COMPLIANCE INSPECTION REPORT

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure

Board of Registration in Pharmacy
250 Washington Street, Boston, MA 02108-4619
(617) 973-0800
(617) 973-0988 TTY

DATE(S) OF INSPECTION:		INSPECTION #:	ISP-
PHARMACY DBA NAME:			
STORE NUMBER:			
STREET ADDRESS:			
CITY / STATE / ZIP:			
TELEPHONE:	-		
FAX:			
EMAIL:			
PHARMACY LIC. NUMBERS:			
PHARMACY LIC. EXPIRATION:			
DEA REG. NUMBER:			
DEA REG. EXPIRATION:			
PURPOSE OF INSPECTION:	New		
MANAGER OF RECORD (MOR):			
MOR REG. NUMBER:			
PHARMACY HOURS:	DAILY _____ - _____		
	SATURDAY _____ - _____ SUNDAY _____ - _____		
PRACTICE SETTING:	Community Chain		
	DRIVE-THRU:		
DAILY PHARMACY VOLUME:			
SECURITY CAMERAS?:			
COMPUTER SOFTWARE NAME:			
CDTM PHARMACIST(S)?:			
SPECIAL LICENSE(S) ISSUED?:	TYPE:_____ EXPIRATION:_____		
	TYPE:_____ EXPIRATION:_____		
OUT OF STATE LICENSE(S)?			

PHARMACY STAFFING					
PHARMACY STAFF PRESENT AT TIME OF INSPECTION					
PHARMACISTS	**LICENSE #**		**CURRENT?**		**EXP. DATE**
1					
2					
3					
4					
5					
6					
PHARMACY INTERNS	**LICENSE#**		**CURRENT?**		**EXP. DATE**
1					
2					
3					
4					
PHARMACY TECHNICIANS	**LICENSE #**	**EXP. DATE**	**CURRENT?**	**CERTIFIED?**	**(PTT Only) HOURS/HIRE DATE**
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
OTHER PHARMACY STAFF	**POSITION**				
1					
2					
3					

Item #	Requirements	Yes/No/NA	Comment / Observation
A	**Security**		
1	There shall be a separate working alarm for the pharmacy or pharmacy department which shall be activated when the pharmacy or pharmacy department is closed. 247 CMR 6.02 (6) (d)		
2	The pharmacy department must be secured by a floor to ceiling barrier, securely locked and separately alarmed at all times when the pharmacy department is closed. 247 CMR 6.02 (6) (e)		
3	The pharmacist Manager of Record and the pharmacist on duty shall be responsible for pharmacy security and shall control access to the prescription area. 247 CMR 6.02 (6) (f)		
4	All controlled substances in Schedules II through VI shall be stored within the prescription area. 247 CMR 6.02 (6) (a & b)		
5	Controlled substances in Schedules II, III, IV, and V shall be stored in a securely locked and substantially constructed cabinet, or dispersed in the prescription drug storage area throughout the stock of Schedule VI controlled substances in such a manner as to obstruct the theft or diversion of these controlled substances. 247 CMR 6.02 (6) (c)		
6	The pharmacy shall have written policies and procedures regarding the operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods. 247 CMR 9.01 (1); Board Policy No. 2000-03		
7	A pharmacist shall maintain patient confidentiality at all times. Confidential information shall include information maintained by the pharmacist in the patient's records or information which is communicated to the patient as part of patient counseling. 247 CMR 9.01 (19)		
B	**Display**		
8	The following shall be conspicuously displayed within the pharmacy or pharmacy department: (a) the pharmacy permit; (b) the pharmacy's Massachusetts controlled substance registration; (c) the pharmacy's U.S. Drug Enforcement Administration controlled substance registration; and (d) whenever applicable, the pharmacy's certificate of fitness. 247 CMR 6.02 (3) (a) (b) (c) (d)		
9	A pharmacy or a pharmacy department shall conspicuously display, in legible letters not less than one inch high, over, on or adjacent to the main entrance of the pharmacy or pharmacy department, the name of the pharmacist Manager of Record who is responsible for the management and operation of the pharmacy or pharmacy department. 247 CMR 6.02 (7)		
10	A pharmacy or pharmacy department shall have a reasonably-sized sign affixed to the main entrance of the business or otherwise installed in an easily observable area outside the premises, identifying the presence of a pharmacy or pharmacy department. 247 CMR 6.02 (5)		
11	The hours of operation shall be prominently posted at all consumer entrances to the pharmacy and, in the case of a pharmacy department, the hours shall also be posted at all consumer entrances to the retail store and at the pharmacy department. 247 CMR 6.02 (8) (a)		

