

West Virginia Board of Pharmacy

Phone (304) 558-0558

2310 Kanawha Boulevard East

Fax (304) 558-0572

Charleston, West Virginia 25311

OUTPATIENT PHARMACY INSPECTION REPORT

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

| Item | Question | Reference | Yes | No | NA |
|------|-----------------------------------------------------------------------------------|------------------------------|--------------|----|----|
| 1 | Does this Pharmacy have an automated dispensing system? | 15-1-16.2.11 | | | |
| 2 | What is the name of this system? | | | | |
| 3 | Has the Board been notified in writing of its installation? | 15-1-16.2.11 | | | |
| 4 | Does this pharmacy perform USP 795 Non-Sterile Compounding? | | | | |
| 5 | If Yes attach a USP 795 Inspection Form. | Board Policy | | | |
| 6 | Does this pharmacy perform USP 797 Sterile Compounding? | 15-1-12 | | | |
| 7 | If Yes attach a USP 797 Inspection Form. Ship out of state use NABP Universal. | WV _____ or NABP _____ | Board Policy | | |
| 8 | Is there an alarm system installed according to Rule? | 15-15-6.2.1 | | | |
| 9 | Does the alarm system include a battery back-up power source? | 15-15-6.2.1 | | | |
| 10 | Are there barriers installed to Rule including Drive-Up window? | 15-1-15 | | | |
| 11 | Are controlled substances dispersed? Or | 15-2-5.5.1 | | | |
| 12 | Stored in a 20 gauge (or better) locked metal cabinet or drawer? | 15-2-5.5.1 | | | |
| 13 | Are all losses or thefts of controlled drugs reported to DEA and WVBOP? | 15-2-5.4 | | | |
| 14 | Only authorized non-registered person(s) in prescription area? | 15-1-14.7 | | | |
| 15 | Only pharmacists have key or code access to prescription area? | 15-15-6.3.1 | | | |
| 16 | Is generic sign visible to the public? | 30-5-12b.(o) | | | |
| 17 | Are Rules of Professional Conduct posted in a conspicuous place? | 15-1-15.5 | | | |
| 18 | Are the Pharmacy's Permit and DEA License posted in a conspicuous place? | 15-15-3.3 | | | |
| 19 | Are all pharmacist and pharmacy technician licenses posted? | 30-5-11 | | | |
| 20 | Is a copy of the Combined Technician List and Confidentiality Statement posted? | 15-1-16.3.1 | | | |
| 21 | Is there a proper sign available to post when a pharmacist is not on duty? | 15-15-6.4 | | | |

