§291.31 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(23) Full-time pharmacist—A pharmacist who works in a pharmacy from 30 to 40 hours per week or, if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.
§291.32 Personnel

(a) Pharmacist-in-charge.

(1) General.

(A) Each Class A pharmacy shall have one pharmacist-in-charge who is employed on a full-time basis, who may be the pharmacist-in-charge for only one such pharmacy; provided, however, such pharmacist-in-charge may be the pharmacist-in-charge of:

(i) more than one Class A pharmacy, if the additional Class A pharmacies are not open to provide pharmacy services simultaneously; or

(ii) during an emergency, up to two Class A pharmacies open simultaneously if the pharmacist-in-charge works at least 10 hours per week in each pharmacy for no more than a period of 30 consecutive days.

(B) The pharmacist-in-charge shall comply with the provisions of §291.17 of this title (relating to Inventory Requirements).

(2) Responsibilities. The pharmacist-in-charge shall have responsibility for the practice of pharmacy at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacist-in-charge may advise the owner on administrative or operational concerns. The pharmacist-in-charge shall have responsibility for, at a minimum, the following:

(A) educating and training of pharmacy technicians and pharmacy technician trainees;

(B) supervising a system to assure appropriate procurement of prescription drugs and devices and other products dispensed from the Class A pharmacy;

(C) disposing of and distributing drugs from the Class A pharmacy;

(D) storing all materials, including drugs, chemicals, and biologicals;

(E) maintaining records of all transactions of the Class A pharmacy necessary to maintain accurate control over and accountability for all pharmaceutical materials required by applicable state and federal laws and sections;

(F) supervising a system to assure maintenance of effective controls against the theft or diversion of prescription drugs, and records for such drugs;

(G) adhering to policies and procedures regarding the maintenance of records in a data processing system such that the data processing system is in compliance with Class A (community) pharmacy requirements;
(H) legally operating the pharmacy, including meeting all inspection and other requirements of
all state and federal laws or sections governing the practice of pharmacy; and

(I) if the pharmacy uses an automated pharmacy dispensing system, shall be responsible for
the following:

(i) consulting with the owner concerning and adherence to the policies and procedures for
system operation, safety, security, accuracy and access, patient confidentiality, prevention of
unauthorized access, and malfunction;

(ii) inspecting medications in the automated pharmacy dispensing system, at least monthly,
for expiration date, misbranding, physical integrity, security, and accountability;

(iii) assigning, discontinuing, or changing personnel access to the automated pharmacy
dispensing system;

(iv) ensuring that pharmacy technicians, pharmacy technician trainees, and licensed
healthcare professionals performing any services in connection with an automated pharmacy
dispensing system have been properly trained on the use of the system and can demonstrate
comprehensive knowledge of the written policies and procedures for operation of the system;
and

(v) ensuring that the automated pharmacy dispensing system is stocked accurately and an
accountability record is maintained in accordance with the written policies and procedures of
operation.

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§291.72 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(24) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.
§291.73 Personnel

(b) Pharmacist-in-charge.

(1) General.

(A) Each institutional pharmacy in a facility with 101 beds or more shall have one full-time pharmacist-in-charge, who may be pharmacist-in-charge for only one such pharmacy except as specified in subparagraph (C) of this paragraph.

(B) Each institutional pharmacy in a facility with 100 beds or less shall have one pharmacist-in-charge who is employed or under contract, at least on a consulting or part-time basis, but may be employed on a full-time basis, if desired, and who may be pharmacist-in-charge for no more than three facilities or 150 beds.

(C) A pharmacist-in-charge may be in charge of one facility with 101 beds or more and one facility with 100 beds or less, including a rural hospital, provided the total number of beds does not exceed 150 beds.

(D) The pharmacist-in-charge shall be assisted by additional pharmacists, pharmacy technicians and pharmacy technician trainees commensurate with the scope of services provided.

(E) If the pharmacist-in-charge is employed on a part-time or consulting basis, a written agreement shall exist between the facility and the pharmacist, and a copy of the written agreement shall be made available to the board upon request.

(2) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum, the following:

(A) providing the appropriate level of pharmaceutical care services to patients of the facility;

(B) ensuring that drugs and/or devices are prepared for distribution safely, and accurately as prescribed;

(C) supervising a system to assure maintenance of effective controls against the theft or diversion of prescription drugs, and records for such drugs;

(D) providing written guidelines and approval of the procedure to assure that all pharmaceutical requirements are met when any part of preparing, sterilizing, and labeling of sterile preparations is not performed under direct pharmacy supervision;

(E) participating in the development of a formulary for the facility, subject to approval of the appropriate committee of the facility;
(F) developing a system to assure that drugs to be administered to patients are distributed pursuant to an original or direct copy of the practitioner's medication order;

(G) developing a system for the filling and labeling of all containers from which drugs are to be distributed or dispensed;

(H) assuring that the pharmacy maintains and makes available a sufficient inventory of antidotes and other emergency drugs as well as current antidote information, telephone numbers of regional poison control center and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the facility;

(I) maintaining records of all transactions of the institutional pharmacy as may be required by applicable law, state and federal, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials including pharmaceuticals, components used in the compounding of preparations, and participate in policy decisions regarding prescription drug delivery devices;

(J) participating in those aspects of the facility's patient care evaluation program which relate to pharmaceutical utilization and effectiveness;

(K) participating in teaching and/or research programs in the facility;

(L) implementing the policies and decisions of the appropriate committee(s) relating to pharmaceutical services of the facility;

(M) providing effective and efficient messenger or delivery service to connect the institutional pharmacy with appropriate areas of the facility on a regular basis throughout the normal workday of the facility;

(N) developing a system for the labeling, storage, and distribution of investigational new drugs, including access to related drug information for healthcare personnel in the pharmacy and nursing station where such drugs are being administered, concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions and symptoms of toxicity of investigational new drugs;

(O) assuring that records in a data processing system are maintained such that the data processing system is in compliance with Class C (Institutional) pharmacy requirements;

(P) assuring that a reasonable effort is made to obtain, record, and maintain patient medication records;

(Q) assuring the legal operation of the pharmacy, including meeting all inspection and other requirements of all state and federal laws or rules governing the practice of pharmacy; and

(R) if the pharmacy uses an automated medication supply system, shall be responsible for the following:
(i) reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(ii) inspecting medications in the automated medication supply system, at least monthly, for expiration date, misbranding, physical integrity, security, and accountability; except that inspection of medications in the automated medication supply system may be performed quarterly if:

(I) the facility uses automated medication supply systems that monitors expiration dates of prescription drugs; and

(II) security of the system is checked at regularly defined intervals (e.g., daily or weekly);

(iii) assigning, discontinuing, or changing personnel access to the automated medication supply system;

(iv) ensuring that pharmacy technicians, pharmacy technician trainees, and licensed healthcare professionals performing any services in connection with an automated medication supply system have been properly trained on the use of the system and can demonstrate comprehensive knowledge of the written policies and procedures for operation of the system; and

(v) ensuring that the automated medication supply system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation.

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