Title 20—DEPARTMENT OF COMMERCE AND INSURANCE
Division 2220—State Board of Pharmacy
Chapter 2—General Rules

PROPOSED AMENDMENT

20 CSR 2220-2.090 Pharmacist-in-Charge. The board is deleting sections (1) and (2), and adding new sections (1)-(3).

PURPOSE: This amendment updates compliance requirements and responsibilities for the designated pharmacist-in-charge of a board licensed pharmacy.

[(1) A pharmacist may be a pharmacist-in-charge of a licensed pharmacy; provided, that s/he complies with all provisions of this rule.

(2) The responsibilities of a pharmacist-in-charge, at a minimum, will include:
(A) The management of the pharmacy must be under the supervision of a Missouri-licensed pharmacist at all times when prescriptions are being compounded, dispensed or sold;
(B) The traffic in the prescription area must be restricted to authorized personnel only so that proper control over the drugs can be maintained at all times;
(C) All the required signs are displayed in the appropriate places when there is no pharmacist on duty;
(D) The licenses of all pharmacists employed are conspicuously displayed in the pharmacy;
(E) Assurance that all procedures of the pharmacy in the handling, dispensing and recordkeeping of controlled substances are in compliance with state and federal laws;
(F) Any excessive or suspicious requests, or both, for the dispensing of controlled substances be verified prior to dispensing;
(G) All labeling requirements are complied with according to section 338.059, RSMo, federal laws where required and board regulations governing auxiliary labeling of drugs and devices;
(H) The prescription files are maintained according to the requirements of this board and the other state and federal controlled substance laws and regulations;
(I) The Missouri Revised Negative Drug Formulary and state laws governing drug substitution be complied with when generic substitution takes place;
(J) If exempt narcotics are sold, complete records be kept of all exempt narcotics in a bound exempt narcotic register;
(K) If poisons are sold, the pharmacy maintain a poison register;
(L) The pharmacy maintain and have on file at all times the required reference library;
(M) The pharmacy be kept in a clean and sanitary condition;

(N) The pharmacist-in-charge will be responsible for the supervision of all pharmacy personnel, to assure full compliance with the pharmacy laws of Missouri;

(O) All Missouri and federal licenses are kept up-to-date;

(P) Policies and procedures are in force to insure safety for the public concerning any action by pharmacy staff members or within the pharmacy physical plant;

(Q) All equipment, as prescribed through regulation, is available and in good working order;

(R) Security is sufficient to insure the safety and integrity of all legend drugs located in the pharmacy;

(S) Any changes of the following are appropriately carried out:

1. Pharmacy permit transfer of any type or manner;

2. Regulation requirements completed satisfactorily when a change of pharmacist-in-charge occurs;

3. Change of pharmacist's own address as it appears on his/her license;

(T) When the board-recognized pharmacist-in-charge is changed at that licensed facility, an appropriate documented inventory of controlled substances must be taken;

(U) Assure that the appropriate handling and disposal of controlled substances is done and verified through appropriate documentation and when necessary that controlled substances be disposed of through appropriate procedures involving the Missouri Board of Pharmacy or the Bureau of Narcotics and Dangerous Drugs;

(V) No outdated drugs are dispensed or maintained within the active inventory of the pharmacy, including prescription and related nonprescription items;

(W) Assure full compliance with all state and federal drug laws and rules;

(X) Compliance with state and federal requirements concerning drug samples;

(Y) Assure that all state and federal laws concerning drug distribution and control are complied with and that no violations occur that would cause a drug or device or any component thereof to become adulterated or misbranded;

(Z) Maintain compliance with all state and federal laws governing drug distributor activities and assure that appropriate licensure as a drug distributor is secured if lawful thresholds for unlicensed drug distributions are exceeded;

(AA) Assure overall compliance with state and federal patient counseling requirements;

(BB) Maintain a current list of all personnel employed by the pharmacy as pharmacy technicians. The list shall include the name, registration number or a copy of an application for registration that has been submitted to the board and a description of duties to be performed by each person contained on the list;

(CC) Maintain written standards setting out the responsibilities of registered pharmacy technicians as well as the procedures and policies for supervision

of registered pharmacy technicians, as required by 4 CSR 220-2.700(1). Said standards shall be available to the board and its designated personnel for inspection and/or approvals;

(DD) Any person other than a pharmacist or permit holder who has independent access to legend drug stock on a routine basis in a pharmacy shall be required to register with the board as a pharmacy technician. The determination of whether or not an individual must register as a pharmacy technician will be the responsibility of the pharmacist-in-charge; and

(EE) Maintain compliance of automated dispensing and storage systems with applicable board rules and regulations.]

(1) Except as otherwise authorized by law, each pharmacy shall designate a pharmacist-in-charge who is responsible for managing pharmacy compliance and supervising pharmacy staff. At a minimum, the pharmacist-in-charge shall assist the permit holder in ensuring pharmacy operations and clinical activities comply with the rules of the board and all applicable state and federal law governing pharmacy practice.

(A) The pharmacist-in-charge must be regularly involved in, and engaged with, pharmacy operations and monitoring pharmacy compliance. Except in the event of an emergency or other urgent need, the pharmacist-in-charge must be consulted and given an opportunity to provide input prior to implementation of any pharmacy policy, procedure, system or practice that will modify or expand the delivery of pharmacy services.

(B) The pharmacist-in-charge must be physically present at the pharmacy for a sufficient amount of time as needed to effectively supervise pharmacy activities and ensure pharmacy compliance. Additionally, the permit holder must provide the pharmacist-in-charge designated time to review pharmacy compliance on a regular basis while not engaged in medication dispensing or providing patient services.

(C) The pharmacist-in-charge must have authority to temporarily suspend or restrict pharmacy operations or the activity of licensees/registrants, if deemed reasonably necessary or appropriate to ensure pharmacy compliance or the safe provision of pharmacy services, pending final direction or approval from the permit holder.

(D) The permit holder must have policies and procedures in place for regularly reviewing staffing and resource needs with the pharmacist-in-charge, including, policies and procedures for requesting additional staff or staffing modifications.

(2) A pharmacist must immediately notify the board electronically or in writing on a form designated by the board if he/she stops serving as the designated pharmacist-in-charge. At or immediately prior to a pharmacist-in-charge change, a controlled substance inventory must be taken by a designee of the permit holder that complies with state and federal controlled substance inventory requirements, including, 21 CFR § 1304.11. The signature of the individual(s) taking the required inventory must be documented on the inventory.

(3) This rule does not exempt a permit holder from responsibility for compliance with applicable state or federal law.

AUTHORITY: sections 338.140, 338.240 and 338.280, RSMo 2000. This rule originally filed as 4 CSR 220-2.090. Emergency rule filed April 12, 1984, effective April 22, 1984, expired Aug. 20, 1984. Original rule filed April 12, 1984, effective Aug. 11, 1984. For intervening history, please consult the* ***Code of State Regulations****. Amended: filed January 20, 2022.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will cost private entities approximately one hundred fifteen thousand, four-hundred and six dollars and twenty cents ($115,406.20) during the first year of rule implementation, and fifteen thousand four-hundred and seventy dollars ($15,470) annually over the life of the rule. Costs may vary with inflation, and are expected to increase at the rate projected by the Legislative Oversight Committee.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 526-3464, or via email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this rule in the ***Missouri Register****. No public hearing is scheduled.*