

AGENDA  
DEPARTMENT OF HEALTH  
BOARD OF PHARMACY  
RULES COMMITTEE MEETING

February 11, 2014

The Florida Hotel & Conference Center  
1500 Sand Lake Road  
Orlando, FL 32809  
(407) 859-1500

---

Committee Members:

Jeffrey J. Mesaros, PharmD, Tampa, Chair  
Debra Glass, BPharm, Tallahassee  
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, February 11, 2014 – 9:00 a.m.

1. 64B16-26.2034 – Direct Supervision of a Registered Pharmacy Technician. (new). Defines Direct Supervision.
2. 64B16-26.1031 and DH Form 1997 – Influenza Immunization Certification Program. JAPC Comments
3. Rules to be Reviewed for Four (4) Year Records Retention.
  - a. 64B16-26.351 Standards for Approval of Registered Pharmacy Technician Training Programs.
  - b. 64B16-26.601 Standards for Approval of Courses and Providers.
  - c. 64B16-26.603 Continuing Education Records Requirements.
  - d. 64B16-27.210 General Terms and Conditions to be Followed by a Pharmacist When Ordering and Dispensing Approved Medicinal Products.
  - e. 64B16-27.300 Standards of Practice – Continuous Quality Improvement Program.
  - f. 64B16-27.800 Requirements for Patient Records.
  - g. 64B16-27.851 Record-Keeping for Orthotics and Pedorthics.
  - h. 64B16-28.2021 Change of Ownership.
  - i. 64B16-28.503 Transmission of Starter Dose Prescriptions for Patients in Class I Institutional or Modified II B Facilities.
  - j. 64B16-28.605 Class II Institutional Pharmacies – Automated Distribution and Packaging.

- k. 64B16-28.606 Remote Medication Order Processing for Class II Institutional Pharmacies.
  - l. 64B16-28.607 Automated Pharmacy System – Long Term Care, Hospice, and Prison.
  - m. 64B16-28.702 Modified Class II Institutional Pharmacies.
  - n. 64B16-29.0041 Record Maintenance Systems for Animal Shelter Permits.
4. 64B16-28.101 – Prescription Area Accessible to Inspection. Review of Inspection Frequency and Violation-Free Periods to be consistent with 4-year record retention requirements.
  5. 64B16-28.450 – Centralized Prescription Filling, Delivering and Returning. Review of (6)(a)1. – labeling and whether clarity is needed regarding no application.
  6. 64B16-26.2032 – Pharmacy Intern Registration Internship Requirements (U.S. Pharmacy Students/Graduates) & 64B16-26.2033 – Pharmacy Intern Registration and Internship Requirements (Foreign Pharmacy Graduates). Discussion of time limit on internships.
  7. 64B16 – 64B16-28.203 – Transfer of Medicinal Drugs; Change of Ownership; Closing a Pharmacy. Discussion.

## **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.

### **Proposed Definition:**

#### **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 \_\_\_\_\_.

## TAB 2. 64B16-26.1031: Influenza Immunization Certification Program and Form DH-MQA 1997.

JAPC comment: Subsection (2)(c) does not contain the title of DH Form 1997, effective 10/07, "Authorized Licensed Pharmacist User Agreement for Access to Florida SHOTS (Florida State Health Online Tracking Systems)." Also, the form needs to be updated.

### 64B16-26.1031 Vaccine Certification Program.

(1) All applications for vaccine certification programs shall be made on board approved form DH-MQA 1234, "Vaccine Immunization Certification Program Application", effective 01/13, which is hereby incorporated by reference. To obtain an application, <http://www.flrules.org/Gateway/reference.asp?No=Ref-02897> or contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254 or (850) 488-0595, or download the application from the web at <http://www.doh.state.fl.us/mqa/pharmacy>.

