

# West Virginia Board of Pharmacy

Phone (304) 558-0558

Fax (304) 558-0572

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

## NEW/RELOCATED PHARMACY - GENERAL INSPECTION REPORT

#N/A #N/A #N/A #N/A Email #N/A Fax: #N/A	Date: WVBOP#: DEA License#: #N/A Pharmacist in Charge: #N/A Phone: #N/A Hours: Inspection Type:    New Pharmacy: <input type="checkbox"/> Relocation: <input type="checkbox"/>
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Item	Question	Observation	Reference	Inspector Comments
1	Will <USP 795> Non-Sterile Compounding be performed? (If Yes, a NEW non-sterile compounding inspection should be completed)		15-1-11.1.2	(If YES, complete corresponding inspection):
2	Will <USP 797> Sterile Compounding be performed? (If Yes, a NEW sterile compounding inspection should be completed)		15-1-12 15-1-11.1.2	(If YES, complete corresponding inspection):
3	Will compounding (Non-Sterile or Sterile) be performed with Hazardous drugs as per <USP 800>? (If Yes, a NEW HD compounding inspection should be completed)		15-1-11.1.2	(If YES, complete corresponding inspection):
4	Is this pharmacy prepared to 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 which will be generated and received an EPA ID Number?		15-1-2.1.44.a	
6	If this pharmacy will utilize an Automated Pharmacy System, has this been communicated to the board as part of the new pharmacy application process?		15-1-16.2.11	
7	Has an alarm system been 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	Have barriers been installed according to Rule, including on the Drive-Up window?		15-15-7.4 15-2-5.1.1	
10	Will controlled substances be dispersed? (List schedule(s) to be dispersed in Inspector Comments) <b>OR</b>		15-2-5.5.1	Schedules Dispersed:
11	Stored in a 20 gauge (or better) locked metal cabinet or drawer? (List schedule(s) to be locked in cabinet or drawer in Inspector Comments)		15-2-5.5.1	Schedules locked in cabinet:
12	Has the pharmacy developed a system of controlled drug reconciliation which will effectively detect diversion?		15-2-7.2.4.a	
13	Will only pharmacists have key or code access to the prescription area?		15-15-7.3.1	
14	Is a generic substitution sign visible to the public?		30-5-12b.(o)	
15	Are Rules of Professional Conduct posted in a conspicuous place?		15-1-15.15	
16	Are the Pharmacy's Permit and DEA License current and posted in a conspicuous place?		15-15-4.3	
17	Is the Pharmacy's CMEA Certificate current and posted in a conspicuous place? (If the pharmacy does not plan to sell pseudoephedrine without a prescription, this should be marked "N/A")		15-15-4.3 15-1-2.1.44.a	
18	Is a proper sign available to post when a pharmacist is not on duty? (If this is an inpatient pharmacy, or the entire building will be closed when no pharmacist is on duty, this should be answered "N/A")		15-15-7.4	
19	Does Form 222 or CSOS require a Power of Attorney and, if yes, have these been issued appropriately? (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	
20	If the pharmacy will sell over-the-counter (OTC) controlled drugs, is a Schedule V book available? (If the pharmacist does not plan to 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	
21	Is a connection to the CSMP available?		15-8-3.1	
22	Will all OTC pseudoephedrine sales be reported via the NPLEX System? (If pseudoephedrine sales will be dispensed via prescription only, please note in inspector comments)		15-11-4.3 60A-10-8	

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23	Can the planned process for pharmacist verification of prescriptions/orders be demonstrated or explained to the inspector and the pharmacist(s) surveyed affirm that the final verification process will be capable of sufficiently aiding pharmacists in the detection of errors to ensure patient safety?		15-1-15.13.2	
24	Will the manufacturer be shown on the prescription record files?		30-5-12b(j)	
25	Will the dispensing pharmacist's initials be recorded on the prescription record files?		15-1-15.13.4	
26	Will the initials of all personnel who have worked on the prescription be recorded?		15-1-15.13.4	
27	Do prescription containers meet the FDA and USP requirements?		15-1-11.1.2	
28	Will proper closures be used and documented if non-safety?		Consumer Protection	
29	Will the pharmacist's initials appear on the prescription label?		15-1-18.1.4.h	
30	Will the manufacturer's name and drug generic name appear on the prescription label?		15-1-18.1.4.i	
			15-1-18.1.4.m	
31	If dispensed as equivalent, will the prescription label show "Substituted for (brand)"?		15-1-18.1.4.i.1	
32	Will the prescription label show a beyond use date?		15-1-18.1.4.n	
33	Will the prescription label show the prescriber's name?		15-1-18.1.4.c	
34	Will the prescription label show all necessary auxiliary information?		15-1-18.1.4.l	
35	If the pharmacy will mail or deliver prescriptions, is the method of "Offer to Counsel" for these prescriptions adequate and appropriate? (Describe how the "Offer to Counsel" on these prescriptions will be done in Inspector Comments)		15-1-15.13.5	
36	Is the counseling area convenient to the pharmacist?		15-1-11.1.1	
37	Is the counseling area private for the patient?		15-1-11.1.1	
38	If the pharmacy will repack medication from the manufacturer container into a specialized dispensing system, the assigned beyond-use date will 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	
39	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	
40	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	
41	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	
42	Are all areas where drugs and devices will be stored dry, well lighted, well ventilated, and maintained in a clean and orderly condition?		15-1-14.1.5	
43	Is sufficient compounding equipment available?		15-1-11.2	
44	Is a sanitary method of measuring liquids available?		15-1-11.2.1	
45	Is a sink for cleaning hands and equipment available?		15-1-14.1.6	
46	Does the pharmacy have Board approved clinical reference materials?		15-15-3.2.3	
47	Does the pharmacy have access to current WVBOP Laws and Rules?		15-1-11.2.8	
48	Is an approved Pharmacy Technician Training Manual available?		15-1-16.2.4 15-7-4.1	
49	Will pharmacists, technicians, and others have a proper name tag on their garment?		15-1-14.1.4	
			15-7-8.2	

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Item	Question	Observation	Reference	Inspector Comments
50	Has the pharmacy developed written duties for all pharmacy technicians?		15-1-16.3.2	
51	Has the pharmacy developed a Quality Assurance program?		15-1-16.2.3	
52	Will the pharmacy keep complete and accurate records showing pharmacists' daily break periods?		15-15-8.3	
53	Will the pharmacy administer vaccines? (If no, this should be answered "N/A")		15-12-5	
54	Does the pharmacy have written emergency procedures in place?		15-12-7	
55	Is an Emergency Kit available which meet the CDC guidelines?		15-12-7	
56	Are all pharmacists and/or technicians who will administer immunizations properly registered with the board and have current BLS/CPR certification(s)?		15-12-3.1.c	

ALL QUESTIONS HAVE NOT BEEN ANSWERED, PLEASE REVIEW!

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#N/A

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#N/A