Happy New Year 2016 – Here's Some New Laws!

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Disclosures

- With regard to this program, we have nothing to disclose.

Learning Objectives

- Describe the new pharmacy-related State laws of 2016.
- Recall changes in the Illinois Pharmacy Practice Act Rules that were accepted in 2015 and discuss potential changes to the Practice Act Compounding Rules of 2016.
- Describe the efforts for obtaining provider status at the State and Federal level in 2016.
- Discuss potential State legislation that may be introduced in Springfield this spring.

Public Act 099-0163 Controlled Substance/Pharmacy Practice Acts

- Effective January 1, 2016
- Allows APNs, PAs, RNs, LPNs to pick up, deliver, and possess controlled substances for patients in hospice care or home health care.

Public Act 099-200 Biosimilars

- Effective January 1, 2016
- Amends the Pharmacy Practice Act
- Defines Biologic Product:
  - In this section, the term ''biological product'' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.
- Interchangeable Biological Product

Public Act 099-200 Biosimilars

- Requires notification of the patient if interchange occurs.
- Requires notification of the prescriber within 5 business days following interchange via:
  - Interoperable electronic medical record,
  - An electronic prescribing technology,
  - Pharmacy benefit management system, or
  - Pharmacy Record
- If the prescriber does not have access to those systems, the pharmacist must notify them of the interchange via facsimile, telephone, electronic transmission or other prevailing means.

Public Act 099-0226 – Topical Eye Medication Act

- Effective January 1, 2016
- Amends the Illinois Insurance Code
- Removes early refill restrictions for eye drops being used to treat chronic conditions.
- Number of early refills may not exceed the total number of refills prescribed.
- The refill is requested by the insured prior to the last day of the prescribed dosage period and after at least 75% of the predicted days of use.

Public Act 099-0270 Right to Try Act

- Effective January 1, 2016
- Allows terminally ill patients to obtain an investigational medication that has completed Phase 1 clinical trials, but not yet FDA approved.
- Requires a physician to determine the patient is terminally ill.
- Does not require manufacturers to participate or provide medication at no cost.
- Does not require insurers to cover costs.

Public Act 099-0473 Amends Pharmacy Practice Act

- Newly hired pharmacy inspectors now must be pharmacists. Effective August 27, 2015.
- Creates a one year pilot program with voluntary participation by pharmacy for using **medication locking containers**.
  - Medicaid, Medicare Part D and LTC patients are exempt from pilot program.
  - Prescribers may authorize patient exemption from pilot on prescription.
  - Effective January 1, 2016 subject to appropriations.

Public Act 099-0473 Amends Pharmacy Practice Act

- Pharmacy Technician CPE is now required.
- 20 hours every two years with one hour in law and one hour in patient safety. (Just like PTCB)
- Clarifies when pharmacy technicians must become certified.
- Effective January 1, 2017

Public Act 099-0480 Heroin Crisis Act

- Effective September 9, 2015
- Medication Take Back program to be established by IEPA by June 1, 2016. Pharmacies must display sign of local State-approved drop off sites.
- A pharmacy shall maintain a policy regarding the type of identification necessary, if any, to receive a prescription in accordance with State and Federal law. The pharmacy must post such information where prescriptions are filled.

Public Act 099-0480 Heroin Crisis Act

- Requires prescribers to document reason of medical necessity for 2 additional sequential 30-day supplies of CII prescriptions in the medical record.
- Prescription Monitoring Program reporting is now set at the end of the next business day, no longer within 7 days.
- Illinois Dept. of Public Health is to establish a standing order for pharmacist dispensing of opioid antagonists (naloxone). Pharmacists must complete training program.

Self-Assessment

- Public Act 099-0473 amended the Pharmacy Practice Act by which of the following?
  A. Requiring pharmacies to be inspected annually.
  B. Requiring all new pharmacy inspectors to be pharmacists.
  C. Requiring pharmacy technicians to be certified.
  D. Requiring pharmacies to use special locking vials for opiate prescriptions.

PPA Rule Changes in 2015

- New Definitions
  - Dispensing error
  - Electronic format
  - Home Pharmacy
  - Remote Consultation Site
  - Remote Dispensing Site
- Removed the definition of Unprofessional Conduct and placed most of it in the Section on Unprofessional and Unethical Conduct.

