

Burgos, Alexander N

Subject: FW: [External] Technical Changes to Rules For Sept Meeting
Attachments: 21 ncac 46 .2403 4894-8366-6215 v.1.doc; 21 ncac 46 .1317 with technical changes 4869-7000-8368 v.1.doc

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Tuesday, August 30, 2022 11:01 AM
To: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: McGhee, Dana <dana.McGhee@oah.nc.gov>; Clint Pinyan <CPINYAN@brookspierce.com>
Subject: FW: [External] Technical Changes to Rules For Sept Meeting

Hey all,

These are the final versions of these rules, to which I am recommending approval.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
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brian.liebman@oah.nc.gov

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From: Clint Pinyan <CPINYAN@brookspierce.com>
Sent: Tuesday, August 30, 2022 10:56 AM
To: Rules, Oah <oah.rules@oah.nc.gov>
Cc: Liebman, Brian R <brian.liebman@oah.nc.gov>; jcampbell <jcampbell@ncbop.org>
Subject: [External] Technical Changes to Rules For Sept Meeting

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I've attached technical changes that the Board of Pharmacy has made to two rules up in September. Please let me know if you have any questions.

[Clint Pinyan](#)



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Burgos, Alexander N

Subject: FW: [External] RE: 21 NCAC 46 Request for Changes - September 2022 RRC

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Tuesday, August 30, 2022 10:16 AM
To: Clint Pinyan <CPINYAN@brookspierce.com>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: [External] RE: 21 NCAC 46 Request for Changes - September 2022 RRC

OK, I think I can get behind that change, and I don't think it's substantial. Go ahead and resubmit the edited version to Dana, and I'll recommend approval.

Thanks!
Brian

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From: Clint Pinyan <CPINYAN@brookspierce.com>
Sent: Tuesday, August 30, 2022 9:43 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: [External] RE: 21 NCAC 46 Request for Changes - September 2022 RRC

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My trip through Westlaw suggests that – as you can imagine – there are different definitions for different purposes (taxes, voting, driver's license, in-state tuition, etc.) HOWEVAH, seeing how the statutes define it does suggest a potential change:

North "North Carolina resident" resident or resident "resident of North Carolina. Any Carolina" includes not just any patient who is a temporary or permanent resident of domiciled in the State of North Carolina or Carolina, but also any patient who is present in the State of North Carolina at the time a drug, device, or medical equipment is dispensed to that person.

"Domicile" does have an established legal meaning: "Dom" meaning "home" and "icile" meaning "where you keep your popsicles."

Clint Pinyan



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Burgos, Alexander N

From: Liebman, Brian R
Sent: Monday, August 29, 2022 5:51 PM
To: Clint Pinyan
Cc: Burgos, Alexander N
Subject: RE: [External] RE: 21 NCAC 46 Request for Changes - September 2022 RRC

Hey Clint,

Thanks for getting these back so soon. I think most everything looks good, but I'm still catching up on the "resident/temporary resident" thing. I see what the purpose of the definition is, and I think it accomplishes that purpose. However, my concern is that there's no definition of a "resident" or "temporary resident". Presumably these rules would apply to a NC resident/temp resident who was *not* present in the state at the time the drug, device, or equipment was dispensed (I'm thinking along the lines of someone having a prescription delivered by mail to their home while they're on vacation), but there's no definition of "resident" to make that determination. Is there a statute or other regulation you can point to that defines permanent or temporary resident?

Thanks,
Brian

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From: Clint Pinyan <CPINYAN@brookspierce.com>
Sent: Monday, August 29, 2022 5:16 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: [External] RE: 21 NCAC 46 Request for Changes - September 2022 RRC

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Here goes. I've attached my musings about your requests, plus the corrected .1317. (I didn't attach the others to show just the revised effective date. I figured I could do that correctly without making you look at them.)

If this is dandy, let me know and I'll submit all the changes to the appropriate e-mail address. Thanks.

