

From: [Cover, William](#)
To: [2022 Active State Board Execs](#)
Cc: [NABP Executive Office; Executive Committee](#)
Subject: North Carolina Board Action- Fletcher Panacea
Date: Monday, October 10, 2022 2:06:12 PM
Attachments: [image001.png](#)
[image003.png](#)
[image004.png](#)
[image005.png](#)
[image006.png](#)
[image007.png](#)
[Fletcher Panacea LLC Summary Suspension Order.pdf](#)
[RPH. Michael Shane Miller 23190 Summary Suspension Order.pdf](#)
[NCBOP Summary Report 202200285 Fletcher Panacea.pdf](#)
[MEMO - EO - Fletcher Panacea Inspection Report \(002\).pdf](#)

EXTERNAL: Do not open attachments or click on links unless you recognize and trust the sender.

Good Monday to you all.

Please note the information below, as well as the attached documents, from the North Carolina Board of Pharmacy that detail disciplinary actions taken against Fletcher Panacea pharmacy located in Arden, NC. This is a follow up to the Executive Officer memo (attached) dated September 29, 2022. Please contact Krystal with the North Carolina Board of Pharmacy if you have any questions or additional information.

Best regards, Bill

Bill Cover BSPHarm, RPh

Associate Executive Director, State Pharmacy Affairs

Phone: 224-565-5694

National Association of Boards of Pharmacy

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From: Krystal Stefanyk

The North Carolina Board of Pharmacy convened a hearing on October 5, 2022, to hear information concerning Fletcher Panacea submitting altered inspection reports to several states to obtain a pharmacy permit. Based on the information presented the Board Summarily Suspended the pharmacy permit as well as Michael Shane Miller's Pharmacist License. The suspension orders were served on October 7, 2022. Attached are copies of the Summary Suspension Orders as well as a summary of the case. If you have any questions please feel free to reach out to me. Thanks

Krystal Brashears Stefanyk, CISCITM

Director of Inspections
North Carolina Board of Pharmacy
6015 Farrington Road
Suite 201
Chapel Hill, NC 27517
Telephone: 919.246.0089
Fax: 919.258.2807

This e-mail message and any replies potentially are subject to disclosure under the North Carolina Public Records Act and therefore could be disclosed to third parties.

NORTH CAROLINA BOARD OF PHARMACY

In Re:)	
)	ORDER SUMMARY
Fletcher Panacea Inc)	SUSPENDING PHARMACY
(Permit No. 14741))	PERMIT
)	

Pursuant to G.S. § 150B-3(c) and 21 N.C.A.C. 46.2006(b), the North Carolina Board of Pharmacy ("Board"), vis Members Wallace Nelson, Mischelle Johnson Corbin, Ashley Duggins, Dr. Keith Vance, Chris Sain, and Dr. Andrew Bowman, find that the protection of the public health, safety and welfare requires emergency action. Accordingly, the Board hereby Summarily Suspends Permit No. 14741 issued to Fletcher Panacea Inc, LLC ("Respondent Pharmacy"), effective upon service of this Order. Respondent Pharmacy shall immediately cease any practice of pharmacy in North Carolina pending issuance by the Board of a Final Agency Decision.


Respondent Pharmacy may request a hearing on the charges against you by submitting a written request within sixty (60) days of service of this order, pursuant to 21 N.C.A.C. 46. 2004. Within sixty (60) days of receipt of your written request, the Board will issue a notice of hearing with respect to whether the summary suspension should be continued. That notice will advise Respondent Pharmacy of the date and time of the hearing, which will be set within the discretion of the Board. In the event that Respondent Pharmacy requests a hearing, this summary suspension remains in effect until the issuance of a further decision by the Board.

If Respondent Pharmacy does not request a hearing as set forth above, the Respondent Pharmacy waives the right to contest the Board's decision and the summary suspension imposed upon the permit by this order. However, the Respondent Pharmacy retains the right to file a written petition for reinstatement of permit at any time following this order. The Board will set a

hearing at a time and place within its discretion and will rule on the petition for reinstatement, in its discretion, under its duty to consider the public health, safety and welfare.

By Order of the Board, this 5th day of October, 2022.

NORTH CAROLINA BOARD OF PHARMACY

/s/ Wallace Nelson
Wallace Nelson
President 

CERTIFICATE OF SERVICE

I certify that on the _____, day of _____, 2022, I hand served a copy of the Order Summary Suspending Pharmacy Permit No. 14741, Fletcher Panacea Inc, to Pharmacist Manager Michael Shane Miller.

Kristy Edmondson
Investigator/Inspector
North Carolina Board of Pharmacy

Fletcher Panacea #14741
2712 Hendersonville Rd Ste 200
Arden, NC 28704
202200285

- Permit application was submitted on June 18, 2021 (**Exhibit #1**).
 - The name of the submitter and PM was Michael Shane Miller #23190.
 - In the application, RPh. Miller advised that the pharmacy was a retail pharmacy that is open to the public. He advised the pharmacy did not have a call center and that no functions were performed outside of the pharmacy. He also indicated that the pharmacy was the main office.
 - Owner of the pharmacy was Jason Vasquez.
 - Application was approved and the pharmacy was permitted on July 12, 2021.

- On May 23, 2022, Director of Inspections, Krystal Stefanyk received a call from RPh. Michael Miller requesting an inspection at Fletcher Panacea. Director Stefanyk notified Investigator Kristie Edmondson that the pharmacy had requested an inspection.
 - On May 27, 2022, Director Stefanyk received a voicemail from West Palm Beach FL from an “Alicia” calling on behalf of Jason Vasquez requesting an inspection.

