

Illinois Healthcare Legislation

Christopher W Crank, PharmD, MS, BCPS
AQ ID
Director of Pharmacy Services
Rush Copley Medical Center

Conflict of Interest

- Neither I nor my spouse have actual or potential conflicts of interest in relation to this activity.

Learning Objectives

- List new legislation that will impact the practice of pharmacy.
- Review proposed legislation that pertains to the practice of pharmacy.

How to Look Up Proposed Legislation

- Current Session (101st General Assembly)
 - <http://www.ilga.gov/legislation/>
- Previous Sessions
 - <http://www.ilga.gov/previousga.asp>

Pharmaceutical Compounding Standards (Section 1330.640)

- November 9th 2018
 - All pharmaceutical compounding standards, both sterile and nonsterile, shall be governed by USP 41-NF36 compounding compendium.
 - Excludes USP 800
- May 1st 2019
 - All pharmaceutical compounding standards, both sterile and nonsterile, shall be governed by USP 42-NF37 compounding compendium.
 - Excludes USP 800

Pharmaceutical Compounding Standards (Section 1330.640)

- Sets rules on sterile and nonsterile compounding for office use.

Pharmaceutical Compounding Standards (Section 1330.640)

- All compounding pharmacies must maintain/control:
 - Separate storage area for materials
 - Scales and measuring devices with sufficient accuracy
 - Exclusive compounding area
 - Logbook (lot, expiration date, and BUD) for any product with a BUD greater than 24 hours
 - Current USP-NF compendium
 - Appropriate consumable materials

Pharmaceutical Compounding Standards (Section 1330.640)

- Updates to:
 - Patient profiles or medication record systems
 - Drug distribution and control
 - Delivery/mailing services
 - Additional reference requirements
 - Staffing requirements
 - PIC requirements

Pharmaceutical Compounding Standards (Section 1330.640)

- Sterile Compounding
 - References
 - PPA and 1130.640, Illinois Controlled Substances Act [720 ILCS 570] and 77 Ill. Adm. Code 3100, 21 CFR (Food and Drugs), and the Illinois Hypodermic Syringes and Needles Act [720 ILCS 635]
 - Staffing
 - Pharmacist is available 24/7 for questions

Public Act 100-0789 CONTROLLED SUB-SYNTHETIC DRUG

- Amends the Illinois Controlled Substances Act.
- Expands the existing list of specified synthetic cathinones that are Schedule I controlled substances to include any synthetic cathinone which is not approved by the United States Food and Drug Administration or, if approved, is not dispensed or possessed in accordance with State or federal law.

Public Act 100-0789 CONTROLLED SUB-SYNTHETIC DRUG

- Provides that synthetic cannabinoids and piperazines are Schedule I controlled substances when they are not approved by the United States Food and Drug Administration.

Public Act 100-1005 PMP Access

- 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.
- Allows PBMs access to PMP

Public Act 100-0804 Pharmacy Prescriptions

- Amends the Pharmacy Practice Act and the Illinois Food, Drug and Cosmetic Act.
- Provides that a prescription for medication shall be valid for up to 15 months from the date issued for the purpose of refills, unless the prescription states otherwise.
 - Excludes controlled substances

PROPOSED LEGISLATION FOR THE 101ST GENERAL ASSEMBLY

HB 0010 and HB 0197 Pharmacy Prescription Limits

- Amends the Pharmacy Practice Act.
- 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 and any activities or external factors that interfere with the pharmacist's ability to provide appropriate professional services.

HB 0010 and HB 0197 Pharmacy Prescription Limits

- Provides that a pharmacist shall receive specified break periods.
- Provides that a pharmacy may not require a pharmacist to work during a break period, shall make available a break room meeting specified requirements, shall keep a complete and accurate record of the break periods and may not require a pharmacist to work more than 8 hours a workday.
- Provides for enforcement and penalties.
- Provides whistleblower protections for an employee of a pharmacy if the pharmacy retaliates against the employee for certain actions.
- Requires pharmacies to maintain a record of any errors in the receiving, filling, or dispensing of prescriptions.

HB 0162 Controlled Substances – Fentanyl Analogues

- Amends the Illinois Controlled Substances Act.
- Provides that a sentencing enhancement of an additional 3 years imprisonment is applicable when the controlled substance also contains any amount of a fentanyl analog for the following violations:
 - Manufacture or delivery, or possession with intent to manufacture or deliver, a controlled substance, a counterfeit substance, or controlled substance analog; controlled substance trafficking; calculated criminal drug conspiracy; criminal drug conspiracy; street gang criminal drug conspiracy; or delivery of a controlled, counterfeit, or look-alike substance to a person under 18 years of age
 - (currently, the
- Currently sentencing enhancement is applicable only to additional amounts of fentanyl

HB 0163 Prescription Monitoring

- Amends the Illinois Controlled Substances Act.
- Provides that the information required to be transmitted under the Prescription Monitoring Program must be transmitted not later than the end of the business day on which a controlled substance is dispensed, or at such other time as may be required by the Department of Human Services by administrative rule (rather than at the end of the next business day on which the controlled substance is dispensed).

HB 0239**Controlled Substance Overdose Immunity**

- Provides limited immunity for a person who seeks or obtains emergency medical assistance for someone experiencing an overdose or for a person who is experiencing an overdose in a reasonably prudent manner (rather than in good faith).

HB 0345**Tobacco Products – Under 21**

- Amends the Prevention of Tobacco Use by Minors and Sale and Distribution of Tobacco Products Act.
- Changes the name of the Act to the Prevention of Tobacco Use by Persons under 21 Years of Age and Sale and Distribution of Tobacco Products Act.
- Raises the age for whom tobacco products, electronic cigarettes, and alternative nicotine products may be sold to and possessed by from at least 18 years of age to at least 21 years of age.

HB 0349**Drug and Sharps Waste Program**

- Creates the Drug and Sharps Waste Stewardship Act.
- Directs the Environmental Protection Agency to administer a drug and sharps waste stewardship program.
- Provides that the State Board of Pharmacy is to guide and advise the Agency in its administration of the program. Requires that all counties have at least one collection site for unused drugs and sharps per 50,000 people, and no fewer than 5 such collection sites.
- Requires counties that do not have the necessary number of collection sites to establish a mail-back program, or alternative collection program for covered products, or both.
- Imposes an administrative fee on covered entities.
- Provides penalties for covered entities that fail to comply with the provisions of the Act.

HB 0891**Insurance Code – PBM**

- Amends the Illinois Insurance Code.
- Creates the Pharmacy Benefits Managers Article
- Provides that a pharmacy or pharmacist shall have the right to provide an insured information regarding the amount of the insured's cost share for a prescription drug and that neither a pharmacy nor a pharmacist shall be penalized by a pharmacy benefits manager for discussing certain information or for selling a lower-priced drug to the insured if one is available.
- Provides that a pharmacy benefits manager shall not, through contract, prohibit a pharmacy from offering and providing direct and limited delivery services to an insured as an ancillary service of the pharmacy, as delineated in the contract between the pharmacy benefits manager and the pharmacy.
- Provides that a pharmacy benefits manager shall not charge, or attempt to collect from, an insured a copayment that exceeds the total charges submitted by the network pharmacy.

HB 1441**Imported Prescription Drugs**

- Creates the Wholesale Importation of Prescription Drugs Act.
- Requires the Department of Public Health to design an importation program where the State is the licensed wholesaler of imported drugs from licensed, regulated Canadian suppliers.
- Requires the program to address specified issues, including billing issues, cost savings issues, and safety and regulatory issues.
- Contains auditing and reporting requirements.

HB 1442**Insurance Code – Birth Control**

- Amends the Department of Public Health Powers and Duties Law of the Civil Administrative Code of Illinois.
- Provides that the Director of Public Health or the Medical Director shall establish a standing order complete with the issuance of a prescription for a hormonal contraceptive in accordance with the requirements of the provisions
- Amends the Illinois Insurance Code
 - Requires a group or individual policy of accident and health insurance or managed care plan to provide coverage for patient care services provided by a pharmacist. Amends the Pharmacy Practice Act.
 - Provides that the definition of "practice of pharmacy" includes the dispensing of hormonal contraceptives pursuant to the standing order under provisions of the Department of Public Health Powers and Duties Law of the Civil Administrative Code of Illinois.
- Amends the Illinois Public Aid Code
 - Requires the medical assistance program to cover patient care services provided by a pharmacist for hormonal contraceptives assessment and consultation.

HB 2160**Drugs – Prior Authorization Form**

- Amends the Illinois Insurance Code.
 - Requires the Department of Insurance to develop a uniform electronic prior authorization form to be used by an insurer that provides prescription drug benefits when requiring prior authorization.
- Amends the Illinois Public Aid Code
 - Requires the Department of Healthcare and Family Services to develop a uniform electronic prior authorization form to be used by a managed care organization that provides prescription drug benefits when requiring prior authorization.
- Includes procedures for when a completed and accurate uniform electronic prior authorization form is not accepted by the managed care organization.

HB 2259**DHFS-MCO Preferred Drug Lists**

- Amends the Medical Assistance Article of the Illinois Public Aid Code.
- Requires the Department of Healthcare and Family Services to develop, no later than January 1, 2020, a standardized format for all Medicaid managed care organization preferred drug lists in collaboration with Medicaid managed care organizations and other stakeholders, including, but not limited to, organizations that serve individuals impacted by HIV/AIDS or epilepsy, and community-based organizations, providers, and entities with expertise in drug formulary development.
 - Medicaid managed care organizations 6 months from the completion date of the standardized format to comply with the new Preferred Drug List format.
 - Medicaid managed care organization to post its preferred drug list on its website without restricting access and to update the preferred drug list posted on its website no less than 30 days prior to the date upon which any update or change takes effect.
- Requires the Department to establish, no later than January 1, 2020, the Illinois Drug and Therapeutics Advisory Board to have the authority and responsibility to provide recommendations to the Department regarding which drug products to list on the Department's preferred drug list.

HB 2638**Opioid Prescriber Requirements**

- Amends the Illinois Controlled Substances Act
 - Provides that a prescriber shall offer a prescription for naloxone hydrochloride or another drug approved by the United States Food and Drug Administration for the complete or partial reversal of opioid depression to a patient when one or more of the following conditions are present:
 - (1) the prescription dosage for the patient is 90 or more morphine milligram equivalents of an opioid medication per day
 - (2) an opioid medication is prescribed concurrently with a prescription for benzodiazepine
 - (3) the patient presents with an increased risk for overdose, including a patient with a history of overdose, a patient with a history of substance use disorder, or a patient at risk for returning to a high dose of opioid medication to which the patient is no longer tolerant

HB 3647**Pharmacy Drug Disposal Kiosk**

- Amends the Pharmacy Practice Act
- Requires a pharmacy to offer a kiosk to dispose of prescription and over-the-counter medications free of charge

SB 0021**TOBACCO PRODUCTS-UNDER 21**

- Raises the age for whom tobacco products, electronic cigarettes, and alternative nicotine products may be sold to and possessed by from at least 18 years of age to at least 21 years of age.

SB 1900**Controlled Substances – Schedule II**

- Amends the Illinois Controlled Substances Act.
 - Provides that when issuing a prescription for an opiate to a patient 18 years of age or older for outpatient use for the first time, a practitioner may not issue a prescription for more than a 7-day supply.
 - Provides that a practitioner may not issue an opiate prescription to a person under 18 years of age for more than a 7-day supply at any time and shall discuss with the parent or guardian of the person under 18 years of age the risks associated with opiate use and the reasons why the prescription is necessary.
 - Provides that the condition triggering the prescription of an 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.

Self Assessment Questions

- Public Act 100-804 provides that a prescription for medication shall be valid for up to _____ months from the date issued for the purpose of refills, unless the prescription states otherwise.
 - A. 6
 - B. 12
 - C. 15
 - D. 24

Self Assessment Questions

- If signed into law, SB 1900 would limit first time opioid prescriptions to what duration.
 - A. 3 days
 - B. 7 days
 - C. 14 days
 - D. 30 days

QUESTIONS?