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Administrative Code Division
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DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF ADOPTED AMENDMENTS

- 1) Heading of the Part: Pharmacy Practice Act
- 2) Code Citation: 68 Ill. Adm. Code 1330
- 3)

<u>Section Numbers:</u>	<u>Adopted Actions:</u>
1330.30	Amendment
1330.700	Amendment
- 4) Statutory Authority: Implementing the Pharmacy Practice Act [225 ILCS 85] and authorized by Section 2105-15 of the Civil Administrative Code of Illinois [20 ILCS 2105/2105-15].
- 5) Effective Date of Rules: August 18, 2017
- 6) Does this rulemaking contain an automatic repeal date? No
- 7) Does this rulemaking contain incorporations by reference? No
- 8) A copy of the adopted rules, including any material incorporated by reference, is on file in the principal office of the Division of Professional Regulation and is available for public inspection.
- 9) Notice of Proposal published in the *Illinois Register*: 41 Ill. Reg. 1283; February 10, 2017
- 10) Has JCAR issued a Statement of Objection to this rulemaking? No
- 11) Differences between Proposal and Final Version: The Department made a clarification to an existing provision that was not modified in the proposed rulemaking per a request from a public comment that the current rule more specifically address the current provision that on-site and off-site institutional pharmacies are exempt from the specific counseling requirements set forth in Section 1330.700, unless dispensing to a patient being discharged from the institution. The Department agreed to amend the language of Section 1330.700(f) to read: "A pharmacist at an on-site or off-site institutional pharmacy shall not be required to provide patient counseling as required in this Section unless drugs are dispensed by the pharmacy upon a patient's discharge from the institution."
- 12) Have all changes agreed upon by the Agency and JCAR been made as indicated in the agreements issued by JCAR? None were made.

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- 13) Will this rulemaking replace an emergency rule currently in effect? No
- 14) Are there any rulemakings pending on this Part? No
- 15) Summary and Purpose of Rulemaking: This adopted rulemaking mandated pharmacists to counsel patients on pertinent medication information, including potential drug interactions (This changes the current "offer" to counsel). It also added a requirement for signage notifying customers of the above requirement and provides that failure of a pharmacist to provide counseling or attempts to circumvent counseling requirements constitutes unprofessional and unethical conduct. The purpose of this adopted rulemaking is to help reduce medication error rates, including the harmful effects of adverse medication interactions that may result in admission to long-term care facilities, hospitals, and emergency rooms.
- 16) Information and questions regarding these adopted rules shall be directed to:

Department of Financial and Professional Regulation
Attention: Craig Cellini
320 West Washington, 3rd Floor
Springfield IL 62786

217/785-0813
fax: 217/557-4451

The full text of the Adopted Amendments begins on the next page:

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

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TITLE 68: PROFESSIONS AND OCCUPATIONS

CHAPTER VII: DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

SUBCHAPTER b: PROFESSIONS AND OCCUPATIONS

PART 1330

PHARMACY PRACTICE ACT

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- 1330.400 Application for a Pharmacy License
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- 1330.600 Security Requirements
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- 1330.630 Sanitary Standards
- 1330.640 Pharmaceutical Compounding Standards
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- 1330.660 Pharmacist-in-Charge
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SUBPART G: PHARMACY OPERATIONS

Section

- 1330.700 Patient Counseling
- 1330.710 Reporting Theft or Loss of Controlled Substances
- 1330.720 Transfer of Prescription
- 1330.730 Drug Prepackaging
- 1330.740 Multi-Med Dispensing Standards for Community Pharmacies
- 1330.750 Return of Drugs

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1330.760	Electronic Transmission of Prescriptions
1330.770	Centralized Prescription Filling
1330.780	Change of Ownership of a Pharmacy
1330.790	Closing a Pharmacy
1330.800	Pharmacy Self-Inspection

AUTHORITY: Implementing the Pharmacy Practice Act [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 26 Ill. Reg. 18338, effective December 13, 2002; amended at 27 Ill. Reg. 19389, effective December 11, 2003; emergency amendment at 29 Ill. Reg. 5586, effective April 1, 2005, for a maximum of 150 days; amended at 29 Ill. Reg. 13639, effective August 25, 2005; amended at 30 Ill. Reg. 14267, effective August 21, 2006; amended at 30 Ill. Reg. 16930, effective October 12, 2006; emergency amendment at 31 Ill. Reg. 16045, effective November 19, 2007, for a maximum of 150 days; amended at 32 Ill. Reg. 3262, effective February 21, 2008; amended at 32 Ill. Reg. 7116, effective April 16, 2008; old Part repealed at 34 Ill. Reg. 6688, effective April 29, 2010; new Part adopted at 34 Ill. Reg. 6690, effective April 29, 2010; amended at 39 Ill. Reg. 6267, effective April 23, 2015; amended at 41 Ill. Reg. 10643, effective August 18, 2017.

SUBPART A: GENERAL PROVISIONS

Section 1330.30 Unprofessional and Unethical Conduct

Unprofessional and unethical conduct by a licensee or registrant shall include, but not be limited to:

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- a) Failing to establish and maintain effective controls against diversion of prescription drugs.
- b) Committing theft or diversion, or attempting to commit theft or diversion, by a registrant or licensee.
- c) Making or filing a report or record that a pharmacist or pharmacy knows to be false or intentionally or negligently failing to file a report or keep records as required by the Act or this Part.
- d) Knowingly dispensing a prescription drug after the death of the person for whom the prescription was written.
- e) Billing or charging for quantities of drugs greater than that which was delivered or charging patients for a brand drug when a generic is dispensed.
- f) Submitting fraudulent billing or reports to a third party payer or claiming a fee for a service that is not performed or earned.
- g) Filling a prescription when a pharmacist knows, or reasonably should know, that no valid physician-patient relationship exists or failing to exercise sound professional judgment with respect to the accuracy and authenticity of any prescription/drug order dispensed.
- h) Failing to provide ensure that patient counseling in accordance with this Part, failing to respond to requests for patient counseling, attempting to circumvent patient counseling requirements, or otherwise discouraging patients from receiving patient counseling concerning their prescription medications~~is offered or refusing to respond to requests for patient counseling.~~
- i) Discriminating in any manner against a person or group based upon that person or group's religion, race, creed, color, gender, sexual orientation, age or national origin.
- j) Knowingly dispensing a prescription drug without a valid prescription. Dispensing or offering to dispense any drug not approved by the Food and Drug Administration (FDA), found in the USP-NF, or found on the list promulgated by the FDA for bulk drug substances that may be used to compound drug products.

