Burgos, Alexander N

From: Clint Pinyan <CPINYAN@brookspierce.com>
Sent: Friday, October 4, 2024 11:08 AM
To: Rules, Oah
Cc: Liebman, Brian R; Burgos, Alexander N
Subject: [External] Technical Changes to 21 NCAC 46 .1401 and .1415
Attachments: 21 ncac 46 .1401 with changes 4855-2433-5084 v.1.doc; 21 ncac 46 .1415 with changes 4876-1198-4364 v.1.doc

Please see attached for RRC meeting. Thanks.

Clint Pinyan

BROOKS PIERCE

t: 336.271.3157
f: 336.232.9157

2000 Renaissance Plaza
230 North Elm Street
Greensboro, NC 27401
P.O. Box 26000 (27420)

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

AGENCY: N.C. Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1401

DEADLINE FOR RECEIPT: Thursday, October 17, 2024.

***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:

Throughout the rule, has "dispensing area" been defined?

Also as to "dispensing areas" generally, does each area have its own pharmacist-manager? As I read G.S. 90-85.21(a), each pharmacy is required to have a pharmacist-manager. Reversing the logic, if each "dispensing area" has its own pharmacist-manager, would it not be a pharmacy?

In (b), line 16, please define "routine". How often must a dispensing area dispense drugs for outside use before it needs its own permit?

In (c), I assume that "administration" means literally handing someone their previously dispensed medication, and that "dispensing" means actually measuring it out, making sure there aren't contraindications, etc.? Are these terms defined?

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: October 3, 2024

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

AGENCY: N.C. Board of Pharmacy

RULE CITATION: 21 NCAC 64 .1415

DEADLINE FOR RECEIPT: Thursday, October 17, 2024.

***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 (b)(5), line 23, what is a "safety closure container"? I'm assuming we're talking about the traditional orange vials we all get when we go to the pharmacist, but not sure.

With respect to (b)(4) and (5), do the drugs pre-packaged by the manufacturer need to be enclosed in safety closure containers?

With respect to (b)(5), line 24, is an emergency department the location of an "auxiliary medication inventory"? Rule .1414(d)(4) covers "auxiliary medication inventories".

In (b)(6), line 35, what is a "perpetual record"? Does "perpetual" mean "three years" as on line 36?

In (b)(7), p.2, line 7, you need to strike through "(6)".

In (b)(7), line 7-8, what "regulatory agencies"?

Also in (b)(7), line 8, does "health care facility" need to be capitalized?

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: October 3, 2024

21 NCAC 46 .1401 is amended with changes as published in 38:24 NCR 1649-50 as follows:

SECTION .1400 - HOSPITALS: OTHER HEALTH FACILITIES

21 NCAC 46 .1401 REGISTRATION AND PERMITS

(a) ~~Registration Required.~~ All Health Care Facilities ~~places~~ providing services ~~which embrace~~ within the practice of pharmacy shall apply for and receive a pharmacy permit ~~register with the North Carolina Board of Pharmacy~~ as provided in G.S. 90-85.21. ~~G.S. 90-85.21 and acquire a permit to do so. Application for such registration and permit shall be on forms provided by the Board. If the Board is satisfied that proper facilities and adequately trained and properly licensed personnel have been obtained which will assure compliance with all laws regulating the compounding and distribution of drugs, the practice of pharmacy and the rules of the Board, a permit shall be issued by the Board attesting such registration.~~

(b) [~~Separate]~~ Physically separate dispensing areas operated by a Health Care Facility are not required to secure separate permits if those dispensing areas are (a) contained in the same building as the permitted pharmacy or (b) contained in a building located on property contiguous to the permitted pharmacy. However, even as to dispensing areas otherwise within the coverage of this Paragraph, a separate permit is required for a physically separate dispensing area for which the majority of its [~~engaged in the routine]~~ activity is [~~of]~~ dispensing drugs to or compounding drugs for a patient's use outside the Health Care Facility.

