Illinois Law Update 2018

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Illinois Pharmacists Association
Garth 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.
Pharmacist Objectives

At the conclusion of the program, the pharmacists will be able to:

- Discuss pharmacy and healthcare related legislation from the 2018 session.
- Outline pharmacy-related Federal legislation, including Pharmacist Provider Status and Pharmacy Benefit Manager reform.
- Describe updates to the Federal and Illinois regulations related to pharmacy.
- Report the status of IPhA legislation and regulatory initiatives.
At the conclusion of this program, the pharmacy technician will be able to:

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- Report the status of IPhA legislation and regulatory initiatives.
How many days supply can you provide for an Emergency Refill?

a) 5
b) 3
c) 14
d) 30
e) 7
Medication synchronization is allowed if which of the following is met:

a) Not a controlled substance (C-II, C-III, & C-IV)
b) Medication must be covered by insurance
c) Medication must be a maintenance medication
d) All the above
What is the bill number for the IPhA Managed Medicaid/PBM Reform legislation?

a) SB4277
b) HB3479
c) SB1889
d) HB272
e) SR1
Who is part of the success of IPhA’s advocacy efforts?

a) Lobbyists
b) IPhA Staff
c) Members (Pharmacists, Technicians, Student Pharmacists)
d) Patients
e) All of the above
100th General Assembly

- Senate: 37 Democrats | 22 Republicans
- House: 67 Democrats | 51 Republicans
- Democrats have Super Majority in the Senate

- Currently - 9,585 bills | 3,139 resolutions
- Usually monitoring between 150-300 bills/resolutions
- 100th General Assembly
- January 1, 2017 - December 31, 2018
General Assembly Committees

House
- Appropriations - Human Services
- Health & Healthcare Disparities
- Health Care Availability Access
- Health Care Licenses
- Human Services
- Insurance
- Labor and Commerce
- Revenue & Finance

Senate
- Appropriations
- Human Services
- Insurance
- Licensed Activities and Pensions
- Public Health
- Revenue
Illinois Departments That Impact Pharmacy

- Department of Financial and Professional Regulation - DFPR
- Department of Healthcare and Family Services - HFS
- Department of Human Services - DHS
- Department of Insurance - Insurance
- Department of Public Health - DPH
- Dept of Central Management Services - CMS
Pharmacy Related Statutes & Administrative Code

- Illinois Pharmacy Practice Act & Rules
- Illinois & Federal Controlled Substance Act & Rules
- Illinois Hypodermic Needle and Syringe Act
- Wholesale Drug Distribution Licensing Act and Rules
- Illinois Health Facilities Planning Act
- Illinois Poison Prevention Packaging Act
- Poison Prevention Packaging Act of 1970
- Cannabis Control Act
- Compassionate Use of Medical Cannabis Pilot Program Act
2018 Spring Session
Oral Contraceptives | HB274 HB5747

- **Sponsor(s):** Rep. Michelle Mussman (D-Schaumburg)
- Add dispensing of hormonal contraceptives pursuant to a statewide standing order to the definition of “Practice of Pharmacy”.
- Requires completed training course.
- Requires patients complete a self-screening risk assessment tool prior to dispensing.
- Establishes coverage for pharmacist care service/consult (commercial and Medicaid).
- Dept of Public Health to oversee requirements of Statewide Standing Order.

- **Status:** Re-referred to (H) Rules Committee Rule 19(a) | 04/27\(^\text{HB274}\)
  - Was a House Floor debates and successful vote but not plurality
- Referred to (H) Rules Committee | 02/16 \(^\text{HB5747}\)
Managed Care Audit Reform | HB3285 SB1844

- Amends the Illinois Insurance Code
- Provide increased transparency in the auditing process and provide for a balanced approach to control costs to the sponsors of pharmacy and prescription health plans.
- Lengthy negotiations with PBM/Managed Care lobby → Heading towards Agreed Bill

- Status: Re-referred to (H) Rules Committee | 03/31 HB3285
- Re-referred to (S) Assignments Committee | 05/05 SB1844
Managed Medicaid | HB3479 SB1888

  - Sen. Sam McCann (R-Jacksonville)
- Amend the Public Aid Code
- Establishes a fair and reasonable reimbursement rate to pharmacy providers for pharmaceutical services, prescription drugs and drug products, and pharmacy or pharmacist-provided services. Reimbursement rate should be at least equal to FFS Medicaid.

