



AGENDA

Florida Board of Pharmacy Rules Committee Meeting October 1, 2018 – 2:00 p.m. October 2, 2018 – 9:00 a.m.

*Embassy Suites Ft. Lauderdale
1100 SE 17th Street
Ft. Lauderdale, FL 33316
954-315-1326*

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
Shay Marcelus, JD - Prog. Operations Administrator

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. **Rules Workshop: Automation**
3. **Discussion: Rule 64B16-26.351, F.A.C. - Standards for Approval of Registered Pharmacy Technician Training Programs**
 - JAPC Letter
 - Comments to Proposed Rule Changes
 - Discussion on Further Rule Amendments
 - Laws and Rules Coursework
 - Approval of programs whose graduates are eligible for registration/certification in other states/territories
4. **Discussion: Rule 64B16-30.001, F.A.C. - Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances**
 - JAPC Letter and draft response
 - Proposed language
5. **Discussion: Rule 64B16-27.410, F.A.C. - Registered Pharmacy Technician to Pharmacist Ratio**

6. **Discussion: Rule 64B16-28.110, F.A.C.** - Outdated Pharmaceuticals
7. **Discussion: Rule 64B16-30.003, F.A.C.** - Citations
8. **Discussion: 64B16-26.400, F.A.C.** - Pharmacy Interns; Registration; Employment
9. **Old Business / New Business**
10. **Public Comment**
11. **Adjourn**



TAB #2

DISCUSSION ITEM FOR NEW RULES REGARDING PATIENT ACCESSED AUTOMATIC
PHARMACY SYSTEMS (NON-DISPENSING) AND AUTOMATED PATIENT ACCESSED
COMMUNITY PHARMACIES

AUGUST 2018

Pursuant to the statutes identified below, the Board may want to consider adopting rules to allow for expanded use of two (2) classes of automated devices.

1. Rules regarding the use of devices which perform the sales/delivery of medicinal drugs, but do not provide “storage” or “dispensing” of medicinal drugs and thus do not require a permit.
2. Rules to implement a subset of community pharmacy permitted entities - fully automated, direct patient accessed, community pharmacies. These pharmacies would be under common ownership with a permitted “full” community pharmacy, which would provide centralized prescription filling for the automated pharmacy, including consulting, drug utilization, and claims adjudication type activities. The rules would have to specify exemptions from the normal space and equipment requirements for community pharmacies and enumerate how the “prescription department” would be open through technological means that do not require the physical presence of a pharmacist.

465.003 Definitions. As used in this chapter, the term:

(6) “Dispense” means the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent. As an element of dispensing, the pharmacist shall, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist shall also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary. **The actual sales transaction and delivery of such drug shall not be considered dispensing.** The administration shall not be considered dispensing.

(11)(a) “Pharmacy” includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, and an Internet pharmacy.

1. The term “community pharmacy” includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.

2. The term “institutional pharmacy” includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as “health care institutions,” where medicinal drugs are compounded, dispensed, stored, or sold.

3. The term “nuclear pharmacy” includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term “nuclear pharmacy” does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.

4. The term “special pharmacy” includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.

5. The term “Internet pharmacy” includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to

dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of pharmacy as defined in subsection (13).

(b) The pharmacy department of any permittee shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. The term “not present and on duty” shall not be construed to prevent a pharmacist from exiting the prescription department for the purposes of consulting or responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist’s responsibility to provide pharmacy services.

(16) “Centralized prescription filling” means the filling of a prescription by one pharmacy upon request by another pharmacy to fill or refill the prescription. The term includes the performance by one pharmacy for another pharmacy of other pharmacy duties such as drug utilization review, therapeutic drug utilization review, claims adjudication, and the obtaining of refill authorizations.

(17) “Automated pharmacy system” means a mechanical system that delivers prescription drugs received from a Florida licensed pharmacy and maintains related transaction information.

465.0265 Centralized prescription filling. —

(1) A pharmacy licensed under this chapter may perform centralized prescription filling for another pharmacy, provided that the pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which the pharmacies will comply with federal and state laws, rules, and regulations.

(2) Each pharmacy performing or contracting for the performance of centralized prescription filling pursuant to this section must maintain a policy and procedures manual, which shall be made available to the board or its agent upon request. The policy and procedures manual shall include the following information:

(a) A description of how each pharmacy will comply with federal and state laws, rules, and regulations.

(b) The procedure for maintaining appropriate records to identify the pharmacist responsible for dispensing the prescription and counseling the patient.

(c) The procedure for tracking the prescription during each stage of the filling and dispensing process.

(d) The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription.

(e) The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information.

(f) The procedure to be used by the pharmacy in implementing and operating a quality assurance program designed to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care.

(3) The filling, delivery, and return of a prescription by one pharmacy for another pursuant to this section shall not be construed as the filling of a transferred prescription as described in s. 465.026 or as a wholesale distribution as defined in s. 499.003.

(4) The board shall adopt rules pursuant to ss. 120.536(1) and 120.54 necessary to implement this section.

History.—s. 2, ch. 2002-182; s. 40, ch. 2008-207; s. 38, ch. 2010-161; s. 34, ch. 2014-89.



TAB #3

JOE NEGRON
President



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

RICHARD CORCORAN
Speaker



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www.japc.state.fl.us
joint.admin.procedures@leg.state.fl.us

THE FLORIDA LEGISLATURE
**JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE**

August 27, 2018

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

RECEIVED

AUG 28 2018

ADMINISTRATIVE LAW

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

Dear Mr. Flynn:

I have reviewed proposed rule 64B16-26.351, "Standards for Approval of Registered Pharmacy Technician Training Programs," which was advertised in the Florida Administrative Register on August 9, 2018. I have the following comment.

64B16-26.351(6): Form DH-MQA 1239, Application for Registered Pharmacy Technician Training Programs, dated 6/18:
Page 1, Number 13: There is a discrepancy between the wording of the standard for approval of pharmacy technician training programs provided by a branch of the federal armed services in subsection (2) and the wording of this item in the application. Subsection (2) of the rule text states that the standard is, "whether the curriculum of such course was developed on or before June 1, 2018," whereas number 13 on this page states that such programs have to be provided by a branch of the federal armed services on or before June 1, 2018. It appears the wording of these provisions should be identical.

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

Sincerely,

A handwritten signature in blue ink that reads "Marjorie C. Holladay".
Marjorie C. Holladay
Chief Attorney

cc: Mr. Edward A. Tellechea, Chief Assistant Attorney General
Mr. Lawrence Harris, Assistant Attorney General

NOTICE OF PROPOSED RULE

DEPARTMENT OF HEALTH
BOARD OF PHARMACY

RULE TITLE:

RULE NO.:

Standards for Approval of Registered Pharmacy Technician Training Programs. 64B16-26.351

PURPOSE AND EFFECT: The Board proposes the rule amendment to update the approval date for accredited Registered Pharmacy Technician Training Programs and to update language regarding training programs.

SUMMARY: The approval date for accredited Registered Pharmacy Technician Training Programs will be updated and language will be updated regarding training programs.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST AND LEGISLATIVE

RATIFICATION: The agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the agency. The agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time. Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

RULEMAKING AUTHORITY: 465.005, 465.014(4), (7) FS.

LAW IMPLEMENTED: 465.014(2), (4) FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: C. Erica White, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254.

THE TEXT OF THE PROPOSED RULE IS:

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 accredited by one of the following organizations:

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

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

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

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

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

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

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

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

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

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

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

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

(2) Federal Armed Services programs. The standard for approval of pharmacy technician training programs provided by a branch of the federal armed services shall be whether the curriculum of such course was developed on or before ~~June~~ April 1, 2018.

(3) Other non-employer based programs. The standard for approval of all programs offered or accredited by an entity not listed in subsection (1) or (2), and which are not employer based programs, is whether the program:

(a) through (b) No change.

(c) Applies directly to the Board of Pharmacy on approved form DH-MQA 1239 "Application for Registered Pharmacy Technician Training Programs," 04/17, ~~which is hereby incorporated by reference. Applications may be obtained from <https://www.flrules.org/Gateway/reference.asp?No=Ref 08275>, or the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399 3254, or (850)488-0595, or the board's website at <http://floridaspharmacy.gov/Applications/app-reg-pharm-tech-prog.pdf>.~~ All applications must include the following information:

1. through 3. No change.

(d) through (e) No change.

(4) Employer sponsored training programs. All other pharmacy technician training programs not identified in subsections (1) – (3) must be employer sponsored based. Any pharmacy technician training program sponsored by a Florida permitted pharmacy, or affiliated group of pharmacies under common ownership and, must contain a minimum of one hundred sixty (160) hours of training, which that extends over a period not to exceed six (6) months; is provided solely to employees of said pharmacy or affiliated group; and has been approved by the Board. An application for approval of a Registered Pharmacy Technician Training Program shall be made on Board of Pharmacy approved form DH MQA 1239 "Application for Registered Pharmacy Technician Training Programs" 04/17. The applicant must attach to the application a copy of the curriculum or other course description. All employer based programs must:

(a) No change.

(b) Be provided solely to employees of the permitted pharmacy or affiliated group;

(c) Contain a minimum of one hundred sixty (160) hours of training, which shall not exceed six (6) months. Employer sponsored pharmacy technician training programs may request the program length exceed six (6) months in length under the following circumstances:

1. For programs containing a minimum of one hundred eighty (180) hours, the program length shall not exceed nine (9) months;

2. For programs containing a minimum of two hundred (200) hours, the program length shall not exceed twelve (12) months.

3. In no event shall the total length of the training program exceed twelve (12) months.

For programs of any length, the Program Director may extend participation in the program for an individual employee. In no event shall an employee's training be extended more than six (6) months beyond the program's length.

