

2015 Pharmacy Law Review

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Disclosures/Conflict of Interest

- Garth K. Reynolds declares no conflicts of interest, real or apparent, and no financial interests in any company, product or service mentioned in this program, including grants, employment, gifts, stock holdings and honoraria.

Objectives Pharmacists

At the conclusion of this program, the pharmacist will be able to:

- Discuss new or pending pharmacy-related legislation.
- Explain the revisions to the Illinois Administrative Code in relation to the Pharmacy Practice Acts, Controlled Substance Acts and PMP.
- Describe the status of pharmacy-related Federal legislation, including Pharmacist Provider Status.
- Explain the regulatory changes and updates for Medicare Part D, including Star Ratings and Measures.
- Describe the impact and timeline of implementation of the Drug Supply Chain Security Act (DSCSA).
- Discuss status of IPHA sponsored legislation initiatives.

Objectives Pharmacy Technicians

At the conclusion of this program, the pharmacy technician will be able to:

- Discuss new or pending pharmacy-related legislation.
- Explain the revisions to the Illinois Administrative Code in relation to the Pharmacy Practice Acts, Controlled Substance Acts and PMP.
- Describe the status of pharmacy-related Federal legislation, including Pharmacist Provider Status.
- Explain the regulatory changes and updates for Medicare Part D, including Star Ratings and Measures.
- Describe the impact and timeline of implementation of the Drug Supply Chain Security Act (DSCSA).
- Discuss status of IPHA sponsored legislation initiatives.

CPE Activity Information

- Target Audience: Pharmacists, Technicians
- Activity Type: Knowledge-Based
- Contact Hours: 2.0
- UAN: 0135-0000-15-0XX-L03-P
0135-0000-15-0XX-L03-T

What is the civil fine imposed for not filing a PMP report as per rule?

- A) \$100/day
- B) \$150/day
- C) \$100/day/patient
- D) \$250,000/day
- E) \$100,000/patient

HB3219 would require CPhT to obtain how many hours of CPE every 2 years?

- A) 30 contact hours
- B) 20 contact hours
- C) 15 contact hours
- D) 10 contact hours
- E) 40 contact hours

What is the FDA reference for determining an interchangeable?

- A) Orange Book
- B) Pink Book
- C) Yellow Book
- D) Purple Book
- E) Red Book

How long must the pharmacy maintain records of a self-inspection?

- A) 1 year
- B) Until the inspector reviews the self-inspection
- C) 10 years
- D) Until any change in pharmacist-in-charge
- E) 5 years

How many counties in Illinois are considered to be Medically Underserved Areas (MUAs)?

- A) 97
- B) 102
- C) 50
- D) 79
- E) 42

What is the Enforcement Discretion date for the next phase of traceability of the DSCSA?

- A) 11/01/2015
- B) 11/15/2015
- C) 12/31/2015
- D) 01/01/2016
- E) 07/01/2016

Which of the following is not a current Medicare Part D measure?

- A) Medication Adherence for Hypertension (RAS antagonists)
- B) High Risk Medication in the Elderly
- C) Medication Adherence to Injectable Diabetes Medications
- D) Appropriate Treatment of Hypertension in Persons with Diabetes Treatment
- E) Medication Adherence for Cholesterol (Statins)

99th General Assembly: Pharmacy Legislation Passed

Pharmacy Technician CPE HB3271

- Sponsor: Rep. Michael Zalewski (D-Riverside)
- Amends Pharmacy Practice Act
- Clarifies Technician registration
- Establishes that CPhT to obtain 20 contact hours of CPE every 2 years (Effective 01/01/2017)
 - 1 contact hour in pharmacy law
 - 1 contact hour in patient safety
- Pharmacy Inspectors (Effective 08/27/2015)
 - IPhA supported language from IDFPR to revert that all future pharmacy inspectors must be registered pharmacists.
 - Does not impact any currently employed non-pharmacist inspectors.
- Combined with Medication Locking Cap bill HB3219 (Effective 01/01/2016 until 12/31/2016)
 - IPhA, working with IRMA and ICHP, were able to minimize the impact of this section concerning medication locking caps.
 - Creates a one year pilot program – voluntary participation by pharmacy.
 - For hydrocodone containing – Schedule II prescriptions.
 - Medicaid, Medicare Part D, and LTC patients exempt from pilot program.
 - Prescribers may exempt any patient from the pilot program by indicating on the prescription order (This provision was added in the Senate, which is why HB3219 returned to the House for concurrence).
 - DFPR may not expend more than \$150,000 for this pilot.
- STATUS: Public Act 99-0473 (08/27) HB3219

Biosimilars SB1611/HB3519/SB455

- Sponsor(s): Sen. Anthony Muñoz (D-Chicago)/ Rep. David Harris (R-Mount Prospect)
- Amends Pharmacy Practice Act – Defines Biosimilars, Biologics, Interchangeable
- Requires notification of patient by pharmacist of interchange.
- "The communication shall be conveyed by making an entry that can be electronically accessed by the prescriber through:
 - an interoperable electronic medical records system; an electronic prescribing technology;
 - a pharmacy benefit management system; or a pharmacy record."
- "Entry into an electronic records system as described in this subsection (c) is presumed to provide notice in accordance with this subsection (c). Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, except that communication shall not be required where:
 - there is no United States Food and Drug Administration-approved interchangeable biological product for the product prescribed; or
 - a refill prescription is not changed from the product dispensed on the prior filling of the prescription."
- STATUS: Postponed - Executive (03/26)^{SB1611} / Re-referred to Rules (04/24)^{HB3519} / Public Act 99-0200 (07/30)^{SB455}

Heroin Crisis Act HB1

- Sponsor: Rep. Lou Lang (D-Skokie)
- Provide mechanism for Medication Take Back at law enforcement facilities
- Restricts on C-II that prescriber must document reason for the (2) additional 30-Day supply
- Additional data required from prescribers and pharmacies and integrate EHR/Phcy Records/PMP
- PMP changes from 6:6:1 to 3:3:1 and report to 1 day
- Statewide standing order for pharmacists to dispense naloxone
- Limited liability coverage (only cost of medication)
- STATUS: Public Act 99-0480 (09/09)

Right to Try ^{HB207/HB496/HB1335/HB2508/SB29}

- Sponsor(s): Rep. Mary Flowers (D-Chicago) / Sen. Michael Connelly (R-Wheaton) / Rep. Daniel Beiser (D-Alton) / Rep. Greg Harris (D-Chicago)
- Creates the Right to Try Act
- Allows patients to obtain investigational medication that has completed Phase 1 clinical trials
- Manufacturers may charge the patient
- Insurer not required to cover, but encouraged
- Some immunity for physicians
- No civil or criminal immunity for Pharmacy or Pharmacist
- STATUS: Public Act 99-0270 (08/05)^{HB1335}

APN – Collaborative Practice ^{HB421/SB1315}

- Sponsor(s): Rep. Sara Feigenholtz (D-Chicago) / Sen. Heather Steans (D-Chicago)
- Amends Nurse Practice Act
- Eliminates requirement for written collaborative agreements
- Eliminates requirement for anesthesia plan for certified registered nurse anesthetists
- STATUS: Public Act 99-0173 (07/29)^{HB421} / Postponed - Licensed Activities & Pensions Committee (04/29)^{SB1315}

Controlled Substances ^{SB689}

- Sponsor(s): Sen. Matt Murphy (R-Palatine)
- Amends Pharmacy Practice & Controlled Substances Act
- Allows APN/Practical Nurse/RN to pick up and possess Controlled Substances for a patient utilizing hospice services
- Amendment to allow Physician Assistant
- STATUS: Public Act 99-0163 (07/28)

Eye Drops ^{HB499/HB3137}

- Sponsor: Rep. Dan Brady (R-Normal)
- Amends Insurance Code
- Removes early refill restrictions for all eye drops from individual and group policies
- STATUS: Re-referred to Rules Committee (03/27)^{HB499}
 - Public Act 99-0226 (08/03)^{HB3137}

Screening Act ^{SB661}

- Sponsor: Sen. John Mulroe (D-Chicago)
- Creates Hepatitis C Screening Act
- Individuals born b/w 1945-1965 who receive services from inpatient or ER be offered a hepatitis C related test
- **STATUS: Veto by Governor (08/21) – On Senate Veto Calendar (09/09)**

MCPP Medical Condition ^{SB33}

- Sponsor: Sen. Michael Hastings (D-Matteson)
- Amends the Medical Cannabis Pilot Program
- Adds Post-traumatic Stress Disorder - PTSD
- **STATUS: Governor Vetoed (09/10)**

Illinois Pharmacy Practice Act Rules

68 IAC 1330
Effective April 23, 2015

Pharmacy Practice Act Rules 1330.10

- "Dispensing Error" means any preventable event that may cause or lead to inappropriate medication use or patient harm. Such events may be related to professional practice, health care products, procedures and systems, including: prescribing; order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.
- "Electronic Format" includes, but is not limited to, information obtained via the Internet or stored on personal digital assistant, smart phone, tablet, etc.
- "Home Pharmacy" means the location of a pharmacy's primary operations.
- "Patient Counseling" clarified that technicians can offer counseling of both pharmacists and student pharmacists.

Pharmacy Practice Act Rules 1330.10

- "Pharmacist" removes reference to registered assistant pharmacist.
- "Remote Consultation Site" means a location, other than that of the home pharmacy, where prescriptions filled at the home pharmacy are stored and dispensed by a pharmacy technician, certified pharmacy technician and/or student pharmacist under the direct, remote supervision of a pharmacist located at, or contracted with, the home pharmacy.
- "Remote Dispensing Site" means a location other than that of the home pharmacy where a supply of prescription drugs is maintained and prescriptions are filled and dispensed by a certified pharmacy technician and/or student pharmacist under the direct, remote supervision of a pharmacist located at, or contracted with, the home pharmacy.
- "Unprofessional Conduct" definition removed.

Pharmacy Practice Act Rules 1330.20

- Fees clarifies pharmacy technician, certified pharmacy technician, and student pharmacists fees.

Pharmacy Practice Act Rules 1330.30

- Committing theft or diversion, or attempting to commit theft or diversion, by a registrant or licensee.
- Submitting fraudulent billing or reports to a third party payer or claiming a fee for a service that is not performed or earned.
- Filling a prescription when a pharmacist knows, or reasonably should know, that no valid physician-patient relationship exists or failing to exercise sound professional judgment with respect to the accuracy and authenticity of any prescription/drug order dispensed.
- Removed - Unreasonably refusing to compound a valid prescription.

Pharmacy Practice Act Rules 1330.30

- Knowingly dispensing/selling a prescription drug without a valid prescription. Dispensing or offering to dispense any drug not approved by the Food and Drug Administration (FDA), found in the USP-NF, or found on the list promulgated by the FDA for bulk drug substances that may be used to compound drug products.
- Failing Failure of a licensee or registrant to keep one's self/himself or herself and one's/his or her apparel clean or to wear identification bearing his or her name and designation.
- Actively or passively participating in any arrangement or agreement in which a prescription order-blank is prepared, written, or issued in a manner that refers to a specific pharmacist or pharmacy. Pharmacy-branded enrollment forms, when a patient requests his or her prescriptions be filled at a specific pharmacy, and Risk Evaluation and Mitigation Strategies documents containing prescription information are not prohibited by this subsection.

