipment permits and without regard to the
10 number of persons employed by the permit holder.
- 11 ~~(12)~~ Executive Director. The Secretary Treasurer and Executive Director of the Board.
- 12 ~~(13)~~(6) Graduate of an approved school of college of pharmacy. ~~Approved School or College of~~
13 ~~Pharmacy.~~ A person who has received an undergraduate professional degree in pharmacy from an
14 approved school or college of pharmacy. ~~pharmacy,~~ or a person who has graduated from a foreign
15 professional school of pharmacy and has successfully completed the Foreign Pharmacy Graduate
16 Equivalency Examination offered by the National Association of Boards of Pharmacy and the Test
17 of English as a Foreign Language.
- 18 ~~(14)~~ HMES. Home medical equipment supplier.
- 19 ~~(15)~~(7) Health Care Facility. ~~Any organization~~ One of the following organizations whose primary purpose
20 is to provide a physical environment for patients to obtain health care services; ~~services.~~ This
21 shall include:
- 22 (a) a hospital;
- 23 (b) a long-term care facility;
- 24 (c) a mental health facility;
- 25 (d) a drug abuse treatment center;
- 26 (e) an assisted living facility;
- 27 (f) an ambulatory surgical center;
- 28 ~~(e)~~ (g) a penal institution; or
- 29 ~~(f)~~ (h) a hospice.
- 30 ~~(16)~~(8) Health Care Facility Pharmacy. A pharmacy permitted by the Board that provides services to
31 patients of a Health Care Facility.
- 32 ~~(17)~~ Indulgence in the Use of Drugs. ~~The use of narcotic drugs or other drugs affecting the central~~
33 ~~nervous system or the use of intoxicating beverages to an extent as to deprive the user of~~
34 ~~reasonable self-control or the ability to exercise such judgment as might reasonably be expected of~~
35 ~~an average prudent person.~~
- 36 ~~(18)~~(9) Internet pharmacy. ~~Pharmacy.~~

- 1 (a) A pharmacy that maintains an Internet web site for the purpose of selling or distributing
2 prescription drugs; or
3 (b) A pharmacy that uses the ~~internet, Internet,~~ either itself, or through agreement with a
4 third party, to communicate with or obtain information from patients; uses such
5 communication or information, in whole or in part, to solicit, fill or refill prescriptions; or
6 otherwise uses such communication or information, in whole or in part, to engage in the
7 practice of pharmacy. ~~pharmacy as defined in G.S. 90-85.3(r).~~

8 Notwithstanding Sub-items (a) and (b) above, a pharmacy shall not be deemed an Internet
9 pharmacy if it maintains an each Internet web site for the following purposes only:

- 10 (i) To post mere advertisements that do not attempt to facilitate, directly or through
11 agreement with a third party, an actual transaction involving a prescription drug;
12 (ii) To allow a patient to communicate a request for a refill of a legitimate valid
13 prescription originally filled by the pharmacy that maintains the Internet web
14 site;
15 (iii) To allow a customer to research drug interactions and clinical pharmacology
16 information; or
17 (iv) To allow a patient to send an electronic mail message to a pharmacist licensed in
18 North Carolina.

19 ~~(19) Limited Service Pharmacy Permit. A pharmacy permit issued by the Board to an applicant who~~
20 ~~wishes to render in an institutional setting pharmaceutical services not limited to scope and kind~~
21 ~~but to time and conditions under which such services are rendered.~~

22 ~~(20) Medication Therapy Management Services and Related Functions. Services and functions~~
23 ~~included in the practice of pharmacy as part of monitoring, recording and reporting drug therapy~~
24 ~~and device usage.~~

25 ~~(21) Medication Administration Record. A record of drugs administered to a patient.~~

26 ~~(22)(10) Medication Order. An order for a prescription drug or other medication or a drug, device device,~~
27 ~~or medical equipment for a patient from a person authorized by law to prescribe them.~~
28 ~~medications.~~

29 ~~(23)(11) Mobility equipment. Devices that aid a person in self movement, self-movement other than~~
30 ~~walking, including manual or power wheelchairs and scooters.~~

31 (12) North Carolina resident or resident of North Carolina. Any patient who is a temporary or
32 permanent resident of the State of North Carolina or present in the State of North Carolina at the
33 time a drug, ~~[device]~~ device, or medical equipment is dispensed to that person.

