

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Board of Pharmacy

RULE CITATION: All Rules

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Please change the effective date. The earliest possible effective date for rules approved at the September meeting is October 1, 2022.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: August 29, 2022

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1317

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

In order to conform with the Administrative Rule Style Guide, structure definitions as follows: "Ambulation assistance equipment" means devices that aid in walking, excluding canes, crutches, and walkers. See G.S. § 90-85.3 as an example.

In item (2), line 11, place an Oxford comma after "certification" for clarity in the list of items.

In item (5), lines 20 and 21, consider placing commas after "locations" and "State" for clarity.

In item (6), line 23, should the term be "Graduate of an approved school or college of pharmacy"?

In Item (9)(b)(i), what is an "actual transaction"? Also what is an advertisement that doesn't attempt to facilitate a transaction? Isn't that the point of advertising, to create business for the pharmacy?

Also, should the paragraph under (b) be labeled (c), which would make this (9)(c)(i) and so forth?

In item (12), I think this definition is a little circular. How do you define "temporary or permanent resident"?

I am a little confused by item (18). I always thought there was a distinction between undergraduate and professional degrees. Is it the Board's intent to label a Doctor of Pharmacy degree as an "undergraduate" degree? Please clarify.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel

Date submitted to agency: August 29, 2022

1 21 NCAC 46 .1317 is amended as published in 36:19 NCR 1557 as follows:

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3 **21 NCAC 46 .1317 DEFINITIONS**

4 Terms used in this Chapter and G.S. 90, Article 4A, are defined as follows, unless otherwise defined in G.S. 90,
5 Article 4A:

- 6 (1) Ambulation assistance equipment. Devices that aid in walking, excluding canes, crutches, and
7 walkers.
- 8 (2) Approved school or college of pharmacy. A school or college of pharmacy accredited by the
9 ~~American Accreditation Council for Pharmacy Education on Pharmaceutical Education. ("ACPE")~~
10 through its PharmD Program Accreditation Standards. It does not include any accreditation,
11 certification or other designation through the ACPE's International Services Program.
- 12 (3) Diagnostic equipment. Equipment used to record physiological information while a person goes
13 about normal daily living or while asleep in order to document a disease process. Early pregnancy
14 tests (EPTs), thermometers, glucose meters, and cholesterol equipment are not included as
15 diagnostic equipment.
- 16 (4) Drug regimen review or drug use review. A review of a patient's record by a licensed pharmacist
17 that involves interpretation and evaluation of the drug therapy and other pharmaceutical care
18 services to achieve intended medication outcomes and minimize negative effects of drug therapy.
- 19 (5) Employee. A person who is or would be considered an employee under the North Carolina
20 Workers' Compensation Act. This definition applies to locations both within and outside of this
21 State holding pharmacy or device and medical equipment permits and without regard to the
22 number of persons employed by the permit holder.
- 23 (6) Graduate of an approved school of college of pharmacy. A person who has received an
24 undergraduate professional degree in pharmacy from an approved school or college of pharmacy.
- 25 (7) Health Care Facility. One of the following organizations whose primary purpose is to provide a
26 physical environment for patients to obtain health care services:
- 27 (a) a hospital;
- 28 (b) a long-term care facility;
- 29 (c) a mental health facility;
- 30 (d) a drug abuse treatment center;
- 31 (e) an assisted living facility;
- 32 (f) an ambulatory surgical center;
- 33 (g) a penal institution; or
- 34 (h) a hospice.
- 35 (8) Health Care Facility Pharmacy. A pharmacy permitted by the Board that provides services to
36 patients of a Health Care Facility.
- 37 (9) Internet 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, either itself, or through agreement with a third party,
4 to communicate with or obtain information from patients; uses such communication or
5 information, in whole or in part, to solicit, fill or refill prescriptions; or otherwise uses
6 such communication or information, in whole or in part, to engage in the practice of
7 pharmacy.