- On May 30, 2022, Director Stefany spoke with Investigator Edmondson who advised she had driven to the address listed on the permit for Fletcher Panacea and all she found was a CBD outlet.
 - Director Stefanyk called PM Miller to ask if the pharmacy had moved and was told by RPh. Miller that they were in the back of the CBD outlet. This was not indicated on the permit application. Director Stefanyk asked PM Miller what types of medications the pharmacy dispensed, and PM Miller stated they dispensed diabetic supplies as well as diabetic pain creams.

- On May 31, 2022, Investigator Edmondson conducted an inspection of Fletcher Panacea.
 - During the inspection PM Miller noted the pharmacy was a mail order pharmacy that utilizes off-site representatives in Florida to conduct verbal orders. PM Miller advised the pharmacy primarily provides migraine pain support, arthritis creams, arthritis support, pain support, and diabetic testing supplies.

 - Investigator Edmondson also noted the pharmacy was in the back of a CBD outlet.

 - During the investigation Investigator Edmondson PM Miller explained sales representatives will call doctor’s offices for prescriptions at the patient’s request and obtain authorization via verbal order. Once the order is approved, PM Miller checks and signs off on the prescription to then fill the medication. Investigator Edmondson asked to listen to an example of a verbal order. PM Miller pulled up a verbal order for diabetic supplies belonging to patient Bernice Black. On the recording, a man with a foreign

accent was asking for approval of diabetic supplies, which was given by the medical assistant. Investigator Edmondson then heard the representative say, "are you able to tell us if the patient has high blood pressure so that we can authorize the use of Omega 3". The medical assistant said "no" to that question. The verbal order is entered by the call center and sent to the pharmacy for approval.

- Investigator Edmondson added on the inspection report that she had some concerns about the pharmacy's business model regarding the verbal order method that required further investigation.
 - Investigator Edmondson requested the pharmacy provide a dispensing report with the patient's name, address, provider, provider's address, medication, qty, third party payer etc.
 - Case 202200285 was opened
 - Inspection report was completed and sent to PM Miller on July 12, 2022. (**Exhibit #2**)
- August 2022-PM Miller contacted Investigator Edmondson several times asking if she would remove the comments in the inspection report because it would hinder his ability to obtain permits in other states and contracts with PBMs.
 - August 25, 2022, Director Stefanyk received an email from PM Miller asking if we could remove the comments or write a statement saying there was a satisfactory conclusion. Since the investigation was still ongoing, Director Stefanyk responded that the Board staff was not going to remove the comments because they were observations as part of the inspection and we still investigating what was gathered by Investigator Edmondson (**Exhibit #3**).
 - On September 20, 2022, Director Stefanyk received an email from Amanda Harding with the Kentucky Board of Pharmacy advising Fletcher Panacea had applied with them and she was having trouble reading the inspection report and she asked for a clearer copy. Director Stefanyk asked her to send a copy of what was sent to her. Ms. Harding sent the bad copy of the inspection report that Fletcher Panacea submitted with their KYBOP application. The report appeared to be the NCBOP inspection report, but most of the comments that indicated concern with the pharmacy had been erased. The case number at the top of the inspection report was also erased (**Exhibit #4**).
 - Ms. Harding asked the pharmacy for a clearer copy of the inspection report and was sent a clear copy of the altered inspection (**Exhibit #5**).
 - On September 22, 2022, Amanda Harding also sent a copy of Fletcher Panacea's permit application (**Exhibit #6**). The application was submitted on May 22, 2022. In the application PM Miller signed the information submitted was true and correct. PM Miller also checked "no" to the question, "Does the pharmacy dispense any prescriptions to citizens of the Commonwealth of Kentucky that have been referred, in whole, or in part, by any outside agent?" The pharmacy

admitted during the NCBOP inspection that they utilize off-site marketing representatives to obtain prescription orders. The application was also notarized in Florida

- On September 20, 2022, Ms. Harding emailed the owner of the pharmacy Jason Vasquez requesting a copy of an NCBOP inspection. The pharmacy submitted an altered version.
- Later on, September 22, 2022, Director Stefanyk found that Fletcher Panacea was permitted in four states (West Virginia, Virginia, South Dakota, and Arizona). Director Stefanyk also found the pharmacy also had pending applications in seven other states (Kentucky, Connecticut, Delaware, New Jersey, New York, New Mexico, and Rhode Island).
 - Director Stefanyk emailed the Executive Directors and collected the following information.
- West Virginia Board of Pharmacy sent a copy of Fletcher Panacea's application (**Exhibit #7**). The application was submitted on May 11, 2022. The application requested a copy of the most recent inspection report. The pharmacy submitted a memo that stated the North Carolina Board of Pharmacy not conducting inspections due to COVID-19 restrictions and this was per NCBOP rules. The application had a box that was checked stating "I do solemnly swear and affirm that all statements made herein are true and correct"
- Virginia Board of Pharmacy sent a copy of the inspection report the pharmacy submitted. This inspection report was accurate and unaltered (**Exhibit #8**).
- Arizona Board of Pharmacy Executive Director, Kam Gandhi, contacted Director Stefanyk and advised that AZBOP did not request an inspection report at the time the pharmacy applied and was permitted.
 - Executive Director Gandhi later requested from the pharmacy a copy of the NCBOP inspection report. Fletcher Panacea emailed the AZBOP a copy of an altered inspection report with the case number and comments removed (**Exhibit #9**).
 - On September 30, 2022, Jason Vasquez, owner of Fletcher Panacea, signed an Interim Consent Agreement for Interim Suspension Of Permit with the Arizona Board of Pharmacy (**Exhibit #10**).
- South Dakota Board of Pharmacy sent a copy of the permit application that Fletcher Panacea submitted on July 7, 2022 (**Exhibit #11**). In the application, PM Miller indicates the last inspection was conducted on June 1, 2022, and no deficiencies were found.
 - The application indicated that no pharmacy technicians were working at the location, but PM Miller advised during the inspection the pharmacy had a remote technician that was working. NCBOP Database indicates two other technicians listed who reside in Florida.
 - After putting in the application that the pharmacy was last inspected on June 1, 2022, PM Miller submitted a document that stated the pharmacy was waiting on the final results of the inspection and did not submit a copy of the inspection.

