AGENDA

Florida Board of Pharmacy
Rules Committee Meeting
December 11, 2018 – 10:00 a.m.

*Orlando Marriott Lake Mary * 1501 International Parkway * Lake Mary, FL 32746*

Committee Members:
Jeffrey Mesaros, PharmD, JD – Chair
David Bisaillon
Jonathan Hickman, PharmD
Jeenu Philip, BPharm
Blanca Rivera, BPharm, MBA

Board Staff
C. Erica White, MBA, JD - Executive Director
Jessica Hollingsworth – Government Analyst II

Board Counsel:
David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

Note: Participants in this public meeting should be aware that these proceedings are being recorded.

1. **Call to Order**

2. **Discussion: Rule 64B16-26.351, F.A.C. - Standards for Approval of Registered Pharmacy Technician Training Programs**
   - Resolve the JAPC concern with incorporating the FDOE standards for the postsecondary school PTTPS; and
   - Attempt to streamline language regarding the preapproved programs.

3. **Discussion: Rule 64B16-30.003, F.A.C. - Citations**

4. **Discussion: Rule 64B16-28.110, F.A.C. - Outdated Pharmaceuticals**
   - Additional changes to Rule 64B16-30.0020
   - Additional changes to Rule 64B16-30.003

5. **Discussion: Rule 64B16-27.410, F.A.C. - Registered Pharmacy Technician to Pharmacist Ratio**

6. **Discussion: 64B16-26.400, F.A.C. - Pharmacy Interns; Registration; Employment**

7. **Discussion of Annual Regulatory Plan**

8. **Old Business / New Business**

9. **Public Comment**

10. **Adjourn**

TAB #2

PAM BONDI
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Administrative Law Bureau

Lawrence D. Harris
Assistant Attorney General
PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3771 Fax (850) 922-6425
Lawrence.Harris@myfloridalegal.com

November 2, 2018

Ms. Marjorie C. Holladay
Chief Attorney
Joint Administrative Procedures Committee
Room 680, Pepper Building
111 W. Madison Street
Tallahassee, Florida 32399-1400

RECEIVED
2018 NOV -6 PM 2:39
JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE

Re: Department of Health, Board of Pharmacy
Rule 64B16-26.351, F.A.C.

Dear Ms. Holladay:

I am writing in response to your October 30, 2018 correspondence regarding the above rule, wherein you make one well-taken comment. Resolution of your comment will require action by the Board at an upcoming Board meeting; the next meeting is scheduled for December 11, 2018.

This rule project was initiated in response to the concerns of major pharmacies in the state, who are losing qualified technician trainees due to the current rule's limitations on employer-sponsored training programs. It is my understanding that those concerns have become more pressing since the project was initiated in August. Accordingly, the Board intends to file the rule for adoption, as modified by the Notice of Change. However, you have my commitment that this rule and your correspondence will be presented to the Board at the December meeting, with my recommendation that an additional rulemaking project be initiated to amend the rule to incorporate the FDOE Pharmacy Technician Training Curriculum Framework.

As always, thank you for your time, assistance, and thoughtful comments regarding the Board's rulemaking endeavors. Please do not hesitate to contact me if you have any further questions or concerns.

Sincerely,

Lawrence D. Harris
Assistant Attorney General

Counsel to the Florida Board of Pharmacy

cc: C. Erica White, Executive Director
Angela Southwell, Paralegal Specialist

RECEIVED
2010 NOV -6 PM 2:39
JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE

JOE NEGRON
President

RICHARD CORCORAN
Speaker

THE FLORIDA LEGISLATURE

JOINT ADMINISTRATIVE PROCEDURES COMMITTEE

Senator Kevin Rader, Chair
Representative George R. Moraitis, Jr., Vice Chair
Senator Daphne Campbell
Senator George B. Gainer
Senator Rene Garcia
Senator Keith Perry
Representative Jason Fischer
Representative Michael Grant
Representative Sam H. Killebrew
Representative Amy Mercado
Representative Barrington A. "Barry" Russell

KENNETH J. PLANTE
COORDINATOR
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October 30, 2018

Mr. Lawrence Harris
Assistant Attorney General
Office of the Attorney General
PL-01, The Capitol
Tallahassee, Florida 32399-1050

Re: Department of Health: Board of Pharmacy
Proposed Rule 64B16-26.351

Dear Mr. Harris:

I have reviewed the notice of change that was published for proposed rule 64B16-26.351 in the October 29, 2018, Florida Administrative Register. I have the following comments.