Pharmacy Practice Act Rules 1330.30

- Committing dispensing errors that result in hospitalization of a patient or demonstrating a pattern and practice of dispensing errors.
- Committing an act or acts that are of a flagrant and obvious nature so as to constitute conduct of such a distasteful nature that accepted codes of behavior or codes of ethics are breached.
- Committing an act or acts in a relationship with a patient that violate common standards of decency or propriety.
- Willfully violating, or knowingly assisting in the violation of, any law relating to the use of habit-forming controlled substances.

Pharmacy Practice Act Rules 1330.40

- Engage in a ~~business relationship~~ ~~professional association~~, with any place defined as a drug store or pharmacy in the Act where the practice of pharmacy is engaged in by any person who is not authorized to practice under the Act or that is not operated and conducted in compliance with the Act.
- If a licensee or registrant is disciplined in another state, he or she must inform the Division within 60 days.

Pharmacy Practice Act Rules 1330.50

- A pharmacist, or student pharmacist under the direct supervision of a pharmacist, may administer **influenza** (inactivated influenza vaccine and live attenuated influenza intranasal vaccine) and **Tdap** (tetanus, diphtheria, acellular pertussis) vaccines/immunizations to persons who are **10 to 13 years of age** pursuant to a valid patient specific prescription or a standing order by a physician licensed to practice medicine in all of its branches under the Medical Practice Act of 1987.
- 2 other adjustments - clarifying the age ranges for immunization care.

Pharmacy Practice Act Rules 1330.80

- Pharmacy technicians shall be required to submit with their second renewal proof of certification as a certified pharmacy technician, proof of enrollment in a first professional degree program in pharmacy, or proof of enrollment in clinical training by a graduate a foreign pharmacy program, as provided in Section 9 of the Act. This requirement does not apply to pharmacy technicians licensed prior to January 1, 2008. Failure to provide proof of certification results in non-renewal of the pharmacy technician's registration.

Pharmacy Practice Act Rules 1330.90

- Amends registrant to pharmacist in all cases.
- A ~~pharmacist registrant~~ who is unable to submit proof of satisfaction of either subsection (c)(1)(A) or (B) shall submit proof of completion of:
 - A) ~~3015 clock-hours of refresher courses or continuing education for each year the license was expired, and/or~~
 - B) Either:
 - i) ~~600 up to 400~~ hours of clinical practice under the supervision of a licensed pharmacist completed within 2 years prior to restoration; or
 - ii) Successful completion of the Pharmacist Assessment for Remediation Evaluation (PARE) examination. To be successful, an applicant must receive an overall score of 80 or higher, as well as a minimum score of 75 in each of the 3 content areas on the PARE examination.

Pharmacy Practice Act Rules 1330.110

- Standard DFPR language concerning Confidentiality during examination or investigation.

Pharmacy Practice Act Rules 1330.200

- No person who holds an active Illinois pharmacist's license may concurrently hold an active Illinois pharmacy technician registration.
- Any pharmacy technician who is permitted to use the title "**student pharmacist**" pursuant to Section 9 of the Act shall notify the Division within 30 days if he or she has permanently separated from or been expelled from an ACPE accredited college or school of pharmacy; failed to complete his or her 1,200 hours of Board approved clinical training within 24 months; or failed the pharmacist licensure examination 3 times. When this occurs, the technician shall have 90 days to obtain a certified pharmacy technician license as provided in Section 1330.220, unless that certified pharmacy technician was registered prior to January 1, 2008. During the period prior to registering as a pharmacy technician, the individual is not permitted to use the title "student pharmacist". If the individual does not become registered as a certified pharmacy technician within 90 days, the pharmacy technician registration shall expire.

Pharmacy Practice Act Rules 1330.210

- Ensuring registered pharmacy technicians and certified pharmacy technicians are properly trained shall be the **responsibility of the pharmacy, the pharmacist-in-charge, and the pharmacy technician.**

Pharmacy Practice Act Rules 1330.220

- Updated **National Commission for Certifying Agencies of the Institute for Credentialing Excellence (NCCA)** versus National Organization for Competency Assurance (NOCA) & **Institute for the National Healthcareer Association (or its successor)** versus Institute for the Certification of Pharmacy Technicians.
- No pharmacist whose license has been denied, revoked, suspended or restricted for disciplinary purposes may be eligible to be registered as a certified pharmacy technician. No person who holds an active Illinois pharmacist license may concurrently hold an active Illinois certified pharmacy technician registration.

Pharmacy Practice Act Rules 1330.400

- Any **reduction in hours of operation** shall be reported to the Division within 30 days.
- Upon receipt by the Division of a **change of ownership application**, the purchaser may begin operations prior to the issuance of a new pharmacy license only when the purchaser and seller have a written power of attorney agreement. This agreement shall provide, among other things, that violations during the pendency of the application process shall be the sole responsibility of the seller. This agreement shall be provided to the Division upon request.
- **No pharmacy shall relocate prior to the inspection of the premises.** All drugs shall be transferred **within 24 hours** after issuance of the license unless otherwise approved by the Department.

Pharmacy Practice Act Rules 1330.500

- Grammar changes
- **Any drug** that is dispensed pursuant to prescription, other than vaccinations administered in the pharmacy, **shall have affixed** to its container a **label** as provided in Section 22 of the Act.
- All pharmacies shall be required to maintain the following current resource materials, either in hard copy or electronic format:
 - 1) Copies of the Act and this Part;
 - 2) The Illinois Controlled Substances Act and 77 Ill. Adm. Code 3100;
 - 3) 21 CFR (Food and Drugs; 2014); and
 - 4) The Illinois Hypodermic Syringes and Needles Act [720 ILCS 635].

Pharmacy Practice Act Rules 1330.500

- Any **mail order pharmacy** that provides services in Illinois **shall provide, during its regular hours of operation**, but not less than 6 days per week for a minimum of 40 hours per week, a **toll-free telephone service to facilitate communication between patients in this State and a pharmacist retained by the mail order pharmacy who has access to the patient's records.** The **toll free number** must be disclosed on the **label affixed to each container** of drugs dispensed to residents of the State.

Pharmacy Practice Act Rules 1330.510

- Home pharmacies that are located outside of Illinois must be licensed as a nonresident pharmacy. Nonresident pharmacies shall abide by all Illinois laws and rules when filling prescriptions for Illinois residents, except that the dispensing pharmacist and the pharmacist-in-charge shall not be required to be licensed in Illinois, except as otherwise provided in this Part.
- Counseling must be done by a pharmacist via video link and audio link before the drug or medical device is released. The pharmacist must counsel the patient or the patient's agent on all new prescriptions and refills. The pharmacist providing counseling, pursuant to this subsection, must be employed or contracted by the home pharmacy or by a pharmacy contracted with the home pharmacy and have access to all relevant patient information maintained by the home pharmacy.

Pharmacy Practice Act Rules 1330.510

- The pharmacy technician located at the remote dispensing site must have one year of experience and be registered as a **certified pharmacy technician**, or be a **student pharmacist**.
- Security of filled prescriptions must be maintained by storing them in a separate lock drawer or cabinet.
- The facility shall have an area for patient consultation, exclusive of any waiting area.
- These sites must be staffed with a pharmacy technician or certified pharmacy technician who has the knowledge necessary to use computer audio/video link for dispensing and consultation to occur. Pharmacist and pharmacy technician initials or unique identifiers must appear on the prescription record and the prescription label.

Pharmacy Practice Act Rules 1330.510

- Automated Pharmacy Systems (Section 22(b) of the Act)- NEW
 - Remote Automated Pharmacy Systems (RAPS)
- These devices shall maintain a prescription drug inventory that is controlled electronically by the home pharmacy or, when operated by a pharmacy contracted with the home pharmacy, by the contracted pharmacy, which shall be utilized to dispense patient specific prescriptions.
- These systems shall sites have prescription inventory, which must be secured in an automated pharmacy system and electronically dispensing device connected to and controlled by the home pharmacy.
- A pharmacist, or prescriber when the RAPS is located on the same premises as the prescriber, must approve all the prescription orders before they are released from the RAPS automated dispensing device.

Pharmacy Practice Act Rules 1330.510

- Dispensing and counseling are performed by a pharmacist employed or contracted by the home pharmacy via audio link and video link or by the prescriber when the RAPS is located on the same premises as the prescriber.
- RAPS replaces remote telepharmacy dispensing machine
- The RAPS must be licensed with the Division as an automated pharmacy system and will be subject to random inspection by pharmacy investigators. Notwithstanding that the RAPS shall possess a license, the home pharmacy shall remain responsible for inventory control and billing. For purposes of random inspections, a pharmacist with access to the system must be available at the site within one hour, or as otherwise approved by the drug compliance investigator. In the event the Chief Pharmacy Coordinator determines that the RAPS poses a significant risk of patient harm, the RAPS must be disabled until such time as the pharmacist with access to the system is available to the site.

Pharmacy Practice Act Rules 1330.510

- Medication dispensed at the automated pharmacy system site may only be packaged by a licensed manufacturer or repackager, or prepackaged by a licensed pharmacy in compliance with this Section. Repackaging must occur at the home pharmacy, a pharmacy sharing common ownership with the home pharmacy, or a pharmacy that has contracted with the home pharmacy to perform repackaging services in compliance with Section 1330.730. The following requirements shall apply whenever medications are prepackaged by a pharmacy other than the home pharmacy:
 - i) The prepackaging pharmacy shall be licensed in Illinois as a resident or nonresident pharmacy.
 - ii) The prepackaging pharmacy shall share a common database with the home pharmacy, or have in place an electronic or manual process to ensure that both pharmacies have access to records to verify the identity, lot numbers and expiration dates of the prepackaged medications stocked in the RAPS.
 - iii) The prepackaging pharmacy shall maintain appropriate records to identify the responsible pharmacist who verified the accuracy of the prepackaged medication.

Pharmacy Practice Act Rules 1330.510

- **Written prescriptions may be received at an RAPS.** All written prescriptions presented to an RAPS shall be scanned utilizing imaging technology that permits the reviewing pharmacist to determine its authenticity. The sufficiency of the technology shall be determined by the Department. If sufficient technology is not used, **the written prescriptions must be delivered to the home pharmacy and reviewed by a pharmacist prior to being dispensed to the patient.**

Pharmacy Practice Act Rules 1330.510

- A) A kiosk is a device that maintains individual patient prescription drugs that were verified and labeled at the home pharmacy.
- B) A home pharmacy may only use the kiosk with prior approval of a patient.
- C) A kiosk located on the same premises or campus of the home pharmacy shall operate under the same license as the home pharmacy. However, a kiosk must be licensed with the Division if it is not so located.
- D) A kiosk shall:
 - i) When located on the same premises or campus as the pharmacy, inform a patient, if he or she is using the device when the pharmacy is open, that the patient may address questions and concerns regarding the prescription to a pharmacist at the pharmacy;
 - ii) When not located on the same premises or campus as the pharmacy, inform a patient, if he is using the device when the pharmacy is closed, that he or she may immediately direct any questions and concerns regarding the prescription to a licensed pharmacist via a pharmacy provided audio/video link;
 - iii) Inform a patient that a prescription is not available to be delivered by the device if the pharmacist has determined that he or she desires to counsel the patient in person regarding the prescription.

