

INSTITUTIONAL FACILITY INSPECTION

| RULE | PHARMACY AREA STANDARDS | C | NC | NA |
|---|---|---|----|----|
| 019 | Current pharmacy license immediately retrievable. | | | |
| 601.01 | Pharmacy is well-lit, ventilated, temperature controlled and has sufficient floor and counter space to avoid overcrowding and to allow the pharmacy to be maintained in a clean and sanitary condition appropriate for the safe preparation and compounding of prescriptions. | | | |
| 601.02 | Pharmacy is equipped with a sink with hot and cold water, appropriate fixtures for waste disposal, and refrigerated storage equipment of reasonable capacity. | | | |
| 630.06 | Discontinued, expired, and damaged drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper handling. | | | |
| 260 | Drugs are stored in accordance with USP-NF requirements in an area maintained and secured appropriately to maintain product integrity and protect against theft or diversion. | | | |
| 611.04 | During pharmacist temporary absence from the institutional pharmacy only pharmacy students and technicians remain in the pharmacy. | | | |
| 611.04.c | During periods of pharmacist absence from the institutional facility student pharmacists and technicians do not remain in the pharmacy. | | | |
| PHARMACY REFERENCES – HARD COPY OR ELECTRONIC EDITIONS AND SUPPLEMENTS OF THE FOLLOWING: | | | | |
| 603.01 | Pharmacy Laws and Rules | | | |
| 603.02.a-d | One (1) additional current pharmacy references: Facts and Comparisons; Clinical Pharmacology; Micromedex or Lexicomp. | | | |
| 603.03 | One (1) additional current pharmacy reference relevant to the practice setting. | | | |
| EMERGENCY DRUG ACCESS IN PHARMACIST ABSENCE: | | | | |
| 631.01.a | Only one R.N. designated per shift for emergency access to the pharmacy. | | | |
| 631.01.b | Controlled substances are secured in a locked cabinet or other appropriate means to prevent unauthorized access. | | | |
| 631.01.c | Only non-controlled substances are removed from the pharmacy and only in the amount necessary to treat a patient's immediate needs until the pharmacist is on duty. | | | |
| EMERGENCY OUTPATIENT DRUG DELIVERY BY HOSPITAL EMERGENCY ROOMS: | | | | |
| 633.01 | Emergency kits or crash carts must be sealed in a tamper-evident manner and stored in limited access areas to prevent unauthorized access and to ensure a proper environment for preservation of the drugs within them. | | | |
| 637 | Only an R.N. is allowed to deliver prepackaged prescription drugs to outpatients receiving emergency treatment. | | | |
| 637.01 | Delivery of prepackaged medication is pursuant to a valid drug order and documented according to emergency drug access rules. | | | |
| 637.04 | Label on prepackaged container contains all necessary information required for outpatient dispensing. | | | |

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| PHARMACY STAFFING AND RATIO: | | | | |
| 607.02 | The ratio of pharmacists to student pharmacists and technicians does not exceed one (1) pharmacist for every six (6) student pharmacists and technicians in total in any practice setting. | | | |
| 621.01 | Staffing of additional pharmacists, student pharmacists and technicians sufficient to operate the pharmacy competently, safely and adequately to meet the needs of the patients. | | | |
| TECHNICIAN AND STUDENT IDENTIFICATION: | | | | |
| 400.04.a 360.03.a | Each technician/student is identified by a clearly visible name badge designating the individual as a technician/student. | | | |
| 400.04.b 360.03.b | Technicians and student pharmacists must identify themselves as technician/student on any phone calls initiated or received while on duty. | | | |
| VERIFICATION TECHNICIAN PROGRAM – IF APPLICABLE: | | | | |
| 410.01 | Written program description on file. | | | |
| 410.02.b | Verification technicians verifying only manufacturer prepared or robotically prepared unit dose drugs identified as written program description. | | | |
| 410.02.d | Documentation of ongoing monitoring and evaluation of each verification technician. | | | |
| 410.02.e | Verification technician wearing identification that includes the title "Verification Technician." | | | |
| ADS SYSTEMS: | | | | |
| 021.03.k.ii | Registered as required by the board. | | | |
| 143 | The containers of prepackaged drugs prepared for ADS systems or other authorized uses must include a label | | | |
| 290.03 | System access to ADS system is monitored and changes to access control are done by authorized personnel only. | | | |
| 292.01 | Drugs contained in manufacturer's sealed, original packages or in prepackaged unit-of-use containers and labeled as required. | | | |
| 292.03 | Drug or device returned according to rule. | | | |
| 292.04 | ADS system provides a mechanism for securing and accounting for wasted and discarded drugs. | | | |
| CONTROLLED SUBSTANCES – RECORDS & INVENTORIES | | | | |
| 630.03 | Distribution, dispensing, delivery or administration of controlled substances with the facility is properly documented and reported in time and manner required. | | | |
| 207.01 | Inventories and records of controlled substances listed in Schedules I and II are maintained separately from all other records of registrant. | | | |
| 207.02 | Inventories and records of controlled substances listed in Schedules III, IV, and V are maintained separately from all other records or in a manner that the information required is readily retrievable | | | |
| 636.03.c | Controlled substances removed from floor stock are documented by appropriate written drug orders and proofs of use, when applicable. | | | |
| 636.03.d | Controlled substances maintained as floor stock are inventoried at least weekly. | | | |

C=COMPLIANT NC=NOT COMPLIANT NA=NOT APPLICABLE

DATE CS INVENTORY COMPLETED _____

OPEN _____ CLOSE _____ RPH _____

Remarks: _____

| | | |
|---------------------|-----------------------|-------|
| Compliance Officer: | Pharmacist Signature: | Date: |
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