

ILLINOIS REGISTER

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF EMERGENCY AMENDMENT

TITLE 68: PROFESSIONS AND OCCUPATIONS

CHAPTER VII: DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

SUBCHAPTER b: PROFESSIONS AND OCCUPATIONS

PART 1330

PHARMACY PRACTICE ACT OF 1987

Section

- 1330.5 Definitions
- 1330.10 Application for Certificate of Registration as a Pharmacy Technician
- 1330.20 Approval of Pharmacy Programs
- 1330.30 Graduates of Programs Not Approved Pursuant to the Provisions of Section 1330.20
- 1330.40 Application for Examination
- 1330.50 Examination for Licensure
- 1330.55 Application for Licensure on the Basis of Examination
- 1330.60 Endorsement
- 1330.65 Patient Counseling
- 1330.70 Definitions (Renumbered)
- 1330.75 Security Requirements
- 1330.76 Reporting Theft or Loss of Controlled Substances
- 1330.80 Violations
- 1330.90 Divisions of Pharmacy Licenses
- 1330.91 Division I Pharmacies

EMERGENCY

- 1330.92 Division II Pharmacies
- 1330.93 Division III Pharmacies
- 1330.94 Division IV Pharmacies
- 1330.95 Division V Pharmacies
- 1330.96 Nonresident Pharmacies
- 1330.98 Automated Dispensing and Storage Systems
- 1330.99 Parenteral Product Standards
- 1330.100 Application for a Pharmacy License
- 1330.110 Granting Variances
- 1330.120 Renewals
- 1330.130 Restoration
- 1330.140 Continuing Education

ILLINOIS REGISTER

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF EMERGENCY AMENDMENT

AUTHORITY: Implementing the Pharmacy Practice Act of 1987 [225 ILCS 85] and authorized by Section 2105-15 of the Civil Administrative Code of Illinois [20 ILCS 2105/2105-15].

SOURCE: Rules and Regulations Promulgated for the Administration of the Illinois Pharmacy Practice Act, effective August 20, 1975; amended March 8, 1977; amended at 4 Ill. Reg. 1234, effective July 11, 1980; amended at 5 Ill. Reg. 2997, effective March 11, 1981; codified at 5 Ill. Reg. 11049; emergency amendment at 6 Ill. Reg. 916, effective January 6, 1982, for a maximum of 150 days; amended at 6 Ill. Reg. 7448, effective June 15, 1982; amended at 7 Ill. Reg. 6496, effective June 30, 1983; amended at 9 Ill. Reg. 16918, effective October 23, 1985; amended at 10 Ill. Reg. 21913, effective December 17, 1986; transferred from Chapter I, 68 Ill. Adm. Code 330 (Department of Registration and Education) to Chapter VII, 68 Ill. Adm. Code 1330 (Department of Professional Regulation) pursuant to P.A. 85-225, effective January 1, 1988, at 12 Ill. Reg. 2957; amended at 12 Ill. Reg. 17394, effective October 14, 1988; amended at 16 Ill. Reg. 19811, effective December 7, 1992; amended at 21 Ill. Reg. 12600, effective August 29, 1997; amended at 22 Ill. Reg. 21959, effective December 1, 1998; amended at 23 Ill. Reg. 14131, effective November 18, 1999; amended at 24 Ill. Reg. 8548, effective June 9, 2000; amended at 27 Ill. Reg. 18338, effective December 13, 2002; amended at 27 Ill. Reg. 19389, effective December 11, 2003; emergency amendment at 29 Ill. Reg. _____, effective _____, for a maximum of 150 days;

Section 1330.91 Division I Pharmacies

EMERGENCY

- a) Retail pharmacies which engage in general community pharmacy practice and are open to, or offer pharmacy service to, the general public shall, in addition to any other requirements of the Act and this Part, comply with Section 1330.91. A retail pharmacy which, in addition to offering pharmacy services to the general public, provides pharmacy services to an institution or facility listed in Sections 1330.92(a) need not register as a Division II pharmacy if the sales do not exceed 49% of total sales, but the pharmacy shall comply with requirements of Sections 1330.92(b), (c) and (d).
- b) Recordkeeping Requirements for Filling Prescriptions
 - 1) Every prescription filled or refilled shall contain the name, initials or other unique identifier of the person authorized to practice pharmacy under the provisions of the Pharmacy Practice Act who fills or refills the prescription. Additionally, the label affixed to the drug container must

ILLINOIS REGISTER

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF EMERGENCY AMENDMENT

indicate the name, initials or other unique identifier of the person(s) authorized to practice pharmacy in the State of Illinois who filled or refilled the prescription. No prescription may be filled or refilled for a period in excess of one year from the date of the original issuance of the prescription by the prescriber.