[Clint Pinyan](#)

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

21 NCAC 46 .1317 DEFINITIONS

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

- (1) **Ambulation**—~~Ambulation assistance equipment. Devices equipment~~ **“Ambulation assistance equipment” means devices** that aid in walking, excluding canes, crutches, and walkers.
- (2) **Approved**—~~Approved school or college of pharmacy. A pharmacy” means a school or college of pharmacy accredited by the American Accreditation Council for Pharmacy Education on Pharmaceutical Education. (“ACPE”) through its PharmD Program Accreditation Standards. It does not include any accreditation, [certification] certification, or other designation through the ACPE’s International Services Program.~~ **“Approved” school or college of pharmacy. A pharmacy” means a** school or college of pharmacy accredited by the ~~American Accreditation Council for Pharmacy Education on Pharmaceutical Education. (“ACPE”) through its PharmD Program Accreditation Standards. It does not include any accreditation, [certification] certification, or other designation through the ACPE’s International Services Program.~~
- (3) ~~Diagnostic equipment. Equipment~~ **“Diagnostic equipment” means equipment** used to record physiological information while a person goes about normal daily living or while asleep in order to document a disease process. Early pregnancy tests (EPTs), thermometers, glucose meters, and cholesterol equipment are not included as diagnostic equipment.
- (4) **Drug**—~~Drug regimen review” review or drug—drug use review. A review” means a~~ **“Drug regimen review” review or drug—drug use review. A review” means a** review of a patient's record by a licensed pharmacist that involves interpretation and evaluation of the drug therapy and other pharmaceutical care services to achieve intended medication outcomes and minimize negative effects of drug therapy.
- (5) **Employee. A “Employee” means a** person who is or would be considered an employee under the North Carolina Workers' Compensation Act. This definition applies to ~~locations locations,~~ both within and outside of this ~~State State,~~ holding pharmacy or device and medical equipment permits and without regard to the number of persons employed by the permit holder.
- (6) ~~Graduate—Graduate of an approved school of or college of pharmacy. A pharmacy” means a~~ **“Graduate” of an approved school of or college of pharmacy. A pharmacy” means a** person who has received an undergraduate professional degree in pharmacy from an approved school or college of pharmacy.
- (7) **Health**—~~Health Care Facility. One Facility” means one~~ **“Health Care Facility. One Facility” means one** of the following organizations whose primary purpose is to provide a physical environment for patients to obtain health care services:
 - (a) a hospital;
 - (b) a long-term care facility;
 - (c) a mental health facility;
 - (d) a drug abuse treatment center;
 - (e) an assisted living facility;
 - (f) an ambulatory surgical center;
 - (g) a penal institution; or
 - (h) a hospice.

1 (8) ~~Health~~ **“Health** Care Facility ~~Pharmacy. A Pharmacy”~~ **means a** pharmacy permitted by the Board
2 that provides services to patients of a Health Care Facility.

3 (9) ~~Internet pharmacy. “Internet pharmacy”~~ **means:**

4 (a) A pharmacy that maintains an Internet web site for the purpose of selling or distributing
5 prescription drugs; or

6 (b) A pharmacy that uses the Internet, either itself, or through agreement with a third party,
7 to communicate with or obtain information from patients; uses such communication or
8 information, in whole or in part, to solicit, fill or refill prescriptions; or otherwise uses
9 such communication or information, in whole or in part, to engage in the practice of
10 pharmacy.

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

13 (i) To post advertisements that do not attempt to facilitate, directly or through
14 agreement with a third party, an actual transaction involving a prescription drug;

15 (ii) To allow a patient to communicate a request for a refill of a valid prescription
16 originally filled by the pharmacy that maintains the Internet web site;

17 (iii) To allow a customer to research drug interactions and clinical pharmacology
18 information; or

19 (iv) To allow a patient to send an electronic mail message to a pharmacist licensed in
20 North Carolina.

21 (10) ~~Medication Order. An “Medication Order”~~ **means an** order for a drug, device, or medical
22 equipment for a patient from a person authorized by law to prescribe them.

23 (11) ~~Mobility equipment. Devices “Mobility equipment”~~ **means devices** that aid a person in self-
24 movement other than walking, including manual or power wheelchairs and scooters.

25 (12) ~~North “North Carolina resident” resident or resident “resident of North Carolina. Any Carolina”~~
26 **includes not just any** patient who is a temporary or permanent resident of the State of North
27 ~~Carolina or Carolina, but also any patient who is~~ present in the State of North Carolina at the time
28 a drug, device, or medical equipment is dispensed to that person.