Item #	Requirements	Yes/No/NA	Comment / Observation
B	**Display (continued)**		
12	A sign of not less than 11 inches in height by 14 inches in width shall be posted in a conspicuous place, adjacent to the area where prescriptions are dispensed, informing customers of their rights, pursuant to 247 CMR 9.07 and to M.G.L. c. 94C, § 21A, to counseling by a pharmacist where their prescription was filled. Said sign shall read, in letters not less than ½" in height: "Dear patients, you have the right to know about the proper use of your medication and its effects. If you need more information, please ask the pharmacist." 247 CMR 9.07 (3) (c)		
13	A pharmacy must provide a designated consultation area with signage stating, "Patient Consultation Area". 247 CMR 6.01 (5) (d) (1)		
14	Pharmacy has a display sign on or near the pharmacy counter that: (i) is at least 4 inches by 5 inches; and (ii) includes the following statement in legibly printed font: "Lock boxes for securing your prescription medications are available at this pharmacy". 247 CMR 9.01 (1); Session Laws: Ch. 244 Section 6 (b) of the Acts of 2012		
C	**Licensure and Registration of Pharmacy Staff**		
15	A pharmacist shall carry, or have readily available at all times where the pharmacist is employed, a certificate of personal registration or an official statement from the Board which indicates that the pharmacist is currently registered by the Board to practice pharmacy. 247 CMR 6.05 (3)		
16	A pharmacy technician shall carry, or have readily available, at all times where the pharmacy technician is employed, evidence of current registration with the Board. 247 CMR 8.02 (1)		
17	Pharmacy technicians currently registered by the Board and certified by a Board-approved certifying body, may perform the duties as authorized to be performed by a certified pharmacy technician in 247 CMR 8.04 (2); Evidence of current National Certification required. 247 CMR 8.04 (1)		
D	**Manager of Record**		
18	The responsibilities of the pharmacist Manager of Record shall include the establishment, monitoring and enforcement of policies and procedures which maintain the standards of professional practice as such standards relate to the dispensing of pharmaceuticals, including the proper supervision of technicians, and the delegation of authority to another pharmacist when not on duty. 247 CMR 6.07 (1) (e)		
19	The responsibilities of the pharmacist Manager of Record shall include the maintenance of adequate staff in the pharmacy or pharmacy department in order to ensure that the practice of pharmacy shall be carried out in accordance with Board regulations at 247 CMR 2.00 et seq. and all other applicable federal and state laws and regulations. 247 CMR 6.07 (1) (f)		