- Status: Re-referred to (S) Assignments Committee | 5/31 HB3479
- Senate Amendment #5 - Current Language
- Re-referred to (S) Assignments Committee | 05/05 SB1888

Controlled Substance Reporting | HB5442

- **Sponsor(s):** Rep. Jim Durkin (R-Burr Ridge)
- **Amend the Controlled Substances Act**
- **Provides that hospitals or institutions licensed shall report controlled substances ordered and the quantity actually administered.**
  - Currently, only applies for more than a 72-hour supply of a discharge medication. [Removed in HA #1]
- **Provides that required information be transmitted not later than the end of the business day**
  - Currently, at the end of the next business day.
- **Status:** Tabled | 04/12

IDPH Drug Repository | SB2849

- Sponsor(s): Sen. Patricia Van Pelt-Watkins (D-Chicago)
- Creates the Prescription Drug Repository Act
- Requires the Department of Public Health to establish a prescription drug repository program, under which any person may donate a prescription drug or supplies needed to administer a prescription drug for use by an individual who meets eligibility criteria specified by the Department.
- Sets forth requirements that prescription drugs or supplies must meet in order to be accepted and dispensed under the program.
- Provides that no drugs or supplies donated under the prescription drug repository program may be resold.
- Provides that nothing in the Act requires that a pharmacy or pharmacist participate in the prescription drug repository program.
- Provides for civil and criminal immunity for drug and supply manufacturers and individuals in relation to the donation, acceptance, or dispensing of prescription drugs or supplies under the prescription drug repository program. [Removed in SA #1]

- Status: Re-referred to (S) Assignments Committee Rule 3-9(a) | 04/13

C-II (Opioid) Limitations | SB3431

- **Sponsor(s):** Sen. Sue Rezin (R-Peru)
- **Amends the Illinois Controlled Substances Act.**
- **Opiate to a patient 18 years of age or older for outpatient use for the first time, no more than a 7-day supply.**
- **Prohibits under 18 years of age for more than a 7-day supply at any time and shall discuss with the parent or guardian risks associated with opiate use and the reasons why the prescription is necessary.**
- **Allows professional medical judgment of a practitioner, more than a 7-day supply of an opiate is required to treat the patient’s acute medical condition or is necessary for the treatment of chronic pain management, pain associated with a cancer diagnoses, or for palliative care,**
- **Opiate for more than a 7-day supply shall be documented in the patient’s medical record and the practitioner shall indicate that a non-opiate alternative was not appropriate to address the medical condition.**
- **Provides that these provisions do not apply to medications designed for the treatment of substance abuse or opioid dependence.**

- **Status:** Re-referred to (S) Assignements Committee Rule 3-9(a) | 04/13
Generic Pricing | HB4900

- Sponsor(s): Rep. Will Guzzardi (D-Chicago)
- Creates the Illinois Generic Drug Pricing Fairness Act.
- Provides that a manufacturer or wholesale drug distributor shall not engage in price gouging in the sale of an essential off-patent or generic drug.
- Provides that the Director of Healthcare and Family Services or Director of Central Management Services may notify the Attorney General of any increase in the price of any essential off-patent or generic drug under the Medical Assistance Program under the Illinois Public Aid Code or a State health plan, respectively, that amounts to price gouging.
- Provides that whenever the Attorney General has reason to believe that a manufacturer or wholesale drug distributor of an essential off-patent or generic drug has violated the Act, the Attorney General shall send a notice to the manufacturer or wholesale drug distributor requesting a specified statement.

- Status: Passed House 065-038-001 | 04/19
  - Re-referred to (S) Assignments Committee | 05/31
Medicaid Exception to Rx Limit | HB2511 SB2827

- Sponsor(s): Rep. Sara Feigenholtz (D-Chicago) Sen. Laura Murphy (D-Elk Grove)
- Amends the Medical Assistance Article of the Illinois Public Aid Code.
- Provides that drugs prescribed for residents of licensed long-term care facilities shall not be subject to prior approval as a result of the 4-prescription limit.

- Status: Rule 19 (a) Re-referred to (H) Rules Committee 04/27 HB2511
- Rule 3-9 (a) Re-referred to (S) Assignments Committee 05/31 SB2827
Prior Authorization Form | HB5769

- **Sponsor(s):** Rep. Deb Conroy (D-Villa Park)
- Requires the Department of Insurance and Department of Healthcare and Family Services to develop a uniform electronic prior authorization form.
- **Taskforce of Insurers and Healthcare Providers (IPhA would get two members)**