| Item | Question | Reference | Yes | No | NA |
|------|-----------------------------------------------------------------------------------------------|-----------------|-----|----|----|
| 22 | Are completed prescriptions stored in pharmacy area which does not have unlicensed personnel? | 15-15-6.5 | | | |
| 23 | Last Biennial Inventory is dated: / / and is correct? | 15-2-7.5 | | | |
| 24 | Does Form 222 or CSOS require a Power of Attorney? | DEA | | | |
| 25 | Has Power(s) of Attorney been issued? To Whom: | 15-2-4.6 | | | |
| 26 | Are controlled substance invoices or packing slips signed by a pharmacist? | 15-2-9.4.2 | | | |
| 27 | Are there completed Return & Destruction records of controlled drugs? | 15-2-4.9.2.2 | | | |
| 28 | Does the pharmacy sell Over-the-Counter controlled drugs? | 15-11-3.3.5 | | | |
| 29 | Is the Schedule V Book complete and correct? | 15-11-3.3.5 | | | |
| 30 | Has the pharmacy filled any telephoned Emergency CII prescriptions? | 15-1-17.6 | | | |
| 31 | The emergency quantity only filled? | 15-1-17.1.6.a | | | |
| 32 | Is there a signed written Rx that was provided within 7 days? | 15-1-17.1.6.c | | | |
| 33 | Do all controlled drug prescriptions show practitioners printed name? | 15-2-8.5.1 | | | |
| 34 | Do hospital prescriptions show the practitioners issued suffix #? | 15-1-6.2.a.3.B | | | |
| 35 | Patient's address shown? | 15-2-8.5.1 | | | |
| 36 | Date of Issue shown? | 15-2-8.5.1 | | | |
| 37 | Partial fills documented correctly? | 30-5-27.a | | | |
| 38 | Are controlled Rx's on a separate prescription blank? | 15-2-8.6.1 | | | |
| 39 | No controlled Rx's are filled after 90 days (unless provider called)? | 15-2-8.9.1.a | | | |
| 40 | Are all pseudoephedrine sales reported via the NPLEX System? | 15-11-4.1 | | | |
| 41 | Is there a reasonable effort to obtain patient I.D. for the patient record? | 60A-3-308.d.2.B | | | |
| 42 | Is the I.D. of the person receiving a controlled Rx being recorded? | 60A-9-4.(b).(8) | | | |
| 43 | Are any outdated drugs found among shelf stock? Number found _____ | 15-1-15.9.2 | | | |
| 44 | Are refrigerator temperatures all between 2 to 8°C (36 to 46°F)? | 15-1-11.2.4 | | | |
| 45 | List refrigerator temperatures: | | | | |
| 46 | Are freezer temperatures between -10 to -25°C (-13 to 14°F)? | 15-1-11.2.4 | | | |
| 47 | List the freezer temperatures: | | | | |
| 48 | Is the pharmacy area temperature controlled and between 20 to 25°C (68 to 77°F)? | 15-1-11.2.4 | | | |
| 49 | What is the pharmacy area current temperature? | | | | |
| 50 | Is the prescription counter clean and dust free? | 15-1-14.1 | | | |
| 51 | Is the prescription counter only used for prescription preparation? | 15-1-14.2 | | | |
| 52 | Is the prescription preparation room clean, orderly and dust free? | 15-1-14.5 | | | |
| 53 | Is the sink used only for cleaning hands and equipment? | 15-1-14.3 | | | |
| 54 | Do pharmacists have a proper name tag on their garment? | 15-1-14.4 | | | |
| 55 | Are electronic prescription transmissions certified? | 15-1-17.1.7.b | | | |
| 56 | Do all prescriptions appear prescribed for a legitimate medical use? | 15-1-17.1 | | | |
| 57 | Are telephoned prescriptions properly & completely documented? | 15-1-19.13.1 | | | |

| Item | Question | Reference | Yes | No | NA |
|------|-----------------------------------------------------------------------------------------|-----------------------|-----|----|----|
| 58 | Is the manufacturer shown on the prescription record file? | 30-5-12b(j) | | | |
| 59 | Is the dispensing pharmacist's initials recorded on the Rx record file? | 15-1-15.13.4 | | | |
| 60 | Are the initials of all personnel who have worked on Rx recorded? | 15-1-15.13.4 | | | |
| 61 | Are transferred prescriptions properly recorded (both in and out)? | 15-1-8.2.1 | | | |
| 62 | Is there any sign that prescriptions have been refilled after 12 months? | 15-1-7.3 | | | |
| 63 | Does it appear that all CFNP and PA prescribing is according to Rules? | 11-1B-15.19.8.5 | | | |
| 64 | Is there a proper record of emergency dispensing of maintenance meds? | 15-1-22.1 | | | |
| 65 | Are complete patient profiles maintained on all patients? | 15-1-11.2.7 | | | |
| 66 | Is one full year of dispensing records available online? | 15-4-4 | | | |
| 67 | Can the pharmacy generate five full years of dispensing's on request? | 15-4-4 | | | |
| 68 | Are sales of Rx drugs without a prescription properly recorded? | 15-1-6.1.1 | | | |
| 69 | If servicing a nursing home is a log of returned drugs maintained? | 15-1-9.3 | | | |
| 70 | Is there sufficient compounding equipment available? | 15-1-11.2 | | | |
| 71 | Is there a sanitary method of measuring liquids? | 15-1-11.2.1 | | | |
| 72 | Does the pharmacy have Board approved clinical reference materials? | 15-15-2.2.3 | | | |
| 73 | Does the pharmacy have a current copy of WVBP Law and Rules? | 15-1-11.2.8 | | | |
| 74 | Does the pharmacy have an adequate balance and weights or electronic balance available? | 15-1-11.2.2 | | | |
| 75 | Do prescription containers meet the FDA and USP requirements? | 15-1-11.1.2 | | | |
| 76 | Are proper closures used and documented if Non-Safety? | Consumer Protection | | | |
| 77 | Do the pharmacist's initials appear on the Rx label? | 15-1-18.1.4.h | | | |
| 78 | Does the manufacturer's name and drug generic name appear on the Rx label? | 15-1-18.1.4.m | | | |
| 79 | If dispensed as equivalent does the Rx label show "Substituted for" "brand"? | 15-1-18.1.4.i.1 | | | |
| 80 | Does the Rx label show a beyond use date? | 15-1-18.1.3.g | | | |
| 81 | Does the Rx label show the prescriber's name? | 15-1-18.1.4.c | | | |
| 82 | Is a proper offer to counsel made on pickup of each new prescription? | 15-1-15.13.6 | | | |
| 83 | How is "Offer to Counsel" documented on mail or delivered Rx's? | 15-1-15.13.6 | | | |
| 84 | Is the counseling area convenient to the pharmacist? (unless excused prior to 5/1/99) | 15-1-11.1.1 | | | |
| 85 | Is the Counseling area private for the patient? (unless excused) | 15-1-11.1.1 | | | |
| 86 | Does this pharmacy employ technician trainees? | | | | |
| 87 | Is an approved Technician Training Manual available? | 15-1-16.2.4 | | | |
| 88 | Is documentation of training by the P.I.C. available? | 15-1-16.2.4 | | | |
| 89 | Are there written records that document the required elements? | 15-1-16.2.4 | | | |
| 90 | Do trainees wear proper attire? | 15-1-14.4 15-7-8.2 | | | |
| 91 | Do trainees have a proper name tag? | 15-1-14.4 15-7-8.2 | | | |
| 92 | No trainee has exceeded 12 months training plus 3 months for testing? | 15-7-4.2 15-7-4.4e | | | |