Item #	Requirements	Yes/No/NA	Comment / Observation
D	**Manager of Record (continued)**		
20	Supervisory Ratios. (a) A pharmacist utilizing pharmacy interns, certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees to assist in filling prescriptions may utilize such support personnel in accordance with the following ratio requirements: 1. 1:4 One pharmacist for a maximum of four support personnel; provided: a. at least one of the four support personnel is a certified pharmacy technician and one is a pharmacy intern; or b. at least two of the support personnel are certified pharmacy technicians. 2. 1:3 One pharmacist for a maximum of three support personnel; provided at least one of the three support personnel is a pharmacy intern or a certified pharmacy technician. 247 CMR 8.06 (3)		
21	The responsibilities of the pharmacist Manager of Record shall include the establishment of procedures for validating questionable purported controlled substance prescriptions and for reviewing existing prescription information, to deter the willful and unlawful dispensing of controlled substances. 247 CMR 6.07 (1) (j)		
22	The responsibilities of the pharmacist Manager of Record shall include the proper maintenance of records as required by the Massachusetts Controlled Substances Act (c. 94C), Board regulations at 247 CMR et. seq., and all other applicable state and federal laws and regulations. 247 CMR 6.07 (1) (b)		
E	**Pharmacy Interns & Technicians**		
23	A pharmacy intern shall wear a name tag which indicates the intern's name and the words “pharmacy intern”. 247 CMR 8.01 (14)		
24	A pharmacy technician eligible to function as a certified pharmacy technician shall wear a name tag with the individual’s name and the title “Certified Pharmacy Technician”. 247 CMR 8.04 (4) (a)		
25	A pharmacy technician shall wear a name tag which indicates the individual’s name and the title “Pharmacy Technician”. 247 CMR 8.02 (6) (a)		
26	A pharmacy technician trainee shall wear a name tag with the individual’s name and the title “Pharmacy Technician Trainee”. 247 CMR 8.03 (4) (a)		
27	An individual may act and be designated as a pharmacy technician trainee for not more than 1500 hours or for more than 1 year, unless an extension is granted by the Board. Pharmacy technician trainees under the age of 18 are not subject to the 1500 hour or 1 year limitation. 247 CMR 8.03 (3)		
28	A written description of the duties delegated to certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees shall be made available to the Board upon request. 247 CMR 8.06 (1) (b)		
29	A written description of the scopes of responsibility for certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees shall be made available to the Board upon request. 247 CMR 8.06 (1) (c)		

Item #	Requirements	Yes/No/NA	Comment / Observation
E	**Pharmacy Interns & Technicians (continued)**		
30	Copies of pharmacy technician training program guidelines shall be provided to the Board on request. 247 CMR 8.06 (2)		
F	**Controlled Substances Records**		
31	A pharmacist shall keep a perpetual inventory of each controlled substance in Schedules II which the pharmacist has received, dispensed or disposed of in accordance with the law. This inventory must be reconciled at least once every ten days. 247 CMR 9.01(14)		
32	The responsibilities of the pharmacist Manager of Record shall include taking an inventory of controlled substances in Schedules II, III, IV and V, based upon federal biennial inventory requirements. 247 CMR 6.07 (1) (i)		
33	Biennial Inventory; each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location, the inventory may be taken either as of opening or as of the close of business on the inventory date and it shall be indicated on the inventory. 247 CMR 9.01 (1); 21 CFR 1304.11(a)		
34	A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records. 247 CMR 9.01 (1); 21 CFR 1305.05 (a)		
35	Each DEA Form 222 must be signed and dated by a person authorized to sign an application for registration or a person granted power of attorney to sign a Form 222 under §1305.05. The name of the purchaser, if different from the individual signing the DEA Form 222, must also be inserted in the signature space. 247 CMR 9.01 (1); 21 CFR 1305.12 (d)		
36	The purchaser must record on Copy 3 of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser. 247 CMR 9.01 (1); 21 CFR 1305.13 (e)		
37	CSOS: When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived. 247 CMR 9.01 (1)); 21 CFR 1305.22 (4) (g)		
38	The date on which the controlled substances are actually received shall be used as the date of receipt (e.g., invoices or packing slips). 247 CMR 9.01 (1); 21 CFR 1304.21 (d)		
39	Every registrant required to keep records pursuant to Sec.1304.03 shall maintain on a current basis a complete and accurate record of each such substance disposed of by him/her (e.g., disposal/destruction records). (247 CMR 9.01 (1)) 21 CFR 1304.21 (a)		
40	A registrant shall keep for at least two years from the date of preparation, every report, inventory and record he is required to keep by 105 CMR 700.000. 247 CMR 9.01 (1); 105 CMR 700.006 (b)		

