

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	PM Michael Shane Miller	Inspection Date	05/31/2022
# RPhs	1	Providing Info	Michael Shane	Inspection User	Edmondson , Kristy
# Techs	1 (Not on site, does remote data entry)	Person In	Miller	Inspection District	DISTRICT2
Follow-Up CAP	No	Charge	8-10		
CAP Requested	No	Hours	Monday - Thursday 9 AM to 2 PM, Friday Saturday an		
CAP	No	Office	No		
Documentation	No	Commercial Use	No		
Received		Ship to Other	No		
Non-Sterile		States			
Compounding		States Shipped			
Levels		To			
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) 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	NCGS 90-85.15A (c) - 2:1 ratio, if ratio above provide waiver documentation. Any technician above the 2:1 ratio must be certified. Comments: PM Miller advised Technician Chase Sterling does remote data entry off site.
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

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	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

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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

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# RPhs	1	Providing Info	Miller	Inspection User	Edmondson , Kristy
# Techs	1 (Not on site, does remote data entry)	Person In	Michael Shane	Inspection	DISTRICT2 ⓘ
Follow-Up CAP	No	Charge	Miller	District	
CAP Requested	No	Rx Volume/Date	8-10		
CAP	<input type="button" value="No"/>	Hours	Monday - Thursday 9 AM to 2 PM, Friday Saturday an		
Documentation		Office	No		
Received		Commercial Use	No		
Non-Sterile		Ship to Other	No		
Compounding		States			
Levels		States Shipped			
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What is the P:T ratio at the time of inspection: 1:0	How often is there only one pharmacist on duty: Always
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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.

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General Pharmacy Regulations

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