~~(b) Exemptions.~~ (c) Nothing in these rules shall be construed to require the registration with the Board of those ~~health care facilities~~ Health Care Facilities in which there occurs only the administration of drugs.

~~(c) Separate Registration Required. The dispensing of drugs from separate locations owned by a health care facility, such as satellite pharmacies, outside clinics, health maintenance organizations, or physician's offices owned by the health care facility shall require separate registration if any one of the following criteria exists:~~

~~(1) The drugs dispensed at the location are ordinarily and customarily obtained from a source outside of the health care facility;~~

~~(2) The pharmacist manager is controlled and supervised from a source other than the health care facility pharmacy; or~~

~~(3) The routine activity at the location is dispensing drugs to outpatients.~~

~~(d) Any pharmacy that provides compounding or dispensing services to one or more health care facilities for individual patient administration bearing any labeled name other than that under which it is registered shall require a separate registration.~~

~~(e) Health care facilities which do not have a pharmacy permit shall secure their pharmaceutical services through a pharmacist holding a current license from the Board.~~

History Note: *Authority G.S. 90-85.6; 90-85.21;*
Eff. April 1, 1983;
Amended Eff. May 1, 1997; May 1, 1989; March 1, 1984;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, ~~2017.~~ 2017;

Amended Eff. Nov. 1, 2024.

21 NCAC 46 .1415 is amended with changes as published in 38:24 NCR 1650-52 as follows:

21 NCAC 46 .1415 MEDICATION IN HEALTH CARE FACILITY EMERGENCY DEPARTMENTS

(a) In those ~~health care facilities~~ Health Care Facilities with ~~having 24 hour~~ 24-hour outpatient pharmacy service, all drugs dispensed to ~~outpatients~~ outpatients, including emergency department patients, ~~patients~~ must be dispensed by the permitted pharmacy during times that it is open for outpatient pharmacy service. ~~a pharmacist.~~

(b) When the permitted pharmacy in the Health Care Facility is closed for outpatient service, ~~drugs are not otherwise available from a pharmacist,~~ drugs may be dispensed for use outside the emergency department by the physician, registered nurse under physician supervision, or a person authorized to prescribe and dispense drugs pursuant to G.S. 90-18.1 or 90-18.2 subject to the following:

(1) Drugs shall be dispensed only to a ~~registered~~ patient of the emergency department;

(2) The pharmacist-manager shall develop and supervise a system of control and accountability of all drugs administered in, or dispensed from, ~~from~~ the emergency department;

(3) The pharmacist-manager ~~pharmacist manager, in conjunction with the committee responsible for policy in the emergency department,~~ shall develop ~~an emergency department~~ a formulary of prescription drugs that ~~which~~ may be dispensed from the emergency department for patients receiving care in that department. This formulary shall consist of drugs of the nature and type to meet the immediate needs of emergency department patients; ~~patients, and quantities in each container shall be limited to not more than a 24 hour supply or the smallest commercially available quantity;~~

(4) The emergency department staff may dispense no more than a seven-day supply or the smallest quantity prepackaged by the manufacturer for patient dispensing, whichever is greater;

~~(4)~~ (5) Drugs shall be prepackaged in safety closure containers and shall be pre-labeled by ~~the~~ a pharmacist to comply with Rule .1414(d)(4) of this Section. Prior to dispensing, the following information shall be placed on the label:

(A) the name, address, and telephone number of the health care facility pharmacy;

(B) the dispensing date;

(C) the full name of patient;

(D) the generic or trade name, or in the absence of a brand name, the established name of the product dispensed;

(E) directions for use to the patient;

(F) the name of physician prescribing and dispensing the product; and

(G) required precautionary or further accessory cautionary information as may be desirable for proper use and safety to the patient;

~~(5)~~(6) A perpetual record of dispensing of all drugs, including drug samples and starter packages, shall be maintained as part of the pharmacy's records for three years. The pharmacist-manager or

designee shall verify the accuracy of these records at least once a month. The record shall contain the following:

(A) the date dispensed;

(B) the patient's name;

(C) the physician's name; and

(D) the name, strength, dosage form, quantity, and dose of the drug dispensed.