64B16-26.351(1)(o): This notice of change adds this paragraph that approves "[p]harmacy technician training programs within the public-school system of the State of Florida that comply with the Florida Department of Education Curriculum Framework for Pharmacy Technician, program number H170500." Please provide a copy of the "Florida Department of Education Curriculum Framework for Pharmacy Technician, program number H170500" to the committee for review. Further, as compliance with this curriculum framework is an optional requirement for board approval of certain pharmacy technician training programs, it appears this curriculum framework should be specifically incorporated by reference in the rule text. *See* § 120.52(16), Fla. Stat.; Fla. Admin Code R. 1-1.013.

Please publish another notice of change that specifically incorporates this curriculum framework by reference.

64B16-26.351(6): Form DH-MQA 1239, dated 06/18:
Page 2, Number 16: This item lists "[p]harmacy technician training programs within the public-school system of the State of Florida that comply with the Florida Department of Education Curriculum Framework for the Pharmacy Technician, program number H170500." Perhaps the board would consider removing the word "the" following "for" and preceding "Pharmacy Technician" in order to be consistent with the language in paragraph (1)(o).

Please let me know if you have any questions. Otherwise, I look forward to your response.

Sincerely,

Marjorie C. Holladay
Chief Attorney

cc: Mr. Edward A. Tellechea, Chief Assistant Attorney General
Mr. David Flynn, Assistant Attorney General

MCH:DF WORD/MARJORIE/64B16_26.351LS103018_165226

Board Counsel Suggested Language to Simplify Board Approved Academic/Educational PTTPs.
December 2018

64B16-26.351 Standards for Approval of Registered Pharmacy Technician Training Programs.
Pursuant to Section 465.014, F.S., in order to be registered as a pharmacy technician in Florida, an applicant must have completed a pharmacy technician training program approved by the Board. The standards for approval of a registered pharmacy technician training program are as follows.

(1) Preapproved pharmacy technician training programs. The standard for approval of Registered Pharmacy Technician Training programs provided or offered by accredited institutions or entities is whether the program or institution is, as of December 1, 2018,

(a) accredited by a regional and national accrediting agency; a regional or national institutional accrediting agency; or a specialized accrediting agency recognized by the Secretary of the United States Department of Education;

(b) accredited by an accrediting agency whose accreditation establishes eligibility to participate in the Title IV student financial assistance program administered by United States Department of Education; or

~~one of the following organizations:~~

~~Pharmacy technician training programs accredited on or before June 1, 2018, by the Pharmacy Technician Accreditation Commission (PTAC);~~

~~(b) Pharmacy technician training programs accredited on or before June 1, 2018, by the Accreditation Council on Pharmacy Education (ACPE);~~

~~(c) Pharmacy technician training programs accredited on or before June 1, 2018, by the American Society of Health System Pharmacists (ASHP);~~

~~(d) Pharmacy technician training programs at institutions accredited on or before June 1, 2018, by the Southern Association of Colleges and Schools (SACS);~~

~~(e) Pharmacy technician training programs approved on or before June 1, 2018, by the Florida Commission for Independent Education (CIE);~~

~~(f) Pharmacy technician training programs at institutions accredited on or before June 1, 2018, by the Council on Occupational Education (COE);~~

~~(g) Pharmacy technician training programs at institutions accredited on or before June 1, 2018, by the Middle States Commission on Secondary Schools;~~

~~(h) Pharmacy technician training programs at institutions accredited on or before June 1, 2018, by the Middle States Commission on Higher Education;~~

~~(i) Pharmacy technician training programs at institutions accredited on or before June 1, 2018, by the New England Association of Schools and Colleges, Commission on Technical and Career Institutions;~~

