Burgos, Alexander N

Subject: FW: [External] RE: Bd of Pharmacy Request for Changes

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From: Peaslee, William W <bill.peaslee@oah.nc.gov>
Sent: Monday, July 31, 2023 5:34 PM
To: Clint Pinyan <CPINYAN@brookspierce.com>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: [External] RE: Bd of Pharmacy Request for Changes

Good afternoon. Thank you for your email.

It is my intention to recommend that 21 NCAC 46 .1616 as amended be approved by the RRC.

Regarding 21 NCAC 46 .1821, please see the following comments:

Page 1, Lines 22-24: It would be better to simply strike "completed" and not add the additional verbiage. As written, it appears that the locker must be "filled up".

Page 1, Lines 30: Add after "Board", "pursuant to Rule _____."

Page 1, Lines 34-35: "Permit portal" does not appear in the Board's rules. Are home pharmacies required to have an online permit portal? If so, pursuant to what rule? How is this not a substantial difference pursuant to G.S. 150B-21.2(g)?

Page 1, Line 35: Define location. If the Board is requiring the address, state so. (While the General Assembly is under no requirement to be clear and unambiguous, the Board does not have that luxury. See G.S. 150B-21.9(a)(2)) "Precise location" does not provide a remedy. This should be an easy fix.

Page 2, Line 10: Explain the Board's authority over prescribers (Doctors).

Page 2, Line 13-14: What does the Board mean by "secured"? For example, if the locker needs to be bolted to the floor, the Board needs to state that lockers shall be bolted to the floor. It is entirely unclear what the requirements are for a locker in a hospital or in front of a 7-11. I don't know that the first sentence of subparagraph (c)(6) can be defined without it being a substantial difference pursuant to G.S. 150B-21.2(g).

Page 2, Lines 13-16: While the Board has stated in its response that the pharmacist must be able to communicate with the patient, that is not required by <u>this</u> subparagraph rule. Just fyi.

Page 2, Lines 26-36, Page 3, Lines 1-12: You did not answer my question as to whether these policies and procedures need to be approved by anyone other than the home pharmacy and if so, by whom? Whether other rules have similar ambiguities or whether the regulated public understands what is required is irrelevant and my experience is that the RRC doesn't give much quarter to such averments.

Please respond no later than August 11. Sooner would be better.

As always, please let me know if you have any questions. Thank you.

William W. Peaslee
Rules Review Commission Counsel / Legislative Liaison
Office of Administrative Hearings
1711 New Hope Church Road
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Burgos, Alexander N

Subject: FW: [External] RE: Bd of Pharmacy Request for Changes
Attachments: 21 NCAC 46 .1821 with changes 4863-6098-1362 v.1.docx; 21 NCAC 46. 1616 4887-7685-6175 v.1.docx; 08.2023 - Response to Reqeusts for Changes 4881-2763-4290 v.1.docx

From: Clint Pinyan <CPINYAN@brookspierce.com>
Sent: Wednesday, July 26, 2023 9:49 AM
To: Peaslee, William W <bill.peaslee@oah.nc.gov>
Subject: [External] RE: Bd of Pharmacy Request for Changes

Bill,

I've attached some revisions and some explanations (in red after each paragraph of the request). See if these address your concerns. If not, lemme know and I'll massage some more. If they do, lemme know and I'll submit them.

Thanks.

Clint

Clint Pinyan

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

AGENCY: North Carolina Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1616

DEADLINE FOR RECEIPT: August 4, 2023

***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:

Generally, to the Rule: The Board uses the term "limited service permit" throughout the rule. Where is this term defined?

By way of introduction, this is a rule we just adopted a couple of years ago. So it's recent enough that I should remember everything about it, but far enough away that I don't.

The answer is that a "limited service permit" is defined as one that falls within one of the categories in (a). The impact of being a limited service permit is that certain normal pharmacy requirements are modified as set out in (b), (c), and (d). (Essentially, these are types of pharmacy locations that need less oversight than others because of the limited services they provide.)

My recollection is that sticking the term in quotes was the way that Liebman and I decided we would say that the term "limited service permit" is defined by the rest of (a). But see if you like the way I beefed it up.

Generally, to the Rule: Change all "must" to "shall".

Done.

Page 1, Paragraph (b): This paragraph implies that the option assistant pharmacist manager must be selected at the time of application only. See "on the limited service permit application." Can this option be elected after permitting?

Yes. I think this is fixed now.

William W. Peaslee
Commission Counsel
Date submitted to agency: July 21, 2023

Page 1, Line 24-25, Paragraph (b): The Board uses the phrase "is not present at the limited service permit." Is the "permit" a location or authorizing documentation? Choose one.