- **Status:** Rule 19 (a) Re-referred to (H) Rules Committee | 05/31

Pharmacy Legislation that Passed
Pharmacy Practice Act | HB3462

- **Sponsor:** Representative Michael Zalewski (D-Riverside)
- Renews and Extends the Pharmacy Practice Act until January 1, 2020;
- Various technical and terminology updates to the Pharmacy Practice Act;
- Updates the definitions of “Electronic Transmitted Prescription” and “Address of Record”;
- Adds the definition of “Email Address of Record”
- Provides that applicants and licensees will keep the Department informed of a valid address and email address of record;
- Creation of a Collaborative Pharmaceutical Task Force charged with discussing advancements of pharmacy practice and the needs of patients, pharmacies, pharmacists, and pharmacy technicians. This Task Force shall produce recommendations by September 1, 2019 and the Department will propose rules for adoption, based on the recommendations, by November 1, 2019;
- Minimum number of pharmacy compliance investigators was removed;
- Adds Confidentiality section protecting information gathered during an examination or investigation;
- Makes the Citation Program for minor violations permanent.

- **Status:** PA 100-0497 | Effective - 09/08/2017
Alpha-Hydroxyprogesterone Caproate  |  SB317

- Sponsor: Senator John Mulroe (D-Chicago)
- Amends the Pharmacy Practice Act, specifically the definition of the “Practice of Pharmacy” and would allow pharmacists with appropriate training to administer alpha-hydroxyprogesterone caproate pursuant to a prescription order.

- Status:  PA 100-0208 08/18 |Effective 01/01/2018
Pharmacy Dialysis Drugs | SB636

- **Sponsor(s):** Sen. Terry Link (D-Gurnee)
- Amends the Pharmacy Practice Act ‘Exemptions’ Section;
- Provides that the Act shall not apply to, or in any manner interfere with, the sale or distribution of dialysate or devices necessary to perform home peritoneal renal dialysis for patients with end-stage renal disease so long as certain conditions are met; The dialysate or devices may be held at a manufacturer or manufacturer’s agent, which is properly registered;
- Dialysate or devices can only be delivered to the patient upon receipt of physician’s prescription by a licensed pharmacy (and processed in accordance with the Act);
- Does not include any other drugs for peritoneal dialysis, except dialysate.

- **Status:** PA 100-0218 08/18 | Effective 08/18/2017
Emergency Refill | SB1790

- **Sponsor:** Senator Steve Stadelman (D-Rockford)
- Interruption of therapy might reasonably produce undesirable consequences or cause patient suffering;
- Pharmacy previously dispensed or refilled a prescription from the prescriber for the same patient and medication;
- Not for a controlled substance;
- Inform the patient or the patient's agent at the time of dispensing that prescriber authorization is required for future refills;
- Emergency dispensing is documented in the patient's prescription record and the pharmacist informs the prescriber of the emergency refill;
- Emergency supply must be limited to the amount needed for the emergency period;
- Total amount dispensed shall not exceed a 30-day supply.

- **Status:** PA 100-0237 08/18 | Effective 08/18/2017
Hypodermic Syringes and Needles | SB1944

- Sponsor: Senator Chris Nybo (R-Lombard) | Rep. LaShawn Ford (D-Chicago)
- Increases the limit from 20 to 100 hypodermic syringes or needles to a person without a prescription being required;
- Reduces barriers for patients to access and obtain hypodermic syringes and needles, without the need for a prescription and increased health expenditures for a medical visit;
- Clarifies that electronic prescriptions may be used for hypodermic syringes and needles;
- Increases access to safe and clean needles to individuals who may utilize illicit substances.

- Status: PA 100-0326 08/24 | Effective 01/01/2018
Safe Pharmaceutical Disposal | HB524
Expired Unused Drug Disposal | SB680

- **Sponsor(s):** Rep. Barbara Wheeler (R-Crystal Lake) | Sen. Pamela Althoff (R-McHenry)
- Amends the Safe Pharmaceutical Disposal Act and Environmental Protection Act.
- Provides that pharmaceuticals disposed of under the Act may be destroyed in a drug destruction device.
- Expands the definition of "drug evidence" to include any used, expired, or unwanted pharmaceuticals collected.

- **Status:** HB524 - PA 100-0250 08/22 | Effective 08/22/2017
Sponsor: Representative Norine Hammond (R-Macomb)


Removes provision requiring manufacturers to provide Public Health with a notification containing product technical bioequivalence information no later than 60 days prior to specified generic drug product substitution.

Referring to the Illinois State Pharmaceutical Formulary.

Status: PA 100-0065 08/11 | Effective 08/11/2017
Controlled Substances Info | HB2708

- **Sponsor:** Representative Tom Demmer (R-Rochelle)
- Amends the Illinois Controlled Substances Act.
- DHS may release information received by the central repository to select representatives of the DCFS through the indirect online request process.
- Provides that access shall be established by the Prescription Monitoring Program Advisory Committee by rule.