(2) The Board shall approve for initial certification of pharmacist administration of vaccines, programs of study not less than 20 hours that include coursework covering all of the following;

(a) Mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;

(b) Immunization Schedules;

(c) Immunization screening questions, provision of risk/benefit information, informed consent, recordkeeping, and electronic reporting into the statewide immunization registry through enrollment application DH Form 1997, "Authorized Licensed Pharmacist User Agreement for Access to Florida SHOTS (Florida State Health Online Tracking Systems)," (effective 10/07) herein incorporated by reference, and may be obtained from the Board office by writing to the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254 or by telephoning 1(877)888-7468, or online at \_\_\_\_\_;

(d) Vaccine storage and handling;

(e) Bio-Hazardous waste disposal and sterile techniques;

(f) Entering, negotiating and performing pursuant to physician oversight protocols;

(g) Community immunization resources and programs;

(h) Identifying, managing and responding to adverse incidents including but not limited to potential allergic reactions associated with vaccine administration;

(i) Procedures and policies for reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS);

(j) Reimbursement procedures and vaccine coverage by federal, state and local governmental jurisdictions and private third party payors;

(k) Administration techniques;

(l) Administration of epinephrine using an autoinjector delivery system.

(m) The current influenza, pneumococcal and shingles vaccine guidelines and recommendations of the United States Department of Health Centers for Disease Control and Prevention, which are entitled "Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP) – United States, 2012-13 Influenza Season," dated August 17, 2012, <http://www.flrules.org/Gateway/reference.asp?No=Ref-02898>; "Updated Recommendations for Prevention of Invasive Pneumococcal Disease Among Adults Using the 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23)," dated September 3, 2010, <http://www.flrules.org/Gateway/reference.asp?No=Ref-02899>; "Prevention of Pneumococcal Disease Among Infants and Children – Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine," dated December 10, 2010, <http://www.flrules.org/Gateway/reference.asp?No=Ref-02900>; "Prevention of Herpes Zoster: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," dated June 6, 2008,

<http://www.flrules.org/Gateway/reference.asp?No=Ref-02901>; which are hereby incorporated by reference and published at <http://www.cdc.gov/vaccines/pubs/ACIP-list.htm>;

(n) Review of Section 465.189, F.S.; and

(o) Cardiopulmonary Resuscitation (CPR) training.

Successful completion of the certification program must include a successful demonstration of competency in the administration technique and a cognitive examination.

*Rulemaking Authority 465.005 FS. Law Implemented 465.189 FS. History—New 3-20-08, Amended 8-30-10, 7-29-13.*

See DH Form 1997 and JAPC letter.

DON GAETZ  
President



Representative Mike Fasano, Chair  
Senator Rene Garcia, 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**

June 14, 2013

Mr. David Flynn  
Assistant Attorney General  
Department of Legal Affairs  
PL-01, The Capitol  
Tallahassee, Florida 32399-1050

**Re: Department of Health: Board of Dentistry  
Rule 64B16-26.1031, F.A.C.**

Dear Mr. Flynn:

In addition to the concerns previously raised regarding the above-referenced rule, I have the following comment.

**64B16-26.1031(2)(c):** This paragraph incorporates by reference DH Form 1997, effective 10/07. The title of this form is not included in the rule text, but is required pursuant to subparagraph 120.55(1)(a)4., Florida Statutes. Please include the title of the form, which appears to be "Authorized Licensed Pharmacist User Agreement for Access to Florida SHOTS (Florida State Health Online Tracking System)," in the rule text.

Also, it has come to my attention that this form has been revised since October of 2007, and is currently dated 07/09: [http://www.flshots.com/\\_pdfs/PharmacistsDH1997.pdf](http://www.flshots.com/_pdfs/PharmacistsDH1997.pdf). Accordingly, it appears that this paragraph should be revised to incorporate the form that is currently in use.

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

Sincerely,

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

Marjorie C. Holladay  
Senior Attorney



**Authorized Licensed Pharmacist  
User Agreement  
For Access to Florida SHOTS  
(Florida State Health Online Tracking System)**



Florida SHOTS is the centralized electronic state immunization registry for recording and tracking immunizations as authorized by s. 381.003, F.S.