~~(j) Pharmacy technician training programs at institutions accredited on or before June 1, 2018, by the Western Association of Schools and Colleges, Accrediting Commission for Community and Junior Colleges;~~

~~(k) Pharmacy technician training programs at institutions accredited on or before June 1, 2018, by the Northwest Commission on Colleges and Universities;~~

~~(l) Pharmacy technician training programs at institutions accredited on or before June 1, 2018, by the Distance Education Accrediting Commission;~~

~~(m) Pharmacy technician training programs at institutions accredited on or before June 1, 2018, by the Accrediting Council for Independent Colleges and Schools;~~

~~(n) Pharmacy technician training programs at institutions accredited on or before June 1, 2018, by the Accrediting Commission of Career Schools and Colleges.~~

(c)~~(o)~~ Pharmacy technician training programs within the public-school system of the State of Florida that comply with the Florida Department of Education Curriculum Framework for Pharmacy Technician, program number H170500; which is incorporated herein by reference and which can be obtained at http://www.fldoe.org/core/fileparse.php/18567/urlt/H170500-1819.rtf.

(2) - (6) No Change.

Rulemaking Authority 465.005, 465.014(4), (7) FS. Law Implemented 465.014(2), (4) FS. History–New 6-23-10, Amended 11-17-11, 6-19-17.

TAB #3

Language to allow issuance of a citation for violation of Pharmacist/Technician ratios.
December 2018

64B16-30.003 Citations.

(1) Pursuant to section 456.077, F.S., the Board sets forth in subsection (3) of this rule, those violations for which there is no substantial threat to the public health, safety and welfare. Next to each violation is the fine to be imposed.

(2) The following violations with accompanying fines may be disposed of by citation:

(a) Practicing pharmacy as an inactive licensee. (Section 465.015(2)(b), F.S.)	Fine based on length of time in practice while inactive; $200/month or $5,000 maximum (penalty will require licensee to renew license or cease practice).
(b) Operating a pharmacy with an inactive permit. (Section 465.015(1)(a), F.S.)	$500 per month to a maximum of $5000 (penalty will require permittee to renew permit or cease practice).
(c) First time failure to complete the required continuing education during the biennial licensure period. (Section 456.072(3)(a), F.S.	
Failure to complete less than 10 hours	$500
Failure to complete 10 or more hours	$1,000

In addition, licensees shall take two additional hours of continuing education for each of the continuing education deficiencies. Said hours shall not count for continuing education renewal requirements for the next biennium.

(d) Failure to timely pay a fine or costs imposed by a final order.	$500 per month late to a maximum of $5,000 (penalty will require permittee or licensee to also pay the original fine and/or costs).
(e) Failure to display any sign, license or permit required by statute or rule.	$500
(f) Failure to have any reference material required by statute or rule available.	$500
(g) Failure to notify the board of a change in a prescription department manager or consultant pharmacist. (Rule 64B16-27.450 or 64B16-28.501, F.A.C.)	Fine based on the length of time prior to notifying board. $200 a month to $5,000 maximum.
(h) Using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as authorized in section 465.019(6) or 465.025, F.S.; or dispensing a medication with dosage instructions different in any way than prescribed, provided that the medication was not used or ingested. (Section 465.016(1)(g), F.S.)	$250 fine, Completion of an approved CE course in the prevention of medication errors of no less than 8 hours.
(i) Tendering a check payable to the Board of Pharmacy or to the Department of Health that is dishonored by the Institution upon which it is drawn.	$100 fine plus payment of the check within 30 days.
(j) Failing to comply with the Educational course requirements for Human immunodeficiency virus and Acquired immune deficiency syndrome (HIV/AIDS), or medical errors. (Section 465.033(1), F.S.)	$500
(k) Failure to correct Minor violation as listed in rule 64B16-30.002, F.A.C.	$250
(l) First time failure to report controlled substance dispensing information	$100

