

West Virginia Board of Pharmacy

Phone (304) 558-0558

Fax (304) 558-0572

1207 Quarrier St, 4th Floor
Charleston, West Virginia 25301

CHARITABLE PHARMACY - INSPECTION REPORT

Email: Fax:	Date: WVBOP#: DEA License#: Pharmacist in Charge: Phone: Hours:
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Item	Question	Observation	Reference	Inspector Comments
1	Has any addition, removal, or change of an Automated pharmacy system been communicated in writing to the Board? (If the pharmacy has not added, removed or changed an Automated pharmacy system this should be marked "N/A")		15-1-16.2.11	
2	Is there an alarm system installed according to Rule?		15-15-7.2	
3	Does the alarm system include a battery back-up power source?		15-15-7.2.1	
4	Are there barriers installed to Rule including Drive-Up window?		15-15-7.4	
5	Any non-licensed person(s) in the prescription area have the proper authorization to be there?		15-2-5.1.1 15-7-5.3	
6	Only pharmacists or prescribing practitioners have key or code access to prescription area?		15-7-5.5 15-13-4.2.1	
7	Is generic substitution sign visible to the public?		15-13.4.2.2	
8	Are Rules of Professional Conduct posted in a conspicuous place?		30-5-12b.(o)	
9	Is the pharmacy's Charitable Clinic Pharmacy permit current and posted in a conspicuous place?		15-1-15.15	
10	Are all pharmacist, pharmacy intern, pharmacy technician, and pharmacy technician trainee licenses current and posted in a conspicuous place?		15-13-3.1	
11	Has the PIC assured that all pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician trainees employed at the pharmacy are currently licensed and/or registered with the Board?		15-15-4.3	
12	Is a current copy of the Combined Technician List and Confidentiality Statement posted and is it on file with the Board? (Inspector to verify in Database)		15-1-16.2.6 30-5-20	
13	Are completed prescription orders bagged and kept in the pharmacy (prescription area) and not dispensed until checked by a pharmacist or prescribing practitioner?		15-1-16.2.6	
14	Is the Patient's address shown on all prescriptions?		15-1-16.2.6	
15	Is the Date of Issue shown on all prescriptions?		15-13-4.2.3	
16	Do all prescriptions appear prescribed for a legitimate medical use?		15-2-8.5.1	
17	Are electronic prescription transmissions certified?		15-2-8.5.1	
18	Are telephoned prescriptions properly & completely documented?		15-1-17.1	
19	Are transferred prescriptions properly recorded (both in and out)?		15-1-17.1.7	
20	Is there a proper record of emergency dispensing of maintenance meds?		15-1-17.1.8	
21	Are complete patient profiles maintained on all patients?		15-1-17.1.2	
22	Is one full year of dispensing records available online?		15-1-8.2.1	
23	Can the pharmacy generate five full years of records of dispensing on request?		15-1-22.1	
24	Are manifests for donated drugs that are dispensed pursuant to prescriptions created and maintained as required for all prescription records?		15-1-11.2.7	
25	Are partial fills documented correctly?		15-4-4	
26	Pharmacist and/or prescribing practitioner verification process of prescriptions/orders has been reviewed and pharmacists can demonstrate process to inspector. The pharmacist(s) surveyed affirm that the final verification process is capable of sufficiently aiding pharmacists in the detection of errors to ensure patient safety		15-4-4 15-13-6.2.5	
			30-5-27	
			15-1-15.13.2 15-13-4.2.1	