- **Status:** PA 100-0125 08/18 | Effective 01/01/2018
Medication Synchronization | HB2957

- Sponsor: Representative Laura Fine (D-Glenview)
- Allows for the coordination of two or more medications for one or more chronic conditions;
- Synchronization shall be allowed at least one occasion per insured per year;
- Medications must be covered and considered maintenance medications under the policy;
- Medications are not Schedule II, III, or IV;
- Medications can safely be utilized into a short-fill scenario to achieve synchronization;
- Medications do not have special handling or sourcing requirement under the policy;
- Policy shall allow a prorated daily cost-sharing rate to any medication dispensed;
- No dispensing fees shall be prorated, and dispensing fees shall be based on number of prescriptions filled or refilled.

- Status: PA 100-0138 08/18 | Effective 08/18/2017
Opioid Website | HB3161

- **Sponsor:** Representative Tom Demmer (R-Rochelle)
- Requires DHS to create and maintain a website to educate the public on heroin and prescription opioid abuse.

- **Status:** PA 100-0494 | Effective 06/01/2018
“Full Practice Authority” APRNs | HB313

- **Sponsor:** Representative Sara Feigenholtz (D-Chicago)
- Grants Advanced Practice Registered Nurse, certified as a nurse practitioner, nurse midwife, or clinical nurse specialist the ability to practice without a written collaborative agreement.
- A notarized attestation, signed by both the APRN and collaborating physician of
  - 4000 hours of clinical experience
  - 250 hours of continuing education or training after first attaining national certification
- Effective date of 01/01/2018 - all APRNs who meet the above requirements will be required to file the notarized attestation.
- **Scope of practice for APRNs with Full Practice Authority:**
  - No written collaborative agreement in any practice setting.
  - Authority to prescribe legend and Schedule II-V controlled substances.
  - When prescribing benzodiazepines and opioids:
    - Consultation relationship between the APRN and a physician must be registered with the PMP and specific opioids indicated for prescribing.
    - This is not a signed agreement, no delegation and no written document.
    - Communication is required at least once every 30 days between the APRN and physician for the purpose of discussing opioid or benzodiazepine therapy.
- The physician's name is not required on any prescription for an APRN with full practice authority.

“Full Practice Authority” APRNs | HB313

- **Sponsor:** Representative Sara Feigenholtz (D-Chicago)

- APRNs who do not meet the above requirements for Full Practice Authority will work with a collaborative agreement with a physician. Scope of Practice and Written Collaborative Agreement requirements and delegated prescriptive authority will be as currently regulated.

- APRNs with Full Practice Authority will be eligible for a controlled substance license and not have a "mid-level provider controlled substance license"

- **Status:** PA 100-0513 | Effective 09/20/2017

Prescription Monitoring Program | SB1607 - SB772

- **Sponsor:** Senator Melinda Bush (D-Grayslake)

- Prescribers would be mandated to register with the PMP;

- Each Prescriber (or their designee) shall document an attempt to access the PMP to assess the patient on initial prescription of a Schedule II narcotic (opioid) - such documentation shall be in the patient’s medical record;

  - Except for prescriptions for: Oncology Treatment, Palliative Care, 7-Day or less supply provided by an Emergency Department (treating an acute, traumatic medical condition)

- **Status:** Sent to the Governor | 11/09 (SB772)
Sponsor(s): Sen. Steve Stadelman (D-Rockford)


Provides that a prescription for medication other than controlled substances shall be valid for up to 15 months from the date issued for the purpose of refills, unless the prescription states otherwise.

Status: Public Act 100-0804 | 08/13
Effective January 1, 2019

Hydrocodone | HB4707

- **Sponsor(s):** Rep. Sue Scherer (D-Decatur)
- **Amends the Illinois Controlled Substances Act.**
- **Changes the classification of Hydrocodone from a Schedule II controlled substance to a Schedule I controlled substance.**
- [HA -#1 Will instead form a Prescription Drug Task Force to review the issue]

- **Status:** Public Act 100-0989 | 08/20
- **Effective August 20, 2018**
Unused Antibiotics - Disposal | SB2524

- Sponsor(s): Sen. Chapin Rose (R-Champaign)
- Amends the Department of Public Health Powers and Duties Law of the Civil Administrative Code of Illinois.
- Requires the Department of Public Health and Illinois Emergency Management Agency to collaborate to review and recommend new State laws for the disposal of unused antibiotics.
- SA #1 - Amends the Environmental Protection Act.
  - Creates the Pharmaceutical Disposal Task Force. (which IPhA will be a part)

- Status: Public Act 100-0925 | 08/17
- Effective January 1, 2019
Epinephrine Administration | SB2889

- **Sponsor(s):** Sen. Chapin Rose (R-Champaign)
- Creates the Epinephrine Administration Act.
- Provides that a health care practitioner may prescribe epinephrine pre-filled syringes in the name of an authorized entity where allergens capable of causing anaphylaxis may be present.
- Provides that an authorized entity may acquire and stock a supply of undesignated epinephrine pre-filled syringes provided the undesignated epinephrine pre-filled syringes are stored in a specified location.

