The New Illinois Pharmacy Practice Act Rules 2010

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Disclosures

• The speaker spends a significant portion of his work reviewing, assisting in the revision of, and explaining the Pharmacy Practice Act and Rules. There are no relevant financial conflicts that would influence this presentation.

Learning Objectives

• List the sections of the Rules which are new.
• Describe the requirements pharmacists must meet in order to provide immunizations to their patients.
• Discuss how health-system pharmacy departments may use telepharmacy to provide improved care to their patients.

Learning Objectives (cont.)

• Describe how health-system pharmacy departments may use remote prescription/medication order processing to provide improved care to their patients.
• Describe the changes in physical requirements of pharmacies in the new rules.
• Explain how centralized prescription filling can be used by health-system pharmacy departments to reduce costs and improve efficiency.

New Rules

• On the IDFPR Website www.idfpr.com
• If you haven’t looked at them, you definitely should later today or tomorrow!
  http://www.ilga.gov/commission/jcar/admincode/068/06801330sections.html

New Sections in the Rules

• 1330.20 Fees
  ○ Moved from the Act
  ○ Fees have remained the same
  ○ $25 fee to change PIC

• 1330.30 Unprofessional/Unethical Conduct
  ○ Many deal with billing issues
  ○ Also discrimination
  ○ Unwillingness to compound
New Sections in the Rules

- **1330.50 Vaccinations/Immunizations**
- **1330.60 Internet Pharmacies**
  - Refers to Federal Ryan Haight Online Pharmacy Consumer Protection Act of 2008
- **1330.220 Certified Pharmacy Technicians**
  - Must become certified before second registration renewal
  - Applies to newly registered techs only
- **1330.420 Emergency Remote Temporary Pharmacy License**
  - For situations like fire, flood, tornado, earthquake
- **1330.500 Community Pharmacy Services**
  - Old Division I language
- **1330.510 Telepharmacy**
- **1330.520 Offsite Institutional Pharmacy Services**
  - Old Division II language
- **1330.530 Onsite Institutional Pharmacy Services**
  - Old Division III language
- **1330.540 Nuclear Pharmacy Services**
  - Division IV language
- **1330.550 Nonresident Pharmacies**
- **1330.560 Remote Prescription/Medication Order Processing**
- **1330.610 Pharmacy Structural/Equipment Standards**
- **1330.620 Electronic Equipment Requirements**
  - Computer, scanner, fax, and printer at remote pharmacies
- **1330.630 Sanitary Standards**
- **1330.640 Pharmaceutical Compounding Requirements**
- **1330.650 Pharmacy Computer Regulations**
  - Only pharmacists, technicians and certified pharmacy technicians may enter prescriptions/medication orders into the system.
- **1330.660 Pharmacist-in-Charge**
  - Pharmacist may now be PIC at multiple pharmacies as long as they work ave. 8hrs/week
  - PIC is required to inform the Dept. of change of services within 30 days.
New Sections in the Rules

- **1330.770 Centralized Prescription Filling**
  - New pharmacy application must be filed whenever more than 10% of the ownership changes (except publicly held companies)
  - When more than half of the Board of Directors or executive officers change

- **1330.780 Change of Ownership of a Pharmacy**
  - When more than half of the Board of Directors or executive officers change

- **1330.790 Closing a Pharmacy**

**1330.50 Vaccinations/Immunizations**

- May now be performed by a pharmacist or student pharmacist who has:
  - Successfully completed a course of training accredited by ACPE and approved by the Division of Professional Regulation.
  - Completed and maintained Basic Life Support Certification.
  - Has a current copy of the CDC reference “Epidemiology and Prevention of Vaccine-Preventable Diseases” (hard copy or electronic).

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  - Successfully completed a course of training accredited by ACPE and approved by the Division of Professional Regulation.
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- **1330.50 Vaccinations/Immunizations**
  - Vaccines may be administered to persons 14 years of age or older.
  - Pursuant to a valid prescription or standing order by a physician.
  - Must be performed by the pharmacist or the student pharmacist under the direct supervision of the pharmacist.
  - Reporting within 30 days to the patient’s primary healthcare provider.

