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| West Virginia Board of Pharmacy | | |
| **Phone (304) 558-0558 2310 Kanawha Boulevard East Fax (304) 558-0572** | | |
| **Charleston, West Virginia 25311** | | |
| **INSTITUTIONAL PHARMACY INSPECTION REPORT** | | |
|  | E-Mail Address  «E | Date |
| Phone | Fax  «Fax» |
| DEA License # | WVBOP # |
| P.I.C. | License # |
| Hours |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Item | | Question | | Reference | Yes | No | NA |
|  | | | Does this Pharmacy have an automated dispensing system? | 15-1-16.2.11 |  |  |  |
|  | | | What is the name of system and has the Board been notified in writing of its installation? | 15-1-16.2.11 |  |  |  |
|  | | | Does this pharmacy perform USP 795 Non-Sterile Compounding? |  |  |  |  |
|  | | | If Yes attach a USP 795 Inspection Form. |  |  |  |  |
|  | | | Does this pharmacy perform USP 797 Sterile Compounding? |  |  |  |  |
|  | | | If Yes attach a USP 797 Inspection Form. If shipping out of state use NABP Universal. | NABP or WV |  |  |  |
|  | | | Is there an alarm system installed according to Rule? | 15-15-6.2 |  |  |  |
|  | | | Does the alarm system includes a battery back-up power source? | 15-15-6.2.1 |  |  |  |
|  | | | Are barriers installed according to Rule? | 15-1-15 |  |  |  |
|  | | | Are controlled substances dispersed? Or | 15-2-5.5.1 |  |  |  |
|  | | | Stored in a locked 20-gauge (or better) metal cabinet or drawer? | 15-2-5.5.1 |  |  |  |
|  | | | Are all losses or thefts of controlled drugs reported to DEA and WVBOP? | 15-2-5.4 |  |  |  |
|  | | | Only authorized non-registered person(s) in prescription area? | 15-1-14.7 |  |  |  |
|  | | | Only pharmacists have key or code access to prescription area if not 24/7? | 15-15-6.3.1 |  |  |  |
|  | | | Are Rules of Professional Conduct posted in a conspicuous place? | 15-1-15.15 |  |  |  |
|  | | | Are the Pharmacy's Permit and DEA License posted in a conspicuous place? | 15-15-3.3 |  |  |  |
|  | | | Are all pharmacist and pharmacy technician licenses posted? | 30-5-11 |  |  |  |
|  | | | Is a copy of the Combined Technician List and Confidentiality Statement posted? | 15-1-16.3.1 |  |  |  |
|  | | | Are after hours’ entry rules followed? | 15-15-6.3.2 |  |  |  |
|  | | | Is there proper documentation of afterhours entry? | 15-15-6.3.2 |  |  |  |
|  | | | Are I.V. solutions properly stored? | Board Policy |  |  |  |
|  | | | Is satellite pharmacy supervised by pharmacist when open? | Board Policy |  |  |  |
|  | | | Last Biennial Inventory is dated: and is correct? | 15-2-7.5 |  |  |  |
|  | |  | |  |  |  |  |
| Item | | Question | | Reference | Yes | No | NA |
|  | | | Does Form 222 or CSOS require a Power of Attorney? | 15-2-4.6 |  |  |  |
|  | | | Has Power(s) of Attorney been issued? To Whom: | 15-2-4.6 |  |  |  |
|  | | | Are controlled substance invoices or packing slips signed by a pharmacist? | 15-2-9.4.2 |  |  |  |
|  | | | Are there completed Return & Destruction records of controlled drugs? | 15-2-9.2.1 |  |  |  |
|  | | | Are any outdated drugs found among shelf stock? Number found \_\_\_\_\_ | 15-1-15.9.2 |  |  |  |
|  | | | Are refrigerator temperatures all between 36 to 46º F? (2-8º C) | 15-1-11.2.4 |  |  |  |
|  | | | List refrigerator temperatures: |  |  |  |  |
|  | | | Are freezer temperatures between -4 to14º F (-25 to -10º C)? | 15-1-11.2.4 |  |  |  |
|  | | | List the freezer temperatures: |  |  |  |  |
