

AGENDA
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
RULES COMMITTEE MEETING

April 1, 2014

Marriott Westshore
1001 N. Westshore Boulevard
Tampa, FL 33607
(800) 627-7468

Committee Members:

Jeffrey J. Mesaros, PharmD, Tampa, Chair
Debra Glass, BPharm, Tallahassee
Mark Mikhael, PharmD, Orlando
Jeenu Philip, BPharm, Jacksonville
Michele Weizer, PharmD, Boca Raton

Board Staff:

Tammy Collins, Acting Executive Director
Jay Cumbie, Regulatory Specialist II

Board Counsel:

David Flynn, Assistant Attorney General
Lynette Norr, Assistant Attorney General

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

Tuesday, April 1, 2014 – 9:00 a.m.

Old Business: JAPC comments and other changes or comments pertaining to rules previously noticed for development and published.

1. 64B16-26.2034: Direct Supervision of a Registered Pharmacy Technician. (New)
2. 64B16-28.450: Centralized Prescription Filling, Delivering and Returning.
3. 64B16-28.101: Citations.
4. 64B16-26.2032: Pharmacy Intern Registration Internship Requirements (U.S. Pharmacy Students/Graduates).
5. 64B16-28.202, 2021, 203: Closing of a Pharmacy.

New Business: Rules for June 2014 Agenda.

DON GAETZ
President



Senator Rene Garcia, Chair
Representative James W. "J.W." Grant, Vice Chair
Senator Dwight Bullard
Senator Nancy C. Detert
Senator Miguel Diaz de la Portilla
Senator Geraldine F. "Geri" Thompson
Representative Douglas Vaughn "Doug" Broxson
Representative Charles David "Dave" Hood, Jr.
Representative Dave Kerner
Representative George R. Moraitis, Jr.
Representative Hazelle P. "Hazel" Rogers

WILL W. WEATHERFORD
Speaker



KENNETH J. PLANTE
COORDINATOR
Room 680, Pepper Building
111 W. Madison Street
Tallahassee, Florida 32399-1400
Telephone (850) 488-9110
Fax (850) 922-6934
www.japc.state.fl.us
joint.admin.procedures@leg.state.fl.us

THE FLORIDA LEGISLATURE
**JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE**

February 28, 2014

Ms. Lynette Norr
Assistant Attorney General
Department of Legal Affairs
PL-01, The Capitol
Tallahassee, Florida 32399-1050

**Re: Department of Health: Board of Pharmacy
Rule 64B16-28.100, F.A.C.**

Dear Ms. Norr:

I have reviewed proposed rule 64B16-28.100, "Pharmacy Permits – Applications and Permitting," which was advertised in the Florida Administrative Register on February 20, 2014. I have the following comments.

64B16-28.100(5): This subsection incorporates by reference Form DH-MQA 1220, entitled "Special Pharmacy Permit Application and Information," effective December 2013.

Form DH-MQA 1220:

Instructions, page two: The paragraph describing who must submit fingerprints with the application does not appear to describe accurately the fingerprint requirements contained in subsection 465.022(2), Florida Statutes. For example, the instructions state that "all officers, officers [sic] and prescription department managers are required to submit a set of fingerprints unless the corporation is exempt under the [sic] Section 465.022, Florida Statutes for corporations having more than \$100 million of business taxable assets in this state."

Paragraph 465.022(3)(a) requires that an application for a pharmacy permit "must include a set of fingerprints from each person having an ownership interest of 5 percent or greater and from any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant, including officers and members of the board of directors of an applicant that is a corporation" unless exempted pursuant to the provisions of subparagraph 465.022(3)(a)1. Please revise these instructions to be consistent with the provisions of section 465.022.

Application, page three: Please explain why this page states that questions 15 through 21 are asked pursuant to “Section [sic] 456.0635(2) and 465.022(5), Florida Statutes.” Question 17 does not appear to be asked pursuant to either of these statutes. Further, it appears that questions 22 and 23 are asked pursuant to these statutes. Please clarify this sentence in the application.

Application, page four: Question 17 asks the person signing the application to respond “yes” or “no” to the following:

I have been provided and read the statement from the Florida Department of Law Enforcement regarding sharing, retention, privacy and right to challenge incorrect criminal history records and the “Privacy Statement” document from the Federal Bureau of Investigation. (Found on Page 8 of this application).

As mentioned above, fingerprints may be required from persons other than the person signing the application. This application requires the signature of the “Owner/Officer.” Please revise question 17 or explain why the question is phrased in this manner.

Application, page five: Question 30 asks whether “the policy and procedure manual for preventing controlled substance dispensing based on fraudulent representation or invalid practitioner-patient relationship [is] available for inspection by DOH.” Subsection 465.022(4) requires these policies and procedures to be submitted with the application for a pharmacy permit. Please revise the application accordingly. *See* § 120.52(8)(c), Fla. Stat.

Application, page eight: It appears the citation to rule 11C8.001, F.A.C. should be to rule 11C-8.001, F.A.C.

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

Sincerely,



Marjorie C. Holladay
Chief Attorney



PAM BONDI
ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Administrative Law

Lynette Norr
Assistant Attorney General
Administrative Wage Garnishment Hearing Officer
PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3604 Fax (850) 922-6425
<http://www.myfloridalegal.com>
Lynette.Norr@myfloridalegal.com

March 3, 2013

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

Re: Department of Health: Board of Pharmacy
Rule 64B16-28.100 F.A.C.

Dear Ms. Holladay:

This is in response to your February 28, 2014, letter identifying corrections needed to Form DH-MQA 1220, which is incorporated by reference into rule 64B16-28.100.

I have asked the Department to make the recommended corrections for consideration by the Board of Pharmacy at its April 2, 2014, meeting. Our office will provide you with a copy of the corrected form following approval by the Board.

Please feel free to call if you have additional questions or comments.

Sincerely,

Lynette Norr
Assistant Attorney General

cc: Tammy Collins, Acting Executive Director
Jennifer A. Tschetter, General Counsel
Ed Tellechea, Chief
Angela Southwell, paralegal specialist

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2014 MAR -6 PM 3:14
OFFICE OF THE ATTORNEY GENERAL
STATE OF FLORIDA

64B16-28.100 Pharmacy Permits – Applications and Permitting.

This section addresses the application and permitting requirements of business establishments regulated under Chapter 465, F.S. Any establishment that is required to have a permit shall apply to the board for the appropriate permit on forms indicated in this rule. Applications and forms referenced in this section may be accessed or downloaded from the web at <http://www.doh.state.fl.us/mqa/pharmacy> or may be obtained by contacting the Board the Board of Pharmacy, at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850) 488-0595. Inquiries regarding the status of the application or license verification may be obtained at <http://www.FLHealthsource.com>. The application must be accompanied with a \$250 initial permit fee, payable to the Board.

(1)-(4) No Change

(5) Special Pharmacy Permits as authorized in Section 465.0196, F.S., is required for any location where medicinal drugs are compounded, dispensed, stored, or sold and which are not a community pharmacy, institutional pharmacy, nuclear pharmacy or internet pharmacy. Applicants for a Special-Limited Community, Special – Parenteral and Enteral, Special – Closed System Pharmacy, Special – End Stage Renal Disease (ESRD), Special – Parenteral/Enteral Extended Scope, and Special – Assisted Living Facility (ALF) permits must complete an application for a permit using an original Form DH-MQA 1220, “Special Pharmacy Permit Application and Information,” effective ~~August 2012~~ _____, which is incorporated by reference herein and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-02303>.

(5)(a)-(c) and (6)-(7) No Change

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 456.013, 456.025(3), 465.018, 465.019, 465.0193, 465.0196, 465.0197, 465.022 FS. History—New 2-21-13.

APPLICATION: December 4, 2013, Board approved changes to page 1 of Form DH-MQA 1220:

1. **Special- Limited Community Pharmacy Permit** are only available to Institutional Class II permittees as an additional permit to allow the Institutional Class II permit to provide medications to employees, medical staff, ~~and~~ up to a three-day supply of medication to patients being discharged under certain conditions, and to discharged patients of the hospital who are under a continuation of a course of therapy using multi-dose medicinal drugs when the requirements in rule 64B16-28.810(4) are met.

**DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4292**



**SPECIAL PHARMACY PERMIT APPLICATION AND
INFORMATION**

December 2013

Dear Florida Pharmacy Permit Applicant,

Thank you for applying for a pharmacy permit in the State of Florida. The information in this packet has been designed to provide the essential information required to process your application in a timely manner. Your assistance in providing all required information will enable the Florida Board of Pharmacy (the board) staff to process your application as soon as possible. You are encouraged to apply as early as possible, to avoid delays due to a large volume of applicants.

Florida Statutes require a completed application and fees before your application can be reviewed. Please read these instructions carefully and fully before submitting the application. You should keep a copy of the completed application and all other materials sent to the board office for your records. When you mail the completed application and fees, use the address noted in the instructions and on the application form.

When your application arrives, your fees will be deposited and verified before the staff review can begin. You will receive a letter acknowledging receipt of your application. The staff will notify you within 30 days if any materials are incomplete.

If you need to communicate with the board staff, you are encouraged to email the board staff at info@floridaspharmacy.gov, or you may call us at (850) 245-4292. Phone calls are returned within 24 hours and emails are responded to within 48 hours during normal business hours. Our staff is committed to providing prompt and reliable information to our customers. Many procedures have been streamlined to expedite the processing of applications; we certainly welcome your comments on how our services may be improved.

Sincerely,

The Board of Pharmacy

Special Pharmacy Permit Application Information

Whether opening a new establishment, changing locations, or changing owners, a pharmacy permit is required prior to operating in the State of Florida. The permit application must be completed and returned to the Florida Board of Pharmacy with the required fee of \$255.00. The application must have the original signatures of the owner or officer of the establishment and the Prescription Department Manager (PDM) or Consultant Pharmacist of Record.

Chapter 465, F.S., requires Special Pharmacies to be under the professional supervision of the PDM or Consultant Pharmacist of Record licensed in the State of Florida. A Florida licensed pharmacist shall perform compounding and dispensing of medicinal drugs.

Please read the descriptions below. Check which permit type you are applying on the application.

- 1. Special- Limited Community Pharmacy Permit** are only available to Institutional Class II permittees as an additional permit to allow the Institutional Class II permit to provide medications to employees, medical staff, up to a three-day supply of medication to patients being discharged under certain conditions, and to discharged patients of the hospital who are under a continuation of a course of therapy using multi-dose medicinal drugs when the requirements in rule 64B16-28.810(4) are met.
- 2. Special- Parenteral and Enteral Pharmacy Permits** provide parenteral (IV), enteral, and cytotoxic pharmacy services to outpatients. The applicant must be compliant with the Standard for Compounding Sterile Preparations found in Rule 64B16-27.797, F.A.C. The permittee must provide 24-hour telephone accessibility.
- 3. Special- Closed System Pharmacy Permits** provide medicinal drugs, utilizing closed delivery systems, to facilities where prescriptions are individually prepared for the ultimate consumer, including nursing homes, jails, Assisted Living Facilities (ALF's), Intermediate Care Facility/Mentally Retarded (ICF-MR's) or other custodial care facilities when defined by Agency for Health Care Administration (AHCA) rules. A Special- Closed System Pharmacy may share locations with an establishment that holds a Community Pharmacy Permit; however, recordkeeping and inventory for each permittee must be maintained separately and distinct.
- 4. Special- Non-Resident Registration** is required for those pharmacies located outside the state and ships, mails, or delivers a dispensed medicinal drug into this state.
- 5. Special- End Stage Renal Dialysis (ESRD) Pharmacy** provides dialysis products and supplies to persons with chronic kidney failure and requires the services of a Consultant Pharmacist.
- 6. Special- Parenteral/Enteral Extended Scope** is required to compound patient specific enteral/parenteral preparations in conjunction with institutional pharmacy permits, provided requirements set forth herein are satisfied.
- 7. Special- Assisted Living Facility (ALF)** is an optional permit for those ALF's providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging.

Application Processing

Please read all application instructions before completing your application.

- 1) Please mail the application and the \$255.00 application fee and fingerprint fees (check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

Department of Health
Board of Pharmacy
P.O. Box 6320
Tallahassee, Florida 32314-6320

OR, use the following address if you are using express mail:

Department of Health
Board of Pharmacy
4052 Bald Cypress Way, Bin C-04
Tallahassee, FL 32399-3254

Within 7-14 days of receipt of your application and fees, the board office will notify you of the receipt of your application, any required documents, and your status. If the application is complete, you will be notified that an inspector will contact you to setup an inspection appointment. Please do not contact the board office concerning your inspection date, and allow 30 days for the inspector to contact you. If the inspector has not contacted you within 30 days, then notify the board. If your application is incomplete, you will be notified in writing of what is required to make your application complete.

- 2) Submit fingerprint results

Failure to submit fingerprints will delay your application. All owners, officers and prescription department managers are required to submit a set of fingerprints unless the corporation is exempt under the Section 465.022, Florida Statutes for corporations having more than \$100 million of business taxable assets in this state. These corporations are only required to have the prescription department manager or consultant of record to submit fingerprints. The statute allows the prescription department manager for a corporation having more than \$100 million of business taxable assets in this state to submit results from AHCA if the results were also available to the Department and are within one year of the receipt date of the application. If the manager prints were submitted to DOH within one year of the date of the application, they are not required to submit them over.

Applicants can use any Livescan vendor that has been approved by the Florida Department of Law Enforcement to submit their fingerprints to the department. Please ensure that the Originating Agency Identification (ORI) number is provided to the vendor when you submit your fingerprints. If you do not provide an ORI number or if you provide an incorrect ORI number to the vendor, the Board of Pharmacy will not receive your fingerprint results. The applicant is fully responsible for selecting the vendor and ensuring submission of the prints to the Department.

1. **How do I find a Livescan vendor in order to submit my fingerprints to the department?**

The Department of Health accepts electronic fingerprinting service offered by Livescan device vendors that are approved by the Florida Department of Law

Enforcement and listed at their site. You can view the vendor options and contact information at <http://www.doh.state.fl.us/mqa/background.html>.

2. What information must I provide to the Livescan vendor I choose?

a) If you are an applicant seeking a license for any profession regulated by the Department of Health, which requires a criminal background search as a condition of licensure, you must provide accurate demographic information at the time your fingerprints are taken, **including your Social Security number**. The Department will not be able to process a submission that does not include your Social Security number

b) You must provide the correct ORI number.

3. Where do I get the ORI number to submit to the vendor?

The ORI number for the pharmacy profession is EDOH4680Z

3) Attestation for Business Taxable Assets

If the applicant has more than \$100 million dollars of business taxable assets in this state, please submit a formal opinion letter from a Certified Public Accountant duly licensed in the state of your principal place of business attesting the corporation has more than \$100 million of business taxable assets in this state for the previous tax year. In lieu of submitting a formal opinion letter from a Certified Public Accountant, the applicant may submit its Florida Corporate Income/Franchise and Emergency Excise Tax Return (Form F-1120, Effective 01/09).

4) Special- Parenteral and Enteral, and Special- Parenteral/Enteral Extended Scope Pharmacy Applicants must complete and submit answers to questions below with the application.

Special- Parenteral and Enteral and Special- Parenteral/Enteral Extended Scope Applicants Complete the Following Questions.

The Consultant Pharmacist of Record is responsible for developing and maintaining a current policy and procedure manual. The permittee must make available the policy and procedure manual to the appropriate state or federal agencies upon inspection. Do not send the policy and procedure manual to the board office. The board office will approve the policy and procedure manual based upon answers submitted for the following questions, where applicable, by using excerpts or summaries from the policy and procedure manual.

- 1) List the following:
Firm Name:
Doing business as (d/b/a):
Telephone number:
Address:
Permit number (if already licensed as an institutional pharmacy):
- 2) Explain the practice setting of the proposed facility.
- 3) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.

- 4) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.
- 5) Address the ratio of supportive personnel to each pharmacist. How will the supportive personnel be utilized? Include a job description for any such supportive personnel.
- 6) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.
- 7) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.
- 8) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.
- 9) Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.
- 10) Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.
- 11) What is the procedure for the annual review and updating of the policy and procedure manual?
- 12) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink, and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.
- 13) Include a sample copy of a patient profile.
- 14) Address the use of aseptic techniques.
- 15) Describe the Quality Assurance Program.
- 16) Describe with detail the policy and procedure for patient education, including the personnel involved.
- 17) Address the policy and procedure for handling waste and returns.
- 18) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.
- 19) Describe the refrigerator/freezer to be used.
- 20) Describe appropriate waste containers for:
 - a. Used needles and syringes.
 - b. Cytotoxic waste including disposable apparel used in preparation.
- 21) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.
- 22) Address the following references to be used:
 - a. Chapters 465 and 893, F.S., and Rule Title 64B16, F.A.C.

