



Florida Board of Pharmacy Update

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 President and Owner, XRX Solutions, LLC
 Chair, Probable Cause Panel
 Member, Tripartite Continuing Education Committee
 Member, Sterile Compounding Subcommittee

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Disclosure Statement


- Member of Probable Cause Panel, BOP
- Non-voting member, Sterile Compounding Subcommittee
- I do not have (nor does any immediate family member have):
 - a vested interest in or affiliation with any corporate organization offering financial support or grant monies for this continuing education activity
 - any affiliation with an organization whose philosophy could potentially bias my presentation

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CPE INFORMATION


- iCARE Pharmacy Services, Inc. is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider for continuing pharmacy education.
- **This activity offers 1.5 contact hours (0.15 CEU).**
- Target Audience: Pharmacists and Registered Pharmacy Technicians
- ACPE #: 0675-0000-24-010-L03
- Activity Type:
 - Knowledge based
 - Application based

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Objectives 


- Review upcoming changes to 64B16.27.797 and 64B16.27.700 (Compounding Definition and Standards)
- Discuss the rule changes that have become effective in 2023, or recently noticed and discussed during the Rules Committee meeting(s)
- Provide an update on e-Licensing and how to obtain electronic blue license and pharmacy permit
- Examine processes associated with emergency orders enacted by the Governor

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Learning Assessments 

- These will be dispersed throughout the presentation

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Board of Pharmacy 

[Florida Board of Pharmacy- Licensing, Renewals & Information \(floridasparmacy.gov\)](http://floridasparmacy.gov)

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Renewals- 2024

- Consultant RPh by 12/31/2024 at 2359 (24 Board approved hours)
- Registered Pharmacy Technician 12/31/2024 at 2359

REQUIRED SUBJECT AREA	REQUIRED NUMBER OF HOURS	IMPORTANT INFORMATION
General Hours	18	General hours can be either ACPE or Board approved, 4 of the 20 must be live, live video conference, or through an interactive computer-based application.
Medication Errors	2	Medication Errors Must be Board Approved

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Permit Application Clarifications



- Applications are valid for 1 (one) year from the date of submission
- Make sure ALL requested information is submitted prior to this date
- Deficiency letters are sent out every 30 days which includes a list of missing information
- This reduces the amount of time the application has for review/approval
- Permit applications SHOULD be filled out by the Consultant of Record or Prescription Department Manager (rather than office staff)


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Most Common List of Deficiencies:



- Missing active fingerprints on file
- Diagram or Layout request (hand drawn is not allowable)- must have architecture rendition submitted
- Policies and Procedures- excerpts are acceptable (do not need the entire P & P= just the parts that are applicable for the pharmacy department/store/ etc; Looking for the excerpt that answers the question
- Review the application carefully and do NOT skip any lines (enter NA when asked)

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TRUE OR FALSE 

The purpose of Board of Pharmacy is to represent the interests of pharmacists, pharmacy interns, pharmacy technicians, and pharmacies.


A Yes True or **B** No False

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Board of Pharmacy (and all healthcare boards)

- **Protect the Health and Safety of the citizens of the great state of Florida**
- If the board has the ability to do so by also assisting permits and licensees then by all means the board will

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TRUE OR FALSE 

Section 465.002, F.S., provides that the sole legislative purpose for enacting Chapter 465 is to ensure that every pharmacist practicing in this state and every pharmacy meet minimum requirements for safe practice.

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This is true – see below:

The 2023 Florida Statutes (including Special Session C)

[Title XXXII](#) [Chapter 465](#) [View Entire Chapter](#)
REGULATION OF PROFESSIONS AND OCCUPATIONS PHARMACY

465.002 Legislative findings; Intent.—The Legislature finds that the practice of pharmacy is a learned profession. **The sole legislative purpose for enacting this chapter is to ensure that every pharmacist practicing in this state and every pharmacy meet minimum requirements for safe practice.** It is the legislative intent that pharmacists who fall below minimum competency or who otherwise present a danger to the public shall be prohibited from practicing in this state.

History.—s. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 1, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

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Board's Purpose



What is the purpose and function of the Board of Pharmacy?

1. Promote the practice of the learned profession of pharmacy.
2. Ensure that every pharmacist practicing in this state and every pharmacy meet minimum requirements for safe practice.
3. Provide technical assistance to support the practice of pharmacy.

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QUESTION



How many **consumer** members are on the Florida Board of Pharmacy?

- A** 0
- B** 1
- C** 2
- D** 3
- E** 4

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Overview of the Board



Board Pharmacy Composition – (s).465.004, F.S.:

- **NINE** total members appointed by the Governor.
 - **SEVEN** members are licensed pharmacists;
 - TWO** must practice in a community pharmacy;
 - TWO** must practice of pharmacy in a Class II /III institutional pharmacy or a Modified Class II institutional pharmacy; and
 - THREE** must be pharmacists licensed in FL.
 - **TWO** members are consumer members;
 - Of the nine total members, **ONE** member must be over the age of 60 years old.

