PHARMACY INSPECTION REPORT

North Carolina Board of Pharmacy
Investigations and Inspections

6015 Farrington Rd. Suite 201
Chapel Hill, NC 27517-8822
919-246-1050

Firm Name:		**Permit:**	**Date:**	**Case:**
Address:		**RPh. Providing Info. & License #:**		
Type:		**RPh. Mgr. & License #**		
# of RPhs.:	**# of Techs:**	**Rx Volume/Day:**	**Hours of Operation:**	

S	U	N/A	INSPECTION ITEMS	COMMENTS
○	○	○	**1)** 90-85.15A (a) - tech must register with the Board within 30 days after the date of completing the training program.	
○	○	○	**2)** 90-85.15A (c) - 2:1 ratio	
○	○	○	**3)** 90-85.23- PM license, permit and current renewal shall be posted. Licenses and renewals of each RPh. are readily available for inspection.	
○	○	○	**4)** 90-85.25 (b) - PM shall report within 10 days any disaster, accident, theft.	
○	○	○	**5)** 90-85.26 (a) - prescriptions preserved for 3 years. (b) - Documentation of alleged medication errors.	
○	○	○	**6)** 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)** 90-85.32 (a) - prescriptions marked PRN not refilled more than 1 yr. after issue date.	
○	○	○	**8)** 90-85.47 - Quality Assurance Program	
○	○	○	**9)** 90-93 (3)(d): Sch. V log book or record of disposition.	
○	○	○	**10)** 90-106.1 (a) - documentation system of photo ID. Kept on premises or central location for 3 years.	
○	○	○	**11)** 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.	

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			12) 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) 90-640 (b) - ID badge	
			14) 21 CFR 201.17- Misbranded drugs: lacks expiration date.	
			15) 21 CFR 201.18- Misbranded drugs: lacks Lot #	
			16) 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.)	
			17) .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 rph-mgr. as represented in the application.	
			18) .1802 (a) - refills limited to prescriber's orders.	
			19) .1803 - All records pertaining to the filling and refilling of prescriptions shall be available to designated employees of the Board during normal business hours.	
			20) .1806 - proper documentation and handling of transferred rxs.	
			21) .1818 - label shall list generic name of drug, even if unavailable to dispense or generic is not authorized.	
			22) .2302 (a)(1-5) - records of dispensing shall be kept for 3 yrs.	
			23) .2303 - records of prescription filling and refilling shall be kept for 3 yrs.	
			24) 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	

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			25) .2305 - To maintain the confidentiality of patients' prescription orders, there must be adequate safeguards or security of the records.	
			26) .2502 (a) - PM shall assure that rx meds & cs meds are safe/secure within the pharmacy. (b) - PM 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.	
			27) .2504 (a) - effective communication of information to the patient(s). (b) - offer to counsel for all new and transfer prescriptions. (g) - Documentation of refusals.	
			28) **.**2800 USP <795> and <797>. **Simple Non-Sterile Compounding:** Making a preparation that has a USP compounding monograph or appears in a peer-reviewed journal that contains specifics on component quantities, compounding procedure, equipment and stability data for the formulation and appropriate Beyond Use Dates (BUD), or reconstituting or manipulating commercial products that require addition of one or more ingredients as directed by the manufacturer. (If pharmacy is doing any Moderate or Complex non sterile compounding or doing any type of Sterile Compounding please see NCBOP-Non Sterile or Sterile Compounding Inspection Report.)	
			28 a) Official name, strength, and dosage of preparation.	
			28 b) Name and quantities of all components.	
			28 c) Sources, lot numbers, and expiration dates of components.	
			28 d) Name of person who compounded and the person verified the preparation.	
			28 e) Date preparation.	

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○	○	○	**28 f)** Assigned BUD.	
○	○	○	**28 g)** Description of final preparation.	
○	○	○	**29)** .3001 (a) - policy/procedure for all out dated, improperly labeled, adulterated damaged or unwanted drugs or drug containers are destroyed or disposed.	
○	○	○	**30)** .3301 (b) - Current registration of a pharmacy tech shall be readily available for inspection.	
○	○	○	**31)** CFR 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.	
○	○	○	**32)** CFR 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.	
○	○	○	**33)** CFR 1304.11 (a) - complete/accurate inventory of all cs meds and maintained at the registered location. (c) - Biennial inventory.	
○	○	○	**34)** CFR 1305.05 (a) - power of attorney on file at registered location.	
○	○	○	**35)** CFR 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.	
○	○	○	**36)** CFR 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.	
○	○	○	**37)** CFR 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.	

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			38) CFR 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 for 2 years. (c) If electronic order records are maintained on a central server, records must be readily retrievable at the registered location.	
			39) CFR 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	
			40) CFR 1306.08 (3)(b) - pharmacy may fill electronically transmitted prescription for a cs med provided the pharmacy complies with all requirements.	
			41) CFR 1306.11 (a) - a Sch. II order signed by the practitioner.	
			42) CFR 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.	
			43) CFR 1306.21 (a) - order for Sch. III, IV, or V that is a facsimile is signed by practitioner.	
			44) CFR 1306.22 (b) - cs refills entered on a medication record or electronic record must be uniformly maintained and readily retrievable.	
			45) CFR 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.	

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			46) CFR 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.	
			47) CFR 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.	
			48) CFR 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.	
			49) CFR 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.	

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○	○	○	**50)** CFR 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. (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.	

Notes

Notes

Inspector Signature: _____ Date: _____

☐ By Checking this box, I acknowledge that by my signature I have reviewed this inspection report with the investigator.

Pharmacist Signature : _____ Date: _____

E-mail Address : _____