- b. Authoritative Therapeutic Reference.
 - c. Handbook of Injectable Drugs by American Society of Health-System Pharmacists.
- 23) Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.

If applying for a Special- Parenteral/Enteral Extended Scope Permit, answer the additional questions below:

- 24) Describe the individual responsibilities of the Special- Parenteral/Enteral Extended Scope Permit and the supplied institutional pharmacy permits, if applicable.
- 25) Address the maintenance of patient profiles and the offer to counsel if dispensing to outpatients.
- 26) Describe the system for the maintenance of compounding records.

An application for a pharmacy permit must include the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. Submit a copy of your policy and procedure manual with your application. The board must review the policies and procedures and may deny a permit if the policies and procedures are insufficient to reasonably prevent such dispensing.

Licensure Process

Once the application is deemed complete, the board staff authorizes an inspection. Upon completion of the inspection, the inspector notifies the board office as to whether the inspection was satisfactory or unsatisfactory. If the inspection is satisfactory, a permit number is issued within 10 days. **Please wait 15 days from your satisfactory inspection before checking on the status of your permit.** You may lookup your license number on our website at <http://www.doh.state.fl.us/mqa> under “Lookup Licensee.”

Drug Enforcement Administration (DEA)

The DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit.

If controlled substances will be involved in your pharmacy practice, you must make an Application for Registration under the Controlled Substance Act of 1970 with the DEA. If possible, you are encouraged to use the on-line form system provided by the DEA. Information is available by visiting their website at <http://www.DEAdiversion.usdoj.gov>. DEA Form 224 may be obtained in paper form by writing to:

Drug Enforcement Administration
Attn: ODR
PO Box 2639
Springfield, VA 22152-2639

Form 224 should be completed and mailed via U.S. Postal service to the address listed on the form.

Contact DEA at 1-800-667-9752 or 954-306-4654 for information on change of location or change of name.

If your pharmacy does change locations, you are required to have a pharmacy inspection prior to operating in the new location.

PRE-INSPECTION CHECKLIST

- _____ Is there an adequate sink in workable condition that is easily accessible to the prescription counter that will be available during the hours when the prescription department is normally open for business pursuant to Rule 64B16-28.102, F.A.C.?
- _____ Is the pharmacy department equipped an area suitable for private patient counseling if applying for a community pharmacy permit pursuant to Rule 64B16-28.1035, F.A.C.?
- _____ Are all required signs displayed?
- Daily operating hours pursuant to Rule 64B16-28.1081, F.A.C.
 - “Consult your pharmacist regarding the availability of a less expensive generically equivalent drug and the requirements of Florida law” pursuant to Section 465.025(7), F.S.
 - Prescription Department Closed pursuant to Rule 64B16-28.109, F.A.C.
 - Pharmacist meal breaks pursuant to Rule 64B16-27.1001(6), F.A.C.
 - Patient Consultation Area pursuant to Rule 64B16-28.1035, F.A.C.
- _____ If compounding sterile preparations submit an additional application on form DH-MQA 1270 Special Sterile Compounding Pharmacy Permit Application.

You may download a copy of the inspection form from the website at <http://www.floridahealth.gov/licensing-and-regulation/enforcement/inspection-program/inspection-forms.html>

IMPORTANT NOTICE: The department or board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:

- (a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009.**
- (b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009.**
- (c) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period.**
- (d) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application.**
- (e) Has obtained a permit by misrepresentation or fraud.**
- (f) Has attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation.**
- (g) Has been convicted of, or entered 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, the profession of pharmacy.**
- (h) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.**
- (i) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.**
- (j) Has dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. [465.003\(14\)](#) or s. [893.02](#) when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.**

If applicable to you, please provide the documentation to the Florida Board of Pharmacy.



**FLORIDA BOARD OF
PHARMACY**
P.O. Box 6320
Tallahassee, FL 32314-6320
Telephone (850) 488-0595

SPECIAL PHARMACY PERMIT APPLICATION

Application Type – Please choose one of the following:

- New Establishment \$255 fee(1022)**
 Change of Location \$100 fee (3011) _____ (existing permit number)
 Change of Ownership (a new permit number will be issued) \$255 (1022) _____ (existing permit number)

Type of Special Pharmacy Permit - Please choose one of the following:

- Special- Limited Community** _____ **Special- Parenteral and Enteral** _____ **Special- Closed System Pharmacy**
 Special- ESRD _____ **Special- Parenteral/Enteral Extended Scope** _____ **Special- ALF**

Will the Pharmacy Dispense Schedule II and/or III Controlled Substances? **Yes** **No**

Please list your Federal Employer Identification Number _____

1. Corporate Name	Telephone Number

2. Doing Business As (d/b/a)	E-Mail Address

3. Mailing Address

City	State	Zip

4. Physical Address

City	State	Zip

5. List Prescription Department Manager (PDM) or Consultant Pharmacist of Record			
Name	License No.	Start Date	Signature

6. Contact Person	Telephone Number

7. DEA Registration Number	8. Date ready for inspection (must be within 90 days of the date of the application)

9. Please provide the name, address, telephone number, and permit number of your prescription drug wholesale distributor. If not available you may write in pending.

Name	Telephone Number	Permit Number	
Street Address	City	State	Zip

10. Pharmacy Technician Ratio 2:1 or 3:1 (Optional)

13a Has anyone listed in 12.d had an ownership interest of 5% or more in a pharmacy or any other business permit which was voluntarily relinquished or closed voluntarily within the past 5 years?

Yes _____ No _____ If yes, please provide a signed affidavit disclosing the reason the entity was closed.

14. Has anyone listed in 12.d ever obtained a pharmacy permit by misrepresentation or fraud or been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud?

Yes _____ No _____ If yes, please provide documents concerning this conviction.

Pursuant to Section 456.0635(2) and 465.022(5), *Florida Statutes*, questions 15 through 21 are being asked. If you answer yes to any of the following questions, explain on a separate sheet providing accurate details and submit copies of supporting documentation.

15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, Chapter 817, or Chapter 893, Florida Statutes; or a similar felony offense in another state or jurisdiction since July 1, 2009? (If yes, provide court documents concerning this conviction)

Yes _____ No _____

15a. If “yes” to 15, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).

Yes _____ No _____

15b. If “yes” to 15, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?

Yes _____ No _____

15c. If “yes” to 15, has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If “yes”, please provide supporting documentation).

Yes _____ No _____

16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication to a felony under 21 U.S.C. ss.801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

16a. If “yes” to 16, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?

Yes _____ No _____

17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 19.)

(If yes, explain on a separate sheet providing accurate details)

Yes _____ No _____

18. If the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant has been terminated, has the applicant been reinstated and in good standing with the Florida Medicaid Program for the most recent five years?

(If yes, explain on a separate sheet providing accurate details)

Yes _____ No _____

19. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 21 and 22)

(If yes, explain on a separate sheet providing accurate details)

Yes _____ No _____

20. Has the applicant been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?

(If yes, explain on a separate sheet providing accurate details)

Yes _____ No _____

21. Did the termination occur at least 20 years prior to the date of this application?

(If yes, explain on a separate sheet providing accurate details)

Yes _____ No _____

22. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant listed on the United States Department of Health Human Services Office of Inspector General's List of Excluded Individuals and Entities?

