

West Virginia Board of Pharmacy

Phone (304) 558-0558

Fax (304) 558-0572

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

OUTPATIENT PHARMACY - INSPECTION REPORT

		Date:	
		WVBOP#:	
		DEA License#:	
		Pharmacist in Charge:	
Email		Phone:	
Fax:		Hours:	

Item	Question	Observation	Reference	Inspector Comments
1	Is <USP 795> Non-Sterile Compounding being Performed?		15-1-11.1.2	(If YES, complete corresponding inspection):
2	Is <USP 797> Sterile Compounding being Performed?		15-1-12 15-1-11.1.2	(If YES, complete corresponding inspection):
3	Is compounding (Non-Sterile or Sterile) being performed with Hazardous drugs as per <USP 800>?		15-1-11.1.2	(If YES, complete corresponding inspection):
4	Does this pharmacy meet the current requirements of the DSCSA?		15-1-2.1.44.a	
5	Has this pharmacy notified WV DEP of types of Hazardous Wastes generated and received an EPA ID Number?		15-1-2.1.44.a	
6	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	
7	Is there an alarm system installed according to Rule?		15-15-7.2	
8	Does the alarm system include a battery back-up power source?		15-15-7.2.1	
9	Are there barriers installed to Rule including Drive-Up window?		15-15-7.4 15-2-5.1.1	
10	Are controlled substances dispersed? (List schedule(s) dispersed in Inspector Comments) OR		15-2-5.5.1	Schedules Dispersed:
11	Stored in a 20 gauge (or better) locked metal cabinet or drawer? (List schedule(s) locked in cabinet or drawer in Inspector Comments)		15-2-5.5.1	Schedules locked in cabinet:
12	Has any loss or theft of controlled drugs been reported to the proper authorities using the appropriate forms? (If there has been no loss or theft since the last inspection, this should be marked "N/A")		15-2-5.4 15-2-9.3.1	
13	Any non-licensed person(s) in the prescription area have the proper authorization to be there?		15-7-5.3 15-7-5.5	
14	Only pharmacists have key or code access to prescription area?		15-15-7.3.1	
15	Is generic substitution sign visible to the public?		30-5-12b.(o)	
16	Are Rules of Professional Conduct posted in a conspicuous place?		15-1-15.15	
17	Are the Pharmacy's Permit and DEA License current and posted in a conspicuous place?		15-15-4.3	
18	Is the Pharmacy's CMEA Certificate current and posted in a conspicuous place? (If the pharmacy does not sell psuedoephedrine without a prescription, this should be marked "N/A")		15-15-4.3 15-1-2.1.44.a	

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19	Are all pharmacist, pharmacy intern, pharmacy technician, and pharmacy technician trainee licenses current and posted in a conspicuous place?		15-1-16.2.6 30-5-20	
20	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?		15-1-16.2.6	
21	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)		15-1-16.3.1	
22	Is there a proper sign available to post when a pharmacist is not on duty?		15-15-7.4	
23	Are completed prescription orders bagged and kept in the pharmacy (prescription area) and not removed from the pharmacy unless the pharmacist is present?		15-15-7.5	
24	Last Biennial Inventory is in the correct format? (List date of last biennial inventory in Inspector Comments)		15-2-7.5	Date of last Biennial Inventory:
25	Does Form 222 or CSOS require a Power of Attorney? (If yes, list individuals to whom power of attorney has been issued in Inspector Comments)		DEA/21 CFR 1305.05(a) 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?		15-2-9.2.1	
28	Is there proper disposal of all unused medications (controls & other)?		15-2-9.2.1	
29	If the pharmacy sells over-the-counter (OTC) controlled drugs, is the Schedule V book complete and correct? (If the pharmacist does not sell OTC controlled drugs, this should be marked "N/A")		15-2-8.19 15-11-3.1 15-11-3.3.5 15-11-3.3.b	
30	If the pharmacy has filled any telephoned emergency CII prescriptions, only the emergency quantity was filled and a signed, written Rx was provided within 7 days (If no telephoned emergency CII prescriptions have been filled since the last inspection, this should be marked "N/A")		15-1-17.1.6	
31	Is the Patient's address shown on all prescriptions?		15-2-8.5.1	
32	Is the Date of Issue shown on all prescriptions?		15-2-8.5.1	
33	Do hospital prescriptions contain DEA number suffix for applicable prescribers?		15-1-6.1.2.a.3.B	
34	Do all prescriptions appear prescribed for a legitimate medical use?		15-1-17.1	
35	Are electronic prescription transmissions certified?		15-1-17.1.7 15-1-17.1.8	
36	Are telephoned prescriptions properly & completely documented?		15-1-17.1.2	
37	Are transferred prescriptions properly recorded (both in and out)?		15-1-8.2.1	