PPA Rule Changes in 2015

- Added the following to Unprofessional and Unethical conduct.
  - "Committing theft or diversion"
  - Failing to exercise sound professional judgement with regard to prescription authenticity.
  - Dispensing unapproved/non-USP/NF drugs
  - Committing dispensing errors
  - Willfully violating or knowingly assisting in the violation of any law relating to the use of controlled substances.

PPA Rule Changes in 2015

- Pharmacists and student pharmacists may now vaccinate patients age 10-13 for influenza and tDaP.
- New requirements for restoring a pharmacist license that has lapsed more than 5 years.
- The responsibility for training pharmacy technicians and certified pharmacy technicians now rests with the PIC, pharmacy and the pharmacy technician equally.

PPA Rule Changes in 2015

- No pharmacy shall relocate prior to inspection of the premises.
- All drugs must be transferred within 24 hours after issuance of the license unless otherwise approved.
- Any reduction of hours of operation of a pharmacy must be reported to the Dept. within 30 days.

PPA Rule Changes in 2015

- Mail order pharmacies must provide a toll-free telephone number to patients operational at least 40-hours and 6-days a week to reach a pharmacist with access to their patient records.
- Non-resident pharmacies may provide telepharmacy services but must be licensed in Illinois.
- Remote dispensing sites must use certified pharmacy technicians or student pharmacists.

PPA Rule Changes in 2015

- Kiosks used for telepharmacy are described.
- Describes medication dispensing in the absence of the pharmacist for off-site institutional pharmacies.
- If a PIC is on leave for more than 90 days, a new PIC must be designated.
- Non-resident pharmacies providing services to Automated dispensing and storage systems in Illinois must be serviced by Illinois licensed pharmacists and technicians.

PPA Rule Changes in 2015

- Any theft or loss of a controlled substance requiring a Form 106 to be sent to the DEA now must be sent to the Department concurrently.
- Multi-med Paks may now be returned to the dispensing pharmacy for modification. Any meds removed may not be reused.

PPA Rule Changes in 2015

- Pharmacy Self-Inspections
  - Required annually
  - Retained for 5 years
  - Includes forms for compounding
  - Forms are available online.

Pending Rule Changes

- Draft of the revised Compounding Standards has been completed and currently awaits the Governor's review.
- Incorporates USP Chapters 795, 797, 800 and more.

Self-Assessment

- For your pharmacy, which self-inspection (SI) form(s) must be completed annually?
  A. Community Pharmacy SI Form
  B. On-site Institutional Pharmacy SI Form
  C. Telepharmacy SI Form
  D. Offsite Institution Pharmacy SI Form
  E. Non-sterile Compounding SI Form
  F. Sterile Compounding SI Form

What else is ICHP Government Affairs working on these days?

- USP Chapter 800 (June)
- 340B Mega-guidance comments (Nov.)
- EPA Hazardous Pharmaceutical Waste rule revisions. (Dec.)
- USP Chapter 797 Revision (Jan.)
- Draft Illinois PPA Compounding Rule Revisions (Feb.-Mar.)
- Legislative Day – March 2nd

797 Revision Comments

- Comments submitted by ICHP and ASHP
- Increased requirement for QA sampling by pharmacy
  - Quarterly: fingertip, media fill, garbing observation
  - "Regular" air sampling
  - Surface sampling: monthly!

797 Revision Comments

- Many cGMP requirements included
  - ASHP commented draft more geared for compounding facility versus acute care setting compounding
- Requirement for soap dispensers
  - Cannot add soap to a partially filled dispenser
    - "Topping off" not allowed
- No "expiration" date on CSP label
  - Change terminology to BUD

797 Revision Comments

- Compounding document requirements
  - Master Formulation Record
    - Standardized process for how to compound each batch
    - More of a policy/procedure
      - Ingredients, specific procedure, equipment used and testing needed for each CSP
  - Compounding record
    - For *each* CSP compounding procedure
    - Permit traceability of all ingredients
    - Mounds of paperwork!

Current Legislation in the General Assembly

***"No man's life, liberty or property are safe while the legislature is in session."* – Mark Twain**

SB2461 & HB4970

- Sen. Barickman, R-Bloomington and Rep. Stewart, R-Freeport
- Removes the statutory requirement for two deputy pharmacy compliance coordinators.
- Removes the limitations on the number of pharmacy investigators from the practice act.