- PM Miller electronically signed the application as well as checked the box that states “I declare and affirm under the penalty of perjury that this application has been examined by me, and to the best of my knowledge and belief, is in all things true and correct.
- Connecticut Department of Consumer Protection sent in a copy of the pharmacy permit application Fletcher Panacea submitted on September 6, 2022 (**Exhibit #12**). The application appears to be signed by Jason Vasquez the owner of the pharmacy.
 - Applicant submitted a copy of an altered inspection with the case number and comments removed.
- New Jersey Board of Pharmacy sent a copy of the pharmacy permit application Fletcher Panacea submitted on September 6, 2022 (**Exhibit #13**).
 - The applicant answered “no” to any previous disciplinary action of the Pharmacist in Charge. PM Miller has several previous disciplinary actions on his license. PM Miller signed the application was signed by PM Miller that the information was true and correct. The application was notarized in Florida.
 - The pharmacy submitted a copy of an altered NCBOP inspection report with the case number and comments deleted.
- New York Office Of Professionals, Alexander Goh advised that New York did not request a copy of the inspection report when the pharmacy applied. Mr. Goh stated he would be sending the information provided to their investigations department.
- Rhode Island sent a copy of the pharmacy permit application Fletcher Panacea submitted on September 8, 2022 (**Exhibit #14**).
 - The application was signed by Jason Vasquez on July 20, 2022 and notarized in Florida.
 - The application includes a copy of an altered inspection report with the case number and comments removed.
 - The application also asked if any license has ever been denied and the submitted answered “no” to this question. PM Miller’s reciprocity pharmacist license was initially denied by NCBOP. He reapplied a year later per his consent order and was granted a NC license.
- Missouri Board of Pharmacy sent in a copy of the pharmacy permit application Fletcher Panacea submitted on September 2, 2022 (**Exhibit #15**). The application was signed by PM Miller.
 - The inspection report submitted with the application was altered with the case number and comments removed.
- On October 7, 2022, the North Carolina Board of Pharmacy served summary suspension orders for Fletcher Panacea and RPh. Michael Miller.



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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY
FROM: William Cover, Associate Executive Director State Pharmacy Affairs
DATE: September 29, 2022
RE: Altered North Carolina Inspection Report- Fletcher Panacea, Inc.

The North Carolina Board of Pharmacy has recently informed NABP of a concern with a pharmacy operating under the business name of Fletcher Panacea, Inc. which holds an NABP Business eProfile ID of 1592723 and is located within their state at 2712 Hendersonville Road, Suite 200 Arden, NC 28704.

The North Carolina Board of Pharmacy (NC board) received information that Fletcher Panacea, Inc has been submitting applications to states for non-resident pharmacy licensure which included a NC board inspection report that has been altered. During the NC board inspection of the pharmacy, conducted in May of 2022, the inspector made several observations and noted those concerns in the inspection report. It appears that the pharmacy has removed the inspector's comments from the submitted inspection report.

Attached are two documents that demonstrate the valid NC board inspection report as well as the altered inspection document used during nonresident licensure application. To date the pharmacy has reportedly submitted this altered NC board inspection report to four states. The NC board has learned that this pharmacy has also falsely reported to three states that North Carolina was not conducting inspections due to COVID-19.

The NC board has already reached out to several states where it learned that this pharmacy is currently licensed or have pending applications. Please inform the NC board contact below if this pharmacy has submitted an application in your state and what documents were provided as part of their licensure application.

Krystal Brashears Stefanyk, CISCI
Director of Inspections
North Carolina Board of Pharmacy
6015 Farrington Road, Suite 201
Chapel Hill, NC 27517
Telephone: 919.246.0089
Fax: 919.258.2807

cc: NABP Executive Committee
Lemrey "Al" Carter, Executive Director/Secretary



Inspection Details

Name	FLETCHER PANACEA INC	Case #	202200285	Permit	14741
Address	2712 Hendersonville Rd Ste 200 Arden, NC 28704	Person Providing Info Person In Charge	PM Michael Shane Miller Michael Shane Miller	Inspection Date Inspection User	05/31/2022 Edmondson , Kristy
# RPhs	1	Rx Volume/Date Hours	8-10 Monday - Thursday 9 AM to 2 PM, Friday Saturday an	Inspection District	DISTRICT2
# Techs	1 (Not on site, does remote data entry)	Office	No		
Follow-Up CAP CAP Requested CAP	No No <input type="button" value="No"/>	Commercial Use Ship to Other States States Shipped To	No No No		
Documentation Received Non-Sterile Compounding Levels Sterile Compounding Levels					

Pharmacy Staffing

What is the P:T ratio at the time of inspection: 1:0	How often is there only one pharmacist on duty: Always
If ratio is above 1:2 at the time of inspection, how many certified technicians are on shift: N/A	How many technicians are usually on shift at a time: 0
What is the approved Pharmacist: Technician ratio?	Are pharmacists asked to do any duties outside of the pharmacy : Not yet.