- **Status:** Public Act 100-0799 | 08/10
- **Effective January 1, 2019**
Sponsor(s): Rep. Michael Zalewski (D-Riverside)

Amends the Illinois Controlled Substance Act.

Defines "pharmacist" to include, but be not limited to, a pharmacist associated with a health maintenance organization or a Medicaid managed care entity providing services under the Illinois Public Aid Code.

Status: Public Act 100-1005 | 08/21

Effective August 21, 2018
PMP | HB4907

- Sponsor(s): Rep. Michael McAuliffe (D-Chicago)
- Amends the Illinois Controlled Substance Act.
- Allows prescribers or pharmacists to authorize a licensed or non-licensed designee (rather than any designee) employed in that licensed prescriber's office or licensed pharmacist's pharmacy and who has received training in the federal Health Insurance Portability and Accountability Act to consult the Prescription Monitoring Program on their behalf. [Now Only Licensed Designee in Pharmacy - HA #1]
- Selection of 3 physicians, 2 pharmacists, and one dentist, of the Prescription Monitoring Program Advisory Committee to serve as members of the peer review subcommittee.

- Status: Public Act 100-0861 | 08/15
- Effective August 14, 2018

PMP | SB2952

- Sponsor(s): Sen. Melinda Bush (D-Grayslake)
- Amends the Illinois Controlled Substance Act.
- Selection of Prescription Monitoring Program Advisory Committee to serve as members of the peer review subcommittee.
- Amended to 7 then 9 Members, one additional physician and pharmacist
  - Dentist, APRN, PA, Optometrist

- Status: Public Act 100-1093 | 08/26
- Effective August 26, 2018

Asthma Medication | SB3015

- **Sponsor(s):** Sen. David Koehler (D-Peoria)
- **Amends the School Code.**
- **Allows self-administration and self-carry of asthma medication, provides that a school district, public school, charter school, or nonpublic school may authorize a school nurse or trained personnel to provide undesignated asthma medication to a student for self-administration only or to any personnel authorized under a student's Individual Health Care Action Plan or asthma action plan**

- **Status:** Public Act 100-0726 | 08/03
- **Effective January 1, 2019**
Patient Rights - Transition | HB4146

- Sponsor(s): Rep. Laura Fine (D-Glenview)
- Amends the Managed Care Reform and Patient Rights Act.
- During an enrollee's plan year, prohibits a health care plan from removing a drug from its formulary or negatively changing its preferred or cost-tier sharing unless, at least 60 days before making the formulary change, the health care plan provides certain notifications to current and prospective enrollees and prescribing providers.
- For Plans starting January 1, 2019.

- Status: Public Act 100-1052 | 08/24
- Effective August 24, 2018

Sponsor(s): Rep. Patti Bellock (R-Westmont)

Amends the Telehealth Act.

Amends "health care professional" includes dentists, occupational therapists, pharmacists, physical therapists, clinical social workers, speech-language pathologists, audiologists, and hearing instrument dispensers (rather than any clinician licensed to provided medical services under Illinois law).

Status: Public Act 100-0644| 07/27

Effective January 1, 2019
Telehealth Diabetes | HB5351

- **Sponsor(s):** Rep. Ryan Spain (R-Peoria)
- Amends the Illinois Insurance Code.
- Individual or group policy provides coverage for telehealth, provides that the individual or group policy must provide coverage for licensed dietitian nutritionists and certified diabetes educators (rather than licensed dietitians, nutritionists, and diabetes educators).

- **Status:** Public Act 100-1009 | 08/21
- **Effective:** January 1, 2019

Administrative Rules
Patient Counseling Rule

- Direct response to the Chicago Tribune Investigation (December 2016)

- 68 IAC 1330.30 (Unprofessional and Unethical Conduct)
  - Change to h): Makes failure to respond to requests to provide patient counseling, attempts to circumvent the patient counseling requirements, or discouraging patients from receiving patient counseling as unprofessional and unethical conduct.

