West Virginia Board of Pharmacy

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Charleston, West Virginia 25301

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 perform USP 795 Non-Sterile Compounding? 15-1-11.1.2				
2	If Yes, must complete NABP USP 795 Non-Sterile Compounding Inspection Form.				
3	Does this pharmacy perform USP 797 Sterile Compounding?	15-1-12; 15-1-11.1.2			
4	If Yes, must complete NABP USP 797 Sterile Compounding Inspection Form.				
5	Does this pharmacy perform compounding with Hazardous Drugs as per USP 800?	15-1-11.1.2			
6	If Yes, must complete NABP Hazardous Drug Inspection Form for Compounding Pharmacies.				
7	Does this pharmacy meet the current requirements of the DSCSA?	15-1-2.1.42.a			
8	Has this pharmacy notified WV DEP of types of Hazardous Wastes generated and	15-1-2.1.42.a			
	received an EPA ID Number?	17 1 1 () 11			
9		15-1-16.2.11			
10	If Yes, describe above change.				
11	Has the Board been notified in writing of this change?				
12	Is there an alarm system installed according to Rule? 15-15-6.2				
13	Does the alarm system include a battery back-up power source? 15-15-6.2.1				
14	Are there barriers installed to Rule including Drive-Up window?	parriers installed to Rule including Drive-Up window? 15-15-6.4; 15-2-5.1.1			
15	Are controlled substances dispersed?	15-2-5.5.1			
	OR Schedule(s):				
16	Stored in a 20 gauge (or better) locked metal cabinet or drawer?	15-2-5.5.1			
	Schedule(s):				
17	Are all losses or thefts of controlled drugs reported to DEA and WVBOP? 15-2-5.4; 15-2-9.3.1				
18	Only authorized non-licensed person(s) in prescription area?	15-7-5.3; 15-7-5.5			
19	Only pharmacists have key or code access to prescription area?	15-15-6.3.1			
20	Is generic substitution sign visible to the public?	30-5-12b.(o)			
21	Are Rules of Professional Conduct posted in a conspicuous place?	15-1-15.15			
22	Are the Pharmacy's Permit and DEA License <u>current</u> and posted in a conspicuous place?	15-15-3.3			

