

# **Illinois Department of Financial and Professional Regulation**

## **Division of Professional Regulation**

### **Frequently Asked Questions (FAQs) on New Patient Counseling Rules**

Effective August 18, 2017, the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation (“Division”) adopted new rules related to patient counseling that will affect your practice of pharmacy. In mandating patient counseling on all new prescriptions, patients receive greater protection against potential problems associated with medications. A direct pharmacist-patient encounter also provides the pharmacist one final opportunity to ensure the patient is receiving the appropriate medication. Signage notifying patients of their right to counseling encourages participation in meaningful dialogue.

Answers to Frequently Asked Questions (FAQs) about these changes are provided below. These FAQs are NOT a substitute for reviewing the law in its entirety. For more information, please visit the “Laws and Rules” section of the Division’s Pharmacy Home Page, linked [here](#).

#### **1. When is a pharmacist, or student pharmacist directed and supervised by the pharmacist, required to counsel a patient?**

*Answer:* A pharmacist, or student pharmacist directed and supervised by the pharmacist, **must** provide verbal counseling on pertinent medication information:

- Prior to dispensing a prescription to a new patient of the pharmacy;
- Prior to dispensing a new medication to an existing patient of the pharmacy; and
- Prior to dispensing a medication where the dose, strength, route of administration, or directions for use has changed for an existing prescription previously dispensed to an existing patient of the pharmacy.

#### **2. If an existing patient is having a prescription refilled or reauthorized by a prescriber with no change in dose, strength, route of administration or directions for use, must the patient be offered counseling?**

*Answer:* Yes. An *offer* to provide counseling must still be made on all other prescriptions where counseling is not mandated. Any registrant under the Illinois Pharmacy Practice Act may make the offer to counsel on behalf of a pharmacist, but if the patient requests counseling, only a pharmacist, or student pharmacist directed and supervised by the pharmacist, may provide patient counseling.

### **3. What does patient counseling entail?**

*Answer:* Patient counseling shall include, but not be limited to:

- the name and description of the medication;
- dosage form, dosage, route of administration and duration of therapy;
- techniques for self-monitoring;
- proper storage;
- refill information;
- actions to be taken in cases of missed doses;
- special directions and precautions for preparation, administration and use; and
- 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.

A pharmacist, or student pharmacist directed and supervised by the pharmacist, should use his/her professional judgment to determine what to discuss with a patient during counseling. Please be aware that counseling related to protected health information must be provided in a discreet, supportive and informative manner.

### **4. Can a prescription be dispensed to a patient if the patient refuses to be counseled?**

*Answer:* Yes, but the patient's decision to refuse counseling must be documented in the pharmacy's records.

Be aware that attempting to circumvent patient counseling requirements or otherwise discouraging patients from receiving patient counseling concerning their prescription medications is considered unprofessional and unethical conduct.

### **5. Are mail order pharmacies required to provide counseling to patients?**

*Answer:* Where oral counseling is not practicable, such as a mail order pharmacy set-up, a pharmacist must use alternate forms of patient information, and must advise the patient in writing that the pharmacist may be contacted for consultation in person at the pharmacy or by toll-free or collect telephone service. A pharmacist must be available to provide counseling.

Moreover, the signage requirement in the new rules require pharmacies that do not maintain a physical location directly serving patients to include a copy of the required patient notification sign within any dispensed prescription. See FAQ #7 for information on the signage requirement.

**6. Must pharmacists at onsite and offsite institutional pharmacies provide counseling?**

*Answer:* A pharmacist at an on-site or off-site institutional pharmacy shall not be required to provide patient counseling unless drugs are dispensed by the pharmacy upon a patient's discharge from the institution.

**7. Must the pharmacy notify patients of their right to counseling under the new rules?**

*Answer:* Yes, every 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.

Licensed pharmacies that do not maintain a physical location directly serving patients must include a copy of this sign within any dispensed prescription.

**8. Where can I find a copy of the required sign for posting or mailing?**

*Answer:* You may find the sign available for download on the Division's website, linked [here](#). The posted sign must be printed in color ink, or displayed electronically in color, measure at least 8 ½ x 11 inches in size, and be posted at either a cashier counter or waiting area clearly visible to patients. If included within mailing, black and white photocopies are acceptable, but the sign must be legible and meet the size specification.

**9. How will counseling and signage requirements be monitored and enforced?**

*Answer:* The Division appreciates a pharmacist's vital role in serving patients. Counseling ensures patients have the information necessary to comply with medication regimens and avoid potentially harmful interactions. Counseling also helps to reduce prescription and medication errors. The Division will enforce this provision by incorporating observation of counseling and required signage in its routine inspections of pharmacies, as well as employing mystery shoppers to monitor compliance. The Division will also review counseling procedures whenever a prescription or dispensing error or complaint for failure to counsel is brought to its attention.

*DISCLAIMER: The above questions and answers are provided for general information purposes only and may not be applicable to your unique circumstances; do not purport to be legal advice; and are not intended to be legally binding on the Division or a pharmacist in a particular case. Questions involving interpretation of the law and your legal rights and obligations should be addressed to your own lawyer.*