- 2) Whenever a prescription is filled or refilled, by a registered pharmacy technician under the supervision of a pharmacist, the prescription shall contain the names, initials or other unique identifier of both the supervising pharmacist and the registered pharmacy technician who fills or refills the prescription. Additionally, the label affixed to the drug container must indicate the initials of the pharmacy technician and pharmacist.
- 3) Refilling a Prescription
 - A) Each refilling of a prescription shall be entered on the prescription or on another appropriate, uniformly maintained, readily retrievable record, which indicates by the number of the prescription the following information:
 - i) The name and dosage form of the drug;
 - ii) The date of each refilling;
 - iii) The quantity dispensed;
 - iv) The name or initials of the pharmacist and the pharmacy technician, if applicable, in each refilling; and
 - v) The total number of refills for the prescription.
 - B) If the pharmacist doesn't otherwise indicate in a uniformly maintained record, he/she shall be deemed to have dispensed a refill for the full face amount of the prescription.
- 4) Presentation of a written prescription copy or prescription label shall be for information purposes only and has no legal status as a valid prescription order. The recipient pharmacist of the copy or prescription

ILLINOIS REGISTER

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF EMERGENCY AMENDMENT

label shall contact the prescribing practitioner to obtain a new prescription order.

- 5) A pharmacist providing a copy of a prescription to an ultimate consumer for the purpose of transfer or any other purpose shall cancel the uniformly maintained record and record the date the copy is issued, to whom issued and his/her name, initials or unique identifier. Copies of prescriptions shall be marked "For Information Purposes Only" and require a new prescription from the prescriber.
- 6) Subject to Section 18 of the Act, any information which is required to be kept pursuant to this Section may be recorded and stored in a computerized pharmaceutical information system which meets the standards of performance required by the regulations of the Drug Enforcement Administration (21 CFR 1306) (1998), and which contain no further amendments or editions, and shall include the capability to:
 - A) Retrieve the original prescription order information for those prescription orders which are currently authorized for refilling;
 - B) Retrieve the current prescription orders which shall, at a minimum, include name of drug, date of refill, quantity dispensed, name and identification code of the manufacturer in the case of a generically written prescription or a generic interchange, name or initials of the dispensing pharmacist and technician for each refill and the total number of refills dispensed to date;
 - C) Supply documentation of refill information entered by the pharmacist using the system by way of a hard copy printout of each day's refill data which has been verified for correctness. This printout must include for each prescription filled at least the following information:
 - i) The name and dosage form of the drug;
 - ii) The date of each refilling;
 - iii) The quantity dispensed;

ILLINOIS REGISTER

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF EMERGENCY AMENDMENT

- iv) The name or initials of the pharmacist in each refilling and the pharmacy technician, if applicable;
- v) The patient's name;
- vi) The prescriber's name; and
- vii) The prescription number for the prescription.

In lieu of the printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in the dispensing shall sign a statement each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him/her and is correct as shown. The book or file must be maintained at the pharmacy employing the system for a period of 5 years after the date of dispensing the appropriately authorized refill.

- 7) All refill data shall be maintained by the pharmacy on the premises for 5 years in accordance with Section 18 of the Act. The pharmacy shall have the appropriate equipment on the premises to provide readily retrievable information in the course of an on-site inspection. A hard copy printout shall be provided to the ~~Division~~Department upon request within 48 hours.

c) Transfer of Prescription Information

- 1) A prescription may be transferred between pharmacies for the purpose of original fill or refill dispensing provided that:
 - A) The transferor pharmacist invalidates the prescription on file and records to whom transferred, the date of issuance of such copy and the name of the transferor pharmacist issuing the transferred prescription order; and
 - B) The transferee pharmacist, upon receiving the prescription directly from another pharmacist, records the following:

ILLINOIS REGISTER

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF EMERGENCY AMENDMENT

- i) The name, address and original prescription number of the pharmacy from which the prescription was transferred;
 - ii) All information constituting a prescription order including the following: name of the drug, original amount dispensed, date of original issuance of the prescription and number of valid refills remaining; and
 - C) The transferee pharmacist informs the patient that the original prescription has been cancelled at the pharmacy from which it has been transferred.
- 2) A prescription for Schedule III, IV and V drugs may be transferred only from the original pharmacy and only one time for the purpose of refill dispensing and may not be transferred further. However, a pharmacist who is electronically sharing real-time on line computerized systems may transfer up to the maximum refills permitted by law and the prescriber's authorization in accordance with CFR 1306.26(a).
- 3) Computerized systems must satisfy all information requirements of this subsection (c), including invalidation of the original prescription when transferred between pharmacies accessing the same prescription records or between pharmacies of the same ownership. If those systems that access the same prescription records have the capability of cancelling the original prescription, pharmacies using such a system are exempt from the requirements of this subsection (c) if the transferred prescription can always be tracked to the original prescription order from the prescribing practitioner and the original prescription can be produced.
- d) Staffing of the Pharmacy
 - 1) Whenever the hours of the pharmacy (prescription department) differ from those of the establishment in which the pharmacy is located, there shall be compliance with the following:
 - A) The schedule during which the practice of pharmacy is carried on in the pharmacy shall be conspicuously displayed.