~~(6)~~(7) The drug may be dispensed only if there is an order from a prescriber that complies with applicable laws governing such prescriptions. ~~The physician shall sign all orders for medication within the time frame established by regulatory agencies and health care facility policies and procedures.~~

(c) The physician, registered nurse under physician supervision, or person who is authorized to prescribe and dispense drugs pursuant to G.S. 90-18.1 or 90-18.2 shall comply with all rules governing the dispensing of medications including patient counseling as defined in 21 NCAC 46 .2504.

History Note: *Authority G.S. 90-85.6; 90-18.1; 90-18.2; 90-85.21; 90-85.32; 90-85.33;*
Eff. May 1, 1997;
Amended Eff. March 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, ~~2017.~~ 2017;
Amended Eff. Nov. 1, 2024.

Burgos, Alexander N

Subject: FW: [External] RE: October 2024 RRC - Request for Changes - Board of Pharmacy

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Friday, October 4, 2024 10:03 AM
To: Clint Pinyan <CPINYAN@brookspierce.com>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; jcampbell <jcampbell@ncbop.org>
Subject: RE: [External] RE: October 2024 RRC - Request for Changes - Board of Pharmacy

Sounds good to me then.

Thanks, Clint!

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Clint Pinyan <CPINYAN@brookspierce.com>
Sent: Thursday, October 3, 2024 8:03 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; jcampbell <jcampbell@ncbop.org>
Subject: Re: [External] RE: October 2024 RRC - Request for Changes - Board of Pharmacy

No. Not a problem, since those would be in their own types of compliant prepackaging already. If that makes sense, I'll submit.

Clint Pinyan
Brooks Pierce

Burgos, Alexander N

Subject: FW: [External] RE: October 2024 RRC - Request for Changes - Board of Pharmacy

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Thursday, October 3, 2024 5:23 PM
To: Clint Pinyan <CPINYAN@brookspierce.com>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; jcampbell <jcampbell@ncbop.org>
Subject: RE: [External] RE: October 2024 RRC - Request for Changes - Board of Pharmacy

Looks pretty good.

In .1415, my concern with (4) and (5) was that you wouldn't be making pharmacists try to squeeze Z-packs or other pre-packaged medications into vials, if that makes sense. To be clear, I don't care about that from a policy perspective, I just wonder if that was your intent, because it sounds like that's what's required, so there's a potential ambiguity here.

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Clint Pinyan <CPINYAN@brookspierce.com>
Sent: Thursday, October 3, 2024 4:32 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; jcampbell <jcampbell@ncbop.org>
Subject: [External] RE: October 2024 RRC - Request for Changes - Board of Pharmacy

See if this makes more sense. Thanks.

Clint Pinyan

BROOKS PIERCE

t: 336.271.3157
f: 336.232.9157

2000 Renaissance Plaza
230 North Elm Street
Greensboro, NC 27401
P.O. Box 26000 (27420)

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

AGENCY: N.C. Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1401

DEADLINE FOR RECEIPT: Thursday, October 17, 2024.

***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:

Throughout the rule, has "dispensing area" been defined?

Also as to "dispensing areas" generally, does each area have its own pharmacist-manager? As I read G.S. 90-85.21(a), each pharmacy is required to have a pharmacist-manager. Reversing the logic, if each "dispensing area" has its own pharmacist-manager, would it not be a pharmacy?

In (b), line 16, please define "routine". How often must a dispensing area dispense drugs for outside use before it needs its own permit?

In (c), I assume that "administration" means literally handing someone their previously dispensed medication, and that "dispensing" means actually measuring it out, making sure there aren't contraindications, etc.? Are these terms defined?

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: October 3, 2024

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

AGENCY: N.C. Board of Pharmacy

RULE CITATION: 21 NCAC 64 .1415

DEADLINE FOR RECEIPT: Thursday, October 17, 2024.