34 ~~(24)(13) Oxygen and respiratory care equipment. Equipment or devices used to administer oxygen or other~~
35 ~~legend drugs, maintain viable airways airways, or monitor cardio-respiratory conditions or events,~~
36 ~~including the following:~~

- 37 (a) compressed medical gases;

- (b) oxygen concentrators;
- (c) liquid oxygen;
- (d) nebulizers;
- (e) compressors;
- (f) aerosol therapy devices;
- (g) portable suction machines;
- (h) nasal continuous positive airway pressure (CPAP) machines;
- (i) Bi-phasic positive pressure devices (BiPAP);
- (j) infant monitors, such as apnea monitors and cardio-respiratory monitors;
- (k) positive and negative pressure mechanical ventilators; and
- (l) pulse oximeters.

~~(25)~~(14) Patient medication profile, patient ~~[profile]~~ profile, or pharmacy profile. ~~Medication Profile.~~ A list of all ~~prescribed~~ medications ~~prescribed for or dispensed to~~ a patient.

~~(26)~~ — Pharmacist. Any person within the definition set forth in G.S. 90-85.3(p), including any druggist.

~~(27)~~(15) Pharmacist-Manager. The person who accepts responsibility for the operation of a pharmacy in conformance with all statutes and rules pertinent to the practice of pharmacy and distribution of drugs by signing the permit application, its ~~renewal~~ renewal, or addenda thereto.

~~(28)~~ — Pharmacy. Any place within the definition set forth in G.S. 90-85.3(q), including any apothecary or drugstore.

~~(29)~~(16) Pharmacy Intern. Any person who is registered with the Board under the internship program of the Board to acquire pharmacy experience or enrolled in approved academic internship programs. A pharmacy intern working under a pharmacist preceptor or supervising pharmacist may, while under supervision, perform all acts constituting the practice of pharmacy.

~~(30)~~ — Place of residence. Any place used as an individual's temporary or permanent home.

~~(31)~~ — President. The President of the Board.

~~(32)~~(17) Rehabilitation environmental control equipment. Equipment or devices that permit a person with disabilities to control his or her immediate surroundings.

~~(33)~~ — Rehabilitation Services. Services and equipment required to maintain or improve functional status and general health as prescribed by the physician which are uniquely specified for each individual's lifestyle. The people involved in this process include the patient, caregiver, physician, therapist, rehabilitation equipment supplier and others who impact on the individual's life style and endeavors.

~~(34)~~ — Signature. A written or electronic signature or computerized identification code.

~~(35)~~ — Two Years of College Work. Attendance at a college accredited by an accrediting agency recognized by the United States Department of Education for two academic years of not fewer than eight and one half months each and the completion of work for credit leading to a

1 ~~baccalaureate degree or its equivalent and that would permit the student to advance to the next~~
2 ~~class.~~

3 ~~(36)(18) Undergraduate professional degree in pharmacy. Professional Degree in Pharmacy. A B.S. or~~
4 ~~Pharm. D. degree. A Bachelor of Science in Pharmacy or a Doctor of Pharmacy degree.~~

5 ~~(37) Vice President. The Vice President of the Board.~~

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7 *History Note: Authority G.S. 90-85.3; 90-85.6; ~~90-85.8~~; 90-85.13; 90-85.14; 90-85.15; 90-85.21; 90-85.21A;*
8 *90-85.22; 90-85.26; 90-85.32; 90-85.33; 90-85.34; 90-85.38; 90-85.40;*
9 *Eff. May 1, 1989;*
10 *Amended Eff. March 1, 2013; February 1, 2007; March 1, 2004; April 1, 1999; May 1, 1997;*
11 *September 1, 1995; September 1, 1993; October 1, 1990; January 1, 1990;*
12 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*
13 *2017; ~~2017~~.*
14 *Amended Eff. November 1, 2021.*

