RETAIL COMPLIANCE[1] 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) 973-0960
(617) 973-0960 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:	Compliance		
MANAGER OF RECORD (MOR):			
MOR REG. NUMBER:			
PHARMACY HOURS:	MON	TUE	WED
	SAT	SUN	
PRACTICE:	☐ COMMUNITY CHAIN	☐ LONG TERM CARE	☐ RESEARCH DRUGS
	☐ COMMUNITY INDEPENDENT	☐ SPECIALTY	☐ DRIVE-THRU
DAILY PHARMACY VOLUME:			
SECURITY CAMERAS?:			
COMPUTER SOFTWARE NAME:			
CDTM PHARMACIST(S)?:	Agreement availability required under 247 CMR 9.19 (8) (c)		
SPECIAL LICENSE(S) ISSUED?:			
OUT OF STATE LICENSE(S)?			

[1] MA Board of Registration in Pharmacy: Pharmacy Practice Resources - https://www.mass.gov/lists/pharmacy-practice-resources (last accessed 12.5.24)

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/N/A	Comment / Observation
A	**Security**		
1	A pharmacy shall store all controlled substances within the secured prescription area and in a safe and secure manner. *247 CMR 9.21 (1)*		
2	A pharmacy shall store Schedules II through V controlled substances in a securely locked and substantially constructed cabinet, or similarly secured storage area, or dispersed throughout the stock of Schedule VI controlled substances and in such a manner as to obstruct theft and diversion. *247 CMR 9.21 (2)*		
3	A pharmacy shall maintain a centrally monitored security system that is able to detect a breach in security and is designed to prevent theft. A pharmacy shall activate the security system when the pharmacy is closed. *247 CMR 9.21 (3)*		
4	A pharmacy shall maintain surveillance cameras in a manner designed to record theft and diversion of controlled substances. A pharmacy shall retain video records for at least 14 days or, in the case of known or suspected theft or diversion, at least two years. *247 CMR 9.21 (4)*		
5	A pharmacy shall be secured by a floor to ceiling barrier, securely locked and separately alarmed at all times when the pharmacy is closed. *247 CMR 9.21 (5)*		
6	The pharmacist Manager of Record and the pharmacist on duty are responsible for pharmacy security and shall control access to the prescription area. They are also responsible for the proper preservation, storage, and security of all controlled substances in the pharmacy. They shall be on the pharmacy premises at all times the pharmacy is open for business and shall be present at all times non-pharmacist personnel have unrestricted access to the pharmacy. They shall limit access to all pharmacy areas to authorized personnel only. *247 CMR 9.21 (6); 247 CMR 9.01 (8); 247 CMR 9.19 (16) (a); 247 CMR 9.19 (16) (b) (ii); 247 CMR 9.19 (16) (b) (iv)*		
7	All drug order deliveries containing controlled substances shall be delivered directly to the pharmacy. *247 CMR 9.21 (7)*		
B	**Display**		
8	A pharmacy in Massachusetts shall conspicuously display within the pharmacy the pharmacy's Massachusetts Drug Store pharmacy license, any other pharmacy license(s) issued by the Board, as applicable; the pharmacy's Massachusetts controlled substance registration; and the pharmacy's U.S. Drug Enforcement Administration registration. *247 CMR 9.19 (8) (a) thru (d)*		
9	The hours of operation shall be prominently posted at all consumer entrances to the pharmacy and, in the case of a pharmacy located within a retail establishment, the hours shall also be posted at all consumer entrances to the retail store and at the pharmacy. If the hours of operation of a pharmacy located within another retail establishment are different from those of the retail establishment, all advertising referring to the pharmacy shall clearly specify the pharmacy's hours of operation. *247 CMR 9.19 (14) (a) and (b)*		
10	A pharmacy shall have a sign affixed to each customer entrance that is easily observable from the outside and clearly identifies the presence of a pharmacy. *247 CMR 9.19 (10)*		

Item #	Requirements	Yes/No/N/A	Comment / Observation
B	**Display**		
11	A pharmacy shall conspicuously display, in legible letters **not less than one inch high**, over, on, or adjacent to the main entrance of the pharmacy, the name of the Manager of Record. *247 CMR 9.19 (11)*		
12	A pharmacy shall have a designated patient consultation area, with signage stating, "Patient Consultation Area," designed to provide adequate privacy for confidential visual and auditory patient counseling. The private consultation area shall 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 9.18 (6)*		
13	A pharmacy shall post sign **of not less than 11 inches in height by 14 inches in width** in a conspicuous place, adjacent to each area where prescriptions are dispensed, for the purpose of informing customers of their right to counseling by a pharmacist. Said sign shall read, in letters **not less than ½ inch** 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 9.18 (7)*		
14	A Massachusetts-located pharmacy may not engage in any **sterile compounding** unless it holds a drug store pharmacy license and a sterile compounding pharmacy license. *247 CMR 6.02 (2) (a)*		
15	A Massachusetts-located pharmacy may not engage in any **complex non-sterile compounding** unless it holds a drug store pharmacy license and a complex non-sterile compounding pharmacy license. *247 CMR 6.02 (3)*		
C	**Pharmacist Manager of Record**		
16	A pharmacy shall designate a Manager of Record who is licensed as a pharmacist in Massachusetts. *247 CMR 9.23 (1)*		
17	A Manager of Record is responsible for the operation of the pharmacy and ensuring compliance with all state and federal laws and regulations governing the practice of pharmacy, the **proper maintenance of records** as required by all state and federal laws and regulations, planning and maintaining **adequate staffing** that promotes patient safety, and enforcement of policies and procedures which maintain the standards of professional practice. *247 CMR 9.23 (2) (a) thru (d)*		
18	A Manager of Record of a retail drug store pharmacy may not be the Manager of Record of more than one pharmacy at a time. *247 CMR 9.23 (3)*		
19	A Manager of Record shall work an average of **at least 30 hours per week** at the pharmacy they manage. *247 CMR 9.23 (4)*		
20	A pharmacy located in Massachusetts shall notify the Board **within 14 calendar days** of the resignation, or termination, or change of its Manager of Record. An application for change of Manager of Record shall satisfy this requirement. *247 CMR 6.10 (1); 247 CMR 20.05 (1); 247 CMR 20.05 (3)*		

