COMPLIANCE CAPSULE *with* IDFPR

Quarterly Newsletter

Illinois Department of Financial and Professional Regulation

SPRING 2025

QUICK UPDATES FOR PHARMACY LICENSEES

Page 3

ALSO INSIDE:

CONTENTS

QUICK UPDATES FOR PHARMACY LICENSEES

Update to the Risk Evaluation and Mitigation Strategy ("REMS") for Opioid Analgesics

REMS changes requiring manufacturers of opioid analgesics dispensed in outpatient settings to provide pre-paid drug mail-back envelopes start March 31, 2025. The information related to obtaining pre-paid drug mail-back envelopes and additions to the patient guide and education sheet can be found here.

CE Requirement Reminder for Pharmacy Technicians

The Illinois Department of Financial and Professional Regulation ("IDFPR") recently received questions regarding certified pharmacy technician continuing education ("CE") requirements. Specifically, is CE required for technicians licensed prior to January 1, 2008? The CE is not required for technicians licensed prior to January 1, 2008 unless the technician has become certified. If certified, these technicians are required to complete the required CE.

Updating the Sterile Compounding Self-Inspection Form

IDFPR recently updated its Sterile Compounding Self-Inspection Form to include the most recent revisions in USP 797. The new version can be found on the Department's website by going here.

Pharmacies should begin using the new form immediately.

Free Standing Emergency Centers

Pharmacies servicing Free Standing Emergency Center locations that are at a distant location must apply to add Off-site Institutional Pharmacy operations to their license. Pharmacies may apply to make this addition to their license by logging into their online account with IDFPR and completing the application there or by completing and submitting a paper application.

NOTIFICATION WHEN A REMOTE DISPENSING PHARMACY CHANGES HOME PHARMACIES

When there is a change to the Home Pharmacy, an application must be completed and submitted to IDFPR by the Remote Dispensing Pharmacy. The application should be documented as “Change of Operations” and all required information should be that of the Remote Dispensing Pharmacy license. A cover letter should be submitted along with the application that clearly indicates that the Remote Dispensing Pharmacy is requesting to change the current Home Pharmacy. The cover letter must include the following information:

Current home pharmacy:
- Pharmacy license number
- Pharmacy name
- Pharmacy address

New Home pharmacy:
- Pharmacy license number
- Pharmacy name
- Pharmacy address

Submit the application (found here) and cover letter via e-mail to fpr.DrugComplianceUnit@Illinois.gov. After processing, the applicant will be provided an e-mail with a link to submit payment for application processing.

SEMAGLUTIDE UPDATE

On March 10, 2025, the U.S. Food and Drug Administration ("FDA") provided the following timeline updates for compounders regarding semaglutide. The FDA provided the following timeframes for which it does not intend to take action against compounders for violations of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") arising from conditions that depend on semaglutide injection products' inclusion on the FDA's drug shortage list:

- **For a state-licensed pharmacy or physician compounding under section 503A of the FD&C Act:** until April 22, 2025, or until the date of the district court's decision on the plaintiffs' forthcoming preliminary injunction motion in Outsourcing Facilities Association (OFA) v. FDA, 4:25-cv-00174 (N.D. Tex.), whichever is later.

- **For outsourcing facilities under section 503B of the FD&C Act:** until May 22, 2025, or until the date of the district court's decision on the plaintiffs' forthcoming preliminary injunction motion in OFA v. FDA, 4:25- cv-00174, whichever is later.

The FDA may still take action regarding violations of any other statutory or regulatory requirements, such as to address findings that a product may be of substandard quality or otherwise unsafe.

The complete update from the FDA may be found here.

Tirzepatide Compounding Update

On March 10, 2025, the U.S. Food and Drug Administration ("FDA") provided the following timeline updates for compounders regarding tirzepatide. This comes after a district court denied the plaintiffs' preliminary injunction motion in Outsourcing Facilities Association v. FDA, 4:24-cv-00953 (N.D. Tex.) on March 5, 2025. Therefore, consistent with the FDA's February 11, 2025 update:

- **For a state-licensed pharmacy or physician compounding under section 503A of the FD&C Act:** the period of enforcement discretion has ended.

- **For outsourcing facilities under section 503B of the FD&C Act:** the FDA does not intend to take action against compounders until March 19, 2025 for violations of the FD&C Act arising from conditions that depend on tirzepatide injection products' inclusion on the FDA's drug shortage.

The FDA may still take action regarding violations of any other statutory or regulatory requirements, such as to address findings that a product may be of substandard quality or otherwise unsafe.

The complete update from the FDA may be found here.

CONTACT US

Have questions? Call IDFPR at 1-888-473-4858.

State of Illinois
Illinois Department of Financial and Professional Regulation

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