Pharmacy Practice Act Rules 1330.510

- A pharmacy may use an automated pharmacy system to deliver prescriptions to a patient when the device:
 - A) Is secured against a wall or floor;
 - B) Provides a method to identify the patient and delivers the prescription only to that patient or the patient's authorized agent;
 - C) Has adequate security systems and procedures to prevent unauthorized access, to comply with federal and State regulations, and to maintain patient confidentiality;
 - D) Records the time and date that the patient removed the prescription from the system.
- A licensed automated pharmacy system shall not be utilized by prescribers. Nothing in this Section shall prevent a prescriber from utilizing an automated pharmacy system in connection with his or her own dispensing. However, a prescriber may not utilize or access an automated pharmacy system licensed pursuant to this Section.

Pharmacy Practice Act Rules 1330.510

- All pharmacists performing services in support of at the remote dispensing site, remote consultation site, kiosk, or RAPS sites must display a copy or electronic image of their licenses at their any remote site where they provide services, or shall otherwise make their license visible to the patient, and be licensed in this State, unless employed by a pharmacy licensed in Illinois as a nonresident pharmacy, in which case, the pharmacist providing the services shall hold an active license as a pharmacist in the state in which the nonresident pharmacy is located and only the pharmacist-in-charge of the remote site must be licensed in Illinois.
- No remote site may be open when the home pharmacy is closed, unless at the pharmacist employed or contracted by the home pharmacy, or by a pharmacy contracted with the home pharmacy, is present at the remote site or is remotely providing supervision and consultation as required under this Section. No employees are allowed access to the remote site when the home pharmacy is closed. The security system must allow for tracking of entries into a pharmacy. The pharmacist in charge must review the log of entries weekly.

Pharmacy Practice Act Rules 1330.520

- Medication Dispensing in the Absence of a Pharmacist. The availability of necessary medications for immediate therapeutic use during those hours when the institutional pharmacy is not open shall be met in the following manner:
 - 1) An **after-hour cabinet**, which is a locked cabinet or other enclosure located outside of the pharmacy area containing a minimal supply of the most frequently required medication, **may be utilized provided that only personnel specifically authorized by the institution in which the pharmacy is located may obtain access and it is sufficiently secure to deny access to unauthorized persons. After-hour cabinets shall only be used in the absence of a pharmacist.** When medication is removed from the cabinet or enclosure, written physician's orders authorizing the removal of the medication shall be placed in the cabinet or enclosure. **A log shall be maintained** within the cabinet or enclosure and authorized personnel removing medication shall indicate on the log the **signature of the authorized personnel** removing the medication, the **name of the medication removed**, the **strength** (if applicable), the **quantity removed** and the **time of removal**. An **automated dispensing and storage system may be used as an after hours cabinet**. This use shall be in compliance with Section 1330.680.

Pharmacy Practice Act Rules 1330.520

- Emergency kits containing those drugs that may be required to meet the immediate therapeutic needs of the patient, and that are not available from any other source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining the drugs from the other source, may be utilized. **Emergency kits shall be supplied and maintained under the supervision of a pharmacist. Drugs shall be removed from emergency kits only by authorized pharmacy personnel or persons authorized to administer medication pursuant to a valid physician's order of a physician licensed to practice medicine in all of its branches in Illinois.** Emergency kits shall be sealed in some manner that will indicate when the kit has been opened. **A label shall be affixed to the outside of the emergency kit indicating the beyond use date of the emergency kit.** The beyond use date of the emergency kit shall be the earliest beyond use date of any drug contained in the kit. After an emergency kit has been used or upon discovery that the seal has been broken or upon the occurrence of the beyond use date, **the kit shall be secured and returned to the pharmacy to be checked and/or restocked by the last authorized user. If the pharmacy is closed at that time, the kit shall be returned when it opens. An automated dispensing and storage system may be used as an emergency kit.** This use shall be in compliance with Section 1330.680.

Pharmacy Practice Act Rules 1330.520

- Whenever any drug is not available from night cabinets or emergency kits, and the drug is required to treat the immediate needs of a patient, **the drug may be obtained from the pharmacy in sufficient quantity to meet the immediate need by an authorized nurse.** When medication is removed from the pharmacy by an authorized nurse, **a copy of the physician's order authorizing the removal of the medication shall be conspicuously placed in the pharmacy with the container from which the drug was removed so that it will be found by a pharmacist and checked promptly.** A form shall be available in the pharmacy upon which shall be recorded the **signature of the authorized nurse who removed the medication, the name, strength (if applicable) and quantity of medication removed.**

Pharmacy Practice Act Rules 1330.530

- Labels on all medications dispensed by the pharmacy for immediate dispensing to a patient being discharged, emergency room patient and/or employee shall contain the following:
 - A) The name and dosage form of the drug;
 - B) The date filled; and
 - C) The quantity dispensed; and
 - D) Directions for use.
- After Hours Cabinet: An automated dispensing and storage system may be used as an after hours cabinet. This use shall be in compliance with Section 1330.680.

Pharmacy Practice Act Rules 1330.550

- The Division shall require and provide for an annual **nonresident special pharmacy** registration for all pharmacies located outside of this State that dispense medications for Illinois residents and mail, ship or deliver prescription medications into this State, **including home pharmacies of remote pharmacies located in Illinois that are located outside of Illinois. Unless there is a direct conflict between Illinois pharmacy law and the pharmacy laws of the state in which the nonresident pharmacy is located, nonresident pharmacies shall abide by all Illinois laws and rules when filling prescriptions for Illinois residents, except that pharmacists employed at those pharmacies and the pharmacist-in-charge of those pharmacies shall not be required to be licensed in Illinois except as otherwise provided in this Part.** Nonresident special pharmacy registration shall be granted by the Division upon the disclosure and certification by a pharmacy:
 - That, during its regular hours of operation, but not less than 6 days per week for a minimum of 40 hours per week, a toll-free telephone service is provided to facilitate communication between patients in this State and a **pharmacist retained by the nonresident at the pharmacy** who has access to the patients' records. The toll-free number must be disclosed on the label affixed to each container of drugs dispensed to residents of this State.

Pharmacy Practice Act Rules 1330.560

- Any nonresident pharmacy remote prescription/medication order processing services shall first be registered in its resident state and registered in this State.
- All pharmacists providing remote prescription/medication order processing/practicing at a remote pharmacy shall be licensed in Illinois. However, when pharmacists are providing remote prescription/medication order processing for a community pharmacy licensed in Illinois from a community pharmacy licensed in Illinois but located out-of-state, only the pharmacist-in-charge of the remote pharmacy must be licensed in Illinois.

Pharmacy Practice Act Rules 1330.600

- ~~a) Whenever the pharmacy (prescription area) is not occupied by a registrant, the pharmacy (prescription area) must be secured and inaccessible to non-licensed persons (employees and public). This may be accomplished by measures such as walling off, locking doors or electronic security equipment, as approved by the Division.~~
- ~~b) Schedule II drugs shall be secured in rooms, vaults, safes, cabinets, etc., under lock, whether by key, combination or electronically.~~
- ~~c) Schedule II drugs shall not be distributed among regular stock.~~
- ~~d) All secured Schedule II drugs shall be accessible only when a pharmacist is physically present, except as provided for in Section 1330.530(e).~~
- ~~e) A pharmacist shall be physically present whenever Schedule II drugs are not secured and are to be dispensed, except as provided for in Section 1330.530(e).~~

Pharmacy Practice Act Rules 1330.610

- ~~All pharmacies~~ Any new pharmacy or any existing pharmacy that is remodeled, ~~other than institutional pharmacies,~~ must comply with the following provisions:
 - Other than on-site institutional pharmacies, all All dispensing and drug storage areas of the pharmacy must be contiguous.

Pharmacy Practice Act Rules 1330.620

- All remote pharmacies operating in Illinois shall meet the following equipment requirements, except that subsections (a) through (d) shall not apply to RAPS:
 - a) The pharmacy shall have a computer, scanner, fax capability and printer.
 - b) All prescriptions shall be scanned and sequentially numbered, and the prescription labels shall be produced on site and viewed at the home pharmacy.
 - c) Scanned prescriptions shall be displayable on a computer terminal at both the remote pharmacy and home pharmacy.
 - d) All patient's demographic and prescription information shall be viewable at both the remote and home pharmacy in real time.
 - e) Prescriptions dispensed at the remote pharmacy site must be distinguishable from those dispensed at the home pharmacy.
 - f) In all cases in which electronic data processing equipment is used, the original prescription (either hard copy or an exact, unalterable image) shall be retained on file according to law to assure access to the information contained on the prescription in the event of a computer malfunction.

Pharmacy Practice Act Rules 1330.640

Pharmaceutical Compounding Standards

Pharmacy Practice Act Rules 1330.660

- A pharmacist may be the pharmacist-in-charge for more than one pharmacy; however, the pharmacist-in-charge must work an average of at least 8 hours per week at each location where he or she is the pharmacist-in-charge. If a pharmacist in charge is on a leave of more than 90 days, a new pharmacist-incharge must be designated.

Pharmacy Practice Act Rules 1330.680

- Automated Dispensing and Storage Systems
- ~~1) Automated dispensing and storage systems may be utilized in licensed community or institutional pharmacies.~~
- Automated dispensing and storage systems shall be used only in settings that ensure medication orders and prescriptions are reviewed by a pharmacist in accordance with established policies and procedures and good pharmacy practice. This provision shall not apply when used as an after hours cabinet or emergency kit as provided in Section 1330.530(e).
- The pharmacy providing services to the University of Illinois College of Veterinary Medicine shall be exempt from the requirement that all medications stored in the automated dispensing and storage systems be packaged as a unit for single patient use. This exemption is solely for dispensing medications to animals.

Pharmacy Practice Act Rules 1330.680

- Policies and procedures for the use of the automated dispensing and storage systems shall include the following:
 - A) List of medications to be stored in each system;
 - B) List of medications qualifying for emergency or first dose removal without pharmacist prior review of the prescription or medication order; and
 - ~~C) List of medications qualifying for control purposes.~~

Pharmacy Practice Act Rules 1330.680

- An automated dispensing and storage system is authorized for use in any licensed hospital, long-term care facility, or hospice residence ("facility"). **For all nonresident pharmacies, the pharmacist-in-charge and all pharmacy personnel who provide services while physically present at a facility located in Illinois must be licensed in Illinois.** In addition to compliance with all other provisions in this Section, an automated dispensing and storage system shall comply with the following:
 - 1) Drugs in the automated dispensing and storage system are not considered dispensed until removed from the system by authorized personnel at the facility, after being released by the pharmacy pursuant to a prescription, unless otherwise provided for in this Part.
 - 2) Only the doses of medication needed for contemporaneous administration may be removed from the automated pharmacy system at one time.
 - 3) Automated dispensing and storage systems utilized at a facility shall operate under the same license as the pharmacy utilizing it.
 - 4) All records shall be maintained for a period of 5 years either at the pharmacy providing services to the facility or a central location where records are readily retrievable.
 - 5) Only pharmacies under common ownership may share an automated pharmacy system at a facility.

Pharmacy Practice Act Rules 1330.710

- In every instance that a pharmacy is required by federal regulation (21 CFR 1301.76; 2014) to file with the U.S. Drug Enforcement Agency a Report of Theft or Loss of Controlled Substances (Form 106), a copy shall concurrently be sent to the Division, Attention of the Drug Compliance Unit, along with the printed name of the person who signed the form. Failure to do so may result in discipline of the pharmacy or the pharmacist-in-charge.

