Burgos, Alexander N

Subject: FW: [External] RE: RFC for BOP 21 NCAC 46 .1418
Attachments: 21 NCAC 46. 1418 Final 4920-6668-4800 v.1.doc

From: Clint Pinyan <CPINYAN@brookspierce.com>
Sent: Friday, February 6, 2026 9:50 AM
To: Ascher, Seth M <seth.ascher@oah.nc.gov>; jcampbell <jcampbell@ncbop.org>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: [External] RE: RFC for BOP 21 NCAC 46 .1418

This morning, I figured, "I guess I better check to make sure nothing else got messed up." And somehow the numbering in the list in (c) got messed up. I've now fixed it back to match the notice of text. So please replace the one I sent yesterday with this one.

Somehow, after doing this dozens of times over 20 years, it seems my process suddenly went to crap. Sorry about that.

Clint Pinyan

BROOKS PIERCE

t: 336.271.3157
f: 336.232.9157

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

21 NCAC 46 .1418 is amended with changes as published in 40:08 NCR 767-69 as follows:

21 NCAC 46 .1418 HEALTH CARE FACILITY PHARMACY TECHNICIANS ~~SUPERVISION OF UNIT DOSE MEDICATION SYSTEMS~~

(a) ~~The purpose of this Section is to set out requirements in the event that pharmacists elect to supervise designated pharmacy technicians' validation of stocking and prepackaging functions in acute care hospital pharmacy practice settings as a means of facilitating pharmacists' delivery of clinical services.~~

~~(b) A Hospital's pharmacist manager is responsible for the oversight of all validation of floor stock and unit dose distribution systems, and that responsibility may not be delegated pursuant to 21 NCAC 46 .1411. In the event that the Hospital's pharmacist manager elects to utilize Validating Technicians in the filling of floor stock and unit dose distribution systems, the pharmacist manager shall develop written policies and procedures that:~~

~~(1) permit a Validating Technician to validate only the following functions of other registered pharmacy technicians in filling floor stock and unit dose distribution systems for inpatients in a Hospital:~~

~~(A) stocking of patient care unit medication inventories;~~

~~(B) stocking of ancillary drug cabinet inventories;~~

~~(C) stocking of automated dispensing or drug supply devices;~~

~~(D) stocking of emergency kits; and~~

~~(E) prepackaging of prescription drugs within the Hospital pharmacy;~~

~~(2) establish the parameters for pharmacist supervision of pharmacy technician validation functions;~~

~~(3) establish facility specific training for pharmacy technician validation functions;~~

~~(4) establish an ongoing evaluation and assessment program to ensure that pharmacy technician validation functions are performed safely and accurately; and~~

~~(5) establish a recordkeeping system that shall permit the identification of the Validating Technician who performs activities authorized by this Rule. Readily retrievable records generated by this system shall be maintained for the period of time specified in 21 NCAC 46 .1414(j)(1) and (2).~~

~~(c) With respect to compounded or admixed prescription drugs (whether sterile or non sterile), a Validating Technician may validate the filling of floor stock and unit dose distribution systems only after a pharmacist has verified that the compounded or admixed prescription drugs have been prepared correctly.~~

~~(d) This Rule does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.~~

~~(e) Validating Technician.~~ For the purposes of this Rule, a "Validating Technician" shall be a pharmacy technician who:

(1) is registered with the Board and trained as specified in G.S. 90-85.15A;

(2) is a certified technician;

(3) is employed by a Health Care Facility pharmacy; and

(4) ~~holds~~ either:

(A) holds an associate's degree in pharmacy technology conferred by one of the following: ~~either~~(i) an institution within the North Carolina Community College System or University System; (ii) an institution accredited by one of the regional accrediting agencies recognized by the United States Department of Education; or (iii) a program accredited by the American Society of Health System Pharmacists; or

~~[(i)] an institution within the North Carolina Community College System or [University] System;~~

(ii) ~~(B) an associate's degree in pharmacy technology conferred by an institution accredited by one of the regional accrediting agencies recognized by the United States Department of Education; or~~

(iii) ~~(C) an associate's degree in pharmacy technology conferred by a program accredited by the American Society of Health System Pharmacists; and [or]~~

(B) holds a current Advanced Certified Pharmacy Technician (CPhT-Adv) credential from the Pharmacy Technician Certification Board (PTCB), and also holds a current Technician Product Verification Certificate either as part of or in addition to the CPhT-Adv credential. The Subparagraphs in this Rule may require other specific certifications for functions described in those Subparagraphs.