Y *Completion of this agreement according to the following conditions and instructions is required for authorized access to Florida SHOTS. Pursuant to section 465.189(4), F.S., licensed pharmacists certified by the Florida Board of Pharmacy to administer influenza vaccinations to adults must report such vaccinations to the state immunization registry (Florida SHOTS). Please follow the instructions below in order to access Florida SHOTS for reporting purposes.*

### TERMS OF AGREEMENT

**PLEASE READ CAREFULLY. As a CONDITION for enrolling in the Florida State Health Online Tracking System, the LICENSED PHARMACIST (licensed pursuant to s. 465.007, F.S.) identified on this application for enrollment and certified to provide adult influenza virus immunizations AGREES TO:**

1. Use the database to register and record immunization information for patients currently receiving immunizations under their care.
2. Enter accurate and current data in Florida SHOTS at the time of immunization administration.
3. Accept and abide by all relevant state statutes concerning medical record confidentiality and Florida SHOTS access.
4. Ensure pharmacy staff accessing Florida SHOTS, as authorized by the licensed pharmacist applicant, adheres to all laws and regulations pertaining to use and access.
5. Maintain user accounts such that only current authorized users have access to Florida SHOTS and all terminated staff are appropriately removed from access.
6. Safeguard user IDs and passwords against unauthorized use and assume responsibility for staff access to Florida SHOTS.
7. Notify Florida SHOTS personnel immediately upon revocation or suspension of license.

***In addition, for all authorized users of Florida SHOTS, it is UNDERSTOOD that:***

1. Authorized users may assign staff access to Florida SHOTS and are solely responsible for managing such access.
2. The authorized licensed pharmacist agrees to be solely liable and hold the Department of Health harmless for any breaches of confidentiality by the pharmacist or the pharmacist's staff.
3. Access to Florida SHOTS will be terminated immediately upon license revocation or suspension, or for breaches of confidentiality or failure to adhere to any portion of this agreement.

**Complete and sign the attached form according to the following instructions:**

### INSTRUCTIONS:

**REVIEW SECTION I AND FILL OUT SECTION II ACCORDING TO THE FOLLOWING INSTRUCTIONS:**

1. Provide the pharmacy facility name, address, city, zip, phone, fax, pharmacy permit number and county where pharmacy is located.
2. Provide the information for the pharmacist applicant. The pharmacist whose name appears on this enrollment application will be responsible for granting Florida SHOTS access to other authorized pharmacy staff and will receive a user ID and password to access Florida SHOTS.
3. The pharmacist must sign the agreement in the space provided. By signing the agreement, the pharmacist agrees to ensure that staff accessing Florida SHOTS under his or her authorization will adhere to the same laws and regulations pertaining to access and maintenance of confidential information.

**SECTION III – Agreement Submission** - Mail or fax this form to the address or fax number indicated. If you have any questions regarding completion of the form or about Florida SHOTS, please call the telephone number provided.



**Authorized Licensed Pharmacist  
User Agreement  
For Access to Florida SHOTS  
(Florida State Health Online Tracking System)**



**Section I – Pharmacists** *(licensed under Section 465.007, F.S.)*

./ Pursuant to section 465.189(4), F.S., pharmacists certified by the Florida Board of Pharmacy to administer influenza virus immunizations to adults must report such vaccinations to the state immunization registry (Florida SHOTS). Upon approval of this application, pharmacists will be issued a user identification and password for access to Florida SHOTS. Pharmacists may then allow their individual staff who are authorized or approved (following standard internal security procedures such as background checks conducted by the facility) to access Florida SHOTS using the pharmacist's authorization. **Pharmacists are responsible for contributing to the immunization registry as required by statute, and must ensure staff adherence to confidentiality and information security, management of system accounts (including immediate termination of accounts for staff no longer employed), and maintenance of new user identification and temporary password assignment.**

**Section II – Pharmacist**

Licensed Pharmacist's Name: \_\_\_\_\_

(First) (Last)

Phone: \_\_\_\_\_ Fax: (\_\_\_\_\_) \_\_\_\_\_ Email: \_\_\_\_\_

Pharmacist's License #: \_\_\_\_\_ Board Certification Number #: \_\_\_\_\_

**Permitted Pharmacy Practice Location (Pursuant to s. 465.003, F.S.)**

Facility Name: \_\_\_\_\_ Address: \_\_\_\_\_

City: \_\_\_\_\_ Zip: \_\_\_\_\_ Phone: (\_\_\_\_\_) \_\_\_\_\_ Fax: (\_\_\_\_\_) \_\_\_\_\_

Pharmacy Permit # \_\_\_\_\_ County: \_\_\_\_\_

**Agreement - By signing below, authorized user(s) agree to abide by all terms of this agreement.**

Job Title: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**SECTION III - Agreement Submission**

Please keep a copy of this agreement for your files and mail or fax this side of the form to:

