

Illinois Law Update – New Practice Act Rules

Scott A. Meyers, RPh, MS,
FASHP
Executive Vice President

Disclosure

- The Speaker has no financial conflicts or interests related to this talk except that if he is not diligent on behalf of the members of ICHP in this area, he could be unemployed!

Learning Objectives

- Upon completion of the program, participants should be able to:
 - Differentiate between the requirements of the recently passed Illinois Pharmacy Practice Act Rules and the previous Rules.
 - Describe the implications of the recent changes on current and future pharmacy practice in Illinois.
 - Analyze other pharmacy and health care related legislation pending in the Illinois General Assembly and translate each bills potential effect on pharmacy practice.

Definitions

- Two definitions were moved from their respective sections to this section of consistency. (Automated Dispensing and Storage Systems, Electronic transmission of prescriptions).
- Patient Counseling no longer focuses on the offer to counsel but actually mirrors the definition in the Act.
- Divisions of Pharmacy are now renamed:
 - Division I is now Community Pharmacy
 - Division II is now Off-site Institutional Pharmacy
 - Division III is now On-site Institutional Pharmacy
 - Division IV is now Nuclear Pharmacy
 - Division V no longer exists
 - Division VI no longer exists but is dealt with in Remote Prescription/Medication Order Processing and is licensed as a pharmacy.

Registration as a Pharmacy Technician

- Not much has been changed from previous rules.
- Working for up to 60 days following submission of check and application is not acceptable for technicians seeking reinstatement due to disciplinary action.
- Technicians must notify the Department within 30 days or address change.
- No pharmacist whose license has been revoked, suspended or restricted may apply for a technician registration.

Pharmacy Technician Training

- Remains the same as in the old Rules.
- Same as it reads in the Act.

Certified Pharmacy Technician

- Before a pharmacy technician renews their registration the second time they now must become Certified.
 - 18 years of age,
 - Completed nationally accredited training or provide proof of training from PIC
 - Successfully pass NCCA accredited Certification Exam
- No Pharmacist who has had their license revoked, suspended, denied or restricted may be eligible to be registered as a certified pharmacy technician.

Approval of Pharmacy Programs

- ACPE accredited programs or other Board approved programs currently,
- Not sure this section is close to finalized yet.

Graduates of Program Outside the United States

- Must submit FPGEC, and
- Must pass FPGEE, and
- Must pass TOEFL with a score of at least 550, and
- Must pass TSE with a score of at least 50, and
- Must complete 1,200 hours of clinical training approved in advance by the Board of Pharmacy, or be licensed for at least one year in another U.S. jurisdiction.

Fees and Application for Examination

- Fees remain the same!
- Application requirement of graduation from a 5-year program is no longer in place.
- Examination processes remain the same.

Pharmacy Security and Reporting Theft of Loss of Controlled Substances

- Remains relatively unchanged.
- Requires person signing DEA Form 106 to print their name on the copy sent to the State.

Pharmacy Structural/Equipment Standards

- No longer require specific size or square footage.
- Must notify the Division of Professional Regulation when remodeling existing pharmacy.
- Must be properly lighted and ventilated.
- Must have a refrigerator exclusively for medications.
- Pharmacy must not be used to store non-pharmacy items.
- Pharmacy must have suitable current references.
- Must have a telephone.

Sanitary Conditions

- Clean and in good repair,
- All waste is immediately deposited in appropriate waste receptacle,
- Sink with hot and cold running water if drug inventory is present,
- Dry and free of vermin,
- Food and beverages shall be placed in designated areas away from dispensing activities, and
- Personal items shall not interfere with dispensing,

Pharmaceutical Compounding Standards

- Separate storage area for materials used in compounding,
- Scales and balances for compounding,
- An area used for compounding,
- Heating apparatus,
- Logbook or recording keeping system to track compounded prescriptions and components used,
- Reference containing formulas with directions for compounding,

Pharmaceutical Compounding Standards

- Policies and Procedures pertinent to the level of complexity and the size of the compounding operations of the practice,
- Consumable materials (filter papers, capsules, powder papers, jars, bottles, etc.).
- Sale of compounded products used by practitioners is acceptable,
- Sale of compounded products to other pharmacies not under common ownership is not acceptable.