21 NCAC 46 .1616 is adopted with changes as published in 35:22 NCR 2440 as follows:

21 NCAC 46 .1616 LIMITED SERVICE PERMITS

(a) The following pharmacy practice locations are eligible to apply for [permits are described in this Chapter as] “limited service [permits:”] permits” whose operations are modified by the provisions set forth in this Rule:

- (1) auxiliary medication inventories permitted and operating in health care facilities pursuant to Rule .1414(d) of this Chapter;
- (2) automated dispensing or drug supply devices permitted and operating in health care facilities pursuant to Rule .1419 of this Chapter;
- (3) facilities where drugs are dispensed only by nurse practitioners or physician assistants pursuant to Section .1700 of this Chapter;
- (4) county health departments or other governmental entities providing local health services under G.S. 130A-34 where drugs are dispensed only by registered nurses and only pursuant to G.S. 90-85.34A and Section .2400 of this Chapter;
- (5) county health departments or other governmental entities providing local health services under G.S. 130A-34 that engage in dispensing beyond that set out in [G.S. 90-85,34A] G.S. 90-85.34A and Section .2400 of this Chapter;
- (6) free clinics, as defined in G.S. 90-85.44(a)(6); or
- (7) critical access hospitals, as defined in G.S. 131E-76.

(b) A pharmacist-manager for a limited service permit may designate one assistant pharmacist-manager but is not required to do so. [A#] The assistant pharmacist-manager [is] shall be responsible for exercising all of the responsibilities of a pharmacist-manager when the assistant pharmacist-manager is present [but] and the pharmacist-manager is not present at the limited service permit. If the pharmacist-manager chooses to designate an assistant pharmacist-manager, the pharmacist-manager shall notify the Board on the limited service permit application and, in writing, within 15 days of any change in the designation. Notwithstanding the pharmacist-manager’s designation of an assistant pharmacist-manager, the pharmacist-manager shall be responsible for ensuring the pharmacy’s compliance with all statutes, [rules] rules, and standards at all times.

(c) For limited service permits, the pharmacist-manager attendance requirements set out in Rule .2502(b) of this Chapter are modified only as set forth herein:

- (1) For limited service permits described in Subparagraphs (a)(1) and (2) of this Rule, either the pharmacist-manager or the assistant pharmacist-manager must perform an in-person, on-site visit at least once per calendar quarter to inspect the permit, review the operations of the permit with the persons involved in accessing [them] them, and ensure that the permits are operated in compliance with all applicable [state] State and federal laws.
- (2) For limited service permits described in Subparagraphs (a)(3) and (4) of this Rule, either the pharmacist-manager or the assistant pharmacist-manager must perform an in-person, on-site visit at least once per week to inspect the permit, review the operations of the permit with the persons

1 involved in ~~[dispensing]~~ dispensing, and ensure that the permits are operated in compliance with
2 all applicable ~~[state]~~ State and federal laws.

3 (3) ~~For limited service permits described in Subparagraphs (a)(5), ~~[(6)]~~ (6), and (7) of this Rule,~~
4 ~~either the pharmacist-manager or the assistant pharmacist-manager employed or otherwise~~
5 ~~engaged to supply pharmaceutical services may have a flexible schedule of attendance but shall be~~
6 ~~present for at least one-half of the hours the pharmacy is open or 20 hours a week, whichever is~~
7 ~~less. For the limited service permits described in Subparagraphs (a)(5) and (6) of this Rule, a~~
8 ~~licensed pharmacist must be present when the pharmacy is open as described in Rule .2502(e) of~~
9 ~~this Chapter. For the limited service permits described in Subparagraph (a)(7) of this Rule, the~~
10 ~~limited service may operate in the absence of a pharmacist only as set out in Rule .1413 of this~~
11 ~~Chapter.~~