Yes _____ No _____ (If yes, submit proof)

23. Are you currently registered or permitted in any other states? If yes, provide the state, permit type, and permit number for each permit. *Attach a separate sheet if necessary.*

Yes _____ No _____

State	Permit Type	Permit Number

24. Has the applicant, affiliated persons, partners, officer, directors, or PDM or Consultant Pharmacist of Record ever owned a pharmacy? If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. *Attach a separate sheet if necessary.*

Yes _____ No _____ (If yes, please list them below, you may provide additional sheet)

Pharmacy Name	State	Status

25. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated persons, partners, officers, directors or Consultant Pharmacist of Record in this state or any other?
Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details and submit documentation from the licensing agency who took the disciplinary action)
26. Has the applicant, or any officer, member or partner ever been convicted of a felony or misdemeanor, excluding minor traffic convictions?
Yes _____ No _____ (You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is <u>NOT</u> a minor traffic offense for the purposes of this question.)
27. Is there any other permit issued by the Department of Health located at the physical location address on this application?
No _____ Yes _____ (If yes, explain on a separate sheet providing accurate details)
28. Does the applicant, affiliated person, partner, officer, director have any outstanding fines, liens or overpayments assessed by a final order of the department? If yes, please answer 29a.
No _____ Yes _____ (If yes, explain on a separate sheet providing accurate details)
28a. Does the applicant, affiliated person, partner, officer, director have a repayment plan approved by the department?
No _____ Yes _____
29. Is the policy and procedure manual for preventing controlled substance dispensing based on fraudulent representation or invalid practitioner-patient relationship available for inspection by DOH?
No _____ Yes _____
30. I have been provided and read the statement from the Florida Department of Law Enforcement regarding sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation. (Found on Page 8 of this application.)
Yes _____ No _____

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I certify that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board, or any municipal, county, state, or federal governmental agencies or units, and I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

Under penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that providing false information may result in disciplinary action against my license or criminal penalties.

SIGNATURE _____ TITLE _____ DATE _____

Owner/Officer

PHARMACY PERMIT 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 attach any required document, or to have required documentation sent to the Board, will result in an incomplete application. Final approval for inspection cannot be granted until the application is complete. Faxed applications will not be accepted.

- Application completed (all questions answered)**
- Application signed**
- Consultant Pharmacist of Record/Prescription Department Manager Listed with Signature**
- \$255.00 Fee Attached (Permit fee includes \$250 application fee and \$5.00 unlicensed activity fee)**
- Copy of Articles of Incorporation from the Secretary of State's Office**
- Fingerprints have been submitted via livescan for all officers and owners and the prescription department manager or consultant pharmacist of record.**
- Attach proof from AHCA of fingerprint results if applicable for prescription department manager or consultant pharmacist of record. Fingerprint results must be within one year of the application date.**
- Attestation for Business Taxable Assets of \$100 million if applicable**
- Bill of Sale is required for Change of Ownership**

Electronic Fingerprinting

Take this form with you to the Live Scan service provider. Please check the service provider's requirements to see if you need to bring any additional items.

- Background screening results are obtained from the Florida Department of Law Enforcement and the Federal Bureau of Investigation by submitting to a fingerprint scan using the livescan method;
- You can find a Livescan service provider at: <http://www.doh.state.fl.us/mqa/background.html>;
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida Department of Law Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the livescan service provider the Board office will not receive your background screening results;
- You must provide accurate demographic information to the livescan service provider at the time your fingerprints are taken, **including your Social Security number (SSN)**;
- If you do not have a SSN you will need to contact the Board office for a fingerprint card then return the card to the Board office;
- The ORI number for the Board of Pharmacy is EDOH4680Z
- Typically background screening results submitted through a Livescan service provider are received by the Board within 24-72 hours of being processed.
- If you obtain your livescan from a service provider who does not capture your photo you may be required to be reprinted by another agency in the future.

Name: _____ Social Security Number: _____

Aliases: _____

Date of Birth: _____ Place of Birth: _____ (MM/DD/YYYY)

Citizenship: _____ Race: _____ (W-White/Latino(a); B-Black; A-Asian; NA-Native American; U-Unknown)

Sex: _____ Weight: _____ Height: _____
(M=Male; F=Female)

Eye Color: _____ Hair Color: _____

Address: _____ Apt. Number: _____

City: _____ State: _____ Zip Code: _____

Transaction Control Number (TCN#): _____
(This will be provided to you by the Live Scan Service provider.)

Keep this form for your records.

FLORIDA DEPARTMENT OF LAW ENFORCEMENT

NOTICE FOR APPLICANTS SUBMITTING FINGERPRINTS WHERE CRIMINAL RECORD RESULTS WILL BECOME PART OF THE CARE PROVIDER BACKGROUND SCREENING CLEARINGHOUSE

NOTICE OF:

- **SHARING OF CRIMINAL HISTORY RECORD INFORMATION WITH SPECIFIED AGENCIES,**
- **RETENTION OF FINGERPRINTS,**
- **PRIVACY POLICY, AND**
- **RIGHT TO CHALLENGE AN INCORRECT CRIMINAL HISTORY RECORD**

This notice is to inform you that when you submit a set of fingerprints to the Florida Department of Law Enforcement (FDLE) for the purpose of conducting a search for any Florida and national criminal history records that may pertain to you, the results of that search will be returned to the Care Provider Background Screening Clearinghouse. By submitting fingerprints, you are authorizing the dissemination of any state and national criminal history record that may pertain to you to the Specified Agency or Agencies from which you are seeking approval to be employed, licensed, work under contract, or to serve as a volunteer, pursuant to the National Child Protection Act of 1993, as amended, and Section 943.0542, Florida Statutes. "Specified agency" means the Department of Health, the Department of Children and Family Services, the Division of Vocational Rehabilitation within the Department of Education, the Agency for Health Care Administration, the Department of Elder Affairs, the Department of Juvenile Justice, and the Agency for Persons with Disabilities when these agencies are conducting state and national criminal history background screening on persons who provide care for children or persons who are elderly or disabled. The fingerprints submitted will be retained by FDLE and the Clearinghouse will be notified if FDLE receives Florida arrest information on you.

Your Social Security Number (SSN) is needed to keep records accurate because other people may have the same name and birth date. Disclosure of your SSN is imperative for the performance of the Clearinghouse agencies' duties in distinguishing your identity from that of other persons whose identification information may be the same as or similar to yours.

Licensing and employing agencies are allowed to release a copy of the state and national criminal record information to a person who requests a copy of his or her own record if the identification of the record was based on submission of the person's fingerprints. Therefore, if you wish to review your record, you may request that the agency that is screening the record provide you with a copy. After you have reviewed the criminal history record, if you believe it is incomplete or inaccurate, you may conduct a personal review as provided in s. 943.056, F.S., and Rule 11C-8.001, F.A.C. If national information is believed to be in error, the FBI should be contacted at 304-625-2000. You can receive any national criminal history record that may pertain to you directly from the FBI, pursuant to 28 CFR Sections 16.30-16.34. You have the right to obtain a prompt determination as to the validity of your challenge before a final decision is made about your status as an employee, volunteer, contractor, or subcontractor.

Until the criminal history background check is completed, you may be denied unsupervised access to children, the elderly, or persons with disabilities.

The FBI's Privacy Statement follows on a separate page and contains additional information.
US Department of Justice, Federal Bureau of Investigation,
Criminal Justice Information Services Division

Privacy Statement

Authority: The FBI's acquisition, preservation and exchange of information requested by this form is generally authorized under 28 U.S.C. 534. Depending on the nature of your application, supplemental authorities include numerous Federal statutes, hundreds of State statutes pursuant to Pub.L.92-544, Presidential executive orders, regulations and/or orders of the Attorney General of the United States, or other authorized authorities. Examples include, but are not limited to: 5 U.S.C. 9101; Pub.L.94-29; Pub.L.101-604; and Executive Orders 10450 and 12968. Providing the requested information is voluntary; however, failure to furnish the information may affect timely completion of approval of your application.

Social Security Account Number (SSAN): Your SSAN is needed to keep records accurate because other people may have the same name and birth date. Pursuant to the Federal Privacy Act of 1974 (5 USC 552a), the requesting agency is responsible for informing you whether disclosure is mandatory or voluntary, by what statutory or other authority your SSAN is solicited, and what uses will be made of it. Executive Order 9397 also asks Federal Agencies to use this number to help identify individuals in agency records.

Principal Purpose: Certain determinations, such as employment, security, licensing and adoption, may be predicated on fingerprint based checks. Your fingerprints and other information contained on (and along with) this form may be submitted to the requesting agency, the agency conducting the application investigation, and/or FBI for the purpose of comparing the submitted information to available records in order to identify other information that may be pertinent to the application. During the processing of this application, and for as long hereafter as may be relevant to the activity for which this application is being submitted, the FBI(may disclose any potentially pertinent information to the requesting agency and/or to the agency conducting the investigation. The FBI may also retain the submitted information in the FBI's permanent collection of fingerprints and related information, where it will be subject to comparisons against other submissions received by the FBI. Depending on the nature of your application, the requesting agency and/or the agency conducting the application investigation may also retain the fingerprints and other submitted information for other authorized purposes of such agency(ies).