Item #	Requirements	Yes/No/N/A	Comment / Observation
C	**Pharmacist Manager of Record**		
21	**Extended Absence of a Manager of Record** The pharmacy shall appoint a Board-licensed pharmacist Interim Manager prior to any planned absence of the Manager of Record that is expected to last **30 days or longer**. The Interim Manager is expected to fulfill the duties of the MOR in their absence. The pharmacy shall appoint a Board-licensed pharmacist Interim Manager **within five days** of any unplanned absence of the Manager of Record that is likely to last **30 days or longer**. Prior to their absence, a Manager of Record shall perform a controlled substances inventory that is signed by the Manager of Record and the Interim Manager. If the Manager of Record is unexpectedly not available, another licensed pharmacist shall perform the controlled substances inventory. In the event a Manager of Record is away from their position for **100 days or more**, the pharmacy shall submit an application for a change of Manager of Record. *247 CMR 9.23 (5) (a) thru (d); Board Policy No. 2022-02*		
22	**Supervisory Ratios** A pharmacist utilizing pharmacy interns, certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees to assist in filling prescriptions shall comply with the following supervisory ratios: One pharmacist for a maximum of four support personnel, provided: • one is a pharmacy intern and at least one is a certified pharmacy technician; or • at least two are certified pharmacy technicians; or • two are pharmacy interns One pharmacist for a maximum of three support personnel, provided that one is a pharmacy intern or at least one is a certified pharmacy technician. Cashiers, messengers, delivery personnel, secretaries, and any other persons who do not fall within the definitions of a pharmacy intern, certified pharmacy technician, pharmacy technician, or pharmacy technician trainee shall not be included for purposes of determining the ratios as long as such persons are not supporting the pharmacist in any professional capacity. *247 CMR 8.06 (3); Board Policy No. 2024-03*		
23	Licensed Pharmacists on duty shall ensure compliance with supervisory ratios in accordance with 247 CMR 8.06, report problems with sanitary conditions or repair to Manager of Record, be familiar with applicable Board approved audit tool(s), and have access to all pharmacy records and be able to provide requested records to Board investigators. *247 CMR 9.19 (16) (b) (i), (iii), (v), and (vi)*		
24	A pharmacy shall maintain written policies and procedures regarding the operation of the pharmacy during the temporary absence of a pharmacist. *247 CMR 9.19 (17) (e)*		
25	A pharmacy shall perform a self-inspection **within seven days** of any renovation, expansion, relocation, or change of Manager of Record, and at least **one time per year**, utilizing a Board-approved inspection tool for routine compliance, sterile compounding, and non-sterile compounding, as applicable. The pharmacy shall retain the completed self-inspection tool for at least two years. *247 CMR 9.19 (21)*		
26	A pharmacy shall maintain a written continuity of care plan that describes the manner in which patient needs will be met in the event the pharmacy is unexpectedly unable to provide pharmacy services. The pharmacy shall notify the Board if pharmacy operations are unexpectedly suspended for more than 24 hours. *247 CMR 9.19 (15)*		

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C	**Pharmacist Manager of Record**		
27	A licensee may not practice in a pharmacy for more than 12 hours in a 24-hour period without completing an eight consecutive hour rest period prior to resuming work in a pharmacy. In the event of an extenuating circumstance, a licensee may exceed 12 hours in order to act in the best interest of the patient, provided the time in excess of 12 hours is minimized and the licensee documents the extenuating circumstance. *247 CMR 9.01 (17)*		
28	A Manager of Record of a pharmacy shall report to the Board any improper dispensing of a prescription drug that results in serious injury or death **within seven business days** of discovery of serious injury or death related to the improper dispensing. *247 CMR 20.02 (1)*		
29	A Manager of Record of a pharmacy, shall report any serious adverse drug event that occurs as a result of a patient's interaction with any drug or pharmaceutical manufactured, produced, or compounded at the pharmacy, to: the Board, the Federal Food and Drug Administration MedWatch Program, and the Betsy Lehman Center for Patient Safety and Medical Error Reduction. A Manager of Record shall report a serious adverse drug event within **seven business days** of the knowledge of the serious adverse drug event by any pharmacy employee. *247 CMR 20.02 (2) (a) thru (c)*		
30	The duty to report to the Board improper dispensing of a prescription drug that results in serious injury or death or a serious adverse drug event shall be in addition to the Continuous Quality Improvement (CQI) Program requirements of 247 CMR 15.00. *247 CMR 20.02 (3)*		
31	A pharmacy shall retain all records relating to the improper dispensing of a prescription drug that results in serious injury or death and all records relating to serious adverse drug events for a minimum period of five years from the date the report is filed with the Board. The records shall be readily retrievable. *247 CMR 20.02 (4)*		
D	**Licensure, Registration, Certification, Training of Pharmacy Staff**		
32	A licensee shall practice pharmacy within the scope of their education, training, and experience and within the recognized licensee scope of practice. *247 CMR 9.01 (4); Board Policy 2020-15 Scope of Practice*		
33	No individual may serve as a pharmacy intern, certified pharmacy technician, pharmacy technician or pharmacy technician trainee without holding a valid license (PI, PT or PTT) from the Board. *247 CMR 8.01 (6); 247 CMR 8.02 (1); 247 CMR 8.03 (1); 247 CMR 8.04 (1)*		
34	A pharmacy intern shall wear a name tag which indicates the intern's name and the words "Pharmacy Intern" and adhere to the regulations and board policies associated with pharmacy interns. *247 CMR 8.01 (14); 247 CMR 8.01*		
35	A certified pharmacy technician shall wear a name tag with the individual's first name and the title "Certified Pharmacy Technician" and adhere to the regulations and board policies associated with certified Pharmacy technicians. *247 CMR 8.04 (4) (a); 247 CMR 8.04;*		
36	A pharmacy technician shall wear a name tag which indicates the individual's first name and the title "Pharmacy Technician" and adhere to the regulations and board policies associated with pharmacy technicians. *247 CMR 8.02 (6) (a); 247 CMR 8.02;*		

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D	**Licensure, Registration, Certification, Training of Pharmacy Staff**		
37	A pharmacy technician trainee shall wear a name tag with the individual's first name and the title "Pharmacy Technician Trainee" and adhere to the regulations and board policies associated with pharmacy technician trainees. *247 CMR 8.03 (4) (a); 247 CMR 8.03*		
38	Limitation on Period of Employment as a Pharmacy Technician Trainee. An individual may not work as a pharmacy technician trainee for more than 1500 hours or for more than one year, whichever period is shorter, unless the Board grants an extension; the individual has not yet reached 18 years of age; or the individual has not yet completed at least 500 hours of employment as a pharmacy technician trainee. An individual who has worked as a pharmacy technician trainee for more than 1500 hours or for more than one year prior to his or her 18th birthday shall submit an application for a pharmacy technician license within 30 days of his or her 18th birthday. *247 CMR 8.03 (5) (a) thru (c)*		
39	A pharmacist may train a pharmacy technician or pharmacy technician trainee through an on-the-job training program, in accordance with 247 CMR 8.00. All such training programs shall comply with written guidelines formulated by the pharmacy in a manner consistent with professional, ethical, and legal standards of proper pharmacy practice. Copies of training program guidelines shall be provided to the Board on request. *247 CMR 8.06 (2)*		
E	**Controlled Substance Management**		
40	A pharmacy shall post on the wall or maintain in a readily retrievable location current power of attorney (POA) forms required for DEA 222 forms, as applicable. 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 9.19 (8) (b); 247 CMR 9.01 (1); 21 CFR 1305.05 (a)*		
41	A pharmacy and pharmacist shall maintain a perpetual inventory of each controlled substance in Schedule II which the pharmacy has received, dispensed, or disposed of. The perpetual inventory may be in a hard copy, written format or in an electronic format. The perpetual inventory shall reflect the amount of each Schedule II controlled substance that is located on the pharmacy premises. *247 CMR 9.21 (8) (a)*		
42	The perpetual inventory record shall include the names and strengths of each Schedule II control substance, quantity of each drug purchased or added to inventory, starting inventory, prescription numbers, dispensed quantity, remaining balance, and pharmacist identification for each transaction. *247 CMR 9.21 (8) (b)*		
43	A pharmacy shall reconcile the perpetual inventory for each Schedule II controlled substance **at least once every ten days** by performing an accurate physical count of inventory on hand and comparing that number with the perpetual inventory. The Manager of Record shall investigate any discrepancy and report any significant loss or suspected theft in accordance with federal and state requirements. *247 CMR 9.21 (8) (c)*		