to the Prescription Drug Monitoring Program Controlled Substance Dispensing Information Electronic System. (Section 893.055(3)(a), F.S.)	
(m) First time (initial) failure to consult the Prescription Drug Monitoring Program Controlled Substance Dispensing Information Electronic System prior to dispensing a controlled substance. (Section 893.055(8), F.S.)	$100
(n) Failure to request photo of other verification of identity prior to dispensing a controlled substance to a person not known. (Section 465.0155(2), F.S.)	$100
(o) Failure to inform customers of less expensive drug when cost sharing obligation to customer exceeds retail price. (Section 465.0244(2), F.S.)	$100
(p) Failure to comply with pharmacist to registered pharmacist technician ratio for activities not involving sterile compounding; no injury to patient/customer. (Rule 64B16-27.410(5) or (6), F.A.C.)	$ xxx

(3) Once the citation becomes a final order, the citation and complaint become a public record pursuant to chapter 119, F.S., unless otherwise exempt from the provisions thereof. The citation and complaint may be considered as aggravating circumstances in future disciplinary actions pursuant to paragraph 64B16-30.001(3)(a), F.A.C.

(4) The procedures described herein apply only for an initial offense of the alleged violation. Subsequent violation(s) of the same rule or statute shall require the procedures of section 456.073, F.S., to be applied. In addition, should an initial offense for which a citation could be issued occur in conjunction with violations not described herein, then the procedures of section 456.073, F.S., shall apply.

Rulemaking Authority 456.073, 456.077, 465.005 FS. Law Implemented 456.077 FS. History–New 12-22-91, Formerly 21S-30.003, 61F10-30.003, 59X-30.003, Amended 4-3-00, 1-2-02, 8-26-02, 1-12-03, 2-1-12, 9-27-18,_____.

TAB #4

AMENDMENTS REGARDING OUTDATED/EXPIRED ITEMS
DECEMBER 2018

64B16-28.110 Outdated Pharmaceuticals.

Under no circumstances may prescription drugs, pharmaceuticals or devices which bear upon the container an expiration date which has been reached be sold or dispensed to the public. Accordingly, pharmacies ~~Persons qualified to do so~~ shall examine the stock of the prescription department ~~of each pharmacy at a minimum interval of four months,~~ and shall remove all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs and pharmaceuticals, ~~or pharmaceuticals which bear upon the container an expiration date which date has been reached. and under no circumstances will pharmaceuticals or devices which bear upon the container an expiration date which has been reached be sold or dispensed to the public.~~

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.023(1)(c), 499.006(9), 499.0121(5), 465.022 FS. History–New 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.17, 21S-1.017, 21S-28.110, 61F10-28.110, 59X-28.110.

64B16-30.003 Citations.

(1) Pursuant to section 456.077, F.S., the Board sets forth in subsection (2) of this rule, those violations for which there is no substantial threat to the public health, safety and welfare. Next to each violation is the fine to be imposed.

(2) The following violations with accompanying fines may be disposed of by citation:

(a) Practicing pharmacy as an inactive licensee. (Section 465.015(2)(b), F.S.)	Fine based on length of time in practice while inactive; $200/month or $5,000 maximum (penalty will require licensee to renew license or cease practice).
(b) Operating a pharmacy with an inactive permit. (Section 465.015(1)(a), F.S.)	$500 per month to a maximum of $5000 (penalty will require permittee to renew permit or cease practice).
(c) First time failure to complete the required continuing education during the biennial licensure period. (Section 456.072(3)(a), F.S.	
Failure to complete less than 10 hours	$500
Failure to complete 10 or more hours	$1,000

In addition, licensees shall take two additional hours of continuing education for each of the continuing education deficiencies. Said hours shall not count for continuing education renewal requirements for the next biennium.