Routine Uses: The fingerprints and information reported on this form may be disclosed pursuant to your consent, and may also be disclosed by the FBI without your consent as permitted by the Federal Privacy Act of 1974 (5 USC 552a(b)) and all applicable routine uses as many be published at any time in the Federal Register, including the routine uses for the FBI Fingerprint Identification Records System (Justice, FBI-009) and the FBI's Blanket Routine Uses (Justice/FBI-BRU). Routine uses include, but are not limited to, disclosures to: appropriate governmental authorities responsible for civil or criminal law enforcement counterintelligence, national security or public safety matters to which the information may be relevant; to State and local governmental agencies and nongovernmental entities for application processing as authorized by Federal and State legislation, executive order, or regulation, including employment, security, licensing, and adoption checks; and as otherwise authorized by law , treaty, executive order, regulation, or other lawful authority. If other agencies are involved in processing the application, they may have additional routine uses.

Additional Information: The requesting agency and/or the agency conducting the application investigation will provide you additional information pertinent to the specific circumstances of this application, which may include identification of other authorities, purposes, uses, and consequences of not providing requested information. In addition, any such agency in the Federal Executive Branch has also published notice.

TAB 1. 64B16-26.2034: Direct Supervision of a Registered Pharmacy Technician (New)

Section 465.014(1), Florida Statutes, requires that when a pharmacist delegates acts to be performed by a registered pharmacy technician, the delegated acts must be under the direct supervision of the pharmacist making such delegation. The Board has not formally defined the term direct supervision. The term should be defined by rule of the Board. This rule has been noticed for development in the Florida Administrative Register.

Proposed Definition Discussed February 2014:

64B16-26.2034 Direct Supervision of a Registered Pharmacy Technician.

(1) When a licensed pharmacist delegates a task or tasks to a registered pharmacy technician, the task or tasks performed by the registered pharmacy technician must be performed under the direct supervision of the delegating pharmacist.

(2) Direct Supervision: means the licensed pharmacist has authorized the task or tasks to be performed and is present in the pharmacy or pharmacy suite and immediately available to provide assistance and direction throughout the time the delegated task or tasks is or are being performed by the registered pharmacy technician.

Rulemaking Authority 465.005 FS. Law Implemented 465.014 FS. History–New

Other Proposed language:

(1) Direct Supervision, pursuant to Section 465.014, shall have the same meaning as direct personal supervision.

(2) Direct Supervision: means the physical or real-time act of oversight and management by a licensed pharmacist of a pharmacy technician’s work or work product. Pharmacy Technicians must be under direct supervision either through a direct line of sight and hearing, or via technological means that allow a pharmacist to adequately ensure quality of that work or work product. If a pharmacy is using technological means to supervise technicians, they must have documented policies and procedures and other adequate safeguards to protect against patient harm, diversion, and privacy incidents.

Note: Board Counsel suggests not including (1) and instead revise existing rules to consistently use “direct supervision” when referring to pharmacy technicians. Also, direct supervision for RPTs should

be clearly distinguished from the “direct and immediate personal supervision” required for pharmacy interns.

For consideration: Does “direct and immediate personal supervision” for interns also need to be defined?

Suggested Hybrid Revision and Notes by Board Counsel:

(1) When a licensed pharmacist delegates a task or tasks to a registered pharmacy technician, those tasks must be performed under the direct supervision of the delegating pharmacist.

(2) “Direct Supervision” means the physical or real-time act of oversight and management of a pharmacy technician’s work and work product by a licensed pharmacist. Registered pharmacy technicians must be in a direct line of sight and hearing either physically or via technological means that allow an on-site pharmacist to ensure the quality of the technician’s work and work product. If a pharmacy is using technological means to supervise technicians, the pharmacy must have documented policies and procedures and other adequate safeguards to protect against patient harm, diversion, and privacy incidents.

NOTES AND THINGS TO CONSIDER:

- Rules citing “direct personal supervision” and “direct and immediate personal supervision” for pharmacy technicians are presented below.
- Please consider changing these terms to “direct supervision,” which will now have a definition.
- What does “a continuing review and ultimate supervision” mean in rule 27.1001(7)?
- “Direct and immediate personal supervision” in Chapter 465 refers to pharmacists and pharmacy interns. “Direct personal supervision” in rule 64B16-27.105 should be consistent with the statutes and be changed to “direct and immediate personal supervision.”

Those functions within the definition of the practice of the profession of pharmacy, as defined by Section 465.003(13), F.S., are specifically reserved to a pharmacist or a duly registered pharmacy intern in this state acting under the direct and immediate personal supervision of a pharmacist. The following subjects come solely within the purview of the pharmacist.

(1) A pharmacist or registered pharmacy intern must:

(a) Supervise and be responsible for the controlled substance inventory.

(b) Receive verbal prescriptions from a practitioner.

(c) Interpret and identify prescription contents.

(d) Engage in consultation with a practitioner regarding interpretation of the prescription and date in patient profile.

(e) Engage in professional communication with practitioners, nurses or other health professionals.

(f) Advise or consult with a patient, both as to the prescription and the patient profile record.

(2) When parenteral and bulk solutions of all sizes are prepared, regardless of the route of administration, the pharmacist must:

(a) Interpret and identify all incoming orders.

(b) Mix all extemporaneous compounding or be physically present and give direction to the registered pharmacy technician for reconstitution, for addition of additives, or for bulk compounding of the parenteral solution.

(c) Physically examine, certify to the accuracy of the final preparation, thereby assuming responsibility for the final preparation.

(d) Systemize all records and documentation of processing in such a manner that professional responsibility can be easily traced to a pharmacist.

(3) Only a pharmacist may make the final check of the completed prescription thereby assuming the complete responsibility for its preparation and accuracy.

(4) The pharmacist, as an integral aspect of dispensing, shall be directly and immediately available to the patient or the patient's agent for consultation and shall not dispense to a third party. No prescription shall be deemed to be properly dispensed unless the pharmacist is personally available.

(5) The pharmacist performing in this state any of the acts defined as "the practice of the profession of pharmacy" in Section 465.003(13), F.S., shall be actively licensed as a pharmacist in this state, regardless of whether the practice occurs in a permitted location (facility) or other location.

(6) The pharmacist may take a meal break, not to exceed 30 minutes in length, during which the pharmacy department of a permittee shall not be considered closed, under the following conditions:

(a) The pharmacist shall be considered present and on duty during any such meal break if a sign has been prominently posted in the pharmacy indicating the specific hours of the day during which meal breaks may be taken by the pharmacist and assuring patients that a pharmacist is available on the premises for consultation upon request during a meal break.

(b) The pharmacist shall be considered directly and immediately available to patients during such meal breaks if patients to whom medications are delivered during meal breaks are verbally informed that they may request that a pharmacist contact them at the pharmacist's earliest convenience after the meal break, and if a pharmacist is available on the premises during the meal break for consultation regarding emergency matters. Only prescriptions with the final certification by the pharmacist may be delivered.

(c) The activities of registered pharmacy technicians during such a meal break shall be considered to be under the ~~direct and immediate personal supervision~~ of a pharmacist if the pharmacist is available on the premises during the meal break to respond to questions by the technicians, and if at the end of the meal break the pharmacist certifies all prescriptions prepared by the registered pharmacy technicians during the meal break.

(7) The delegation of any duties, tasks or functions to registered pharmacy interns and registered pharmacy technicians must be performed subject to a **continuing review and ultimate supervision** of the pharmacist who instigated the specific task, so that a continuity of supervised activity is present between one pharmacist and one registered pharmacy technician. In every pharmacy, the pharmacist shall retain the professional and personal responsibility for any delegated act performed by registered pharmacy interns and registered pharmacy technicians in the licensee's employ or under the licensee's supervision.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.003(11)(b), (13), 465.014, 465.026 FS. History—New 11-18-07, Amended 1-1-10.

64B16-27.105 Transfer of Prescriptions.

(1) A pharmacist or registered pharmacy intern acting under the **direct and immediate personal supervision** of a Florida ~~licensed registered pharmacist~~ licensed pharmacist may transfer a valid prescription which is on file in another pharmacy in this state or any other state if such transfer is consistent with the conditions set forth in Section 465.026, F.S. Prior to dispensing, the pharmacist or pharmacy where the prescription is on file shall be notified verbally, or by any electronic means that the former prescription must be voided.

