

West Virginia Board of Pharmacy

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Charleston, West Virginia 25311

OUTPATIENT PHARMACY INSPECTION REPORT

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|--|----------------|-----------|
| | E-Mail Address | Date |
| | Phone | Fax |
| | DEA License # | WVBOP # |
| | P.I.C. | License # |
| | Hours | |

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| <p>1 Does this Pharmacy have an automated dispensing system? 15-1-20.3.2.11 NA_Y_N__</p> <p>2 What is the name of this system?</p> <p>3 Has the Board been notified in writing of its installation? 15-1-20.3.2.11 NA_Y_N__</p> <p>4 Does this pharmacy perform USP 795 Non-Sterile Compounding? NA_Y_N__</p> <p>5 If Yes attach a USP 795 Inspection Form.</p> <p>6 Does this pharmacy perform USP 797 Sterile Compounding? NA_Y_N__</p> <p>7 If Yes attach a USP 797 Inspection Form.</p> <p>8 Is there an alarm system installed according to Rule? 15-1-14.7.2 NA_Y_N__</p> <p>9 Does the alarm system includes a battery back-up power source? 15-1-14.7.2.2 NA_Y_N__</p> <p>10 Are there barriers installed to Rule including Drive-Up window? 15-1-14.7(d).1 NA_Y_N__ & 15-2-4</p> <p>11 Are controlled substances dispersed? Or 15-2-4.6.9 NA_Y_N__</p> <p>12 Stored in a 20 gauge (or better) locked metal cabinet or drawer? 15-2-4.6.a NA_Y_N__</p> <p>13 Are all losses or thefts of controlled drugs reported to DEA and WVBOP? 15-2-8.3.a NA_Y_N__</p> <p>14 Only authorized non-registered person(s) in prescription area? 15-1-18.7 NA_Y_N__</p> <p>15 Only pharmacists have key or code access to prescription area? 15-1-14.7.3.1 NA_Y_N__</p> <p>16 Is generic sign visible to the public? 30-5-12b.(o) NA_Y_N__</p> <p>17 Are Rules of Professional Conduct posted in a conspicuous place? 15-1-19.15 NA_Y_N__</p> <p>18 Are the Pharmacy's Permit and DEA License posted in a conspicuous place? 15-1-14.3.3 NA_Y_N__</p> <p>19 Are all pharmacist and pharmacy technician licenses posted? 30-5-11 NA_Y_N__</p> <p>20 Is a copy of the Combined Technician List and Confidentiality Statement posted? 15.1-20.3.3.1 NA_Y_N__ 15-1-20.3.2.10</p> <p>21 Is there a proper sign available to post when a pharmacist is not on duty? 15-1-14.7.4 NA_Y_N__</p> <p>22 Are completed prescriptions stored in pharmacy area which does not have unlicensed personnel? 15-1-14.7.5 NA_Y_N__</p> | <p>23 Last Biennial Inventory is dated: 15-2-6.5 NA_Y_N__ ____/____/____ and is correct?</p> <p>24 Does Form 222 or CSOS require a Power of Attorney? 15-2-3.4 NA_Y_N__</p> <p>25 Has Power(s) of Attorney been issued? To Whom: 15-2-3.4 NA_Y_N__ _____</p> <p>26 Are controlled substance invoices or packing slips signed by a pharmacist? 15-2.8.4.b NA_Y_N__</p> <p>27 Are there completed Return & Destruction records of controlled drugs? 15-2-6.13a.1 NA_Y_N__</p> <p>28 Does the pharmacy sell Over-the-Counter controlled drugs? 15-2-7.19.a.5 NA_Y_N__</p> <p>29 Is the Schedule V Book complete and correct? 15-2-9.22 NA_Y_N__</p> <p>30 Has the pharmacy filled any telephoned Emergency CII prescriptions? 15-2-7.9.b NA_Y_N__</p> <p>31 The emergency quantity only filled? 15-2-7.9.4.1 NA_Y_N__</p> <p>32 Is there a signed written Rx that was provided within 7 days? 15-2-7.9.b.3 NA_Y_N__</p> <p>33 Do all controlled drug prescriptions show practitioners printed name? 15-2-7.6.c NA_Y_N__</p> <p>34 Do hospital prescriptions show the practitioners issued suffix #? 15-2-7.6.c NA_Y_N__</p> <p>35 Patient's address shown? 15-2-7.5.a NA_Y_N__</p> <p>36 Date of Issue shown? 