|  | | | Is the pharmacy area temperature controlled between 68 and 77º F (20-25ºC)? | 15-1-11.2.4 |  |  |  |
|  | | | What is the pharmacy area current temperature? |  |  |  |  |
|  | | | Are work counters clean and dust free? | 15-1-14.2 |  |  |  |
|  | | | Are the counters only used for medication preparation? | 15-1-14.2 |  |  |  |
|  | | | Is the medication preparation room clean, orderly and dust free? | 15-1-14.5 |  |  |  |
|  | | | Is the sink used only for cleaning hands and equipment? | 15-1-14.3 |  |  |  |
|  | | | Do pharmacists have a proper name tag on their garment? | 15-1-14.4 |  |  |  |
|  | | | Does the pharmacy have an adequate balance and weights available or electronic digital balance | 15-1-11.2.2 |  |  |  |
|  | | | Does the pharmacy have Board approved clinical reference materials? | 15-15-2.2.3 |  |  |  |
|  | | | Does the pharmacy have a current copy of WVBOP Law and Rules? | 15-1-11.2.8 |  |  |  |
|  | | | Is there sufficient compounding equipment available? | 15-1-11.2.2 |  |  |  |
|  | | | Is there a sanitary method of measuring liquids? | 15-1-11.2.1 |  |  |  |
|  | | | Are inpatient unit-dose drugs properly labeled? | 15-1-18.1.1 |  |  |  |
|  | | | Does multiple dose system meet the labeling requirements? | 15-1-18.1.1 |  |  |  |
|  | | | Is one full year of dispensing records available online? | 15-4-4 |  |  |  |
|  | | | Can the pharmacy generate five full years of dispensing's on request? | 15-4-4 |  |  |  |
|  | | | Are sales of Rx drugs without a prescription properly recorded? | 15-1-6.1.1 |  |  |  |
|  | | | Does PIC work 30 or more HR/WK if pharmacy is open more than 40HR/WK? | 15-1-2.41.c |  |  |  |
|  | | | Does PIC work 50% of hours in a pharmacy open less than 40 HR/WK? | 15-1-2.41c |  |  |  |
|  | | | Has an Interim PIC been utilized? | 15-15-5.1 |  |  |  |
|  | | | Has the PIC seen current licenses of all current employees? | 15-1-16.2.6 |  |  |  |
|  | | | Does the pharmacy have an ongoing Quality Assurance program in place? | 15-1-16.2.3 |  |  |  |
|  | | | Are written reports prepared when dispensing errors occur? | Board Policy |  |  |  |
|  | | | Are these reports formally discussed with prescription dept. personnel? | Board Policy |  |  |  |
|  | | | Is a perpetual inventory maintained for controlled drugs? | 15-2-7.2.4(a) |  |  |  |
|  | | | Does reconciliation of controlled drugs effectively detect diversion? | 15-2-7.2.4(a) |  |  |  |
|  | | | Have any & all complaints about a pharmacist been sent to Board? | 15-15-8.3 |  |  |  |
|  | | | Has the Board been notified of any pharmacists recently discharged? | 15-15-8.2 |  |  |  |
| Item | **Question** | | | **Reference** | **Yes** | **No** | **NA** |
|  | | | **Has PIC notified permit holder of any & all violations of Law or Rules?** | **15-1-16.2.2** |  |  |  |
|  | | | Is there documentation of such with a copy to Board office? | 15-1-16.2.2 |  |  |  |
|  | | | If not, explain why? | 15-1-16.2.2 |  |  |  |
|  | | | Is there a connection to the CSMP available? | 15-8-3.1 |  |  |  |
|  | | | Is 12-hour shift not exceeded? | 15-15-7.1 |  |  |  |
|  | | | Is there documentation if 12-hour shift is exceeded? | 15-15-7.1 |  |  |  |
|  | | | Is the ratio of Technicians to Pharmacist correct at this time? | 15-7-5.3 |  |  |  |
|  | | | Currently on Duty: Technicians\_\_\_\_\_ Pharmacists\_\_\_\_\_ |  |  |  |  |
|  | | | Is the PIC assisted by sufficient staff? | 15-1-16.3 |  |  |  |