(d) ~~(b)~~ through (e) ~~(e)~~ No change.

(f) ~~(d)~~ Designate a ~~person~~ Program Director to assume responsibility for registered pharmacy technician training program. If the contact person is not a licensed pharmacist or registered pharmacy technician, provision shall be made for insuring licensed pharmacist or registered pharmacy technician input in overall program planning and evaluation.

(g) ~~(e)~~ through (j) ~~(h)~~ No change.

(k) Apply directly to the Board of Pharmacy on approved form DH-MQA 1239 "Application for Registered Pharmacy Technician Training Programs."

(5) Reenrollment in employer-sponsored training programs. Any student who failed to complete an employer sponsored training program within the time periods established in paragraph (4)(c) must be terminated from the program. After termination, the Program Director may allow a student to reenroll in the program, at the Program Director's discretion and pursuant to the program's written policies and procedures. Reenrolled students must complete the entire program, including all required program hours, and no coursework or hours previously completed may be carried forward into the subsequent enrollment.

(6) All applications for approval of a Registered Pharmacy Technician Training Program shall be made on approved form DH-MQA 1239 "Application for Registered Pharmacy Technician Training Programs," 06/18, which is hereby incorporated by reference. Applications may be obtained from <https://www.flrules.org/Gateway/reference.asp?No=Ref->, or the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254, (850)488-0595, or the board's website at <http://floridaspharmacy.gov/Applications/app-reg-pharm-tech-prog.pdf>, and must include the items required by subsections (3) or (4), above.

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, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Board of Pharmacy

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: June 12, 2018

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR:

White, Erica

From: Cynthia Henderson <cyhenderson@me.com>
Sent: Thursday, September 6, 2018 2:51 PM
To: White, Erica
Cc: Runk, Paul
Subject: Comments to the Proposed Rule Changes to FAC 64B16-26.351
Attachments: Proposed changes to Pharmacy Tech Rule.pages

Erica:

Thank you for your consideration of this request. On behalf of our client, Ascend Learning, we are submitting language to consider for the proposed rule, version date 08/09/2018, attached below.

As you may be aware, there has been a movement towards expanding the responsibilities and duties of pharmacy technicians, including registered pharmacy technicians. The education they receive is an important part of their training to ensure the public is adequately protected. We have seen legislation increasing the number of pharmacy technicians under supervision of a pharmacist, and last session was a push for remote pharmacies with only online supervision. We strongly support the availability of registered and certified pharmacy technicians in Florida. As I understand the training, once a registered pharmacist completes its course work, they are available to advance to a certified pharmacy technician with an examination and approval. This is a great pathway and manner for which the Department can be assured the training was understood and comprehended in practice. As there is an expansion of scope for technicians, we are hopeful the Board would consider specifically creating a pathway for certification in order to ensure protection of the public.

We have included language highlighted in yellow that expands the approved training. Additionally, there is language that would provide a pathway for certification.

Please let me know if there is a good time to schedule a call with you to discuss this further.

Thank you so much for your consideration and time.

Cynthia Henderson
(850) 559-0855

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**DIVISION OF MEDICAL QUALITY ASSURANCE
FLORIDA BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4292**



Board of Pharmacy

**Application for Registered Pharmacy Technician Training
Programs**

June 2018

**Please submit the following to the Florida Board of Pharmacy:
P.O. Box 6320, Tallahassee, FL 32314-6320**

Please note: Pursuant to the provisions set forth in Rule 64B16-26.351, FAC, the following programs are approved Registered Pharmacy Technician Training Programs and do not require application to the Board of Pharmacy:

1. Pharmacy technician training programs accredited on or before April 1, 2018, by the American Society of Health-System Pharmacists (ASHP).
2. Pharmacy technician training programs at institutions accredited on or before April 1, 2018, by the Southern Association of Colleges and Schools (SACS).
3. Pharmacy technician training programs accredited on or before April 1, 2018, by the Florida Commission for Independent Education (CIE).
4. Pharmacy technician training programs accredited on or before April 1, 2018, by the Pharmacy Technician Accreditation Commission (PTAC).
5. Pharmacy technician training programs accredited on or before April 1, 2018, by the Accreditation Council on Pharmacy Education (ACPE).
6. Pharmacy technician training programs at institutions accredited on or before April 1, 2018, by the Middle States Commission on Secondary Schools.
7. Pharmacy technician training programs at institutions accredited on or before April 1, 2018, by the New England Association of Schools and Colleges, Commission on Technical and Career Institutions.
8. Pharmacy technician training programs at institutions accredited on or before April 1, 2018, by the Western Association of Schools and Colleges, Accrediting Commission for Community and Junior Colleges.
9. Pharmacy technician training programs at institutions accredited on or before April 1, 2018, by the Northwest Commission on Colleges and Universities.
10. Pharmacy technician training programs at institutions accredited on or before April 1, 2018, by the Distance Education Accrediting Commission.
11. Pharmacy technician training programs at institutions accredited on or before April 1, 2018, by the Accrediting Council for Independent Colleges and Schools.
12. Pharmacy technician training programs at institutions accredited on or before April 1, 2018, by the Accrediting Commission of Career Schools and Colleges.
13. Pharmacy technician training programs provided by a branch of the federal armed services using a curriculum developed on or before April 1, 2018.
14. Pharmacy technician training programs at institutions accredited on or before April 1, 2018, by the Council on Occupational Education (COE).

15. Pharmacy technician training programs at institutions accredited on or before April 1, 2018, by the Middle States Commission on Higher Education;

Application Processing

Please read all application instructions before completing your application.

Within 7-14 days of receipt of your application, the board office will notify you of the receipt of your application, any required documents, and your status. All sections must be completed in full. Failure to submit a complete application will result in a delay of processing. If you provide false information, the board may deny your application for registration.

APPLICATION CHECKLIST

Keep a copy of the completed application for your records.

It is recommended that you use the following checklist to help ensure that your application is complete. Failure to submit required documentation to the Board will result in an incomplete application. Faxed applications will not be accepted.

Non-Employer Based Programs (Complete questions 1-6 and Section I)

- _____ Evidence of licensure by the Florida Commission for Independent Education or equivalent licensing authority of another state or jurisdiction or be within the public school system of the State of Florida
- _____ Sample Transcript and Sample Diploma
- _____ Copy of curriculum, catalog or other course descriptions
- _____ Copy of Faculty Credentials (job description, resume or curriculum vitae)

Employer Based Programs (Complete questions 1-6 and Section II)

- _____ Copy of Faculty Credentials (job description, resume or curriculum vitae)
- _____ Copy of curriculum, catalog or other course descriptions
- _____ Sample evaluation to be filled out by participants at completion of program



APPLICATION FOR REGISTERED PHARMACY TECHNICIAN TRAINING PROGRAMS

Check the application types you are applying:			
() Non-Employer Based Registered Pharmacy Technician Training Program Complete questions 1-6 and Section I.			
() Employer Based Registered Pharmacy Technician Training Program Complete questions 1-6 and Section II.			
1. List Full Corporate or Legal Name of Business Entity			
2. List the Name of the Owner or Program Director			
3. List Mailing Address			
City	State	Zip Code	
4. List Site Address			Telephone Number
City	State	Zip Code	County
List E-Mail Address (Optional)*		List Fax Number (Optional)	
5. Who should the Board contact with questions regarding this application?			
Name (Last, First)			
Address			Telephone Number
City	State	Zip Code	
E-Mail Address (Optional)*		Fax Number (Optional)	
6. List the name and title of the administrative authority/authorities of the training program.			
Name (Last, First)		Position/Title	

* By providing an email address you agree to allow the board office to contact you with information regarding your application via e-mail. Under Florida law, e-mail addresses are public records. If you do not want your e mail address released in response to a public records request, do not send electronic mail to this entity. Instead, contact this office by phone or in writing.

SECTION I: NON-EMPLOYER BASED TRAINING PROGRAMS	
7. Please attach evidence of licensure by the Florida Commission for Independent Education, equivalent licensing authority of another state or jurisdiction or that you are within the public school system of the State of Florida and the sample transcript and sample diploma.	
8. Please attach a copy of program curriculum, catalog or other course descriptions. Indicate what percentage (%) of the following subject matter is included in the training program:	
<input type="checkbox"/> Introduction to pharmacy and health care systems <input type="checkbox"/> Pharmacy law <input type="checkbox"/> Pharmaceutical-medical terminology, abbreviations, and symbols	<input type="checkbox"/> Records management and inventory control <input type="checkbox"/> Interpersonal relations, communications, and ethics <input type="checkbox"/> Pharmaceutical calculations <input type="checkbox"/> Other
9. List names of faculty that will be utilized for each educational activity of the training program. Provide evidence of academic preparation or experience in the subject matter (Attach copy of job description, resume or curriculum vitae). Use additional sheets if needed.	
Name (Last, First)	Position/Title
10. Has a licensed pharmacist or registered pharmacy technician with expertise in pharmacy technician practice been involved in the planning and instruction of this training program?	
Yes _____ No _____	If yes, please indicate the individual name(s) and license number(s): _____ _____ _____

Please Note: The following section is to be completed by Employer Based Training Programs Only