~~(4) assists pharmacists with the preparation, dispensing and distribution of prescription medications that will be administered by a licensed health care provider to an inpatient in a Hospital under this Rule.~~

(b) A Health Care Facility may utilize Validating Technicians to validate the following functions for a Health Care Facility pharmacy:

(1) stocking of patient care unit medication inventories;

(2) stocking of ancillary drug cabinet inventories;

(3) stocking of automated dispensing or drug supply devices;

(4) stocking of emergency kits;

(5) prepackaging of prescription drugs within the Health Care Facility pharmacy;

(6) selection of the correct dose by an automated medication system that has been stocked and restocked in compliance with 21 NCAC 46 .3404, only in the following circumstances:

(A) If a pharmacist has performed a Drug Regimen Review to ensure that dispensing the order is safe and effective for the patient, and that the requirements of 21 NCAC 46. 1414 have been met; and

(B) If the order has not changed following the Drug Regimen Review and review for compliance with 21 NCAC 46 .1414;

(7) preparation of a product by an automated compounding device, only in the following circumstances:

(A) If the technician qualifies as a Validating Technician by virtue of holding the certifications set out in Paragraph (a)(4)(B) of this Rule, in addition to those qualifications, the Validating Technician must hold a current Certified Compounded Sterile Preparation Technician credential from the PTCB. If the technician qualifies as a Validating Technician by virtue of the educational requirements set out in Paragraph (a)(4)(A) of this Rule, the technician is not required to hold this credential;

(B) A Health Care Facility pharmacist must prepare the automated compounding device to compound the appropriate compounded product; and

(C) The automated compounding device must automatically measure and compound the components for the compounded product, and must keep and maintain records of all steps in the compounding process; or

(8) validating the preparation and repackaging by other registered pharmacy technicians of non-sterile low-risk products that are compounded in multi-patient volume and whose composition does not vary by patient. If the technician qualifies as a Validating Technician by virtue of holding the certifications set out in Paragraph (a)(4)(B) of this Rule, in addition to those qualifications, the Validating Technician must hold a current Nonsterile Compounding Certificate from the PTCB, either as part of or in addition to the CPhT-Adv credential. If the technician qualifies as a Validating Technician by virtue of the educational requirements set out in Paragraph (a)(4)(A) of this Rule, the technician is not required to hold this credential.

(c) If the Health Care Facility elects to utilize Validating Technicians for functions described in this Rule, the pharmacist-manager shall develop written policies and procedures that:

(1) establish the parameters for pharmacist supervision of pharmacy technician validation functions;

(2) establish facility-specific training for pharmacy technician validation functions;

(3) establish an ongoing evaluation and assessment program to ensure that pharmacy technician validation functions are performed safely and accurately; and

(4) establish a recordkeeping system that shall permit the identification of the Validating Technician who performs activities authorized by this Rule. Readily retrievable records generated by this system shall be maintained for the period of time specified in 21 NCAC 46 .1414(j)(1) and (2).

(d) A Health Care Facility's pharmacist-manager is responsible for the oversight of all validation functions, and that responsibility may not be delegated pursuant to 21 NCAC 46 .1411. This Rule does not permit a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

~~(f) Hospital. For the purposes of this Rule, a Hospital is either:~~

~~(1) a hospital licensed by the North Carolina Medical Care Commission; or~~

~~(2) a psychiatric hospital operated by the Secretary of the Department of Health and Human Services.~~

~~(g)~~ (e) Pursuant to G.S. 90-85.15A(c), the Board approves a pharmacist's supervision of more than two pharmacy technicians where the additional technicians are Validating Technicians. This Rule does not relieve the pharmacist-manager of the obligation to request and receive written Board approval for a pharmacist's supervision of more than

two pharmacy technicians where the additional technicians are certified pharmacy technicians but are not Validating Technicians.

