

## West Virginia Board of Pharmacy

Phone (304) 558-0558

Fax (304) 558-0572

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

### INPATIENT PHARMACY - INSPECTION REPORT

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

Item	Question	Observation	Reference	Inspector Comments
1	Is <b>USP &lt;795&gt;</b> Non-Sterile Compounding being Performed?		15-1-11.1.2	
2	Is <b>USP &lt;797&gt;</b> Sterile Compounding being Performed?		15-1-12 15-1-11.1.2	
3	Is compounding (Non-Sterile or Sterile) being performed with Hazardous drugs as per <b>USP &lt;800&gt;</b> ?		15-1-11.1.2	
4	Does this pharmacy operate an outpatient pharmacy? (To be fully compliant, the outpatient pharmacy must be separately licensed and inspected by the board with an accompanying Outpatient Pharmacy-Inspection Report)		15-1-2.1.37 15-19-2.10	
5	Does this pharmacy meet the current requirements of the DSCSA?		15-1-2.1.44.a	
6	Has this pharmacy notified WV DEP of types of Hazardous Wastes generated and received an EPA ID Number?		15-1-2.1.44.a	
7	Has any addition, removal, or change of an Automated pharmacy system been communicated in writing to the Board?		15-1-16.2.11	
8	Is there an alarm system installed according to Rule?		15-15-7.2	
9	Does the alarm system include a battery back-up power source?		15-15-7.2.2.1	
10	Are there barriers installed to rule?		15-15-7.4 15-2-5.1.1	
11	Are controlled substances dispersed? (List schedules dispersed in Inspector Comments) <b>OR</b>		15-2-5.5.1	Schedule(s) dispersed:
12	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	Schedule(s) locked in cabinet:
13	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	
14	Any non-licensed person(s) in the prescription area have the proper authorization to be there?		15-7-5.3 15-7-5.5	
15	Only pharmacists have key or code access to prescription area if not 24/7? (if 24/7 please note in comments)		15-15-7.3.1	
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?		15-15-3.3	
18	Are all pharmacist, pharmacy intern, pharmacy technician, and pharmacy technician trainee licenses current and posted?		15-1-16.2.6 30-5-20	
19	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	
20	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	
21	If being done remotely has PIC seen DUR pharmacist's license?		15-14-4.1.b	

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22	Are afterhours entry rules followed?		15-15-7.3.2	
23	Is there completed documentation of afterhours entry?		15-15-7.3.2	
24	Is satellite pharmacy supervised by pharmacist when open?		15-1-16.3.2	
25	Last Biennial Inventory is in the correct format? (List date of last biennial inventory in Inspector Comments)		15-2-7.5	Last Biennial Inventory Date:
26	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	
27	Are controlled substance invoices or packing slips signed by a pharmacist?		15-2-9.4.2	
28	Are there completed Return & Destruction records of controlled drugs?		15-2-9.2.1 15-2-9.4.1	
29	Is there proper disposal of <u>all</u> unused medications (controls & other)?		15-2-9.2.1 15-1-16.2.5	
30	In acute care hospitals, discontinued individual patient medications not supplied by the hospital that remain in the hospital after discharge and are considered abandoned have been destroyed according to rule and in compliance with federal law (In order to be compliant, all conditions of 15-2-9.2.3 must be met)		15-2-9.2.3	
31	Are complete patient profiles maintained on all patients?		15-1-11.2.7	
32	Is one full year of dispensing records available online?		15-4-4	
33	Can the pharmacy generate five full years of records of dispensing on request?		15-4-4	
34	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	
35	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	
36	Can the licensee demonstrate the Controlled Drug perpetual inventory & monthly review?		15-2-7.2.4.a	
37	Does the reconciliation of controlled drugs effectively detect diversion?		15-2-7.2.4.a	
38	Is there a connection to the CSMP available?		60-A-9-5a.(a) 60-A-9-5a.(b)	
39	Are any outdated drugs found among shelf stock? (List number found in inspector comments)		15-1-15.9.2	Number of Outdates found:
40	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	