Good catch. It is common parlance to refer to both the permit and the permitted location as the "permit." But it is better to be clear. Fixed.

Pages 1-2, Paragraph (c): See note from Page 1, Line 24-25, Paragraph (b).

Same fix. That sentence also refers to "a permit" and then "permits," so I made that more grammatically parallel.

Page 1, Line 34, Paragraph (c)(1): By "inspect the permit" is the Board requiring an inspection of the pharmacy which holds the permit or an inspection of the documentation granting the permit?

Same fix.

Page 1, Line 34, Paragraph (c)(1): By "review the operations of the permit with the persons involved in accessing them" the Board implies that "permit" means the pharmacy and not the location or the documentation, but it is unclear. Further, who are the "persons involved in accessing them"? Aren't the accessors the pharmacist-managers?

Same fix as to the first.

As to the second, no, it's not. (a)(1), (2) and (3) are all machines, rather than what you would think of as a pharmacy. For instance, (a)(1) refers to machines that a pharmacy might place in a nursing home so that a nurse can go get certain drugs that are needed in an emergency. That machine can be accessed by the pharmacy personnel stocking the machine (almost never the PM himself) and by the nurses who can take out the drugs. Each of (a)(1), (2) and (3) refer to some other subsection under which that type of machine operates. So, (a)(1) refers to .1414(d), which has a long description of who may access the machines. It's not possible to provide much more explanation without repeating the underlying requirements. But see if I cleared it up enough.

Page 2, Lines 3-4, Paragraph (c)(2): See the note for Page 1, Line 34, Paragraph (c)(1).

Same fix.

Page 2, Line 14, Paragraph (c)(4): Who has the authority to name the temporary pharmacist?

The person to whom the permit is issued. Fixed.

Page 2, Line 22-23, Paragraph (d): This needs to be re-written. Either I have not had enough coffee or it makes no sense.

William W. Peaslee
Commission Counsel
Date submitted to agency: July 21, 2023

Why can't both of those things (coffee deprivation and my nonsense) be true? It might make more sense if you knew the general rule, set out in .2502, that a person can be the pharmacist-manager of only one pharmacy at a time (unless it's during a brief period when a new pharmacy is opening). So, since these are machines or other things that don't require full-time attention, a person can be the pharmacist-manager of multiple limited service permits, along with at most one full service permit. I think taking out some extra words makes it make sense. See if you agree.

Page 2, Lines 24-25, Paragraph (d): These lines set an ambiguous standard which is open to arbitrary or capricious enforcement.

Does it? The standard is that they have failed to fulfill their responsibilities. But I think I may have made it clearer.

Page 2, Lines 26-28, Paragraph (e): Explain why this paragraph is necessary.

Good question. The point is this is that the things set out in this paragraph are the only ways in which the responsibilities are modified. I think this is clearer now that I hacked it down.

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

William W. Peaslee
Commission Counsel
Date submitted to agency: July 21, 2023

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

AGENCY: North Carolina Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1821

DEADLINE FOR RECEIPT: August 4, 2023

***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:

Generally, to the Rule: Change "must" to "shall".

I shall.

Page 1, Line 16, Paragraph (b)(1)(D): Neither "licensee" nor "permittee" is defined. Either add a definition or a reference such as "pursuant to (add in license statute or rule."

Good point. "Licensee" is a term used frequently in the statute, but "permitee" is not. See how this fix grabs you. There are multiple applicable statutes and rules (license by examination vs. reciprocated license, in-state permit vs. out-of-state permit), so seems like the easiest, clearest fix.

Page 1, Line 2, Paragraph (b)(3): What does the Board mean by "completed"?

A "locker" is like an Amazon or Home Depot locker, where the pharmacy sticks a filled bag for you to pick up. (Unlike the kiosk, which sticks drugs into a bottle while you're standing there.) So that was the point of "completed." See if this is better.

Page 1, Line 24, Paragraph (b)(4): Should there be a comma after "labeling"?

Depends on your view of the Oxford comma. I stuck one in.

Page 1, Line 29, Paragraph (c)(1): "Permitted" pursuant to what? Cite rule or statute by which the pharmacy is permitted.

See how this grabs you. Again, the problem is that there are multiple provisions about permitting. These could be in-state or out-of-state, which is two different statutes. But this change covers them all.

William W. Peaslee
Commission Counsel
Date submitted to agency: July 21, 2023

Page 1, Line 30-31, Paragraph (c)(1): What is a "limited service permit"? Cite rule or statute by which the limited service permit is issued.

OK.

