

# THE FLORIDA BOARD OF PHARMACY

## ANNUAL REGULATORY PLAN 2018-19

This Annual Regulatory Plan is being filed and published pursuant to section 120.74, *Florida Statutes* (2018). The Plan covers the period beginning October 1, 2018 and ending September 30, 2019.

### PART ONE LAWS ENACTED OR AMENDED

Part One of the Plan addresses each law enacted or amended during the 2018 Legislative Session which creates or modifies the duties or authority of the Board of Pharmacy. §120.74(1)(a), Fla. Stat. (2018).

| Law Enacted or Modified on or after Oct. 1, 2017             | 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. 2018-13, Laws of Florida, Effective July 1, 2018 (HB 21) | §§ 465.0155(2); 893.055(3); 893.055(8); 893.0551(6), F.S. | 64B16-30.001, F.A.C. (Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances) | Yes                      | 7/6/2018<br>Vol. 44/131                                                                      | 7/26/2018<br>Vol. 44/145                                    | N/A                                  |
|                                                              |                                                           | 64B16-30.003, F.A.C. (Citations)                                                                             | Yes                      | 7/6/2018<br>Vol. 44/131                                                                      | 7/26/2018<br>Vol. 44/145                                    | N/A                                  |

|                                                                   |                                                              |                                                                                                              |     |                         |                          |                                                                                                                                                                       |
|-------------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|-----|-------------------------|--------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ch. 2018-91, §1, Laws of Florida, Effective July 1, 2018 (HB 351) | §465.0244(2), F.S. (Information Disclosure)                  | 64B16-30.001, F.A.C. (Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances) | Yes | 7/6/2018<br>Vol. 44/131 | 7/26/2018<br>Vol. 44/145 | N/A                                                                                                                                                                   |
|                                                                   |                                                              | 64B16-30.003, F.A.C. (Citations)                                                                             | No  | 7/6/2018<br>Vol. 44/131 | 7/26/2018<br>Vol. 44/145 | Rulemaking is not mandatory. However, the Board has voted to designate a first-time violation of this new subsection as a citation offense pursuant to §456.077, F.S. |
| Ch. 2018-95, Laws of Florida, Effective July 1, 2018 (HB 675)     | §§465.003; 465.004; 465.019; 465.0252; 499.003; 499.01, F.S. | 64B16-28.501, F.A.C. (Consultant Pharmacist of Record; Initial Designation; Change).                         | Yes | 7/6/2018<br>Vol. 44/131 | 7/26/2018<br>Vol. 44/145 | N/A                                                                                                                                                                   |
|                                                                   |                                                              | 64B16-28.502, F.A.C. (Class I, Class II, Class III Institutional Permit ...)                                 | Yes | 7/6/2018<br>Vol. 44/131 | 7/26/2018<br>Vol. 44/145 | N/A                                                                                                                                                                   |
|                                                                   |                                                              | 64B16-28.602, F.A.C. (Institutional Class II or Class III Dispensing)                                        | Yes | 7/6/2018<br>Vol. 44/131 | 7/26/2018<br>Vol. 44/145 | N/A                                                                                                                                                                   |
|                                                                   |                                                              | 64B16-28.6021, F.A.C. (Institutional Class II and Class III Pharmacy – Emergency Department Dispensing)      | Yes | 7/6/2018<br>Vol. 44/131 | 7/26/2018<br>Vol. 44/145 | N/A                                                                                                                                                                   |
|                                                                   |                                                              | 64B16-28.603, F.A.C. (Class II and Class III Institutional Pharmacy Operating Hours)                         | Yes | 7/6/2018<br>Vol. 44/131 | 7/26/2018<br>Vol. 44/145 | N/A                                                                                                                                                                   |

|  |  |                                                                                                                              |     |                          |                          |     |
|--|--|------------------------------------------------------------------------------------------------------------------------------|-----|--------------------------|--------------------------|-----|
|  |  | <u>64B16-28.606</u> , F.A.C.<br>(Remote Medication Order Processing For Class II and Class III Institutional Pharmacies ...) | Yes | 7/6/2018<br>Vol. 44/131  | 7/26/2018<br>Vol. 44/145 | N/A |
|  |  | <u>64B16-28.750</u> , F.A.C.<br>(Class III Institutional Pharmacies)                                                         | Yes | 7/20/2018<br>Vol. 44/141 | 8/7/2018<br>Vol. 44/153  | N/A |
|  |  | <u>64B16-28.810</u> , F.A.C.<br>(Special Pharmacy – Limited Community Pharmacy Permit).                                      | Yes | 7/6/2018<br>Vol. 44/131  | 7/26/2018<br>Vol. 44/145 | N/A |

**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, 2019 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, 2019. §120.74(1)(b), Fla. Stat. (2018).