Pharmacy Volume

Does pharmacy administer vaccines: No	Does pharmacy conduct any point of care testing such as COVID: No
What is the daily average of vaccines:	What is the daily average of testing:
What staff members are administering vaccines and what type of vaccines:	What staff is responsible for administering test and what is testing procedure:
How far behind is the pharmacy on filling and verifying prescriptions: Not behind	Are administered vaccines reported to the appropriate vaccine registry:
How long has this backlog persisted: N/A	In your opinion is the rate you are dispensing per hour or per day safe or does it pose a threat to public health and safety: Safe.

Comments

This pharmacy is in a shared building with the CBD Factory Outlet located in Suite 200 and is located in the back of the store. PM Miller advised that the pharmacy is primarily a mail order pharmacy and utilizes off site marketing representatives in Florida to conduct verbal orders. The pharmacy primarily provides migraine pain support, arthritis creams and arthritis support, pain support, and diabetic testing supplies.

During the inspection, PM Miller explained that the representatives will call doctor's offices for prescriptions at patient request and obtain authorization via a verbal order. Once the order is approved, PM Miller checks and signs off on the prescription to then fill the medication. The R/I listened to an example of a verbal order while on site. The R/I has concerns about the pharmacy's business model regarding the verbal order method and requires further investigation by the R/I.

General Pharmacy Regulations

Answer	Question
1) <input type="button" value="Satisfactory"/>	NCGS 90-85.15A (a) - tech must register with the Board within 30 days after the date of completing the training program.

General Pharmacy Regulations

Answer	Question
2) Satisfactory	<p>NCGS 90-85.15A (c) - 2:1 ratio, if ratio above provide waiver documentation. Any technician above the 2:1 ratio must be certified.</p> <p>Comments: PM Miller advised Technician Chase Sterling does remote data entry off site.</p>
3) Unsatisfactory	<p>NCGS 90-85.23- PM license, permit and current renewal shall be posted. Licenses and renewals of each RPh. are readily available for inspection.</p> <p>Comments: PM's License of Reciprocity and the pharmacy's current 2022 renewal need to be posted.</p>
4) Satisfactory	NCGS 90-85.25 (b) - PM shall report within 10 days any disaster, accident, theft.
5) Satisfactory	NCGS 90-85.26 (a) - prescriptions preserved for 3 years. (b) - Documentation of alleged medication errors.
6) Satisfactory	NCGS 90-85.29 (1) - prescription label shall contain a discard date that is earlier of 1 yr. from date dispensed or manuf's exp. date, whichever is earlier. (2) - not obscure exp. date and storage statement when product dispensed in manuf's original container.
7) Satisfactory	NCGS 90-85.32 (a) - prescriptions marked PRN not refilled more than 1 yr. after issue date.
8) Satisfactory	NCGS 90-85.47 - Quality Assurance Program
9) Not Applicable	NCGS 90-93 (3)(d): Sch. V log book or record of disposition.
10) Not Applicable	<p>NCGS 90-106.1 (a) - documentation system of photo ID. Kept on premises or central location for 3 years.</p> <p>Comments: No C2s or pseudoephedrine products sold at this facility.</p>
11) Not Applicable	NCGS 90-113.52 (b) - pseudoephedrine Products kept behind counter. (c) - record of every purchaser, amount of product in grams. (d) - records kept for two 2 years.
12) Not Applicable	NCGS 90-113.54 - posting of sign prohibiting sale of more than 2 pkgs (3.6grams total) of pseudoeph. /day, no more than 3 pkgs (9grams total) within 30- day period.
13) Satisfactory	NCGS 90-640 (b) - ID badge
	Comments: It is recommended to get a new name badge that does not have CVS on the badge.
14) Satisfactory	21CFR 201.17- Misbranded drugs: Medications stored in pharmacy should be labeled with an expiration date and manufacturer lot number. Note: Return to stock prescription vial with the pharmacy's own label affixed will not be deemed misbranded
15) Unsatisfactory	<p>21 NCAC 46.106-134.1 (4)(b)- label lacks any requirement listed in the subsection. (px name, name/add. of pharmacy, disp. rph's name, rx #, fill date of rx, prescriber name, dir. for use, name & strength of drug.)</p> <p>Comments: Label had RPH initials only. The label needs at minimum the RPH first initial and full last name.</p>
16) Satisfactory	21 NCAC 46.1601 (a)(2)- posted Pharmacy hours. (4)(A-E)- reference library, hard copy or electronic. (5)- lavatory facilities w/ hot and cold running water; clean, orderly and sanitary. (b)(1)- records are readily retrievable. (b)(2)- toll free number on labels of dispensed medications. (e)- pharmacy permit is countersigned by rphmgr. as represented in the application.
17) Satisfactory	21 NCAC 46.1802 (a) - refills limited to prescriber's orders.
18) Satisfactory	21 NCAC 46.1803 - All records pertaining to the filling and refilling of prescriptions shall be available to designated employees of the Board during normal business hours.
19) Satisfactory	21 NCAC 46.1806 - proper documentation and handling of transferred rxs
20) Satisfactory	21 NCAC 46.1818 - label shall list generic name of drug, even if unavailable to dispense or generic is not authorized.
21) Satisfactory	21 NCAC 46.2302 (a)(1-5) - records of dispensing shall be kept for 3 years.
22) Satisfactory	21 NCAC 46.2303 - records of prescription filling and refilling shall be kept for 3 yrs.
23) Satisfactory	21 NCAC 46.2304 (1) - produce sight-readable documents. (3) - RPh. responsible for completeness and accuracy of entries, provides documentation that prescription information entered is correct. (5) - pharmacy has auxiliary recordkeeping system. (7) - current version of drug interactions software is utilized
24) Satisfactory	21 NCAC 46.2305 - To maintain the confidentiality of patients' prescription orders, there must be adequate safeguards or security of the records.
25) Unsatisfactory	21 NCAC 46.2502 (a) - PM shall assure that rx meds & cs meds are safe/secure within the pharmacy. (b) - PM