***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 (b)(5), line 23, what is a "safety closure container"? I'm assuming we're talking about the traditional orange vials we all get when we go to the pharmacist, but not sure.

With respect to (b)(4) and (5), do the drugs pre-packaged by the manufacturer need to be enclosed in safety closure containers?

With respect to (b)(5), line 24, is an emergency department the location of an "auxiliary medication inventory"? Rule .1414(d)(4) covers "auxiliary medication inventories".

In (b)(6), line 35, what is a "perpetual record"? Does "perpetual" mean "three years" as on line 36?

In (b)(7), p.2, line 7, you need to strike through "(6)".

In (b)(7), line 7-8, what "regulatory agencies"?

Also in (b)(7), line 8, does "health care facility" need to be capitalized?

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: October 3, 2024

Request for Changes Pursuant to N.C. Gen. Stat. § 150B-21.10

Staff reviewed these Rules to ensure that each Rule is within the agency's statutory authority, reasonably necessary, clear and unambiguous, and adopted in accordance with Part 2 of the North Carolina Administrative Procedure Act. Following review, staff has issued this document that may request changes pursuant to G.S. 150B-21.10 from your agency or ask clarifying questions.

If the request includes questions, please contact the reviewing attorney to discuss.

In order to properly submit rewritten rules, please refer to the following Rules in the NC Administrative Code:

- Rule 26 NCAC 02C .0108 – The Rule addresses general formatting.
- Rule 26 NCAC 02C .0404 – The Rule addresses changing the introductory statement.
- Rule 26 NCAC 02C .0405 – The Rule addresses properly formatting changes made after publication in the NC Register.

Note the following general instructions:

1. You must submit the revised rule via email to oah.rules@oah.nc.gov. The electronic copy must be saved as the official rule name (XX NCAC XXXX).
2. For rules longer than one page, insert a page number.
3. Use line numbers; if the rule spans more than one page, have the line numbers reset at one for each page.
4. Do not use track changes. Make all changes using manual strikethroughs, underlines and highlighting.
5. You cannot change just one part of a word. For example:
    - Wrong: "~~a~~Association"
    - Right: "~~association~~ Association"
6. Treat punctuation as part of a word. For example:
    - Wrong: "day~~,~~; and"
    - Right: "~~day,~~ day; and"
7. Formatting instructions and examples may be found at: www.ncoah.com/rules/examples.html

If you have any questions regarding proper formatting of edits after reviewing the rules and examples, please contact the reviewing attorney.

Brian Liebman
Commission Counsel
Date submitted to agency: October 3, 2024

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

AGENCY: N.C. Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1401

DEADLINE FOR RECEIPT: Thursday, October 17, 2024.

***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:

Throughout the rule, has "dispensing area" been defined?

Good question. It has not, but we're meaning physically separated areas from which drugs are dispensed. Without this rule, you would need two permits if you had two pharmacy areas that are physically separated – i.e., at opposite ends of the UNC Hospital. The idea here is that it doesn't matter how many areas you have and how separate they are. As long as they're on the same campus, you can have one permit. So, the concept of a "dispensing area" is important here only to the extent that the rule exists to tell you that it isn't important. See how the changes grab you.

Also as to "dispensing areas" generally, does each area have its own pharmacist-manager? As I read G.S. 90-85.21(a), each pharmacy is required to have a pharmacist-manager. Reversing the logic, if each "dispensing area" has its own pharmacist-manager, would it not be a pharmacy?

Another good one. You're on a roll. In the absence of this rule, separate locations would be separate pharmacies, which would require separate pharmacist-managers. This rule defines all of the areas to be the same pharmacy under one permit, which requires one pharmacist-manager.

In (b), line 16, please define "routine". How often must a dispensing area dispense drugs for outside use before it needs its own permit?

The intent was basically to say that, if your primary purpose is to dispense takeout orders (to use a restaurant metaphor), then you need a separate permit. The occasional use doesn't. I've put it in more objective terms. See what you think.