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E	**Controlled Substance Management**		
44	A pharmacy shall require any inventory adjustment resulting from a discrepancy be performed only by the pharmacist Manager of Record. In the absence of the Manager of Record, a pharmacist designee may make the changes and report to the Manager of Record. *247 CMR 9.21 (8) (d)*		
45	An unlicensed individual may not make any entry into or adjust the perpetual inventory. *247 CMR 9.21 (8) (e)*		
46	**General/Initial/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. An inventory shall be conducted upon initial receipt of controlled substances and at least every 2 years. *247 CMR 9.01 (1); 21 CFR 1304.11(a) thru (c)*		
47	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)*		
48	The purchaser must record on its copy 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)*		
49	**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 (g)*		
50	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)*		
51	A pharmacy shall maintain an accurate record of all controlled substances returned to a reverse distributor or disposed of in accordance with state and federal laws and regulations, including proper DEA forms in the case of Schedule II controlled substances. *247 CMR 9.21 (9)*		
52	Each requirement of 247 CMR 9.21 shall apply to controlled substances that are expired, quarantined, or pending reverse distribution. *247 CMR 9.21 (10)*		
53	Accountability for and security of Schedule II controlled substances shall be the direct responsibility of the pharmacist if/when pharmacy technicians are involved in handling. *247 CMR 8.05 (1)*		

Item #	Requirements	Yes/No/N/A	Comment / Observation
E	**Controlled Substance Management**		
54	Under the supervision of a pharmacist a pharmacy technician may assist in the transporting of Schedule II controlled substances, and certified pharmacy technician's may assist in the transporting and handling of Schedule II controlled substances, provided, the pharmacist has approved the certified pharmacy technician or pharmacy technician to assist the pharmacist in the handling or transporting of Schedule II controlled substances, in accordance with 247 CMR 8.05(2) and as evidenced by written policies and procedures to be followed in the pharmacy. Such policies and procedures shall be made available to the Board on request. *247 CMR 8.05 (2) (a) and (b)*		
55	A certified pharmacy technician, pharmacy technician, or pharmacy technician trainee may not handle any hydrocodone-only extended-release medication that is not in an abuse deterrent form. Pharmacy interns under the direct supervision of a registered pharmacist may handle hydrocodone-only extended-release medication that is not in an abuse deterrent formulation. *247 CMR 8.05 (3)*		
56	A licensee shall adhere to 105 CMR 721.000 when dispensing a controlled substance in Schedule II in an emergency situation. *247 CMR 9.04 (6)*		
57	A pharmacist who dispenses prescriptions that are reported to the Massachusetts Prescription Monitoring Program (known as PMP or MassPAT) shall register with and maintain login information for the electronic system to monitor the prescribing and dispensing of controlled substances as authorized by M.G.L. c. 94C, § 24A. *247 CMR 9.15 (1)*		
58	A Drug Store pharmacy, sterile compounding pharmacy, complex non-sterile compounding pharmacy, and nuclear pharmacy located in Massachusetts shall report a theft or loss of a significant amount of controlled substances by submitting to the Board a copy of "Report of Theft or Loss of Controlled Substance" and (DEA Form 106), **within seven days** of such theft or significant loss and, where applicable, shall comply with the reporting requirements of the DEA, the Department and the state and local police. *247 CMR 20.03 (7)*		
59	Every pharmacy licensed by the Board that dispenses controlled substances in Schedules II thorough V pursuant to a prescription shall, in accordance with standards established by the Department, transmit to the Department or its agent, required information for each prescription, in accordance with Prescription Monitoring Program reporting requirements (105 CMR 700.012). *247 CMR 20.04 (1)*		
60	Since all areas of Massachusetts experience high incidences of opioid-related overdoses or deaths, Massachusetts pharmacies are required to stock naloxone in accordance with M.G.L. c. 94C, § 19C. Pharmacies must maintain a continuous, sufficient supply of naloxone to meet the needs of the community. *247 CMR 9.06 (2) (a) and (b), Policy 2024-01: Naloxone Dispensing*		
61	A pharmacy that dispenses a naloxone rescue kit or other approved opioid antagonist shall provide counseling and the "opioid antagonist information pamphlet" at the time of dispensing. *247 CMR 9.06 (3)*		

Item #	Requirements	Yes/No/N/A	Comment / Observation
E	**Controlled Substance Management**		
62	A pharmacy that does not have a naloxone rescue kit or other approved opioid antagonist readily available for dispensing at the time requested shall refer the requestor to the nearest location that has a naloxone rescue kit or other approved opioid antagonist readily available. *247 CMR 9.06 (4)*		
F	**Equipment, Facility, and Drug Storage**		
63	Drug Store pharmacies shall have a prescription area that is at least **325 square feet**. *247 CMR 9.19 (2)*		
64	The prescription area shall provide for the arrangement and storage of drugs, supplies, and equipment in a manner that is calculated to prevent accidental misuse, cross contamination, and error. *247 CMR 9.19 (4)*		
65	A pharmacy shall store medications in the manufacturer's stock bottles or in other stock containers that are clearly labeled with the product name, strength or concentration, NDC number, manufacturer or supplier, lot number, assigned expiration date, and date that the medication was transferred out of its original stock bottle. *247 CMR 9.19 (5)*		
66	A pharmacy shall be clean and sanitary and in good repair at all times. *247 CMR 9.19 (6)*		
67	Pharmacy equipment shall be clean and sanitary and in good repair at all times. *247 CMR 9.19 (7)*		
68	A pharmacy shall store and dispose of waste in a sanitary and timely manner. *247 CMR 9.19 (19)*		
69	A balance capable of accurately weighing quantities as small as 10 milligrams, which shall be tested and sealed by the state or local sealer of weights and measures **at least once each calendar year**. All new balances shall have "legal for trade" designation. *247 CMR 9.19 (1) (e)*		
70	The pharmacy shall maintain equipment, supplies, and medications necessary to conduct the practice of pharmacy in accordance with the usual needs of the community and scope of practice of the pharmacy. *247 CMR 9.19 (1) (f)*		
71	A potable water supply in or near the prescription area is available in order to wash hands and equipment. The sink shall have hot and cold water, soap or detergent, and single use towels. *247 CMR 9.19 (1) (i)*		
72	Policies and procedures are available to ensure supplies, tools, utensils, and equipment are used and maintained in a manner that avoids cross contamination and ensures proper functioning. *247 CMR 9.19 (1) (h)*		
G	**Proper Storage of Refrigerated and Frozen Medications**		
73	A pharmacy shall maintain policies and procedures to ensure proper refrigeration equipment is available, of adequate size, and utilized to maintain proper refrigeration and freezer temperatures. The policies and procedures shall include a protocol to respond to any out-of-range temperature, including an assessment of the integrity of the medication. *247 CMR 9.22 (1); Board Policy 2020-05: Proper Storage of Refrigerated and Frozen Medications*		

