CHAPTER 6
GENERAL PHARMACY PRACTICE
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 2]

657—6.1(155A) Purpose and scope. A general pharmacy is a location where a pharmacist provides pharmaceutical services or dispenses pharmaceutical products to patients in accordance with pharmacy laws. This chapter does not apply to a hospital pharmacy as defined in 657—Chapter 7. The requirements of these rules for general pharmacy practice are in addition to the requirements of 657—Chapter 8 and other rules of the board relating to services provided by the pharmacy.

657—6.2(155A) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, the following:

1. Ensuring that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services.
2. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy.
3. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.
4. Ensuring that a pharmacist performs prospective drug use review as specified in rule 657—8.21(155A).
5. Ensuring that a pharmacist provides patient counseling as specified in rule 6.14(155A).
6. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.
7. Delivering drugs to the patient or the patient's agent.
8. Ensuring that patient medication records are maintained as specified in rule 6.13(155A).
9. Training pharmacy technicians and supportive personnel.
10. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.
11. Distributing and disposing of drugs from the pharmacy.
12. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.
13. Establishing and maintaining effective controls against the theft or diversion of prescription drugs and records for such drugs.
14. Establishing and implementing policies and procedures for all operations of the pharmacy.
15. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.
16. Ensuring that there is adequate space within the prescription department or a locked room not accessible to the public for the storage of prescription drugs, devices, and controlled substances and to support the operations of the pharmacy.

657—6.3(155A) Reference library. References may be printed or computer-accessed. A reference library shall be maintained which includes, as a minimum, one current reference from each of the following categories, including access to current periodic updates.

1. The Iowa Pharmacy Law and Information Manual.
2. A patient information reference that includes or provides patient information in compliance with rule 6.14(155A).
3. A reference on drug interactions.
4. A general information reference.
5. A drug equivalency reference.
6. A reference on natural or herbal medicines.
7. The readily accessible telephone number of a poison control center that serves the area.

8. Additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served.

657—6.4(155A) Exemption from duplicate requirements. A pharmacy established in the same location as another licensed pharmacy and with direct and immediate access to required references, patient counseling area, refrigerator, or sink with hot and cold running water may utilize the references, counseling area, refrigerator, or sink of the other pharmacy to satisfy the requirements of rule 6.3(155A), subrule 6.14(3), or rule 657—8.5(155A), paragraphs "1" and "2."

657—6.5 and **6.6** Reserved.

657—6.7(124,155A) Security. While on duty, each pharmacist shall be responsible for the security of the prescription department, including provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs, records for such drugs, and patient records as provided in 657—Chapter 21.

6.7(1) *Department locked.* The prescription department shall be locked by key or combination so as to prevent access when a pharmacist is not on site except as provided in subrule 6.7(2).

6.7(2) *Temporary absence of pharmacist.* In the temporary absence of the pharmacist, only the pharmacist in charge may designate persons who may be present in the prescription department to perform technical and nontechnical functions designated by the pharmacist in charge. Activities identified in subrule 6.7(3) may not be performed during such temporary absence of the pharmacist. A temporary absence is an absence of short duration not to exceed two hours. In the absence of the pharmacist, the pharmacy shall notify the public that the pharmacist is temporarily absent and that no prescriptions will be dispensed until the pharmacist returns.

6.7(3) *Activities prohibited in absence of pharmacist.* Activities which shall not be designated and shall not be performed during the temporary absence of the pharmacist include:

a. Dispensing or distributing any prescription drugs or devices to patients or others.

b. Providing the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order.

c. Conducting prospective drug use review or evaluating a patient's medication record for purposes identified in rule 657—8.21(155A).

d. Providing patient counseling, consultation, or drug information.

e. Making decisions that require a pharmacist's professional judgment such as interpreting or applying information.

f. Transferring prescriptions to or from other pharmacies.

657—6.8(124,155A) Prescription processing documentation. All prescriptions shall be dated and assigned a unique identification number that shall be recorded on the original prescription. The original prescription, whether transmitted orally, electronically, or in writing shall be retained by the pharmacy filling the prescription. Refill documentation shall include date of refill and the initials or other unique identification of the pharmacist. The name, strength, and either the manufacturer's or distributor's name or the National Drug Code (NDC) of the actual drug product dispensed shall be maintained and be readily retrievable.

657—6.9(124,155A) Transfer of prescription. The transmission of a prescription drug order from a pharmacy to a pharmacy engaged in centralized prescription filling or processing on behalf of the originating pharmacy pursuant to the requirements of 657—Chapter 18 shall not constitute the transfer of a prescription. Upon the request of a patient or the patient's caregiver, a pharmacy shall transfer original prescription drug order information and prescription refill information to a pharmacy designated by the patient or the patient's caregiver, central fill or processing pharmacies excepted, subject to the following requirements:

6.9(1) *Schedule III, IV, or V prescriptions.* The transfer of original prescription drug order information for controlled substances listed in Schedule III, IV, or V is permissible between pharmacies on a one-time basis except as provided in subrule 6.9(9).