Item #	Requirements	Yes/No/NA	Comment / Observation
F	**Controlled Substances Records (continued)**		
41	A pharmacist shall maintain prescription files as follows: (1) Prescriptions for controlled substances in Schedule II shall be segregated from all other records and shall be maintained in a separate file identified as such. (2) Prescriptions for controlled substances in Schedules III, IV, and V shall be maintained in a separate file identified as such. (3) Prescriptions for controlled substances in Schedule VI, prescriptions for non-controlled substances, and prescriptions for syringes and instruments adaptable to hypodermic administration, shall be segregated from all other records and shall be maintained together in a separate file identified as such. 247 CMR 9.05 (1-3)		
42	Authorization for Emergency Dispensing of Controlled Substances in Schedule II: Upon receipt of the written prescription (with "Authorization for Emergency Dispensing" written on its face), the dispensing pharmacist shall attach the prescription to the orally or electronically transmitted emergency prescription which had earlier been reduced to writing. 247 CMR 5.03(3) (4)		
43	Procedures for transferring a prescription between pharmacies or pharmacy departments for prescriptions issued for controlled substances in Schedules III, IV, and V are followed and performed by a pharmacist only. 247 CMR 9.02 (2)		
44	Procedures for transferring a prescription between pharmacies or pharmacy departments for prescriptions issued for controlled substances in Schedule VI are followed and performed by a pharmacist or certified pharmacy technician only. 247 CMR 9.02 (3)		
45	Subject to the provisions of federal regulations at 21 CFR 1306, an automated data-processing system may be used as an alternative to the provisions of 247 CMR 9.04 (4) and (5). This data-processing system may be used for the storage and retrieval of information pertaining to the refilling of prescriptions for controlled substances in Schedules III through VI (e.g., daily reports or logs signed by pharmacist). 247 CMR 9.04 (6)		
G	**Equipment, Facility and Drug Storage**		
46	The equipment necessary to conduct the practice of pharmacy. 247 CMR 6.01 (5) (a) (5)		
47	The premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner. 247 CMR 6.02 (1)		
48	A balance capable of accurately weighing quantities as small as 13 milligrams, which balance shall be tested and sealed by the state or local sealer of weights and measures annually. **NOTE:** All new equipment must meet the requirements in MGL c. 98 Section 29. 247 CMR 6.01 (5) (a) (4); 247 CMR 9.01 (1)		
49	Appropriate sanitary appliances, including a suitable sink which shall be equipped for hot and cold running water and which shall be situated in or near the area in which prescriptions are to be filled. 247 CMR 6.01 (5) (a) (7)		
50	While on duty, a pharmacist shall be responsible for the proper preservation and security of all drugs in the pharmacy or pharmacy department, including the proper refrigeration and storage of said drugs. 247 CMR 9.01 (5)		

Item #	Requirements	Yes/No/NA	Comment / Observation
G	**Equipment, Facility and Drug Storage (continued)**		
51	A pharmacist shall not dispense or distribute expired, outdated or otherwise substandard drugs or devices or counterfeit drugs or devices to any person or entity who is not licensed or legally authorized to receive such drugs or devices (Quarantine area available). 247 CMR 9.01 (10)		
52	There shall be within every pharmacy or pharmacy department a prescription area of not less than 300 square feet to accommodate the appropriate pharmaceutical equipment, apparatus, and supplies, and to facilitate the proper preparation and compounding of prescribed medications. This area shall provide for an arrangement and storage of drugs that is calculated to prevent their accidental misuse. 247 CMR 6.01 (5) (b)		
53	A pharmacy must provide a designated consultation area designed to provide adequate privacy for confidential visual and auditory patient counseling. The private consultation area must be accessible by a patient from the outside of the prescription dispensing area without having to traverse a stockroom or the prescription dispensing area. 247 CMR 6.01 (5) (d) (1)		
H	**Refrigeration**		
54	Pharmacy utilizes either: (a) combination refrigerator/freezer; or (b) a stand-alone refrigerator or freezer that has self-defrosting compartments. 247 CMR 9.01 (1) and (5); Board Policy No. 2020-05		
55	Refrigerators and freezers are maintained within proper range (Refrigeration at 36º to 46ºF/2º to 8ºC; Freezer at-13º to 14ºF/-25º to -10ºC USP recommended range) in accordance with manufacturer recommended medication storage requirements. 247 CMR 9.01 (1) and (5); Board Policy No. 2020-05		
56	Pharmacy refrigerators and freezers are kept clean, organized, and defrosted. 247 CMR 9.01 (1) and (5); Board Policy No. 2020-05		
57	Does the Pharmacy utilize a certified thermometer with; a) an out of range alarm[1] ☑ Yes ☐ No ☐ N/A b) a daily temperature log ☑ Yes ☐ No ☐ N/A 247 CMR 9.01 (1) and (5); Board Policy No. 2020-05		
58	Action policy and procedure developed to respond to any out of range temperature reading to ensure the integrity of stored medications. 247 CMR 9.01 (1) and (5); Board Policy No. 2020-05		
59	Refrigerated inventory is organized to allow for proper air flow. No cardboard or solid plastic shelving is utilized (impedes proper air circulation). 247 CMR 9.01 (1) and (5); Board Policy No. 2020-05		
60	Refrigerators and freezers provide adequate space for amount and type of medications stored by the pharmacy. No medications are overstocked. 247 CMR 9.01 (1) and (5); Board Policy No. 2020-05		

