The Department of Financial and Professional Regulation is posting these proposed amendments in an effort to make the public aware of possible changes that may have an impact on the profession.

The general public may submit written comments to the Department during the first 45 day public comment period. Any suggested changes will be considered by the Department and the appropriate Board.

These proposed amendments were published in the February 10, 2017 Illinois Register. The 45 day comment period will end March 27, 2017.

Please submit written comments to Craig Cellini as stated in the attached notice.

THESE PROPOSED CHANGES ARE NOT IN EFFECT AT THIS TIME AND THE ADOPTED RULES MAY DIFFER FROM THOSE ORIGINALLY PUBLISHED.

1) Heading of the Part: Pharmacy Practice Act

2) Code Citation: 68 Ill. Adm. Code 1330

3) Section Numbers: Proposed Actions:
   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) A Complete Description of the Subjects and Issues Involved: This rulemaking mandates pharmacists to counsel patients on pertinent medication information, including potential drug interactions (This changes the current ‘offer’ to counsel). It also adds 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 proposed 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.

6) Any published studies or reports, along with the sources of underlying data, that were used when comprising this rulemaking, in accordance with 1 Ill. Adm. Code 100.355: None
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

7) Will this rulemaking replace any emergency rulemaking currently in effect? No

8) Does this rulemaking contain an automatic repeal date? No

9) Does this rulemaking contain incorporations by reference? No

10) Are there any other proposed rulemakings pending on this Part? No

11) Statement of Statewide Policy Objectives: This rulemaking will not require a local government to establish, expand or modify its activities in such a way as to necessitate additional expenditures from local revenues.

12) Time, Place, and Manner in which interested persons may comment on this proposed rulemaking: Persons who wish to comment on this proposed rulemaking may submit written comments no later than 45 days after the publication of this Notice to:

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

   Phone: 217/785-0813     Fax: 217/557-4451

   All written comments received within 45 days after this issue of the Illinois Register will be considered.

13) Initial Regulatory Flexibility Analysis:

   A) Types of small businesses, small municipalities and not for profit corporations affected: Licensed pharmacists, pharmacy technicians, and pharmacies may be affected.

   B) Reporting, bookkeeping or other procedures required for compliance: None

   C) Types of professional skills necessary for compliance: Licensure pursuant to the Pharmacy Practice Act.

14) Regulatory Agenda on which this rulemaking was summarized: This rule was not included on either of the 2 most recent agendas.
NOTICE OF PROPOSED AMENDMENTS

The full text of the Proposed Amendments begins on the next page:
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

TITLE 68: PROFESSIONS AND OCCUPATIONS
CHAPTER VII: DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SUBCHAPTER b: PROFESSIONS AND OCCUPATIONS

PART 1330
PHARMACY PRACTICE ACT

SUBPART A: GENERAL PROVISIONS

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>1330.10</td>
<td>Definitions</td>
</tr>
<tr>
<td>1330.20</td>
<td>Fees</td>
</tr>
<tr>
<td>1330.30</td>
<td>Unprofessional and Unethical Conduct</td>
</tr>
<tr>
<td>1330.40</td>
<td>Violations</td>
</tr>
<tr>
<td>1330.50</td>
<td>Vaccinations/Immunizations</td>
</tr>
<tr>
<td>1330.60</td>
<td>Internet Pharmacies</td>
</tr>
<tr>
<td>1330.70</td>
<td>Granting Variances</td>
</tr>
<tr>
<td>1330.80</td>
<td>Renewals</td>
</tr>
<tr>
<td>1330.90</td>
<td>Restoration of a Pharmacist License</td>
</tr>
<tr>
<td>1330.100</td>
<td>Continuing Education</td>
</tr>
<tr>
<td>1330.110</td>
<td>Confidentiality</td>
</tr>
</tbody>
</table>

SUBPART B: PHARMACY TECHNICIAN

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>1330.200</td>
<td>Application for Certificate of Registration as a Pharmacy Technician</td>
</tr>
<tr>
<td>1330.210</td>
<td>Pharmacy Technician Training</td>
</tr>
<tr>
<td>1330.220</td>
<td>Application for Certificate of Registration as a Certified Pharmacy Technician</td>
</tr>
</tbody>
</table>

SUBPART C: PHARMACIST

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>1330.300</td>
<td>Approval of Pharmacy Programs</td>
</tr>
<tr>
<td>1330.310</td>
<td>Graduates of Programs Outside the United States</td>
</tr>
<tr>
<td>1330.320</td>
<td>Application for Examination</td>
</tr>
<tr>
<td>1330.330</td>
<td>Examination for Licensure</td>
</tr>
<tr>
<td>1330.340</td>
<td>Application for Licensure on the Basis of Examination</td>
</tr>
<tr>
<td>1330.350</td>
<td>Endorsement</td>
</tr>
</tbody>
</table>

SUBPART D: PHARMACY LICENSURE
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

Section
1330.400 Application for a Pharmacy License
1330.410 Pharmacy Licenses
1330.420 Emergency Remote Temporary Pharmacy License

SUBPART E: TYPES OF PHARMACIES

Section
1330.500 Community Pharmacy Services
1330.510 Telepharmacy
1330.520 Offsite Institutional Pharmacy Services
1330.530 Onsite Institutional Pharmacy Services
1330.540 Nuclear Pharmacy Services
1330.550 Nonresident Pharmacies
1330.560 Remote Prescription/Medication Order Processing

SUBPART F: PHARMACY STANDARDS

Section
1330.600 Security Requirements
1330.610 Pharmacy Structural/Equipment Standards
1330.620 Electronic Equipment Requirements for Remote Pharmacies
1330.630 Sanitary Standards
1330.640 Pharmaceutical Compounding Standards
1330.650 Pharmacy Computer Regulations
1330.660 Pharmacist-in-Charge
1330.670 Compounded Sterile Preparation Standards
1330.680 Automated Dispensing and Storage Systems

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
1330.760 Electronic Transmission of Prescriptions
1330.770 Centralized Prescription Filling
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

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].


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:

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 provideensure 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.

k) Failing to keep one's self and one's apparel clean or to wear identification bearing name and designation.
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

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. ___________, effective ____________________)

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 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
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.

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 8 ½ x 11 inches in size.
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

NOTICE OF PROPOSED AMENDMENTS

...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) 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) 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) A pharmacist at an institutional pharmacy shall provide patient counseling as required in this Section when drugs are dispensed by the pharmacy upon a patient's discharge from the institution.

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

h) 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. __________, effective _________________)