Florida Department of Health  
Bureau of Immunization  
4052 Bald Cypress Way  
Bin # A11  
Tallahassee, Florida 32399-1719

Telephone (850) 245-4342

Fax (850) 922-4195



### **TAB 3. Rules To Be Reviewed for Four (4) Year Records Retention**

- A. 64B16-26.351 Standards for Approval of Registered Pharmacy Technician Training Programs.
- B. 64B16-26.601 Standards for Approval of Courses and Providers.
- C. 64B16-26.603 Continuing Education Records Requirements.
- D. 64B16-27.210 General Terms and Conditions to Be Followed by a Pharmacist When Ordering and Dispensing Approved Medicinal Drug Products.
- E. 64B16-27.300 Standards of Practice - Continuous Quality Improvement Program.
- F. 64B16-27.800 Requirement for Patient Records.
- G. 64B16-27.851 Record-Keeping for Orthotics and Pedorthics.
- H. 64B16-28.2021 Change of Ownership.
- J. 64B16-28.605 Class II Institutional Pharmacies – Automated Distribution and Packaging.
- K. 64B16-28.606 Remote Medication Order Processing for Class II Institutional Pharmacies.
- L. 64B16-28.607 Automated Pharmacy System – Long Term Care, Hospice, and Prison.
- M. 64B16-28.702 Modified Class II Institutional Pharmacies.
- N. 64B16-29.0041 Record Maintenance Systems for Animal Shelter Permits.

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

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

(1) The following programs are approved Registered Pharmacy Technician Training programs:

(a) Pharmacy technician training programs accredited, on or before January 1, 2011 by the American Society of Health-System Pharmacists,

(b) Pharmacy technician training programs at institutions accredited, on or before January 1, 2011 by the Southern Association of Colleges and Schools,

(c) Pharmacy technician training programs approved on or before January 1, 2011 by the Florida Commission for Independent Education,

(d) Pharmacy technician training programs provided by a branch of the federal armed services on or before January 1, 2011.

(e) Pharmacy technician training programs at institutions accredited on or before January 1, 2011 by the Council on Occupational Education.

(2) All programs not listed in paragraphs (1)(a) through (e) and which are not employer based programs, must:

(a) Meet the requirements of and be licensed by the Commission for Independent Education pursuant to Chapter 1005, F.S., or the equivalent licensing authority of another state or be within the public school system of the State of Florida; and:

(b) Offer a course of study that includes classroom study and clinical instruction that includes the following:

1. Introduction to pharmacy and health care systems:

a. Confidentiality,

b. Patient rights and Health Insurance Portability and Accountability Act (HIPAA),

2. Pharmacy law:

a. Federal law,

b. Florida State law,

c. Florida State rules,

d. Pharmacy technician Florida rules and law,

3. Pharmaceutical – medical terminology, abbreviations, and symbols:

a. Medication safety and error prevention,

b. Prescriptions and medication orders,

4. Records management and inventory control:

a. Pharmaceutical supplies,

- b. Medication labeling,
  - c. Medication packaging and storage,
  - d. Controlled substances,
  - e. Adjudication and billing,
5. Interpersonal relations, communications, and ethics:
- a. Diversity of communications,
  - b. Empathetic communications,
  - c. Ethics governing pharmacy practice,
  - d. Patient and caregiver communication,
6. Pharmaceutical calculations.

(c) Apply directly to the Board of Pharmacy on approved form DH-MQA 1239 "Board of Pharmacy Application for Registered Pharmacy Technician Training Programs," effective December 2010, <https://www.flrules.org/gateway/reference.asp?NO=Ref-00717>, which is hereby incorporated by reference. To obtain an application, contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254, or (850) 488-0595, or download the application from the board's website at <http://www.doh.state.fl.us/mqa/pharmacy> and provide the following information:

1. Sample transcript and diploma;
2. Copy of curriculum, catalog or other course descriptions; and
3. Faculty credentials.

(d) Use materials and methods that demonstrate that:

1. Learning experiences and teaching methods convey the content stated above.
2. Time allocated for each participant shall be sufficient to meet the objectives of each activity.
3. Principles of adult education are utilized in determining teaching strategies and learning activities.