Page 1, Line 32, Paragraph (c)(2): It is unclear whether the Board wants notification for each use, or only upon the first use. Further, the Board does not appear to have adopted an agency contact rule, so it is unclear where and how the notifications are to be sent. See the RRC style guide Chapter 4.

First use. Fixed.

And I actually wasn't clear on the method of contact myself. But I'm told it's being programmed into the usual online location where permit holders go to change employees, renew their permits, etc., and that will be ready to roll as soon as there's an approved rule allowing these things. So that's fixed.

Page 1, Line 33, Paragraph (c)(2): By "location" does the Board mean address? If a pharmacy replied "down east" would that be sufficient?

We usually require addresses and geographical coordinates for permits. These machines could theoretically could be in the middle of a corn field with no useful address (though that would be a money-losing proposition). Since the notification is through the online portal, which will ask for the specific info, is "location" good enough? If not, I guess we could use "precise location." I note that a number of provisions in the pharmacy statute refer to "locations" without more. (See, e.g., 90-85.15A(a), 90-85.21(a1), 90-25.21C.)

Page 1, Line 336-37, Paragraph (c)(2): It is unclear what the even is that triggers the required notification. Is it within 10 days from when the determination has been made to discontinue use? When is "discontinuing use"?

It's discontinuing patient use. So I stuck that in. That makes it clear that it's 10 days after they no longer make it available to patients. Not when they think about it. Nor when they end up taking the drugs out.

Page 2, Line 1, Paragraph (c)(3): Consider a re-write. This appears to be unnecessarily wordy. It appears that the Board is simply requiring exclusive use of any DTP employed by the home pharmacy.

It is intended to be that, and it is wordy. I was trying to make clear that it was exclusive, whether the pharmacy buys or rent it. See fix.

Page 2, Line 3, Paragraph (c)(4): "in order to facilitate supervision of the DTP system" is unnecessary verbiage.

Ah, it's now unnecessary verbiage. But it was necessary to tell pharmacies why we're adopting that provision to keep them from freaking out so much. I'll take it out.

Page 2, Lines 5-6, Paragraph (c)(5): The home pharmacy must own and control the DTP system but not have exclusive use? What does this subparagraph do that isn't covered by Paragraph (3)? Further, the subparagraph is permissive in nature. Consider re-writing. Consider "Any DTP located within a prescriber's office shall be under the exclusive use and control of the home pharmacy."

This does something other than (c)(3). We are concerned that a manufacturer will stick a machine in a doctor's office and just tell the doctor, "You take care of this thing, we'll find some pharmacy to claim they own it, and we'll split the profits with you." We wanted to cut that off. So it's not so much about exclusive use but about making clear who is running these things. The second sentence is there to let them know that the doctor can't make the patient use these machines, and that there can't be kickbacks. I took out "ownership" because that is duplicative, and I think this makes it clearer.

Page 2, Lines 5-6, Paragraph (c)(5): Is there any circumstance under which the home pharmacy is not responsible for compliance with the law regarding the DTP system or is it only under this circumstance?

No, they are responsible here – as everywhere else. That was the point, which may be clearer now.

Page 2, Line 9, Paragraph (c)(6): What does the Board mean by "secured"? For example, if the locker needs to be bolted to the floor, the Board needs to state that lockers shall be bolted to the floor.

We're trying to leave the method of securing to the pharmacy, since it will depend on the location. These are often marketed to put in a hospital for the hospital employees to use to get their own prescriptions after hours, which obviously is itself a secured location and could be further secured by placing it in an employee-only area. If you stick it in front of a busy 7-11, it might be a different level of security. The standard is that it needs to be secured enough to prevent unauthorized access to drugs and info. See if that explanation is ok with you. We don't try to micromanage folks.

Page 2, Lines 9-13, Paragraph (c)(6): This subparagraph is unnecessarily wordy. Consider a re-write. Define "continuous supervision". The rules tells the pharmacist what they do not have to do but fails to tell the pharmacist that which is required.

I think this is better now.

Page 2, Line 13, Paragraph (c)(6): What does the Board mean by "electronically supervises"? Pursuant to Subparagraph (c)(8)?

I think this is better now. The pharmacist has to be able to see and talk to people using the machine at all times. But it could be the same or different than the video surveillance cameras. (I expect it would, in fact, be different because the security

camera is presumably pointed at the machine, while the pharmacist camera is presumably pointed at the patient.)

Page 2, Lines 18, Paragraph (c)(8): Is the video surveillance continuous? 24-7?

Yes. They have to keep a security tape of the thing.

Page 2, Line 19, Paragraph (c)(8): Are recordings required? The rule is ambiguous on this point. The rules simply states that any recording be maintained for 90 days but it does not require recordings.

Fixed, as above.