Item #	Requirements	Yes/No/N/A	Comment / Observation
G	**Proper Storage of Refrigerated and Frozen Medications**		
74	A pharmacy shall utilize a combination refrigerator / freezer or a standalone refrigerator or standalone freezer. Freezer units shall be frost-free with an automatic defrost cycle, unless otherwise approved by the Board. A pharmacy may not utilize an appliance that contains a freezer compartment within the refrigerator space, such as a dorm-style refrigerator. *247 CMR 9.22 (2); Board Policy 2020-05: Proper Storage of Refrigerated and Frozen Medications*		
75	A pharmacy shall measure and maintain refrigerator and freezer temperatures in accordance with Board guidance. *247 CMR 9.22 (3); Board Policy 2020-05: Proper Storage of Refrigerated and Frozen Medications*		
76	A pharmacy shall maintain temperature logs to clearly identify out of range temperatures and shall document actions taken in response to an out-of-range temperature. A pharmacy shall maintain records for at least one year. *247 CMR 9.22 (4); Board Policy 2020-05: Proper Storage of Refrigerated and Frozen Medications*		
77	A pharmacy may not store any food or beverage in a refrigerator or freezer used to store medications. *247 CMR 9.22 (5); Board Policy 2020-05: Proper Storage of Refrigerated and Frozen Medications*		
H	**Non-Sterile Compounding**		
78	Unless otherwise regulated by the Board, a licensee shall adhere to the most current standards established by each chapter of the United States Pharmacopeia (USP). *247 CMR 9.01 (3); Board Policy 2023-07: Non-Sterile Compounding*		
79	The pharmacy has a designated compounding area for simple and moderate non-sterile compounding. *247 CMR 9.19 (1) (j); Board Policy 2023-07: Non-Sterile Compounding*		
80	The pharmacy has the equipment necessary to perform simple and moderate non-sterile compounding. *247 CMR 9.19 (1) (g); Board Policy 2023-07: Non-Sterile Compounding*		
81	With the exception of complex non-sterile compounded preparations, a licensee may not refuse to compound non-sterile compounded preparations customary to the community needs except upon extenuating circumstances or by a waiver of Board regulation. *247 CMR 9.01 (15); Board Policy 2023-07: Non-Sterile Compounding*		
82	A licensee may not place more than one commercially available medication into an oral-liquid-single-dose package unless compounded pursuant to a prescription. *247 CMR 9.08 (1) (h)*		
83	**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 Inspection.** *247 CMR 9.01 (3); USP Chapter <795>; Board Policy 2023-07: Non-Sterile Compounding; USP Chapter <800>*		
84	All significant procedures performed in the compounding area are covered by written standard operating procedures (SOPs). *247 CMR 9.01 (3); USP Chapter <795>; Board Policy 2023-07: Non-Sterile Compounding*		
85	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>; Board Policy 2023-07: Non-Sterile Compounding*		

Item #	Requirements	Yes/No/N/A	Comment / Observation
H	**Non-Sterile Compounding**		
86	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>; Board Policy 2023-07: Non-Sterile Compounding*		
87	All equipment used in compounding is clean, properly maintained, and used appropriately. *247 CMR 9.01 (3); USP Chapter <795>; Board Policy 2023-07: Non-Sterile Compounding*		
88	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>*		
89	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>*		
90	In the absence of stability information that is applicable to a specific drug and preparation, the following BUDs are not exceeded. a) Non-preserved aqueous formulations – The BUD is not later than 14 days when stored under refrigeration. b) Preserved aqueous formulations – The BUD is not later than 35 days when stored at either controlled room temperature or under refrigeration. c) Oral liquids (non-aqueous) – The BUD is not later than 90 days when stored at controlled room temperature or under refrigeration. d) Other non-aqueous formulations – The BUD is not later than 180 days when stored at controlled room temperature or under refrigeration. *247 CMR 9.01 (3); USP Chapter <795>; Board Policy 2023-07: Non-Sterile Compounding*		
91	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, the Board of Registration in Pharmacy expects this “Best Practice” to be followed.) *247 CMR 9.01 (3); USP Chapter <795>*		
92	A Master Formulation Record shall be followed each time that preparation is made. *247 CMR 9.01 (3); USP Chapter <795>*		
93	Compounding Record is completed each time a preparation is compounded. (The Board's interpretation of the language in USP mandates this standard be followed.) *247 CMR 9.01 (3); USP Chapter <795>*		
94	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>*		
95	The labeling indicates that “this is a compounded preparation”. (The Board's interpretation of the language in USP mandates this standard be followed.) *247 CMR 9.01 (3); USP Chapter <795>; Board Policy 2023-07: Non-Sterile Compounding; MGL c. 94C s. 21*		
96	Does the pharmacy maintain a defective drug log for any compounded drug preparation that is or may be defective as defined by the Board? *Board Policy 2024-04: Defective Drug Preparations*		

Item #	Requirements	Yes/No/N/A	Comment / Observation
I	**Standards for Prescription Labeling, Format & Containers**		
97	A licensee may not process a prescription; dispense a drug, device, or other substance; or administer a controlled substance including a vaccine in a manner which is intended, either directly or indirectly, to circumvent any law or regulation governing the practice of pharmacy. *247 CMR 9.01 (2)*		
98	A licensed pharmacist is responsible for the final dispensing process validation of a prescription. *247 CMR 9.04 (1)*		
99	A pharmacy shall utilize a computerized pharmacy system for processing prescriptions and for maintaining patient profiles. *247 CMR 9.04 (2)*		
100	A licensee may only dispense pursuant to a patient-specific prescription. *247 CMR 9.04 (3)*		
101	A licensee shall ensure the label affixed to a prescription drug container or package is clearly printed by a computerized pharmacy system. In the event of printing or equipment failure, a prescription label may be legibly handwritten or typed during an emergency period. *247 CMR 9.04 (4)*		
102	A pharmacy that provides bedside delivery service of discharge prescriptions to patients in an inpatient healthcare facility must obtain patient consent to provide such services and may not restrict a patient's freedom of choice of pharmacy services. A pharmacy that provides bedside delivery service shall deliver any medications directly to the patient or patient's agent. *247 CMR 9.04 (5)*		
103	Whenever a prescription drug has been distributed solely under a generic name, the dispensing pharmacist shall record the NDC number in the computerized pharmacy system. In the event an NDC number does not exist, the pharmacist shall record the name of the manufacturer, or, if the manufacturer's name is not available, the name of the distributor, packer, or repacker. *247 CMR 9.04 (8)*		
104	A pharmacy may not dispense any medication that was processed outside its licensed pharmacy premises unless said process was verified by a Massachusetts licensed pharmacist or performed in a pharmacy licensed by the Board. *247 CMR 9.04 (11)*		
105	A prescription for a Schedule VI medication is valid for one year from the date of issue. A licensee may not refill a Schedule VI prescription after one year. In the event a Schedule VI prescription expires or has no remaining refills, and the pharmacist is unable to obtain prescriber authorization in a timely manner, the pharmacist in their professional judgment may dispense a quantity not to exceed 30 days or the smallest available unit of use packaging. *247 CMR 9.04 (12)*		