6.9(2) *Noncontrolled substances prescriptions.* The transfer of original prescription drug order information for noncontrolled prescription drugs between pharmacies is permissible as long as the number of transfers does not exceed the number of originally authorized refills and the original prescription is still valid.

6.9(3) *Communication.* The transfer is communicated directly between pharmacists or as authorized in subrule 6.9(9).

6.9(4) *Prescriptions maintained.* Both the original and the transferred prescription drug orders are maintained for a period of two years from the date of last refill.

6.9(5) *Record of transfer out.* The pharmacist transferring the prescription drug order information shall:

a. Invalidate the prescription drug order;

b. Record on or with the invalidated prescription drug order the following information:

(1) The name, address, and, for a controlled substance, the DEA registration number of the pharmacy to which such prescription is transferred;

(2) The name of the pharmacist receiving the prescription drug order information;

(3) The name of the pharmacist transferring the prescription drug order information; and

(4) The date of the transfer.

6.9(6) *Original prescription status.* The original prescription drug order shall be invalidated in the data processing system for purposes of filling or refilling, but shall be maintained in the data processing system for refill history purposes.

6.9(7) *Controlled substance prescription status.* The data processing system shall have a mechanism to prohibit the transfer or refilling of controlled substance prescription drug orders that have been previously transferred.

6.9(8) *Record of transfer received.* The pharmacist receiving the transferred prescription drug order information shall:

a. Indicate that the prescription drug order has been transferred;

b. Record on or with the transferred prescription drug order the following information:

(1) Original date of issuance and date of dispensing, if different from date of issuance;

(2) Original prescription number;

(3) Number of valid refills remaining, the date of last refill, and, for a controlled substance, the dates and locations of all previous refills;

(4) Name, address, and, for a controlled substance, the DEA registration number of the pharmacy from which such prescription drug order information is transferred;

(5) The date of the transfer;

(6) Name of the pharmacist receiving the prescription drug order information;

(7) Name of the pharmacist transferring the prescription drug order information; and

(8) If transferring a controlled substance prescription from a pharmacy utilizing a shared electronic database system as described in subrule 6.9(9) to a pharmacy outside that shared system, the pharmacy name, location, DEA registration number, and prescription number from which the prescription was originally filled.

6.9(9) *Electronic transfer between pharmacies.* Pharmacies electronically accessing the same prescription drug order records via a real-time, on-line database may electronically transfer prescription information, including controlled substance prescription information, up to the maximum refills permitted by law and the prescriber's authorization, if the following requirements are met.

a. The data processing system shall have a mechanism to send a message to the transferring pharmacy containing the following information:

(1) The fact that the prescription drug order was transferred;

(2) The unique identification number of the prescription drug order transferred;

(3) The name, address, and DEA registration number of the pharmacy to which the prescription drug order was transferred and the name of the pharmacist receiving the prescription information; and

(4) The date and time of transfer.

b. A pharmacist in the transferring pharmacy shall review the message and document the review by signing and dating a hard copy of the message or logbook containing the information required on the message as soon as practical, but in no event more than 72 hours from the time of such transfer.

c. For transfers of controlled substance prescriptions, all information requirements included in subrules 6.9(1) and 6.9(3) through 6.9(8) shall be satisfied in the electronic system. Transfers of controlled substance prescriptions shall also identify the pharmacy name, address, DEA registration number, and prescription number from which the prescription was originally filled.

657—6.10(126,155A) Prescription label requirements.

6.10(1) *Required information.* The label affixed to or on the dispensing container of any prescription drug or device dispensed by a pharmacy pursuant to a prescription drug order shall bear the following:

a. Serial number (a unique identification number of the prescription);

b. The name, telephone number, and address of the pharmacy;

c. The name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner;

d. The name of the prescribing practitioner;

e. The date the prescription is dispensed;

f. The directions or instructions for use, including precautions to be observed;

g. Unless otherwise directed by the prescriber, the label shall bear the name, strength, and quantity of the drug dispensed.

(1) If a pharmacist selects an equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label shall identify the generic drug and may identify the brand name drug for which the selection is made, such as "(generic name) Generic for (brand name product)."

(2) If a pharmacist selects a brand name drug product for a generic drug product prescribed by a practitioner, the prescription container label shall identify the brand name drug product dispensed and may identify the generic drug product ordered by the prescriber, such as "(brand name product) for (generic name)";

h. The initials or other unique identification of the dispensing pharmacist.

6.10(2) *Exceptions.* The requirements of subrule 6.10(1) do not apply to unit dose dispensing systems, 657—22.1(155A); sterile products, 657—Chapter 13; and patient med paks, 657—22.5(126,155A).

657—6.11 and **6.12** Reserved.

657—6.13(155A) Patient record system.

6.13(1) *Information required.* A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall be responsible for obtaining, recording, and maintaining the following information:

a. Full name of the patient for whom the drug is intended;

b. Address and telephone number of the patient;

c. Patient's age or date of birth;

d. Patient's gender;

e. Known allergies;

f. Significant patient information including a list of all prescription drug orders dispensed by the pharmacy during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and

g. Pharmacist comments relevant to the individual's drug therapy, including:

(1) Known drug reactions,

(2) Identified idiosyncrasies,

(3) Known chronic conditions or disease states of the patient,

(4) The identity of any other drugs, over-the-counter drugs, herbals, other alternative medications, or devices currently being used by the patient that may relate to prospective drug review.