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38	Is there a proper record of emergency dispensing of maintenance meds?		15-1-22.1	
39	Are complete patient profiles maintained on all patients?		15-1-11.2.7	
40	Is one full year of dispensing records available online?		15-4-4	
41	Can the pharmacy generate five full years of records of dispensing on request?		15-4-4	
42	Are sales of Rx drugs without a prescription properly recorded? (If the pharmacy does not sell Rx drugs without a prescription, this should be marked "N/A")		15-1-6.1.1	
43	If servicing a nursing home is a log of returned drugs maintained? (If the pharmacy does not service a nursing home, this should be marked "N/A")		15-1-9.3	
44	Do all controlled drug prescriptions show practitioners printed name?		15-2-8.5.1	
45	Are partial fills documented correctly?		30-5-27	
46	Are controlled Rx's on a separate prescription blank?		15-2-8.6.1	
47	No Schedule II (C2) controlled Rx's are filled after 90 days (unless provider called)?		15-2-8.9.1.a	
48	Can the pharmacy demonstrate the Controlled Drug perpetual inventory & monthly review?		15-2-7.2.4.a	
49	Is there a connection to the CSMP available?		15-8-3.1	
50	Are controlled substance dispensing's and all required data being reported to the CSMP?		15-8-3.1	
51	If this pharmacy has dispensed opioid antagonists, is there documentation of reporting opioid antagonists to CSMP? (If no opioid antagonists have been dispensed since the last inspection, this should be marked "N/A")		60A-9-4(a)(3) 15-8-3.1	
52	Is there a reasonable effort to obtain patient I.D. for the patient record?		60A-3-308.d.2.B	
53	Is the I.D. of the person receiving a controlled Rx being recorded?		60A-9-4.(b).(8)	
54	Are all OTC pseudoephedrine sales reported via the NPLEX System? (If pseudoephedrine sales are dispensed via prescription only, please note in inspector comments)		15-11-4.3 60A-10-8	
55	Pharmacist 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.		15-1-15.13.2	
56	Is the manufacturer shown on the prescription record file?		30-5-12b(j)	
57	Are the dispensing pharmacist's initials recorded on the Rx record file?		15-1-15.13.4	
58	Are the initials of all personnel who have worked on the Rx recorded?		15-1-15.13.4	
59	Do prescription containers meet the FDA and USP requirements?		15-1-11.1.2	
60	Are proper closures used and documented if non-safety?		Consumer Protection	
61	Do the pharmacist's initials appear on the Rx label?		15-1-18.1.4.h	

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62	Does the manufacturer's name and drug generic name appear on the Rx label?		15-1-18.1.4.l 15-1-18.1.4.m	
63	If dispensed as equivalent does the Rx label show "Substituted for" "brand"?		15-1-18.1.4.i.1	
64	Does the Rx label show a beyond use date?		15-1-18.1.4.n	
65	Does the Rx label show the prescriber's name?		15-1-18.1.4.c	
66	Does the Rx label show all necessary auxiliary information?		15-1-18.1.4.l	
67	Is a proper offer to counsel made on pickup of each new prescription?		15-1-15.13.5	
68	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	
69	Is the counseling area convenient to the pharmacist? (Unless excused prior to 5/1/1999)		15-1-11.1.1	
70	Is the counseling area private for the patient? (Unless excused)		15-1-11.1.1	
71	Are any outdated drugs found among shelf stock? (List number found in inspector comments)		15-1-15.9.2	
72	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	
73	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	
74	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	
75	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	
76	Is the prescription counter clean, dust free, and in an orderly condition?		15-1-14.1.3	
77	Is the prescription counter only used for prescription preparation?		15-1-14.1.3	
78	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	
79	Is there sufficient compounding equipment available?		15-1-11.2	
80	Is there a sanitary method of measuring liquids?		15-1-11.2.1	
81	Is the sink used only for cleaning hands and equipment?		15-1-14.1.6	
82	Do pharmacists have a proper name tag on their garment?		15-1-14.1.4	
83	Does the pharmacy have Board approved clinical reference materials?		15-15-3.2.3	
84	Does the pharmacy have access to current WVBOP Laws and Rules?		15-1-11.2.8	

