

## Illinois Pharmacy Law Update: New Laws, New Rules, Where Do I Begin?

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## Disclosures

- This speaker has no financial interests related to the subject matter except that he spends much of his work-life addressing these laws and rules.



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## Learning Objectives

- ▶ Explain how the divisions of pharmacy licensure have been replaced in the new Pharmacy Practice Act and how a pharmacy determines which practice related rules it must follow.
- ▶ Identify opportunities to improve patient drug therapy management as a result of the new Pharmacy Practice Act.
- ▶ Identify new opportunities to utilize certified pharmacy technicians to improve patient care in health-systems.



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## Learning Objectives

- Describe proposed legislation before the 96<sup>th</sup> General Assembly that may impact pharmacy practice if enacted.
- List steps pharmacists and pharmacy technicians can take to impact the legislative process in Illinois in 2010 and beyond.




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## Bye-Bye Divisions Bye-Bye!

- In 2007 (hard to believe it has been that long already) the Pharmacy Practice Act (PPA) was revised and the Divisions of Pharmacy were dropped.
- This allows any pharmacy to provide any pharmacy service!
- This created some headaches for the Department of Financial and Professional Regulations (Department).
- 2010 is the first year that a single pharmacy license is being granted.




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## Bye-Bye Divisions Bye-Bye!

- Pharmacies that were Division II – VI will be given new pharmacy license numbers and must notify your suppliers, wholesalers, DEA and third party payers of the new number!
- If you haven't done this, Monday is probably a good time to start!
- So why did we get rid of the Divisions?
  - Limitation of one pharmacist-in-charge per pharmacy
  - Pharmacies may now add services quickly and efficiently without being held up by the Department.




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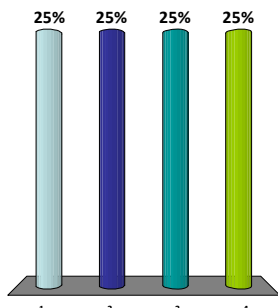
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### Will eliminating the Divisions of Pharmacy help or hurt the profession?

1. This will be an improvement!
2. It will make no difference.
3. This will allow all kinds of shady practice to occur!
4. Beats me?




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### MTM – the next Generation

- ***"Medication therapy management services" may also include: Patient care functions authorized by a physician licensed to practice medicine in all its branches for his or her identified patient or groups of patients under specified conditions or limitations in a standing order from the physician. 225 ILCS 85/3 aa)***




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### MTM – the next Generation

- ***"Medication therapy management services" in a licensed hospital may also include the following:***
  - ***(1) reviewing assessments of the patient's health status; and***
  - ***(2) following protocols of a hospital pharmacy and therapeutics committee with respect to the fulfillment of medication orders. 225ILCS85/3 aa)***




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## MTM – the next Generation

- The opportunity to manage patients' medication therapy has never been more accessible.
- While this doesn't necessarily make the pharmacist a mid-level practitioner, it is clear that the pharmacist can initiate therapies, change dosages, discontinue medications and more as long as there is a standing order to do so and a clear directive from the physician for that individual patient.




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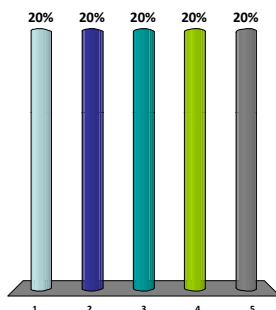
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Do you think pharmacists will jump at the chance to provide MTM Services?

1. Most will!
2. About half of us will.
3. Some will.
4. A few will.
5. Why take the risk?




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## Certified Pharmacy Technicians

- Required for new technicians prior to their second registration renewal.
- Requirement officially begins this year!
- The Department was not ready for the change, are we shocked?
- Exemptions from Certification includes pharmacy students and Foreign Graduates completing their 1,200 hours of clinical training.




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## Certified Pharmacy Technicians

- 225 ILCS 85/25.10 Remote Prescription Processing
- 225 ILCS 85/25.15 Telepharmacy
  - Only Certified Pharmacy Technicians may prepare prescriptions for dispensing at a remote pharmacy with pharmacist supervision.
  - Video and audio communications must be established to ensure accuracy of filling.




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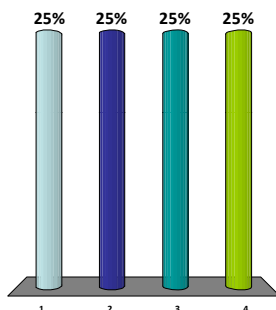
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How does your facility deal with pharmacy technician certification?

1. Pay for their test
2. Pay raise
3. Both
4. Neither
5. Something else in addition to above




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## SB2552 Amends the PPA

- Requires **ALL** pharmacies to maintain *"a representative assortment of drugs in order to meet the pharmaceutical needs of their patients."*
- Pharmacies have the duty to deliver lawfully prescribed drugs or devices to patients in a timely manner.
- Does allow for refusal based on clinical judgment, market shortages or temporary outages.