15-2-7.5.a NA_Y_N__</p> <p>37 Partial fills documented correctly? 15-2-7.11 NA_Y_N__</p> <p>38 Are controlled Rx's on a separate prescription blank? 15-2-7.6.a NA_Y_N__</p> <p>39 No controlled Rx's are filled after 90 days (unless provider called)? 15-2-7.9.a.1 NA_Y_N__</p> <p>40 Are all pseudoephedrine sales reported via the NPLEX System? 60A-10-8.b NA_Y_N__</p> <p>41 Is there a reasonable effort to obtain patient I.D. for the patient record? 60A-3-308.d.2.B NA_Y_N__</p> <p>42 Is the I.D. of the person receiving a controlled Rx being recorded? 60A-9-4.a NA_Y_N__</p> <p>43 <i>Blank Line</i></p> |
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| 44 | Are any outdated drugs found among shelf stock? Number found _____ | 15-1-19.9.2 | NA__Y__N__ | 75 | Is there sufficient compounding equipment available? | 15-1-15.2.2 | NA__Y__N__ |
| 45 | Are refrigerator temperatures all between 36 & 46 degrees F? | 15-1-15.1.2 | NA__Y__N__ | 76 | Is there a sanitary method of measuring liquids? | 15-1-15.2.1 | NA__Y__N__ |
| 46 | List refrigerator temperatures: | | | 77 | Does the pharmacy have Board approved clinical reference materials? | Board Policy | NA__Y__N__ |
| 47 | Are freezer temperatures between -4 and 14 degrees F? | 15-1-15.1.2 | NA__Y__N__ | 78 | Does the pharmacy have a current copy of WVBP Law and Rules? | 15-1-15.2.8 | NA__Y__N__ |
| 48 | List the freezer temperatures: | | | 79 | Does the pharmacy have an adequate balance and weights available? | 15-1-15.2.2 | NA__Y__N__ |
| 49 | Is the pharmacy area temperature controlled and between 59 and 77 F? | 15-1-15.1.2 | NA__Y__N__ | 80 | Do prescription containers meet the FDA and USP requirements? | 15-1-15.1.2 | NA__Y__N__ |
| 50 | What is the pharmacy area current temperature? _____ | | | 81 | Are proper closures used and documented if Non-Safety? | Consumer Protection | NA__Y__N__ |
| 51 | Is the prescription counter clean and dust free? | 15-1-18.2 | NA__Y__N__ | 82 | Do the pharmacist's initials appear on the Rx label? | 15-1-19.13.4 | NA__Y__N__ |
| 52 | Is the prescription counter only used for prescription preparation? | 15-1-18.2 | NA__Y__N__ | 83 | Does the manufacturer's name and drug generic name appear on the Rx label? | 30-5-12b(j) | NA__Y__N__ |
| 53 | Is the prescription preparation room clean, orderly and dust free? | 15-1-18.5 | NA__Y__N__ | 84 | If dispensed as equivalent does the Rx label show "Substituted for" "brand"? | 15-1-22.1.4(i)1 | NA__Y__N__ |
| 54 | Is the sink used only for cleaning hands and equipment? | 15-1-18.3 | NA__Y__N__ | 85 | Does the Rx label show a beyond use date? | 15-1-22.1.4(k) | NA__Y__N__ |
| 55 | Are pharmacists wearing white coats, lab jackets or smocks? | 15-1-18.4 | NA__Y__N__ | 86 | Does the Rx label show the prescriber's name? | 15-1-22.1.4.c | NA__Y__N__ |
| 56 | Do pharmacists have a proper name tag on their garment? | 15-1-18.4 | NA__Y__N__ | 87 | Does the Rx label show proper title for mid-level practitioners? | Not currently required by | NA__Y__N__ |
| 57 | Are electronic prescription transmissions certified? | 15-1-21.1.7.b | NA__Y__N__ | 88 | Is a proper offer to counsel made on pickup of each new prescription? | 15-1-19.13.6 | NA__Y__N__ |
| 58 | Do all prescriptions appear prescribed for a legitimate medical use? | 15-1-21.1 | NA__Y__N__ | 89 | How is "Offer to Counsel" documented on mail or delivered Rx's? | 15-1-19.13.6 | NA__Y__N__ |