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27	Is the manufacturer shown on the prescription record file?		30-5-12b(j)	
28	Are the dispensing pharmacist's initials recorded on the Rx record file?		15-1-15.13.4	
29	Are the initials of all personnel who have worked on the Rx recorded?		15-1-15.13.4	
30	Do prescription containers meet the FDA and USP requirements?		15-1-11.1.2	
31	Are proper closures used and documented if non-safety?		Consumer Protection	
32	Does the Rx label show the name including store number, if any, address, and telephone number of the pharmacy?		15-1-18.1.4.a	
33	Does the Rx label show the name of the patient, or if the patient is an animal, the last name of the owner, name and species of the animal, or, in the case of expedited partner therapy, the label displays the words "Expedited Partner Therapy" or "EPT" instead of the name of the patient?		15-1-18.1.4.b	
34	Does the Rx label show the prescriber's name?		15-1-18.1.4.c	
35	Does the Rx label show directions stated on the prescription order, and medication purpose/indication if included on the prescription order?		15-1-18.1.4.d	
36	Does the Rx label show the date filled?		15-1-18.1.4.e	
37	Does the Rx label show any cautions which may be required by federal or state law?		15-1-18.1.4.f	
38	Does the Rx label show the prescription number?		15-1-18.1.4.g	
39	Does the Rx label show the name or initials of the dispensing pharmacist?		15-1-18.1.4.h	
40	Does the Rx label show the generic drug name and strength of the drug?		15-1-18.1.4.i	
41	If dispensed as equivalent does the Rx label show "Substituted for" "brand"?		15-1-18.1.4.i.1	
42	Does the Rx label show the quantity filled?		15-1-18.1.4.j	
43	Does the Rx label show the number of remaining refills?		15-1-18.1.4.k	
44	Does the Rx label show all necessary auxiliary information?		15-1-18.1.4.l	
45	Does the Rx label show the name of the manufacturer or distributor?		15-1-18.1.4.m	
46	Does the Rx label show a beyond use date?		15-1-18.1.4.n	
47	If the pharmacy is repackaging medication from the manufacturer container in to a specialized dispensing system, the assigned beyond-use date does not exceed 6 months from the date of repackaging; or the manufacturer's expiration date; whichever is earlier; Except as modified in W. Va. Code R § 15-5 et seq. (If the pharmacy is not performing any repackaging this should be answered "N/A")		15-1-20.1.1 15-1-20.3.2	
48	Is the counseling area convenient to the pharmacist? (Unless excused prior to 5/1/1999)		15-1-11.1.1	
49	Is the counseling area private for the patient? (Unless excused)		15-1-11.1.1	
50	Is a proper offer to counsel made on pickup of each new prescription?		15-1-15.13.5	
51	Is the method of "Offer to Counsel" on mail or delivered Rx's adequate and appropriate? (Describe how the "Offer to Counsel" on these prescriptions is being done in Inspector Comments)		15-1-15.13.5	
52	If the pharmacy transports completed prescriptions to another remote clinic operated by the charitable clinic, are all rules pertaining to this practice for charitable clinics being followed? (If the charitable clinic does not transfer drugs off premises for remote dispensing, this question should be answered "N/A")		15-13-4.4	
53	No misbranded drugs are observed on the premises (including lost identity or unknown drugs)?		15-13-7.2 15-13-7.3	
54	Are any outdated drugs found among shelf stock? (List number found in inspector comments)		15-1-15.9.2	# Outdates Found:
55	Are samples dispensed in the manufacturer's original packaging, clearly marked sample, contain an expiration date and lot number, are not expired, and not a controlled substance?		15-13-5.1	