Item #	Requirements	Yes/No/N/A	Comment / Observation
I	**Standards for Prescription Labeling, Format & Containers**		
106	Medical Emergencies In a medical emergency a pharmacist may fill a prescription marked "no substitution" by dispensing a less expensive interchangeable drug product as allowed by the *Massachusetts List of Interchangeable Drugs* if the particular brand is not in stock; similarly, a pharmacist may fill a prescription not marked "no substitution" in a medical emergency by dispensing the brand name product as written if they have no less expensive interchangeable drug product in stock to be dispensed. In such instances, the pharmacist must record the date, hour, and nature of the medical emergency on the back of the prescription or in the computerized pharmacy system and the person purchasing the drug product must indicate acceptance of this deviation from the law in writing. All such prescriptions shall be clearly identifiable and available for review by the Board. *247 CMR 9.05 (1) (a) and (b)*		
107	Generic Prescriptions Upon receiving a prescription for a generic name drug product with no manufacturer specified by the prescriber, a pharmacist may select, regardless of whether or not the prescriber has marked "no substitution" on the prescription, any legally marketed drug product whether or not it appears in the *Massachusetts List of Interchangeable Drugs*, in accordance with the prescriber's intent and the normal exercise of professional judgment. *247 CMR 9.05 (2)*		
108	Labeling 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 in the following manner: "Interchange": (generic name of less expensive drug product dispensed plus manufacturer). 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 in the following manner: "Interchange": (generic name of less expensive brand drug plus manufacturer of brand name of less expensive drug product). In addition to the above, the brand name of the prescribed drug product may also appear on the label in the following manner: "Interchange": (name of less expensive generic drug product plus manufacturer or brand name drug product actually dispensed) for (brand name drug product dispensed). Abbreviations are permissible as long as they are commonly understood. For example, "IC" may be used for "interchange" and manufacturers' names may be abbreviated as shown in the *Massachusetts List of Interchangeable Drugs.* *247 CMR 9.05 (3) (a) thru (d)*		
109	A pharmacy shall obtain and record consent from a patient or patient's agent prior to enrolling that patient in an automatic refill program. A pharmacy shall provide a method for patients to discontinue participation in an automatic refill program. *247 CMR 9.19 (12)*		
110	A pharmacy and pharmacist shall dispense or recommend a proper measuring device with all liquid medications. *247 CMR 9.18 (9)*		

Item #	Requirements	Yes/No/N/A	Comment / Observation
I	**Standards for Prescription Labeling, Format & Containers**		
111	A pharmacy shall maintain a readily accessible policy and procedure for computer downtime which shall include a process for filling prescriptions during downtime, a process for ensuring prescriptions dispensed during computer downtime are duly recorded in the patient's medication profile of the computerized pharmacy system when it becomes operational; continuity of care, if necessary; and process for performing an appropriate drug utilization review. *247 CMR 9.19 (21) (a) thru (d)*		
112	A pharmacy and pharmacist may dispense prescription drugs by mail or common carrier in a manner consistent with federal and state laws and regulations. *247 CMR 9.02 (1)*		
113	A pharmacy shall ensure that packing, shipping, and transportation processes do not adversely affect the integrity or stability of medications dispensed by mail. *247 CMR 9.02 (2)*		
114	A pharmacy shall maintain policies and procedures regarding packing, shipping, transporting, and delivering controlled substances. *247 CMR 9.02 (3)*		
115	A pharmacist shall comply with all elements of a drug's FDA required risk evaluation and mitigation strategy (REMS), including any distribution or dispensing restriction included in its REMS. *247 CMR 9.01 (18)*		
J	**Daily Planners, Compliance Packaging, Single and Multidose Packaging**		
116	At the patient's or patient's agent's request medications may be dispensed in a reusable daily dosage planner provided the medication was not previously dispensed by another pharmacy, a space is dedicated and allows for the orderly placement of equipment, materials, and medications for the proper preparation, and for the prevention of cross-contamination, policies and procedures for cleaning, labeling, dispensing, and proper hand hygiene are available. The pharmacy cleans and stores reusable daily dosage planners in a manner that prevents contamination of both the pharmacy and the planner. Labeling must meet requirements of M.G.L. c. 94C, § 21 for each medication. *247 CMR 9.07 (1) thru (5)*		
117	A pharmacy or pharmacist may utilize compliance packaging provided there is a designated space that allows for the orderly placement of equipment, materials, and medications for proper preparation, prevention of cross contamination. Policies and procedures pertaining to each type of compliance packaging utilized including cleaning, labeling, dispensing, proper hand hygiene, quarantine, and reverse distribution are available. Compliance packaging does not conflict with the USP-DI monograph or FDA-approved labeling and medications are compatible with packaging components and with each other. The compliance packaging is designed to prevent the container from being re-closed, to show evidence of having been opened, and in such a manner that the label cannot be altered or removed. The quantity of drugs in each package does not exceed the capacity of the container or potentially cause damage to the individual dosage forms. The compliance packaging must adhere to USP requirements for containers and packaging. *247 CMR 9.08 (1) (a) thru (h)*		