Pharmacy Practice Act Rules 1330.740

- Once a med pak has been delivered to an institution, a patient, or a patient's agent, the drugs in the **med pak can be accepted for return by the pharmacy only when a medication must be added or removed, or when drug therapy is discontinued. Med paks returned to the pharmacy can only be re-dispensed for the same patient.** Medications removed from the med pak shall not be reused and must be disposed of properly. The revised med pak shall be given a new serial number. ~~Once a patient med pak has been delivered to an institution or to a patient, the drugs dispensed in the med pak shall not be accepted for return to the pharmacy.~~

Pharmacy Practice Act Rules 1330.750

- Once a dispensed drug is removed from the premises by a patient or the patient's agent, that drug shall not be accepted for return or exchange by a pharmacy or pharmacist.
- The provisions of subsection (a) shall not apply to drugs returned when the wrong medication was dispensed to the patient or in the instance of a drug recall. In no instance may returned drugs be reused or returned to active stock.

Pharmacy Practice Act Rules 1330.780

- Any change of ownership of a parent company that owns a pharmacy shall not be considered a change of ownership of the pharmacy.

Pharmacy Practice Act Rules 1330.790

- Provide notice to the Drug Compliance Unit of ~~Notify~~ the Division, in writing, postmarked at least 30 days in advance of the closing date.

Pharmacy Practice Act Rules 1330.800

- Every licensed pharmacy shall conduct an annual self-inspection using forms provided by the Division. The annual self-inspection shall be conducted during the same month, annually, as determined by the pharmacy. **Documentation of the self-inspection shall be maintained at the pharmacy for 5 years.** The primary objective of the self-inspection is to create an opportunity for a pharmacy to identify and correct areas of noncompliance with State and federal law. This includes, but is not limited to, recordkeeping, inventory, labeling and sanitation requirements.

Illinois Controlled Substances Act Rules

77 IAC 3100

Effective February 27, 2015

Controlled Substances Act Rules 3100.10

- "Administration" means the Drug Enforcement Administration, United States Department of Justice, or its successor agency.
- "Address of Record" means the designated address recorded by the Department in the applicant's application file or the licensee's license file, as maintained by the Department's licensure maintenance unit.
- "~~DEA Registration~~ ~~Controlled Substances Code Number~~" means the number assigned to controlled substances and controlled drug preparations by the Drug Enforcement Administration of the Department of Justice as defined by 21 CFR 1308.03 (April 1, 2014).

Controlled Substances Act Rules 3100.10

- "Individual Practitioner" means a physician, dentist, veterinarian, podiatrist or ~~therapeutically certified~~ optometrist licensed in the State of Illinois to practice his/her profession, a licensed physician assistant with prescriptive authority ~~who issues a prescription for a Schedule III, IV, or V controlled substance in accordance with Section 303.05 of the Act and the written supervision agreement guidelines required under Section 7.5 of the Physician Assistant Practice Act of 1987 [225 ILCS 95], or a licensed advanced practice nurse with prescriptive authority, in accordance with Section 303.05 of the Act and a written collaborative agreement as provided in Section under Sections 65-4015-15 and 15-20 of the Nurse Nursing and Advanced Practice Nursing Act [225 ILCS 65] except as provided in Section 3100.80(c).~~

Controlled Substances Act Rules 3100.10

- Removes Institutional Practitioner
- "License" or "Licensure" encompasses licensure, registration, certification or other approval of an individual in accordance with State or federal statute.
- "Mid-level Practitioner" means:
 - a physician assistant who has been delegated authority to prescribe through a written delegation of authority by a physician licensed to practice medicine in all of its branches, in accordance with Section 7.5 of the Physician Assistant Practice Act of 1987;
 - an advanced practice nurse who has been delegated authority to prescribe through a written delegation of authority by a physician licensed to practice medicine in all of its branches or by a podiatrist, in accordance with Section 65-40 of the Nurse Practice Act; or
 - an animal euthanasia agency

Controlled Substances Act Rules 3100.10

- "Mid-Level Practitioner Controlled Substances License" is a license issued to a mid-level practitioner licensed physician assistant or licensed advanced practice nurse authorized to prescribe by a physician in accordance with the professional licensure Act of the profession or a euthanasia agency.
- "Pre-printed Prescription" means a written prescription upon which the designated drug has been indicated prior to the time of issuance, including any pre-inked stamp that would be applied to a prescription blank. The term does not mean a written prescription that is individually generated by machine or computer in the prescriber's place of business.
- "Registrant" means a person or party registered or licensed under or holding a certificate of registration or license pursuant to the Act.

Controlled Substances Act Rules 3100.310

- Removal of Administrative Hearing language.
- c) Any additional security evidence, including but not limited to: video surveillance, computer access logs or records, or falsified prescription/medical documentation that demonstrates or captures diversion or other illicit activity involving controlled substances shall be made available to the Division upon request, along with a copy of any DEA Form 106 filed pursuant to Section 3100.360(e).
- d) Personal bags of any kind, including but not limited to purses, handbags and backpacks, are prohibited in any area where controlled substances are handled and/or stored.
- e) A basic alarm system that detects unauthorized entry into the pharmacy area. This does not apply to 24-hour pharmacies that never close.
- f) All pharmacies are required to maintain a key to the licensed pharmacy area held by an employee of the pharmacy who is a licensed pharmacist or a registered pharmacy technician or certified pharmacy technician.
- c) Physical security controls of locations registered under the federal Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 90-513, 84 Stat. 1256), shall be deemed to comply substantially with the standards set forth herein. Any new facilities or work or storage areas constructed or utilized for controlled substances, which facilities or work or storage areas have not been previously approved, shall not necessarily be deemed to comply substantially with the standards set forth herein, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved.

Controlled Substances Act Rules 3100.320

- The adequacy of supervision over employees having access to manufacturing and storage areas;
- The applicability of the security requirements contained in all federal, State and local laws and regulations governing the management of waste.

Controlled Substance Act Rules 3100.340

- a) Controlled substances listed in ~~Schedules~~ **Schedule I and II** shall be stored in a securely locked, substantially constructed cabinet.
- b) Controlled substances listed in Schedules ~~II, III, IV and V~~ shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and ~~institutional practitioners (as defined under federal statutes)~~ may disperse ~~those~~ such substances throughout the stock of non-controlled substances in such a manner so as to obstruct the theft or diversion of the controlled substances.
- c) This Section shall also apply to non-practitioners authorized to conduct instructional activities or chemical analysis under another registration.

Controlled Substances Act Rules 3100.360

- a) Every licensee ~~registrant~~ shall keep records and maintain inventories in conformance with the record keeping and inventorying requirements of federal law, including the requirements prescribed in ~~21 CFR Part 1304 (April 1, 2014) of Title 21 of the Code of Federal Regulations, and, for pharmacies, the rules promulgated pursuant to the Pharmacy Practice Act (68 Ill. Adm. Code 1330).~~
- b) All prescription information for electronic controlled substance prescriptions shall be readily retrievable and immediately available to any Division inspector upon request.
- c) Every licensee shall conduct an annual inventory that includes an inventory with an actual count of the inventory on hand for all Schedule II Controlled Substances and an approximate inventory for all Schedule III, IV and V Controlled Substances. The inventory shall be maintained for a period of not less than 5 years.
- d) After a loss or theft of controlled substances, a licensee shall conduct an approximate count inventory with a start date of the last inventory for the controlled substance that was either lost or stolen.
- e) In every instance that a licensee is required by 21 CFR 1301.76 (April 1, 2014) to file with the DEA a Report of Theft or Loss of Controlled Substances (Form 106), a copy shall be sent to the Division within one business day after submission to the DEA, along with the printed name of the person who signed the form. Failure to do so may result in discipline of the licensee. This information should be sent to the Drug Compliance Unit of the Division.

Controlled Substances Act Rules 3100.360

- The following shall apply to all licensed pharmacies:
- 1) Every licensee shall keep a suitable book, file or electronic record keeping system in which shall be preserved for a period of not less than 5 years the original, or an exact, unalterable image, of every written prescription and the original transcript or copy of every verbal prescription filled, compounded or dispensed. The book or file of prescriptions shall at all reasonable times be open to inspection by the duly authorized agents or employees of the Division.
- 2) Every prescription filled or refilled shall contain in the prescription record the **unique identifiers of the persons** authorized to practice pharmacy under the Pharmacy Practice Act **who fills or refills the prescription**.

Controlled Substances Act Rules 3100.360

- 3) Records kept pursuant to this Section may be maintained in an alternative data retention system, such as a direct digital imaging system, provided that:
 - i) The records maintained in the alternative data retention system contain all of the information required in a manual record;
 - ii) The data processing system is capable of producing a hard copy of the electronic record on the request of the Division, its representative, or other authorized local, State, or federal law enforcement or regulatory agency;
 - iii) The digital images are recorded and stored only by means of a technology that does not allow subsequent revision or replacement of the images; and
 - iv) The prescriptions may be retained in written form or recorded in a data recording processing system, provided that the order can be produced in printed form upon lawful request.
- 4) As used in subsection (f)(3), "digital imaging system" means a system, including people, machines, methods of organization and procedures, that provides input, storage, processing, communications, output and control functions for digitized representations of original prescription records.

Controlled Substances Act Rules 3100.380

- A practitioner shall not self-prescribe or self-dispense controlled substances. A practitioner may not prescribe controlled substances to an immediate family member unless there is a bona fide practitioner-patient relationship and appropriate records are maintained for all treatment of the family member.
- The provisions of the federal Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act) (21 USC 801 et seq.) also apply and all federal regulations (74 Fed. Reg. 15596 (April 6, 2009)) adopted under that Act are hereby incorporated by reference.

Controlled Substances Act Rules 3100.390

- All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address, and DEA federal registration number of the practitioner. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (e.g., "J. H. Smith" or "John H. Smith"). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner except in the instances of a Schedule II prescription, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by this Part.

Controlled Substances Act Rules 3100.390

- b) A practitioner may sign a paper prescription in the same manner as he or she would sign a check or legal document (e.g., J.H. Smith or John H. Smith). **When an oral order is not permitted, paper prescriptions shall be written with ink or printed and shall be manually signed by the practitioner.** A computer-generated prescription that is printed out or faxed by the practitioner must be manually signed.
- c) A prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the Act and this Part. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form required by this Part. **Neither a pharmacist nor a pharmacy technician may act as an agent for a practitioner.**
- d) Prescriptions sent via a facsimile transmission do not constitute electronic prescriptions in accordance with Section 311.5 of the Act.

Controlled Substances Act Rules 3100.390

- e) Electronic prescribing is permitted as described in Section 311.5 of the Act.
- b) Any person referred to in Section 3100.80 who is exempted from registration under statute or this Part shall include on all prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution as provided in statute or this Part, in lieu of the registration number of the practitioner required by this Part. Each prescription shall have the name of the person so specified by Section 1650.80 printed on it.
- c) An official exempted from registration under statute shall include on all prescriptions issued by him, his branch of service or agency (e.g., "U. S. Army" or "Public Health Service") and his service identification number, in lieu of the registration number of the practitioner required by these regulations. The service identification number for a Public Health Service practitioner is his social security identification number. Each prescription shall have the name of the officer stamped or printed on it, as well as the signature of the officer. Public Health Service practitioners shall issue prescriptions for Schedule II controlled substances on conventional prescription forms, not triplicate prescription blanks.