Pages 2, Lines 20-36 and Page 1-7, Paragraph (c),(9): Do the polices and procedures need to be approved by anyone other than the home pharmacy? If so, by who and by what procedure? Does the Board require these to be kept on file or submitted to the Board? If so, by what time, manner, and place?

This is similar to any number of other rules that we have (e.g., .1410(c), .1411(b)(1), (7), (9), (10), and (12), .1418(b), .1607(c)(4), .1816(d)(3)(B)). In this and any other similar rules, they have to have procedures for all these things. But the procedures depend on the machine and how it is used, which is solely in their control. We don't want to dictate how they run their business. In inspections, we just check to see if they have policies and procedures. Because this is similar to any number of other rules, the regulated folks are very familiar with these types of plans.

Pages 2, Lines 20-36 and Page 1-7, Paragraph (c),(9): How will this be enforced?

See above.

Page 3, Line 7, Paragraph (c),(9): "If needed" is ambiguous. Define or delete.

In the context of the answers above, it is clearer that this means if that they need to update it if they think it's needed. The RRC recently approved similar language in .1816(d)(3). If I take it out, pharmacies may think that they need to stick a new date on the policies and procedures just to satisfy the rule, even if it's all ok. But I've done that.

Page 3, Line 14, Paragraph (c),(11): Consider re-wording to avoid the permissive. Use "shall".

If I make it active voice, like my 8th grade English teacher told me, it's clearer. I guess she was right.

Page 3, Line 14, Paragraph (c),(11): As written, the patient could not remove drugs, devices, or medical equipment from the DTP. This seems to defeat its purpose.

Changed it to removing "from inventory," which clears that up, I think.

Page 3, Line 19, Paragraph (c),(12): Consider re-wording to avoid the permissive. Use "shall".

OK done.

Page 3, Line 20-21, Paragraph (c),(13): This appears to be redundant as a pharmacist must be licensed to be a pharmacist. See G.S. 90-85.3(p)

You would think, but it is not. There was a lot of talk about whether we should let, say, a Virginia pharmacist in Danville dispense stuff to patients in a kiosk in Greensboro with no NC license. It was Board staff's position that the statute requires exactly what you say it does – the dispensing is done in Greensboro, so the pharmacist must be licensed to dispense in Greensboro. Others (who want to own these things but don't want to pay for licenses) opined that, since the Danville pharmacist never left Danville, he didn't need to be licensed here. So (a) you're preaching to the choir but (b) not everybody is in the choir.

Page 3, Line 23, Paragraph (c),(14): Where is "drug utilization review" defined?

It's a common industry term that all pharmacists know. It's one of the things listed in 90-85.3A as an act in the practice of pharmacy, but it's so well known that the General Assembly didn't define it in the statute. So, we're all good here. (For your knowledge, it's checking to make sure you're not allergic to a drug, you're not taking drugs that have interactions, etc. It's reviewing to make sure it's safe for you to use the drug.)

Page 3, Line 28, Paragraph (c),(16): To what "required records" is the Board referring? Either list them or cite a statute or rule.

Here's the problem with citations: There are lots of them. As you have identified below, we have a basic recordkeeping series of rules in Section .2300, but there are other rules that require records. And, if controlled substances are dispensed, there are many federal statutes and regulations. And if Medicaid items are dispensed, they have a number of records required. Etc., etc. There's no easy way to list them all and, if we did, we'd have to amend it all the time. We have a large number of similar rules that similarly reference keeping all records required by law. (e.g., .1411(b)(8), .1608(a)(4), .1703(e), .1816(c)(3)(C), .2401(5)). I'd propose we handle this like .1703€, which we recently amended and is the cleanest.

Page 3, Line 30, Paragraph (c),(16): To what "automated data processing system" is the Board referring? Is it required? 21 NCAC 46 .2304 does not appear to require an automated data processing system. Is it the Board's intention to require one when kiosks are employed?

That's a good question. As a practical matter, 99.9999 percent of pharmacies use an automated system, since the alternative is keeping paper files of prescriptions and writing down that they've dispensed me my blood pressure medications. Maybe there's

a pharmacy in some small town that still does that. But I can assure you they ain't buying no machines.

That background explains why this sentence has two different clauses. You would necessarily have to have an automated recordkeeping system to use a kiosk. Because the person walks up and effectively says, "I'm here. Prepare my prescription," there could be no adequate records kept of the dispensing unless an automated system was used. There's nobody there to write it down on paper. And the kiosk has to be linked to the in-house system so that if someone wants to know whether they dispensed Lipitor to Joe Bob, the pharmacist doesn't have to drive 60 miles to go look at the records on the machine.