Item #	Requirements	Yes/No/N/A	Comment / Observation
J	**Daily Planners, Compliance Packaging, Single and Multidose Packaging**		
118	**Single-Drug-Single-Dose Packaging** A pharmacy or pharmacist may utilize single-drug-single-dose packaging for solid oral dosage forms. If a pharmacy or pharmacist places a medication in a single-drug-single-dose package prior to the receipt of a patient specific prescription, the pharmacy and pharmacist shall properly label the package and utilize bar-code scanning or similar technology to ensure proper identification of the pre-packaged medication at the time of dispensing. *247 CMR 9.08 (2) (a) and (b); Policy 2023-01: Compliance Packaging and Reusable Dose Planners*		
119	**Multi-Drug-Single-Dose Packaging** A pharmacy or pharmacist may utilize multi-drug-single-dose packaging for solid oral dosage forms provided not more than a 60-day supply of medication is dispensed, , Schedules II or III controlled substances are not dispensed, and medications to be taken on an as needed basis are not dispensed in a multi-drug-single-dose package. *247 CMR 9.08 (3) (a) thru (c); Policy 2023-01: Compliance Packaging and Reusable Dose Planners*		
120	**Return and Repackaging of Multi-Drug-Single-Dose Packaging** A pharmacy or pharmacist may accept a return of a multi-drug-single-dose package that the pharmacy previously dispensed for the purpose of repackaging and re-dispensing to that same patient. If a patient's medication was discontinued, a pharmacy may remove the discontinued drug(s) from the multi-drug-single-dose package and re-dispense the remaining medications in the multi-drug-single-dose package to the same patient. If a patient's drug therapy changed, a pharmacy may remove the discontinued drug(s) from the multi-drug-single-dose package(s) and may add a new medication(s) to the multi-drug-single-dose package and re-dispense the multi-drug-single-dose package to the same patient. A pharmacy shall label the multi-drug-single-dose package in accordance with 247 CMR 9.08(6) prior to re-dispensing. A pharmacy shall implement policies and procedures pertaining to security and accountability of controlled substances during return and repackaging. *247 CMR 9.08 (4) (a); Policy 2023-01: Compliance Packaging and Reusable Dose Planners*		
121	A licensee may not return any medication removed from a multi-drug-single-dose package to inventory. A licensee may not dispense any medication removed from a multi-drug-single-dose package to any patient other than the patient who returned the multi-drug-single-dose package. *247 CMR 9.08 (4) (b); Policy 2023-01: Compliance Packaging and Reusable Dose Planners*		
122	A pharmacy shall maintain a record that accounts for and documents any repackaging, removal, or re-dispensing of any medication it previously dispensed in a multi-drug-single-dose package. The record shall identify the pharmacist making the change. *247 CMR 9.08 (4) (a) thru (c)*		
123	A licensee shall label each oral-liquid-single dose, single-drug-single-dose, and multi-drug-single-dose package with information required by M.G.L. c. 94C, § 21 and USP for each medication in the package including the name, strength, physical description, and total quantity of each drug dispensed; the dispensing or preparation date; a beyond-use date, which may not exceed the expiration date on the original manufacturer's container or **60 days**, whichever is shorter, for each drug contained in a multi-drug-single-dose package; and the telephone number of the pharmacy. *247 CMR 9.08 (5) (a) thru (e)*		
124	If the compliance package has removable cells, a pharmacy shall utilize a label of sufficient size to label each cell properly and clearly with each drug name and strength. *247 CMR 9.08 (6)*		

Item #	Requirements	Yes/No/N/A	Comment / Observation
K	**Use, Reuse, Return, and Disposal of Medications**		
125	Unless otherwise permitted by law, regulation, or Board policy, a licensee may not accept or re-dispense any medication which has been previously dispensed. *247 CMR 9.01 (5)*		
126	A licensee may not accept, or purchase medications designated as "drug samples not for resale" for the purpose of compounding, repacking, or in any way reselling said medications. *247 CMR 9.01 (6)*		
127	A pharmacy shall accept a medication that it previously dispensed to a patient if the medication was dispensed to the patient in error; or is suspected to be defective or contaminated. A medication accepted by a pharmacy pursuant to this section may not be returned to the pharmacy's inventory and must be quarantined and properly disposed. A pharmacy is not required to accept a medication from a patient that was properly dispensed and not defective at the time it was dispensed. *247 CMR 9.01 (7) (a) and (b)*		
128	A licensee may not dispense or distribute any expired, outdated, defective, contaminated, counterfeit, contraband, or otherwise substandard drug or device to any person or entity who is not licensed or legally authorized to receive such drug or device. *247 CMR 9.01 (12)*		
129	In the event a pharmacy prepares a prescription for dispensing, but the medication is not dispensed, the pharmacy may return the medication to stock as long as they do not return a medication to the manufacturer's stock bottle. The pharmacy shall keep a medication to be returned to stock in the original patient container or place medication an appropriate container and shall affix a label to the container containing the product name, strength or concentration, name of the manufacturer, supplier, or NDC number; and the expiration date assigned at the time of filling. *247 CMR 9.13 (1) (a) and (b)*		
130	A pharmacy shall maintain a policy and procedure regarding returning medications to stock. *247 CMR 9.13 (2)*		
131	In the event of a recall, a pharmacy may not dispense any medication that has been returned to stock and is potentially subject to the recall unless it can confirm the specific lot number is not included in the recall. *247 CMR 9.13 (3)*		
132	A pharmacy shall effectuate a recall of medication that is or may be defective in any way. *247 CMR 9.19 (11)*		
L	**Emergency Kits, Automated Pharmacy Systems, Pharmacy Processing Automation, and Automated Dispensing Devices**		
133	A pharmacy shall maintain a policy and procedure for the proper dispensing of medication through emergency medication kits pertaining to security, maintenance, and use. *247 CMR 9.09 (1)*		
134	A pharmacy shall reconcile medication dispensed through emergency medication kits with prescriptions or orders. *247 CMR 9.09 (2)*		
135	A pharmacy may only provide emergency medication kits to facilities approved by the Department. *247 CMR 9.09 (3)*		

Item #	Requirements	Yes/No/N/A	Comment / Observation
L	**Emergency Kits, Automated Pharmacy Systems, Pharmacy Processing Automation, and Automated Dispensing Devices**		
136	A pharmacy may dispense Schedule IV through VI controlled substances from an Automated Pharmacy System (APS) to a patient or a patient's agent during or after pharmacy hours of operation provided the APS is located within the same building as the pharmacy, is secured against or within a wall or floor in a manner that prevents unauthorized access and removal, location and APS are monitored by continuous, recordable video surveillance, the APS does not stock medications that require refrigeration or reconstitution, utilizes industry standard technological verification, such as bar code verification, electronic verification, weight verification, radio frequency identification, or another similar process, to ensure the correct medication is dispensed to the correct patient, electronic data is maintained that creates an audit trail of activity and includes the identity of each person to whom a drug was released, the patient is allowed to choose whether or not to use an APS. the offer to counsel is provided to the patient in the case of new or changed therapy before placing the filled prescription in the APS, and the means and opportunity for a pharmacist consultation is provided during the pharmacy's usual hours of operation. *247 CMR 9.10 (1) (a) thru (i); Policy 2022-07: Automated Pharmacy Systems*		
137	A pharmacy utilizing an APS shall maintain policies and procedures pertaining to the APS that include APS location(s); operation and maintenance; security; controlled substances accountability; quality assurance; stocking and return activities; and patient confidentiality. *247 CMR 9.10 (2) (a) thru (g); Policy 2022-07: Automated Pharmacy Systems*		
138	A pharmacy may utilize Pharmacy Processing Automation (PPA) to count, fill vials or compliance packaging, and label, provided the PPA utilizes technological verification, such as bar code verification, electronic verification, weight verification, radio frequency identification ("RFID"), or another similar process, to ensure that the correct medication is dispensed; and if lot numbers are comingled in a single cell, the pharmacy maintains a policy and procedure to quarantine all comingled lot numbers in the event a single lot number is recalled. *247 CMR 9.11 (1) (a) and (b)*		
139	The pharmacy shall implement and maintain policies and procedures pertaining to the PPA that include operation and maintenance; security; controlled substance accountability; quality assurance; and stocking and return activities. *247 CMR 9.11 (2) (a) thru (e)*		
140	A pharmacy may utilize an automated dispensing device (ADD) for controlled substances provided that the ADD is in a licensed health care facility; dispensing is pursuant to a valid patient specific prescription or order; utilization is in accordance with all laws, regulations, and policies; and the pharmacy maintains ADD policies and procedures including the location operation and maintenance; security; controlled substances accountability; quality assurance; stocking and return activities; and patient confidentiality. *247 CMR 9.12 (1) thru (4); Policy 2019-02: Automated Dispensing Device Use*		
M	**Patient Records, Transfers, Counseling, and Prospective Drug Utilization**		
141	A pharmacy shall transfer a prescription to another pharmacy at the request of a patient or their agent in a timely manner so as not to delay patient therapy. *247 CMR 9.14 (1)*		
142	The pharmacy may act as the patient's agent in order to facilitate a transfer. *247 CMR 9.14 (2)*		
143	A pharmacy may not charge a fee for transferring a prescription. 247 CMR 9.14 (3)		