- 68 IAC 1330.700 (Patient Counseling)
  - Change to a): Patient counseling (verbal) shall be provided to the patient or patient's agent if any of the following:
    - New Patient
    - New Medication to an existing patient
    - Medication that has a Change in the Dose, Strength, Route of Administration, or Directions for Use
  - Offer to counseling shall be made on all other prescriptions (refills, etc)
  - Change to c): Required Signage to be placed in the Pharmacy Department. The sign will be available to download on the Division's website.” (This sign available on the Department website - ilboard.pharmacy.)
  - Change to f): On-site and off-site institutional pharmacy are not required to provide patient counseling unless "drugs are dispensed by the pharmacy upon a patient's discharge from the institution."
  - Change to g): "Nothing in this Section shall be construed as requiring a pharmacist to provide counseling when a patient or patient's agent refuses such counseling."

- Effective 08/18/2017 | Enforcement 09/01/2017

City of Chicago
Pharmacy Work Rules | O2017-979

- Sponsor: Alderman Ed Burke (14th Ward)
- Requires that at least one registered pharmacy technician be on duty whenever the practice of pharmacy is conducted.
- Requires that pharmacies fill no more than 10 prescriptions per hour.
- Requires 10 pharmacy technician hours per 100 prescriptions filled.
- Prohibits pharmacies from requiring pharmacists to participate in advertising or soliciting activities that may jeopardize patient health, safety, or welfare.
- Provides that a pharmacist shall receive specified break periods.
- Requires pharmacies to maintain a record of any errors in the receiving, filling, or dispensing of prescriptions.

- Status: Passed Finance Committee | 10/10; Remains “Held in Committee” | 10/11/2017
Sec. 38. It is declared to be the public policy of this State, pursuant to paragraphs (h) and (i) of Section 6 of Article VII of the Illinois Constitution of 1970, that any power or function set forth in this Act to be exercised by the State is an exclusive State power or function. Such power or function shall not be exercised concurrently, either directly or indirectly, by any unit of local government, including home rule units, except as otherwise provided in this Act. (Source: P.A. 85-796.)
IPhA Legislative and Regulatory Initiatives
2018 has been a Busy Year!

- Pharmacy Practice Act negotiations - Collaborative Pharmaceutical Taskforce
- PBM / Managed Care Reform (Audit Bill) - SB1844 | HB3285
- Managed Medicaid (Reimbursement Reform) SB1888 | HB3479
- State-level Provider Status
- Pharmacy Robbery & Burglary
Naloxone & Opioid Epidemic
State of Illinois Opioid Action Plan

September 2017
Bruce Rauner, Governor

State of Illinois Opioid Action Plan

OVERALL GOAL
Reduce Opioid-Related Deaths by 33% Against Estimated Deaths in Three Years

PREVENTION
A Safer Prescribing and Dispensing
1 Increase PMP use by providers
2 Reduce high-risk opioid prescribing through provider education and guidelines
B Education and Stigma Reduction
3 Increase accessibility of information and resources
4 Increase impact of prevention programming in communities and schools
C Monitoring and Communication
5 Strengthen data collection, sharing, and analysis to better identify opportunities for intervention

TREATMENT AND RECOVERY
D Access to Care
6 Increase access to care for individuals with opioid use disorder
E Supporting Justice-Involved Populations
7 Increase the capacity of treatment and diversion programs statewide

RESPONSE
F Rescue
8 Increase the number of first responders as well as community members who are trained and have access to naloxone
Supporting Justice-Involved Populations
9 Decrease the number of overdose deaths after an at-risk individual’s immediate release from a correctional or other institutional facility

Stakeholder Collaboration

Illinois Naloxone Standardized Procedure

This updated Naloxone Standardized Procedure outlines how entities may become authorized to obtain, dispense, and administer naloxone hydrochloride for the purpose of reversing an opioid overdose. This Procedure also presents the educational requirements for obtaining the Illinois Naloxone Standing Order and the technique for administering naloxone.

Introduction

In September 2015, Illinois enacted Public Act 99-0480 (Act), expanding access to the opioid antagonist, naloxone. Naloxone may be used to reverse opioid overdoses, including those caused by heroin, fentanyl, and certain prescription pain medications. The law authorizes trained pharmacists and first responders to dispense naloxone as an opioid antagonist intervention.

Pursuant to the Act, the Illinois Department of Financial and Professional Regulation (IDFPR) – in consultation with the Illinois Department of Public Health (IDPH) and Illinois Department of Human Services (IDHS) – has issued a standardized procedure for appropriately trained professionals to obtain, dispense, or administer naloxone.