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41	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	Storage area room temperature:
42	Are refrigerator temperatures all between 2 to 8°C (36 to 46°F)? (List the current refrigerator temperatures in Inspector Comments; if drugs are not currently being stored in the refrigerator, this should be marked "N/A")		15-1-11.2.4 15-1-14.1.5	Refrigerator temperature(s):
43	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	Freezer temperature(s):
44	Are work counters clean and dust free?		15-1-14.1.3	
45	Are work counters only used for medication preparation?		15-1-14.1.3	
46	Is the medication preparation room/area clean, orderly, and dust free?		15-1-14	
47	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	
48	Is there sufficient compounding equipment available?		15-1-11.2	
49	Is there a sanitary method of measuring liquids?		15-1-11.2.1	
50	Is the sink used only for cleaning hands and equipment?		15-1-14.1.6	
51	Do pharmacists have a proper name tag on their garment?		15-1-14.1.4	
52	Does the pharmacy have Board approved clinical reference materials?		15-15-3.2.3	
53	Does the pharmacy have access to current WVBOP Laws and Rules		15-1-11.2.8	
54	Are inpatient unit-dose drugs properly labeled?		15-1-18.1.1	
55	Do all multiple-dose systems being utilized meet the labeling requirements?		15-1-18.1.1	
56	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 56 to 60 should be marked "N/A")		15-1-16.2.4 15-7-4.1	
57	Do pharmacy technician trainees wear proper attire?		15-1-14.1.4 15-7-8.2	
58	Do pharmacy technician trainees have a proper name tag?		15-1-14.1.4 15-7-8.2	
59	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	
60	Has PIC provided all necessary documentation to Board of any PTT that has discontinued the PTT program at this pharmacy?		15-7-4.4	
61	Are all licensed pharmacy technicians (PT) wearing proper attire and name tags?		15-1-14.1.4 15-7-8.1	
62	Does the pharmacy maintain written duties for all pharmacy technicians?		15-1-16.3.2	
63	No pharmacy technician is observed violating legally authorized duties?		15-7-5.1	
64	All technicians are directly supervised by the pharmacist on duty?		15-1-16.3.2	

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65	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	
66	Is the ratio of Technicians to Pharmacist correct at this time? (List in Inspector Comments)		15-7-5.3	Pharmacists:      Technicians:
67	Does PIC work 30 or more hours/week if pharmacy is open more than 40 hours/week? <b>OR</b> 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	
68	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	
69	Has the PIC seen current licenses of all current employees?		15-1-16.2.6	
70	Does the pharmacy have an ongoing Quality Assurance program in place?		15-1-16.2.3	
71	Are written reports prepared when dispensing errors occur?		Guidance Only	
72	Are these reports formally discussed with prescription department personnel?		Guidance Only	
73	Has the Board been notified, in writing, of any violations of board rules or laws by the licensed pharmacist? (If there have been no complaints since the last inspection, this should be marked "N/A")		15-15-9.3	
74	Has the Board been notified, in writing, of any discharge or termination of a licensed pharmacist or change of the status of the PIC? (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	
75	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	
76	Has the 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	
77	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	

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78	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	
79	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	
80	Does the pharmacy demonstrate complete and accurate records showing its pharmacists' daily break periods?		15-15-8.3	
81	Is the PIC assisted by sufficient staff?		15-1-16.3 15-7-5.3	
82	Does the pharmacy follow CDC guidelines for administration of immunizations? (If the pharmacy does not administer immunizations, questions 82 to 91 should be marked "N/A")		15-12-5.2.b	
83	Does the pharmacy have written emergency procedures in place?		15-12-7	
84	Does the Emergency Kit meet the CDC guidelines?		15-12-7	
85	Are appropriate records kept for immunizations?		15-12-6	
86	Do immunizing pharmacists have current BLS/CPR certification?		15-12-3.1.c	
87	Have immunizing pharmacists completed a minimum of 2 hours of CPE related to immunizations <i>each licensing year</i> for a total of 4 hours each renewal period?		15-12-3.1.d	
88	Do pharmacy technicians (PT) administer immunizations? (If the pharmacy does administer immunizations but these are only administered by pharmacists, questions 88 to 91 to should be marked "N/A")		15-12-3.3	
89	Are all pharmacy technicians who administer immunizations registered with the Board?		15-12-3.3.a 15-12-4.4	
90	Do immunizing pharmacy technicians have current BLS/CPR certification?		15-12-3.3.d	
91	Have immunizing PT completed a minimum of 2 hours of CPE related to immunizations <i>each licensing renewal period</i> ?		15-12-3.3.e	
92	Are CE certificates or records for all pharmacists available for inspection?		15-3-12.3 15-3-9.1	
93	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	
94	Do all pharmacists have at least 6 hours of live CE for reporting period?		15-3-4.3	

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95	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 \_\_\_\_\_