SECTION II: EMPLOYER BASED TRAINING PROGRAMS	
11. Please attach a copy of program curriculum, catalog or other course descriptions. Indicate what percentage (%) of the following subject matter is included in the training program:	
<input type="checkbox"/> Introduction to pharmacy and health care systems <input type="checkbox"/> Pharmacy law <input type="checkbox"/> Pharmaceutical-medical terminology, abbreviations, and symbols	<input type="checkbox"/> Records management and inventory control <input type="checkbox"/> Interpersonal relations, communications, and ethics <input type="checkbox"/> Pharmaceutical calculations <input type="checkbox"/> Other
12. Indicate the number of hours of training that is intended to be offered and length of training period.	
Number of hours of training _____	Length of training period _____
13. List names of faculty that will be utilized for each educational activity of the training program. Provide evidence of academic preparation or experience in the subject matter (Attach copy of job description, resume or curriculum vitae). Use additional sheets if needed.	
Name (Last, First)	Position/Title

14. Has a licensed pharmacist or registered pharmacy technician with expertise in pharmacy technician practice been involved in the planning and instruction of this training program?	
Yes _____ No _____	If yes, please indicate the individual name(s) and license number(s): _____ _____ _____
15. If the program offering includes clinical practice training in Florida, will a licensed pharmacist competent in the practice area provide supervision?	
Yes _____ No _____	If no, please explain.
16. For self-directed learning experience, please indicate the minimum number of questions to be utilized to evaluate the participant knowledge at the completion of the learning experience. Also indicate the minimum score allowed in order to receive the certificate of completion.	
Minimum number of evaluation questions _____ Minimum score allowed _____	
17. Describe the course materials that will be provided to each student.	
_____ _____ _____	
18. Are program participants given an opportunity to evaluate learning experiences, instructional methods, facilities and resources used for the offering?	
Yes _____ No _____	If yes, please provide a sample of this evaluation. If no, please explain.
19. Has the provider established written policies and procedures for implementation of this training program?	
Yes _____ No _____	If no, please explain.
20. Has the applicant established a maintenance system of record-keeping which provides for storage of program information?	
Yes _____ No _____	If no, please explain.
21. Are records of programs maintained for three years?	
Yes _____ No _____	If no, please explain.
22. Does the applicant provide a certificate of completion to each participant?	
Yes _____ No _____	If yes, provide a sample of certificate of completion. If no, please explain.
I understand that the information provided as part of this application is accurate, and that, if approved I agree to abide by the requirements established by the Board of Pharmacy in Rule 64B16-26.351, F.A.C., for all Board approved Registered Pharmacy Technician Training Programs.	
_____ Signature Owner/Director	_____ Date

FL 45605 2018**Citation:** FAC 64B16-26.351**Agency:** Department of Health/Board of Pharmacy**Version:** Proposed Rule**Version Date:** 08/09/2018

Notice of Proposed Rule

DEPARTMENT OF HEALTH**Board of Pharmacy**

RULE NO.: RULE TITLE:

64B16-26.351 Standards for Approval of Registered Pharmacy Technician Training Programs

PURPOSE AND EFFECT: The Board proposes the rule amendment to update the approval date for accredited Registered Pharmacy Technician Training Programs and to update language regarding training programs.

SUMMARY: The approval date for accredited Registered Pharmacy Technician Training Programs will be updated and language will be updated regarding training programs.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:

The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

RULEMAKING AUTHORITY: 465.005, 465.014(4), (7) FS.

LAW IMPLEMENTED: 465.014(2), (4) FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: C. Erica White, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254.

THE FULL TEXT OF THE PROPOSED RULE IS:

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 accredited by one of the following organizations:

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

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

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

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

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

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

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

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

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

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

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

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

(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

(2) Federal Armed Services programs. The standard for approval of pharmacy technician training programs provided by a branch of the federal armed services shall be whether the curriculum of such course was developed on or before ~~June~~April 1, 2018.

(3) Other non-employer based programs. The standard for approval of all programs offered or accredited by an entity not listed in subsection (1) or (2), and which are not employer based programs, is whether the program:

(a) ~~Meets the requirements of and is licensed by the Commission for Independent Education pursuant to chapter 1005, F.S., or the equivalent licensing authority of another state or jurisdiction or is within the public school system of the State of Florida;~~

(b) No change.

(c) Applies directly to the Board of Pharmacy on approved form DH-MQA 1239 "Application for Registered Pharmacy Technician Training Programs. ~~7~~" ~~04/17, which is hereby incorporated by reference. Applications may be obtained from https://www.flrules.org/Gateway/reference.asp?No=Ref-08275, or the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254, or (850)488-0595, or the board's website at https://floridaspharmacy.gov/Applications/app-reg-pharm-tech-prog.pdf.~~ All applications must include the following information:

1. through 3. No change.

(d) through (e) No change.

(4) Employer sponsored training programs. All other pharmacy technician training programs not identified in subsections (1) through (3) must be employer sponsored based. ~~Any pharmacy technician training program sponsored~~ by a Florida permitted pharmacy, or affiliated group of pharmacies under common ownership and, ~~must contain a minimum of one hundred sixty (160) hours of training, which that extends over a period not to exceed six (6) months; is provided solely to employees of said pharmacy or affiliated group; and has been approved by the Board. An application for approval of a Registered Pharmacy Technician Training Program shall be made on Board of Pharmacy approved form DH-MQA 1239 "Application for Registered Pharmacy Technician Training Programs" 04/17. The applicant must attach to the application a copy of the curriculum or other course description. All employer-based programs must:~~

(a) No change.

(b) Be provided solely to employees of the permitted pharmacy or affiliated group;

(c) Contain a minimum of one hundred sixty (160) hours of training, which shall not exceed six (6) months. Employer sponsored pharmacy technician training programs may request the program length exceed six (6) months in length under the following circumstances:

1. For programs containing a minimum of one hundred eighty (180) hours, the program length shall not exceed nine (9) months;

2. For programs containing a minimum of two hundred (200) hours, the program length shall not exceed twelve (12) months.

3. In no event shall the total length of the training program exceed twelve (12) months.

For programs of any length, the Program Director may extend participation in the program for an individual employee. In no event shall an employee's training be extended more than six (6) months beyond the program's length.

(b) through (c) re-designated (d) through (e) No change.

(f) ~~(d)~~ Designate a ~~person~~ Program Director to assume responsibility for registered pharmacy technician training program. If the contact person is not a licensed pharmacist or registered pharmacy technician, provision shall be made for insuring licensed pharmacist or registered pharmacy technician input in overall program planning and evaluation.

(e) through (h) re-designated (g) through (j) No change.

(k) Apply directly to the Board of Pharmacy on approved form DH-MQA 1239 "Application for Registered Pharmacy Technician Training Programs."

(5) Reenrollment in employer-sponsored training programs. Any student who failed to complete an employer sponsored training program within the time periods established in paragraph (4)(c) must be terminated from the program. After termination, the Program Director may allow a student to reenroll in the program, at the Program Director's discretion and pursuant to the program's written policies and procedures. Reenrolled students must complete the entire program, including all required program hours, and no coursework or hours previously completed may be carried forward into the subsequent enrollment.

(6) All applications for approval of a Registered Pharmacy Technician Training Program shall be made on approved form DH-MQA 1239 "Application for Registered Pharmacy Technician Training Programs," 06/18, which is hereby incorporated by reference. Applications may be obtained from <https://www.flrules.org/Gateway/reference.asp?No=Ref->, or the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254, (850)488-0595, or the board's website at <https://floridaspharmacy.gov/Applications/app-reg-pharm-tech-prog.pdf>, and must include the items required by subsections (3) or (4), above.

(7) All approved training programs must provide a pathway for students to obtain a national pharmacy technician certification from a program accredited by the National Commission for Certifying Agencies (the National Healthcareer Association's ExCPT and the Pharmacy Technician Certification Board's PTCE). Each approved training program shall require certification be obtained by each student who completes the training program in order to maintain training program approval.

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, .

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Pharmacy

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: June 12, 2018

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: July 23, 2018

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TAB #4



PAM BONDI
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Administrative Law Bureau

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

, 2018

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

Re: Department of Health, Board of Pharmacy
Rule 64B16-30.001, F.A.C.

Dear Ms. Holladay:

I am writing in response to your August 9, 2018, correspondence regarding the above referenced rule, wherein you make a number of comments, which I will address in turn, below.

30.001(2)(a)1. You ask for explanation how the penalty range for the first violation provides meaningful notice to the public regarding the proscribed conduct. Because it is typically very difficult to prove the intent necessary to charge fraud, the vast majority of licensees who submit applications with less than accurate information are charged with negligent misrepresentation. Because the factual circumstances vary greatly, the Board believes the range is meaningful. For example, an applicant who believed criminal records had been sealed or expunged, and therefore did not need to be disclosed, is very different from one who “forgot” being incarcerated several times, and the penalty range needs to be appropriately broad to encompass both scenarios.

30.001(2)(a)2 and (2)(b)2. The Board agrees with your comment and will change the penalty range to reflect the statutory requirement of a \$10,000 fine.

30.001(2)(d). You ask for explanation how the penalty range for the first violation provides meaningful notice to the public regarding the proscribed conduct. To protect public safety, the Board requires licensees in these situations to make contact with the Professionals Resource Network (PRN), be evaluated, and receive a recommendation from PRN that the licensee is again able to practice with reasonable skill and safety to the public. Because the public is placed directly at risk, suspension of the license until the determination of ability to practice safely is necessary. Because the time period it may take a licensee to receive a safe to practice recommendation is different for each individual, no time period can be specified. In addition, depending on the harm to patients or the public that the

licensee's conduct caused, or the degree of impairment, in some situations, revocation is the only option. Accordingly, the Board believes the penalty range is appropriate and meaningful.

30.001(2)(e)1.q. The Board agrees with your comment and will make this correction.