Controlled Substances Act Rules 3100.400

- A pharmacist may fill a Schedule II controlled substance prescription ~~only upon a written or electronic prescription that conforms to the requirements of Section 311.5 or 312 Paragraph 1311 of the Act, respectively, and the requirements of this Part, except a prescription issued by a Public Health Service practitioner or out-of-state practitioner may be filled when written upon a conventional prescription form.~~

Controlled Substances Act Rules 3100.400

- Changes in a Prescription
- 1) A pharmacist may not change the following components of a prescription for a Schedule II controlled substance:
 - A) Date written, or add the date;
 - B) Name of the patient;
 - C) Name of the prescriber, or add a signature; and
 - D) Name of the drug.
- 2) Any other components of a prescription for a Schedule II controlled substance may be changed after consultation with the prescriber.
- c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

Controlled Substances Act Rules 3100.400

- Notwithstanding any other provision in this Section, prescriptions for Schedule II controlled substances may be sent to a pharmacy via facsimile in accordance with Section 313 of the Act.

Controlled Substances Act Rules 3100.410

- Each refilling of a prescription of a controlled substance listed in Schedules III, IV or V:
 - 1) shall be entered on the back of the prescription or in the electronic prescription record;
- A pharmacist may contact the prescriber to refill a Schedule III, IV or V controlled substance **only at the request of a patient or patient's representative**. The patient's agreement to utilize a pharmacy auto-fill program, medication adherence plan or long term care or similar related care contract constitutes a request from the patient.

Controlled Substances Act Rules 3100.420

- Each partial filling is recorded in the same manner as a refill, but shall not be considered a refill.
- When Partial Filling of a Schedule II Controlled Substance is Permissible
- Except as provided in subsection ~~subparagraph~~ (b)(2), below, the partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he or she makes a notation of the quantity supplied on the face of the written prescription, ~~(or written record of the emergency oral prescription, or in the electronic prescription record).~~ The remaining portion of the prescription may be filled within 72 hours ~~after~~ of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription

Controlled Substances Act Rules 3100.420

- A ~~prescription~~Prescriptions for Schedule II controlled substances written for a ~~patient~~patients in a long term care facility ~~Long-Term Care Facilities (LTCF)~~ or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities, to include individual dosage units. If there is any question whether the patient may be classified as having a terminal illness, contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is terminally ill or an LTCF patient. A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions, for patients in ~~an~~ LTCF or for patients with a medical diagnosis documenting a terminal illness, shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

Controlled Substances Act Rules 3100.420

- Information pertaining to current Schedule II prescriptions for patients in ~~an~~ LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit:
 - A) Output (display or printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, ~~address of the identification of LTCF or address of the hospital or residence of the terminally ill patient~~, identification of medication authorized (to include dosage form, strength and quantity), listing of partial fillings that have been dispensed under each prescription and the information required in ~~subsection~~ ~~subparagraph~~ (b)(2), above.
 - B) Immediate (real time) updating of the prescription record each time a partial filling of the Schedule II prescription is conducted.
 - C) Retrieval of partially filled Schedule II prescription information is the same as required by ~~21~~ CFR ~~Section 1306.22(b)(4) and (5) (April 1, 2014)~~ of Title ~~21~~ of the Code of Federal Regulations for Schedule III and IV prescription refill information.

Controlled Substances Act Rules 3100.430

- a) Notwithstanding any other provision of this Part, Illinois pharmacists may fill prescriptions for controlled substances issued by a practitioner actively licensed in another United States jurisdiction and who holds an active DEA registration in conformance with the Act and this Part. Every pharmacist who fills an emergency Schedule II prescription, or a Schedule II prescription issued by an out-of-state practitioner or an exempt federal practitioner, shall make a copy and endorse on the reverse side of such copy the name and address of the pharmacy, the date when filled and the signature of the pharmacist who filled such prescription and forward said copies as set forth in Paragraph ~~13311~~ of the Act.
- b) For purposes of this Section, an out-of-state practitioner is one who is of a category licensed in this state to issue prescriptions.

Controlled Substances Act Rules 3100.440

- In carrying out its functions under the Act, the Division, Department through its inspectors, is authorized in accordance with Section 302 Paragraph 1302 of the Act to enter controlled premises and conduct administrative inspections of those premises, thereof with subpoena or notice, during regular business hours and without disrupting patient care, for the purpose of:
 - 1) Inspecting, copying and verifying the correctness of records, reports or other documents required to be kept or made under the Act and this Part. Upon the Division's request, the licensee's agent or employee shall produce those records, the rules promulgated under the Act, including, but not limited to, inventory and other records required to be kept pursuant to this Part, order form records required to be kept pursuant to this Part, prescription and distribution records required to be kept pursuant to this Part, shipping records identifying the name of each carrier used and the date and quantity of each shipment, and storage records identifying the name of each warehouse used and the date and quantity of each storage;

Controlled Substances Act Rules 3100.440

- Checking of records and information on distribution of controlled substances by the registrant as they relate to total distribution of the registrant (i.e., has the distribution in controlled substances increased markedly within the past year and, if so, why?); and
- Except as provided by law, all other things therein (including records, files, papers, processes, controls and facilities) appropriate for verification of the records, reports and documents referred to above or otherwise bearing on the above provisions of the Act and the rules thereunder.
- Refusal by the licensee, registrant or owner, operator, agent or other person in charge of the controlled premises to allow inspection and fully comply with the inspection pursuant to this Part, shall constitute a basis for suspension or revocation of registration.

Controlled Substances Act Rules 3100.500

- Schedule II controlled substances shall be distributed to a licensee and received by a licensee only upon completion of an Administration Form 222.

Controlled Substances Act Rules 3100.510

- Records for dispensing and administering required by Section 312(d) of the Act shall be kept in accordance with 21 CFR 1304 (April 1, 2014).

Controlled Substances Act Rules 3100.530

- Transfer between pharmacies of prescription information shall be done in accordance with 68 Ill. Adm. Code 1330.720 (rules of the Pharmacy Practice Act).

Electronic Prescription Monitoring Program Rules

77 IAC 2080

Effective April 22, 2015

PMP Rules 2080.20

- "Account" refers to the clinical entity that is providing direct patient care and is registered with the PMP to have access to patient specific data through the Prescription Information Library (PIL).
- "Account Custodian" means the licensed healthcare professional whose registration may be used by other members of the healthcare group for access to the PIL.
- "Clinical Director" means a Department of Human Services administrative employee licensed to either prescribe or dispense controlled substances who shall run the clinical aspects of the Department of Human Services Prescription Monitoring Program and its Prescription Information Library [720 ILCS 570/102 (d-5)].

PMP Rules 2080.20

- "Controlled Substance" means a drug, substance, or immediate precursor in the Schedules of Article II of the Illinois Controlled Substances Act or a drug or other substance, or immediate precursor, designated as a controlled substance by DHS [720 ILCS 570/102(f)].
- "Dispenser" means any practitioner or pharmacy that dispenses a controlled substance to an alternative user or research subject by or pursuant to the lawful order of a prescriber [720 ILCS 570/102(p) and (q)].
- "Exempt Prescribers in Hospitals and Institutions" means prescribers in hospitals or institutions licensed under the Hospital Licensing Act [210 ILCS 85] who authorize the administration or dispensing of Schedule II drugs within the hospital or institution, for consumption within the hospital or institution (e.g., controlled substance prescriptions when a prescriber does not maintain his or her own DEA and State controlled substance license, but prescribes based upon the institution's (hospital's) controlled substance license).

PMP Rules 2080.20

- "Freestanding Clinic" means urgent care operations or outpatient surgery centers and similar operations that do not provide overnight in-house stays.
- "Illinois Healthcare License Number" means the license assigned by DPH to facilities designated to provide specific types or levels of healthcare.
- "Licensed Healthcare Entity" means those operations that are licensed to provide health services by either DPH or DFPR.
- "Licensed Healthcare Provider" means any individual who meets the professional licensing requirements and follows the standards set forth by DFPR and is authorized to prescribe or dispense controlled substances within Illinois.

PMP Rules 2080.20

- "Licensed Professional Administrator" means the clinical director of the Prescription Monitoring Program, who must be licensed to either prescribe or dispense controlled substances.
- "Medication Shopping" means the conduct prohibited under Section 314.5(a) of the Act.
- "Mid-level Practitioner" means:
 - a physician assistant who has been delegated authority to prescribe through a written delegation of authority by a physician licensed to practice medicine in all of its branches, in accordance with Section 7.5 of the Physician Assistant Practice Act of 1987 [225 ILCS 95];
 - an advanced practice nurse who has been delegated authority to prescribe through a written delegation of authority by a physician licensed to practice medicine in all of its branches or by a podiatrist, in accordance with Section 65.40 of the Nurse Practice Act [225 ILCS 65]; or
 - an animal euthanasia agency.

PMP Rules 2080.20

- "Patient Location Code" means the location of the patient when receiving pharmacy services.
- "Pharmacist-In-Charge" means the licensed pharmacist whose name appears on the pharmacy license and who is responsible for all aspects of the operation related to the practice of pharmacy.
- "Pharmacy Shopping" means the conduct prohibited under Section 314.5(b) of the Act.
- "Prescriber" means the healthcare professional that is authorized to prescribe medications as set forth in the various professional practices of the State of Illinois.

PMP Rules 2080.20

- "Prescription Monitoring Program" or "PMP" means the entity that collects, tracks, and stores reported data on controlled substances and select drugs [720 ILCS 570/102(nn-10)].
- "Prescription Monitoring Program Advisory Committee" or "PMPAC" means a committee consisting of licensed healthcare providers representing all professions that are licensed to prescribe or dispense controlled substances. The committee serves in a consultant context regarding longitudinal evaluations of compliance with evidence based clinical practice and controlled substances. The committee makes recommendations regarding scheduling of controlled substances and recommendations concerning continuing education designed to improve the health and safety of the citizens of Illinois regarding pharmacotherapies of controlled substances.

PMP Rules 2080.20

- "Push Reports" means the electronic exchange of patient specific health care information contained in electronic medical records from the PMP, without the requirement of the individual clinician having to "sign" into the PMP and request the patient information.
- "Sample Trend Analysis" means the summary reports that look at utilization rates for specific classes of medications over time.
- "Schedule Drug" means any substances listed in the federal Controlled Substances Act (21 USC 812) or the Illinois Controlled Substances Act [720 ILCS 570] or by the Department pursuant to its authority under Section 202 of the Illinois Controlled Substances Act [720 ILCS 570/202]. Schedule I, II, III, IV and V substances are listed in section 812 of the federal Controlled Substances Act (21 USC 812(b)(2), (b)(3), (b)(4), (b)(5) and (c)) and Sections 204, 206, 208, 210 and 212 of the Illinois Controlled Substances Act [720 ILCS 570/204, 206, 208, 210 and 212].