SB2515 & HB5591 PBMs

- Sen. Tony Munoz, D-Chicago and Rep. Lou Lang, D-Skokie.
- Registers and creates regulations for PBMs operating in Illinois.
- Allows community pharmacies to provide 90-day supplies for the same price as mail order.
- Allows for medication synchronization.
- Create standardized audit criteria.
- Adds "Pharmacist provided services" to insurance code and allows for billing.

SB2901 & HB5949 Locking clousures

- Sen. Iris Martinez, D-Chicago and Rep. Michael Zalewski, D-Riverside.
- Extends the medicine locking closure package pilot an additional year to Jan. 1, 2018.

SB3336 & HB6180 Pharmacy Quality Assurance Programs

- Requires all pharmacies to establish quality assurance programs.
- Protects reports and other documents from discovery for arbitration, civil and criminal proceedings.
- Does allow access to the Department of Financial and Professional Regulation.

HR0944 – e-prescribing

- Urges IDFPR to study the impact of a mandatory mechanism within e-prescribing systems to transmit all discontinuation, stop and cancel orders to pharmacies.
- Urges IDFPR to study the impact auto-refill programs have on continued filling of discontinued medications.

HR1018 – Direct to consumer advertising

- Bill Mitchell, R-Decatur
- Urges Congress to prohibit all direct to consumer advertising of prescription medications.
- Urges the FDA to adopt appropriate rules and regulations banning direct to consumer advertising of prescription medications.

HB3627 - Immunizations

- Marcus Evans, Jr. – D, Chicago
- Expands pharmacists' ability to immunize patients ages 10-13 for all diseases.
- Requires pharmacists to report all immunizations provided to this age group on I-CARE.

HB5809 Oral Contraceptives

- Rep. Michelle Mussman, D-Schaumburg.
- Add prescribing and dispensing of hormonal contraceptives to the definition of "Practice of Pharmacy".
- Requires the pharmacist to complete a training course.
- Requires pharmacists to provide patients with aa self-screening risk assessment tool prior to dispensing.
- Requires the pharmacist to refer the patient to their primary care provider or women's health care practitioner.

Various and Sundry

- Appropriations for State Colleges of Pharmacy
- Changes to the penalties for late payment of bills by the State.
- Technical changes to the Pharmacy Practice Act.
- Changes to the Public Aid Code.

Self-Assessment

- If immunization authority by pharmacists is expanded, which disease states will be included?
  A. Influenza
  B. TDaP
  C. Mennigitis
  D. All disease states

Federal Legislation

- HR592 and S314 The Pharmacy and Medically Underserved Enhancement Act.
- Enables Medicare beneficiaries access to pharmacist-provided services under Medicare Part B by amending the Social Security Act.
- These services would be reimbursable if provided in medically underserved communities.
- Currently 79 of Illinois' 102 Counties qualify as medically underserved.

HR592 and S314 The Pharmacy and Medically Underserved Enhancement Act.

- State licensed pharmacists with additional training or certificates may provide services if consistent with State laws.
- Reimbursement would be consistent with rates provided to PAs, APNs or other non-physician practitioners. (Typically 85% of physician rate)
- Eligible services would be governed by State law.

Track and Trace

- The Drug Quality and Security Act
- Drug manufacturers and distributors are required to provide pharmacies with complete pedigrees for all medications.
- Pharmacies must have a plan to identify "suspect" products, quarantine them and conduct an investigation into their legitimacy.
- Goes into effect March 1, 2016.

Other federal issues

- Compounding
- Drug Shortages
- Health Care Reform
- REMS
- FDA Funding

Self-Assessment

- With HR592 and S312, if provider status for pharmacists is obtained, which of the following criteria is most important?
  A. Services must be provided in underserved counties in Illinois.
  B. Pharmacists providing the services must have special training.
  C. This applies to Medicare only.
  D. State law will play a major role.

If we have time!

- Let's talk about the changes to the Controlled Substance Act Rules that were approved in 2015!

CSA Rule Changes in 2015

- PAs and APNs in hospitals, hospital affiliates and ambulatory surgical centers may prescribe, dispense and administer CSs as privileged by the facility.
- Personal bags including purses, handbags and backpacks are prohibited in any area where controlled substances are handled or stored.
- Basic alarm system is required in pharmacies not open 24/7.

CSA Rule Changes in 2015

- Annual inventory of all controlled substances is now required.
  – Exact counts for CIIs, approximate count for III-V
  – Records retained for 5 years
- After loss or theft an inventory is also required for that controlled substance.
- DEA 106 form to DEA and then to the Department within one business day.