(2) In processing a transferred prescription pursuant to Section 465.026, F.S., the pharmacist has the option of substituting a generically equivalent product if such substitution is consistent with the provisions of Section 465.025, F.S.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.026 FS. History—New 1-3-79, Formerly 21S-1.33, 21S-1.033, Amended 7-30-91, Formerly 21S-27.105, 61F10-27.105, Amended 9-19-94, Formerly 59X-27.105, Amended 6-15-98.

64B16-27.410 Registered Pharmacy Technician, to Pharmacist Ratio.

(1) Registered pharmacy technicians may assist a pharmacist in performing professional services within a pharmacy environment provided that no pharmacist shall supervise more than one registered pharmacy technician unless otherwise permitted by the Florida Board of Pharmacy. A pharmacist's supervision of a registered pharmacy technician in a working environment requires that a registered pharmacy technician be under the **direct personal supervision** of a licensed pharmacist.

(2) The prescription department manager or consultant pharmacist of record is required to submit a written request and receive approval prior to the pharmacy's allowing a pharmacist to supervise more than one registered pharmacy technician as permitted by law. Such requests shall be reviewed and pre-approved by Board staff according to the guidelines adopted herein, and submitted to the Board for ratification.

(3) The request to practice with a ratio greater than 1:1 shall include a brief description of the workflow needs that justify the ratio request. The brief description of workflow needs shall include the operating hours of the pharmacy, number of pharmacists, registered interns, and registered pharmacy technicians employed.

(4) A pharmacy that employs pharmacy technicians shall meet the following conditions:

(a) Establish written job descriptions, task protocols, and policies and procedures that pertain to duties performed by the registered pharmacy technician and provide this information to the Board upon request;

(b) Establish that each registered pharmacy technician is knowledgeable in the established job descriptions, task protocols, and policy and procedures in the pharmacy setting in which the technician is to perform his or her duties;

(c) Ensure that the duties assigned to any registered pharmacy technician do not exceed the established job descriptions, task protocols, and policy and procedures, nor involve any of the prohibited tasks in Rule 64B16-27.420, F.A.C.; or

(d) Ensure that each registered pharmacy technician receives employer-based or on-the-job training in order for the registered pharmacy technician to assume his or her responsibilities and maintain documentation of the training.

(5) The pharmacy shall maintain a policy and procedure manual with regard to registered pharmacy technicians which shall include the following:

(a) Supervision by a pharmacist;

(b) Minimum qualifications as established by law;

(c) Documentation of in-service education and/or on-going training and demonstration of competency, specific to practice site and job function;

(d) General duties and responsibilities of registered pharmacy technicians;

(e) Retrieval of prescription files, patient files, patient profile information and other records pertaining to the practice of pharmacy;

(f) All functions related to prescription processing;

(g) All functions related to prescription legend drug and controlled substance ordering and inventory control, including procedures for documentation and recordkeeping;

(h) Prescription refill and renewal authorization;

(i) Registered pharmacy technician functions related to automated pharmacy systems; and

(j) Continuous quality improvement program.

Rulemaking Authority 465.005 FS. Law Implemented 465.014, 893.07(1)(b) 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.

Law Implemented (for technicians requiring direct supervision):

465.014 Pharmacy technician.—

(1) A person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the purview of s. 465.003(13). **All such delegated acts shall be performed under the direct supervision of a licensed pharmacist who shall be responsible for all such acts performed by persons under his or her supervision.** A pharmacy registered technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization requests. A licensed pharmacist may not supervise more than one registered pharmacy technician unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one but not more than three pharmacy technicians.

(2) Any person who wishes to work as a pharmacy technician in this state must register by filing an application with the board on a form adopted by rule of the board. The board shall register each applicant who has remitted a registration fee set by the board, not to exceed \$50 biennially; has completed the application form and remitted a nonrefundable application fee set by the board, not to exceed \$50; is at least 17 years of age; and has completed a pharmacy technician training program approved by the Board of Pharmacy. Notwithstanding any requirements in this subsection, any registered pharmacy technician registered pursuant to this section before January 1, 2011, who has worked as a pharmacy technician for a minimum of 1,500 hours under the supervision of a licensed pharmacist or received certification as a pharmacy technician by certification program accredited by the National Commission for Certifying Agencies is exempt from the requirement to complete an initial training program for purposes of registration as required by this subsection.

(3) A person whose license to practice pharmacy has been denied, suspended, or restricted for disciplinary purposes is not eligible to register as a pharmacy technician.

(4) Notwithstanding the requirements of this section or any other provision of law, a pharmacy technician student who is enrolled in a pharmacy technician training program that is approved by the board may be placed in a pharmacy for the purpose of obtaining practical training. A pharmacy technician student shall wear identification that indicates his or her student status when performing the functions of a pharmacy technician, and registration under this section is not required.

(5) Notwithstanding the requirements of this section or any other provision of law, a person who is licensed by the state as a pharmacy intern may be employed as a registered pharmacy technician without paying a registration fee or filing an application with the board to register as a pharmacy technician.

(6) As a condition of registration renewal, a registered pharmacy technician shall complete 20 hours biennially of continuing education courses approved by the board or the Accreditation Council for Pharmacy Education, of which 4 hours must be via live presentation and 2 hours must be related to the prevention of medication errors and pharmacy law.

(7) The board shall adopt rules that require each registration issued by the board under this section to be displayed in such a manner as to make it available to the public and to facilitate inspection by the department. **The board may adopt other rules as necessary to administer this section.**

(8) If the board finds that an applicant for registration as a pharmacy technician or that a registered pharmacy technician has committed an act that constitutes grounds for discipline as set forth in s. 456.072(1) or has committed an act that constitutes grounds for denial of a license or disciplinary action as set forth in this chapter, including an act that constitutes a substantial violation of s. 456.072(1) or a violation of this chapter which occurred before the applicant or registrant was registered as a pharmacy technician, the board may enter an order imposing any of the penalties specified in s. 456.072(2) against the applicant or registrant.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 10, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 242, ch. 97-103; s. 192, ch. 97-264; s. 120, ch. 99-397; ss. 2, 3, 4, ch. 2008-216.

Law Implemented (for interns requiring “direct and immediate personal supervision):

465.016(1)(c) (Disciplinary Actions) Permitting any person not licensed as a pharmacist in this state or not registered as an intern in this state, or permitting a **registered intern** who is not acting under the **direct and immediate personal supervision** of a licensed pharmacist, to fill, compound, or dispense any prescriptions in a pharmacy owned and operated by such pharmacist or in a pharmacy where such pharmacist is employed or on duty.

64B16-27.430 Responsibilities of the Pharmacist.

The delegation of any duties, tasks or functions to registered pharmacy interns and registered pharmacy technicians must be performed subject to a continuing review and ultimate supervision of the pharmacist who instigated the specific task, so that a continuity of supervised activity is present between one (1) pharmacist and one (1) registered pharmacy technician. In every pharmacy, the licensed pharmacist shall retain the professional and personal responsibility for any delegated act performed by registered pharmacy interns and registered pharmacy technicians in his employ and under his supervision.

Rulemaking Authority 465.005 FS. Law Implemented 465.014 FS. History—New 2-14-77, Formerly 21S-4.03, Amended 9-1-87, Formerly 21S-4.003, 21S-27.430, 61F10-27.430, 59X-27.430, Amended 1-1-10.

TAB 2. 64B16-28.450 Centralized Prescription Filling, Delivering and Returning.

For Review of subparagraph (6)(a)1. labeling and whether clarity is needed regarding no application needed.

64B16-28.450 Centralized Prescription Filling, Delivering and Returning.

(1) As used herein:

(a) The term “originating pharmacy” means a pharmacy wherein the prescription which will be filled by the central fill pharmacy is initially presented; and

(b) The term “central fill pharmacy” means a pharmacy which performs centralized prescription filling, delivering, and returning for one or more originating pharmacies.

(2) Pharmacies acting as the central fill pharmacy must be authorized to dispense medications under the provisions of Chapter 465, F.S., and the rules promulgated thereto.