Naloxone Entity

Naloxone Entities may include pharmacies, pharmacists, or opioid overdose education and naloxone distribution (OEND) programs.

- Participating pharmacies and pharmacists must be licensed under the Illinois Pharmacy Practice Act (225 ILCS 85), complete training approved by IDBS pursuant to Public Act 99-0480, and have knowledge of this document, the Illinois Naloxone Standardized Procedure. Pharmacies/pharmacists should report naloxone dispensing to the Illinois Prescription Monitoring Program at https://www.ipmp.gov/.
- Any non-pharmacy OEND program must be registered as a Drug Overdose Prevention Program with the IDHS’s Division of Alcoholism and Substance Abuse, at http://www.dhs.state.il.us/. This may include law enforcement agencies, drug treatment programs, local health departments, hospitals or urgent care facilities, or other for-profit or not-for-profit community-based organizations.

Educational Requirement

Under this standardized procedure, eligible entities must complete training in opioid overdose reversal, which includes the following:

- Opioid overdose recognition and prevention
- Naloxone administration techniques
- The importance of calling 911 for the care of the overdose victim after naloxone administration

Effective September 2017
Kelly Gable, PharmD, BCPP, Chris Herndon, PharmD, BCPS, Jessica Kerr, PharmD, CDE, & Garth Reynolds, BSPharm, RPh
Illinois State Opioid Antagonist Training Program

- Released: March 11, 2016 | 1.75 Contact Hours of CPE

- The Illinois State Opioid Antagonist Training Program has been approved by the Illinois Department of Public Health, the Illinois Department of Financial and Professional Regulation, and the Illinois Department of Human Services and meets the requirements set forth in PA 99-0480.

- Training Program Objectives
  1. Describe the opioid abuse and overdose epidemic on a state and national level.
  2. Review unique pharmacological properties of commonly prescribed opioids and heroin.
  3. Discuss the neurobiology of addiction and opioid use disorder.
  4. Understand risk factors, signs of an opioid overdose, and the role of opioid antagonist therapy.
  5. Describe the role of pharmacy personnel in opioid overdose management.
  6. Evaluate key elements of patient and caregiver education on opioid overdose management.
  7. Discuss standardized procedures, naloxone standing order sets, and clinical documentation.
Federal Legislation
Pharmacists Provider Status

H.R. 592: Pharmacy and Medically Underserved Areas Enhancement Act
- Rep. Brett Guthrie (R-KY), G.K. Butterfield (D-NC), and Ron Kind (D-WI) - Introduced January 20, 2017
- Cosponsors - 292 (16 Illinois) as of 09/12/2018
  - Bost, Bustos, R. Davis, Fost, Gutierrez, Kelly, Hultgren, Kinzinger, Krishnamoorthi, LaHood, Lipinski, Roskam, Rush, Schakowsky, Schneider, Shimkus
  - D. Davis and Quigley
- Republican - 169 | Democrats - 123

S. 109: Pharmacy and Medically Underserved Areas Enhancement Act
- Senators Chuck Grassley (R-IA), Sherrod Brown (D-OH), and Robert Casey (D-PA) - Introduced January 12, 2017
- Cosponsors - 53 as of 09/12/2018 (Duckworth - IL)
- Democrats - 29 | Republican - 23 | Independent - 1

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)
Access to health care is a serious issue in Illinois. 87 of 102 Illinois counties include areas designated as "medically underserved".

Currently most Illinois residents on Medicare do not have access to important services provided by pharmacists, including:

- Chronic Disease Management (e.g. Diabetes, Heart Disease)
- Drug Therapy Management
- Preventive Screenings & Related Counseling and Education
  - Glucose Testing
  - Blood Pressure
  - Cholesterol

Over 12,500 Pharmacists Licensed in Illinois

If H.R.592/S.109 becomes law, pharmacists - a qualified and underutilized health care provider - can help address the needs of Illinois’ medically underserved.
The Expanding Role of Pharmacists in a Transformed Health Care System

Executive Summary
Pharmacists practice in a variety of health care settings. Although they are most often associated with dispensing medications in retail pharmacies, they also work in hospitals, clinics, nursing homes, home health care, and managed care settings. Pharmacists’ involvement in patient care has expanded through new technologies, tools, and regulations governing the professions to address the challenges in pharmacists practicing to the full scope of their professional training.