However, the second sentence is there because, if you're just putting it into a locker, you can write it down in a manual system. The Smithsonian will then come by and gather it up to show people how pharmacy was practiced a century ago.

Page 3, Line 32, Paragraph (c),(16): Consider whether "reflect" is the best word.

The two clauses of the sentence are redundant. If I take out the first one, it solves that problem.

Page 3, Lines 35-36, Page 4, Lines 1-2, Paragraph (c),(17): The first and second lines of Subparagraph 17 are in conflict. How does a DPT system "identify" a person?

Again, this is something that we didn't want to mandate specifically, for fear of limiting technology and business change. But the idea is that you have to have some way to tell that the person is authorized. I believe most of these systems do it like a Target pickup, where the patient will put in the name of any person who is authorized to pick it up, and that person has to have a QR code or something to pick it up. You are correct that the two sentences seem to be in conflict. Should have said it's an either/or. But I've fixed it and made it simplier.

Page 4, Line 3, Paragraph (c),(18): How does a "system" "offer" to counsel a patient?

Changed it a little. The point of this is that the system can have a message that says "Do you have any questions? Poke the green button for yes," instead of having a human get on the phone every time a patient picks it up to say that.

Page 4, Line 19, Paragraph (c),(19): What is the "quality assurance program"? 21 NCAC 46 .3406 does not appear to have been adopted. Does the Board mean "…pursuant to 21 NCAC 46 .3402" which applies only to automated medication systems?

There's a whole statutory section dealing with quality assurance programs. NCGS 90-85.45 et seq. As a result, everybody in the industry knows what it is. I don't know where you're seeing a reference to .3406. I did a search and didn't see that.

Page 4, Line 34, Paragraph (d),(3): Change "may" to "shall".

Done.

Page 4, Line 36, Paragraph (d),(3): Does the Board mean the rules of Chapter 46 of the North Carolina Administrative Code?

Fixed.

Page 5, Line 3, Paragraph (d),(5): Change "may" to "shall". Where is "compounded medications" defined?

It's defined in the statutory definitions section (90-85.3(c)). It's also basic pharmacy term that all the regulated people know. A compounded drug is something that a pharmacist mixes up for your particular needs instead of something off-the-shelf.

Page 4, Line 6, Paragraph (e): Change "may" to "shall".

Done.

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

William W. Peaslee
Commission Counsel
Date submitted to agency: July 21, 2023

21 NCAC 46 .1821 is adopted with changes as proposed in 37:20 NCR 2030-34 as follows:

21 NCAC 46 .1821 DIRECT-TO-PATIENT DELIVERY SYSTEMS

(a) This Rule sets out the requirements under which pharmacies may utilize "direct-to-patient" or ("DTP") delivery systems for dispensing in the State of North Carolina.

(b) Definitions.

(1) "Direct to patient system" or "DTP system" means any delivery system through which a pharmacy dispenses drugs, devices or medical equipment to a patient through any means other than:

(A) in-person dispensing to a patient by pharmacy personnel inside a pharmacy,

(B) in-person dispensing by delivery to a patient's residence or to a health care provider treating that patient,

(C) shipping through common carrier to a patient or to a health care provider treating that patient, or

(D) the use of an automated dispensing device by a health care facility pharmacy that is governed by Rule .1419 of this Chapter.

Except as provided in this Rule or one of the exceptions set out above, no ~~licensee or permitee~~ person holding any license or permit from the Board shall participate in any arrangement whereby prescriptions may be left at, picked up from, accepted by, or delivered to any other place. The only DTP systems allowed are "lockers" and "kiosks" as defined herein.

(2) The "home pharmacy" means the pharmacy responsible for dispensing drugs, devices or medical equipment through a DTP system.

(3) A "locker" means a secure container in which pharmacy personnel place ~~completed and~~ labeled patient-specific drugs, devices, or medical equipment that have been filled up to the point of dispensing to the patient, so that the item may ~~to~~ be picked up by the patient.

(4) A "kiosk" means an automated system that is capable of filling, ~~labeling~~ labeling, and dispensing drugs, devices, or medical equipment to be dispensed to a patient.

(c) Any DTP system located within the State of North Carolina (whether a locker or a kiosk) ~~must~~ shall meet the following requirements:

(1) Before any drugs, devices, or medical equipment may be dispensed from a DTP system, the home pharmacy ~~must be permitted~~ shall have been issued a pharmacy permit by the Board. In addition, before any drugs, devices, or medical equipment may be dispensed from the DTP system, the DTP system ~~must~~ shall hold a limited service permit under Rule .1616 of this Section if it is not located at the home pharmacy's permitted facility.