PMP Rules 2080.70

- A dispenser may fill a prescription for a Schedule II, III, IV or V drug upon receipt of a written, electronic, facsimile or verbal order of a physician unless otherwise specifically exempted or allowed by federal or State law.
- A prescription for a Schedule II, III, IV or V drug shall:
 - Have affixed to the face of the prescription the prescriber's electronic or handwritten signature, initials, thumbprint or other biometric or electronic identification process approved by DFPR pursuant to Section 3 of the Pharmacy Practice Act [225 ILCS 85];
 - ~~If written, be signed by the prescriber in the same manner as the prescriber would sign a check or legal document;~~

PMP Rules 2080.70

- A prescription for a Schedule II, III, IV or V drug shall:
 - 10) Not allow more than a 30 day supply of a Schedule II drug on any one prescription;
 - 11) Not allow for any refills of Schedule II drugs;
 - 15) Allow electronic prescriptions in accordance with federal rules set forth in 21 CFR 1300, 1304, 1306, 1311 (2010) [720 ILCS 570/311.5]; and
 - 16) Allow an individual physician the authority to prescribe multiple prescriptions (3 sequential 30-day supplies) for the same Schedule II controlled substance, authorizing up to a 90-day supply [720 ILCS 570/312(a-5)].

PMP Rules 2080.70

- Patient ID for Proper Filling:
- The sex field is a verifying element of a patient ID. ~~The patient's gender shall~~ needs to be entered in the sex field.
- The birth date is a verifying element of a patient ID and needs to be entered in the birth date field (yyyyymmdd).
- The final verifying element of a patient ID for an animal or individual is not a set standard. Each pharmacy or chain ~~may~~ will adopt its own standard. The concern is that if a standard is too rigid, the enterprise's business activity will suffer. Any of the following may be used. If the primary choice is not available (e.g., if the patient is an undocumented alien), another choice may be used. **[Removal of SSN]**

PMP Rules 2080.100

- Dispenser full name and address
- Prescriber full name
- Patient sex (M for male, F for female or U for unknown ~~for animal~~)
- Date dispensed
- Payment type (i.e., Medicaid, cash, third-party insurance)
- Patient location code (i.e., home, nursing home, outpatient, etc.)
- Days' supply (based on dispensed quantity)

PMP Rules 2080.100

- For hospitals licensed under the Hospital Licensing Act [210 ILCS 85], any discharge or outpatient prescription exceeding a 72 hour quantity must be reported to the PMP central repository within 7 days after dispensing (may be reported more frequently). The report shall contain the following data or any other data deemed necessary by the PMPAC:
 - 1) Dispenser DEA number.
 - 2) Dispenser name and address.
 - 3) Recipient's (or animal and owner's) name and address.
 - 4) NDC identification number of the Schedule II, III, IV or V drug dispensed.
 - 5) Quantity of the Schedule II, III, IV or V drug dispensed.
 - 6) Date prescription filled.
 - 7) Date prescription written.
 - 8) Prescriber DEA number.
 - 9) Prescriber name and address.

PMP Rules 2080.100

- 10) Patient ID.
- 11) Patient sex (M for male, F for female or U for unknown).
- 12) Patient birth (yyyymmdd – year, month, day).
- 13) Date dispensed
- 14) Payment type (i.e., Medicaid, cash, third-party insurance).
- 15) Patient location code (i.e., home, nursing home, outpatient, etc.).
- 16) Days' supply (based on dispensed quantity).
- c) The Department shall impose a **civil fine of \$100 per day** for willful failure to comply with statutory reporting requirements. Assessment of the fine begins on the day after the report was required to be submitted and ends on the day the failure to report is remedied. Fines shall be payable to the Prescription Monitoring Program.

PMP Rules 2080.190

- a) For the purpose of intervention to prevent misuse, a prescriber or dispenser may request that reports about his or her patients be sent to them via a secure method if a patient meets the current PMP indications of potential misuse criteria set forth by the PMPAC.
- b) A personal information report of a patient's prescription profile may be obtained if:
 - 1) The patient, parent or guardian completes a notarized request; and
 - 2) The patient, parent or guardian submits the notarized request by mail to the PMP at: Illinois Prescription Monitoring Program 401 North 4th Street, First Floor Springfield, Illinois 62702
- c) When a person has been identified as having **6 or more prescribers or 6 or more pharmacies, or both, that do not utilize a common electronic file as specified in Section 20 of the Pharmacy Practice Act [225 ILCS 85] for controlled substances within the course of a continuous 30-day period**, the PMP may issue an unsolicited report to the prescribers informing them of the potential medication shopping [720 ILCS 570/314.5(d)]. The individual prescriber's judgment determines what actions, if any, he or she should take upon receipt of the unsolicited **6-6-1 reports**.

PMP Rules 2080.190

- d) The PMP is authorized to develop operational push reports to entities with compatible electronic medical records [720 ILCS 570/318(n)]. The push report will only include information for patients that are in the PMP organization's electronic medical record (EMR). It is the responsibility of the entity to keep the access to this confidential patient information secure. These entities must:
 - 1) Meet and maintain the PMP's current security standards prior to the electronic transfer of information from the PMP to its respective EMR;
 - 2) Be a licensed healthcare entity; and
 - 3) Only use this confidential patient information for the treatment of the relevant patient.
- e) ~~Technical~~ Other than technical, error and administrative function reports needed to determine that the records are received and maintained in good order may be used.
- f) Sample trend analysis reports may be prepared extemporaneously by PMP staff. The disposition of all extemporaneous reports shall be at the discretion of the licensed, professional administrator of the PMP.

PMP Rules 2080.190

- g) Authorized persons listed in this subsection may request information from the PMP.
 - 1) Official inquiries must be from any one of the following:
 - A) DFPD;
 - B) An investigator from the Illinois Consumer Protection Division of the Office of the Attorney General; or
 - C) A law enforcement officer.
 - 2) Inquiries must be submitted in writing and demonstrate that:
 - A) The applicant has reason to believe that a violation under State or federal law that involves a controlled substance by an individual has occurred; and [720 ILCS 570/318(e)(1)]
 - B) The requested information is reasonably related to the investigation of the individual, adjudication, or prosecution of the violation. [720 ILCS 570/318(e)(2)]
 - 3) The Department may impose a fee for the cost of generating and furnishing the requested information.

PMP Rules 2080.190

- h) ~~Any~~ any other reports concerning the information received from dispensers shall only be prepared at the direction of the Manager, Bureau of Pharmacy and Clinical Support Services, or successor administrator who meets the statutory requirements. The information described in subsection (g) may not be released until it has been reviewed by an employee of the Department who is licensed as a prescriber or a dispenser and until that employee has certified that further investigation is warranted [720 ILCS 570/318(g)], in response to official inquiries from officers of the court. Sample trend analysis reports may be prepared extemporaneously by prescription monitoring program staff. The disposition of all extemporaneous reports shall be at the discretion of the licensed, professional administrator of the prescription monitoring program.
- i) As directed by the PMPAC and the Clinical Director for the PMP, aggregate data that does not indicate any prescriber, practitioner, dispenser, or patient may be used for clinical studies under Article VIII, Part 21 of the Code of Civil Procedure [735 ILCS 5/Art. VIII, Part 21] (Medical Studies).

PMP Rules 2080.210

- Medical prescribers or dispensers may utilize the PIL for patient care after obtaining authorization from the PMP.
- A hospital emergency department or a freestanding healthcare facility providing healthcare to walk-in patients may obtain, for the purpose of improving patient care, a unique identifier for each shift to utilize the PIL system.

PMP Rules 2080.220

- If a prescriber notices an error in his or her prescription information, he or she shall report it to the Department by using the built in PMP error reporting system within 7 days after discovery of the error.
- A dispenser who notices an error in a prescription he or she has dispensed and transmitted shall **retract the incorrect prescription and retransmit the prescription correctly within 7 days** after discovery of the error.

PMP Rules 2080.230

- Defines the Schedules of Controlled Substances I, II, III, IV, and V.

PMP Rules 2080.240

- In order to prevent erroneous association of prescriptions and remain compliant with the PMP, any supervising or collaborating physician who has delegated prescriptive authority to a midlevel practitioner is required to log in and fill out the electronic form on the PMP website (www.ilpmp.org) detailing what prescriptive authority he or she has delegated in compliance with the Act. **It is incumbent upon the collaborating or supervising physician to keep this record up to date.** The form will require, but is not limited to, the following data fields:

PMP Rules 2080.250

- Controlled substances may be mailed if all of the following conditions are met: 1) The controlled substances are not outwardly dangerous and are not likely, of their own force, to cause injury to a person's life or health. 2) The inner container of a parcel containing controlled substances must be marked and sealed as required under the Act and be placed in a plain outer container or securely wrapped in plain paper.
- If the controlled substance consists of prescription medicines, the inner container must be labeled to show the name and address of the pharmacy or practitioner dispensing the prescription. 4) The outside wrapper or container must be free of markings that would indicate the nature of the contents. [720 ILCS 570/312 (k)(1)] b) No controlled substance may be mailed outside the United States, including US territories, without the mailer: 1) Registering the package with the DEA as an exported product as set forth in 21 CFR 1301 and 1309. 2) Obtaining the necessary permits, or submitting the necessary declarations for export as set forth in 21 CFR 1312 and 1313.

Electronic Prescription Monitoring Program - Long Term Care Rules

77 IAC 2081
Effective April 22, 2015

PMP LTC Rules 2081.20

- "Long Term Care" or "LTC" means:
 - any facility defined by Section 1-113 of the Nursing Home Care Act; and
 - any skilled nursing facility or a nursing facility that meets the requirements of section 1819(a), (b), (c) and (d) or section 1919(a), (b), (c) and (d) of the Social Security Act (42 USC 1395i-3(a), (b), (c) and (d) and 1396f(a), (b), (c) and (d)).
- "Long Term Care Pharmacy" or "LTC Pharmacy" means those pharmacies that, either as a primary or secondary focus, provide prescription services to those inpatient institutions licensed as LTC facilities by DPH.

PMP LTC Rules 2081.30

- The PMP monitors all controlled substances for Schedule II, III, IV and V drugs that are dispensed within the State of Illinois, except for those dispensed to hospital inpatients and by drug abuse treatment programs licensed by the Department. The LTC pharmacies transmit patient medication profiles to the PMP. Each time a Schedule II, III, IV or V drug is dispensed, the dispenser must transmit specific information to a central repository designated by the Department.

PMP LTC Rules 2081.40

- LTC pharmacies shall transmit the patient medication profiles to the PMP weekly (see 720 ILCS 570/316(c)). The Department shall impose a **civil fine of \$100 per day** for willful failure to comply with statutory reporting requirements. Assessment of the fine begins on the day after the report was required to be submitted and ends on the day the failure to report is remedied. Fines shall be payable to the Prescription Monitoring Program.
 - 1) Dispenser DEA number.
 - 2) Name of the medication as listed in Appendix A.
 - 3) Dispenser name and address.

PMP LTC Rules 2081.40

- 4) Patient information that should be kept up to date at all times:
 - A) Patient's name.
 - B) Patient ID.
 - C) Patient sex (M for male, F for female or U for unknown).
 - D) Patient birth date (yyyymmdd – year, month, day).
 - E) Patient ethnicity (if available).
 - F) Patient location code (LTC facility State provider number and corresponding location at the facility, i.e., unit and room).
 - G) Pre-existing conditions.
 - H) Patient weight, when available electronically.
 - I) Patient height, when available electronically.