29 (13) ~~Oxygen “Oxygen and respiratory care equipment. Equipment equipment”~~ **means equipment** or
30 devices used to administer oxygen or other legend drugs, maintain viable airways, or monitor
31 cardio-respiratory conditions or events, including the following:

32 (a) compressed medical gases;

33 (b) oxygen concentrators;

34 (c) liquid oxygen;

35 (d) nebulizers;

36 (e) compressors;

37 (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.

(14) ~~Patient~~ **“Patient medication profile,” “patient profile,” profile, patient profile, or pharmacy profile.**

A “pharmacy profile” means a list of all medications prescribed for or dispensed to a patient.

(15) ~~Pharmacist Manager. The~~ **“Pharmacist-Manager” means 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, or addenda thereto.

(16) ~~Pharmacy Intern. Any~~ **“Pharmacy Intern” means 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.

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

(18) ~~Undergraduate~~ **“Undergraduate professional degree in pharmacy. A pharmacy” means a** Bachelor of Science in Pharmacy or a Doctor of Pharmacy degree.

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; 90-85.26; 90-85.32; 90-85.33; 90-85.34; 90-85.38; 90-85.40; Eff. May 1, 1989; Amended Eff. March 1, 2013; February 1, 2007; March 1, 2004; April 1, 1999; May 1, 1997; September 1, 1995; September 1, 1993; October 1, 1990; January 1, 1990; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017; Amended Eff. [September 1, 2022;] October 1, 2022; November 1, 2021.

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.

Done. Sorry about that.

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.

Done. I have assumed that, if multiple alternate terms are defined in the same definition (i.e, "patient profile" and "pharmacy profile"), those should each have their own quotes, since it's defining two separate phrases and not one phrase. If that's not right, let me know.

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

Done.

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

Done.

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

You are correct.

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?

The distinction that we're trying to draw is that a pharmacy is not an internet pharmacy if it just advertises that the pharmacy is great. If there are interactive

Brian Liebman
Commission Counsel

Date submitted to agency: August 29, 2022

portions that allow a patient to provide information to initiate or further an order, then that makes the pharmacy an internet pharmacy. (The point being that an “internet pharmacy” has to get an accreditation that helps ensure that the pharmacy isn’t committing fraud or doing some shady telehealth stuff.) We have had a lot of questions about the “internet pharmacy” definition over the years, but none of the regulated folks has ever failed to understand that particular distinction. If you have a better way to get at it, let’s chat.

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

I don’t think so, since it’s an exception to the first two categories. The newly corrected definition is going to start “Internet pharmacy means . . .” So, if this was an item (c), that would suggest that it is a third alternative definition of an internet pharmacy. In fact, it’s the opposite of that.

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

The point here was supposed to be that it’s not just what the law might consider a resident, but it’s also someone who is present when a drug is delivered. (We get a lot of people saying, “Well, I thought I could ship into the state without a permit because Bob isn’t a resident, he was just there on a two-week vacation.”) See if the definition seems less circular, as I’ve revised it. If not, I can take another hack at it.

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.

You would think. But here’s the explanation: The Pharmacy Practice Act requires an applicant to hold “an undergraduate degree from a school of pharmacy approved by the Board.” That’s because back in the dark ages (i.e., when the Executive Director was in school), UNC and most other schools gave out a B.S. in pharmacy. Since then, all or virtually all pharmacy schools give out Pharm. D. degrees. But the Pharmacy Practice Act hasn’t been updated to change that term, and we still have lots of old B.S.s to go with the young Pharm. D.s. So, this is definition is the hack to say that the statutory term means both old pharmacists and newfangled pharmacists, no matter which type of degree they have.

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



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Sent: Monday, August 29, 2022 3:57 PM
To: Clint Pinyan <CPINYAN@brookspierce.com>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: 21 NCAC 46 Request for Changes - September 2022 RRC

[EXTERNAL]

Hi Clint,

I'm the attorney who reviewed the Rules submitted by the Board for the September 2022 RRC meeting. The RRC will formally review these Rules at its meeting on Thursday, September 15, 2022, at 9:00 a.m. The meeting will be a hybrid of in-person and WebEx attendance, and an evite should be sent to you as we get closer to the meeting. If there are any other representatives from your agency who will want to attend virtually, let me know prior to the meeting, and we will get evites out to them as well.

Please submit the revised Rules and forms to me via email, no later than 5 p.m. on Friday, September 9, 2022.

In the meantime, please do not hesitate to reach out via email with any questions or concerns.

Thanks,

Brian

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