(2) The home pharmacy ~~must~~ shall notify the Board, ~~in writing,~~ through the home pharmacy's online permit portal, prior to beginning to use ~~using~~ any DTP system, including the location of the DTP system and the licensed pharmacist(s) responsible for the DTP system. The home pharmacy ~~must~~ shall notify the Board prior to moving the DTP system and ~~must~~ shall secure a new limited service

permit, if one is required by Subparagraph (c)(1) of this Rule, before operating the DTP system in the new location. The home pharmacy ~~must~~ shall notify the Board within 10 days after discontinuing ~~the~~ patient use of any DTP system.

(3) A DTP system shall be used exclusively by ~~The~~ the home pharmacy. ~~pharmacy shall own or otherwise have the legal right to sole use of the DTP system.~~

(4) Any DTP system ~~must~~ shall be 60 miles or fewer from the home pharmacy (via the shortest surface street route). ~~route) in order to facilitate supervision of the DTP system.~~

(5) A DTP system may be placed in the office of a prescriber only if the DTP system is under the ~~ownership and~~ control of the home pharmacy, which is responsible for compliance with all laws regarding the DTP system. The prescriber ~~must~~ shall offer patients a choice of pharmacy, and neither the home pharmacy nor the prescriber may compensate the other for the placement of the DTP system or for any prescriptions filled by the DTP system.

(6) The DTP system ~~must~~ shall be secured to prohibit access by unauthorized personnel and to maintain confidentiality of patient information. The DTP system ~~must~~ shall be under the continuous supervision of a pharmacist employed by the home pharmacy, which may be satisfied by real-time remote supervision of the pharmacy through video and audio connections. ~~pharmacy. To qualify as continuous supervision, the pharmacist is not required to be physically present at the site of the DTP system if the pharmacist electronically supervises the DTP system.~~

(7) The DTP system ~~must~~ shall display the home pharmacy's name, address, phone number, North Carolina permit number, and the name of the home pharmacy's pharmacist-manager, as well as (where applicable) the limited service permit number for the DTP system and the name of the limited service permit's pharmacist-manager and assistant pharmacist-manager, if any.

(8) The home pharmacy ~~must~~ shall ensure that there is continuous, recorded video surveillance of the DTP system and any persons using or accessing the DTP system. It ~~must~~ shall maintain any recordings for a minimum of 90 days.

(9) The home pharmacy shall develop, maintain, and follow a manual of policies and procedures that includes policies and procedures for:

(A) Maintaining the security of the DTP system and the drugs, devices, and medical equipment within the DTP system.

(B) Determining and applying criteria regarding which drugs, devices, and medical equipment are appropriate for placement in the DTP system and which patients are eligible to use the DTP system.

(C) Maintaining any drugs, devices, and medical equipment at temperatures, humidities and other environmental conditions to ensure that they do not become adulterated under G.S. 106-133 and to ensure that they are transported and stored in accordance with manufacturer's specifications, if any, for those items.

(D) Removing outdated drugs, devices, and medical equipment from the DTP system as set forth in Subparagraph (c)(11) of this Rule on a regular basis so that patients do not receive drugs, devices, and medical equipment with a beyond use date during the period when the patient is to use the item.

(E) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filling procedures for the DTP system.

(F) Orienting participating patients on use of the DTP system; notifying patients when expected drugs, devices, or medical equipment are not available in the DTP system or when the DTP system is not functioning and notifying them of alternate methods for having those prescriptions filled; and ensuring that patient use of the DTP system does not interfere with the delivery of drugs, devices, and medical equipment to patients.

(G) Inspecting the DTP system during each required inspection.

This written manual of policies and procedures shall be reviewed and updated ~~updated, if needed,~~ annually.

(10) The home pharmacy shall comply with any federal and state controlled substance laws and rules, including but not limited to registrations that may be required for any DTP systems, before any controlled substances are dispensed from any DTP systems. The home pharmacy ~~must~~ shall comply with G.S. 90-106.1 in dispensing any drugs covered by that statute from a DTP system, and ~~must~~ shall visually confirm that the person seeking the dispensation is the same as the person on the photographic identification provided.

(11) Only pharmacy personnel who are licensed with this Board as pharmacists or registered with this Board as technicians or pharmacy interns may stock drugs, ~~Drugs,~~ devices, and medical equipment ~~may be stocked in, or removed from, a DTP system in North Carolina only by pharmacy personnel who are licensed with this Board as pharmacists or registered with this Board as technicians or pharmacy interns~~ in, or remove drugs, devices, and medical equipment from the inventory of a DTP system. The home pharmacy ~~must~~ shall maintain records of any access to the DTP system by pharmacy personnel stocking or otherwise accessing the DTP system.