30.001(2)e.5. You ask for explanation how the penalty range for the first violation provides meaningful notice to the public regarding the proscribed conduct. Violations of the Federal Food, Drug, and Cosmetic act vary greatly, not just in the acts committed, but the number and nature of the violations, and the harm to the public. For example, a failure to properly label a product with the pharmacy's contact information is not comparable to a compounding pharmacy which knowingly releases contaminated product to the public, which causes patient harm. Because the factual circumstances will vary greatly, the Board believes the range is meaningful and needs to be appropriately broad to encompass possible scenarios.

30.001(2)(f). In the Notice of Proposed Rule, (2)(f), "Criminal conviction related to Pharmacy" cites sections 465.016(1)(f) and 465.023(1)(d) and does not cite 465.012(1)(d). If that section was cited, it would be a typographical error to be corrected.

30.001(2)(f)2. As with previous responses, "felony criminal convictions" encompasses a broad range of acts – for example, from inappropriate insurance claims to organized, large scale diversion of controlled substances. Because the factual circumstances will vary greatly, the Board believes the range is meaningful and needs to be appropriately broad to encompass all possible scenarios.

30.001(2)(k)1.c. The Board agrees with your comment, and will replace the citation to repealed Rule 64B16-27.101 with a citation to the statutory offense, section 499.005(8), F.S.

To effectuate the above corrections, the Board will publish a Notice of Change in an upcoming edition of the Florida Administrative Register. It is the Board's belief that after review of this written response and the forthcoming Notice of Change, you will determine the Board has completely responded to your comments, and will accordingly so certify, such that the rule can proceed to adoption. 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, require any further information, or wish to discuss.

Sincerely,

Lawrence D. Harris
Assistant Attorney General
Counsel to the Florida Board of Pharmacy

Ms. Marjorie C. Holladay
RE: Rule 64B16-30.001, F.A.C.
Page 3 of 3

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

DRAFT

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President



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THE FLORIDA LEGISLATURE
**JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE**

August 9, 2018

Mr. David Flynn
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 64B16-30.001**

Dear Mr. Flynn:

I have reviewed proposed rule 64B16-30.001, "Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances," which was advertised in the Florida Administrative Register on July 26, 2018. I have the following comments.

- 64B16-30.001(2)(a)1.:** Please explain how the penalty range for the First Violation provides a meaning notice to the public of likely penalties which may be imposed for proscribed conduct, as required by section 456.079(2).
- 64B16-30.001(2)(a)2.:** It appears that the penalty range for the First Violation and Second and Subsequent Violations should include a \$10,000 administrative fine. *See* § 456.072(2)(d), Fla. Stat.
- 64B16-30.001(2)(b)2.:** It appears that the penalty for the First Violation should be a \$10,000 administrative fine instead of a \$5,000 fine. *See* § 456.072(2)(d), Fla. Stat.
- 64B16-30.001(2)(d):** Please explain how the penalty range for the First Violation provides a meaning notice to the public of likely penalties which may be imposed for proscribed conduct, as required by section 456.079(2).
- 64B16-30.001(2)(e)1.q.:** Please close the parenthetical following the citation to section 465.0255(2).

Mr. David Flynn
August 9, 2018
Page 2

- 64B16-30.001(2)(e)5.:** Please explain how the penalty range for the First Violation provides a meaning notice to the public of likely penalties which may be imposed for proscribed conduct, as required by section 456.079(2).
- 64B16-30.001(2)(f):** Please explain why this violation cites section 465.012(1)(d).
- 64B16-30.001(2)(f)2.:** Please explain how the penalty range for the First Violation provides a meaning notice to the public of likely penalties which may be imposed for proscribed conduct, as required by section 456.079(2).
- 64B16-30.001(2)(k)1.c.:** Please explain why this rule sub-subparagraph cites rule 64B16-27.101. That rule was repealed effective October 8, 2015.

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. Lawrence Harris, Assistant Attorney General

Notice of Proposed Rule

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE NO.: RULE TITLE:

64B16-30.001 Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances

PURPOSE AND EFFECT: The Board proposes the rule amendment to update violations and penalties.

SUMMARY: Violations and penalties will be updated in the rule.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:

The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

RULEMAKING AUTHORITY: 456.072, 456.079, 465.005 FS.

LAW IMPLEMENTED: 456.072, 456.079, 465.016, 465.023 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: C. Erica White, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254.

THE FULL TEXT OF THE PROPOSED RULE IS:

64B16-30.001 Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances.

(1) The board sets forth below a range of disciplinary guidelines from which disciplinary penalties will be imposed upon licensees guilty of violating Chapters 456, 465, 499, or 893 or Section 828.055, F.S. The purpose of the disciplinary guidelines is to give notice to licensees of the range of penalties which will normally be imposed upon violations of particular provisions of Chapters 456, 465, 499, 893 or Section 828.055, F.S. The term license means any permit, registration, certificate, or license, including a provisional license, issued by the Department. Penalty ranges are shown as minimum and maximum guidelines as well as for first time single count violations and for multiple or repeated violations of the same statutory provision of ~~Chapter 465, F.S.~~, or the rules promulgated thereunder. If an actual range of penalties is not provided, the listed penalty shall be the guideline penalty for the violation(s) unless aggravating or mitigating factors are shown. All penalties at the upper range of the sanctions set forth in the guidelines, e.g., suspension, revocation, etc., include lesser penalties, e.g., fine, continuing education, probation, or reprimand, which may be included in the final penalty at the board's discretion. Probation may be subject to conditions, including restriction from practice in certain settings, restricting the licensee to working only under designated conditions or in certain settings, requiring continuing or remedial education, or any other restriction found to be necessary for the protection of the public health, safety, and welfare. In addition to any other discipline imposed under these guidelines, the board shall assess costs relating to the investigation and prosecution of the case.

(2) The following disciplinary guidelines shall be followed by the board in imposing disciplinary penalties upon licensees and permittees for violation of the below mentioned statutes and rules. For the purposes of this rule, the descriptions of the violations are abbreviated and the full statute or rule cited should be consulted to determine the prohibited conduct.

VIOLATION	PENALTY RANGE	
	<u>FIRST VIOLATION</u> MINIMUM, INCLUDING FIRST TIME OR SINGLE COUNT VIOLATIONS	<u>SECOND AND</u> <u>SUBSEQUENT</u> <u>VIOLATIONS</u> <u>MAXIMUM,</u> <u>INCLUDING</u> <u>MULTIPLE OR</u> <u>REPEATED</u> <u>VIOLATIONS OF</u> <u>THE SAME</u> <u>PROVISION</u>
(a) Obtaining a license or permit by misrepresentation, fraud, or error. (Section 465.016(1)(a), F.S.); (Section 465.023(1)(a), F.S.)		
1. By negligent misrepresentation on original application or renewal.	\$1,000 fine and 12-hour Laws and Rules course or MPJE and 3-hour ethics course to <u>\$5,000 fine and Revocation.</u>	\$5,000 fine and one (1) year suspension, to Revocation.
2. By fraudulent misrepresentation on original application or renewal.	\$10,000 fine for each count and Revocation.	\$10,000 fine for each count and Revocation.
3. By error of the Department or Board on original application or renewal.	Revocation.	Revocation.
(b) Procuring or attempting to procure a license or permit for another person by false representation. (Section 465.016(1)(b), F.S.); (Section 465.023(1)(b), F.S.)	\$5,000 10,000 fine for each count and Revocation.	\$10,000 fine for each count and Revocation.
(c) Permitting any unlicensed persons, including owner or operator of pharmacy, to practice pharmacy. (Section 465.016(1)(c), F.S.)	\$2,500 fine and 12-hour Laws & Rules course or Multistate Pharmacy Jurisprudence Exam (MPJE) to <u>\$5,000 fine and one (1) year suspension followed by one (1) year probation.</u>	\$5,000 to \$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
(d) Being unfit or incompetent to practice pharmacy by reason of habitual intoxication, medicinal drug abuse, or physical or mental condition that threatens public safety. (Sections 465.016(1)(d), (m), F.S.)	\$250 fine, indefinite suspension with PRN review and board appearance to <u>revocation.</u>	<u>One (1) year suspension followed by one (1) year probation,</u> to Revocation.

(e) Violating laws governing the practice of pharmacy. (Section 465.016(1)(e), F.S.); (Section 465.023(1)(c), F.S.)		
1. Chapter 465, F.S.:		
a. Failure to supervise registered pharmacy technician. (Section 465.014, F.S.)	\$250 fine and one (1) year probation and 12-hour Laws and Rules course or MPJE <u>to \$1,000 fine and one (1) year probation.</u>	\$1,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
b. Operating a pharmacy that is not registered. (Section 465.015(1)(a), F.S.)	\$500 fine per month to maximum of \$5,000 (penalty will require permittee to <u>obtain or renew permit or cease practice</u>) <u>to Revocation.</u>	\$10,000 fine, (penalty will require permittee to renew permit or cease practice), to Revocation, <u>and referral to State Attorney's Office for criminal prosecution.</u>
c. Operating a pharmacy where an unlicensed, unregistered, or unsupervised person practices pharmacy. (Section 465.015(1)(b), F.S.)	\$5,000 fine and one (1) year probation <u>to one (1) year suspension followed by one (1) year probation.</u>	\$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
d. Making a false or fraudulent statement to the board. (Section 465.015(2)(a), F.S.)	\$10,000 fine <u>to Revocation.</u>	\$10,000 fine and Revocation.
e. Practicing pharmacy as an inactive licensee. (Section 465.015(2)(b), F.S.)	<u>\$500 fine per month</u> Fine based on length of time in practice while inactive (maximum \$6000) <u>to \$10,000 \$500 fine and one (1) year suspension per month.</u>	\$10,000 fine and two (2) years suspension, to Revocation.
f. Selling or dispensing drugs without a prescription. (Section 465.015(2)(c), F.S.)		
(I) Non-scheduled legend drugs.	\$1,500 fine <u>to \$5,000 fine and one (1) year probation.</u>	\$5,000 fine and one (1) year probation, to Revocation.
(II) Scheduled (controlled substances) legend drugs.	\$5,000 fine <u>to \$10,000 fine and one (1) year probation.</u>	\$10,000 fine and one (1) year suspension followed by one (1)