General Pharmacy Regulations

Answer Question

is present one-half the hrs. the pharmacy is open or 32 hrs. /wk., whichever is less. (d) - system of inventory recordkeeping and control to detect any shortage or discrepancies of cs meds. (e) - control of all keys to pharmacy. (j) - written disaster plan. (k) - separate from the dispensing stock all drugs more than 6 months out of date.

Comments: Currently, there is a swinging door that is secured with a padlock to lock the pharmacy up. However, there is a half wall of plexiglass utilized to block off the pharmacy from the other business located at the front of the store. The plexiglass is not enough of a security measure to secure the pharmacy after hours.

26) **Satisfactory** 21 NCAC 46.2504 (a) - effective communication of information to the patient(s). (b) - offer to counsel for all new and transfer prescriptions. (g) - Documentation of refusals.

27) **Satisfactory** 21 NCAC 46.3001 (a) - policy/procedure for all out dated, improperly labeled, adulterated damaged or unwanted drugs or drug containers are destroyed or disposed.

28) **Satisfactory** 21 NCAC 46.3301 (b) - Current registration of a pharmacy tech shall be readily available for inspection.

29) **Not Applicable** 21CFR 1301.75 (b) - controlled substances listed in II, III, IV, and V shall be stored in a substantially constructed cabinet, or disbursed throughout the non-controlled substances

Comments: No controls being sold at this facility.

30) **Not Applicable** 21CFR 1304.04 (2)(h)(1) - inventories and records of Sch. I & II substances maintained separate from all other records (2)(h)(2)- paper prescriptions for Sch. II substances maintained in separate file.

31) **Not Applicable** 21CFR 1304.11 (a) - complete/accurate inventory of all cs meds and maintained at the registered location. (c) - Biennial inventory.

32) **Not Applicable** 21CFR 1305.05 (a) - power of attorney on file at registered location.

Comments: Owner Jason Vasquez signed DEA registration, however has not given POA to PM.

33) **Not Applicable** 21CFR 1305.12 (b) - purchaser shall record 1 item on each numbered line. (c) - name/address of supplier on form. Only 1 supplier on any form. (d)- DEA Form 222 properly signed and dated.

34) **Not Applicable** 21CFR 1305.13 (e) - purchaser must record the number of commercial or bulk containers furnished on each item and dates on which the containers are received.

35) **Not Applicable** 21CFR 1305.22 Procedure for filling electronic orders. (g) - purchaser receives shipment, purchaser must create a record of the quantity of each item received and date received. Record must be electronically linked to the original order and archived.

36) **Not Applicable** 21CFR 1305.27 Preservation of electronic orders. (a) purchaser must, for each order filled, retain the original signed order and all linked records for that order for 2 years. Purchaser must also retain all copies of each unaccepted or defective order and each linked statement. (b) supplier must retain each original order filled and the linked records . (Note: 2yrs for Federal Law; 3yrs for NC Law) (c) If electronic order records are maintained on a central server, records must be readily retrievable at the registered location. (Note: 2yrs for Federal Law; 3yrs for NC Law)

37) **Not Applicable** 21CFR 1306.05 (a) - all cs prescriptions shall bear full name and address of the patient along with date, drug, strength, dosage form, quantity, dirs. for use, and name, address and registration number of practitioner. (d) - computer generated prescription that is printed or faxed must be manually signed

38) **Not Applicable** 21CFR 1306.08 (3)(b) - pharmacy may fill electronically transmitted prescription for a cs med provided the pharmacy complies with all requirements. A Sch. II order signed by the practitioner.

39) **Not Applicable** 21CFR 1306.14 (a) - prescription vials labeled for Sch. II display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.

40) **Not Applicable** 21CFR 1306.21 (a) - order for Sch. III, IV, or V that is a facsimile is signed by practitioner.

41) **Not Applicable** 21CFR 1306.22 (b) - cs refills entered on a medication record or electronic record must be uniformly maintained and readily retrievable.

42) **Not Applicable** 21CFR 1306.24 (a) - prescription vials labeled for Sch. III, IV, or V display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.

43) **Not Applicable** 21CFR 1306.26 (b) - not more than 8oz. of any cs containing opium, nor more than 4oz. of any other cs; not more than 48 dosage units of any such cs containing opium, nor more than 24 dosage units of any other such cs to the same purchaser in any 48-hr. period. (c) - purchaser at least 18 yoa (d) - furnish suitable ID (e) - maintain log containing name and address of purchaser, name and qty. of cs, date of purchase, name or initials of RPh. who dispensed the substance.