~~(h) A pharmacy technician performing validation functions described in this Rule as part of a Board approved 21 NCAC 46 .2510 pilot project at Broughton State Hospital or Wake Forest University Baptist Medical Center may continue to perform such functions for a period of three years from this Rule's original effective date, after which time the pharmacy technician must meet all of the requirements specified in Paragraph (e) of this Rule to continue performing such functions.~~

History Note: *Authority G.S. 90-85.6; 90-85.15A; 90-85.21; 90-85.26; 90-85.32; 90-85.33; 90-85.34;*
Eff. June 18, 2011;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017; ~~*2017.*~~
Amended Eff. May 1, 2026.

Burgos, Alexander N

Subject: FW: [External] RE: RFC for BOP 21 NCAC 46 .1418
Attachments: 21 NCAC 46. 1418 Final 4920-6668-4800 v.1.doc; Board of Pharmacy RFC Feb 26 with responses 4901-9123-1629 v.1.docx

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From: Clint Pinyan <CPINYAN@brookspierce.com>
Sent: Thursday, February 5, 2026 1:12 PM
To: Ascher, Seth M <seth.ascher@oah.nc.gov>; jcampbell <jcampbell@ncbop.org>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: [External] RE: RFC for BOP 21 NCAC 46 .1418

Here are the revisions, plus responses to your questions. If this doesn't do it, let me know. Thanks for your help.

Clint Pinyan

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Eff. June 18, 2011;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017; ~~*2017.*~~
Amended Eff. May 1, 2026.

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

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1418

DEADLINE FOR RECEIPT: February 17, 2026

***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:

It appears you didn't use the template, so there are no line numbers in the rule. Please update with line numbers, either by using the template or adding in word.

My bad. I thought I was working off the one I sent with the notice of text (since it hadn't changed). Clearly, I wasn't. Fixed, as is the line spacing and the fact that the heading formerly said the rule was "adopted" instead of "amended." I don't know what I was doing.

For item (a)(4)(A), newly updated rules cannot go to the 4th level of indent (the "i", "ii", "iii"), so this needs to be changed to all be part of A and not new paragraphs. You can maintain the subdivision if you want, or just make it a plain text list. For example: "by one of the the following: (i) an institution . . . (ii) an institution . . . (iii) a program . . ." Note that even if you do not change the text, still strikethrough and highlight the old formatting and add back the text highlighted and underlined.

Fixed and attached.

In (b)(6), is "Drug Regimen Review" a defined term or process somewhere? I did not see it in either cross-referenced rule. The capitalization and phrasing make it seem like a defined term. If so, where is it defined? If not, consider rephrasing: i.e. "if a pharmacist has reviewed the drug regimen" and "if the order has not changed following the pharmacist's review of the drug regimen"

It is defined in the definition rule that applies to all the rules. ("The one rule to bind them all.") 21 NCAC 46 .1317(4).

Am I understanding paragraph (e) correctly that the Board is granting blanket approval to supervise more than two Validating Technicians without additional board action?

Seth Ascher
Commission Counsel
Date submitted to agency: February 5, 2026

That is a fact. This is unchanged from the current practice.

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

Seth Ascher
Commission Counsel
Date submitted to agency: February 5, 2026

Burgos, Alexander N

From: Ascher, Seth M
Sent: Thursday, February 5, 2026 11:56 AM
To: Clint Pinyan; jcampbell
Cc: Burgos, Alexander N
Subject: RFC for BOP 21 NCAC 46 .1418
Attachments: Board of Pharmacy RFC Feb 26.docx

Good afternoon,

I'm the attorney who reviewed the Rules submitted by the Board of Pharmacy for the February 2026 RRC meeting. The RRC will formally review these Rules at its meeting on Thursday, February 26, 2026, 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 close to the meeting. If there are any other representatives from your agency who want to attend virtually, let me know prior to the meeting, and we will get evites out to them as well.

Attached is my initial Request for Changes Pursuant to G.S. 150B-21.10. Please submit your responses, the revised Rules, and forms to me via email, no later than 5 p.m. on February 17, 2026.

Please let me know if you have any questions of concerns.

Seth Ascher
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984) 236-1934