(3) A community pharmacy which acts as the central fill pharmacy and which notifies the Board that its pharmacy practice is limited only to such practice shall be exempt from the following rules:

(a) Rule 64B16-28.1035, F.A.C., Patient Consultation Area;

(b) The signage requirement of subsection 64B16-28.109(1), F.A.C.; and

(c) Rule 64B16-28.1081, F.A.C., Regulation of Daily Operating Hours.

(4) All central fill and originating pharmacies engaged in centralized prescription filling shall create and keep current a Policy and Procedure Manual which shall:

(a) Be maintained at the locations of the central fill and originating pharmacies;

(b) Include the information required in Sections 465.0265(2)(a)-(f), F.S.

(5) Delivery of medications. Delivery of medications must be made in a timely manner. The originating and central fill pharmacies shall each be identified on the prescription container.

(a) Delivery by central fill pharmacy to ultimate consumer. A central fill pharmacy may deliver medications for an originating pharmacy to the ultimate consumer or the consumer’s agent under the following conditions:

1. The pharmacies are under the same ownership or have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with federal and state laws, rules and regulations.

2. The pharmacies shall have a pharmacist available 40 hours a week, either in person or via two-way communication technology, such as a telephone, to provide patient counseling.

3. The pharmacies shall include a toll-free number that allows the patient to reach a pharmacist for the purposes of patient counseling.

4. The pharmacies shall each be identified on the prescription container label. The originating pharmacy shall be identified with pharmacy name and address. The central fill pharmacy may be identified by a code available at the originating pharmacy.

5. The central fill pharmacy shall only deliver via carrier to the ultimate consumer or the consumer's agent those medications which could have been delivered via carrier by the originating pharmacy.

6. The central fill pharmacy shall not deliver to the ultimate consumer or consumer's agent substances listed as controlled substances under Chapter 893, F.S.

(b) The delivery of a filled prescription by a central fill pharmacy to the ultimate consumer or the consumer's agent pursuant to a contract with an originating pharmacy shall not be considered dispensing within the definition set forth in Section 465.003(6), F.S.

(c) Each pharmacist that performs a specific function within the processing of the prescription shall be responsible for any errors or omissions committed by that pharmacist during the performance of that specific function.

(6) The supplying and receiving pharmacy shall each be identified on the prescription container label. The receiving pharmacy shall be identified with pharmacy name and address. The supplying pharmacy may be identified by a code available at the receiving pharmacy. Prescription and labeling requirements for pharmacies participating in central prescription filling, delivering and returning:

(a) Prescriptions may be transmitted electronically from an originating pharmacy to a central fill pharmacy including via facsimile. The originating pharmacy transmitting the prescription information must:

1. Write the word "central fill" on the face of the original prescription and record the name, address, and DEA registration number if a controlled substance of the originating pharmacy to which the prescription has been transmitted and the name of the originating pharmacy's pharmacist transmitting the prescription, and the date of transmittal;

2. Ensure all the information required to be on a prescription pursuant to Sections 456.0392 and 893.04, F.S., is transmitted to the central fill pharmacy either on the face of the prescription or in the electronic transmission of information;

3. Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining;

4. Maintain the original prescription for a period of four (4) years from the date the prescription was last refilled.

5. Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the originating pharmacy's employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

1. Keep a copy of the prescription if sent via facsimile, or an electronic record of all the information transmitted by the originating pharmacy, including the name, address, and DEA registration number, if a controlled substance, of the originating pharmacy transmitting the prescription;

2. Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription;

3. Keep a record of the date the filled prescription was delivered to the originating pharmacy and the method of delivery (private, common or contract carrier).

4. A central fill pharmacy's pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing the date of filling, the receiving pharmacy's name and address, a unique identifier (i.e. the supplying pharmacy's DEA registration number) indicating the prescription was filled at the central fill pharmacy, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.

Rulemaking Authority 465.005, 465.0265 FS. Law Implemented 465.003(16), 465.0265 FS. History—New 9-23-03, Amended 7-27-04, 4-28-08; _____.

Tab 3. 64B16-28.101: Citations.

Request to add standardized language to citation rule to be consistent with Boards of Medicine, Dentistry, Osteopathic Medicine, and Podiatric Medicine.

64B16-30.003 Citations.

(1) Pursuant to Section 456.077, F.S., the Board sets forth in (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 (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).
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(b) Operating a pharmacy with an inactive permit (465.015(1)(a), F.S.)	\$500 per month to a maximum of \$5000 (penalty will require permittee to renew permit or cease practice).
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(c) First time failure to complete the required continuing education during the biennial licensure period.(456.072(3), F.S.)

Failure to complete less than 10 hours	\$500
Failure to complete 10 or more hours	\$1000

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
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	and/or costs).
(e) Failure to display any sign, license or permit required by statute or rule.	\$500
(f) Failure to have any reference material required by statute or rule available.	\$500
(g) Failure to notify the board of a change in a prescription department manager or consultant pharmacist.	Fine based on the length of time prior to notifying board. \$200 a month to \$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.	\$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	\$500

Human immunodeficiency virus and
Acquired immune deficiency
syndrome (HIV/AIDS), or medical errors

(k) Failure to correct \$250

Minor violation as listed in
Rule 64B16-30.002, F.A.C.

(l) Failure to retain continuing education records \$250

(m) Failure to report to the electronic prescription \$250 fine plus submit all required

drug monitoring program (PDMP) the dispensing reports within 30 days.

of a controlled substance, as required by Section

893.055(3), F.S. and Rule 64K-1.004(1) F.A.C.

(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, _____.

TAB 4. 64B16-26.2032 Pharmacy Intern Registration Internship Requirements.

Continued discussion of expiration of student intern registration for US students who are no longer enrolled and who have not graduated. I've proposed some language just to get the discussion going. I've also updated the web site reference and the date of the application in use and made a few grammatical changes.

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.

64B16-26.2032 Pharmacy Intern Registration Internship Requirements (U.S. Pharmacy Students/Graduates).

A U.S. pharmacy student or graduate is required to be registered with the Department of Health as an intern before being employed as an intern in a pharmacy in Florida. If a student has not graduated and is no longer enrolled in a college or school of pharmacy accredited by the ACPE, the student's intern registration becomes null and void after 6 months of non-enrollment.

(1) All applications for registration must be made on form DH-MQA 104, Pharmacy Intern Application for U.S. Pharmacy Students/Graduates and Instructions, (Rev. 10/1309/09), which is hereby incorporated by reference. Contact the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850) 488-0595 to request an application or download the application from the board's website at <http://www.floridaspharmacy.gov/Applications/app-pharmacy-intern-us.pdf> <http://www.doh.state.fl.us/mqa/pharmacy>.

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

(a) Enrollment in an intern program at a college or school of pharmacy accredited by the Accreditation Council of Pharmaceutical Education (ACPE); or

(b) Graduation from a college or school of pharmacy accredited by the ACPE.

(3) Upon the receipt of proof satisfactory to the Board that the intern applicant meets the requirement of either paragraph (2)(a) or (2)(b), 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 filing, 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.

(5) All internship experience for the purpose of qualifying for the examination pursuant to Section 465.007(1)(c), F.S., shall be obtained in a community pharmacy, institutional pharmacy or any Florida Board of Pharmacy approved pharmacy practice ~~that, which~~ includes significant aspects of the practice of pharmacy as defined in Section 465.003(13), F.S.

(6) An internship program at a college or school of pharmacy accredited by the ACPE shall ~~ensure~~ assure that community or institutional pharmacies utilized for ~~the obtaining of~~ internship experience meet the following minimum requirements:

(a) The pharmacy shall hold a current license or permit issued by the state in which they are operating and shall have available all necessary equipment for professional services, necessary reference works, in addition to the official standards and current professional journals.

(b) The pharmacy shall be operated at all times under the supervision of a pharmacist and shall be willing to train persons desiring to obtain professional experience.

(c) The pharmacy shall establish to the program's satisfaction that the pharmacy fills, compounds and dispenses a sufficient number, kind and variety of prescriptions during the course of a year so as to afford to an intern a broad experience in the filling, compounding and dispensing of prescription drugs.

(d) The pharmacy shall have a clear record as to observance of federal, state and municipal laws and ordinances covering any phase of activity in which it is engaged.

(7) The program shall ~~ensure~~ assure that all preceptors meet the following requirements:

(a) The pharmacist shall willingly accept the responsibility for professional guidance and training of the intern and be able to devote time to preceptor training sessions and to instruction of the intern.