		year probation, to Revocation.
g. Selling samples or complimentary drugs. (Section 465.015(2)(d), F.S.)		
(I) Non-scheduled legend drugs.	\$1,500 fine and (1) year probation <u>to \$5,000 fine and one (1) year suspension.</u>	\$5,000 fine and one (1) year <u>suspension followed by one (1) year</u> probation, to Revocation.
(II) Scheduled (controlled substances) legend drugs.	\$5,000 fine and one (1) year probation <u>to Revocation.</u>	\$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
h. Failure to notify the board of, or failure to have, a prescription department manager or a supervising, a responsible, or a consultant pharmacist. (Section 465.018, .019, .0193, .0196, or .0197, F.S. and 465.022(10), (11), F.S.)		
(I) Failure to notify. (Section 465.018, F.S.)	Fine based on length of time prior to notifying board. \$500 per month (<u>maximum \$6,000</u>) to one (1) <u>year probation.</u>	\$7,500 <u>fine and one (1) year suspension to Revocation</u> maximum—(penalty requires notification or ceasing practice).
(II) Failure to have prescription department manager or a supervising, a responsible, or a consultant pharmacist of record.	Fine based on length of time practicing without designated pharmacist, \$750 fine per month and one (1) year probation.	\$2,000 fine per month, to Revocation.
i. Failure to comply with substitution of legend drug requirements. (Sections 465.025(2), (3), (4), F.S.)	\$500 fine and 12-hour Laws & Rules course or MPJE <u>to \$2,200 fine and one (1) year probation.</u>	\$2,500 fine, 12-hour Laws & Rules course or MPJE, and one (1) year probation <u>to Revocation.</u>
j. Failure to follow negative formulary requirements. (Section 465.025(6), F.S.); (Rule 64B16-27.500, F.A.C.)	\$1,000 fine and 12-hour Laws & Rules course or MPJE <u>to \$2,500 fine and one (1) year probation.</u>	\$2,500 fine, 12-hour Laws & Rules course or MPJE, and one (1) year probation <u>to Revocation.</u>
k. Failure to follow emergency prescription requirements. (Section 465.0275, F.S.)	\$500 fine <u>to \$2,500 fine and one (1) year probation.</u>	<u>\$2,500</u> 4,000 fine and one (1) year probation <u>to \$5,000 fine and one (1) year suspension followed</u>

		<u>by one (1) year probation.</u>
l. Engage in prohibited rebate scheme. (Section 465.185, F.S.)	\$1,500 fine and 12-hour Laws & Rules course or MPJE <u>to \$5,000 fine and one (1) year probation.</u>	\$5,000 fine, 12-hour Laws & Rules course or MPJE, and one (1) year probation, to Revocation.
m. Failure to comply with pharmacist dispensing requirements. (Section 465.186, F.S.)		
(I) Failure to follow procedure, but dispense drug appearing on formulary. (Section 465.186(3), F.S.); (Rule 64B16-27.210, F.A.C.)	\$500 fine <u>to \$1,000 fine and one (1) year probation.</u>	\$1000 fine and one (1) year probation to suspension of right to dispense.
(II) Dispensing drug not on the formulary. (Section 465.186(2), F.S.); (Rules 64B16-27.220, .230, F.A.C.)	\$1,500 fine and 12-hour Laws & Rules course or MPJE <u>to \$5,000 fine and one (1) year probation.</u>	\$5,000 fine and one (1) year probation to \$10,000 fine and Revocation.
n. Failure to timely report fraudulent obtaining or attempted obtaining of controlled substances from a pharmacy. (Section 465.015(3), F.S.)		
(I) Failure to timely report.	\$500 fine <u>and 12-hour Laws & Rules course or MPJE to one (1) year probation.</u>	\$1,000 fine and one (1) year probation, <u>to revocation.</u>
(II) Failure to report.	\$1,000 fine and one (1) year probation <u>to one (1) year suspension.</u>	\$5,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
o. Violation of facsimile prescription requirements. (Section 465.035, F.S.)	\$500 fine <u>and 12-hour Laws & Rules course or MPJE to one (1) year probation.</u>	\$1,000 fine and one (1) year probation, <u>to revocation.</u>
p. Violation of requirements for administration of vaccines and epinephrine auto injection. (Section 465.189, F.S.); (Section 465.009(6)(a), F.S.)		
(I) Failure to enter into a written protocol.	\$2,500 fine and 12-hour Laws & Rules course or MPJE <u>to one (1) year probation.</u>	\$5,000 fine and one (1) year probation, <u>to revocation.</u>
(II) Failure to maintain proper insurance.	\$500 fine and	\$1,000 fine,

	suspension until insured to one (1) <u>year probation.</u>	suspension until insured, followed by one (1) year probation <u>to revocation.</u>
(III) Failure to maintain and make available patient records.	\$500 fine to one (1) <u>year probation.</u>	\$1,000 fine and one (1) year probation <u>to revocation.</u>
(IV) Uncertified administration of vaccine.	\$5,000 fine and <u>one (1) year suspension of immunization certification until certified to one (1) year suspension.</u>	\$7,500 fine and suspension until certified, followed by one (1) year probation, to revocation.
(V) Failure to submit copy of protocol or written agreement to the board.	\$500 fine to one (1) <u>year probation.</u>	\$1,000 fine and one (1) year probation <u>to revocation.</u>
q. Failure to request photo or other verification of identity prior to dispensing a controlled substance to a person not known. (465.0155(2), F.S.)	\$500 fine and 12 hour <u>Laws & Rules course or MPJE to one (1) year probation.</u>	\$1,000 fine and one (1) year probation, <u>to revocation.</u>
r. Failure to inform customers of less expensive drug when cost sharing obligation to customer exceeds retail price. (465.0244(2), F.S.)	\$500 fine and 12 hour <u>Laws & Rules course or MPJE to one (1) year probation.</u>	\$1,000 fine to one (1) year suspension <u>of dispensing rights.</u>
2. Chapter 499, F.S.:		
a. Adulteration or misbranding of a drug. (Sections 499.005(2), (3), F.S.); (Section 499.006, F.S.); (Section 499.007, F.S.)		
(I) Adulteration of a drug. (Section 499.005(2), F.S.); (Section 499.006, F.S.)	\$1,000 fine and 12-hour Laws & Rules course or MPJE <u>to one (1) year probation.</u>	\$5,000 fine and one (1) year suspension followed by one (1) year probation, to revocation.
(II) Receipt or delivery of any drug that is adulterated or misbranded. (Section 499.005(3), F.S.)	\$1,000 fine and 12-hour Laws & Rules course or MPJE <u>to one (1) year probation.</u>	\$5,000 fine and one (1) year probation, to revocation.
(III) Incomplete or inaccurate labeling. (Section 499.007, F.S.); (Rule 64B16-28.108, F.A.C.)	\$250 fine and 12-hour Laws & Rules course or MPJE <u>to one (1) year probation.</u>	\$2,500 fine and one (1) year probation, <u>to revocation.</u>
(IV) Fraudulent misbranding of legend drugs. (Section 499.007, F.S.)	\$10,000 fine and one (1) year suspension followed by one (1) year probation <u>to two</u>	\$10,000 fine and two (2) years suspension followed by two (2) years'

	<u>(2) year suspension.</u>	probation, to revocation.
b. Failure to obtain a permit or registration, or operating without a valid permit when it is required. (Section 499.005(22), F.S.)	\$500 fine per month to maximum of \$5,000 (penalty will require permittee to renew permit or cease practice) <u>to one (1) year probation.</u>	\$10,000 fine (penalty will require permittee to renew permit or cease practice), to revocation.
c. Prescription drug pedigree violations. (Section 499.005(28), F.S.); (Section 499.0051, F.S.)	\$500 fine and 12-hour Laws & Rules course or MPJE <u>to one (1) year probation.</u>	\$5,000 fine and one (1) year probation, to revocation.
d. Recordkeeping requirement. (Section 499.0121, F.S.); (Sections 499.005(18), (19), F.S.)	\$500 fine and 12-hour Laws & Rules course or MPJE <u>to one (1) year probation.</u>	\$5,000 fine and one (1) year probation, to revocation.
e. Storage of drugs. (Section 499.0121, F.S.)	\$500 fine and 12-hour Laws & Rules course or MPJE <u>to one (1) year probation.</u>	\$5,000 fine and one (1) year probation, to revocation.
3. Chapter 893, F.S. (Controlled Substances):		
a. Filling a written or oral prescription for controlled substances that does not meet the requirements of Chapter 893, F.S. (Sections 893.04(1)(a), (b), (c), F.S.)	\$1,500 fine <u>and 12-hour Laws & Rules course or MPJE to one (1) year probation.</u>	\$5,000 fine and one (1) year probation, to revocation.
b. Failing to retain prescription records for two (2) years. (Section 893.04(1)(d), F.S.)	\$1,000 fine <u>and 12-hour Laws & Rules course or MPJE to one (1) year probation.</u>	\$5,000 fine and one (1) year probation, to revocation.
c. Failing to appropriately label. (Section 893.04(1)(e), F.S.)	\$250 fine and 12-hour Laws & Rules course or MPJE <u>to one (1) year probation.</u>	\$2,500 fine and (1) year probation, <u>to revocation.</u>
d. Dispensing a Schedule II drug inappropriately with a non-written prescription. (Section 893.04(1)(f), F.S.)	\$5,000 fine and one (1) year probation <u>to one (1) year suspension.</u>	\$10,000 fine and one (1) year suspension followed by one (1) year probation, to revocation.
e. Inappropriate refilling of Schedule III, IV, or V drugs. (Section 893.04(1)(g), F.S.);	\$1,750 fine and one (1) year probation <u>to one (1) year</u>	\$5,000 fine and one (1) year suspension, <u>to revocation.</u>