6.13(2) *Record retained.* A patient record shall be maintained for a period of not less than two years from the date of the last entry in the patient record. This record may be a hard copy or a computerized form.

6.13(3) *Confidential.* Information in the patient record shall be deemed to be confidential and may be released only as provided in rule 657—8.16(124,155A).

657—6.14(155A) Patient counseling and instruction.

6.14(1) *Counseling required.* Upon receipt of a new prescription drug order and following a prospective drug use review pursuant to 657—8.21(155A), a pharmacist shall counsel each patient or patient's caregiver. An offer to counsel shall not fulfill the requirements of this rule. Patient counseling shall be on matters which, in the pharmacist's professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

a. The name and description of the drug;

b. The dosage form, dose, route of administration, and duration of drug therapy;

c. Intended use of the drug, if known, and expected action;

d. Special directions and precautions for preparation, administration, and use by the patient;

e. Common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

f. Techniques for self-monitoring drug therapy;

g. Proper storage;

h. Prescription refill information;

i. Action to be taken in the event of a missed dose;

j. Pharmacist comments relevant to the individual's drug therapy including any other information peculiar to the specific patient or drug.

6.14(2) *Instruction.* A pharmacist may instruct patients and demonstrate procedures for self-monitoring of medical conditions and for self-administration of drugs.

6.14(3) *Counseling area.* A pharmacy shall contain an area which is suitable for confidential patient counseling. Such area shall:

a. Be easily accessible to both patient and pharmacists and not allow patient access to prescription drugs;

b. Be designed to maintain the confidentiality and privacy of the pharmacist/patient communication.

6.14(4) *Oral counseling not practicable.* If in the pharmacist's professional judgment oral counseling is not practicable, the pharmacist may use alternative forms of patient information. "Not practicable" refers to patient variables including, but not limited to, the absence of the patient or patient's caregiver, the patient's or caregiver's hearing impairment, or a language barrier. "Not practicable" does not include pharmacy variables such as inadequate staffing, technology failure, or high prescription volume. Alternative forms of patient information may include written information leaflets, pictogram labels, video programs, or information generated by electronic data processing equipment. When used in place of oral counseling, alternative forms of patient information shall advise the patient or caregiver that the pharmacist may be contacted for consultation in person at the pharmacy by toll-free telephone or collect telephone call. A combination of oral counseling and alternative forms of counseling is encouraged.

6.14(5) *Exception.* Patient counseling, as described above, shall not be required for inpatients of an institution where other licensed health care professionals are authorized to administer the drugs.

6.14(6) *Refusal of consultation.* A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A patient's or caregiver's refusal of consultation shall be documented by the pharmacist. The absence of any record of a refusal of the pharmacist's attempt to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.

657—6.15(124,126) Return of drugs and other items. For the protection of the public health and safety, prescription drugs and devices, controlled substances, and items of personal contact nature may be returned to the pharmacy for reuse or resale only as herein provided:

6.15(1) *Integrity maintained.* Prescription drugs and devices may be returned, exchanged, or resold only if, in the professional judgment of the pharmacist, the integrity of the prescription drug has not in any way been compromised.

6.15(2) *Controlled substances.* Under no circumstances shall pharmacy personnel accept from a patient or a patient's agent any controlled substances for return, exchange, or resale except to the same patient.

6.15(3) *Unit dose returns.* Prescription drugs dispensed in unit dose packaging, excluding controlled substances, may be returned and reused as authorized in 657—subrule 22.1(6).

6.15(4) *Personal contact items.* Pharmacy personnel shall not accept for reuse or resale any items of personal contact nature that have been removed from the original package or container after sale.

657—6.16(124,155A) Records. Every inventory or other record required to be kept under Iowa Code chapters 124 and 155A or rules of the board shall be kept by the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of the inventory or record except as specifically identified by law or rule. Controlled substance records shall be maintained in a readily retrievable manner in accordance with federal requirements and 657—Chapter 10.

6.16(1) *Combined records.* If controlled substances, prescription drugs, or nonprescription drug items are listed on the same record, the controlled substances shall be asterisked, red-lined, or in some other manner made readily identifiable from all other items appearing on the records.

6.16(2) *Prescriptions maintained.* The original prescription drug order shall be maintained for a period of two years following the date of last activity on the prescription.

6.16(3) *Number imprinted.* The original hard-copy prescription shall be imprinted with the prescription or control number assigned to the prescription drug order.

6.16(4) *Alternative data retention system.* Records, except when specifically required to be maintained in original or hard-copy form, may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

a. The records maintained in the alternative system contain all of the information required on the manual record; and

b. The data processing system is capable of producing a hard copy of the record, within two business days, upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

These rules are intended to implement Iowa Code sections 124.301, 124.303, 124.306, 126.10, 126.11, 155A.6, 155A.13, 155A.27, 155A.28, 155A.31, and 155A.33 through 155A.36.

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