| <b>Rule Number<br/>And Title</b>                                                                                   | <b>Law Expected to Be Implemented<br/>Through Rulemaking</b> | <b>Intent of Rulemaking</b>                                                                    |
|--------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| <u>Chapter 64B16</u> , F.A.C.<br>(Board of Pharmacy)                                                               | Multiple / Various<br>Chapter 456 and 465, F.S.              | Clarify, Simplify, and Increase Efficiency<br>by Reviewing and updating all licensure<br>forms |
| <u>64B16-26.351</u> , F.A.C.<br>(Standards for Approval of<br>Registered Pharmacy<br>Technician Training Programs) | § 465.014, F.S.                                              | Clarify and Reduce Regulatory Costs                                                            |
| <u>64B16-26.600</u> , F.A.C.<br>(Tripartite Continuing<br>Education Committee)                                     | §465.009, F.S.                                               | Simply and Increase Efficiency                                                                 |
| <u>64B16-26.6012</u> , F.A.C.<br>(Guidelines for Board Ordered<br>Disciplinary Continuing<br>Education Courses)    | §§456.072(2); 465.016(4), F.S.                               | Clarify and Simplify                                                                           |

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| 64B16-27.1001, F.A.C.<br>(Practice of Pharmacy)                                                                                                     | §§465.003; 465.014; 465.026, F.S. | Clarify and Simply                                                              |
| 64B16-27.104, F.A.C.<br>(Conduct Governing Pharmacists and Pharmacy Permittees)                                                                     | §§465.018; 465.022; 465.024, F.S. | Increase Efficiency and Reduce Regulatory Costs, as related to return to stock. |
| 64B16-27.210, F.A.C.<br>(General Terms and Conditions to Be Followed by a Pharmacist When Ordering and Dispensing Approved Medicinal Drug Products) | §§465.022; 465.186, F.S.          | Clarify and Reduce Regulatory Costs                                             |
| 64B16-27.211, F.A.C.<br>(Prescription Refills)                                                                                                      | §465.022, F.S.                    | Clarify and Increase Efficiency                                                 |
| 64B16-27.220, F.A.C.<br>(Medicinal Drugs Which May be Ordered by Pharmacists)                                                                       | §465.186, F.S.                    | Clarify and Reduce Regulatory Costs                                             |
| 64B16-27.4001, F.A.C.<br>(Delegation to and Supervision of Pharmacy Technicians; Responsibility of Supervising Pharmacist)                          | §465.014, F.S.                    | Clarify and Reduce Regulatory Costs                                             |
| 64B16-27.410, F.A.C.<br>(Registered Pharmacy Technician to Pharmacist Ratio)                                                                        | §§465.014; 465.022, F.S.          | Clarify, Increase Efficiency and Reduce Regulatory Costs                        |
| 64B16-27.420, F.A.C.<br>(Pharmacy Technician – Delegable and Non-Delegable Tasks)                                                                   | §465.014, F.S.                    | Clarify, Increase Efficiency, and Reduce Regulatory Costs                       |

|                                                                                                                                                               |                                                                                                |                                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| 64B16-27.797, F.A.C.<br>(The Standards of Practice for Compounding Sterile Products)                                                                          | §§465.0155; 465.022, F.S.                                                                      | Clarify, Simply, and Increase Efficiency                  |
| 64B16-27.830, F.A.C.<br>(Standards of Practice – Drug Therapy Management)                                                                                     | §§465.003; 465.0155, F.S.                                                                      | Clarify and Reduce Regulatory Costs                       |
| 64B16-27.831, F.A.C.<br>(Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education) | §§456.013; 456.42; 456.43; 465.0155; 465.003; 465.009; 465.016; 465.017; 465.022; 893.04, F.S. | Clarify and Simplify                                      |
| 64B16-28.141, F.A.C.<br>(Requirements for use of an Automated Pharmacy System by a Community Pharmacy)                                                        | §§465.018; 465.022, F.S.                                                                       | Clarify, Increase Efficiency and Reduce Regulatory Costs  |
| 64B16-28.608, Automated Filling Systems within a Pharmacy)                                                                                                    | §§465.003; 465.0155; 465.022, F.S.                                                             | Clarify, Increase Efficiency and Reduce Regulatory Costs  |
| 64B16-28.118, F.A.C.<br>(Unit Dose and Customized Patient Medication Package Returns)                                                                         | §§465.016; 465.019, F.S.                                                                       | Clarify, Increase Efficiency, and Reduce Regulatory Costs |
| 64B16-30.001, F.A.C.<br>(Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances)                                               | §§456.072(2); 456.079(1); 465.016; 465.023, F.S.                                               | Clarify                                                   |

|                                                    |                   |                                                 |
|----------------------------------------------------|-------------------|-------------------------------------------------|
| <u>64B16-30.002</u> , F.A.C.<br>(Minor Violations) | §456.073(3), F.S. | Increase Efficiency and Reduce Regulatory Costs |
| <u>64B16-30.003</u> , F.A.C.<br>(Citations)        | §456.077, F.S.    | Increase Efficiency and Reduce Regulatory Costs |

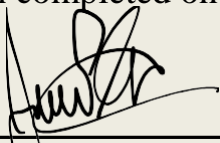
**PART THREE**  
**UPDATES TO PRIOR YEAR'S PLAN**

Part Three of the Plan address whether there are any updates to the prior year's regulatory plan. §120.74(1)(c), Fla. Stat. (2018).

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

**PART FOUR**  
**CERTIFICATION PURSUANT TO §120.74(1)(d), Fla. Stat. (2018)**

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 2018.

 , *BPharm*  
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Electronic Signature  
Jeenu Philip, BPharm

Chair of the Board of Pharmacy

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

**September 04, 2018**  
\_\_\_\_\_  
Date Signed

**September 04, 2018**  
\_\_\_\_\_  
Date Signed