In (c), I assume that "administration" means literally handing someone their previously dispensed medication, and that "dispensing" means actually measuring it out, making sure there aren't contraindications, etc.? Are these terms defined?

Brian Liebman
Commission Counsel
Date submitted to agency: October 3, 2024

They are defined, and you guessed wrong. Administration is "the direct application of a drug to the body of a patient by injection, inhalation, ingestion or other means." NCGS 90-85.3. So, for example, an outpatient surgery center doesn't need a pharmacy permit just because they put some lidocaine on you before they cut off a mole.

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: October 3, 2024

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

AGENCY: N.C. Board of Pharmacy

RULE CITATION: 21 NCAC 64 .1415

DEADLINE FOR RECEIPT: Thursday, October 17, 2024.

***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 (b)(5), line 23, what is a "safety closure container"? I'm assuming we're talking about the traditional orange vials we all get when we go to the pharmacist, but not sure.

That is a fact. It's a vial, or a tube, or blister pack, or whatever the drug comes in. The idea is that the drugs need to be prepackaged in the containers in which they're going out.

With respect to (b)(4) and (5), do the drugs pre-packaged by the manufacturer need to be enclosed in safety closure containers?

The notion here is that – if things come packaged in a ten-day supply, for example – then the emergency room doesn't need to break it up to make it a seven-day supply. So they don't have to squeeze out three days worth of salve or pop out three days worth of a z-pack for an infection. By definition then, these things would have been prepackaged in a safety closure container to be ready to give to a patient.

With respect to (b)(5), line 24, is an emergency department the location of an "auxiliary medication inventory"? Rule .1414(d)(4) covers "auxiliary medication inventories".

Yes to both (though there can be auxiliary medication inventories in other locations). This essentially is a machine that stores commonly used medications (like antibiotics) in prepackaged form, so that people in other locations in the hospital can pull them out without trucking down to the pharmacy.

In (b)(6), line 35, what is a "perpetual record"? Does "perpetual" mean "three years" as on line 36?

I can see how that would be confusing. A perpetual record is a term of art in the pharmacy world that refers to an inventory system that is updated every time that something goes in or goes out. (I.e., it is "perpetually" updated.) The idea is that,

Brian Liebman
Commission Counsel
Date submitted to agency: October 3, 2024

because it's perpetually updated, you know that there are supposed to be 90 tablets of azithromycin in there right now, and you can see if any are missing. That is in contrast to old school pharmacies, where – if you want to know how many are supposed to be there now – you have to go back and add up your orders and then subtract all your dispensing. This is a thing that pharmacists know. With that background, yes, that's what needs to be kept.

In (b)(7), p.2, line 7, you need to strike through "(6)".

Done.

In (b)(7), line 7-8, what "regulatory agencies"?

Any applicable regulatory agencies. It is my amateur understanding that hospitals are generally licensed by DHHS, though they are regulated by different sections, boards, commissions, etc. within DHHS, depending on the type of hospital. DEA and a completely different section of DHHS would have regulations on controlled substance orders. The Med Board may have applicable rules. The idea is that, if drugs are being dispensed from the ED without pharmacy involvement, there must be a signed order from the doctor to match the drug dispensed – they can't just pull it out and hand it over. Maybe a better say to do it would be to say: "The drug may be dispensed only if there is an order from a prescriber that complies with applicable laws governing such prescriptions." Let me stick that in and see if that is better.

Also in (b)(7), line 8, does "health care facility" need to be capitalized?

It would, if I hadn't just taken it out.