(Section 893.04(2)(e), F.S.)	<u>suspension.</u>	
f. Receiving controlled substances without an appropriate order form. (Section 893.06(1), F.S.)	\$2,500 fine <u>to one (1) year probation.</u>	\$5,000 fine and one (1) year probation, to Revocation.
g. Possession of controlled substances outside the regular course of business, occupation, profession, employment, or duty. (Section 893.06(2), F.S.)	\$2,500 fine and one (1) year probation <u>to one (1) year suspension.</u>	\$5,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
h. Failure to take a biennial inventory. (Sections 893.07(1)(a), (2), (3), (4), (5), F.S.)	\$1,000 fine and 12-hour <u>Laws & Rules course or MPJE to one (1) year probation.</u>	\$2,500 fine and one (1) year probation, <u>to revocation.</u>
i. Failure to maintain a complete and accurate record of controlled substances. (Sections 893.07(1)(b), (2), (3), (4), (5), F.S.)	\$1,000 fine, <u>12-hour Laws & Rules course or MPJE to and one (1) year probation.</u>	\$5,000 fine and two (2) years' probation, to Revocation.
j. Dispensing Schedule V controlled substances in other than good faith. (Section 893.08(3)(b), F.S.)	\$5,000 fine and one (1) year probation <u>to one (1) year suspension.</u>	\$10,000 fine and one (1) year suspension followed by one (1) year probation, to revocation.
k. Inappropriate selling of Schedule V controlled substance. (Section 893.08(3)(c), F.S.)	\$1,500 fine and one (1) year probation <u>to one (1) year suspension.</u>	\$5,000 fine and one (1) year suspension, <u>to revocation.</u>
l. Unlawful possession of controlled substance. (Section 893.13, F.S.)	\$5,000 fine and two (2) years' probation <u>to one (1) year suspension.</u>	\$10,000 fine and one (1) year suspension followed by two (2) years' probation, to revocation.
<u>m. Failure to report information regarding dispensed controlled substances to the Prescription Drug Monitoring Program Controlled Substance Dispensing Information Electronic System. (893.055(3), F.S.)</u>	<u>\$250 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.</u>	<u>\$5,000 fine and one (1) year probation, to revocation.</u>
<u>n. Failure to consult the Prescription Drug Monitoring Program Controlled Substance Dispensing Information Electronic System prior to dispensing a controlled substance. (893.055(8), F.S.)</u>	<u>\$250 fine and 12-hour Laws & Rules course or MPJE to one (1) year probation.</u>	<u>\$5,000 fine and one (1) year probation, to revocation.</u>
<u>o. Failure to maintain confidentiality of information obtained from the Prescription Drug Monitoring Program Controlled Substance Dispensing Information Electronic System. (893.0551(6), F.S.)</u>		
<u>(I). Knowing violation.</u>	<u>\$10,000 fine and one</u>	<u>\$10,000 fine and one</u>

	<u>(1) year probation to one (1) year suspension.</u>	<u>(1) year suspension followed by two (2) years' probation, to Revocation.</u>
<u>(II). Negligent violation.</u>	<u>Reprimand to \$500 fine and 12 hour Laws & Rules course or MPJE.</u>	<u>One (1) year probation and \$1,000 fine to one (1) year suspension.</u>
4. Violation of Federal Drug Abuse Act 21 U.S.C. 821 et seq. (Manufacture, Distribution, and Dispensing of Controlled Substances.)	<u>\$1,000 500 fine and one (1) year probation to one (1) year suspension.</u>	\$2,000 fine up to \$10,000 and one (1) year suspension followed by two (2) years' probation, to revocation.
5. Violation of Food and Drug Act 21 U.S.C. 301 – 392.	<u>\$2,500 fine and one (1) year suspension, to revocation.</u>	\$7,500 fine and two (2) years suspension followed by two (2) years' probation, to revocation.
(f) Criminal conviction related to Pharmacy. (Section 465.016(1)(f), F.S.); (Section 465.023(1)(d), F.S.)		
1. Misdemeanor.	<u>\$1,000 fine to one (1) year probation.</u>	\$5,000 fine and one (1) year probation, to revocation.
2. Felony.	\$5,000 fine and one (1) year suspension followed by two (2) years' probation, <u>to revocation.</u>	\$10,000 fine and two (2) years suspension followed by three (3) years' probation, to revocation.
(g) 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), F.S. or Section 465.025, F.S. (Section 465.016(1)(g), F.S.); or, compounding, dispensing or distributing legend drugs outside professional practice of pharmacy. (Section 465.016(1)(i), F.S.)	\$250 fine without ingestion or harm, to \$500 with ingestion, and complete approved CE course in the prevention of medication errors of no less than eight (8) hours <u>to one (1) year probation.</u>	\$500 fine without ingestion or harm, to \$1,000 with ingestion, complete approved CE course in the prevention of medication errors of no less than eight (8) hours, and two (2) years' probation, to revocation.
(h) Filing a false report or failing to file a		

report required by law. (Section 465.016(1)(j), F.S.)		
1. Knowing violation.	\$10,000 fine and one (1) year probation <u>to one (1) year suspension.</u>	\$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
2. Negligent violation.	Reprimand <u>to \$500 fine and 12 hour Laws & Rules course or MPJE.</u>	One (1) year probation and \$1,000 fine <u>to one (1) year suspension.</u>
(i) Failure to make prescription price information available. (Section 465.016(1)(k), F.S.)	\$250 fine and 12-hour Laws & Rules course or MPJE, <u>to \$1,000 fine and one-year probation.</u>	\$1,000 fine and one (1) year probation <u>to one (1) year suspension.</u>
(j) Improperly placing returned drugs into the stock of a pharmacy. (Section 465.016(1)(l), F.S.)	\$1,500 fine <u>to \$1,000 fine and one-year probation.</u>	\$3,000 fine and one (1) year probation <u>to one (1) year suspension.</u>
(k) Violating a rule or order of the Board or Department. (Section 465.016(1)(n), F.S.)		
1. Rules of Board of Pharmacy.		
a. Rules 64B16-28.101 to 64B16-28.1035, F.A.C. Rule 64B16-27.100, F.A.C. Rule 64B16-28.109, F.A.C. Rule 64B16-27.103, F.A.C. Rule 64B16-27.104, F.A.C. Rule 64B16-26.400, F.A.C. Rule 64B16-26.2032 F.A.C. Rule 64B16-28.1081, F.A.C. Rule 64B16-27.105, F.A.C. Rule 64B16-27.211, F.A.C. Rule 64B16-28.113, F.A.C. Rule 64B16-28.2021, F.A.C. Rule 64B16-28.603, F.A.C.	\$500 fine and 12-hour Laws & Rules course or MPJE, <u>to \$1,000 fine and one-year probation.</u>	One (1) year probation and \$2,000 fine <u>to one (1) year suspension</u>
b. Sink and running water, sufficient space, refrigeration, sanitation, equipment. (Rule 64B16-28.102, F.A.C.)	Suspension until compliance.	\$2,000 fine <u>to and</u> revocation.
c. Knowingly purchase, sell, possess, or distribute counterfeit drugs. (Rule 64B16-27.101, F.A.C.)	\$5,000 fine, one (1) year suspension followed by one (1) year probation to revocation.	\$10,000 fine <u>to and</u> revocation.

d. Failure to remove outdated pharmaceuticals, or dispensing of same. (Rule 64B16-28.110, F.A.C.)	\$500 fine for possession, \$1,000 fine for dispensing <u>to one (1) year probation.</u>	\$2,500 – \$5,000 fine and two (2) years' probation, to revocation.
e. Violation of destruction of controlled substances. (Rules 64B16-28.301 and .303 F.A.C.)	\$500 fine and 12-hour Laws & Rules course or MPJE <u>to one (1) year probation.</u>	\$5,000 fine and two (2) years' probation, to revocation.
f. No change.		
g. Violation of requirements for records maintained in a data processing system. (Rule 64B16-28.140, F.A.C.)	\$1,000 fine and 12-hour Laws & Rules course or MPJE plus 8 hours CE course in record keeping <u>to one (1) year probation.</u>	\$5,000 fine and two (2) years' probation, to revocation.
h. Failure to properly store legend drugs. (Rule 64B16-28.120, F.A.C.)	\$1,000 fine and 12-hour Laws & Rules course or MPJE <u>to one (1) year probation.</u>	\$5,000 fine and one (1) year probation, to revocation.
i. No change.		
j. Failure to follow technical requirements for nuclear pharmacy. (Rules 64B16-28.901 and .902, F.A.C.)	One (1) year probation and \$1,000 fine, to \$2,500 fine and six (6) months suspension followed by one (1) year probation <u>to one (1) year suspension.</u>	\$5,000 fine and one (1) year suspension followed by two (2) years' probation, to revocation.
k. through t. No change.		
(l) through (n) No change.		
(o) Failing to notify the Board of commencement or cessation of practice due to discipline in another jurisdiction. (Section 465.016(1)(p), F.S.)	\$500 fine and 12-hour Laws & Rules course or MJPE	\$2,000 fine and two (2) years' probation <u>to revocation.</u>
(p) Using or releasing patient records improperly. (Section 465.016(1)(q), F.S.)	\$1,000 fine and 12-hour Laws & Rules course or MJPE.	\$2,500 fine and one (1) year probation <u>to revocation.</u>
(q) Knowingly, or with reason to believe, dispensing based on purported prescription where patient-prescriber relationship is invalid. (Section 465.016(1)(s), F.S.); (Section 465.023(1)(h), F.S.)		

