

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 responsibilities identified in rule 657—8.3(155A).

[ARC 8673B, IAB 4/7/10, effective 6/1/10; ARC 0501C, IAB 12/12/12, effective 1/16/13; ARC 1961C, IAB 4/15/15, effective 5/20/15]

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

1. A reference including all pertinent Iowa laws, rules, and regulations that impact the pharmacy's practice.
2. A patient information reference that includes or provides patient information in compliance with rule 657—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.

[ARC 2196C, IAB 10/14/15, effective 11/18/15]

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 657—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 and of the provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs, including those collected through an authorized collection program, records for such drugs and authorized collection program activities, and patient records as provided in 657—Chapters 10 and 21 and federal regulations for authorized controlled substance collection programs, which can be found at www.deadiversion.usdoj.gov/drug_disposal/.

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 subrules 6.7(2) and 6.7(4).

6.7(2) Temporary absence of pharmacist. In the temporary absence of the pharmacist, only the pharmacist in charge may designate pharmacy technicians or pharmacy support persons who may be present in the prescription department to perform technical or nontechnical functions, respectively, 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.

a. In the absence of the pharmacist, the pharmacy shall be secured from public access and the pharmacy shall notify the public that the pharmacist is temporarily absent and that no prescriptions will be dispensed until the pharmacist returns. If the pharmacist in charge has authorized the presence in the pharmacy of a pharmacy technician or a pharmacy support person to perform designated functions when the pharmacy is closed, the pharmacy technician or the pharmacy support person may not dispense or deliver any drug, chemical, device, or prepared prescription to a patient or patient's agent.

b. A pharmacy technician or a pharmacy support person who is present in the pharmacy when the pharmacy is closed shall prepare and maintain in the pharmacy a log identifying each period of time that the pharmacy technician or pharmacy support person worked in the pharmacy while the pharmacy was closed and identifying each activity performed during that time period. Each entry shall be dated, and each daily record shall be signed by the pharmacy technician or pharmacy support person who prepared the record. The log shall be periodically reviewed by the pharmacist in charge, and documentation of such review shall be maintained for two years from the date of entry.

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.

6.7(4) *Refill sales during pharmacist break.* At the discretion of the on-duty supervising pharmacist and pursuant to established policies and procedures, the pharmacist may delegate to a technician the dispensing of previously verified prescriptions which have been identified to not require pharmacist counseling pursuant to rule 657—6.14(155A) when the pharmacist is on a break of limited duration and is absent from the pharmacy department.

6.7(5) *Minimum physical security and monitoring system requirements.* Each pharmacy located in Iowa shall develop and implement policies and procedures to ensure appropriate physical security and monitoring of the pharmacy to prevent unauthorized access to prescription drugs, including controlled substances, and pharmacy records. The physical security and monitoring shall include the components identified herein, and the policies and procedures shall establish the utilization of such components commensurate with the pharmacy operation. The policies and procedures shall establish the retention of documentation of activities or recordings retained from the alarm and video surveillance systems, as well as contingencies when the systems are temporarily unavailable.

- a. No later than July 6, 2023, a basic alarm system.
- b. No later than July 6, 2023, a video surveillance system, except in areas where drugs are stored in an automated medication dispensing system or an alternative electronic storage unit which uses biometric restricted access or other electronic monitoring mechanism.
- c. Controlled access to computer records.
- d. A designated location that can be monitored, away from drug storage and handling areas, where personal items of pharmacy staff may be stored while on site.

[ARC 8673B, IAB 4/7/10, effective 6/1/10; ARC 1308C, IAB 2/5/14, effective 3/12/14; ARC 2408C, IAB 2/17/16, effective 3/23/16; ARC 3638C, IAB 2/14/18, effective 3/21/18; ARC 4189C, IAB 12/19/18, effective 1/23/19; ARC 6330C, IAB 6/1/22, effective 7/6/22]

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, except as provided in 657—subrule 21.5(1). The original prescription shall be retained by the pharmacy filling the prescription and shall be maintained in the original format as received by the pharmacy. Dispensing documentation shall include the date of fill or refill; the name, strength, and National Drug Code (NDC)

of the actual drug product dispensed; and the initials or other unique identification of the pharmacist, pharmacist-intern, or technician in an approved technician product verification program. Dispensing documentation shall be maintained and be readily available.

[ARC 3638C, IAB 2/14/18, effective 3/21/18; ARC 5007C, IAB 3/25/20, effective 4/29/20]

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(8).

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) Authorized individuals and means of transmission. Individuals authorized to engage in the transfer of prescriptions include a pharmacist, a pharmacist-intern under the direct supervision of a pharmacist, and a certified pharmacy technician, except as prohibited in 657—subrule 3.23(1). The transferring individual may transmit the prescription and transfer information required under subrule 6.9(5) from the transferring pharmacy via electronic means pursuant to subrule 6.9(8) or, following direct communication between authorized individuals, via oral or facsimile transmission. The receiving individual shall ensure the prescription transfer record maintained in the receiving pharmacy contains all of the information required under subrule 6.9(7).