General Pharmacy Regulations

	Answer	Question
44)	Not Applicable	21CFR 1311.10 Eligibility to obtain a CSOS digital certificate. (a) - person who signed the most recent DEA registration application or renewal application and a person authorized to sign a registration application. (b) - person granted power of attorney by a DEA registrant to sign orders for one or more schedules of controlled substances.
45)	Not Applicable	21CFR 1311.30 Requirements for storing and using a private key for digitally signing orders. (a) - Only the certificate holder may access or use his or her digital certificate and private key. (b) - The certificate holder must provide FIPS approved secure storage for the private key, as discussed by FIPS 140-2, 180-2, 186-2, and accompanying change notices and annexes, as incorporated by reference in §1311.08. (c) - A certificate holder must ensure that no one else uses the private key. While the private key is activated, the certificate holder must prevent unauthorized use of that private key.
46)	Not Applicable	21CFR 1311.35 Number of CSOS digital certificates needed. A purchaser of Schedule I and II controlled substances must obtain a separate CSOS certificate for each registered location for which the purchaser will order these controlled substances.
47)	Not Applicable	21CFR 1311.60 Recordkeeping. (a) - supplier and purchaser must maintain records of CSOS electronic orders and any linked records for 2 years. Records may be maintained electronically. Records regarding controlled substances that are maintained electronically must be readily retrievable from all other records. (Note: 2yrs for Federal Law; 3yrs for NC Law) (b) - Electronic records must be easily readable or easily rendered into a format that a person can read. Must be made available to the Administration upon request. (c) - CSOS certificate holders must maintain a copy of the subscriber agreement that the Certification Authority provides for the life of the certificate.



Deleted
Case #

Inspection Details

Name	FLETCHER PANACEA INC	Case #		Permit	14741
Address	2712 Hendersonville Rd Ste 200 Arden, NC 28704	Person	PM Michael Shane	Inspection Date	05/31/2022
# RPhs	1	Providing Info	Miller	Inspection User	Edmondson , Kristy
# Techs	1 (Not on site, does remote data entry)	Person In Charge	Michael Shane Miller	Inspection District	DISTRICT2 ⓘ
Follow-Up CAP	No	Rx Volume/Date Hours	8-10 Monday - Thursday 9 AM to 2 PM, Friday Saturday an		
CAP Requested	No	Office	No		
CAP	No	Commercial Use	No		
Documentation	No	Ship to Other States	No		
Received		States Shipped To			
Non-Sterile Compounding Levels					
Sterile Compounding Levels					

Pharmacy Staffing

What is the P:T ratio at the time of inspection: 1:0	How often is there only one pharmacist on duty: Always
If ratio is above 1:2 at the time of inspection, how many certified technicians are on shift: N/A	How many technicians are usually on shift at a time: 0
What is the approved Pharmacist: Technician ratio?	Are pharmacists asked to do any duties outside of the pharmacy : Not yet.

Pharmacy Volume

Does pharmacy administer vaccines: No	Does pharmacy conduct any point of care testing such as COVID: No
What is the daily average of vaccines:	What is the daily average of testing:
What staff members are administering vaccines and what type of vaccines:	What staff is responsible for administering test and what is testing procedure:
How far behind is the pharmacy on filling and verifying prescriptions: Not behind	Are administered vaccines reported to the appropriate vaccine registry:
How long has this backlog persisted: N/A	In your opinion is the rate you are dispensing per hour or per day safe or does it pose a threat to public health and safety: Safe.

Comments

Missing
Comments

General Pharmacy Regulations

Answer	Question
1) <input type="radio"/> Satisfactory	NCGS 90-85.15A (a) - tech must register with the Board within 30 days after the date of completing the training program.