(12) Before a home pharmacy dispenses drugs, devices and medical equipment to a patient through a DTP system, the home pharmacy shall secure the affirmative consent of the patient to use the DTP system. ~~The home pharmacy may use DTP system only with prior approval of the patient.~~

(13) The dispensing pharmacist on any drugs, devices, or medical equipment dispensed from a DTP system in the State of North Carolina ~~must~~ shall be licensed with this Board.

(14) Before a prescription is dispensed from the DTP system, the dispensing pharmacist at the home pharmacy ~~must~~ shall verify each prescription and ~~must~~ shall conduct a drug utilization review and otherwise assure that the drug, device, or medical equipment may safely be dispensed to the patient.

(15) The labels of any drugs, devices, and medical equipment dispensed from a DTP system ~~must~~ shall be labeled for the individual patient and contain all information required by law, including but not limited to having the dispensing pharmacist identified on the label.

(16) The home pharmacy ~~must~~ shall create and maintain ~~all required~~ records of dispensing for any drugs, devices, and medical equipment dispensed in a DTP ~~system.~~ ~~system~~ in compliance with State and federal law. Any kiosk ~~must~~ shall be connected to the home pharmacy's automated data processing system, and any drugs, devices, or medical equipment dispensed from any locker ~~must~~ shall be recorded in the home pharmacy's recordkeeping system. The ~~home pharmacy records must shall reflect that the drugs, devices, and medical equipment were dispensed by the DTP system, and the~~ recordkeeping system ~~must~~ shall be capable of producing a record of all drugs, devices, and medical equipment dispensed from the DTP system.

(17) The DTP system ~~must~~ shall have a means to identify each patient (or that patient's authorized agent) and release only that patient's prescription drugs, devices, or medical equipment to the patient (or the patient's authorized agent). ~~patient. In the event that the DTP system releases a patient's drugs to the agent for a patient, the DTP system must shall have a means to ensure that the agent is authorized to receive drugs, devices, or medical equipment for that patient.~~

(18) The DTP system ~~must~~ shall convey the home pharmacy's offer to counsel a patient as required by Rule .2504 of this Chapter and ~~must~~ shall provide the ability for the patient to have an immediate real-time consultation with a pharmacist licensed by this Board and employed by the home pharmacy who has access to all of the home pharmacy's information related to the patient. The communication link shall protect the confidentiality of the patient's information. The home pharmacy ~~must~~ shall check the communication link at least daily and the DTP system ~~must~~ shall be closed if the link malfunctions or if a licensed pharmacist is not available from the home pharmacy for counseling, unless a licensed pharmacist is physically present at the DTP system. A pharmacist who is responsible for counseling may not provide that service for more than three sites simultaneously. In the event that the DTP system is placed in the same physical space as the dispensing area of the home pharmacy, this provision may be satisfied during the time that the pharmacy is open by informing the patient how to receive counseling from a pharmacist in the home pharmacy. If the dispensing pharmacist has determined that the patient should receive counseling before the prescription is dispensed, the DTP system ~~must~~ shall provide the ability for the pharmacist to force counseling before the DTP system dispenses the drug, device, or medical equipment.

(19) The home pharmacy shall record and review any incident involving a complaint, delivery error, or omission regarding a DTP as part of the home pharmacy's quality assurance program.

(20) Drugs, devices, or medical equipment that are not picked up by a patient may be returned to stock under the same conditions as if the item had been maintained in the pharmacy, as long as the requirements of this Rule for operating the DTP system have been followed.

(d) With respect to drugs, devices, or medical equipment dispensed through a kiosk, the following additional requirements shall be met:

(1) The dispensing pharmacist shall electronically compare via video link the stock bottle, drug dispensed, the strength, and the beyond-use date. The dispensing pharmacist ~~must~~ shall verify the entire label for accuracy on the video link.

(2) The kiosk shall utilize a barcode system that prints the barcode of the stock bottle or other packaging on the label of the dispensed drug, device, or medical equipment. If the stock bottle or other packaging does not have a barcode, the home pharmacy shall create one. Pharmacy personnel shall scan both the stock bottle or other packaging and the label of the dispensed drug, device, or medical equipment to verify that the item dispensed is the same as the one in the stock bottle or other packaging for each prescription dispensed.

(3) Drugs, devices, or medical equipment dispensed by the kiosk ~~may~~ shall be packaged only by a licensed manufacturer or repackager, or prepackaged by the home pharmacy in compliance with the Pharmacy Practice Act and this Chapter. ~~its rules.~~

(4) The home pharmacy shall keep a perpetual inventory of controlled substances that are received and dispensed from each kiosk.