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56	Donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, not properly stored, or no identifying drug information are not dispensed to patients?		15-13-6.2b	
57	Donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, not properly stored, or no identifying drug information are quarantined and destroyed?		15-13-6.2c	
58	Is the area of drug storage temperature controlled between 20 to 25°C (68 to 77°F)? (List the current drug storage area temperature in Inspector Comments)		15-1-11.2.4 15-1-14.1.5	
59	Are refrigerator temperatures all between 2 to 8°C (36 to 46°F)? (List the current refrigerator temperatures in Inspector Comments)		15-1-11.2.4 15-1-14.1.5	
60	Are freezer temperatures between -10 to -25°C (-13 to 14°F)? (List the current freezer temperatures in Inspector Comments; if drugs are not currently being stored in the freezer this should be marked "N/A")		15-1-11.2.4 15-1-14.1.5	
61	Is the prescription counter clean, dust free, and in an orderly condition?		15-1-14.1.3	
62	Is the prescription counter only used for prescription preparation?		15-1-14.1.3	
63	Are all areas where drugs and devices are stored dry, well lighted, well ventilated, and maintained in a clean and orderly condition?		15-1-14.1.5	
64	Is there sufficient compounding equipment available?		15-1-11.2	
65	Is there a sanitary method of measuring liquids?		15-1-11.2.1	
66	Is the sink used only for cleaning hands and equipment?		15-1-14.1.6	
67	Do pharmacists have a proper name tag on their garment?		15-1-14.1.4	
68	Does the pharmacy have Board approved clinical reference materials?		15-15-3.2.3	
69	Does the pharmacy have access to current WVBOP Laws and Rules?		15-1-11.2.8	
70	Is an approved Pharmacy Technician Training Manual available? (If the pharmacy does not employ pharmacy technician trainees (PTT) or has not employed any since the last inspection, questions 70 to 74 should be marked "N/A")		15-1-16.2.4 15-7-4.1	
71	Do pharmacy technician trainees wear proper attire?		15-1-14.1.4	
72	Do pharmacy technician trainees have a proper name tag?		15-7-8.2	
73	Does PIC confirm that no PTT has exceeded 12 months of training plus 3 months for testing?		15-7-4.2 15-7-4.4e	
74	Has PIC provided all necessary documentation to Board of any PTT that has discontinued the PTT program at this pharmacy?		15-7-4.4	
75	Are all licensed pharmacy technicians (PT) wearing proper attire and name tags?		15-1-14.1.4 15-7-8.1	
76	Does the pharmacy maintain written duties for all pharmacy technicians?		15-1-16.3.2	
77	No pharmacy technician is observed violating legally authorized duties?		15-7-5.1	
78	Are all technicians supervised by a pharmacist or prescribing practitioner OR, in cases when no pharmacist or prescribing practitioner is available, technicians process and fill prescriptions for no more than 2 hours and no dispensing occurs until prescriptions are checked?		15-13-4.2	
79	Are technicians nationally certified or those licensed in other states are also licensed in WV?		15-7-3.1.b.2 15-7-3.1.b.1.C	
80	If an interim PIC has been utilized, was this done appropriately? (If an interim PIC has not been utilized since the last inspection, this should be marked "N/A")		15-15-6.1	
81	Does the pharmacy have an ongoing Quality Assurance program in place?		15-1-16.2.3	

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Item	Question	Observation	Reference	Inspector Comments
82	Are written reports prepared when dispensing errors occur?		Guidance Only	
83	Are these reports formally discussed with prescription department personnel?		Guidance Only	
84	Has the Board been notified, in writing, of any violations of Board rules or laws by a licensed pharmacist? (If the PIC is not aware of any violations, this should be marked "N/A")		15-15-9.3	
85	Has the Board been notified, in writing, of any discharge or termination of a licensed pharmacist or change of the status of the pharmacist-in-charge? (If no pharmacist has been discharged or no status change of PIC has occurred since last inspection, this should be marked "N/A")		15-15-9.2	
86	Has the Board been notified, in writing, of the separation of employment of any pharmacist, pharmacy intern, PT, or PTT for any confirmed drug-related reason, including but not limited to, adulteration, abuse, theft, or diversion? (If there have been no separations of employees for drug-related reasons since the last inspection, this should be marked "N/A")		15-1-16.2.7.e-f	
87	Has PIC notified the <u>permit holder</u> of any & all violations of Law or Rules? (If the PIC is not aware of any violations of laws or rules since the last inspection, this should be marked "N/A")		15-1-16.2.2	
88	Is there documentation of such PIC notification with a copy to Board office? (If the PIC is not aware of any violations of laws or rules since the last inspection, this should be marked "N/A")		15-1-16.2.2	
89	No pharmacist, pharmacy intern, or pharmacy technician works longer than 12 continuous hours per 24-hour period, inclusive of required breaks? (If the pharmacy is never open more than 12 hours, this should be marked "N/A")		15-15-8.2	
90	Is there documentation if 12-hour shift is exceeded and/or breaks are missed or interrupted? (If the pharmacy is never open more than 12 hours, this should be marked "N/A")		15-15-8.4	
91	Are CE certificates or records for all pharmacists available for inspection?		15-3-12.3 15-3-9.1	
92	Have all pharmacists completed a minimum of 2 hours of drug diversion training and best practice prescribing of controlled substances training within 1 year of receiving initial license from the Board		15-3-4.4	
93	Do all pharmacists have at least 6 hours of live CE for reporting period (Inspector please note that this may include hours earned for working in the charitable clinic as allowed by rule)		15-3-4.3 15-13-8	
94	Do all pharmacists have 30 or more hours of CE for last renewal reporting period?		15-3-4.1	

ALL QUESTIONS HAVE NOT BEEN ANSWERED, PLEASE REVIEW!

PIC: _____ Date _____

Inspector: _____ Date _____