Item	Question	Reference	Yes	No	NA
23	Are all pharmacist, pharmacy intern, pharmacy technician, and pharmacy technician	15-1-16.2.6;			
	trainee licenses current and posted in a conspicuous place?	30-5-20			
24	Is a <u>current</u> copy of the Combined Technician List and Confidentiality Statement	15-1-16.3.1			
	posted and is it on file with the Board? (Inspector to verify in database)				
25	Is there a proper sign available to post when a pharmacist is not on duty?	15-15-6.4			
26	Are completed prescription orders bagged and kept in the pharmacy (prescription	15-15-6.5			
	area) and not removed from the pharmacy unless the pharmacist is present?				
27	Last Biennial Inventory is dated: Click or tap to enter a date. and is the correct format?	15-2-7.5			
28	Does Form 222 or CSOS require a Power of Attorney?	DEA / 21 CFR 1305.05(a)			
29	Has Power(s) of Attorney been issued? To Whom:	15-2-4.6			
30	Are controlled substance invoices or packing slips signed by a pharmacist?	15-2-9.4.2			
31	Are there completed Return & Destruction records of controlled drugs?	15-2-9.4.1			
32	Does the pharmacy sell Over-the-Counter controlled drugs?	15-11-3.1			
33	Is the Schedule V Book complete, and correct?	15-11-3.3.5; 15-11-3.3.b			
34	Has the pharmacy filled any telephoned Emergency CII prescriptions?	15-1-17.6			
35	The emergency quantity only filled? 15-1-17.1.6.a				
36	Is there a signed written Rx that was provided within 7 days? 15-1-17.1.6.c				
37	Do all controlled drug prescriptions show practitioners printed name?	15-2-8.5.1			
38	Do hospital prescriptions contain DEA number suffix for applicable prescribers?	15-1-6.1.2.a.3.B			
39	Is the Patient's address shown?	15-2-8.5.1			
40	Is the Date of Issue shown?	15-2-8.5.1			
41	Are partial fills documented correctly? 30-5-27				
42	Are controlled Rx's on a separate prescription blank?	t's on a separate prescription blank? 15-2-8.6.1			
43	No controlled Rx's are filled after 90 days (unless provider called)?	15-2-8.9.1.a			
44	Are all OTC pseudoephedrine sales reported via the NPLEX System?	15-11-4.3; 60A-10-8			
	Check here if pseudoephedrine sales are dispensed via prescription only. \Box	00A-10-0			
45	Is the Pharmacy's CMEA Certificate <u>current</u> and posted in a conspicuous place?	15-15-3.3; 15-1-2.1.42.a			
46	Is there a reasonable effort to obtain patient I.D. for the patient record?	60A-3-308.d.2.B			
47	Is the I.D. of the person receiving a controlled Rx being recorded?	60A-9-4.(b).(8)			
48	Are any outdated drugs found among shelf stock? Number found:	15-1-15.9.2			
49	Are refrigerator temperatures all between 2 to 8°C (36 to 46°F)?	15-1-11.2.4			
50	List refrigerator temperatures:				
51	Are freezer temperatures between -10 to -25°C (-13 to14°F)?	15-1-11.2.4			
52	List the freezer temperatures:				
53	Is the pharmacy area temperature controlled between 20 to 25°C (68 to 77°F)?	15-1-11.2.4; 15-1-14.1.5			
54	List pharmacy area temperature(s):	13-1-14.1.3			
55	Is the prescription counter clean, dust free, and in an orderly condition?	15-1-14.1.3			
56	Is the prescription counter only used for prescription preparation?	15-1-14.1.3			
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Item	Question	Reference	Yes	No	NA
57	Are all areas where drugs and devices are stored dry, well lighted, well ventilated,	15-1-14.5			
	and maintained in a clean and orderly condition?				
58	Is the sink used only for cleaning hands and equipment?	15-1-14.1.6			
59	Do pharmacists have a proper name tag on their garment?	15-1-14.1.4			
60	Are electronic prescription transmissions certified?	15-1-17.1.7			
61	Do all prescriptions appear prescribed for a legitimate medical use?				
62	Are telephoned prescriptions properly & completely documented?	15-1-17.1.2			
63	Is the manufacturer shown on the prescription record file?	30-5-12b(j)			
64	Are the dispensing pharmacist's initials recorded on the Rx record file?	15-1-15.13.4			
65	Are the initials of all personnel who have worked on Rx recorded?	15-1-15.13.4			
66	Are transferred prescriptions properly recorded (both in and out)?	15-1-8.2.1			
67	Is there any sign that prescriptions have been refilled after 12 months?	15-1-7.3			
68	Is there a proper record of emergency dispensing of maintenance meds?	15-1-22.1			
69	Are complete patient profiles maintained on all patients?	15-1-11.2.7			
70	Is one full year of dispensing records available online?	15-4-4			
71	Can the pharmacy generate five full years of records of dispensing on request?	15-4-4			
72	Are sales of Rx drugs without a prescription properly recorded?	15-1-6.1.1			
73	If servicing a nursing home is a log of returned drugs maintained?	15-1-9.3			
74	Is there sufficient compounding equipment available?	15-1-11.2			
75	Is there a sanitary method of measuring liquids?	15-1-11.2.1			
76	Does the pharmacy have Board approved clinical reference materials?	15-15-2.2.3			
77	Does the pharmacy have a current copy of WVBOP Law and Rules? 15-1-11.2				
78	Do prescription containers meet the FDA and USP requirements? 15-1-11.1.2				
79	Are proper closures used and documented if non-Safety?	er closures used and documented if non-Safety? Consumer Protection			
80	Do the pharmacist's initials appear on the Rx label?	15-1-18.1.4.h			
81	Does the manufacturer's name and drug generic name appear on the Rx label?	15-1-18.1.4.m			
82	If dispensed as equivalent does the Rx label show "Substituted for" "brand"?	15-1-18.1.4.i.1			
83	Does the Rx label show a beyond use date?	15-1-18.1.4.n			
84	Does the Rx label show the prescriber's name?	15-1-18.1.4.c			
85	Does the Rx label show all necessary auxiliary information?	15-1-18.1.4.l			
86	Is a proper offer to counsel made on pickup of each new prescription?	15-1-15.13.6			
87	How is "Offer to Counsel" documented on mail or delivered Rx's?	15-1-15.13.6			
88	Is the counseling area convenient to the pharmacist? (Unless excused prior to 5/1/99)	15-1-11.1.1			
89	Is the Counseling area private for the patient? (Unless excused)	15-1-11.1.1			
90	Does this pharmacy employ pharmacy technician trainees (PTT)?	17.1.1.2.2.2			
91	Is an approved Pharmacy Technician Training Manual available?	15-1-16.2.4; 15-7-4.1			
92	Is documentation of training by the P.I.C. available?	15-1-16.2.4			
93	Are there written records that document the required elements of the PTT program?	15-1-16.2.4			