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85	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 85 to 89 should be marked "N/A")		15-1-16.2.4 15-7-4.1	
86	Do pharmacy technician trainees wear proper attire?		15-1-14.1.4	
87	Do pharmacy technician trainees have a proper name tag?		15-7-8.2	
88	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	
89	Has PIC provided all necessary documentation to Board of any PTT that has discontinued the PTT program at this pharmacy?		15-7-4.4	
90	Are all licensed pharmacy technicians (PT) wearing proper attire and name tags?		15-1-14.1.4 15-7-8.1	
91	Does the pharmacy maintain written duties for all pharmacy technicians?		15-1-16.3.2	
92	No pharmacy technician is observed violating legally authorized duties?		15-7-5.1	
93	All technicians are directly supervised by the pharmacist on duty?		15-1-16.3.2	
94	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	
95	Is the ratio of Technicians to Pharmacist correct at this time? (List in Inspector Comments)		15-7-5.3	Pharmacists: Technicians:
96	If a pharmacist ever works without a technician present, list the number of prescriptions filled per hour without a technician in Inspector Comments (If a pharmacist never works without a technician present, this should be marked "N/A")		15-15-8.5	
97	Does PIC work 30 or more hours/week if pharmacy is open more than 40 hours/week? OR If the pharmacy is open less than 40 hours/week does the PIC work more than 50% of the hours the pharmacy is open?		15-1-2.1.44.c	
98	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	
99	Does the pharmacy have an ongoing Quality Assurance program in place?		15-1-16.2.3	
100	Are written reports prepared when dispensing errors occur?		Guidance Only	
101	Are these reports formally discussed with prescription department personnel?		Guidance Only	
102	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	

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103	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	
104	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	
105	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	
106	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	
107	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	
108	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	
109	Does the pharmacy demonstrate complete and accurate records showing its pharmacists' daily break periods?		15-15-8.3	
110	Is the PIC assisted by sufficient staff?		15-1-16.3 15-7-5.3	
111	Does the pharmacy follow CDC guidelines for administration of immunizations? (If the pharmacy does not administer immunizations, questions 111 to 120 should be marked "N/A")		15-12-5.2.b	
112	Does the pharmacy have written emergency procedures in place?		15-12-7	
113	Does the Emergency Kit meet the CDC guidelines?		15-12-7	
114	Are appropriate records kept for immunizations?		15-12-6	
115	Do immunizing pharmacists have current BLS/CPR certification?		15-12-3.1.c	

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116	Have immunizing pharmacists completed a minimum of 2 hours of CPE related to immunizations <u>each licensing year</u> for a total of 4 hours each renewal period?		15-12-3.1.d	
117	Do pharmacy technicians (PT) administer immunizations? (If the pharmacy does administer immunizations but these are only administered by pharmacists, questions 117 to 120 to should be marked "N/A")		15-12-3.3	
118	Are all pharmacy technicians who administer immunizations registered with the Board?		15-12-3.3.a	
119	Do immunizing pharmacy technicians have current BLS/CPR certification?		15-12-3.3.d	
120	Have immunizing PT completed a minimum of 2 hours of CPE related to immunizations <u>each licensing renewal period?</u>		15-12-3.3.e	
121	Are CE certificates or records for all pharmacists available for inspection?		15-3-12.3 15-3-9.1	
122	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	
123	Do all pharmacists have at least 6 hours of live CE for reporting period?		15-3-4.3	
124	Do all pharmacists have 30 or more hours of CE for last renewal reporting period?		15-3-4.1	

Controlled Substance Audit				
Drug Name, Strength & Dosage Form	NDC	Expected Count	Actual Count	Comments

ALL QUESTIONS HAVE NOT BEEN ANSWERED, PLEASE REVIEW!

PIC: _____ Date: _____

Inspector: _____ Date: _____