|  | | | Is a medication review pharmacist always on staff? | Board Policy |  |  |  |
|  | | | If being done remotely has PIC seen DUR pharmacists license? | 15-14-4.1.b |  |  |  |
|  | | | Is an approved Technician Training Manual available? | 15-1-16.2.4 |  |  |  |
|  | | | Is documentation of training by the P.I.C. available? | 15-1-16.2.4 |  |  |  |
|  | | | Are there written records that document the required elements? | 15-1-16.2.4 |  |  |  |
|  | | | Do trainees wear proper attire? | 15-1-14.4  15-7-8.2 |  |  |  |
|  | | | Do trainees have a proper name tag? | 15-1-14.4  15-7-8.2 |  |  |  |
|  | | | No trainee has exceeded 12 months training plus 3 months for testing? | 15-7-4.2  15-7-4.4e |  |  |  |
|  | | | All licensed technicians are wearing proper attire and name tags? | 15-1-14.4  15-7-8.2 |  |  |  |
|  | | | Does the pharmacy maintain writing duties for all technicians? | 15-1-16.3.2 |  |  |  |
|  | | | No technician is observed violating legally authorized duties? | 15-7-5(1) |  |  |  |
|  | | | All technicians are directly supervised by the pharmacist on duty? | 15-1-16.3.2 |  |  |  |
|  | | | Are techs nationally certified or licensed in other states also licensed in WV? | 15-7-3.1.b.2  15-7-3.1.b.1.c |  |  |  |
|  | | | Are CE certificates or records for all pharmacists available for inspection? | 15-3-13.3 |  |  |  |
|  | | | Do pharmacists have 3 hours CE per renewal on drug diversion & WV statistics? | 15-3-4.4 |  |  |  |
|  | | | Do all pharmacists have at least 6 hours of live CE for reporting period? | 15-3-4.3 |  |  |  |
|  | | | Do all pharmacists have 30 or more hours of CE for reporting period? | 15-3-4.1 |  |  |  |
|  | | | **Does this facility also operate an Outpatient Pharmacy? Y\_\_\_N\_\_\_** |  |  |  |  |
|  | | | **OUTPATIENT PERMIT NUMBER \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |  |  |  |  |
|  | | | Are electronic prescription transmissions certified? | 15-1-17.1.7.b |  |  |  |
|  | | | Do all prescriptions appear prescribed for a legitimate medical use? | 15-1-17.1 |  |  |  |
|  | | | Are telephoned prescriptions properly & completely documented? | 15-1-15.13.1 |  |  |  |
|  | | | Is the manufacturer shown on the prescription record file? | 30-5-12b(j) |  |  |  |
|  | | | Is the dispensing pharmacist's initials recorded on the Rx record file? | 15-1-15.13.4 |  |  |  |
|  | | | Are the initials of all personnel who have worked on Rx recorded? | 15-1-15.13.4 |  |  |  |
| Item | | **Question** | | **Reference** | **Yes** | **No** | **NA** |
|  | | | **Are transferred prescriptions properly recorded (both in and out)?** | **15-1-8.2.1**  **et.al** |  |  |  |
|  | | | Is there any sign that prescriptions have been refilled after 12 months? | 15-1-7.3 |  |  |  |
|  | | | Does it appear that all CFNP and PA prescribing is according to Rules? | 11-1B-12.3  19-8-5 |  |  |  |
|  | | | Is there a proper record of emergency dispensing of maintenance meds? | 15-1-22.1 |  |  |  |
|  | | | Are complete patient profiles maintained on all patients? | 15-1-11.2.7 |  |  |  |
|  | | | If servicing a nursing home is a log of returned drugs maintained? | 15-1-9.3 |  |  |  |
|  | | | Is a proper offer to counsel made on pickup of each new prescription? | 15-1-15.13.6 |  |  |  |
|  | | | How is "Offer to Counsel" documented on mail or delivered Rx's? | 15-1-15.13.6 |  |  |  |
|  | | | Is the counseling area convenient to the pharmacist? (unless excused) | 15-1-11.1.1 |  |  |  |