Item	Question Reference		Yes	No	NA
94	Do pharmacy technician trainees wear proper attire?	15-1-14.4 15-7-8.2			
95	Do pharmacy technician trainees have a proper name tag?	15-7-8.2			
96	Does PIC validate that no PTT has exceeded 12 months of training plus 3 months	15-7-4.2; 15-7-4.4e			
	for testing?				
97	Has PIC provided all necessary documentation to Board of any PTT that has	15-7-4.4.a			
20	discontinued the PTT program at this pharmacy?	15 1 14 4			_
98	Are all licensed pharmacy technicians (PT) wearing proper attire and name tags?	15-1-14.4 15-1-16.3.2			
99	Does the pharmacy maintain written duties for all pharmacy technicians?	15-1-10.5.2			
100	No pharmacy technician is observed violating legally authorized duties?	15-7-5.1			
101	All technicians are directly supervised by the pharmacist on duty?	15-1-16.3.2			
102	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			
103	Does PIC work 30 or more HR/WK if pharmacy is open more than 40HR/WK?	15-1-2.1.42.c			
104	Does PIC work more than 50% of hours in a pharmacy open less than 40 HR/WK?	15-1-2.1.42.c			
105	Has an Interim PIC been utilized?	15-15-5.1			
106	Has the PIC seen current licenses of all current employees?	15-1-16.2.6			
107	Demonstrate the Controlled Drug Perpetual inventory & monthly review.	15-2-7.2.4.a			
108	Does the pharmacy have an ongoing Quality Assurance program in place?	15-1-16.2.3			
109	Are written reports prepared when dispensing errors occur?	Guidance Only			
110	i i i i i i i i i i i i i i i i i i i				
111	Is there a connection to the CSMP available?	15-8-3.1			
112	Are controlled substance dispensing's and <u>all required data</u> being reported to the 15-8-3.1				
	CSMP?				
113	Has this pharmacy dispensed any opioid antagonists?	60A-9-4(a)(3)			
114	Is there documentation of reporting opioid antagonist to CSMP?	60A-9-4(a)(3); 15-8-3.1			
115					
116	Has the Board been notified, in writing, of any discharge or termination of a licensed	ied, in writing, of any discharge or termination of a licensed 15-15-8.2			
	pharmacist or change of the status of the pharmacist-in-charge?			_	_
117	Has the Board been notified, in writing, of the separation of employment of any pharmacist,	15-1-16.2.7.e-f			
	pharmacy intern, PT, or PTT for any confirmed drug-related reason, including but not limited				
110	to, adulteration, abuse, theft, or diversion? Has PIC notified permit holder of any & all violations of Law or Rules?	15-1-16.2.2			
118 119	Is there documentation of such PIC notification with a copy to Board office?	15-1-16.2.2			
120	If NO above, explain why?	10 1-10,2,2			
121	No pharmacist, pharmacy intern, or pharmacy technician works longer than 12	15-15-7.2			
	continuous hours per 24-hour period, inclusive of required breaks?				
122	Is there documentation if 12-hour shift is exceeded and/or breaks are missed or	15-15-7.4			
	interrupted?				

Item	Question	Reference	Yes	No	NA
123	Does the pharmacy demonstrate complete and accurate records showing its	15-15-7.4			
	pharmacists' daily break periods?				
124	Does a pharmacist ever work without a technician present?	15-15-7.5			
125	If YES above, what is the average number of Rx/Hr. dispensed during that period?				
126	Is the ratio of Technicians to Pharmacist correct at this time?	15-7-5.3			
127	Currently on Duty: Technicians: Pharmacists:				
128	Is the PIC assisted by sufficient staff?	15-1-16.3; 15-7-5.3			
129	Do pharmacists administer immunizations?	15-12-5			
130	Does the pharmacy follow CDC guidelines for administration of immunizations?	15-12-5.2.b			
131	Does the pharmacy have written emergency procedures in place?	15-12-7			
132	Does the Emergency Kit meet the CDC guidelines?	15-12-7			
133	Are appropriate records kept for immunizations?				
134	Do immunizing pharmacists have current BLS/CPR certification?				
135	Have immunizing pharmacists completed a minimum of 2 hours of CPE related to	15-12-3.1.d			
	immunizations <u>each licensing year</u> for a total of 4 hours each renewal period?				
136	Do pharmacy technicians (PT) administer immunizations?	15-12-3.3			
137	Are all pharmacy technicians who administer immunizations registered with the Board?	15-12-3.3.a; 15-12-4.4			
138	Do immunizing pharmacy technicians have current BLS/CPR certification?	15-12-3.3.d			
139	Have immunizing PT completed a minimum of 2 hours of CPE related to	15-12-3.3.e			
	immunizations <u>each licensing renewal period</u> ?				
140	Are CE certificates or records for all pharmacists available for inspection?	15-3-13.3; 15-3-9.1			
141	Have all pharmacists completed a minimum of 2 hours of drug diversion training and best	15-3-4.4			
	practice prescribing of controlled substances training within 1 year of receiving initial license				
142	from the Board? Do all pharmacists have at least 6 hours of live CE for reporting period?	15-3-4.3			
	Do all pharmacists have 30 or more hours of CE for last renewal reporting period?	15-3-4.1			
143	Do an pharmacists have 50 or more hours of CE for last renewal reporting period?	13-3-4.1			

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Inspector:

Date

Date

Inspector Comments:

P.I.C.