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: October 3, 2024

21 NCAC 46 .1401 is amended with changes as published in 38:24 NCR 1649-50 as follows:

SECTION .1400 - HOSPITALS: OTHER HEALTH FACILITIES

21 NCAC 46 .1401 REGISTRATION AND PERMITS

(a) ~~Registration Required.~~ All Health Care Facilities ~~places~~ providing services ~~which embrace~~ within the practice of pharmacy shall apply for and receive a pharmacy permit ~~register with the North Carolina Board of Pharmacy~~ as provided in G.S. 90-85.21. ~~G.S. 90-85.21 and acquire a permit to do so. Application for such registration and permit shall be on forms provided by the Board. If the Board is satisfied that proper facilities and adequately trained and properly licensed personnel have been obtained which will assure compliance with all laws regulating the compounding and distribution of drugs, the practice of pharmacy and the rules of the Board, a permit shall be issued by the Board attesting such registration.~~

(b) [~~Separate]~~ Physically separate dispensing areas operated by a Health Care Facility are not required to secure separate permits if those dispensing areas are (a) contained in the same building as the permitted pharmacy or (b) contained in a building located on property contiguous to the permitted pharmacy. However, even as to dispensing areas otherwise within the coverage of this Paragraph, a separate permit is required for a physically separate dispensing area for which the majority of its [~~engaged in the routine]~~ activity is [~~of]~~ dispensing drugs to or compounding drugs for a patient's use outside the Health Care Facility.

~~(b) Exemptions.~~ (c) Nothing in these rules shall be construed to require the registration with the Board of those ~~health care facilities~~ Health Care Facilities in which there occurs only the administration of drugs.

~~(c) Separate Registration Required. The dispensing of drugs from separate locations owned by a health care facility, such as satellite pharmacies, outside clinics, health maintenance organizations, or physician's offices owned by the health care facility shall require separate registration if any one of the following criteria exists:~~

~~(1) The drugs dispensed at the location are ordinarily and customarily obtained from a source outside of the health care facility;~~

~~(2) The pharmacist manager is controlled and supervised from a source other than the health care facility pharmacy; or~~

~~(3) The routine activity at the location is dispensing drugs to outpatients.~~

~~(d) Any pharmacy that provides compounding or dispensing services to one or more health care facilities for individual patient administration bearing any labeled name other than that under which it is registered shall require a separate registration.~~

~~(e) Health care facilities which do not have a pharmacy permit shall secure their pharmaceutical services through a pharmacist holding a current license from the Board.~~

History Note: *Authority G.S. 90-85.6; 90-85.21;*
Eff. April 1, 1983;
Amended Eff. May 1, 1997; May 1, 1989; March 1, 1984;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, ~~2017.~~ 2017;

Amended Eff. Nov. 1, 2024.

21 NCAC 46 .1415 is amended with changes as published in 38:24 NCR 1650-52 as follows:

21 NCAC 46 .1415 MEDICATION IN HEALTH CARE FACILITY EMERGENCY DEPARTMENTS

(a) In those ~~health care facilities~~ Health Care Facilities with ~~having 24 hour~~ 24-hour outpatient pharmacy service, all drugs dispensed to ~~outpatients~~ outpatients, including emergency department patients, ~~patients~~ must be dispensed by the permitted pharmacy during times that it is open for outpatient pharmacy service. ~~a pharmacist.~~

(b) When the permitted pharmacy in the Health Care Facility is closed for outpatient service, ~~drugs are not otherwise available from a pharmacist,~~ drugs may be dispensed for use outside the emergency department by the physician, registered nurse under physician supervision, or a person authorized to prescribe and dispense drugs pursuant to G.S. 90-18.1 or 90-18.2 subject to the following:

(1) Drugs shall be dispensed only to a ~~registered~~ patient of the emergency department;

(2) The pharmacist-manager shall develop and supervise a system of control and accountability of all drugs administered in, or dispensed from, ~~from~~ the emergency department;

(3) The pharmacist-manager ~~pharmacist manager, in conjunction with the committee responsible for policy in the emergency department,~~ shall develop ~~an emergency department~~ a formulary of prescription drugs that ~~which~~ may be dispensed from the emergency department for patients receiving care in that department. This formulary shall consist of drugs of the nature and type to meet the immediate needs of emergency department patients; ~~patients, and quantities in each container shall be limited to not more than a 24 hour supply or the smallest commercially available quantity;~~