CSA Rule Changes in 2015

- Practitioners shall not self-prescribe controlled substances or prescribe for immediate family.
- Prescriptions for controlled substances must be manually signed by the prescriber. Includes computer-generated printed out or faxed prescriptions.
- Prescriptions sent via fax do not constitute electronic prescriptions.

CSA Rule Changes in 2015

- Pharmacists may not change the following on CII prescriptions:
  – Date written or add date, Name of patient, Name of prescriber or add signature, and name of drug.
- Pharmacists may change the following on CII prescriptions:
  – Quantity or strength of drug, instructions, patient address.

CSA Rule Changes in 2015

- Patients in long-term care facilities or diagnosed as terminally ill may receive partial fills of CII prescriptions. The prescription must contain the notation “LTCF patient” or “terminally ill”.

QUESTIONS????

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USP 797 Proposed Revisions:

Table 1. Summary Comparison of Minimum Requirements for Category 1 and Category 2 CSPs[a]

	Category 1 CSPs	Category 2 CSPs
Personnel Qualifications		
Visual observation of hand hygiene and garbing	Quarterly	Quarterly
Gloved fingertip sampling	Quarterly	Quarterly
Media fill testing	Quarterly	Quarterly
Personal Protective Equipment		
See *Table 2*.		
Buildings and Facilities		
Primary engineering control (PEC)	Not required to be placed in a classified area	Required to be placed in a classified area
Recertification	Every 6 months	Every 6 months
Environmental Monitoring		
Nonviable airborne monitoring	Every 6 months	Every 6 months
Viable airborne monitoring	Monthly	Monthly
Surface sampling	Monthly	Monthly
Release Testing		
Physical inspection	Required	Required
Sterility testing	Not required	Based on assigned BUD
Endotoxin testing	Not required	Required if prepared from nonsterile ingredient(s)[b]
BUD		
BUD assignment	≤12 hours at controlled room temperature or ≤24 hours if refrigerated	>12 hours at controlled room temperature or >24 hours if refrigerated

[a] This table summarizes the requirements that apply specifically to Category 1 and Category 2 CSPs. There are numerous requirements in the chapter that are not summarized in this table because they apply to all CSPs, regardless of whether they are Category 1 or Category 2.

[b] See exemptions in *10.3 Bacterial Endotoxins Testing*.

Table 7. BUDs for Category 1 CSPs

	Storage Conditions	
Temperature	Controlled Room Temp (20-25°C)	Refrigerator (2-8°C)
BUD	≤ 12 hours	≤ 24 hours

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Table 8. BUDs for Category 2 CSPs[a]

	Preparation Characteristics			Storage Conditions		
	Method of Achieving Sterility	**Sterility Testing Performed**	**Preservative Added**	**Controlled Room Temperature (20°–25°)**	**Refrigerator (2°–8°)**	**Freezer (–25° to –10°)[b]**
BUD	Aseptically prepared CSPs	No	No	Prepared from one or more nonsterile starting component 4 days	Prepared from one or more nonsterile starting component 7 days	Prepared from one or more nonsterile starting component 45 days
				Prepared from only sterile starting components 6 days	Prepared from only sterile starting components 9 days	Prepared from only sterile starting components 45 days
			Yes[c]	28 days	42 days	45 days
		Yes	No	28 days	42 days	45 days
			Yes[d]	42 days	42 days	45 days
	Terminally Sterilized CSPs	No	No	14 days	28 days	45 days
			Yes[c]	28 days	42 days	45 days
		Yes	No	28 days	42 days	45 days
			Yes[d]	42 days	42 days	45 days

[a] The BUDs specified in the table indicate the days after the Category 2 CSP is prepared beyond which the CSP cannot be used. The BUD is determined from the time the CSP is compounded. One day is equivalent to 24 hours.

[b] The integrity of the container–closure system with the particular CSP in it must have been demonstrated for 45 days at frozen storage. The container–closure integrity test needs to be conducted only once on each formulation in the particular container–closure system in which it will be stored or released/dispensed.