PMP LTC Rules 2081.40

- 5) For each prescription dispensed, the following information must be included:
 - A) The NDC identification number of the Schedule II, III, IV or V drugs or select drugs as provided by the PMP-LTC Advisory Committee.
 - B) Quantity of the drug dispensed.
 - C) Dosing of the drug dispensed.
 - D) Date when the drug was dispensed.
 - E) Date prescription was written.
 - F) Prescriber DEA number.
 - G) Prescriber full name.
 - H) Diagnosis
 - I) Days' supply (based on dispensed quantity)

PMP LTC Rules 2081.40

- 6) For any patient admissions to acute care facilities, the following information shall be included:
 - A) Date admitted, if known to the dispenser.
 - B) Date discharged, if discharged at time of transmission, if known to the dispenser.
 - C) Reason for admission, if known to the dispenser.
 - D) Any changes to medication therapy involving medications in Appendix A, if known to the dispenser.
- As directed by the PMP-LTC CCAG and the Clinical Director for PMP, aggregate data and specialized reports may be developed relative to the selected drugs for clinical studies as covered under Art. VIII, Part. 21 of the Code of Civil Procedure [735 ILCS 5] (Medical Studies).

PMP LTC Rules 2081.50

- If a prescriber notices an error in his or her prescription information, that prescriber shall report it to the Department by using the built-in PMP error reporting system within 7 days after discovery of the error.
- **A dispenser who notices an error in a prescription he or she has dispensed and transmitted shall retract the incorrect prescription and retransmit the prescription correctly within 7 days after discovery of the error.**

PMP LTC Rules 2081.60

- Nothing in the Act or this Part shall be construed as granting access to the patient-specific information to anyone other than to the PMP staff and the PMLTC CAG.
- The intent of the PMP-LTC CAG is to provide continuous clinical quality analysis and research designed to improve the clinical outcomes of the patients.
- **The clinical evaluations of resident specific medications, along with information from the MDS (see subsection (d)), shall be made available to DPH no sooner than 90 days after the information is made available electronically to the respective long term care facility administrator by the consulting pharmacist under contract with the facility. It shall be presumed that the information is received by each facility administrator no later than 5 business days after the information is made available electronically to the consulting pharmacist.**

PMP LTC Rules 2081.70

- Defines the Schedules of Controlled Substances I, II, III, IV, and V.

PMP LTC Rules 2081.80

- In order to prevent erroneous association of prescriptions and remain compliant with the PMP, any supervising or collaborating physician who has delegated prescriptive authority to a midlevel practitioner is required to log in and fill out the electronic form on the PMP website (www.ilpmp.org) detailing what prescriptive authority he or she has delegated (see Section 318(k) of the Act). **It is incumbent upon the collaborating or supervising physician to keep this record up to date.** The form will require, but not be limited to, the following data fields

PMP LTC Rules Appendix A

- BEHAVIORAL HEALTH MEDICATIONS
 - Antipsychotics
 - Anti-anxiety Medications
 - ADHD Medications
 - Antihistamine Medications
 - First Generation
 - Second Generation
 - Other
 - ENZYME INDUCERS/INHIBITORS
- Antidepressants
 - Selective Serotonin Reuptake Inhibitors (SSRIs)
 - Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)
 - Serotonin Antagonist and Reuptake Inhibitors (SARIs)
 - Tricyclic Antidepressants (TCAs)
 - Tetracyclic Antidepressants (TeCAs)
 - Monoamine Oxidase Inhibitors (MAOIs)
 - Miscellaneous Agents
 - Norepinephrine – Dopamine Inhibitor
 - 5-HT_{1A} Receptor Agonists
 - 5-HT_{2A} Receptor Agonists
 - 5-HT₂ Receptor Antagonists
 - Mood Stabilizers

PMP LTC Rules Appendix A

- MEDICATIONS WITH ANTICHOLINERGIC EFFECTS
- Level # 1: Potential ACH activity by receptor binding activity:
 - Antipsychotics
 - Anxiolytic
 - Antidepressant
 - Antibiotics/Antivirals
 - Analgesics
 - Cardiovascular
 - Corticosteroids
 - H₂ Antagonist
 - Anticonvulsants
- Level # 2: ACH adverse events, dose related:
 - Antipsychotics
 - Antihistamine
 - Cardiovascular
 - Muscle Relaxants
 - H₂ Antagonist
 - Anticonvulsants
- Level # 3: Markedly Anticholinergic
 - Antipsychotics
 - Antidepressants
 - Antihistamines
 - Muscle Relaxants
 - GI Antispasmodics
 - Parkinson Disease
 - Urinary Antispasmodics

FY2016 Budget

FY2016 Budget

- IPhA continues to have discussions and contact with the Governor's office, HFS, and CMS.
- Dispensing Fee (March 2015)
 - \$5.50 (multiple source)
 - \$2.40 (single source)
 - \$12.00 for both single source and multiple source drugs purchased through the 340B Drug Pricing Program
- Dispensing Fee (May 2015)
 - \$4.50 (multiple source) **16.75% reduction**
 - \$1.40 (single source) **16.75% reduction**
 - \$12.00 for both single source and multiple source drugs purchased through the 340B Drug Pricing Program
- SB788 (Democrats Alternative Proposal)
 - Dispensing Reduction of 2.5% (\$5.38 multiple source, \$2.35 single source)
- Court Decision and Consent Decrees (July 2015)
 - Directs HFS to continue to pay Medicaid providers for services during FY2016
 - Dispensing Fees return to March 2015 levels
- State Employee Prescription Plans
 - Payments ceasing to medical providers for the self-insured plans
 - Unions have sued to continue payments to healthcare providers for the state employee plans (September 18th)

FY2016 Budget

- Please keep contacting the following:
 - I encourage you to call the following to encourage support for dispensing fees proposed in SB788 and not the severe cuts pharmacy is currently experiencing and what is being proposed in the Governor's budget. Be sure to discuss the impact these cuts and effect on your Patients, your Community, and your Pharmacy.
 - Governor Bruce Rauner: 217/782-0244
 - Jennifer Hammer, Special Counsel to the Governor and Policy Advisor for Healthcare and Human Services: 217/558-1025
 - Felicia Norwood, Director of the Department of Healthcare and Family Services: 217/782-1200
 - Pam Kogler, Deputy Director of Benefits: 217/785-8675

Federal Legislation and Regulation

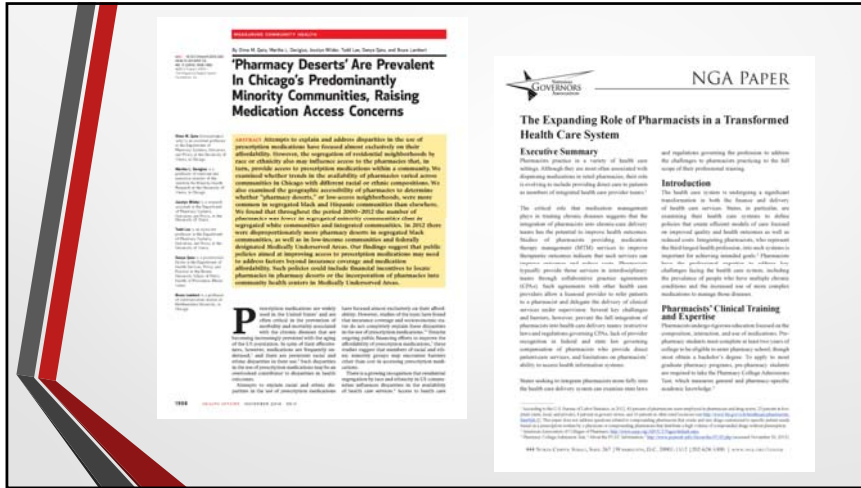
Pharmacists Provider Status

- H.R. 592: **Pharmacy and Medically Underserved Areas Enhancement Act**
- Rep. Brett Guthrie (R-KY), G.K. Butterfield (D-NC), Todd Young (R-IN), and Ron Kind (D-WI) – Introduced January 28, 2015
- Cosponsors – 204 (15 Illinois, including Rep. Schock) as of 09/21/2015
 - Republican – 114 | Democrats – 90
 - Rep. Pete Roskam (R-6), Rep. Darin LaHood (R-18), Rep. Randy Hultgren (R-14), and Rep. Luis Guterrez (D-4) needed
- S. 314: **Pharmacy and Medically Underserved Areas Enhancement Act**
- Senators Chuck Grassley (R-IA), Sherrod Brown (D-OH), Robert Casey (D-PA), and Mark Kirk (R-IL) - Introduced January 29, 2015
- Cosponsors – 28 as of 09/21/2015
 - Democrats – 16 | Republican – 12

Pharmacists Provider Status

- Both bills amend Section 1861 of the Social Security Act to recognize pharmacists services within Medicare Part B.
- Pharmacist services to be provided only in areas that HRSA defines as
 - Medically Underserved Areas (MUAs),
 - Medically Underserved Populations (MUPs),
 - Health Professional Shortage Areas (HPSAs).
- Does not expand existing scope of practice; based on individual States.
- Pharmacist services would be reimbursed at 85% of the physician fee schedule.
 - Similar with Nurse Practitioners (NPs) and Physicians' Assistants (PAs)





Pharmacists Provider Status

- Congressional Budget Office (CBO) Scoring
 - Must score low for legislation to advance
- Demonstrate successes achieved under Medicare Part D – MTM
- Share your experience and encourage your patients to share their stories
- Pharmacistscare.org – Patient Access to Pharmacists’ Care Coalition (PAPCC)
 - IPhA is a member of PAPCC through NASPA.

Any Willing Provider | Preferred Networks

- H.R. 793: **Ensuring Seniors Access to Local Pharmacies Act of 2015**
- Rep. Morgan Griffith (R-VA) and Rep. Peter Welch (D-VT) – Introduced 02/05/2015
- Cosponsors – 58
 - Republican – 42 | Democrats – 16
 - Rep. Daniel Lipinski (D-3) and Rep. Jan Schakowsky (D-9)
- S.1190: **Ensuring Seniors Access to Local Pharmacies Act of 2015**
- Sen. Shelly Moore Capito (R-WV), Sen. Joe Manchin (D-WV), Sen. Tom Cotton (R-AR), and Sen. Sherrod Brown (D-OH)
- Cosponsors – 10
 - Republican – 7 | Democrats – 3

Any Willing Provider | Preferred Networks

- Amend the Social Security Act to ensure that Medicare patients have equal access to community pharmacies in MUAs, MUPs, and HPSAs as network pharmacies under Medicare prescription drug coverage.
- IPhA is part of a pharmacy and patient organization coalition being spearheaded by NCPA.
- Patient access experiences with Preferred Networks

MAC Transparency

- H.R. 244: **MAC Transparency Act**
- Rep. Doug Collins (R-GA) and Rep. Dave Loebsack (D-IA) – Introduced 01/09/2015
- Cosponsors – 25
 - Republican – 20 | Democrats – 5
- Increase transparency of generic drug payment rates under:
 - Medicare Part D
 - Federal Employees Health Benefits program (FEHB)
 - TRICARE
- PBMs required to:
 - Pricing updates at least once every 7 days.
 - Disclose the MAC price sources.
 - Notify of any changes in individual drug prices, in advance.
 - Establish an appeals process.
- Drug Price Standard would specifically include MAC.

