HOSPITAL 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 #:**		
	RPh. Mgr. & License #:		
# of RPhs.: / **# of Techs:**	**Hours of Operation:**		

S	U	N/A	INSPECTION ITEMS	COMMENTS
○	○	○	**1)** 90-85.23- PM license, permit and current renewal shall be posted. Licenses and renewals of each RPh. are readily available for inspection.	
○	○	○	**2)** .1410 (a) - Pharmacy must be directed by a legally qualified pharmacist referred to as Pharmacy Manager (PM).	
○	○	○	(b) - Sufficient number of pharmacists and supportive personnel to operate pharmacy competently.	
○	○	○	(c) - PM must develop and implement written policies and procedures to specify the duties to be performed by pharmacists.	
○	○	○	(d) - Qualified, trained, adequately supervised supportive personnel to provide technical services. Supervising pharmacist must be fully aware of and responsible for all activities involved in the preparation and dispensing of medication.	
○	○	○	**3)** .1411 (a) - The PM shall establish written procedures for the safe and effective distribution of pharmaceutical products. Procedures periodically reviewed. Copy should be readily available in pharmacy.	
○	○	○	(b)(3) - PM is responsible for participation in development and maintenance of a drug formulary when required by the health care facility.	
○	○	○	(b)(6) - drugs disp. only by RPh. or others allowed by law & supportive personnel are directed & supervised.	
○	○	○	(b)(7) - Policy & Procedure that d/c drugs, outdated drugs, recalled drugs, containers w/ worn, illegible or missing labels are rtnd. to pharmacy for disposition.	
○	○	○	(b)(8) - PM must maintain records and reports to ensure patient health, safety & welfare.	

S	U	N/A	INSPECTION ITEMS	COMMENTS
○	○	○	**Cont.** **3)** .1411 (b)(9) - Reports of controlled substance discrepancies including report of action, steps taken to prevent recurrence, recurring losses or mishandling of significant quantities must be reported to the DEA.	
○	○	○	(b)(10) - aux med inventories are inspected.	
○	○	○	(b)(12) - Maintain policy and procedure regarding drug samples and patient's personal medications.	
○	○	○	**4)** .1412 **-** Sufficient floor space to ensure that drugs are prepared in sanitary, well lighted, and enclosed places.	
○	○	○	(1-2) - Compounding and dispensing areas; physically separate parenteral solution additive area when parenteral solutions are compounded.	
○	○	○	(3) - Area for receiving and storage.	
○	○	○	(4) - Packaging and repackaging area.	
○	○	○	(5) - Office space sufficient to allow for administrative function without interference with the safe compounding and dispensing of medication and security of pharmacy.	
○	○	○	(6) - All drugs shall be stored in designated areas within the pharmacy or decentralized pharmacy sufficient to provide sanitation to prevent contamination. Controlled Substances shall be stored in compliance with Federal and State laws and regulations.	
○	○	○	(7) - Security: All areas in the pharmacy, including auxiliary drug supplies and unit dose carts, shall remain secure at all times.	
○	○	○	**5)** .1413 (a)(2) - Authorized personnel allowed in the pharmacy after-hours.	
○	○	○	**6)** .1414 (a)(1) - Policy and procedure to establish a time frame in which oral medication order shall be put into writing and signed.	
○	○	○	(a)(2) - Medication orders must contain: patient name, location, medication name, strength, dosage form, route of and directions for administration, date of order written, and prescriber signature.	
○	○	○	(a)(3) - Policy and Procedure established for continuing therapy. Information required for patient profile includes patient's name, location, clinical information (height, weight, sex, age, and allergies), medication, strength, dosage form, route of and directions, medication start date, medication discontinue date, and identification of pharmacist responsible.	

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			Cont. **6)** .1414 (a)(4) - Abbreviations used in medication orders shall be agreed to, jointly adopted, and published by the medical, nursing, pharmacy, and medical records staff of the health care facility.	
			(a)(5) - Protect health care facility patients from indefinite, open-ended medications orders.	
			(c)(1)- Drugs are labeled and can be identified up to point of administration.	
			(d)(1-7) - Auxiliary Medication Inventories	
			(j)(1) - PM shall develop system of daily accountability for medication compounding & dispensing that permits the identification of the responsible RPh. & pharmacy technicians. Readily retrievable records shall be maintained for thirty (30) days. The system shall identify all personnel who preform these activities & the RPh responsible for: (A-G)	
			(j)(1)(A) - Interpretation & appropriateness of new med orders.	
			(j)(1)(B) - Profile entry of new med orders.	
			(j)(1)(C) - Disp. of new med orders including stat doses.	
			(j)(1)(D) - Daily cart fills.	
			(j)(1)(E) - IV admixtures.	
			(j)(1)(F) - Compounded meds.	
			(j)(1)(G) - Preparation & release of drugs for replenishment of aux. med inventories & Auto. Disp. Devices in locations outside the pharmacy.	
			(j)(2) - Documentation of med errors.	
			(j)(3) - In case of death of patient retain all documents, physical evidence and internal investigative reports related to event; all items made available to North Carolina Board of Pharmacy upon request.	
			(j)(4) - Records of ordering, receiving, and dispensing or transferred of controlled substances.	
			(j)(4)(E) - Perpetual inventory shall be maintained on all controlled substances awaiting destruction.	