|  | | | Is the Counseling area private for the patient? (unless excused) | 15-1-11.1.1 |  |  |  |
|  | | | Are controlled substance dispensing's being reported to the CSMP? | 15-8-3.1 |  |  |  |
|  | | | Do pharmacists administer vaccines? | 15-12-6 |  |  |  |
|  | | | Does the pharmacy follow CDC guidelines for vaccine administration? | 15-12-6.1.a |  |  |  |
|  | | | Does the pharmacy have written emergency procedures in place? | 15-12-8.2 |  |  |  |
|  | | | Does the Emergency Kit meet the CDC guidelines? | 15-12-8.2 |  |  |  |
|  | | | Are appropriate records kept for vaccines? | 15-12-7 |  |  |  |
|  | | | Do immunizing pharmacists have current CPR certification? | 15-12-4.1.(c) |  |  |  |
|  | | | Immunizing R.Ph.- 2 HR CE per year per renewal on vaccines issues? | 15-12-4.1.(d) |  |  |  |
|  | | | Does the pharmacy sell Over-the-Counter controlled drugs? | 15-2-8.19 |  |  |  |
|  | | | Is the Schedule V Book complete and correct? | 15-2-8.19.1.e |  |  |  |
|  | | | Has the pharmacy filled any telephoned emergency CII prescriptions? | 15-1-17.1.6 |  |  |  |
|  | | | The emergency quantity only filled? | 15-1-17.1.6 |  |  |  |
|  | | | Is there a signed written Rx that was provided within 7 days? | 15-1-17.1.6.c |  |  |  |
|  | | | Do all controlled drug prescriptions show practitioners printed name? | 15-1-17.1.6 |  |  |  |
|  | | | Do hospital prescriptions show the practitioners issued suffix #? | 15-1-6.2.a.3.B |  |  |  |
|  | | | Patient's address shown? | 15-2-8.5.1 |  |  |  |
|  | | | Date of Issue shown? | 15-2-8.5.1 |  |  |  |
|  | | | Partial fills documented correctly? | 15-2-8.11 |  |  |  |
|  | | | Are controlled Rx's on a separate prescription blank? | 15-2-8.6.1 |  |  |  |
|  | | | No controlled Rx's for C-II are filled after 90 days (unless provider called)? | 15-2-8.9.1.a |  |  |  |
|  | | | Are all pseudoephedrine sales reported via the NPLEX System? | 15-11-4.3 |  |  |  |
|  | | | Is the I.D. of the patient being recorded in the patient record? | 60A-3-308.d.2.B |  |  |  |
|  | | | Is the I.D. of the person receiving a controlled Rx being recorded? | 60A-9-4.a |  |  |  |
|  | | | Do prescription containers meet the FDA and USP requirements? | 15-1-11.1.2 |  |  |  |
|  | | | Are proper closures used and documented if Non-Safety? | Consumer Protection |  |  |  |
|  | | | Do the pharmacist's initials appear on the Rx label? | 15-1-18.1.4.h |  |  |  |
| Item | | **Question** | | **Reference** | **Yes** | **No** | **NA** |
|  | | | Does the manufacturer's name and drug generic name appear on the Rx label? | 15-1-18.1.4.m |  |  |  |
|  | | | If dispensed as equivalent does the Rx label show "Substituted for" "brand"? | 15-1-18.1.4(i)1 |  |  |  |
|  | | | Does the Rx label show a beyond use date? | 15-1-18.1.4(n) |  |  |  |
|  | | | Does the Rx label show the prescriber's name? | 15-1-18.1.4.c |  |  |  |
|  | | | Does a pharmacist ever work without a technician present? | 15-15-7.2 |  |  |  |
|  | | | If so, what is the average number of Rx/Hr dispensed during that period? | 15-15-7.2 |  |  |  |
|  | | | Has this pharmacy dispensed any opioid antagonists? | 60A-9-4 |  |  |  |
|  | | | Is there documentation of reporting opioid antagonist to CSMP? | 60A-9-4 |  |  |  |

Inspector Comments:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Date |  | Date |
| «PharmacistInCharge» |  | Inspector «Assigned\_Inspector» |  |