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 activity.

6.9(5) Record of transfer out. The individual 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 individual receiving the prescription drug order information;
 - (3) The name of the individual 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) Record of transfer received. The individual 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 individual receiving the prescription drug order information;
- (7) Name of the individual 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(8) 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(8) *Electronic transfer between pharmacies.* Pharmacies may electronically transfer prescription information, including controlled substance prescription information in compliance with federal regulations for controlled substances. For transfers of prescriptions for noncontrolled substances and controlled substances, pharmacies that share a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization. A prescription for a controlled substance transferred between two pharmacies which do not share a real-time, online database may only be transferred one time.

[ARC 7634B, IAB 3/11/09, effective 4/15/09; ARC 8169B, IAB 9/23/09, effective 10/28/09; ARC 0343C, IAB 10/3/12, effective 11/7/12; ARC 3638C, IAB 2/14/18, effective 3/21/18; ARC 4189C, IAB 12/19/18, effective 1/23/19; ARC 5542C, IAB 4/7/21, effective 5/12/21]

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, except as provided in 657—subrule 8.19(7) for epinephrine auto-injectors, 657—subrule 8.19(8) for opioid antagonists, or 657—subrule 8.19(9) for expedited partner therapy.
- 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)”;

(3) If a pharmacist selects an interchangeable biological product for the biological product prescribed by a practitioner, the prescription container label shall identify the interchangeable biological product dispensed and may identify the biological product prescribed by the practitioner, such as “(interchangeable biological product) for (biological product)”;

h. The initials or other unique identification of the dispensing pharmacist, unless the identification of the pharmacist involved in each step of the prescription filling process is electronically documented and retrievable.

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

[ARC 2194C, IAB 10/14/15, effective 11/18/15; ARC 2414C, IAB 2/17/16, effective 3/23/16; ARC 3638C, IAB 2/14/18, effective 3/21/18; ARC 4903C, IAB 2/12/20, effective 3/18/20]

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 contain, at a minimum, the following information:

- a. Full name of the patient;
- b. Address and telephone number of the patient;
- c. Patient's date of birth;
- d. Patient's gender;
- e. Known allergies;
- f. 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 dispensed, and the name of the prescriber; and
- g. Pharmacist comments relevant to the patient's health care, 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, supplements, 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).

6.13(4) Expedited partner therapy. When a pharmacy dispenses a prescription drug pursuant to Iowa Code section 139A.41 and 657—subrule 8.19(9) for expedited partner therapy, a pharmacy is only required to maintain the information about the patient who is known to the pharmacy.

[ARC 3638C, IAB 2/14/18, effective 3/21/18; ARC 4903C, IAB 2/12/20, effective 3/18/20]

657—6.14(155A) Patient counseling and instruction. Every pharmacy that is open to the public and located in Iowa shall post in every prescription pickup area, including in every drive-through prescription pickup lane, in a manner clearly visible to patients, a notice that Iowa law requires the pharmacist to discuss with the patient any prescriptions dispensed to the patient that are new or a change in drug therapy.

6.14(1) Counseling required. Upon receipt of a new prescription drug order, or upon receipt of a change in drug therapy including but not limited to a change of dose, directions, or drug formulation, and following a prospective drug use review pursuant to rule 657—8.21(155A), a pharmacist or pharmacist-intern 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 select and use alternative forms of patient information which shall include information for the patient or patient's caregiver to contact the pharmacist for further consultation. The manner in which the patient or caregiver contacts the pharmacist shall not cause the patient to incur any expense. "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 disorder, or a language barrier. "Not practicable" does not include pharmacy variables such as inadequate staffing, technology failure, or high prescription volume. 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 counseling was provided.

[ARC 8540B, IAB 2/24/10, effective 4/1/10; ARC 9910B, IAB 12/14/11, effective 1/18/12; ARC 3638C, IAB 2/14/18, effective 3/21/18; ARC 5913C, IAB 9/22/21, effective 10/27/21]

657—6.15(124,126) Return of drugs and devices. For the protection of the public health and safety, prescription drugs and devices 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 or device 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).

[ARC 3638C, IAB 2/14/18, effective 3/21/18]

657—6.16(124,155A) Records. Every 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 record or last activity except as specifically identified by law or rule. Controlled substances 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) Storage of records. Original hard-copy prescriptions and other pharmacy records shall be maintained by the pharmacy for a minimum of two years from the date of the record in accordance with this subrule.

a. Records shall be maintained within the licensed pharmacy department for a minimum of 12 months, except as provided herein. Pharmacy records less than 12 months old may be stored in a secure storage area outside the licensed pharmacy department, including at a remote location, if the pharmacy

has retained an electronic copy of the records in the pharmacy that is immediately available and if the original records are available within 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

b. Records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department, including at a remote location, if the records are retrievable within 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

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, except as provided in 657—subrule 21.5(1).

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;

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; and

c. The information maintained in the alternative system is not obscured or rendered illegible due to security features of the original record.

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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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◊ Two or more ARCs