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Answer	Question
2) Satisfactory	NCGS 90-85.15A (c) - 2:1 ratio, if ratio above provide waiver documentation. Any technician above the 2:1 ratio must be certified.
3) Unsatisfactory	NCGS 90-85.23- PM license, permit and current renewal shall be posted. Licenses and renewals of each RPh. are readily available for inspection. Comments: PM's License of Reciprocity and the pharmacy's current 2022 renewal need to be posted.
4) Satisfactory	NCGS 90-85.25 (b) - PM shall report within 10 days any disaster, accident, theft.
5) Satisfactory	NCGS 90-85.26 (a) - prescriptions preserved for 3 years. (b) - Documentation of alleged medication errors.
6) Satisfactory	NCGS 90-85.29 (1) - prescription label shall contain a discard date that is earlier of 1 yr. from date dispensed or manuf's exp. date, whichever is earlier. (2) - not obscure exp. date and storage statement when product dispensed in manuf's original container.
7) Satisfactory	NCGS 90-85.32 (a) - prescriptions marked PRN not refilled more than 1 yr. after issue date.
8) Satisfactory	NCGS 90-85.47 - Quality Assurance Program
9) Not Applicable	NCGS 90-93 (3)(d): Sch. V log book or record of disposition.
10) Not Applicable	NCGS 90-106.1 (a) - documentation system of photo ID. Kept on premises or central location for 3 years. Comments: No C2s or pseudoephedrine products sold at this facility.
11) Not Applicable	NCGS 90-113.52 (b) - pseudoephedrine Products kept behind counter. (c) - record of every purchaser, amount of product in grams. (d) - records kept for two 2 years.
12) Not Applicable	NCGS 90-113.54 - posting of sign prohibiting sale of more than 2 pkgs (3.6grams total) of pseudoeph. /day, no more than 3 pkgs (9grams total) within 30- day period.
13) Satisfactory	NCGS 90-640 (b) - ID badge Comments: It is recommended to get a new name badge that does not have CVS on the badge.
14) Satisfactory	21CFR 201.17- Misbranded drugs: Medications stored in pharmacy should be labeled with an expiration date and manufacturer lot number. Note: Return to stock prescription vial with the pharmacy's own label affixed will not be deemed misbranded
15) Unsatisfactory	21 NCAC 46.106-134.1 (4)(b)- label lacks any requirement listed in the subsection. (px name, name/add. of pharmacy, disp. rph's name, rx #, fill date of rx, prescriber name, dir. for use, name & strength of drug.) Comments: Label had RPH initials only. The label needs at minimum the RPH first initial and full last name.
16) Satisfactory	21 NCAC 46.1601 (a)(2)- posted Pharmacy hours. (4)(A-E)- reference library, hard copy or electronic. (5)- lavatory facilities w/ hot and cold running water; clean, orderly and sanitary. (b)(1)- records are readily retrievable. (b)(2)- toll free number on labels of dispensed medications. (e)- pharmacy permit is countersigned by rphmgr. as represented in the application.
17) Satisfactory	21 NCAC 46.1802 (a) - refills limited to prescriber's orders.
18) Satisfactory	21 NCAC 46.1803 - All records pertaining to the filling and refilling of prescriptions shall be available to designated employees of the Board during normal business hours.
19) Satisfactory	21 NCAC 46.1806 - proper documentation and handling of transferred rxs
20) Satisfactory	21 NCAC 46.1818 - label shall list generic name of drug, even if unavailable to dispense or generic is not authorized.
21) Satisfactory	21 NCAC 46.2302 (a)(1-5) - records of dispensing shall be kept for 3 years.
22) Satisfactory	21 NCAC 46.2303 - records of prescription filling and refilling shall be kept for 3 yrs.
23) Satisfactory	21 NCAC 46.2304 (1) - produce sight-readable documents. (3) - RPh. responsible for completeness and accuracy of entries, provides documentation that prescription information entered is correct. (5) - pharmacy has auxiliary recordkeeping system. (7) - current version of drug interactions software is utilized
24) Satisfactory	21 NCAC 46.2305 - To maintain the confidentiality of patients' prescription orders, there must be adequate safeguards or security of the records.
25) Unsatisfactory	21 NCAC 46.2502 (a) - PM shall assure that rx meds & cs meds are safe/secure within the pharmacy. (b) - PM

General Pharmacy Regulations

Answer Question

is present one-half the hrs. the pharmacy is open or 32 hrs. /wk., whichever is less. (d) - system of inventory recordkeeping and control to detect any shortage or discrepancies of cs meds. (e) - control of all keys to pharmacy. (j) - written disaster plan. (k) - separate from the dispensing stock all drugs more than 6 months out of date.

- 26) **Satisfactory** 21 NCAC 46.2504 (a) - effective communication of information to the patient(s). (b) - offer to counsel for all new and transfer prescriptions. (g) - Documentation of refusals.
- 27) **Satisfactory** 21 NCAC 46.3001 (a) - policy/procedure for all out dated, improperly labeled, adulterated damaged or unwanted drugs or drug containers are destroyed or disposed.
- 28) **Satisfactory** 21 NCAC 46.3301 (b) - Current registration of a pharmacy tech shall be readily available for inspection.
- 29) **Not Applicable** 21CFR 1301.75 (b) - controlled substances listed in II, III, IV, and V shall be stored in a substantially constructed cabinet, or disbursed throughout the non-controlled substances

Comments: No controls being sold at this facility.

- 30) **Not Applicable** 21CFR 1304.04 (2)(h)(1) - inventories and records of Sch. I & II substances maintained separate from all other records (2)(h)(2)- paper prescriptions for Sch. II substances maintained in separate file.
- 31) **Not Applicable** 21CFR 1304.11 (a) - complete/accurate inventory of all cs meds and maintained at the registered location. (c) - Biennial inventory.
- 32) **Not Applicable** 21CFR 1305.05 (a) - power of attorney on file at registered location.

Comments:

- 33) **Not Applicable** 21CFR 1305.12 (b) - purchaser shall record 1 item on each numbered line. (c) - name/address of supplier on form. Only 1 supplier on any form. (d)- DEA Form 222 properly signed and dated.
- 34) **Not Applicable** 21CFR 1305.13 (e) - purchaser must record the number of commercial or bulk containers furnished on each item and dates on which the containers are received.
- 35) **Not Applicable** 21CFR 1305.22 Procedure for filling electronic orders. (g) - purchaser receives shipment, purchaser must create a record of the quantity of each item received and date received. Record must be electronically linked to the original order and archived.
- 36) **Not Applicable** 21CFR 1305.27 Preservation of electronic orders. (a) purchaser must, for each order filled, retain the original signed order and all linked records for that order for 2 years. Purchaser must also retain all copies of each unaccepted or defective order and each linked statement. (b) supplier must retain each original order filled and the linked records . (Note: 2yrs for Federal Law; 3yrs for NC Law) (c) If electronic order records are maintained on a central server, records must be readily retrievable at the registered location. (Note: 2yrs for Federal Law; 3yrs for NC Law)
- 37) **Not Applicable** 21CFR 1306.05 (a) - all cs prescriptions shall bear full name and address of the patient along with date, drug, strength, dosage form, quantity, dirs. for use, and name, address and registration number of practitioner. (d) - computer generated prescription that is printed or faxed must be manually signed
- 38) **Not Applicable** 21CFR 1306.08 (3)(b) - pharmacy may fill electronically transmitted prescription for a cs med provided the pharmacy complies with all requirements. A Sch. II order signed by the practitioner.
- 39) **Not Applicable** 21CFR 1306.14 (a) - prescription vials labeled for Sch. II display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.
- 40) **Not Applicable** 21CFR 1306.21 (a) - order for Sch. III, IV, or V that is a facsimile is signed by practitioner.
- 41) **Not Applicable** 21CFR 1306.22 (b) - cs refills entered on a medication record or electronic record must be uniformly maintained and readily retrievable.
- 42) **Not Applicable** 21CFR 1306.24 (a) - prescription vials labeled for Sch. III, IV, or V display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.
- 43) **Not Applicable** 21CFR 1306.26 (b) - not more than 8oz. of any cs containing opium, nor more than 4oz. of any other cs; not more than 48 dosage units of any such cs containing opium, nor more than 24 dosage units of any other such cs to the same purchaser in any 48-hr. period. (c) - purchaser at least 18 yoa (d) - furnish suitable ID (e) - maintain log containing name and address of purchaser, name and qty. of cs, date of purchase, name or initials of RPh. who dispensed the substance.

Missing
Comments

Missing
Comments

General Pharmacy Regulations

	Answer	Question
44)	Not Applicable	21CFR 1311.10 Eligibility to obtain a CSOS digital certificate. (a) - person who signed the most recent DEA registration application or renewal application and a person authorized to sign a registration application. (b) - person granted power of attorney by a DEA registrant to sign orders for one or more schedules of controlled substances.
45)	Not Applicable	21CFR 1311.30 Requirements for storing and using a private key for digitally signing orders. (a) - Only the certificate holder may access or use his or her digital certificate and private key. (b) - The certificate holder must provide FIPS approved secure storage for the private key, as discussed by FIPS 140-2, 180-2, 186-2, and accompanying change notices and annexes, as incorporated by reference in §1311.08. (c) - A certificate holder must ensure that no one else uses the private key. While the private key is activated, the certificate holder must prevent unauthorized use of that private key.
46)	Not Applicable	21CFR 1311.35 Number of CSOS digital certificates needed. A purchaser of Schedule I and II controlled substances must obtain a separate CSOS certificate for each registered location for which the purchaser will order these controlled substances.
47)	Not Applicable	21CFR 1311.60 Recordkeeping. (a) - supplier and purchaser must maintain records of CSOS electronic orders and any linked records for 2 years. Records may be maintained electronically. Records regarding controlled substances that are maintained electronically must be readily retrievable from all other records. (Note: 2yrs for Federal Law; 3yrs for NC Law) (b) - Electronic records must be easily readable or easily rendered into a format that a person can read. Must be made available to the Administration upon request. (c) - CSOS certificate holders must maintain a copy of the subscriber agreement that the Certification Authority provides for the life of the certificate.

NORTH CAROLINA BOARD OF PHARMACY

In Re:)	
)	ORDER SUMMARY
Michael Shane Miller)	SUSPENDING PHARMACIST
(License No. 23190))	LICENSE
)	

Pursuant to G.S. § 150B-3(c) and 21 N.C.A.C. 46.2006(b), the North Carolina Board of Pharmacy (“Board”), vis Members Wallace Nelson, Ashley Duggins, Mischelle Johnson Corbin, Dr. Keith Vance, Chris Sain, and Dr. Andrew Bowman find that the protection of the public health, safety and welfare requires emergency action. Accordingly, the Board hereby Summarily Suspends License No. 23190 issued to Michael Shane Miller (“Respondent” or “you”), effective upon service of this Order. Pending issuance by the Board of a Final Agency Decision, Respondent shall immediately cease any practice of pharmacy in North Carolina and shall not be present in any North Carolina pharmacy except as a customer, with a valid prescription from a treating health care provider.

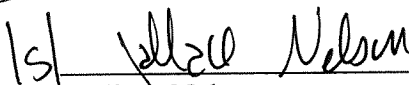
You may request a hearing on the charges against you by submitting a written request within sixty (60) days of service of this order, pursuant to 21 N.C.A.C. 46. 2004. Within sixty (60) days of receipt of your written request, the Board will issue a notice of hearing with respect to whether the summary suspension should be continued. That notice will advise you of the date and time of the hearing, which will be set within the discretion of the Board. In the event that you request a hearing, this summary suspension remains in effect until the issuance of a further decision by the Board.


If you do not request a hearing as set forth above, you waive the right to contest the Board’s decision and the summary suspension imposed upon you by this order. However, you retain the right to file a written petition for reinstatement of your license at any time following

this order. The Board will set a hearing at a time and place within its discretion and will rule on the petition for reinstatement, in its discretion, under its duty to consider the public health, safety and welfare.

By Order of the Board, this 5th day of October, 2022

NORTH CAROLINA BOARD OF PHARMACY



Wallace Nelson
President 

CERTIFICATE OF SERVICE

I certify that on the _____, day of _____, 2022, I hand served a copy of the Order Summary Suspending License No. 23190, upon Respondent Michael Shane Miller:

Kristy Edmondson
Investigator/Inspector
North Carolina Board of Pharmacy