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- k) Failing to keep one's self and one's apparel clean or to wear identification bearing name and designation.
- l) Directly or indirectly furnishing to a medical practitioner prescription order-blanks that refer to a specific pharmacist or pharmacy in any manner.
- m) Actively or passively participating in any arrangement or agreement in which a prescription order-blank is prepared, written, or issued in a manner that refers to a specific pharmacist or pharmacy. Pharmacy-branded enrollment forms, when a patient requests his or her prescriptions be filled at a specific pharmacy, and Risk Evaluation and Mitigation Strategies documents containing prescription information are not prohibited by this subsection.
- n) Dividing a prescription order unless directed by the prescriber, payer or patient or when the full quantity of that prescription medication is not available at that location.
- o) Committing dispensing errors that result in hospitalization of a patient or demonstrating a pattern and practice of dispensing errors.
- p) Committing an act or acts that are of a flagrant and obvious nature so as to constitute conduct of such a distasteful nature that accepted codes of behavior or codes of ethics are breached.
- q) Committing an act or acts in a relationship with a patient that violate common standards of decency or propriety.
- r) Willfully violating, or knowingly assisting in the violation of, any law relating to the use of habit-forming controlled substances.

(Source: Amended at 41 Ill. Reg. 10643, effective August 18, 2017)

SUBPART G: PHARMACY OPERATIONS

Section 1330.700 Patient Counseling

- a) Upon receipt of a new or refill prescription, a prospective drug regimen review or drug utilization evaluation shall be performed. [Prior to dispensing a prescription](#)

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to a new patient, a new medication to an existing patient, or a medication that has had a change in the dose, strength, route of administration or directions for use, the pharmacist, or a student pharmacist directed and supervised by the pharmacist, shall provide verbal counseling to the patient or patient's agent on pertinent medication information. An offer to counsel shall be made on all other prescriptions.~~An offer to counsel shall be made on all prescriptions. If the offer to counsel is accepted, the pharmacist or the student pharmacist, as directed and supervised by the pharmacist, shall counsel the patient or patient's agent using his or her professional judgment.~~ Counseling shall include, but is not limited to:

- 1) Name and description of medication;
 - 2) Dosage form and dosage;
 - 3) Route of administration;
 - 4) Duration of therapy;
 - 5) Techniques for self-monitoring;
 - 6) Proper storage;
 - 7) Refill information;
 - 8) Actions to be taken in cases of missed doses;
 - 9) Special directions and precautions for preparation, administration and use;
 - 10) Common severe side effects, adverse effects, or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur.
- b) If, in the pharmacist's professional judgment, oral counseling is not practicable for the patient or patient's agent, the pharmacist shall use alternative forms of patient information. When used in place of oral counseling, alternative forms of patient information shall advise the patient or agent that the pharmacist may be contacted for consultation in person at the pharmacy or by toll-free or collect telephone service.

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- c) Every licensed pharmacy directly serving patients at a physical location must conspicuously post a sign provided by the Division containing a statement that the patient has the right to counseling, the Division's consumer hotline number, information on how to file a complaint for failure to counsel, and any other information the Division deems appropriate. The sign must be printed in color ink or displayed electronically in color, measure at least 8½ x 11 inches in size, and be posted at either a cashier counter or waiting area clearly visible to patients. Licensed pharmacies that do not maintain a physical location directly serving patients must include a copy of the sign within any dispensed prescriptions. The sign will be available to download on the Division's website.
- d)e) The pharmacist is responsible for maintaining patient profiles as defined in Section 3(s) of the Act. A reasonable effort shall be made to obtain information, including, but not limited to, the following:
- 1) Name, date of birth (age), gender, address and telephone number;
 - 2) Individual history, when significant, including disease state, known allergies, drug interactions, and a comprehensive list of medications and relevant devices; and
 - 3) Pharmacist's comments relevant to the individual's therapy.
- e)d) Patient identifiable information obtained by the pharmacist or the pharmacist's designee for the purpose of patient record maintenance, prospective drug review, drug utilization review and patient counseling shall be considered protected health information, as defined in Section 3(cc) of the Act. A pharmacist shall provide counseling related to protected health information in a discreet, supportive and informative manner.
- f)e) A pharmacist at an on-site or off-site institutional pharmacy shall not be required to provide patient counseling as required in this Section unless when drugs are dispensed by the pharmacy upon a patient's discharge from the institution.
- g)f) Nothing in this Section shall be construed as requiring a pharmacist to provide counseling when a patient or patient's agent refuses such counseling. When a patient or patient's agent refuses to accept patient counseling as provided in this Section, that refusal shall be documented. ~~The absence of any record of a refusal~~

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~~to accept the offer to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.~~

- h)g) A pharmacist operating a remote pharmacy shall comply with the requirements of this Section. Counseling in those circumstances shall be done by both video and audio means.

(Source: Amended at 41 Ill. Reg. 10643, effective August 18, 2017)