Introduction
The health care system is undergoing significant transformations in both the delivery and financing of health care services. States, in particular, are examining their health care systems to define policies that ensure efficient models of care focused on improved quality and health outcomes as well as reduced costs. Integrating pharmacists, who represent the third-largest health profession, into such systems is important for achieving triple bottom line. Pharmacists have the professional expertise to address key challenges facing the health care system, including the prevalence of people who have multiple chronic conditions and the increased use of more complex medications to manage these illnesses.

Pharmacists’ Clinical Training and Expertise
Pharmacists undergo years of education focused on the composition, interaction, and use of medications. Pharmacy students must complete a minimum of two years of college to be eligible to enter pharmacy school, though most obtain a bachelor’s degree. To apply to most graduate pharmacy programs, pre-pharmacy students are required to take the Pharmacy College Admissions Test, which measures general and pharmacy-specific academic knowledge.

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.
Path to Provider Status

- **Federal**
  - Social Security, Medicare Part B & D, CMMI, ACO
  - Federal Regulations (CMS, AHRQ, HRSA)

- **State**
  - Medicaid
  - Health Insurance Exchanges, State Health Plans
  - Existing provider status and collaborative practice

- **Private Payer**
  - Accountable Care Organizations (ACOs)
  - Private or Employer-based Insurers
  - Medical Homes
How to Contact your Legislator
Meet Face-to-Face

- Introduce yourself and state why you are there;
- Mention mutual friends/contacts;
- Emphasize key points that personally concern you;
- Keep the discussion brief;
- Expect questions and be responsive, not argumentative;
- Take a brief synopsis of your key points and supportive material to leave as a reminder;
- Be enthusiastic and show you care about the issue;
- If possible, get a commitment of support; and
- Follow up with a thank you letter, even if you were not successful.

https://www.pharmacist.com/make-your-voice-heard-helpful-hints-contacting-legislators
Communicating with Legislators - Do’s

- Clearly identify the subject in which you are personally interested, including House and Senate bill numbers, if you know them.
- Explain any business connections you may have relative to the issue, and the impact you perceive the issue will have on them.
- Write legibly and briefly.
- Use personal experiences to support your position.
- Use your own words on business or personal stationary.
- Restrict yourself to a single issue.
- Communicate while legislation is under consideration in committee, conference, or on the floor.
- Write more than once on the same issue if the legislation changes favorably, or unfavorably, and note why these changes will help or hurt you.
- Write to the committee and subcommittee chairmen responsible for the legislation if you have specific information that will help them make a more informed judgment on the issue (send a copy to your representative or senators).
Communicating with Legislators - Don’ts

- Do not be rude or threaten.
- Do not pretend to have greater political influence than you really have.
- Do not promise something you can't deliver.
- Do not be self-righteous or all-knowing.
- Do not be vague about the issue (research your member’s position and present facts to support or refute it).
- Do not forget to thank the member for past favors.
- Do not bring up past campaign contributions or present a check during your meeting. (This should be done at events specifically for fundraising.)
How many days supply can you provide for an Emergency Refill?

a) 5  
b) 3  
c) 14  
d) 30  
e) 7
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a) 5
b) 3
c) 14
d) 30
e) 7
Medication synchronization is allowed if which of the following is met:

a) Not a controlled substance (C-II, C-III, & C-IV)
b) Medication must be covered by insurance
c) Medication must be a maintenance medication
d) All the above
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d) All the above
What is the bill number for the IPhA Managed Medicaid/PBM Reform legislation?

a) SB4277
b) HB3479
c) SB1889
d) HB272
e) SR1
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Who is part of the success of IPhA’s advocacy efforts?

a) Lobbyists
b) IPhA Staff
c) Members (Pharmacists, Technicians, Student Pharmacists)
d) Patients
e) All of the above
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References

Pharmacy Legislation and Regulation References:

- Illinois General Assembly
  - http://www.ilga.gov
- Pharmacy Practice Act
- Administrative Rules to the Pharmacy Practice Act
- Illinois Controlled Substances Act
- Administrative Rules to the Illinois Controlled Substances Act
References

Naloxone Standing Order and Training Program References:

- Naloxone Standing Order Form - This form will be used to register for the Naloxone Standing Order
  - http://www.idph.state.il.us/Naloxone/
- FAQ for Naloxone Standing Order
- Sample Naloxone Standing Order (for reference)
- Patient Guide - How to use naloxone

Reminder: You must complete an approved training program to utilize the Naloxone Standing Order.

- Illinois State Opioid Antagonist Training Program
  - http://www.ipha.org/isoatp-registration
Take Home Points

- Be an Advocate
- Stay up-to-date
- Incorporate legislation/regulation changes into your practice
- Maintain your membership with IPhA
Contact Information/Questions

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