Unprofessional/Unethical Conduct

- Pharmacist or pharmacy may not provide prescription pads to a prescriber that refer to specific pharmacy or pharmacist.
- Pharmacist or pharmacy may not actively participate in a program where prescription blanks are prepared in a manner that refers to a specific pharmacist or pharmacy.
- Shall not divide a prescription order unless authorized by prescriber, patient, payer or when full quantity is not available at that location.

Computer Pharmacy Regulations

- Input of drug information shall be performed by a pharmacist, pharmacy technician or certified pharmacy technician.
- Equipment must meet the following requirements:
 - Guarantee confidentiality
 - Transmission of electronic prescriptions from prescriber to pharmacist must not be compromised by inventions, control or manipulation by any other party.

Patient Counseling

- Basically the same except that it provides for counseling for Remote Pharmacies via both audio and video means.

Pharmacist-In-Charge (PIC)

- Must be routinely and actively involved in the operations of the pharmacy.
- May be in charge of more than one pharmacy but must work an average of 8 hours per week at each pharmacy for which he/she is in-charge.
- Must notify the Division of PIC change within 30 days.
- Inventory of all controlled substances must be done at time of change.

Pharmacist-In-Charge (PIC)

- Name and signatures of departing and incoming PICs on the Inventory.
- Affidavit attesting completion of the inventory must be sent to the Division within 30 days after the change in PIC.
- Record retention for invoices for all legend drugs is 5 years with at least one year on-site.
- PIC must notify the Division no less than 30 days prior to changing or adding services.

Prescription Transfer

- Relatively unchanged.
- Transfer is pharmacist to pharmacist, this is not a change.
- When the original prescription is transferred before initial filling, it must still be entered into the system of the pharmacy as if it was filled.

Multi-Med Dispensing Standards

- Must meet all requirements of a regular prescription label plus:
 - Serial number of the Multi-Med Pak in addition to individual prescription serial numbers,
 - Name, address, telephone number of the pharmacy and name of the pharmacist and any other registrant involved in the filling,
- A pharmacy is prohibited from creating a patient med pack utilizing drugs dispensed from a different pharmacy.

Certified Pharmacy Technicians

- Must be 18 years of age.
- Good moral character.
- Graduated from an accredited training program or completed OJT.
- Successfully passed NCCA accredited and Board approved exam.
- Paid fees and completed application.
- No pharmacist whose license has been revoked, suspended or restricted may become a certified technician.

Automated Dispensing Systems

- These are not Pyxis, Omnicell or like machines.
- Provide new and refilled prescriptions from an automated kiosk in a pharmacy or health care facility.
- Must be physically attached to the pharmacy so areas used for restocking are restricted access areas.

Automated Dispensing Systems

- Restocking must be done by register pharmacy technician or pharmacist.
- Products that are temperature sensitive or require further manipulation may not be dispensed in this method.
- Video monitors shall be used for counseling and must be at least 17" diagonally.
- PIC is responsible for overall compliance of these systems.

Compounded Sterile Preparation Standards

- Formerly Parenteral Product Standards
- Basically unchanged.
- Now includes sterile preparations used topically or internally by humans or animals.
- Does not mandate compliance with USP 797 however, in court all pharmacies in the U.S. can now be held to that standard.
- Now requires any pharmacy that provides CSPs to provide upon valid prescription emergency medications for treatment of anaphylaxis or ADRs.

Centralized Prescription Filling

- Must share a common electronic file to allow access to sufficient information necessary to fill the order.
- Must maintain appropriate records identifying the responsible pharmacists in the dispensing process.
- Maintain a mechanism for tracking the prescription order during each step of the process.

Vaccinations/Immunizations

- Entirely new Section.
- Allows pharmacists and pharmacy interns to administer all vaccines to patients 14 years old or older with prescription or standing order.
- Pharmacist or pharmacy intern must have completed an approved training program.
- Must have current Basic Life Support certification by the American Heart Association or American Red Cross.