(d) Failure to timely pay a fine or costs imposed by a final order.	$500 per month late to a maximum of $5,000 (penalty will require permittee or licensee to also pay the original fine and/or costs).
(e) Failure to display any sign, license or permit required by statute or rule.	$500
(f) Failure to have any reference material required by statute or rule available.	$500
(g) Failure to notify the board of a change in a prescription department manager or consultant pharmacist.	Fine based on the length of time prior to notifying board. $200 a month to

(Rule 64B16-27.450 or 64B16-28.501, F.A.C.)	$5,000 maximum.
(h) Using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as authorized in section 465.019(6) or 465.025, F.S.; or dispensing a medication with dosage instructions different in any way than prescribed, provided that the medication was not used or ingested. (Section 465.016(1)(g), F.S.)	$250 fine, Completion of an approved CE course in the prevention of medication errors of no less than 8 hours.
(i) Tendering a check payable to the Board of Pharmacy or to the Department of Health that is dishonored by the Institution upon which it is drawn.	$100 fine plus payment of the check within 30 days.
(j) Failing to comply with the Educational course requirements for Human immunodeficiency virus and Acquired immune deficiency syndrome (HIV/AIDS), or medical errors. (Section 465.033(1), F.S.)	$500
(k) Failure to correct Minor violation as listed in rule 64B16-30.002, F.A.C.	$250
(l) First time failure to report controlled substance dispensing information to the Prescription Drug Monitoring Program Controlled Substance Dispensing Information Electronic System. (Section 893.055(3)(a), F.S.)	$100
(m) First time (initial) failure to consult the Prescription Drug Monitoring Program Controlled Substance Dispensing Information Electronic System prior to dispensing a controlled substance. (Section 893.055(8), F.S.)	$100
(n) Failure to request photo of other verification of identity prior to dispensing a controlled substance to a person not known. (Section 465.0155(2), F.S.)	$100
(o) Failure to inform customers of less expensive drug when cost sharing obligation to customer exceeds retail price. (Section 465.0244(2), F.S.)	$100
(p) Failure to maintain a physically separate and apart quarantine section for outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs. (Section 499.0121(5)(a)1., F.S.)	_____
(q) Failure to remove from active stock and properly quarantine outdated prescription drugs. (Section 499.006(9) through 499.005(2), F.S.) (Section 499.0121(5)(a)2.) (Rule 64B16-28.110, F.A.C.)	_____

(3) Once the citation becomes a final order, the citation and complaint become a public record pursuant to

chapter 119, F.S., unless otherwise exempt from the provisions thereof. The citation and complaint may be considered as aggravating circumstances in future disciplinary actions pursuant to paragraph 64B16-30.001(3)(a), F.A.C.

(4) The procedures described herein apply only for an initial offense of the alleged violation. Subsequent violation(s) of the same rule or statute shall require the procedures of section 456.073, F.S., to be applied. In addition, should an initial offense for which a citation could be issued occur in conjunction with violations not described herein, then the procedures of section 456.073, F.S., shall apply.

Rulemaking Authority 456.073, 456.077, 465.005 FS. Law Implemented 456.077 FS. History–New 12-22-91, Formerly 21S-30.003, 61F10-30.003, 59X-30.003, Amended 4-3-00, 1-2-02, 8-26-02, 1-12-03, 2-1-12, 9-27-18.

TAB #5

64B16-27.410 Registered Pharmacy Technician to Pharmacist Ratio.

(1) General Conditions. When the pharmacist delegates tasks to a registered pharmacy technician, such delegation must enhance the ability of the pharmacist to practice pharmacy to serve the patient population. A pharmacist shall not supervise more than one (1) registered pharmacy technician nor shall a pharmacy allow a supervision ratio of more than one (1) registered pharmacy technician to one (1) pharmacist (1:1), unless specifically authorized to do so pursuant to the provisions of this rule.

(2) Required Documentation. Regardless of the technician ratio, every pharmacy, pharmacist, Prescription Department Manager (PDM) and Consultant Pharmacist (CP) that employs or utilizes registered pharmacy technicians must comply with the following conditions:

(a) Establish and maintain a written Policy and Procedures Manual regarding the number of registered pharmacy technician positions and their utilization that includes the specific scope of delegable tasks of the technicians, job descriptions, and task protocols. The Policy and Procedures Manual or Manuals must include policies and the procedures for implementing the policies for each category enumerated below:

1. Supervision by a pharmacist,
2. Minimum qualifications of the registered pharmacy technician as established by statute and rule,
3. In-service education or on-going training and demonstration of competency specific to the practice site and job function,
4. General duties and responsibilities of the registered pharmacy technicians,
5. All functions related to prescription processing,
6. All functions related to prescription legend drug and controlled substance ordering and inventory control, including procedures for documentation and recordkeeping,
7. All functions related to retrieval of prescription files, patient files, patient profile information and other records pertaining to the practice of pharmacy,
8. All delegable tasks and non-delegable tasks as enumerated in rule 64B16-27.420, F.A.C.,
9. Confidentially and privacy laws and rules,
10. Prescription refill and renewal authorization,
11. Registered pharmacy technician functions related to automated pharmacy systems; and,
12. Continuous Quality Improvement Program.

(b) Establish and maintain documentation that is signed by the registered pharmacy technician acknowledging the technician has reviewed the Policy and Procedures Manual(s). Compliance with this paragraph must be achieved by April 7, 2015, or within ninety (90) days from the date the registered pharmacy technician is hired.

(c) Establish and maintain documentation that demonstrates the registered pharmacy technician has received training in the established job description, delegable tasks, task protocols, and policy and procedures in the specific pharmacy setting where the delegable tasks will be performed. Documentation shall consist of one of the following items:

1. Certification by the supervising licensee,
2. Certification by an instructor, trainer, or other similar person,
3. Training attendance logs or completion certificates, accompanied by an outline of the materials addressed, or
4. Exam or written questionnaires.

(3) The Policy and Procedures Manual(s) required by paragraph (2)(a), must be maintained onsite where the pharmacy technician will perform the delegable tasks and must be available during a Department inspection or at the request of the Board of Pharmacy. However, any and all documentation required by paragraphs (2)(b) and (c), must be maintained and must be provided to the Board of Pharmacy or a Department inspector within 72 hours of a request.

(4) Three to One (3:1) Ratio: Any pharmacy or any pharmacist engaged in sterile compounding shall not exceed a ratio of up to three (3) registered pharmacy technicians to one (1) pharmacist (3:1).

(5) Six to One (6:1) Ratio: Any pharmacy or any pharmacist may allow a supervision ratio of up to six (6) registered pharmacy technicians to one (1) pharmacist (6:1), as long as the pharmacist or pharmacy is not engaged in sterile compounding.

(6) Eight to One (8:1) Ratio:

(a) Non-dispensing pharmacies. Any pharmacy which does not dispense medicinal drugs, and the pharmacist(s) employed by such pharmacy, may allow a supervision ratio of up to eight (8) registered pharmacy technicians to one (1) pharmacist (8:1), as long as the pharmacy or pharmacist is not engaged in sterile compounding.

(b) Dispensing pharmacies. A pharmacy which dispenses medicinal drugs may utilize an eight to one (8:1) ratio in any

physically separate area of the pharmacy from which medicinal drugs are not dispensed. A “physically separate area” is a part of the pharmacy which is separated by a permanent wall or other barrier which restricts access between the two areas.

(7) The determination of the appropriate pharmacist-technician supervision ratio shall be made by the Prescription Department Manager or Consultant Pharmacist of Record. No other person, permittee, or licensee shall interfere with the exercise of the Prescription Department Manager or Consultant Pharmacist of Record’s independent professional judgment in setting the pharmacist to technician ratio(s).

Rulemaking Authority 465.005, 456.069(1), 465.014, 465.017, 465.022 FS. Law Implemented 465.014, 465.022 FS. History–New 2-14-77, Amended 3-31-81, Formerly 21S-4.02, Amended 8-31-87, Formerly 21S-4.002, Amended 9-9-92, Formerly 21S-27.410, 61F10-27.410, Amended 1-30-96, Formerly 59X-27.410, Amended 2-23-98, 10-15-01, 1-1-10, 1-7-15, 7-6-15, 5-8-18.

TAB #6

64B16-26.400 Pharmacy Interns; Registration; Employment.

(1) A pharmacy intern is required to be registered with the Department of Health as an intern before being employed as an intern in a pharmacy in Florida.