(I) Reason to believe.	\$2,000 fine, 12-hour Laws & Rules course or MJPE, and one (1) year probation <u>to one (1) year suspension.</u>	\$2,500 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
(II) Knowingly.	Revocation.	Revocation.
(r) through (t) No change.		
(u) Violating Section 456.072, F.S. (Section 465.016(1)(r), F.S.)		
1. Making misleading, deceptive, or fraudulent representation in or related to the practice of the licensee's profession. (Section 456.072(1)(a), F.S.)	\$10,000 fine and one (1) year probation <u>to one (1) year suspension.</u>	Revocation, and a fine of \$10,000.
2. Intentionally violating any rule adopted by the Board or the Department. (Section 456.072(1)(b), F.S.)	\$2,500 fine and two (2) years' probation <u>to one (1) year suspension.</u>	\$5,000 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
3. Being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession. (Section 456.072(1)(c), F.S.)		
a. Misdemeanor.	\$1,000 fine <u>to one (1) year probation and suspension until compliant.</u>	\$2,500 fine and suspension until compliant, followed by one (1) year probation, to Revocation.
b. Felony.	\$3,000 fine and one (1) year probation <u>to one (1) year suspension.</u>	\$5,000 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
4. Failing to comply with the educational course requirements for human immunodeficiency virus and acquired immune deficiency syndrome, or medical errors. (Section 456.072(1)(e), F.S.) (Rules 64B16-26.103(1)(c), (4)(e), F.A.C.)	\$500 fine <u>and suspension until compliant.</u>	\$1,000 fine <u>and suspension until compliant.</u>
5. through 9. No change.		

10. Failing to perform any statutory or legal obligation placed upon a licensee, including failure to repay student loans or perform scholarship service obligations. (Section 456.072(1)(k), F.S.)		
a. Generally.	\$2,000 fine <u>and suspension until compliant.</u>	\$2,500 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
b. No change.		
11. Making or filing a report which the licensee knows to be false, intentionally or negligently failing to file a report or record required by state or federal law, or willfully impeding or obstructing another person to do so. Such reports or records shall include only those that are signed in the capacity of a licensee. (Section 456.072(1)(l), F.S.)		
a. Knowingly filing a false report or willful obstruction.	\$10,000 fine and two (2) years' probation <u>to one (1) year suspension.</u>	\$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
b. No change.		
12. Making deceptive, untrue, or fraudulent representations in or related to the practice of a profession or employing a trick or a scheme in or related to the practice of a profession. (Section 456.072(1)(m), F.S.)	\$10,000 fine and two (2) years' probation <u>to one (1) year suspension.</u>	\$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
13. No change.		
14. Practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities the licensee knows, or has reason to know, the licensee is not competent to perform. (Section 456.072(1)(o), F.S.)	\$2,000 fine and two (2) years' probation <u>to one (1) year suspension.</u>	\$5,000 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.
15. Delegating or contracting for the performance of professional responsibilities by a person when the licensee delegating or contracting for performance of such responsibilities knows, or has reason to know, such person is not qualified by training, experience, and authorization when	\$2,000 fine and two (2) years' probation <u>to one (1) year suspension.</u>	\$5,000 to \$10,000 fine and one (1) year suspension followed by two (2) years' probation, to Revocation.

required to perform them. (Section 456.072(1)(p), F.S.)		
16. through 27. No change.		
(v) No change.		

(3) through (4) No change.

Rulemaking Authority 456.072, 456.079, 465.005 FS. Law Implemented 456.072, 456.079, 465.016, 465.023 FS. History—New 3-1-87, Amended 5-11-88, Formerly 21S-17.001, 21S-30.001, 61F10-30.001, Amended 6-26-95, 1-30-96, Formerly 59X-30.001, Amended 12-3-97, 11-15-98, 5-3-00, 1-2-02, 11-29-06, 9-26-12, 2-14-13, 2-5-14, 1-10-17,_____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Pharmacy

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: June 12, 2018

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: July 6, 2018

**BOARD COUNSEL SUGGESTED EDITS TO RESOLVE JAPC CONCERNS
OCTOBER 2018**

64B16-30.001 Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances.

(1) **No Change**

(2) The following disciplinary guidelines shall be followed by the board in imposing disciplinary penalties upon licensees and permittees for violation of the below mentioned statutes and rules. For the purposes of this rule, the descriptions of the violations are abbreviated and the full statute or rule cited should be consulted to determine the prohibited conduct.

VIOLATION	PENALTY RANGE	
	FIRST VIOLATION	SECOND AND SUBSEQUENT VIOLATIONS
(a) Obtaining a license or permit by misrepresentation, fraud, or error. (Section 465.016(1)(a), F.S.); (Section 465.023(1)(a), F.S.)		
1. By negligent misrepresentation on original application or renewal.	\$1,000 fine and 12-hour Laws and Rules course or MPJE and 3-hour ethics course to \$5,000 fine and one (1) year suspension, to Revocation.	<u>Revocation</u>
2. By fraudulent misrepresentation on original application or renewal.	\$10,000 fine for each count and Revocation.	\$10,000 fine for each count and Revocation.
3. No change		
(b) Procuring or attempting to procure a license or permit for another person by false representation. (Section 465.016(1)(b), F.S.); (Section 465.023(1)(b), F.S.)	\$\$\$5,000 10,000 fine for each count and Revocation.	\$10,000 fine for each count and Revocation.
(c) No change		
(d) Being unfit or incompetent to practice pharmacy by reason of habitual intoxication, medicinal drug abuse, or physical or mental condition that threatens public safety. (Sections 465.016(1)(d), (m), F.S.)	\$250 fine, indefinite suspension with PRN review and board appearance to revocation.	<u>One (1) year suspension followed by one (1) year probation, to</u> Revocation.
(e) Violating laws governing the practice of pharmacy.		
1. Chapter 465, F.S.:		
a. – p. No change		
q. Failure to request photo or other verification of identity prior to dispensing a controlled substance to a person not known. (465.0155(2), F.S.)	\$500 fine and 12 hour Laws & Rules course or MPJE to one (1) year probation.	<u>\$1,000 fine and one (1) year probation, to</u> revocation.
r. No change		
2. – 4. No change		
5. Violation of Food and Drug Act 21 U.S.C. 301 – 392.	\$2,500 fine and one (1) year suspension, <u>to revocation.</u>	\$7,500 fine and two (2) years suspension followed by two (2) years' probation, to revocation.

(f) Criminal conviction related to Pharmacy. (Section 465.016(1)(f), F.S.); (Section 465.023(1)(d), F.S.)		
1. Misdemeanor.	\$1,000 fine <u>to one (1) year probation.</u>	\$5,000 fine <u>and</u> one (1) year probation, to revocation.
2. Felony.	\$5,000 fine and one (1) year suspension followed by two (2) years' probation, <u>to revocation.</u>	\$10,000 fine and two (2) years suspension followed by three (3) years' probation, to revocation.
(g) – (j) No change		
(k) Violating a rule or order of the Board or Department. (Section 465.016(1)(n), F.S.)		
1. Rules of Board of Pharmacy.		
a. - b. No change		
c. Knowingly purchase, sell, possess, or distribute counterfeit drugs. <u>499.005(8) (Rule 64B16-27.101, F.A.C.)</u>	\$5,000 fine, one (1) year suspension followed by one (1) year probation to revocation.	\$10,000 fine to and revocation.
d. – v. No change		

(3) – (4) **No change**

Rulemaking Authority 456.072, 456.079, 465.005 FS. Law Implemented 456.072, 456.079, 465.016, 465.023 FS. History—New 3-1-87, Amended 5-11-88, Formerly 21S-17.001, 21S-30.001, 61F10-30.001, Amended 6-26-95, 1-30-96, Formerly 59X-30.001, Amended 12-3-97, 11-15-98, 5-3-00, 1-2-02, 11-29-06, 9-26-12, 2-14-13, 2-5-14, 1-10-17.



TAB #5

**SUGGESTED LANGUAGE TO CLARIFY 3:1 RATIO FOR STERILE COMPOUNDING ACTIVITIES ONLY
OCTOBER 2018**

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. Confidentiality 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). The 3:1 ratio only applies to pharmacists and technicians engaged in sterile compounding, and does not affect the technician ratios for other, non-sterile compounding in areas of the pharmacy physically separated from the area in which sterile compounding activities take place.

(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 registered pharmacy technicians are ~~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 or registered pharmacy technicians are ~~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

DISCUSSION ITEM REGARDING INSPECTIONS AND REMOVALS OF OUTDATED PHARMACEUTICALS

AUGUST 2018 RULES COMMITTEE

64B16-28.110 Outdated Pharmaceuticals.

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 deteriorated 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 465.022 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.

465.022 Pharmacies; general requirements; fees.

(1) The board shall adopt rules pursuant to ss. [120.536](#)(1) and [120.54](#) to implement the provisions of this chapter. Such rules shall include, but shall not be limited to, rules relating to:

- (a) General drug safety measures.
- (b) Minimum standards for the physical facilities of pharmacies.
- (c) Safe storage of floor-stock drugs.
- (d) Functions of a pharmacist in an institutional pharmacy, consistent with the size and scope of the pharmacy.
- (e) Procedures for the safe storage and handling of radioactive drugs.
- (f) Procedures for the distribution and disposition of medicinal drugs distributed pursuant to s. [499.028](#).
- (g) Procedures for transfer of prescription files and medicinal drugs upon the change of ownership or closing of a pharmacy.
- (h) Minimum equipment which a pharmacy shall at all times possess to fill prescriptions properly.
- (i) Procedures for the dispensing of controlled substances to minimize dispensing based on fraudulent representations or invalid practitioner-patient relationships.