ILLINOIS REGISTER

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF EMERGENCY AMENDMENT

- B) Whenever an establishment housing a pharmacy is open and a pharmacist is not present and available to provide pharmaceutical services as defined in Section 3 of the Act, a sign shall be conspicuously displayed stating in all capital letters:
PHARMACIST NOT ON DUTY; STATE LAW PROHIBITS FILLING OF PRESCRIPTIONS IN THE ABSENCE OF A PHARMACIST.
 - C) No prescription may be dispensed when a pharmacist is not physically present in the establishment and on duty.
- 2) The pharmacy must provide pharmaceutical services, as defined in Section 3 of the Act, to the public a minimum of 40 hours per week. A pharmacy is considered providing Pharmaceutical Services when a pharmacist is physically present in the establishment and available for consultation.
- e) Pharmacist-in-Charge
- 1) No pharmacy shall be granted a certificate of licensure without a pharmacist being designated on the pharmacy license as pharmacist-in-charge. No pharmacist shall be designated as a pharmacist-in-charge on more than one pharmacy license. The responsibilities of such pharmacist-in-charge shall include:
 - A) Supervision of all activities of all employees as they relate to the practice of pharmacy;
 - B) Establishment and supervision of the method and manner for storage and safekeeping of pharmaceuticals, including maintenance of security provisions to be used when the pharmacy is closed as set forth in Section 1330.75; and
 - C) Establishment and supervision of the recordkeeping system for the purchase, sale, delivery, possession, storage and safekeeping of drugs.

ILLINOIS REGISTER

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF EMERGENCY AMENDMENT

- 2) The operations of the pharmacy and the establishment and maintenance of security provisions are the dual responsibility of the pharmacist-in-charge and the owner of the pharmacy.
- 3) Within 10 days after the change of a pharmacist-in-charge, the Division~~Department~~ shall be so notified in writing by the departing pharmacist-in-charge.
- 4) In addition to notifying the Division~~Department~~ within 10 days, the departing pharmacist-in-charge shall, on the effective date of the change, inventory the following controlled substances:
 - A) All Schedule II drugs, as defined in the Illinois Controlled Substance Act, by actual physical count; and
 - B) All other scheduled drugs, as defined in the Illinois Controlled Substance Act, by estimated count.
- 5) The inventory shall constitute, for the purpose of this Section, the closing inventory of the departing pharmacist-in-charge and the initial inventory of the incoming pharmacist-in-charge. This inventory record shall be preserved in the pharmacy for a period of 5 years. An affidavit attesting to the completion of the inventory and preservation of the inventory record, bearing the date of the inventory and the signatures of the departing and incoming pharmacist-in-charge, shall be submitted to the Department of Financial and Professional Regulation – Division of Professional Regulation, at its principal office, within 10 days after the change in the pharmacist-in-charge.
- 6) Failure on the part of a registrant to provide the information required in subsections (e)(4) and (5)~~above~~ shall be grounds for denying an application or renewal application for a pharmacy license or for disciplinary action against a registrant. Such action shall be based on the recommendation of the Board.
- 7) When the accuracy, relevance or completeness of any submitted documentation is reasonably questioned by the Division~~Department~~, because of a lack of information, discrepancies or conflicts in information given, or a need for clarification, the registrant will be required to:

ILLINOIS REGISTER

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF EMERGENCY AMENDMENT

- A) Provide such information as may be necessary; and/or
 - B) Explain such relevance or completeness during an oral interview;
or
 - C) Appear for an oral interview before the Board when the information available to the Board is insufficient to evaluate compliance with this Section.
- f) Pharmacists and pharmacies are prohibited from accepting from patients or their agents for reuse, reissue or resale any dispensed medications, chemicals, poisons or medical devices except for:
- 1) Medical devices which can be properly sanitized prior to reuse, resale or re-rent; and
 - 2) Medications and medical devices that are dispensed and stored under conditions defined and supervised by the pharmacist and are unopened in sealed, intact and unaltered containers that meet the standards for light, moisture and air permeation as defined by the current United States Pharmacopoeia (U.S.P.)/National Formulary or by the United States Pharmacopoeial Convention, Inc.
- g) Pharmacies that compound and dispense parenteral products shall comply with Section 1330.99 of this Part.
- h) Pharmacies that utilize automated dispensing and storage systems shall comply with Section 1330.98 of this Part.
- i) The development and implementation of a procedure to be utilized in the event of a drug recall that can be readily activated to assure that all drugs included on the recall are returned to the pharmacy for proper disposition.
- j) Duty of Division I Pharmacy to Dispense Contraceptives
- 1) Upon receipt of a valid, lawful prescription for a contraceptive, a pharmacy must dispense the contraceptive, or a suitable alternative permitted by the prescriber, to the patient or the patient's agent without

ILLINOIS REGISTER

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF EMERGENCY AMENDMENT

delay. If the contraceptive, or a suitable alternative, is not in stock, the pharmacy must obtain the contraceptive under the pharmacy's standard procedures for ordering contraceptive drugs not in stock, including the procedures of any entity that is affiliated with, owns, or franchises the pharmacy. However, if the patient prefers, the prescription must either be transferred to a local pharmacy of the patient's choice or returned to the patient, as the patient directs.

- 2) For the purposes of this subsection (j), the term "contraceptive" shall refer to all FDA-approved drugs or devices that prevent pregnancy.

(Source: Amended by emergency rulemaking at 29 Ill. Reg. _____, effective _____, for a maximum of 150 days)