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			Cont. **6)** .1414 (j)(6) - Records must be maintained for three (3) years.	
			7) .1415 (b)(1) - Drugs will only be dispensed to registered patients of the emergency department	
			(b)(2) - The PM develop and supervise a system of control and accountability of all drugs administered in or dispensed from the Emergency Dept.	
			(b)(3) - The pharmacy manager in conjunction with the appropriate committee responsible in the emergency department shall develop an emergency department formulary which may be dispensed to patients receiving care from the emergency department. Medications must be limited to no more than a twenty-four (24) hour supply or the smallest commercially available quantity.	
			(b)(4) - Drugs shall be prepackaged in safety closure containers and pre-labeled by the pharmacist. Prior to dispensing, the following information must be on the label of the medication: name, address, telephone number of the health care facility pharmacy, dispensing date, full name of patient, generic or trade name, directions for use, the name of physician prescribing and dispensing, and cautionary information for the safety of the patient.	
			8).1418(b) - PM shall develop written policies and procedures that: (1) - permit a validating technician to validate only the following functions: (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; (E)- prepackaging of prescription drugs within the Hospital pharmacy;	
			(2) - parameters for RPh. supervision of pharmacy technician validation functions;	
			(3) - facility specific training for technician validation functions;	
			(4) - evaluation and assessment program to ensure functions are performed safely and accurately	
			(5) - recordkeeping system that shall permit the identification of the validating technician. Records are readily retrievable and kept for 3 years.	

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○	○	○	**9)** .1601(a)(3) - Obtaining and maintaining equipment in the pharmacy adequate to meet the pharmaceutical needs of patients. Pharmacy reference library should include medical dictionary, drug interaction reference books, if IV services are provided a reference book on Parenteral Incompatibilities.	
○	○	○	**9a)** (a)(4) - Pharmacy is equipped with sanitary appliances including lavatory with hot and cold running water, well lighted, kept in a clean, and sanitary condition.	
○	○	○	(e) - Pharmacy permit is countersigned by rph-mgr. as represented in the application	
○	○	○	**10)** .2502 (b) - Present in the pharmacy for half the hours open or thirty-two (32) hours a week, whichever is less. Temporary pharmacist in charge should not exceed ninety (90) days, must be present twenty (20) hours a week in the pharmacy.	
○	○	○	(d) - Develop and implement system of inventory record-keeping and control to enable detection of shortage or discrepancies of controlled substance medication at earliest time.	
○	○	○	(e) - Maintain authority and control over all keys to pharmacy and responsible for security of pharmacy. Pharmacy secured to prohibit entry if no pharmacist in pharmacy for ninety (90) minutes or more.	
○	○	○	(j) - Prepare disaster plan.	
○	○	○	(k) - Separate drug products more than six (6) months out of date.	
○	○	○	(l) - Reporting death of a patient or customer to North Carolina Board of Pharmacy within fourteen (14) days of becoming aware of incident.	
○	○	○	**11) .**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.)	

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			Cont. **11)** .2800 USP 795) Official name, strength, and dosage of preparation.	
			.2800 USP 795) Name and quantities of all components.	
			.2800 USP 795) Sources, lot numbers, and expiration dates of components.	
			.2800 USP 795) Name of person who compounded and the person who verified the preparation.	
			.2800 USP 795) Date preparation.	
			.2800 USP 795) Assigned BUD.	
			.2800 USP 795) Description of final preparation.	
			12) 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.	
			13) 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.	
			14)CFR 1304.11 (a) - complete/accurate inventory of all cs meds and maintained at the registered location. (c) - Biennial inventory.	
			15) CFR 1305.05 (a) - power of attorney on file at registered location.	
			16) 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.	
			17) 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.	

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			18) 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.	
			19) 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.	
			20) 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	
			21) CFR 1306.08 (3)(b) - pharmacy may fill electronically transmitted prescription for a cs med provided the pharmacy complies with all requirements.	
			22) CFR 1306.11 (a) - a Sch. II order signed by the practitioner.	
			23) 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.	
			24) CFR 1306.21 (a) - order for Sch. III, IV, or V that is a facsimile is signed by practitioner.	
			25) CFR 1306.22 (b) - cs refills entered on a medication record or electronic record must be uniformly maintained and readily retrievable.	
			26) 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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			27) 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.	
			28) 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.	
			29) 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.	
			30) 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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○	○	○	**31)** 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 : _____