[1] If an out of range alarm is not utilized or available, a daily temperature log must be used.

Item #	Requirements	Yes/No/NA	Comment / Observation
H	**Refrigeration (continued)**		
61	Policy developed that no food or beverage products may be stored in the refrigerators or freezers and monitored. 247 CMR 9.01 (1) and (5); Board Policy No. 2020-05		
I	**Non-Sterile Compounding (Simple & Moderate Compounding Only)**		
62	Hazardous drugs shall be stored, prepared, and handled by appropriately trained personnel under conditions that protect the healthcare workers and other personnel. **NOTE: Compounding of hazardous drugs is not considered simple compounding. A "yes" requires a full USP <795> Inspection.** 247 CMR 9.01 (3); USP Chapter <795>		
63	All significant procedures performed in the compounding area are covered by written standard operating procedures (SOPs). 247 CMR 6.07(1)(d) & (e); 247 CMR 9.01 (3); USP Chapter <795>		
64	Adequate hand and equipment washing facilities shall be easily accessible to the compounding areas. Such facilities shall include, but are not limited to, hot and cold water, soap or detergent, and lint free single-use towels **(Best Practice).** 247 CMR 9.01 (3); USP Chapter <795>		
65	Compounding facilities shall have an adequate space that is specifically designated for compounding of prescriptions and is suitable for its intended purpose. This space shall provide for the orderly placement of equipment and materials to prevent mix-ups among ingredients, containers, labels, in process materials, and finished preparations and is designed, arranged, and used to prevent adventitious cross-contamination. 247 CMR 9.01 (3); USP Chapter <795>		
66	The areas used for compounding shall be maintained in clean, orderly, and sanitary conditions and shall be maintained in a good state of repair. 247 CMR 9.01 (3); USP Chapter <795>		
67	All equipment used in compounding is clean, properly maintained, and used appropriately. 247 CMR 9.01 (3); USP Chapter <795>		
68	Compounding ingredients are purchased from reliable sources and are properly stored according to manufacturer specifications or USP standards. 247 CMR 9.01 (3); USP Chapter <795>		
69	Purified Water (see Purified Water monograph) shall be used for compounding non-sterile drug preparations when formulations indicate the inclusion of water. 247 CMR 9.01 (3); USP Chapter <795>		
70	In the absence of stability information that is applicable to a specific drug and preparation, the following BUDs are not exceeded[2]; a) Non-aqueous Formulations—The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier. b) Water-Containing Oral Formulations—The BUD is not later than 14 days when stored at controlled cold temperatures. c) Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations—The BUD is not later than 30 days. 247 CMR 9.01 (3); USP Chapter <795>		

[2] Non-sterile compounded drug preparations that are packaged in tight, light-resistant containers and stored at controlled room temperature. Per USP <795>: When a manufactured product is used as the source of the API for a nonsterile compounded preparation, the product expiration date cannot be used solely to assign a BUD for the compounded preparation.