(b) The pharmacist shall hold current licensure in the state in which pharmacy is practiced.

(c) The pharmacist shall be ineligible to serve as a preceptor during any period in which the pharmacist's license to practice pharmacy is revoked, suspended, on probation, or subject to payment of an unpaid fine levied by lawful Board order, or during any period in which the pharmacist's license is the subject of ongoing disciplinary proceedings.

(d) The pharmacist shall agree to assist the school or college of pharmacy in the achievement of the educational objectives set forth and to provide a professional environment for the training of the intern.

(e) Evidence shall be provided of the pharmacist's desire to continue broadening professional education and of an active involvement in a patient-oriented practice.

(8) In the event a program meets all the requirements set forth in subsection (6) of this rule, except for prior approval by the Florida Board of Pharmacy, any applicant submitting it for the purpose of qualifying for licensure by examination must show in addition to successful completion of the internship:

(a) Approval of the program by a state board of pharmacy; and

(b) Sufficient hours to total 2080 hours; or

(c) Licensure in another state and work performed as a pharmacist for a sufficient number of hours to total 2080 hours when combined with the internship hours.

(9) All internship hours may be obtained prior to the applicant's graduation.

(10) Proof of completion of an internship program shall consist of a certification that the applicant has completed the program. If additional hours are required to total 2080 hours, satisfactory proof of the additional hours shall be constituted by the program's certification of completion of the additional hours.

(11) Hours worked in excess of 50 hours per week prior to the applicant's graduation or in excess of 60 hours per week after an applicant's graduation, will not be credited toward meeting the required internship hours.

(12) The Board approves all internships that are required to obtain the doctor of pharmacy degree from institutions which are accredited as provided by Section 465.007(1)(b)1., F.S. Applicants graduating after January 1, 2001 with the doctor of pharmacy degree from such institutions shall be deemed to have met the requirements of this section with documentation of graduation.

(13) The Board may conduct periodic review of programs to ensure ~~assure~~ compliance with these rules.

(14) Proof of current licensure in another state and work as a pharmacist for up to 2080 hours may substitute for all or part of the internship requirement.

(15) Governmental and private radiopharmacy internship programs shall not apply to the pharmacy internship required under subsection (5) of this rule.

Rulemaking Authority 465.005 FS. Law Implemented 465.003(12), 465.007, 465.0075, 465.013 FS. History—New 4-1-07, Amended 7-7-10, 10-7-12.

TAB 5. 64B16-28.202, .2021, .203. Closing of a Pharmacy.

64B16-28.202 Closing of a Pharmacy; Transfer of Prescription Files.

(1) The term “prescription files” as used herein shall mean the drug dispensing records of a pharmacy which shall include all orders for drugs or medicinal supplies as defined by Section 465.003(7), F.S., inclusive of dispensing records for medicinal drugs listed within the provisions of Section 893.03, F.S., issued by a duly licensed practitioner, which serve to transfer possession of medicinal drugs from the pharmacy to the ultimate consumer.

(2) The term “closing of a pharmacy” as used herein shall mean the cessation or termination of professional and business activities within a pharmacy for which a permit has been issued under Chapter 465, F.S.

(3) Prior to closure of a pharmacy the permittee shall notify the Board of Pharmacy in writing as to the effective date of closure, and shall:

(a) Return the pharmacy permit to the Board of Pharmacy office or arrange with the local Bureau of Investigative Services of the Department to have the pharmacy permit returned to the Board of Pharmacy;

(b) Advise the Board of Pharmacy which permittee is to receive the prescription files;

(4) On the date of closure of a pharmacy the former permittee shall:

(a) Physically deliver the prescription files to a pharmacy operating within reasonable proximity of the pharmacy being closed and within the same locality. This delivery of prescription files may occur prior to the return of the pharmacy permit to the Board of Pharmacy office; and

(b) Affix a prominent sign to the front entrance of the pharmacy advising the public of the new location of the former permittee’s prescription files or otherwise provide a means by which to advise the public of the new location of their prescription files.

(5) After the closing of a pharmacy as defined herein, the custody of the prescription files of the pharmacy shall be transferred to the new permittee, unless the former permittee and the new permittee inform the Board in writing that custody of the prescription files have been or are to be transferred to a pharmacy other than the new permittee.

(6) A pharmacy receiving custody of prescription files from another pharmacy shall maintain the delivered prescriptions in separate files so as to prevent intermingling with the transferee pharmacy’s prescription files.

Rulemaking Authority 465.022(1)(g) FS. Law Implemented 465.022(1)(g) FS. History—New 12-26-79, Formerly 21S-16.02, 21S-16.002, Amended 7-31-91, Formerly 21S-28.202, 61F10-28.202, 59X-28.202, Amended 4-5-05.

64B16-28.2021 Change of Ownership.

(1) A pharmacy permit is not transferable. Upon the sale of an existing pharmacy, a new application must be filed. In those cases where the permit is held by a corporation, the transfer of all the stock of said corporation to another person or entity does not constitute a change of ownership, provided that the initial corporation holding the permit continues to exist.

(2) A change in ownership (and issuance of a new permit number) requires that new records be started and old records closed. The process for closing a pharmacy, including the transfer of prescription files and medicinal drugs, as outlined in Rules 64B16-28.202 and 64B16-28.203, F.A.C., must be followed for the old permit. If the old permit has controlled substances, the new permit must record an “opening inventory” for DEA purposes. Both the

new permit and the old permit must keep appropriate records for two (2) years for the transfer of legend drugs and controlled substances.

(3) A change in the company or person who leases the building where the permit is housed or a change in the management company which contracts with the owner of the permit for the operation of the permit does not constitute a change in ownership.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a), 465.018, 465.019, 465.0193, 465.0196, 465.022(7) FS. History—New 4-19-00, Amended 1-2-02, Formerly 64B16-28.1135, Amended 4-5-05.

64B16-28.203 Transfer of Medicinal Drugs; Change of Ownership; Closing of a Pharmacy.

Ownership of medicinal drugs, including those medicinal drugs within the provisions of Section 893.03, F.S., may be transferred to a new owner upon the change of ownership of a pharmacy, as defined in Rule 64B16-28.2021, F.A.C., or upon the closing of a pharmacy, as defined in Rule 64B16-28.2021, F.A.C. The transferee entity acquiring ownership shall be authorized to prescribe, dispense or distribute such drugs. The transferor pharmacy shall provide the Florida Board of Pharmacy with the following information:

(1) The name, address, pharmacy permit number and D.E.A. registration number of the transferor pharmacy.

(2) The name, address, permit number, D.E.A. registration number (if available), and authorized business activity of the transferee entity.

(3) The date on which the transfer will occur.

(4) A complete inventory of all medicinal drugs within the provisions of Section 893.03, F.S., as of the date of transfer. If the medicinal drug is listed in Schedule II, the transferor shall make an exact count or measure of the contents. If the medicinal drugs are listed in Schedule III, IV, or V, the transferor shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules, in which case an exact count of the contents shall be made. This inventory shall serve as the final inventory of the permittee transferor and the transfer inventory of the transferee entity. The transferor and transferee shall each retain a copy of the inventory in their records and shall provide the Board of Pharmacy with a copy of such inventory. Transfer of any controlled substance in Schedule II shall require the use of order form, D.E.A. form number 222.

(5) Unless the permittee-transferor is informed by the Board of Pharmacy or the regional D.E.A. Administrator prior to the date on which the transfer was stated to occur, that the transfer may not occur, the permittee-transferor may proceed with the transfer.

(6) On the date of transfer of the medicinal drugs, all records required to be kept by the permittee-transferor of the transferred drugs which are listed in Section 893.03, F.S., shall be transferred to the permittee-transferor. Responsibility for the accuracy of records prior to the date of transfer remains with the permittee-transferor, but responsibility for custody and maintenance shall be upon the permittee-transferee. It is the responsibility of the permittee-transferor to return all unused Schedule II order forms (D.E.A. form no. 222) to the regional D.E.A. office.

Rulemaking Authority 465.005, 465.022(1)(g) FS. Law Implemented 465.022(1)(g) FS. History—New 12-26-79, Formerly 21S-16.03, 21S-16.003, 21S-28.203, 61F10-28.203, 59X-28.203, Amended 4-5-05.