(2) An applicant for pharmacy intern registration must submit proof of:

(a) Enrollment in an intern program at an accredited college or school of pharmacy, or

(b) Graduation from an accredited college or school of pharmacy and not yet licensed in the state. For purposes of this rule only, any individual who has been accepted by the Foreign Pharmacy Graduate Examination Commission to sit for the Foreign Pharmacy Graduate Equivalency Examination shall be considered a graduate of an accredited college or school of pharmacy. The internship experience allowed under this provision shall not count toward the 500-hours internship required subsequent to passage of the Foreign Pharmacy Graduate Equivalency Examination as mandated in Section 465.007(1)(b)2., F.S., and as defined in Rule 64B16-26.203, F.A.C.

(3) Upon the receipt of proof satisfactory to the Board that the intern applicant meets the requirements of either paragraph (a) or (b), of subsection (2), and unless there exists good cause for the Board's refusal to certify an applicant as set forth in Section 465.013, F.S., the Board shall certify the applicant to the Department for registration as an intern.

(4) No intern shall perform any acts relating to the filling, compounding, or dispensing of medicinal drugs unless it is done under the direct and immediate personal supervision of a person actively licensed to practice pharmacy in this state.

Rulemaking Authority 465.005 FS. Law Implemented 465.013 FS. History–Amended 8-20-63, 5-19-72, 8-18-73, Repromulgated 12-18-74, Amended 11-10-80, 4-30-85, Formerly 21S-1.21, Amended 10-20-88, Formerly 21S-1.021, Amended 7-31-91, 1-10-93, Formerly 21S-26.400, 61F10-26.400, 59X-26.400, Amended 3-10-05.

TAB #7

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 Vol. 44/131	7/26/2018 Vol. 44/145	N/A
		64B16-30.003, F.A.C. (Citations)	Yes	7/6/2018 Vol. 44/131	7/26/2018 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 Vol. 44/131	7/26/2018 Vol. 44/145	N/A
		64B16-30.003, F.A.C. (Citations)	No	7/6/2018 Vol. 44/131	7/26/2018 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 Vol. 44/131	7/26/2018 Vol. 44/145	N/A
		64B16-28.502, F.A.C. (Class I, Class II, Class III Institutional Permit ...)	Yes	7/6/2018 Vol. 44/131	7/26/2018 Vol. 44/145	N/A
		64B16-28.602, F.A.C. (Institutional Class II or Class III Dispensing)	Yes	7/6/2018 Vol. 44/131	7/26/2018 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 Vol. 44/131	7/26/2018 Vol. 44/145	N/A
		64B16-28.603, F.A.C. (Class II and Class III Institutional Pharmacy Operating Hours)	Yes	7/6/2018 Vol. 44/131	7/26/2018 Vol. 44/145	N/A

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

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

64B16-27.1001, F.A.C. (Practice of Pharmacy)	§§465.003; 465.014; 465.026, F.S.	Clarify and Simply
64B16-27.104, F.A.C. (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. (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. (Prescription Refills)	§465.022, F.S.	Clarify and Increase Efficiency
64B16-27.220, F.A.C. (Medicinal Drugs Which May be Ordered by Pharmacists)	§465.186, F.S.	Clarify and Reduce Regulatory Costs
64B16-27.4001, F.A.C. (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. (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. (Pharmacy Technician – Delegable and Non-Delegable Tasks)	§465.014, F.S.	Clarify, Increase Efficiency, and Reduce Regulatory Costs

64B16-27.797, F.A.C. (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. (Standards of Practice – Drug Therapy Management)	§§465.003; 465.0155, F.S.	Clarify and Reduce Regulatory Costs
64B16-27.831, F.A.C. (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. (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. (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. (Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances)	§§456.072(2); 456.079(1); 465.016; 465.023, F.S.	Clarify

64B16-30.002, F.A.C. (Minor Violations)	§456.073(3), F.S.	Increase Efficiency and Reduce Regulatory Costs
64B16-30.003, F.A.C. (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

Electronic Signature
Jeenu Philip, BPharm

Chair of the Board of Pharmacy

September 04, 2018
Date Signed

/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