Item #	Requirements	Yes/No/NA	Comment / Observation
I	**Non-Sterile Compounding (Simple & Moderate Compounding Only) (continued)**		
71	For components that do not have expiration dates assigned by the manufacturer or supplier, the compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed one year after receipt to the component. (While not mandated by USP Chapter <795>, the Board of Registration in Pharmacy expects this "Best Practice" to be followed.) 247 CMR 9.01 (3); USP Chapter <795>		
72	A Master Formulation Record shall be followed each time that preparation is made. 247 CMR 9.01 (3); USP Chapter <795>		
73	A Compounding Record is completed each time a preparation is compounded. (The Board's interpretation of the language in USP <795> mandates this standard be followed.) 247 CMR 9.01 (3); USP Chapter <795>		
74	Safety Data Sheets (SDSs) shall be readily accessible to all employees working with drug substances or bulk chemicals located on the compounding facility premises. 247 CMR 9.01 (3); USP Chapter <795>		
75	The labeling indicates that "this is a compounded preparation". (The Board's interpretation of the language in USP <795> mandates this standard be followed.) 247 CMR 9.01 (3); USP Chapter <795>		
J	**Standards for Prescription Labeling, Format & Containers**		
76	Every prescription written in the Commonwealth must be in a prescription format that conforms to the requirements as set forth in 105 CMR 721.020. 247 CMR 9.01 (1); 105 CMR 721.020		
77	The pharmacist filling a written or oral prescription for a controlled substance shall package the controlled substance in a container, affixing to the container a label displaying all required elements as set forth in 105 CMR 722.070. 247 CMR 9.01 (1); 105 CMR 722.070; MGL c. 94C § 21		
78	When a less expensive generic drug product has been dispensed, the words "interchange" plus the generic name and manufacturer of the product shall appear on the label. When a less expensive brand name drug product has been dispensed, the words "interchange" plus either the generic name and manufacturer of the product or the less expensive brand name dispensed shall appear on the label. 247 CMR 9.01 (1); 105 CMR 722.070 (A) (B)		
79	Any drug for human use that is in a dosage form intended for oral administration and that is required by Federal law to be dispensed only on or upon an oral or written prescription of a practitioner licensed by law to administer such a drug shall be packaged in accordance with the provisions of S 1700.15 (a), (b), and (c); unless exempted under the Poison Prevention Packaging Act (PPPA) or; current documented patient request for non-safety closures (Best Practice). 247 CMR 9.01 (1); 16 CFR Ch.II S 1700.14 (10)		
K	**Patient Records, Counseling, and Prospective Drug Utilization**		
80	A pharmacist shall conduct a prospective drug utilization review ("DUR") before each new prescription is dispensed or delivered to a patient or a person acting on behalf of the patient. This DUR may include a review of the patient record and each new prescription presented for dispensing, for the purpose of promoting therapeutic appropriateness. 247 CMR 9.07 (1) (a) and (2) (a)		
81	The pharmacist or pharmacist's designee shall offer the services of the pharmacist to discuss, with all persons presenting new prescriptions, issues that in the pharmacist's professional judgment are deemed to be significant for the health and safety of the patient. 247 CMR 9.07 (3) (a)		

