

# THE FLORIDA BOARD OF PHARMACY

## ANNUAL REGULATORY PLAN 2020-2021

This Annual Regulatory Plan is being filed and published pursuant to section 120.74, *Florida Statutes* (2020). The Plan covers the period beginning October 1, 2020 and ending September 30, 2021.

### PART ONE LAWS ENACTED OR AMENDED

Part One of the Plan addresses each law enacted or amended during the 2020 Legislative Session which creates or modifies the duties or authority of the Board of Pharmacy. §120.74(1)(a), Fla. Stat. (2020).

Law Enacted or Modified on or after Oct. 1, 2019	Florida Statute (modified or created)	Rule (impacted)	Must Agency Adopt Rules?	If Rulemaking Necessary, Notice of Development Published in Florida Administrative Register?	Expected Publication Date for Notice of Proposed Rulemaking	If Rulemaking Not Necessary, Explain
Ch. 2020-124, Laws of Fla., Eff. July 1, 2020 (HB 59 Automated Pharmacy Systems)	§465.0235, Fla. Stat.	Rule 64B16-28.141, Fla. Admin. Code.	No	October 2020	Determined based on further Board Review.	The statute clearly states that the Board “may adopt rules.” However, the Board is reviewing and considering necessary changes to this Rule to ensure it does not conflict with the statute being implemented.

Ch. 2020-125, Laws of Fla, Eff. July 1, 2020 (HB 115: Keep Our Graduates Working Act)	Created §120.82, Fla. Stat.; Amended §456.0635, Fla. Stat., and §456.074, Fla. Stat., and Repealed §456.0721, Fla. Stat.	All application rules.	No	N/A	N/A	All applications are already adopted and incorporated and are not in conflict with this Bill, but all applications will be updated for clarification, uniformity and ease of use.
Ch. 2020-7, Laws of Fla, Eff. July 1, 2020. (HB 389: Practice of Pharmacy)	Amended §465.003(13), Fla. Stat.; Created §§ 465.1865 and 1895, Fla. Stat.	Ch. 64B16-31, Fla. Admin. Code. <a href="#">64B16-31.001</a> Collaborative Practice Certification (CPC). <a href="#">64B16-31.003</a> Collaborative Practice Certification: Initial Certification Course. <a href="#">64B16-31.005</a> Collaborative Practice Certification: Collaborative Pharmacy Practice Agreement Submission. <a href="#">64B16-31.007</a> Collaborative Practice Certification: Chronic Health Conditions. <a href="#">64B16-31.009</a> Collaborative Practice Certification: Mandatory Continuing Education. <a href="#">64B16-31.033</a> Test and Treat Certification (TTC). <a href="#">64B16-31.035</a> Test and Treat Certification: Initial Certification Course. <a href="#">64B16-31.037</a> Test and Treat Certification: Written Protocol	Yes	6/15/2020 Vol 46/116	September/October 2020.	The Board is implementing HB389 via an entirely new Rule Chapter within the <i>Florida Administrative Code</i> .

		<p>and Written Protocol Submission.</p> <p><a href="#">64B16-31.039</a> Test and Treat Certification: Formulary of Medicinal Drugs.</p> <p><a href="#">64B16-31.041</a> Test and Treat Certification: Patient Records.</p> <p><a href="#">64B16-31.043</a> Test and Treat Certification: Follow-Up Care.</p> <p><a href="#">64B16-31.050</a> Mandatory Review of Rule Chapter 64B16-31, F.A.C.</p>				
Ch. 2020-103, Laws of Fla, Eff. July 1, 2020 (HB559: Institutional Formularies Established by Nursing Home Facilities)	Amended §§400.143 and 465.025, Fla. Stat.	None	No	N/A	N/A	The amendments are self-executing and the Board determined no rules were impacted or necessary for full implementation of this Bill.
Ch. 2020-8, Laws of Fla., Eff. July 1, 2020 (HB599: Consultant Pharmacists)	Amended §465.003, Fla. Stat. Amended §465.0125, Fla. Stat.	Rules 64B16-26.300 and 64B16-26.301, Fla. Admin. Code.	Yes	October 2020	December 2020	The Board already has rules in place for Consultant pharmacists and this specific statute. The amendments do not necessitate mandatory rulemaking, but the Board is updating the rules to increase efficiency and remove obsolete or unnecessary or over burdensome requirements.