Item #	Requirements	Yes/No/N/A	Comment / Observation
M	**Patient Records, Transfers, Counseling, and Prospective Drug Utilization**		
144	A certified pharmacy technician may, with the approval of the pharmacist on duty, perform prescription transfers between pharmacies for prescriptions issued for controlled substances in Schedule VI only. *247 CMR 8.04 (4) (d); 247 CMR 9.00*		
145	Schedule VI A pharmacy shall transfer prescriptions for Schedule VI controlled substances in the same manner as prescriptions for Schedules III through V controlled substances. Prescriptions for Schedule VI controlled substances may be transferred up to the maximum number of remaining refills authorized by the prescriber. A pharmacy may not transfer a prescription authorizing refills for Schedule VI controlled substances more than one year after the date the prescription was issued. *247 CMR 9.14 (a) thru (c)*		
146	A DEA registered pharmacy may transfer original prescription information for schedules III, IV, and V controlled substances to another DEA registered pharmacy for the purpose of refill dispensing between pharmacies, on a one-time basis only. Transfer of any original unfilled prescription received in paper (including fax) or oral form to another pharmacy may not be conducted. 21 CFR 1306.25; 21 CFR 1306.25.		
147	A pharmacist may only fill a prescription if in the exercise of their professional judgment, determines that the prescription was issued for a legitimate medical purpose by a practitioner acting in the usual course of their professional practice; there is a valid patient-practitioner relationship; the prescription is authentic; and the dispensing is in accordance with M.G.L. c. 94C, § 19(a). *247 CMR 9.15 (2) (a) thru (d)*		
148	A pharmacist and pharmacy shall maintain prescription records, purchasing and return records, and disposal and destruction records in a readily retrievable manner for at least two years. *247 CMR 9.16 (1)*		
149	Prescriptions for Schedule II, schedule III-V, and schedule VI controlled substances shall be segregated if maintained in paper format and electronically separable if maintained in electronic format. *247 CMR 9.16 (2) thru (4)*		
150	A pharmacy shall be able to print readable copies of electronic prescriptions including electronically stored images of prescriptions. *247 CMR 9.16 (5) and (6)*		
151	A pharmacist and pharmacy shall maintain a confidential patient profile for each patient to whom a prescription is dispensed. The computerized pharmacy system shall provide for the immediate retrieval of information necessary for the pharmacist to identify previously dispensed drugs at the time the prescription is presented for dispensing. The pharmacist or pharmacist's designee shall make a reasonable effort to obtain, record, and maintain the name, address, contact information, date of birth or age, and gender of the patient for whom the prescription is intended patient history, including known drug allergies and drug reactions; a comprehensive list of medications and relevant devices dispensed by the pharmacy; and the pharmacist's comments relevant to the patient's drug therapy. *247 CMR 9.16 (7) (a) thru (d)*		

Item #	Requirements	Yes/No/N/A	Comment / Observation
M	**Patient Records, Transfers, Counseling, and Prospective Drug Utilization**		
152	A pharmacist shall conduct a prospective drug utilization review (DUR) before each prescription or medication order is dispensed or delivered to a patient or a patient's agent. The DUR may include a review of computerized alerts, the patient record, and each new and renewed prescription or medication order for the purpose of promoting therapeutic appropriateness, by making a reasonable effort to identify over-utilization or under-utilization; therapeutic duplication; drug-disease contraindication; drug-drug interaction; drug-food interaction; improper drug dosage, directions, or duration of drug treatment; drug-allergy interactions; abuse or misuse; any significant change in drug, dose, or directions; and any age-related contraindications. *247 CMR 9.17 (1) (a) thru (j)*		
153	Upon identifying any of the above, a pharmacist shall take appropriate measures to ensure the proper care of the patient which may include consultation with the prescribing practitioner or direct consultation with the patient or patient's agent. A pharmacist shall document any measures taken in response to a drug utilization review. *247 CMR 9.17 (2)*		
154	A pharmacist or pharmacist's designee shall offer the counseling services of the pharmacist to each person who receives a prescription medication; The individual must be appropriately trained. Counseling must be provided on each new drug therapy and each drug therapy that in the pharmacist's professional judgment is deemed to be significant for the health and safety of the patient. *247 CMR 9.18 (1) thru (4); 247 CMR 8.04 (4) (b); 247 CMR 8.02 (6) (b)*		
155	When counseling a patient, a pharmacist or pharmacy intern shall provide such information which, in the pharmacist's professional judgment, is necessary for the patient to understand the proper use of the patient's prescription which may include the name, description, and indication of the medication; dosage form, dosage, route of administration and duration of therapy; special directions and instructions for preparation, administration, and use by the patient common side and adverse effects or interactions and therapeutic contraindications or precautions with legend and non-legend medications and other substances which the pharmacist deems relevant; techniques for self-monitoring drug therapy; proper storage and disposal; prescription refill information; and action to be taken in the event of a missed dose or adverse reaction. *247 CMR 9.18 (5) (a) thru (h)*		
156	A licensee shall maintain patient confidentiality and protect a patient's confidential information. *247 CMR 9.01 (16)*		
157	A pharmacy and pharmacist shall ensure counseling is available at all times when a pharmacy is open for business. *247 CMR 9.18 (8)*		
N	**Continuous Quality Improvement**		
158	Continuous Quality Improvement Program Requirements. Each pharmacy shall establish a Continuous Quality Improvement (CQI) Program for the purpose of detecting, documenting, assessing and preventing Quality Related Events (QREs). At a minimum, a 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; identify and document QREs; minimize impact of QREs on patients; analyze data collected in response to QREs to assess causes and any contributing factors; use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs; and provide ongoing education at least annually in the area of CQI to pharmacy personnel. *247 CMR 15.02 (1) (a) thru (f)*		