[c] The particular CSP formulation must pass antimicrobial effectiveness testing in accordance with ⟨51⟩ at the time of preparation. The test must be completed and the results obtained on the specific formulation before any of the CSP is dispensed. The test needs to be conducted only once on each formulation in the

Compounding Records must include at least the following information:

- Name, strength, and dosage form of the CSP
- Master Formulation Record reference for the preparation, when used

- Date and time of preparation of the CSP
- Assigned internal identification number (e.g., prescription or lot number)
- Signature or initials of individuals involved in each step (e.g., technician or pharmacist)
- Name, vendor or manufacturer, lot number, and expiration date of each ingredient and container–closure system
- Weight or measurement of each ingredient
- Documentation of the calculations made to determine and verify quantities and/or concentrations of components, if appropriate
- Documentation of quality control procedures in accordance with the SOP (e.g., filter integrity, pH, and visual inspection)
- Any deviations from the Master Formulation Record, if used, and any problems or errors experienced during the compounding of the CSP
- Total quantity compounded
- Assigned BUD
- Duplicate container label if prepared in a batch

SAVE – Important Information

Instructions to Process Continuing Pharmacy Education (CPE) Credit ONLINE at CESally.com

CPE Program: **Happy New Year 2016 – Here's Some New Laws!**

Program Date: **February 25, 2016**

Access Code: _____
Announced at the session.
You will need this to process your credit.

CPE Processing Deadline:
Feb. 25 Activity–You MUST complete your evaluation submission by end of day April 9, 2016.

Please honor the ICHP deadline! 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!

Note: Attendance is required to obtain CPE credit for this program. No partial credit is available. ACPE requires that the online participants processing CPE for a live program match the attendance registration list for that program.

Detailed instructions to process CPE credit

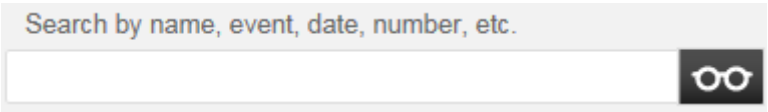
Participants in this CPE program - You will need your own account on CESally.com to access the CPE program, do the evaluation, and submit for credit.

To set up your account:
1. Go to www.CESally.com and click on "Sign Up!" Or log in with your existing account.

2. Complete the Sign Up process and select a username and password.
For HELP at any point, click on the HELP tab or go to: https://www.cesally.com/help/.

3. Enter your NABP eProfile ID and birth day as MMDD when prompted. CESally.com will check with NABP/CPE Monitor in real time, to confirm the NABP eProfile and birth day are a valid account.

4. Once you have created your account, or logged in, use the **Search Box** in the upper right corner to find your activity by typing in the title. You have several options for completing or saving for later.



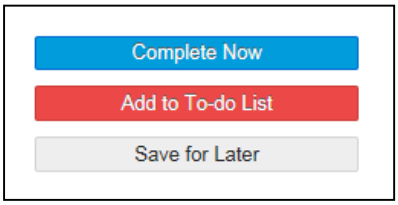
Please pay CLOSE attention to the Title, Date, and if it says Pharmacist or Technician after the title.
- Pharmacists must do P-specific programs only.
- Technicians must do T-specific programs ONLY as of Jan. 1, 2015 for PTCB recertification.

SAVE – Important Information

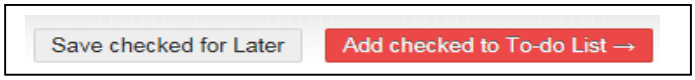
Instructions to Process Continuing Pharmacy Education (CPE) Credit ONLINE at CESally.com

5. Identify the program attended and choose either:

a) Click on that Activity title to open the information page, and you will see your options in the right hand column on the information page.



b) OR Click on the checkbox inside the small information box, then go to the bottom of the page and see your options there.



6. Choose from either a) or b) above, to **Complete Now**, **Save for Later**, OR **ADD to To-do List.**

7. If you Save or Add to To-do List, when you are ready to complete, please go to the appropriate webpage and click on **Start to Do List.** Follow the actions as directed. The status box on the right indicates where you are in the process. You will verify your attendance, provide the session ACCESS code that was given to you during the program, and complete an evaluation of the activity and the speaker(s).

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

9. If an error occurred, 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 so your credit will NOT be reported to CPE Monitor. ***So please confirm your submissions.***

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

Please remember the ICHP CPE processing **DEADLINE** is **April 9, 2016.**

Important: Please honor the ICHP CPE processing deadline! Remember, if you encounter problems, we will need time to assist you before the final CPE Monitor deadline is in effect. If you have any questions, please contact ICHP at members@ichpnet.org.

Thank you!