| Item | Question | Reference | Yes | No | NA |
|------|------------------------------------------------------------------------------------|--------------------------------|-----|----|----|
| 93 | All licensed technicians are wearing proper attire and name tags? | 15-1-14.4 15-7-8.2 | | | |
| 94 | Does the pharmacy maintain written duties for all technicians? | 15-1-16.3.2 | | | |
| 95 | No technician is observed violating legally authorized duties? | 15-7-5(1) | | | |
| 96 | All technicians are directly supervised by the pharmacist on duty? | 15-1-16.3.2 | | | |
| 97 | Are nationally certified or those licensed in other states also licensed in WV? | 15-7-3.1.b.2 15-7-3.1.b.1.c | | | |
| 98 | Does PIC work 30 or more HR/WK if pharmacy is open more than 40HR/WK? | 15-1-2.1.41.c | | | |
| 99 | Does PIC work more than 50% of hours in a pharmacy open less than 40 HR/WK? | 15-1-2.1.41.c | | | |
| 100 | Has an Interim PIC been utilized? | 15-15-5.1 | | | |
| 101 | Has the PIC seen current licenses of all current employees? | 15-1-16.2.6 | | | |
| 102 | Does the pharmacy have an ongoing Quality Assurance program in place? | 15-1-16.2.3 | | | |
| 103 | Demonstrate the Controlled Drug Perpetual inventory & monthly review. | 15-2-7.2.4.a | | | |
| 104 | Are written reports prepared when dispensing errors occur? | Board Policy | | | |
| 105 | Are these reports formally discussed with prescription dept. personnel? | Board Policy | | | |
| 106 | Is there a connection to the CSMP available? | 15-8-3.1 | | | |
| 107 | Are controlled substance dispensing's being reported to the CSMP? | 15-8-3.1 | | | |
| 108 | Has this pharmacy dispensed any opioid antagonists? | 60A-9-4 | | | |
| 109 | Is there documentation of reporting opioid antagonist to CSMP? | 60A-9-4 | | | |
| 110 | Have any & all complaints about a pharmacist been sent to Board? | 15-15-8.3 | | | |
| 111 | Has the Board been notified of any pharmacists recently discharged? | 15-15-8.2 | | | |
| 112 | Has PIC notified permit holder of any & all violations of Law or Rules? | 15-1-16.2.2 | | | |
| 113 | Is there documentation of such with a copy to Board office? | 15-1-16.2.2 | | | |
| 114 | If not, explain why? | | | | |
| 115 | No employee exceeds a 12-hour shift? | 15-15-7.1 | | | |
| 116 | Is there documentation if 12-hour shift is exceeded? | 15-15-7.1 | | | |
| 117 | Does a pharmacist ever work without a technician present? | 15-15-7.2 | | | |
| 118 | If so, what is the average number of Rx/Hr. dispensed during that period? | | | | |
| 119 | Is the ratio of Technicians to Pharmacist correct at this time? | 15-7-5.3 | | | |
| 120 | Currently on Duty: Technicians_____ Pharmacists_____ | | | | |
| 121 | Is the PIC assisted by sufficient staff? | 15-1-16.3 | | | |
| 122 | Is a medication review pharmacist always on staff? | Board Policy | | | |
| 123 | If being done remotely has PIC seen DUR pharmacists license? | 15-14-4.1.b | | | |
| 124 | Do pharmacists administer vaccines? | 15-12-6 | | | |
| 125 | Does the pharmacy follow CDC guidelines for vaccine administration? | 15-12-6.1.a | | | |
| 126 | Does the pharmacy have written emergency procedures in place? | 15-12-8 | | | |
| 127 | Does the Emergency Kit meet the CDC guidelines? | 15-12-8 | | | |
| 128 | Are appropriate records kept for vaccines? | 15-12-7 | | | |
| 129 | Do immunizing pharmacists have current CPR certification? | 15-12-4.1.c | | | |