- **1330.50 Vaccinations/Immunizations**
  - The Pharmacist/Student Pharmacist must have and follow protocols for treatment of severe adverse events following administration.
  - Written policies and procedures for handling disposal of all used supplies.
  - Provide appropriate vaccine information statement (VIS) to the patient or legal representative PRIOR to administration.
  - Must report adverse events as required by the Vaccine Adverse Events Reporting System and to primary care provider.

- **1330.50 Vaccinations/Immunizations**
  - Records must be kept for 5 years:
    - Name, address, DOB of patient,
    - Date of administration and injection site,
    - Name, dose, manufacturer, lot #, beyond use date of vaccine,
    - Name, address of primary care provider named by patient,
    - Name or unique identifier of administering pharmacist,
    - Which VIS was provided.

**1330.510 Telepharmacy**

- a) Telepharmacy shall be limited to the following types of operations. Each site where such operations occur shall be a separately licensed pharmacy.
- b) Operations 3) Remote Automated Pharmacy System (RAPS)
  - Physician or clinic dispensing.
  - All prescriptions must be reviewed prior to dispensing by the pharmacist or prescriber.
### 1330.510 Telepharmacy
- RAPS prescriptions must meet the same label requirements as the Act.
- Monthly inspections are required by the PIC or designee.
- RAPS are subject to random inspections by pharmacy investigators. A pharmacist with access should be available at the site within one hour.

### 1330.510 Telepharmacy
- Each site must display a sign, easily viewable by the customer, that states:
  - The facility is a telepharmacy supervised by a pharmacist located at (address); and
  - The pharmacist is required to talk to you, over an audio/visual link each time you receive a prescription.
- No remote site may be open when the home pharmacy is closed. No access by employees when the home pharmacy is closed. Security must track all entries. Entry logs must be reviewed weekly.

### 1330.560 Remote Prescription-Medication Order Processing
- Any pharmacy may provide remote prescription/medication order processing services to any other pharmacy.
- Non-resident pharmacies must be registered in its resident state.
- Secure HIPAA compliant, electronic communications system in place.
- All relevant patient information must be accessible.

### 1330.560 Remote Prescription-Medication Order Processing
- If the communication system fails, remote processing must cease.
- Record keeping requirements are the same and include electronic communication system maintenance.
- Records for medications entered at the remote processing pharmacy must be distinguishable and readily retrievable from those entered at the institution.

### 1330.610 Pharmacy Structural/Equipment Standards
- Notification shall be submitted prior to remodeling a pharmacy.
- All dispensing and storage areas must be contiguous.
- Well lighted and properly ventilated.
- Refrigerators shall be for prescription medications only with proper temp.
- Storage of merchandise shall not interfere with pharmacy practice.
**1330.610 Pharmacy Structural/Equipment Standards**
- Suitable current references in book or electronic form are acceptable:
  - Facts and Comparisons or other
- Pharmacy must have a telephone in the pharmacy area.
- Equipment and references listed in 1330.640 must be maintained in all dispensing pharmacies.

**1330.640 Pharmaceutical Compounding Standards**
- Scales and balances for compounding
- Heating apparatus
- Logbook or recording keeping system to track each compounded prescription and components used.
- References
- Policies and Procedures pertinent to the level of complexity and size of the compounding operations.

**1330.640 Pharmaceutical Compounding Standards**
- Consumable materials as appropriate to the pharmacy services provided.
- Pharmacies may compound drug products to be used by practitioners in their office for administration to patients.
- Sales of compounded drugs to other pharmacies, clinics, hospitals, or manufacturers are not allowed except when providing central fill services.

**1330.770 Centralized Prescription Filling**
- Pharmacies must share a common electronic file.
- Must maintain appropriate records to identify the pharmacist responsible in the filling process.
- Must maintain a mechanism for tracking the prescription drug order each step in the process.

**Questions??**