(5) The home pharmacy shall not dispense compounded medications through a kiosk.

(6) The kiosk shall not accept returns of drugs, devices and medical equipment from patients.

(e) This Rule does not alter the method by which patients or providers ~~may~~ shall transmit prescriptions to the home pharmacy. Prescriptions may not be collected by the home pharmacy through the DTP system.

History Note: *Authority G.S. 90-85.6; 90-85.15A; 90-85.21; 90-85.32;*
Eff. September 1, 2023.

21 NCAC 46 .1616 is amended with changes as published in 37:20 NCR 2030-34 as follows:

21 NCAC 46 .1616 LIMITED SERVICE PERMITS

(a) The following pharmacy practice locations are eligible to apply for "limited service ~~permits"~~ permits," which are pharmacy locations whose operations are modified by the provisions set forth in subparagraphs (b), (c), and (d) of 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) direct to patient systems that are not located at the home pharmacy's facility pursuant to Rule .1821 of this Chapter;

~~(3)~~(4) facilities where drugs are dispensed only by nurse practitioners or physician assistants pursuant to Section .1700 of this Chapter;

~~(4)~~(5) 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)~~(6) 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 and Section .2400 of this Chapter;

~~(6)~~(7) free clinics, as defined in G.S. 90-85.44(a)(6); or

~~(7)~~(8) 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. The assistant pharmacist-manager shall be responsible for exercising all of the responsibilities of a pharmacist-manager when the assistant pharmacist-manager is present and the pharmacist-manager is not present at the location holding 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~~ application, if an assistant pharmacist-manager is desired at that time. If a designation is made or changed after the limited service permit application is filed, the pharmacist-manager shall notify the Board, ~~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, 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~~ (a)(1), (2) and (3) of this Rule, either the pharmacist-manager or the assistant pharmacist-manager ~~must~~ shall perform an in-person, on-site visit at least once per calendar quarter to inspect the location holding the permit, review the

operations of the location holding the permit with the persons involved in accessing them as permitted by the rules referenced in subparagraphs (a)(1), (2), and (3), ~~them,~~ and ensure that the location holding the permit is ~~permits are~~ operated in compliance with all applicable State and federal laws.

(2) For limited service permits described in Subparagraphs (a)(4) and (5)~~(a)(3) and (4)~~ of this Rule, either the pharmacist-manager or the assistant pharmacist-manager ~~must~~ shall perform an in-person, on-site visit at least once per week to inspect the location holding the permit, review the operations of the location holding the permit with the persons involved in dispensing, and ensure that the location holding the permit is ~~permits are~~ operated in compliance with all applicable State and federal laws.

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

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

(d) A person may serve as the pharmacist-manager or the assistant pharmacist-manager for multiple limited service permits, and may ~~serve as the pharmacist-manager or assistant pharmacist-manager for limited service permits in addition to~~ do so while also serving as the pharmacist-manager for a maximum of one permit other than a limited service permit. A person ~~may serve multiple limited permits only if that person is able to~~ serving multiple limited service permit locations must fulfill all of that person's duties under State and federal law as to each location. ~~law.~~

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

History Note: *Authority G.S. 90-18.1(c); 90-18.2; 90-85.6; 90-85.21; 90-85.32; 90-85.33; 90-85.34; Eff. November 1, 2021; ~~2021.~~*

1 *Amended Eff. September 1, 2023.*

Burgos, Alexander N

From: Clint Pinyan <CPINYAN@brookspierce.com>
Sent: Friday, July 21, 2023 5:56 PM
To: Peaslee, William W
Cc: Burgos, Alexander N; jcampbell
Subject: [External] Re: Bd of Pharmacy Request for Changes

Got it and will take a look next week. Thanks.

Clint Pinyan
Brooks Pierce

On Jul 21, 2023, at 4:06 PM, Peaslee, William W <bill.peaslee@oah.nc.gov> wrote:

[EXTERNAL]

Good afternoon:

I am the attorney assigned to review the rules submitted to the NC Rules Review Commission by the NC Board of Pharmacy.

Attached please find a request for changes. Please respond no later than COB August 4, 2023.

The RRC will review these rules at its next meeting on August 17, 2023.

As always if you have any questions or concerns please do not hesitate to contact me. It is the strong preference of the Office of Administrative Hearings that communications concerning proposed rules be conducted by email.

Thank you.

William W. Peaslee
Rules Review Commission Counsel / Legislative Liaison
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Raleigh NC, 27609
(984) 236-1939
Bill.Peaslee@oah.nc.gov

<08.2023 - Board of Pharmacy Requests for Technical Changes.docx>