(4) The emergency department staff may dispense no more than a seven-day supply or the smallest quantity prepackaged by the manufacturer for patient dispensing, whichever is greater;

~~(4)~~ (5) Drugs shall be prepackaged in safety closure containers and shall be pre-labeled by ~~the~~ a pharmacist to comply with Rule .1414(d)(4) of this Section. Prior to dispensing, the following information shall be placed on the label:

(A) the name, address, and telephone number of the health care facility pharmacy;

(B) the dispensing date;

(C) the full name of patient;

(D) the generic or trade name, or in the absence of a brand name, the established name of the product dispensed;

(E) directions for use to the patient;

(F) the name of physician prescribing and dispensing the product; and

(G) required precautionary or further accessory cautionary information as may be desirable for proper use and safety to the patient;

~~(5)~~(6) A perpetual record of dispensing of all drugs, including drug samples and starter packages, shall be maintained as part of the pharmacy's records for three years. The pharmacist-manager or

designee shall verify the accuracy of these records at least once a month. The record shall contain the following:

(A) the date dispensed;

(B) the patient's name;

(C) the physician's name; and

(D) the name, strength, dosage form, quantity, and dose of the drug dispensed.

~~(6)~~(7) The drug may be dispensed only if there is an order from a prescriber that complies with applicable laws governing such prescriptions. ~~The physician shall sign all orders for medication within the time frame established by regulatory agencies and health care facility policies and procedures.~~

(c) The physician, registered nurse under physician supervision, or person who is authorized to prescribe and dispense drugs pursuant to G.S. 90-18.1 or 90-18.2 shall comply with all rules governing the dispensing of medications including patient counseling as defined in 21 NCAC 46 .2504.

History Note: *Authority G.S. 90-85.6; 90-18.1; 90-18.2; 90-85.21; 90-85.32; 90-85.33;*
Eff. May 1, 1997;
Amended Eff. March 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, ~~2017.~~ 2017;
Amended Eff. Nov. 1, 2024.

Burgos, Alexander N

From: Clint Pinyan <CPINYAN@brookspierce.com>
Sent: Thursday, October 3, 2024 8:03 PM
To: Liebman, Brian R
Cc: Burgos, Alexander N; jcampbell
Subject: Re: [External] RE: October 2024 RRC - Request for Changes - Board of Pharmacy

No. Not a problem, since those would be in their own types of compliant prepackaging already. If that makes sense, I'll submit.

Clint Pinyan
Brooks Pierce

On Oct 3, 2024, at 5:23 PM, Liebman, Brian R <brian.liebman@oah.nc.gov> wrote:

Looks pretty good.

In .1415, my concern with (4) and (5) was that you wouldn't be making pharmacists try to squeeze Z-packs or other pre-packaged medications into vials, if that makes sense. To be clear, I don't care about that from a policy perspective, I just wonder if that was your intent, because it sounds like that's what's required, so there's a potential ambiguity here.

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Clint Pinyan <CPINYAN@brookspierce.com>
Sent: Thursday, October 3, 2024 4:32 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; jcampbell <jcampbell@ncbop.org>
Subject: [External] RE: October 2024 RRC - Request for Changes - Board of Pharmacy

See if this makes more sense. Thanks.

Clint Pinyan

<image001.jpg>

t: 336.271.3157
f: 336.232.9157

2000 Renaissance Plaza
230 North Elm Street
Greensboro, NC 27401
P.O. Box 26000 (27420)

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Thursday, October 3, 2024 2:41 PM
To: Clint Pinyan <CPINYAN@brookspierce.com>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; jcampbell <jcampbell@ncbop.org>
Subject: October 2024 RRC - Request for Changes - Board of Pharmacy

Hi Clint,

I'm the attorney who reviewed the Rules submitted by the Board for the October 2024 RRC meeting. The RRC will formally review these Rules at its meeting on Wednesday, October 30, 2024, at 10:00 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 Thursday, October 17, 2024.

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

Thanks,

Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov