

Illinois Healthcare Legislation: What's New and What's Been Proposed?

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



ICHP Government Affairs Division

- The Division of Government Affairs
 - Reviews and interprets proposed legislation and regulation and its impact on public health, pharmacy and related practice.
 - Works cooperatively with allied organizations and government agencies on all health-care related public policy.
- If you are interested in monitoring legislation and making a difference in government, join Government Affairs.
- *The Division of Government Affairs meets every third Monday of the month at 5:00 pm via conference call.*



Conflict of Interest

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



(225 ILCS 85/) Pharmacy Practice Act

PROFESSIONS, OCCUPATIONS, AND BUSINESS OPERATIONS (225 ILCS 85) Pharmacy Practice Act.

(225 ILCS 85/1) (from Ch. 111, par. 4121)
(Section scheduled to be repealed on January 1, 2020)
Sec. 1. The Practice of Pharmacy in the State of Illinois is declared a professional practice affecting the public health, safety and welfare and is subject to regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the practice of pharmacy, as defined in this Act, merit and receive the confidence of the public and that only qualified persons be permitted to practice pharmacy in the State of Illinois. This Act shall be liberally construed to carry out these objects and purposes.
(Source: P.A. 85-794.)

(225 ILCS 85/2) (from Ch. 111, par. 4122)
(Section scheduled to be repealed on January 1, 2020)
Sec. 2. This Act shall be known as the Pharmacy Practice Act.
(Source: P.A. 95-689, eff. 10-29-07.)

<http://ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1318&ChapAct=225%26nbsp%3BILCS%26nbsp%3B85%2F&ChapterID=24&ChapterName=PROFESSIONS+AND+OCCUPATIONS&ActName=P+harmacy+Practice+Act%2E>



Learning Objectives

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



Joint Committee on Administrative Rules ADMINISTRATIVE CODE

TITLE 68: PROFESSIONS AND OCCUPATIONS CHAPTER VII: DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION SUBCHAPTER 6: PROFESSIONS AND OCCUPATIONS PART 1330 PHARMACY PRACTICE ACT

The General Assembly's Illinois Administrative Code database includes only those rulemakings that have been permanently adopted. This menu will point out the Sections on which an emergency rule (valid for a maximum of 150 days, usually until replaced by a permanent rulemaking) exists. The emergency rulemaking is linked through the notation that follows the Section heading in the menu.

SUBPART A: GENERAL PROVISIONS

- Section 1330.10 Definitions
- Section 1330.20 Fees
- Section 1330.30 Unprofessional and Unethical Conduct
- Section 1330.40 Violations
- Section 1330.50 Vaccinations/Immunizations
- Section 1330.60 Internet Pharmacies
- Section 1330.70 Granting Variances
- Section 1330.80 Renewals
- Section 1330.90 Restoration of a Pharmacist License
- Section 1330.100 Continuing Education
- Section 1330.110 Confidentiality

<http://www.ilga.gov/commission/jcar/admincode/068/06801330sections.html>



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)

- 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)

- 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)

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



Pharmaceutical Compounding Standards (Section 1330.640)

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



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 100-0648
Epinephrine Liability

- Amends the State Police Act and Illinois Police Training Act.
 - Provides that a physician, physician's assistant with prescriptive authority, or advanced practice registered nurse with prescriptive authority who provides a standing order or prescription for epinephrine auto-injectors in the name of the Department of State Police shall incur no civil or professional liability, except for willful and wanton conduct, as a result of any injury or death arising from the use of an epinephrine auto-injector.



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 100-0799
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.



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 100-0799
Epinephrine Administration Act

- Requires specified training program before using a pre-filled syringe to administer epinephrine.
- Provides that a trained employee, agent, or other individual of the authorized entity may either provide or administer an epinephrine pre-filled syringe to a person whom the employee, agent, or other individual believes in good faith is experiencing anaphylaxis.



Public Act 100-0925
Pharmaceutical Disposal Task Force

- Task Force shall coordinate a statewide public information campaign to highlight the benefits of and opportunities to properly dispose of pharmaceutical products.



Public Act 100-1093 and 100-0861 PMP Designees

- Allows licensed prescribers who have registered to access the PMP to authorize a licensed or non-licensed designee employed in that licensed prescriber's office and who has received training in the federal Health Insurance Portability and Accountability Act to consult the Prescription Monitoring Program on their behalf.



Public Act 100-0726 Asthma Medication in Schools

- Amends the School Code.
- School nurse or trained personnel may
 - 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 or individualized education program plan to administer to the student that meets the student's prescription on file
 - Administer an undesignated asthma medication that meets the prescription on file to any student who has an Individual Health Care Action Plan or asthma action plan or individualized education program plan that authorizes the use of asthma medication
 - Administer an undesignated asthma medication to any person that the school nurse or trained personnel believes in good faith is having respiratory distress;



Public Act 100-1093 and 100-0861 PMP Designees

- Allows licensed pharmacists who have registered to access the PMP to authorize a licensed designee employed in that 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.



Public Act 100-0726 Asthma Medication in Schools

- School nurse or trained personnel may administer undesignated asthma medication to any person whom the school nurse or trained personnel in good faith believes to be experiencing respiratory distress (i) while in school, (ii) while at a school-sponsored activity, (iii) while under the supervision of school personnel, or (iv) before or after normal school activities.
- School district, public school, charter school, or nonpublic school may maintain a supply of an asthma medication in any secure location where a person is most at risk.
- Provides that a training curriculum to recognize and respond to respiratory distress may be conducted online or in person.



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




Public Act 100-0989
Prescription Drug Task Force Act

- Creates the Prescription Drug Task Force
 - 18 members, including one member from ICHP.
 - Study the extent of overprescribing of opioids to patients and make recommendations for future legislation to address the issue.




SB 1888 / HB 3479
Medicaid MCCN Pharmacy Rates

- Requires a managed care community network that contracts with the Department of Healthcare and Family Services to establish, maintain, and provide a fair and reasonable reimbursement rate to pharmacy providers for pharmaceutical services, prescription drugs and drug products, and pharmacy or pharmacist-provided services.
- Provides that the reimbursement methodology shall not be less than the current reimbursement rate utilized by the Department for prescription and pharmacy or pharmacist-provided services and shall not be below the actual acquisition cost of the pharmacy provider.
- Requires a managed care community network to ensure that the pharmacy formulary used by the managed care community network and its contract providers is no more restrictive than the Department's pharmaceutical program.




Public Act 100-0644
Telehealth Act

<p>"Health care professional" included:</p> <ul style="list-style-type: none"> • Physicians • Physician assistants • Optometrists • Clinical psychologists licensed in Illinois • Mental health professionals and clinicians authorized by Illinois law to provide mental health services 	<p>"Health care professional" now also includes:</p> <ul style="list-style-type: none"> • Advanced practice registered nurses • Dentists • Occupational therapists • Pharmacists • Physical therapists • Clinical social workers • Speech-language pathologists • Audiologists • Hearing instrument dispensers
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SB 2834
Substance Use Disorder Act

- Amends the Alcoholism and Other Drug Abuse and Dependency Act.
- Changes the short title of the Act to the Substance Use Disorder Act.
- Removes the terms "addict," "addiction," "alcoholic," "alcoholism," and "substance abuse" and their corresponding definitions.
- Requires the Department to design, coordinate, and fund prevention, early intervention, treatment, and other recovery support services for substance use disorders that are accessible and address the needs of at-risk individuals and their families




PROPOSED LEGISLATION THAT DID NOT PASS IN 100TH GENERAL ASSEMBLY



SB 3642
Pharmacy Benefit Managers

- Amends the Illinois Insurance Code.
- Provides that the Third Party Prescription Program Act does not apply to pharmacy benefits managers.
- Creates the Pharmacy Benefits Managers Article in the Code.
- Requires all pharmacy benefits managers doing business in the State to register with the Director of Insurance.
- Includes provisions on applications for registration, discipline of registered pharmacy benefits managers, examinations, fines, multisource generic lists, reimbursements, restricted pharmacy fees, audits, and review by the Director.



HB 0274**Pharmacist Birth Control**

- Amends the Pharmacy Practice Act.
- Provides that “practice of pharmacy” includes the prescribing and dispensing of hormonal contraceptive patches and self-administered oral hormonal contraceptives.

**HB 4096****Medicaid MCO Preferred Rx List**

- Requires each Medicaid Managed Care Organization to post its preferred drug list on its website without restricting access to enrolled members and to update the preferred drug list posted on its website within 2 business days of making any changes to the preferred drug list, including, but not limited to, any and all changes to requirements for prior approval.
- Vetoes by Governor Rauner.

**HB 0274****Pharmacist Birth Control**

- Allows pharmacists to prescribe and dispense contraceptives to a person over 18 years of age and a person under 18 years of age only if the person has evidence of a previous prescription from a primary care or a women’s health care practitioner.
- Requires the Department of Financial and Professional Regulation to adopt rules to establish standard procedures for pharmacists to prescribe contraceptives.



**PROPOSED LEGISLATION FOR THE
101ST GENERAL ASSEMBLY**

**HB 4096****Medicaid MCO Preferred Rx List**

- Amends the Medical Assistance Article of the Illinois Public Aid Code.
- Provides that the Department of Healthcare and Family Services shall require each Medicaid Managed Care Organization to list as preferred on the Medicaid Managed Care Organization’s preferred drug list every pharmaceutical that is listed as preferred on the Department’s preferred drug list.

**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 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 0053 Drug Manufacturer Disclosures

- Amends the Illinois Food, Drug and Cosmetic Act
- Requires manufacturers of brand-name or generic prescription drugs to notify State purchasers, health insurers, health care service plan providers, pharmacy benefit managers, and the General Assembly of specified increases in drug prices at least 60 days before such increase and the cost of specified new prescription drugs within 3 days after approval by the United States Food and Drug Administration.
- Provides that within 30 days after such notifications, prescription drug manufacturers shall report specified information to State purchasers, health insurers, health care service plan providers, pharmacy benefit managers, and the General Assembly.



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).
- Immunity shall not be extended if law enforcement has reasonable suspicion or probable cause to detain, arrest, or search that person for criminal activity and the reasonable suspicion or probable cause is based on information obtained prior to or independent of the individual seeking or obtaining emergency medical assistance and not obtained as a direct result of the action of seeking or obtaining emergency medical assistance (rather than taking action to seek or obtain emergency medical assistance).



HB 0053 Drug Manufacturer Disclosures

- Provides that failure to report such information shall result in a specified civil penalty.
- Requires the General Assembly to conduct an annual public hearing on aggregate trends in prescription drug pricing.
- Provides that if the manufacturer of a prescription drug or its agent meets or otherwise communicates with a prescriber for the purpose of marketing a drug, then the manufacturer or its agent shall disclose to the prescriber if any ingredient in the drug it is marketing is known to pose a risk of dependency in humans.




HB 0239 Controlled Substance Overdose Immunity

- Immunity shall not be extended if law enforcement has reasonable suspicion or probable cause to detain, arrest, or search that person for criminal activity and the reasonable suspicion or probable cause is based on information obtained prior to or independent of the individual seeking or obtaining emergency medical assistance and not obtained as a direct result of the action of seeking or obtaining emergency medical assistance (rather than taking action to seek or obtain emergency medical assistance).




SB 0007
Cannabis Regulation and Taxation Act

- Creates the Cannabis Regulation and Taxation Act.




Self-Assessment Questions

- If signed into law, House Bill 0010 would limit the number of prescriptions that may be filled by a pharmacy to:
 - A. 5 prescriptions per hour
 - B. 10 prescriptions per hour
 - C. 100 prescriptions per hour
 - D. 200 prescriptions per hour




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.




QUESTIONS?



Self-Assessment Questions

- Public Act 100-0804 alters the time period that prescriptions for non controlled substances are valid to:
 - A. 6 months
 - B. 12 months
 - C. 15 months
 - D. 24 months



Save – Important Information

Continuing Pharmacy Education (CPE) Program Instructions to Process Credit

CPE Program: Illinois Healthcare Legislation, What's New and What's Been Proposed?
(Pharmacist-specific and Technician-specific credit available)

Program Date: January 24, 2019

CPE Processing Deadline: by end of day March 9, 2019.

Access Code: _____

Announced at the session. You will need this to process your credit.

Please honor the deadlines! Do NOT Delay in completing your CPE processing. If you encounter problems, we will need time to assist you before the deadline. Once the CPE Monitor deadline passes we are unable to upload your CPE credit into the CPE Monitor system due to the system restrictions put in place by ACPE and NABP. If you miss the deadline you will NOT receive credit for this program!

Sign In Sheets: Please be sure and sign the Attendance Sheet to confirm your presence for our records. Attendance sheets will be emailed or faxed to the ICHP office for the ACPE file. ACPE requires we confirm that live attendance matches those processing online CPE credit.

Detailed instructions to complete evaluations online:

Participants in this CPE program - You will need your own account on **CESally.com** as an **ICHP association member** in order to access the CPE program, do the evaluation, and submit for credit. This NISHP CPE is free to ICHP members. Non-members please contact ICHP to request CE.

PLEASE NOTE: Only ICHP members who have requested / accepted the ICHP association link on CESally and created an account will be able to **SEE and access** ICHP member programs on CESally.com. For information on how to **REQUEST** and / or **ACCEPT** the members' invitation please go to the new link: http://www.ichpnet.org/pharmacy_practice/cesally/.

To set up your account and process your CPE credit:


1. Go to www.CESally.com and click on "Sign Up!" **Or log in** with your existing account. Go to your Account page and accept the association invitation in the right side column, if you have not already done so.

Or REQUEST an invitation to join ICHP on this Account page. We authorize requests throughout the day.
Important: You will need to maintain a valid email address.

- If NEW to CESally.com, to complete the Sign Up process, you will select a username and password. For HELP at any point, click on the HELP tab or go to: <https://www.cesally.com/help/>.
- Enter your NABP eProfile ID and birth day as MMDD when prompted. CESally.com now checks with NABP/CPE Monitor in real time, to confirm the NABP eProfile and birth day are a valid account.

2. Once you have created your account, **or logged in**, and requested / received the ICHP association link on Your Account Page, use the Search Box in the upper right corner to find your activity by **typing in the title**.

Search by name, event, date, number, etc.

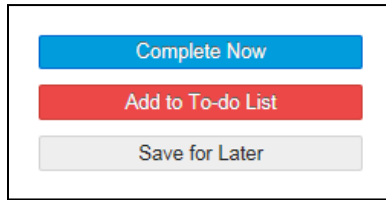


- Program(s) will appear in boxes as Search Results.
- Please select the correct program, identified **as either Pharmacist or Technician**.

NOTE: If the title does not appear to you when you search, that means you are not logged in as an ICHP association member and / or have not requested / accepted the ICHP member link on CESally.com.

Save – Important Information

3. Click on the Activity title for the program you attended, and the information page will open; you will see your options in the right hand column on the information page. Select one.



4. To finish the process after choosing to **Complete Now**, **Save for Later**, OR **ADD to To-do List**.

- a) If you choose **Complete Now**, follow the actions as directed on the webpage. You will verify your attendance, provide the session ACCESS code given to you during the program, and complete an evaluation of the activity and the speaker(s). The status box indicates where you are in the process.
- b) If you **Save for Later** or **Add to To-do List**, when you are ready to complete, please go to the appropriate webpage (tabs are labeled To Do List or Saved for Later).
- c) Click on **Start To-do List**. Follow the actions as directed on the webpage. You will verify your attendance, provide the session ACCESS code given to you during the program, and complete an evaluation of the activity and the speaker(s). The status box indicates where you are in the process.

5. Click **Go To Next Step** at the bottom of the page, as you finalize each step in the process.

6. Click on **Report CE**. Your CPE credit will be uploaded to CPE Monitor automatically upon **successful** completion and **submission** of your evaluation.

7. If an error occurs, the system will tell you on the screen so please wait for any error messages. CPE Monitor will not accept your submission if there are any errors, and your credit will NOT be reported to CPE Monitor. **Please confirm your submissions.**

8. Go to www.NABP.net and CLICK on the CPE Monitor link to log into your personal CPE Monitor account to download an official statement of credit or full transcript.

If you have any questions, please contact ICHP at members@ichpnet.org.

Please remember the ICHP processing deadline is by end of day March 9, 2019.

Thank you!