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### SB2552 Amends the PPA

- **Allows for the pharmacy to provide a therapeutically equivalent drug in a timely manner!**
- **Makes the following grounds for discipline**
  - Destruction of the prescription
  - Refusal to return an unfilled lawful prescription
  - Violation of the patient's privacy
  - Discrimination against a patient or agent
  - Intimidation or harassment of a patient
  - Failure to comply with this section of the Act



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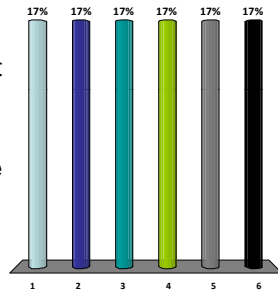
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### How do you feel about Plan B?

1. Wouldn't dispense
2. Would dispense
3. Would dispense but feel others have a right to refuse
4. Believe others have no right to refuse



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### SB1381 Medical Marijuana

- **Creates a Registry for patients with valid prescriptions**
- **Allows possession of up to 2 oz of dried cannabis and 6 cannabis plants (no more than 3 may be mature)**
- **Mature cannabis plant means female with either observable flowers or buds, is at least 12 inches in height, or at least 12 inches in diameter.**



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### SB2060 Amends the PPA

- **Sponsor – Sen. Dan Kotowski – D, Park Ridge**
- **Initially would require the pharmacist to contact the prescriber and inform the patient when a generic is legally substituted.**
- **Amendment #2 requires written notice to the patient if generic substitution is made.**



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### SB3093 – Methamphetamine

- Would require anyone convicted of a violation of the methamphetamine precursor control act to have a prescription in order to possess ephedrine or pseudoephedrine.
- Does not hold the pharmacist responsible if a patient fails to comply.
- Does not require the pharmacist or prescriber to investigate status of patient.




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### SB2604 & HB4975 Amends PPA

- Would allow certain disciplines to be removed from any licensed individuals record
- Requires a completed form and \$200
- Items that may be removed:
  - Late child support payments
  - Late student loan replacement
  - Late State tax payment
  - CE violations
- Would not remove the disciplines from permanent record




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### HB5115 –Drug Repository Act

- Sponsored - Rep. Patty Bellock – R, Westmont
- Creates a program for pharmacies to receive donated medications to be used by indigent patients.
- Oversight provided by IDPH
- No cost to patient except nominal dispensing fee
- No liability for pharmacists who participate
- Voluntary program




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## HB5890 Amends PPA

- Sponsor-Rep. Sandra Pihos – R, Glen Ellyn
- Allows prescriber to place indication for use of drug or device on the prescription
- Does not require the pharmacist to place the indication for use on the label
- Is a voluntary process
- Concept came from a pharmacist




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## The Pharmacy Practice Act Rules

- First draft published in the Illinois Register on September 25, 2009
- A variety of comments were made and several accepted by the Department
- Second notice published on February 26, 2010
- Rules were delayed by JCAR for 45 days on March 9, 2010




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## Proposed Rules

- Many, many revisions and new provisions, including:
  - 1330.10 Definitions
  - 1330.50 Vaccinations/Immunizations
  - 1330.60 Internet Pharmacies




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## Proposed Rules

- SUBPART B: PHARMACY TECHNICIAN
  - 1330.200 Application for Certificate of Registration as a Pharmacy Technician
  - 1330.210 Pharmacy Technician Training-Registration Requirement
  - 1330.220 Certified Pharmacy Technician




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## Proposed Rules

- SUBPART C: PHARMACIST
  - 1330.300 Approval of Pharmacy Programs
  - 1330.310 Graduates of Programs Outside the United States
  - 1330.330 Examination for Licensure




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## Proposed Rules

- SUBPART D: PHARMACY LICENSURE
  - 1330.400 Application for a Pharmacy License
  - 1330.410 Pharmacy Licenses
  - 1330.420 Emergency Temporary Remote Pharmacy License




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## Proposed Rules

### ►SUBPART E: TYPES OF PHARMACIES

- 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
- 1330.560 Remote Prescription / Medication Order Processing




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## Proposed Rules

### ►SUBPART F: PHARMACY STANDARDS

- 1330.610 Pharmacy Structural/Equipment Stds
- 1330.620 Electronic Equipment Requirements
- 1330.640 Pharmaceutical Compounding Stds
- 1330.650 Pharmacy Computer Regulations
- 1330.660 Pharmacist-in-Charge
- 1330.670 Compounded Sterile Prep Stds
- 1330.680 Automated Dispensing and Storage Systems




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## Proposed Rules

### ►SUBPART G: PHARMACY OPERATIONS

- 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




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Questions???

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