| 59 | Are telephoned prescriptions properly & completely documented? | 15-1-19.13.1 | NA__Y__N__ | 90 | Is the counseling area convenient to the pharmacist? (unless excused) | 15-1-15.1.1 | NA__Y__N__ |
| 60 | Is the manufacturer shown on the prescription record file? | 30-5-12b(j) | NA__Y__N__ | 91 | Is the Counseling area private for the patient? (unless excused) | 15-1-15.1.1 | NA__Y__N__ |
| 61 | Is the dispensing pharmacist's initials recorded on the Rx record file? | 15-1-19.13.4 | NA__Y__N__ | 92 | Does this pharmacy employ technician trainees? | | NA__Y__N__ |
| 62 | Are the initials of all personnel who have worked on Rx recorded? | 15-1-19.13.4 | NA__Y__N__ | 93 | Is an approved Technician Training Manual available? | 15-1-20.3.2.4 | NA__Y__N__ |
| 63 | How many files does the computer system generate? _____ | | | 94 | Is documentation of training by the P.I.C. available? | 15-7-4.5 | NA__Y__N__ |
| 64 | Are transferred prescriptions properly recorded (both in and out)? | 15-1-9.1.1.b | NA__Y__N__ | 95 | Are there written records that document the required elements? | 15-7-4.5a.f | NA__Y__N__ |
| 65 | Is there any sign that prescriptions have been refilled after 12 months? | 15-1-10.3 | NA__Y__N__ | 96 | Do trainees wear proper attire? | 15-1-18.4 | NA__Y__N__ |
| 66 | Does it appear that all CFPNP and PA prescribing is according to Rules? | 11-1B-14.8 | NA__Y__N__ | 97 | Do trainees have a proper name tag? | 15-7-6.2 | NA__Y__N__ |
| 67 | Is there a proper record of emergency dispensing of maintenance meds? | 15-1-26.1 | NA__Y__N__ | 98 | No trainee has exceeded 15 months training plus 3 months for testing? | 15-7-4.4(f) | NA__Y__N__ |
| 68 | Are complete patient profiles maintained on all patients? | 15-1-15.2.6 | NA__Y__N__ | 99 | All licensed technicians are wearing proper attire and name tags? | 15-1-18.4 | NA__Y__N__ |
| 69 | Does the pharmacy maintain signed and complete daily Rx reports? | 15-4-5.2.3 | NA__Y__N__ | 100 | Does the pharmacy maintain written duties for all technicians? | 15-1-20.3.2 | NA__Y__N__ |
| 70 | In lieu of a Daily Report does pharmacy maintain a proper log book? | 15-4-5.2.3 | NA__Y__N__ | 101 | No technician is observed violating legally authorized duties? | 15-7-5(1) | NA__Y__N__ |
| 71 | Is one full year of dispensing records available online? | 15-4-4 | NA__Y__N__ | 102 | All technicians are directly supervised by the pharmacist on duty? | 15-1-20.3.2.4 | NA__Y__N__ |
| 72 | Can the pharmacy generate five full years of dispensing's on request? | 15-4-4 | NA__Y__N__ | 103 | Are nationally certified or those licensed in other states also licensed in WV? | 15-7-3.1.c | NA__Y__N__ |
| 73 | Are sales of Rx drugs without a prescription properly recorded? | 15-1-9.1.1 | NA__Y__N__ | 104 | <i>Blank Line</i> | | |
| 74 | If servicing a nursing home is a log of returned drugs maintained? | 15-1-12.3 | NA__Y__N__ | 105 | <i>Blank Line</i> | | |

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| 106 | Does PIC work 30 or more HR/WK if pharmacy is open more than 40HR/WK? | 15-1-2.40c | NA__Y__N__ | 128 | Is 12 hour shift not exceeded? | 15-1-14.8.1 | NA__Y__N__ |
| 107 | Does PIC work 50% of hours in a pharmacy open less than 40 HR/WK? | Board policy | NA__Y__N__ | 129 | Is there documentation if 12 hour shift is exceeded? | 15-1-14.8.1 | NA__Y__N__ |
| 108 | Has an Interim PIC been utilized? | 15-1-14.5.2 | NA__Y__N__ | 130 | Does a pharmacist ever work without a technician present? | 15-1-14.8.2 | NA__Y__N__ |