Item #	Requirements	Yes/No/N/A	Comment / Observation
N	**Continuous Quality Improvement**		
159	QRE Discovery and Notification. All pharmacy personnel shall be trained to bring any QRE to the attention of the pharmacist on duty or the pharmacist Manager of Record immediately upon discovery. The pharmacist who has discovered or been informed of a QRE shall immediately provide notification to the patient or patient's representative, the prescriber (if indicated in the professional judgment of the pharmacist) and other members of the healthcare team; directions for correcting the error; and instructions for minimizing the negative impact on the patient. *247 CMR 15.03 (1) (a) thru (c)*		
160	QRE Documentation: A QRE shall be initially documented by the pharmacist who has discovered or been informed of the QRE within 24 hours after the QRE is discovered by or described to the pharmacist. QRE documentation shall include a description of the event that is sufficient to permit categorization and analysis of the event. QRE documentation shall include the date when the pharmacist discovered or received notification of the QRE and the name of the person who notified the pharmacy; the names and titles of the persons recording the QRE information and performing the QRE analysis; a description of the QRE reviewed; and documentation of the contact with the patient, or patient's representative, and prescribing practitioner (if indicated in the professional judgment of the pharmacist), and other members of the healthcare team. *247 CMR 15.03 (a) and (b)*		
161	QRE Analysis: The investigative and other pertinent data collected in response to QREs shall be analyzed, individually and collectively, to assess the cause and any contributing factors such as system or process failures. The QRE analysis and assessment shall include a consideration of the effects on quality assurance related to workflow processes, technological support, personnel training and staffing levels; any recommended remedial changes to pharmacy policies, procedures, systems, or processes; and the development of indicators that identify means against which a pharmacy's program intends to measure its standards over a designated period of time. *247 CMR 15.03 (3) (a)*		
162	Response: Each pharmacy shall inform pharmacy personnel of changes to pharmacy policies, procedures, systems, or processes resulting from recommendations generated by the CQI Program. *247 CMR 15.03 (3) (b)*		
163	Each pharmacy shall maintain a written copy of its CQI Program description on the pharmacy premises. The CQI Program description shall be readily available to all pharmacy personnel. *247 CMR 15.04 (1)*		
164	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)*		
165	QRE records shall be maintained in an orderly manner and filed by date. *247 CMR 15.04 (3)*		

Item #	Requirements	Yes/No/N/A	Comment / Observation
O	**Immunizations**		
166	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); Board Policy 2023-02: Vaccine Administration*		
167	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)*		
168	As applicable, a pharmacy shall post on the wall or maintain in a readily retrievable location immunization certifications and current CPR card for each licensee that performs immunizations and any standing orders. *247 CMR 9.19 (9) (a) and (e); Board Policy 2023-02*		
169	Does the pharmacy have a standing order to administer single dose emergency epinephrine? Standing Order Physician: _____; Signed/Expiration Date: _____ *247 CMR 9.01 (1); Board Policy 2023-02: Vaccine Administration*		
170	Such administration is conducted pursuant to a standing order of a practitioner? Standing Order Practitioner: _____; Signed/Expiration Date:_____ *247 CMR 9.01 (1); 105 CMR 700.004 (6) (b); Board Policy 2023-02: Vaccine Administration*		
171	Prior to administering a vaccine (other than influenza or COVID-19) the Pharmacy reviews the Massachusetts Immunization Information System ("MIIS") to ensure the vaccine has not been administered by another provider. *247 CMR 9.01 (1); Board Policy 2023-02: Vaccine Administration*		
172	After administration of any vaccine, the vaccination information is reported to "MIIS". *247 CMR 9.01 (1); Board Policy 2023-02: Vaccine Administration*		
P	**References**		
173	A pharmacy shall maintain the following on the pharmacy premises a current copy or access to electronic version of the *Massachusetts List of Interchangeable Drugs*, including the Orange Book, Additional List, and Exception List. *247 CMR 9.19 (1) (a)*		
174	A pharmacy shall maintain the following on the pharmacy premises a current copy or access to electronic version with quarterly updates of a compendia appropriate to the practice setting approved by the Manager of Record. *247 CMR 9.19 (1) (b)*		
175	A pharmacy shall maintain the following on the pharmacy premises a current copy or access to electronic version of laws and regulations governing the practice of pharmacy. *247 CMR 9.19 (1) (c)*		
176	A pharmacy shall maintain the following on the pharmacy premises a current copy or access to electronic version of Plumb's Veterinary Drug Handbook or other veterinary reference approved by the Board. *247 CMR 9.19 (1) (d)*		

Item #	Requirements	Yes/No/N/A	Comment / Observation
Q	**Hazardous Handling Requirements (USP <800>)** *247 CMR 9.01 (3); Advisory: USP <800> in Community Pharmacies*		
177	Does the Pharmacy have a designated person(s) who is(are) qualified and trained to be responsible for developing and implementing procedures, overseeing compliance, as well as other requirements of USP <800>?		
178	Does the Pharmacy review the most recent National Institute for Occupational Safety and Health (NIOSH) list?		
179	Does the Pharmacy have a method to identify all stocked HDs?		
180	Does the Pharmacy review drug on the list at least every 12 months?		
181	Does the Pharmacy have a procedure to assess new drugs?		
182	Does the Pharmacy identify the risk category of each drug as either antineoplastic, non-antineoplastic, reproductive risk only, or alternative method as applicable to the practice setting?		
183	If manipulation of antineoplastic drugs or compounding with any NIOSH hazardous drug API is conducted, does the Pharmacy utilize appropriate containment as described in USP <800>?		
184	Does the Pharmacy provide appropriate PPE to employees based on activities being conducted?		
185	Does the Pharmacy store antineoplastics separate from other inventory?		
186	Does the Pharmacy ensure that antineoplastic HDs in tablet and capsule form are not placed in automated counting or packaging machines?		
187	Before independently handling HDs, are all employees trained based on their job functions (e.g., in the receipt, storage, dispensing, etc.)?		
188			
R	**Drug Supply Chain and Security Act (DSCSA)**		
189	Does the pharmacy have procedures in place to ensure that the manufacturers, repackagers, wholesale distributors, third party logistics providers, and other pharmacies doing business with are properly licensed or registered with the appropriate authority?		
190	Does the Pharmacy ensure that only prescriptions drugs that are accompanied by product tracing information are accepted? If not provided, does the Pharmacy work with the trading partner to acquire such documentation?		
191	Does the Pharmacy have a process to investigate and handle suspect and illegitimate prescription drugs, including drugs that may be or have evidence that it is counterfeit, diverted, stolen, intentionally adulterated or unfit for distribution?		
192	Does the Pharmacy quarantine prescription drugs identified as suspect or illegitimate?		
193	Does the Pharmacy have a process in place for notifying FDA and the trading partner they bought the drug from and/or sold the drug to?		
194	Does the Pharmacy maintain documentation for the appropriate length of time? (i.e. – at least 6 years)		
195	Is the product tracing information readily retrievable for review by Pharmacy staff in either electronic or hard copy form?		

Waivers Granted to Licensee: All approved waivers shall be posted or readily retrievable by the pharmacy including written finding from the Board waiving such Board regulations. 247 CMR 9.19 (8) (d)
N/A
Investigator Notes:

Investigator Notes (continued):

Inspection Completion
Exit Interview
Plan of Correction (POC) Issued: ☐ Yes ☑ No Plan of correction for all findings due within 15 business days. POC Due: _____

Investigator Signatures	
Investigator:	
Date:	
Investigator:	
Date:	
Investigator:	
Date:	
Investigator:	
Date:	