465.0255 Expiration date of medicinal drugs; display; related use and storage instructions.

(1) The manufacturer, repackager, or other distributor of any medicinal drug shall display the expiration date of each drug in a readable fashion on the container and on its packaging. The term “readable” means conspicuous and bold.

(2) Each pharmacist for a community pharmacy dispensing medicinal drugs and each practitioner dispensing medicinal drugs on an outpatient basis shall display on the outside of the container of each medicinal drug dispensed, or in other written form delivered to the purchaser:

(a) The expiration date when provided by the manufacturer, repackager, or other distributor of the drug; or

(b) An earlier beyond-use date for expiration, which may be up to 1 year after the date of dispensing. The dispensing pharmacist or practitioner must provide information concerning the expiration date to the purchaser upon request and must provide appropriate instructions regarding the proper use and storage of the drug.

(3) This section does not impose liability on the dispensing pharmacist or practitioner for damages related to, or caused by, a medicinal drug that loses its effectiveness prior to the expiration date displayed by the dispensing pharmacist or practitioner.

(4) The provisions of this section are intended to notify the patient receiving a medicinal drug of the information required by this section, and the dispensing pharmacist or practitioner shall not be liable for the patient's failure to heed such notice or to follow the instructions for storage.

History.—ss. 1, 2, ch. 93-44; s. 8, ch. 2004-387.

* * * *

499.0121 Storage and handling of prescription drugs; recordkeeping. The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(5) RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.—

(a)1. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier. A quarantine section must be separate and apart from other sections where prescription drugs are stored so that prescription drugs in this section are not confused with usable prescription drugs.

2. Prescription drugs must be examined at least every 12 months, and drugs for which the expiration date has passed must be removed and quarantined.

499.0051 Criminal acts.

(11) **ADULTERATED AND MISBRANDED DRUGS; FALSE ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS.** Any person who violates any of the following provisions commits a misdemeanor of the second degree, punishable as provided in s. [775.082](#) or s. [775.083](#); but, if the violation is committed after a conviction of such person under this subsection has become final, such person commits a misdemeanor of the first degree, punishable as provided in s. [775.082](#) or s. [775.083](#), or as otherwise provided in this part:

(a) The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

499.006 Adulterated drug or device. A drug or device is adulterated:

(9) If it is a drug or device for which the expiration date has passed;

**SUGGESTED AMENDMENTS REGARDING OUTDATED/EXPIRED ITEMS
OCTOBER 2018**

64B16-28.110 Outdated Pharmaceuticals.

(1) Pursuant to section 499.0121(5), F.S., each pharmacy shall maintain a quarantine area, which is physically separated and apart from the active stock of the pharmacy, for the quarantining of outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs. Pursuant to section 499.006(9), F.S., a drug whose expiration date has passed is an “adulterated drug.”

(2) 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, including prescription drugs pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date which date has been reached.

(3) U, and under no circumstances will prescription drugs, 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.

64B16-30.002 Minor Violations.

(1) The Board sets forth the following guidelines for use by Department investigators when a licensee is in noncompliance of an initial offense of a minor violation. The Board deems the following violations, depending upon severity, to be consistent with section 456.073(3), F.S.

(a) Outdated prescription drugs pharmaceuticals, less than xxx items, none less than one (1) month past expiration date – section 499.006(9) through 499.005(s), F.S., section 499.0121(5)(a)2., and rule 64B16-28.110, F.A.C.

(b) Failure to meet regulation of daily operating hours – rule 64B16-28.404, F.A.C.

(c) Generic substitution sign not displayed – section 465.025(7), F.S.

(d) Information required on controlled substance prescriptions: practitioner’s address, practitioner’s DEA registration number, patient’s address – section 893.04, F.S.

(e) Failure to have certified by dispensing pharmacists the daily hard-copy printout or daily log – paragraph 64B16-28.140(3)(c) or (e), F.A.C.

(f) Failure to have pharmacy minimally equipped i.e. references, compounding equipment, and a current copy of the laws and rules governing the practice of pharmacy in the State of Florida – rule 64B16-28.107, F.A.C.

(g) Failure to properly identify pharmacy technicians – rule 64B16-27.410, F.A.C.

(h) Results of P&E quality assurance program not documented or available for inspection – paragraph 64B16-28.820(3)(d), F.A.C.

(i) Improper storage of legend drugs – rule 64B16-28.120, F.A.C.

(j) Improper documentation of destruction of controlled substances – rules 64B16-28.301, 64B16-28.303, F.A.C.

(k) Consultant pharmacist’s monthly reports not current or available for inspection – rule 64B16-28.501, subsection 64B16-28.702(2), F.A.C.

(l) Controlled substance prescription labels lack transfer crime warning labeling – paragraph 64B16-28.502(2)(c), F.A.C.

(m) Failure to maintain proof of licensure, display licenses/registrations or notices, or to properly identify pharmacy staff – rule 64B16-27.100, F.A.C.

(n) Failure to have a continuously designated Prescription Department Manager or Consultant Pharmacist

of Record, if the gap between designations is less than fifteen (15) business days – rules 64B16-27.450 and 64B16-28.501, F.A.C.

(2) The Department’s investigator may issue a Notice of Deficiencies when the above conditions occur and the requirements of section 456.073(3), F.S., are met. In such cases licensees shall correct the violation and respond to the investigator on forms provided by the Department and with other evidence of compliance as may be necessary, within 30 days, to certify current compliance. Failure to do so shall subject the licensee to further proceedings.

Rulemaking Authority 456.073(3), 465.005 FS. Law Implemented 456.073(3) FS. History–New 11-12-90, Formerly 21S-17.002, 21S-30.002, 61F10-30.002, 59X-30.002, Amended 12-9-98, 8-26-02, 11-7-17, 7-11-18.

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; or, if there is a substantial threat to the public health, safety and welfare, such potential for harm has been removed prior to the issuance of the citation. Next to each violation is the fine to be imposed.

(2) Prior to issuance of the citation, the Department must confirm that the violation has been corrected or is in the process of being corrected. If the violation is a substantial threat to the public health, safety and welfare, such potential for harm must be removed prior to issuance of the citation.

(3) 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.

<p>(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.)</p>	<p>\$250 fine, Completion of an approved CE course in the prevention of medication errors of no less than 8 hours.</p>
<p>(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.</p>	<p>\$100 fine plus payment of the check within 30 days.</p>
<p>(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.)</p>	<p>\$500</p>
<p>(k) Failure to correct Minor violation as listed in rule 64B16-30.002, F.A.C.</p>	<p>\$250</p>
<p>(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.)</p>	<p>\$100</p>
<p>(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.)</p>	<p>\$100</p>
<p>(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.)</p>	<p>\$100</p>
<p>(o) Failure to inform customers of less expensive drug when cost sharing obligation to customer exceeds retail price. (Section 465.0244(2), F.S.)</p>	<p>\$100</p>
<p><u>(p) Failure to maintain a physically separate and apart quarantine section for outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.</u> <u>(Section 499.0121(5)(a)1., F.S.)</u></p>	<p>_____</p>
<p><u>(q) Failure to remove from active stock and properly quarantine outdated prescription drugs, less than xxx items, none more than three (3) months past expiration date.</u> <u>(Section 499.006(9) through 499.005(s), F.S.)</u> <u>(Section 499.0121(5)(a)2.)</u> <u>(Rule 64B16-28.110, F.A.C.)</u></p>	<p>_____</p>

(4) 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.

(5) 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 #7

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; or, if there is a substantial threat to the public health, safety and welfare, such potential for harm has been removed prior to the issuance of the citation. Next to each violation is the fine to be imposed.

(2) Prior to issuance of the citation, the Department must confirm that the violation has been corrected or is in the process of being corrected. If the violation is a substantial threat to the public health, safety and welfare, such potential for harm must be removed prior to issuance of the citation.

(3) 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 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

(4) 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.

(5) 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 #8

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.

White, Erica

From: Philip, Jeenu <jeenu.philip@walgreens.com>
Sent: Monday, August 27, 2018 1:25 PM
To: White, Erica
Cc: 'David Flynn'
Subject: List of Interns

Erica,

Do you know if we get an updated list yearly of all students enrolled in pharmacy school here in Florida?

My concern is we may have interns that have dropped out of school that has retained their intern license improperly. Since there is no expiration date on intern permits, I think we need to try and weed out any who are not qualified based on the statute.

(12) “Pharmacy intern” means a person who is currently registered in, and attending, a duly accredited college or school of pharmacy, or who is a graduate of such a school or college of pharmacy, and who is duly and properly registered with the department as provided for under its rules.

Mr. Flynn – please let me know if I’m off base with my thought process here.

Thank you!

Warm Regards,
Jeenu

Jeenu Philip
Senior Manager, Pharmacy Affairs
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The 2018 Florida Statutes

[Title XXXII](#)[Chapter 465](#)[View Entire Chapter](#)

REGULATION OF PROFESSIONS AND OCCUPATIONS

PHARMACY

465.013 Registration of pharmacy interns.—The department shall register as pharmacy interns persons certified by the board as being enrolled in an intern program at an accredited school or college of pharmacy or who are graduates of accredited schools or colleges of pharmacy and are not yet licensed in the state. The board may refuse to certify to the department or may revoke the registration of any intern for good cause, including grounds enumerated in this chapter for revocation of pharmacists' licenses.

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

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