| 109 | Has the PIC seen current licenses of all current employees? | 15-1-20.3.2.6 | NA__Y__N__ | 131 | If so, what is the average number of Rx/Hr dispensed during that period? | | ____Rx/HR |
| 110 | Does the pharmacy have an ongoing Quality Assurance program in place? | 15-1-20.3.2.3 | NA__Y__N__ | 132 | Is the ratio of Technicians to Pharmacist correct at this time? | Board Policy | NA__Y__N__ |
| 111 | Are written reports prepared when dispensing errors occur? | Board Policy | NA__Y__N__ | 133 | Currently on Duty: Technicians____Pharmacists____ | | |
| 112 | Are these reports formally discussed with prescription dept. personnel? | Board Policy | NA__Y__N__ | 134 | Is the PIC assisted by sufficient staff? | 15-1-20.3.3 | NA__Y__N__ |
| 113 | Is a perpetual inventory maintained for commonly diverted drugs? | 15-1-20.3.2.3 | NA__Y__N__ | 135 | Is a medication review pharmacist always on staff? | Board Policy | NA__Y__N__ |
| 114 | Does reconciliation of controlled drugs effectively detect diversion? | 15-1-20.3.2.3 | NA__Y__N__ | 136 | If being done remotely has PIC seen DUR pharmacists license? | Board Policy | NA__Y__N__ |
| 115 | Have any & all complaints about a pharmacist been sent to Board? | 15-1-14.6.4 | NA__Y__N__ | 137 | Do pharmacists administer vaccines? | 15-12-1 | NA__Y__N__ |
| 116 | Has the Board been notified of any pharmacists recently discharged? | 15-1-14.6.3 | NA__Y__N__ | 138 | Does the pharmacy follow CDC guidelines for vaccine administration? | 15-12-5.1.a | NA__Y__N__ |
| 117 | Has PIC notified permit holder of any & all violations of Law or Rules? | 15-1-20.3.2.2 | NA__Y__N__ | 139 | Does the pharmacy have written emergency procedures in place? | 15-12-7.2 | NA__Y__N__ |
| 118 | Is there documentation of such with a copy to Board office? | 15-1-20.3.2.2 | NA__Y__N__ | 140 | Does the Emergency Kit meet the CDC guidelines? | 15-12-7.2 | NA__Y__N__ |
| 119 | If not, explain why? | 15-1-20.3.2.2 | | 141 | Are appropriate records kept for vaccines? | 15-12-6 | NA__Y__N__ |
| 120 | Is there a connection to the CSMP available? | 15-8-3 | NA__Y__N__ | 142 | Do immunizing pharmacists have current CPR certification? | 15-12-3.1.(c) | NA__Y__N__ |
| 121 | Are controlled substance dispensing's being reported to the CSMP? | 15-8-3 | NA__Y__N__ | 143 | Immunizing R.Ph. 2 HR CE per Year per Renewal on vaccines & administration? | 15-12-3.1.(d) | NA__Y__N__ |
| 122 | Does the pharmacy refuse to fill some Controlled Drug Prescriptions? | | NA__Y__N__ | 144 | Are CE certificates or records for all pharmacists available for inspection? | 15-3-13.3 | NA__Y__N__ |
| 123 | Does the pharmacy document the refusal in any manner? | | NA__Y__N__ | 145 | Do pharmacists have 3 hours CE/Renewal on drug diversion & WV statistics? | 15-3-4.4 | NA__Y__N__ |
| 124 | Does the pharmacy review patient's need for Controlled Drugs & the CSMP data? | | NA__Y__N__ | 146 | Do all pharmacists have at least 6 hours of live CE for reporting period? | 15-3-4.3 | NA__Y__N__ |
| 125 | Does the pharmacy maintain any documentation of Item #124? | | NA__Y__N__ | 147 | Do all pharmacists have 30 or more hours of CE for reporting period? | 15-3-4.1 | NA__Y__N__ |
| 126 | Has this pharmacy dispensed any opioid antagonists? | 60A-9-4 | NA__Y__N__ | | | | |
| 127 | Is there documentaion of reporting opioid antagonist to CSMP? | 60A-9-4 | NA__Y__N__ | | | | |
| 148 | Comments: | | | | | | |
| 149 | _____ | | | | | | |
| 150 | _____ | | | | | | |
| 151 | _____ | | | | | | |
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