12 (4) ~~The limited service permit may name a temporary pharmacist-manager or assistant pharmacist-~~
13 ~~manager for a period not to exceed 90 days from the departure date of the previous pharmacist-~~
14 ~~manager or assistant pharmacist-manager. The temporary pharmacist-manager or assistant~~
15 ~~pharmacist-manager must accept the responsibilities of that position and must be present as set~~
16 ~~forth in this Rule. A limited service permit may not operate for a period of more than 30 days~~
17 ~~without a pharmacist employed or otherwise engaged as a permanent or temporary pharmacist-~~
18 ~~manager who has signed the permit for that pharmacy.~~

19 (d) ~~A person may serve as the pharmacist-manager or the assistant pharmacist-manager for multiple limited service~~
20 ~~permits, and may serve as the pharmacist-manager or assistant pharmacist-manager for limited service permits in~~
21 ~~addition to serving as the pharmacist-manager for a maximum of one permit other than a limited service permit. A~~
22 ~~person may serve multiple limited permits only if that person is able to fulfill all of that person's duties under ~~[state]~~~~
23 ~~State and federal law.~~

24 (e) ~~Other than as ~~[expressly]~~ set forth in this Rule, ~~[section,]~~ limited service permits and their personnel must follow~~
25 ~~all requirements of ~~[state]~~ State and federal law. This Rule does not replace or modify the requirements that the~~
26 ~~pharmacist-manager provide oversight and supervision as provided elsewhere in this Chapter. ~~[these Rules.]~~~~

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28 *History Note:* ~~Authority G.S. 90-18.1(c); 90-18.2; 90-85.6; 90-85.21; 90-85.33; 90-85.34;~~

29 ~~Eff. November 1, 2021.~~

1 21 NCAC 46 .1703 is amended **with changes** as published in 35:22 NCR 2440 as follows:

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21 NCAC 46 .1703 DRUGS TO BE DISPENSED

- (a) The nurse practitioner may dispense any and all drugs that the nurse practitioner is authorized by law to prescribe.
- (b) The physician assistant may dispense any and all drugs that the physician assistant is authorized by law to prescribe.
- ~~(c) The pharmacist shall prepare a plan to ensure that there are adequate amounts of each of the drugs dispensed by a nurse practitioner or physician assistant, and that such drugs are properly stored and packaged.~~
- ~~(d) (c) All drugs dispensed by a nurse practitioner or physician assistant must be dispensed from a place holding a current pharmacy permit from the Board as required by G.S. 90-85.21.~~
- ~~(e) (d) The consulting pharmacist-manager, or another licensed pharmacist working under the pharmacist-manager's supervision, shall be available for consultation in person, by telephone, or other means of direct communication at all times when drugs are dispensed, including to perform drug regimen review for patients as needed. dispensed.~~
- ~~(f) (e) All drugs dispensed pursuant to G.S. 90-18.1(c), **90-18.2(e)** **90-18.2(c)**, and the rules of this Section shall be packaged, labeled, and otherwise dispensed in compliance with **[state] State** and federal law, and records of dispensing shall be kept in compliance with **[state] State** and federal law. The pharmacist-manager shall be responsible for compliance with these laws at all times, regardless of whether the pharmacist-manager is present at the time of dispensing. All drugs dispensed by the nurse practitioner or physician assistant shall be prepackaged in safety closure containers and shall be appropriately prelabeled (including necessary auxiliary labels) by the pharmacist with all information required by law except the name of the patient and the directions for use. The name of the patient and directions for use of the drugs shall be placed on the label by the nurse practitioner or physician assistant at the time it is delivered to the patient or his agent.~~

*History Note: Authority G.S. 90-18.1; 90-18.2; 90-85.6;
Eff. April 1, 1983;
Amended Eff. April 1, 1999; May 1, 1997; May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,
2017-2017;
Amended Eff. November 1, 2021.*