| Item | Question | Reference | Yes | No | NA |
|------|------------------------------------------------------------------------------|-------------|-----|----|----|
| 130 | Immunizing R.Ph. 2 HR CE per Year per Renewal on vaccines & administration? | 15-12-4.1.d | | | |
| 131 | Are CE certificates or records for all pharmacists available for inspection? | 15-3-13.3 | | | |
| 132 | Do pharmacists have 3 hours CE/Renewal on drug diversion & WV statistics? | 15-3-4.4 | | | |
| 133 | Do all pharmacists have at least 6 hours of live CE for reporting period? | 15-3-4.3 | | | |
| 134 | Do all pharmacists have 30 or more hours of CE for reporting period? | 15-3-4.1 | | | |

Inspector Comments:

Pharmacist-in-Charge

Date

Inspector

Date

West Virginia Board of Pharmacy

Phone (304) 558-0558

2310 Kanawha Boulevard East

Fax (304) 558-0572

Charleston, West Virginia 25311

Combined Technician List & Confidentiality Statement

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

Pharmacists

License

Expires

Pharmacists/Interns

License

Expires

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Pharmacy Technicians

License

Expires

Pharmacy Technicians

License

Expires

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Pharmacy Technician Trainees

Certificate
Number

Issued Date/
Exp. Date

Pharmacy Technician Trainees

Certificate
Number

Issued Date/ Exp. Date

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This form satisfies the requirement of WV Board of Pharmacy Rules 15-1-16.3.1. Additionally, by signing this form, the P.I.C. certifies that policy & procedures for maintaining the integrity and confidentiality of prescription information and patient health care information have been implemented and all the above listed employees have read and comply with the established policies and procedures. This meets the requirement of WV Board of Pharmacy Rules 15-1-16.2.10. **An up to date copy of this form is to be posted in a conspicuous place at all times with a copy sent to the WV Board of Pharmacy. Prepare a new form each July 1st.**

P.I.C. «PharmacistInCharge»

Date

West Virginia Board of Pharmacy

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Fax (304) 558-0572

Charleston, West Virginia 25311

CONTROLLED SUBSTANCE REVIEW

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

During a pharmacy inspection conducted on the above date a **one day** Controlled Substance Report was run for the below listed dates and included Schedules II, III, IV, and V. Inspectors are to attach the printed copy of the report to this form and submit directly to Cindy Parsons, CSMP Program Assistant as this information is HIPAA protected information.

Date: ____/____/____

Total Rx Dispensed _____

P.I.C «PharmacistInCharge»

Inspector «Assigned_Inspector»

* Some pharmacies, particularly chains, may not be able to generate a report at the store site. If the pharmacy cannot generate this report, have the pharmacy manually total the controlled dispensings from three printed daily reports or request the pharmacist to run a DUR Report for those days.

West Virginia Board of Pharmacy

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Charleston, West Virginia 25311

Non-Compliance Correction Report

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

The following non-compliant items were found during a routine Pharmacy Inspection which was conducted on the above date by Inspector «Assigned_Inspector»

Item # Description

Item # Description

Item # Description

Item # Description

Item # Description

Please show the corrective action you have taken on each of the above to bring your pharmacy into compliance. Return this original copy to The Board address above within 10 working days of your inspection date. FAX, Mail or Scan-E-Mail a copy to your Pharmacy Inspector. «Assigned_Inspector» Fax Email:

Item # Action taken

Item # Action taken

Item # Action taken

Item # Action taken

Item # Action taken

P.I.C «PharmacistInCharge»

Date

This report will be compared with your next inspection and a repeated item will be presented to the Complaint Committee of the Board for formal action.