Home Infusion - Medicare

- H.R. 605: **Medicare Home Infusion Site of Care Act of 2015**
- Rep. Eliot Engel (D-NY) – Introduced 01/28/2015
- Cosponsors – 29
 - Democrats – 16 | Republicans – 13
 - Rep. Jan Schakowsky (D-9)
- S. 275: **Medicare Home Infusion Site of Care Act of 2015**
- Sen. Johnny Isakson (R-GA) – Introduced 01/28/2015
- Cosponsors – 16
- Reimbursement method for the professional services, supplies and equipment associated with infusion therapy in the home under Medicare Part B
- No change to infusion medication coverage under Medicare Part D

Medication Therapy Management (MTM)

- S. 776: **Medication Therapy Management Empowerment Act of 2015**
- Sen. Pat Roberts (R-KS), Sen. Jeanne Shaheen (D-NH), Sen. Mark Kirk (R-IL), and Sen. Sherrod Brown (D-OH) – Introduced 03/18/2015
- Cosponsors – 14
 - Democrats – 10 | Republicans – 4
- Amend eligibility for MTM to include a single chronic disease of cardiovascular disease, chronic obstructive pulmonary disease, hyperlipidemia, or diabetes.

Drug Enforcement

- H.R. 471: **Ensuring Patient Access and Effective Drug Enforcement Act of 2015**
- Rep. Tom Marino (R-PA), Rep. Marsha Blackburn (R-TN), Rep. Peter Welch (D-VT), and Rep. Judy Chu (D-CA-27) – Introduced 01/22/2015
- Cosponsors – 6
 - Republican – 4 | Democrats – 2
- S. 483: **Ensuring Patient Access and Effective Drug Enforcement Act of 2015**
- Sen. Orrin Hatch (R-UT) and Sen. Sheldon Whitehouse (D-RI) – Introduced 02/12/2015
- Cosponsors – 4
 - Republicans – 3 | Democrats – 1
- Prevent prescription drug abuse and diversion.
- More collaborative partnership between drug manufacturers, wholesalers, pharmacies, federal enforcement and oversight agencies.
- Allows pharmacies the opportunity to submit a corrective action plan prior to revocation or suspension of their license.
- Report to Congress on the effects of law enforcement activities on patient access to medications
 - Must incorporate feedback and recommendations from pharmacies.
- Passed House on 04/21/2015

Drug Quality and Security Act (DQSA)

- Title 1: Drug Compounding
- Title 2: Drug Supply Chain Security Act (DSCSA) – “Track and Trace”
- Signed 11/27/2013

Drug Supply Chain Security Act (DSCSA)

- Traceability
- Licensing - National licensing standards for wholesale distributors & third party logistics providers.
- Preemption - Preempts all state laws and regulations for tracing products through the supply chain and licensure.

Drug Supply Chain Security Act (DSCSA)

- Traceability
 - Phase 1: Product tracing – supply chain partners pass transactional data to subsequent purchasers (data exchange occurs with change of ownership only).
 - January 1, 2015: Purchase only from authorized trading partners (manufacturers, repackagers, and wholesalers)
 - July 1, 2015: Require dispensers (Pharmacies) to pass, capture, and maintain transaction data (Enforcement delayed until November 1, 2015)
- Transaction Records
 - Transaction Information (TI)
 - Transaction History (TH)
 - Transaction Statement (TS)
- Phase 2: Unit Level traceability for all supply chains

Drug Supply Chain Security Act timeline

Prescription drug traceability



TI/TI - Transaction Information Statement
 **Dispensers - under PCMA, dispensers include retail pharmacies and hospital pharmacies; groups of them (pharmacies under common ownership and control) are group authorized for sale to dispensers of prescription drug and related supplies or distribution centers of such entities under common ownership or control.

Medicare Part D – Medication Therapy Management

- Range of 2 to 3 Chronic Conditions
 - 82% of programs target at least 3 chronic conditions
- Range of 2 to 8 Medicare Part D medications
 - 56% of programs target at least 8 medications
- Beneficiary Annual Cost threshold – \$3,138 (Contract Year 2015)

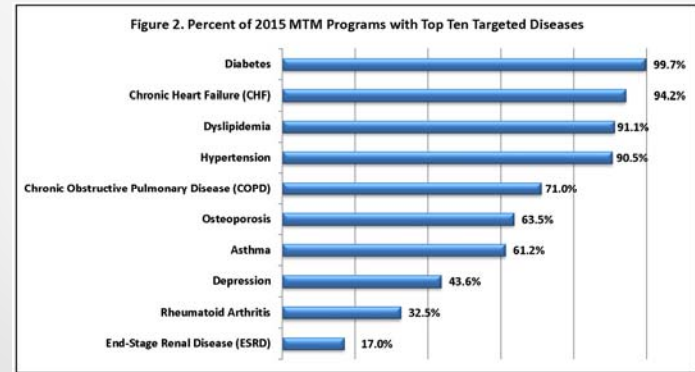


Table 3. 2015 MTM Programs: Qualified Provider of CMR

MTM Provider of CMR	% of Programs
MTM Vendor In-house Pharmacist	66.9%
Plan Sponsor Pharmacist	30.6%
Plan Benefit Manager (PBM) Pharmacist	28.5%
MTM Vendor Local Pharmacist	27.9%
Nurse Practitioner	24.5%
Physician	20.5%
Registered Nurse	18.3%
Licensed Practical Nurse	16.8%
Local Pharmacist	14.6%
Long Term Care (LTC) Consultant Pharmacist	12.1%
Physician's Assistant	10.9%
Hospital Pharmacist	0.1%

Medicare Part D – Star Ratings & Measures

- High Risk Medication in the Elderly
 - (PDP $\leq 6\%$ | MAPD $\leq 7\%$)
- Appropriate Treatment of Hypertension in Persons with Diabetes Treatment
 - (PDP $\geq 90\%$ | MAPD $\geq 90\%$)
- Medication Adherence to Oral Diabetes Medications
 - (PDP $\geq 85\%$ | MAPD $\geq 81\%$)
- Medication Adherence for Hypertension (RAS antagonists)
 - (PDP $\geq 84\%$ | MAPD $\geq 85\%$)
- Medication Adherence for Cholesterol (Statins)
 - (PDP $\geq 78\%$ | MAPD $\geq 83\%$)

CMS 2016 Call Letter

- Preferred Networks:
 - "CMS is concerned about some plans' beneficiary access to preferred cost sharing pharmacies and about the transparency of preferred cost sharing pharmacy network access."
- MTM Eligibility
- Star Rating – addition MTM Program Completion (CMR)
- MAC Pricing:
 - Plans disclose drug prices in advance of their use for reimbursement.
- Opioid overutilization

IPhA Legislative and Regulatory Initiatives

Immunizations HB3627

- **Sponsor: Marcus Evans (D-Chicago)**
- Amends Pharmacy Practice Act
- Changes ability to administer all vaccines from 14 years to 10 years of age
- Failed to obtain votes to get out of committee
- **STATUS: Re-referred to Rules Committee (03/27)**

Pharmacist Provider Designation HB4051

- **Sponsor: Rep. Dan Brady (R-Normal)**
- Amends Care of Students with Diabetes Act, the Health Maintenance Organization Act, the Limited Health Service Organization Act, the Managed Care Reform and Patient Rights Act, the Voluntary Health Services Plans Act, and the Health Care Services Lien Act
- Add pharmacy or pharmacist-provided services to the types of health services under the Acts.
- Add pharmacists as health care providers or health care professionals under the Acts
- **STATUS: Pass – Human Services Committee (03/25) / Re-referred to Rules Committee (04/24)**

Managed Care HB4079

- Sponsor: Rep. Kelly Cassidy (D-Chicago)/ Rep. Jack Franks (D-Woodstock)
- Amends Insurance Code
- Establish registration/oversight for PBMs
- Provides contracting for pharmacist provided care services
- Audit protection conditions
- Increased transparency for pricing
- Strengthens any willing provider
- Allows medication synchronization
- **STATUS: Re-referred to Rules Committee (03/27)**

Managed Medicaid Reimbursements HB4095

- Sponsor: Rep. Sara Feigenholtz (D-Chicago)
- Amends the Public Aid Code
- Fair and reasonable reimbursement rate to pharmacy providers for pharmaceutical services, prescription drugs and drug products, and pharmacy or pharmacist-provided services.
- Fair and reasonable professional dispensing fee
- Reimbursement rate shall not be less than the reimbursement rate utilized by the Illinois Department for reimbursement for prescription and pharmacy or pharmacist-provided services
- **STATUS: Re-referred to Rules Committee (03/27)**

What is the civil fine imposed for not filing a PMP report as per rule?

- A) \$100/day
- B) \$150/day
- C) \$100/day/patient
- D) \$250,000/day
- E) \$100,000/patient

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- A) \$100/day
- B) \$150/day
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- E) \$100,000/patient

HB3219 would require CPhT to obtain how many hours of CPE every 2 years?

- A) 30 contact hours
- B) 20 contact hours
- C) 15 contact hours
- D) 10 contact hours
- E) 40 contact hours

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- E) 40 contact hours

What is the FDA reference for determining an interchangeable?

- A) Orange Book
- B) Pink Book
- C) Yellow Book
- D) Purple Book
- E) Red Book

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- A) Orange Book
- B) Pink Book
- C) Yellow Book
- D) Purple Book**
- E) Red Book

How long must the pharmacy maintain records of a self-inspection?

- A) 1 year
- B) Until the inspector reviews the self-inspection
- C) 10 years
- D) Until any change in pharmacist-in-charge
- E) 5 years

How long must the pharmacy maintain records of a self-inspection?

- a) 1 year
- b) Until the inspector reviews the self-inspection
- c) 10 years
- d) Until any change in pharmacist-in-charge
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How many counties in Illinois are considered to be Medically Underserved Areas (MUAs)?

- A) 97
- B) 102
- C) 50
- D) 79
- E) 42

How many counties in Illinois are considered to be Medically Underserved Areas (MUAs)?

- A) 97
- B) 102
- C) 50
- D) 79
- E) 42

What is the Enforcement Discretion date for the next phase of traceability of the DSCSA?

- A) 11/01/2015
- B) 11/15/2015
- C) 12/31/2015
- D) 01/01/2016
- E) 07/01/2016

What is the Enforcement Discretion date for the next phase of traceability of the DSCSA?

- A) 11/01/2015
- B) 11/15/2015
- C) 12/31/2015
- D) 01/01/2016
- E) 07/01/2016

Which of the following is not a current Medicare Part D measure?

- A) Medication Adherence for Hypertension (RAS antagonists)
- B) High Risk Medication in the Elderly
- C) Medication Adherence to Injectable Diabetes Medications
- D) Appropriate Treatment of Hypertension in Persons with Diabetes Treatment
- E) Medication Adherence for Cholesterol (Statins)

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- D) Appropriate Treatment of Hypertension in Persons with Diabetes Treatment
- E) Medication Adherence for Cholesterol (Statins)

References

- **Illinois General Assembly** – www.ilga.gov
- **Pharmacy Practice Act** - <http://ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1318&ChapterID=24>
- **Administrative Rules to the Pharmacy Practice Act** – <http://ilga.gov/commission/jcar/admincode/068/06801330sections.html>
- **Illinois Controlled Substances Act** – <http://ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1941&ChapterID=53>
- **Administrative Rules to the Illinois Controlled Substances Act** – <http://ilga.gov/commission/jcar/admincode/077/07703100sections.html>
- **Administrative Rules to the Electronic Prescription Monitoring Program** – <http://ilga.gov/commission/jcar/admincode/077/07702080sections.html>
- **Administrative Rules to the Electronic Prescription Monitoring Program – Long Term Care** - <http://ilga.gov/commission/jcar/admincode/077/07702081sections.html>

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