Vaccinations/Immunizations

- Each pharmacy or pharmacist functioning outside a pharmacy must have a copy or access to an online copy of the CDC reference – Epidemiology and Prevention of Vaccine-Preventable Diseases wherever vaccines are administered.
- Must provide the patient with a vaccine information statement (VIS) for the vaccine they are receiving.

Vaccinations/Immunizations

- Must report all adverse events to the Vaccine Adverse Event Reporting System (VAERS).
- Must keep records for 5 years.
 - Including name, lot number and expiration date of the product administered.
 - and which VIS was provided to the patient.
- Must notify the patient’s primary care physician as provided by the patient, within 30 days of administration.

Community Pharmacies

- Formerly Division I and Division V Pharmacies
- Label no longer required to have initials of individual registrants involved in filling or refilling the prescription.
- No other major changes.

Off-Site Institutional Pharmacies

- Formerly Division II Pharmacies
- No major changes.

Onsite Institutional Pharmacies

- Formerly Division III pharmacies.
- Only significant change is now the Department must be notified within 30 days instead of 10 of a change in PIC.

Nuclear Pharmacies

- The Old Division IV pharmacies
- No other changes.

Remote Prescription/Medication Order Processing

- Formerly Division VI pharmacies.
- No significant changes except:
- All pharmacists practicing at the remote pharmacy shall be licensed in Illinois.

Emergency Remote Pharmacy License

- Pharmacy not located at the same location as a home pharmacy at which pharmacy services are provided during an emergency.
- Emergency caused by natural or manmade disaster or any other exceptional situation that causes an extraordinary need for pharmacy services.
- License good for no longer than 6 months.
- Must have a pharmacist in charge.

Automated Dispensing and Storage Systems

- May now be used in community pharmacies as Kiosks for patient use.
 - System prevents unauthorized removal of meds.
 - Provides method to identify the patient.
 - Records the time and date of med removal.
 - Reminds the patient that counseling is available in the pharmacy if open or if closed directs the patient to audio/video link with a pharmacist on duty.
 - Informs the patient that the med is not available because the pharmacist has determined that counseling is required.
 - Must be Board approved system.

Compounded Sterile Product Standards

- Used to be Parenteral Product Standards.
- Not much changed in the Illinois Rules.
- Uses some language from USP 797 but does not refer to that standard.
- Pharmacists and pharmacies will still be held to USP 797 because it is a federal standard.


Continuing Education

- 30 hours of CE credit is now required in the 24 months preceding the expiration date of the license.
- This used to be the two calendar years prior to expiration.
- In other words:
- April 1st through March 31st now instead of January 1st through December 31st!

MSHP 


Pending Legislation in Illinois

What You Don't Know Can Hurt You!

MSHP 

SB1383 and HB1293

- Creates a registration as a Student Pharmacist within the pharmacy technician registration classification.
- Exempts the Student Pharmacist from the Certification Requirement during school and for 18 months following graduation.
- Allows Foreign Graduates completing their 1,200 clinical hours to be student pharmacists for 24 months total.

MSHP 

HB277, HB333, HB2468, SB1288, SB2269

- Creates Prescription or Cancer Drug Repository Programs
- All are voluntary participation by pharmacists and pharmacies.
- Nominal dispensing fee only.
- All regulated by the Department of Public Health.

SB212

- Expedited Partner Therapy for Chlamydia and Gonorrhea.
- Physician, PA or APN may prescribe, dispense treatment for sexual partner without meeting or treating.
- Pharmacists may refuse to fill if prescription would cause them to violate the Pharmacy Practice Act.

SB1919

- Don't Flush Bill
- Prohibits hospitals, nursing homes or other healthcare facilities from flushing unused medications down toilet or pouring down sink.
- Fines of \$500 per incident.

SB2060

- Generic Substitution language
- Would require the pharmacist to get the patient's and physician's permission every time a generic medication is dispensed.
- Doesn't exempt hospitals!
- Is being placed in the Pharmacy Practice Act.



**There's at least another 50
bills with direct impact on
Pharmacy!**

Any Questions????

**Scott A. Meyers, Executive Vice
President**

scottm@ichpnet.org