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

- 10 (i) To post 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 valid prescription
13 originally filled by the pharmacy that maintains the Internet web site;
14 (iii) To allow a customer to research drug interactions and clinical pharmacology
15 information; or
16 (iv) To allow a patient to send an electronic mail message to a pharmacist licensed in
17 North Carolina.
- 18 (10) Medication Order. An order for a drug, device, or medical equipment for a patient from a person
19 authorized by law to prescribe them.
- 20 (11) Mobility equipment. Devices that aid a person in self-movement other than walking, including
21 manual or power wheelchairs and scooters.
- 22 (12) North Carolina resident or resident of North Carolina. Any patient who is a temporary or
23 permanent resident of the State of North Carolina or present in the State of North Carolina at the
24 time a drug, device, or medical equipment is dispensed to that person.
- 25 (13) Oxygen and respiratory care equipment. Equipment or devices used to administer oxygen or other
26 legend drugs, maintain viable airways, or monitor cardio-respiratory conditions or events,
27 including the following:
- 28 (a) compressed medical gases;
29 (b) oxygen concentrators;
30 (c) liquid oxygen;
31 (d) nebulizers;
32 (e) compressors;
33 (f) aerosol therapy devices;
34 (g) portable suction machines;
35 (h) nasal continuous positive airway pressure (CPAP) machines;
36 (i) Bi-phasic positive pressure devices (BiPAP);
37 (j) infant monitors, such as apnea monitors and cardio-respiratory monitors;

- 1 (k) positive and negative pressure mechanical ventilators; and
- 2 (l) pulse oximeters.
- 3 (14) Patient medication profile, patient profile, or pharmacy profile. A list of all medications prescribed
- 4 for or dispensed to a patient.
- 5 (15) Pharmacist-Manager. The person who accepts responsibility for the operation of a pharmacy in
- 6 conformance with all statutes and rules pertinent to the practice of pharmacy and distribution of
- 7 drugs by signing the permit application, its renewal, or addenda thereto.
- 8 (16) Pharmacy Intern. Any person who is registered with the Board under the internship program of the
- 9 Board to acquire pharmacy experience or enrolled in approved academic internship programs. A
- 10 pharmacy intern working under a pharmacist preceptor or supervising pharmacist may, while
- 11 under supervision, perform all acts constituting the practice of pharmacy.
- 12 (17) Rehabilitation environmental control equipment. Equipment or devices that permit a person with
- 13 disabilities to control his or her immediate surroundings.
- 14 (18) Undergraduate professional degree in pharmacy. A Bachelor of Science in Pharmacy or a Doctor
- 15 of Pharmacy degree.

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17 *History Note:* *Authority G.S. 90-85.3; 90-85.6; 90-85.13; 90-85.14; 90-85.15; 90-85.21; 90-85.21A; 90-85.22;*
18 *90-85.26; 90-85.32; 90-85.33; 90-85.34; 90-85.38; 90-85.40;*
19 *Eff. May 1, 1989;*
20 *Amended Eff. March 1, 2013; February 1, 2007; March 1, 2004; April 1, 1999; May 1, 1997;*
21 *September 1, 1995; September 1, 1993; October 1, 1990; January 1, 1990;*
22 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*
23 *2017;*
24 *Amended Eff. September 1, 2022; November 1, 2021.*
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1 21 NCAC 46 .2403 is repealed as published in 36:19 NCR 1559 as follows:

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3 **21 NCAC 46 .2403 DRUGS AND DEVICES TO BE DISPENSED**

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5 *History Note: Authority G.S. 90-12.7; 90-85.6; 90-85.34A; 115C-375.2A;*
6 *Eff. March 1, 1987;*
7 *Amended Eff. September 1, 2016; January 1, 2015; August 1, 2014; May 1, 1989;*
8 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*
9 *2017;*
10 *Amended Eff. March 1, ~~2019~~ 2019;*
11 *Repealed Eff. September 1, 2022.*
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