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Members of the Board of Pharmacy



Members of the Board

 Jesus Philip PharmD St. Johns, FL Term Ends: 01/31/2024 Read More	 Patty Charvini PharmD, BCSCP Chair Tallahassee, FL Term Ends: 01/31/2024 Read More	 Cristina Medina PharmD Miami, FL Term Ends: 01/31/2024 Read More
 Maja Gift MHA, BCSCP, RPh, CPh Tampa, FL Term Ends: 02/29/2024 Read More	 Daniel Kirk MS, CSCE Consumer Bradenton, FL Term Ends: 02/29/2024 Read More	 Dorinda Segovia PharmD, MHA, BCSCP Miami, FL Term Ends: 02/29/2024 Read More
 Jonathan Hickman PharmD Tallahassee, Florida Term Ends: 02/29/2024 Read More	 Jeffrey J. Mesiano PharmD, JD Ocala, FL Term Ends: 02/29/2024 Read More	 Ryan West Consumer Tallahassee Term Ends: 02/29/2024 Read More

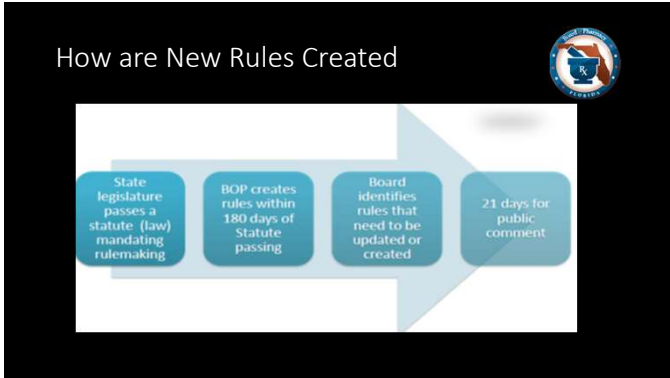
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Current Committees of the Board



- Compounding Committee
- Rules Committee
- Sterile Compounding Subcommittee
- Tripartite Continuing Education Committee

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Creating and/or Modifying Rules

- The Board of Pharmacy Rules Committee meets with each board meeting and more often if needed.
- Rules are opened by the Rules committee, then get published in the Florida Administrative Register.
- After publishing, the rules are listed on the Board agenda, and the Rules Committee updates/ changes the rule.
- The rule is then forwarded to the full board for approval or rejection.
- If approved, the rule it is published in the Florida Register for 21 days for public comment before coming effective.
- Rules may be found on the Florida Administrative Register website at: www.flrules.org

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Licenses and Permits

PROFESSION	In State			Out of State			Military Active	Retired	TOTAL
	Active	Inactive	Delinquent	Active	Inactive	Delinquent			
PHARMACY									
Consultant Pharmacist	3,115	64	411	185	12	40	1	246	4,014
Nuclear Pharmacist	157	0	4	50	2	10	0	17	240
Pharmacist	27,095	52	577	9,256	222	660	96	1,413	38,337
PHARMACY INTERN									
Pharmacist Intern	6,900	0	0	6,605	0	0	0	0	13,503
Registered Pharmacy Technician	46,678	117	13,066	1,014	6	508	52	21	61,402
LICENSED FACILITY BY PROFESSION									
Nonresidential Sterile Compounding Pharmacy		189		24					213
Pharmacy		10,158		289					10,447
Resident Sterile Compounding Pharmacy		454		0					454


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How Much Money for every Licensee under Ch 456 is Collected as the Unlicensed Activity Fee?

- A. Ten dollars
- B. Twenty dollars
- C. Two dollars
- D. Five dollars
- E. Four dollars

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TRUE OR FALSE




Board of Pharmacy Staff may answer practice questions or provide legal advice to licensees about statutes or rules?

A Yes True or **B** No False


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Rules updates



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64b16-27.797 The Standards of Practice for Compounding Sterile Products



• (2) Minimum Standards: Notwithstanding subsection (1) above, *beginning on November 16, 2023 all sterile compounding shall be performed in full compliance with the minimum practice and quality standards of state and federal law, Section 465.016(4)(e), F.S., mandates that those licensed pursuant to Chapter 465, F.S. must comply with ss. 21 U.S.C. 301-392, known as the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 503A of the FD&C Act, codified at 21 U.S.C. 353a, requires compliance with minimum practice and quality standards for compounding sterile drug products pursuant to a valid prescription for an identified patient. When compounding pursuant to this provision of the Act, the Act requires that sterile compounding must be done in compliance with all Chapters related to compounding found in the current United States Pharmacopeia. The Board, until November 2025, shall not take disciplinary action for failing to compound pursuant to the minimum practice and quality standards of this subsection as long as the compounding was done in compliance with the minimum practice and quality standards subsection (1).*

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64b16-27.700 Definition of Compounding

- Open for development
- Need to remove all human reference because requires 503b permit for office use
- Will change to office use for animal use only

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64B16-27.650 Additional Immunizations or Vaccines Which May be Administered

- Those properly certified may administered the additional vaccines:
 COVID19 Vaccines and
 Respiratory Syncytial Virus Vaccines

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eLicensing – BOP joined

- The Health boards no longer send paper/card permits or licenses
- Approved permit holders and licensees must download their “blue” license
- This is obtained in the MQA portal (where renewals are completed).
- [Login Option - MQAServices Portal \(state.fl.us\)](https://state.fl.us)
 - Located under the additional activities section



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BOP Contact Information



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