Ch. 2020-133, Laws of Fla., Eff. July 1, 2020 (HB 713: Health Regulation)	Repealed §456.0721, Fla. Stat.	All Application Rules	No	N/A	N/A	The repeal does not directly impact the applications and the applications are not in direct conflict, so rulemaking is not mandatory. However, the Board will complete a comprehensive review of all applications over the next year and update them for Clarification, Simplicity and Efficiency.
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**PART TWO**  
**LAWS EXPECTED TO BE IMPLEMENTED THROUGH RULEMAKING**

Part Two of this plan addresses those laws which the Board of Pharmacy intends to implement through rulemaking by July 1, 2021 that are otherwise not covered pursuant to Part One of this Plan. This Part does not include emergency rulemaking or any other rulemaking that may become necessary that was not evident to the Board at the time of the submission of this plan. Additionally, the listing of a law to be implemented does not mean the rule will necessarily be adopted or effective by July 1, 2021. §120.74(1)(b), Fla. Stat. (2020).

<b>Rule Number And Title</b>	<b>Law Expected to Be Implemented Through Rulemaking</b>	<b>Intent of Rulemaking</b>
<u>Chapter 64B16</u> , F.A.C. (Board of Pharmacy)	Multiple / Various Chapter 456; 465; 499; 893 and Applicable Federal Law.	Clarify, Simplify and Increase Efficiency. Review all application forms for necessary updates and to amend the Health History Questions within the application; create uniformity and increase ease of use for applicant to expedite license review and increase business productivity.
<u>64B16-27.120</u> , F.A.C. (Ordering and Evaluation of Laboratory Tests)	None	Repeal. The rule is duplicative of the §465.0125, Fla. Stat.
<u>64B16-30.001</u> , F.A.C. (Dis. Guidelines ....)	§§ 456.072; 079; 047; 465.016 and .023, Fla. Stat.	Update; Clarify, Simplify.

<u>64B16-30.002</u> , F.A.C. (Minor Violations)	§ 456.073, Fla. Stat.	Clarify, Simplify, Increase Efficiency and Reduce unnecessary regulatory burden.
<u>64B16-30.003</u> , F.A.C. (Citations)	§456.077, Fla. Stat.	Clarify, Simplify, Increase Efficiency and Reduce unnecessary regulatory burden.

**PART THREE**  
**UPDATES TO PRIOR YEAR'S PLAN**

Part Three of the Plan address whether there are any updates to the prior year's regulatory plan. §120.74(1)(c), Fla. Stat. (2020).

**There are not any updates to the prior year's annual regulatory plan.**

**PART FOUR**  
**CERTIFICATION PURSUANT TO §120.74(1)(d), Fla. Stat. (2020)**

The undersigned hereby certify that they have reviewed this Annual Regulatory Plan and that the Board of Pharmacy regularly reviews all its rules to determine if the rules remain consistent with the Board's rulemaking authority and the laws being implemented, with the most comprehensive enhanced review having been completed on the 30th day of June 2015 with continuing board review through August 2020. The Board is currently completing a 2020 Comprehensive Review for the Office of Fiscal Accountability and Regulatory Reform.

*/S/ Richard E. Montgomery, BPharm, MBA*  
Electronic Signature  
Richard E. Montgomery, BPharm, MBA  
Chair of the Board of Pharmacy

September 3, 2020  
Date Signed

*/S/ David D. Flynn, Esquire*  
Electronic Signature  
David D. Flynn, Esquire  
Senior Assistant Attorney General  
Counsel to the Board of Pharmacy

September 3, 2020  
Date Signed