Item #	Requirements	Yes/No/NA	Comment / Observation
K	**Patient Records, Counseling, and Prospective Drug Utilization**		
82	Counseling must be made by a pharmacist, or a pharmacy intern under the direct supervision of the pharmacist if deemed appropriate by the pharmacist. 247 CMR 9.07 (3) (f)		
L	**Continuous Quality Improvement (CQI)**		
83	Each pharmacy shall maintain a written copy of its CQI Program description on the pharmacy premises. 247 CMR 15.04 (1)		
84	The CQI Program description shall be readily available to all pharmacy personnel. 247 CMR 15.04 (1)		
85	The CQI program shall include provisions to designate an individual or individuals responsible for monitoring CQI Program compliance with the requirements of 247 CMR 15.00. 247 CMR 15.02 (1) (a)		
86	The CQI program shall include provisions to identify and document QREs (Quality Related Events). 247 CMR 15.02 (1) (b)		
87	The CQI program shall include provisions to analyze data collected in response to QREs to assess causes and any contributing factors. 247 CMR 15.02 (1) (d)		
88	The CQI program shall include provisions to use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs. 247 CMR 15.02 (1) (e)		
89	The CQI program shall include provisions to provide ongoing education at least annually in the area of CQI to pharmacy personnel. 247 CMR 15.02 (1) (f)		
90	Each pharmacy shall maintain a record of all QREs for a minimum period of two years from the date of the QRE report. 247 CMR 15.04 (2)		
M	**Immunizations**		
91	A registered pharmacist, pharmacy intern, and pharmacy technician may dispense by administration influenza vaccine, Covid-19 vaccine, and other immunizations designated by the Department to persons 5 years of age or older. 247 CMR 9.01 (1); 105 CMR 700.004 (B) (6)		
92	Such administration is conducted pursuant to a standing order of a practitioner? 247 CMR 9.01 (1)) (105 CMR 700.004 (6) (b)) Standing Order Practitioner: _____; Signed/Expiration Date: _____		
93	Does the pharmacy have a standing order to administer single dose emergency epinephrine? 247 CMR 9.01 (1); Board Policy No. 2023-02 Standing Order Physician: _____; Signed/Expiration Date: _____		
94	Does the pharmacist conduct this activity in accordance with guidelines adopted by the Department which includes requirements for training through an accredited program by the Centers for Disease Control and Prevention, the American Council on Pharmaceutical Education or a similar health authority or professional body. 247 CMR 9.01 (1); 105 CMR 700.004 (B) (6) (d)		
95	Does the pharmacist have evidence of current CPR certification? 247 CMR 9.01 (1); Board Policy No. 2023-02		

Item #	Requirements	Yes/No/NA	Comment / Observation
M	**Immunizations**		
96	Such activity is conducted in accordance with guidelines adopted by the Department which shall include requirements for vaccine storage and handling. **NOTE**: Temperatures must be recorded on a temperature log at least twice daily (AM and PM) for all vaccine storage units. 247 CMR 9.01 (1); 105 CMR 700.004 (B) (6) (d) (3)		
N	**References**		
97	A current copy or electronic version of the Massachusetts List of Interchangeable Drugs (MLID), including the Orange Book, Additional List, Exception List. 247 CMR 6.01 (5) (a) (1)		
98	A current copy or electronic version (with quarterly updates) of a compendia appropriate to the practice setting approved by the pharmacist manager of record. 247 CMR 6.01 (5) (a) (2)		
99	A current copy or electronic version of the Board Regulations. 247 CMR 6.01 (5) (a) (3)		
O	**Naloxone**		
100	Does the pharmacy meet all the requirements[3] for dispensing Naloxone as set forth in Board Policy No. 2024-01?		
101	Does the pharmacy maintain sufficient supply of Naloxone? Board Policy No. 2024-01		
P	**Research Studies**		
102	Is the pharmacy involved in research studies?		

Waivers Granted to Licensee:
Investigator Notes:

[3] The Naloxone requirements can be found in Board Policy 2024-01. Last accessed 1/30/2024 at https://www.mass.gov/doc/2024-01-naloxone-dispensing-pdf/download

Investigator Notes (continued):

Inspection Completion
Plan of Correction (POC) Issued: ☐ Yes ☑ No If yes, the pharmacist Manager of Record will provide a plan of correction for all findings within 15 business days. POC Due: _____

Investigator(s)	
Investigator:	
Date:	
Investigator:	
Date:	

The deficiencies cited in this Compliance Inspection Report are not intended to be an all-inclusive list of deficiencies that exist at this Registrant facility. The pharmacy and the pharmacist Manager of Record are responsible for investigating and determining the causes of the deficiencies identified and for preventing their recurrence and the occurrence of other deficiencies. All licensees are responsible for complying with state and federal laws and regulations governing the practice of pharmacy.

Print

Plan of Correction instructions: https://www.mass.gov/doc/plan-of-correction-directions-for-licensees-0/download

Plan of Correction template: https://www.mass.gov/doc/plan-of-correction-template-0/download