(e) Demonstrate that the faculty is qualified to teach the subject-matter by complying with the following:

1. The program shall provide evidence of academic preparation or experience in the subject matter by submitting a job description, resume or curriculum vitae which describes the faculty member's work experience and level of academic preparation.

2. When the subject matter of an offering includes pharmacy technician practice, a licensed pharmacist or registered pharmacy technician with expertise in the content area must be involved in the planning and instruction.

3. Pharmacy technician faculty supervising learning experiences in a clinical area in this State shall be licensed or registered.

(3) All other training programs must be employer based. Any pharmacy technician training program sponsored by a Florida permitted pharmacy or affiliated group of pharmacies under common ownership, must contain a minimum of 160 hours of training, that extends over a period not to exceed 6 months; is provided solely to employees of said pharmacy or affiliated group; and has been approved by the Board. An application for approval of a Registered Pharmacy Technician Training Program shall be made on Board of Pharmacy approved form DH-MQA 1239 "Board of Pharmacy Application for Registered Pharmacy Technician Training Programs," effective December 2010. The applicant must attach to the application copy of curriculum, catalog or other course description. All employer based programs must:

(a) Offer a course of study that includes a classroom study and clinical instruction that includes the following:

1. Introduction to pharmacy and health care systems:

a. Confidentiality,

b. Patient rights and Health Insurance Portability and Accountability Act (HIPAA).

2. Pharmacy law:

a. Federal law,

b. Florida State law,

c. Florida State rules,

d. Pharmacy technician Florida rules and law.

3. Pharmaceutical-medical terminology, abbreviations, and symbols:

a. Medication safety and error prevention,

b. Prescriptions and medication orders.

4. Records management and inventory control:

a. Pharmaceutical supplies,

b. Medication labeling,

c. Medication packaging and storage,

d. Controlled substances,

e. Adjudication and billing.

5. Interpersonal relations, communications, and ethics:

a. Diversity of communications,

b. Empathetic communications,

c. Ethics governing pharmacy practice,

d. Patient and caregiver communication.

6. Pharmaceutical calculations.

(b) Use materials and methods that demonstrate that:

1. Learning experiences and teaching methods convey the content stated above.

2. Time allocated for each participant shall be sufficient to meet the objectives of each activity.

3. Principles of adult education are utilized in determining teaching strategies and learning activities.

(c) Demonstrate that the faculty is qualified to teach the subject matter by complying with the following:

1. The program shall provide evidence of academic preparation or experience in the subject matter by submitting a job description, resume or curriculum vitae which describes the faculty member's work experience and level of academic preparation.

2. When the subject matter of an offering includes pharmacy technician practice, a licensed pharmacist or registered pharmacy technician with expertise in the content area must be involved in the planning and instruction.

3. Pharmacy technician faculty supervising learning experiences in a clinical area in this State shall be licensed or registered.

4. When an offering includes clinical practice training in Florida, a Florida licensed pharmacist competent in the practice area shall provide supervision.

(d) Give participants an opportunity to evaluate learning experiences, instructional methods, facilities and resources used for the offering. To ensure participants will be given an opportunity to evaluate the program, the applicant must submit a sample evaluation to be reviewed by the Board.

(e) Ensure that self-directed learning experiences, including but not limited to home study, computer programs, internet or web-based courses evaluate participant knowledge at the completion of the learning experience. The evaluation must include a minimum of 100 questions. The participant must achieve a minimum score of 70% on the evaluation to receive the certificate of completion. The evaluation must be graded by the provider.

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

(g) Establish written policies and procedures for implementation of the registered pharmacy technician training program.

(h) Maintain a system of record-keeping which provides for storage of program information.

(i) Maintain program records for a period not less than four (4) ~~three~~ years during which time the records must be available for inspection by the board or department.

(j) Furnish each participant with an authenticated individual Certificate of Completion.

*Rulemaking Authority 465.014 FS. Law Implemented 465.014 FS. History—New 6-23-10, Amended 11-17-11; \_\_\_\_\_.*

## B. 64B16-26.601 Standards for Approval of Courses and Providers.

### **64B16-26.601 Standards for Approval of Courses and Providers.**

(1) Each proposal for program or course approval submitted by a qualified provider must contain a detailed outline of the content of said program or course on forms which will be provided by the Board of Pharmacy upon request, and must build upon Standards of Practice and a basic course or courses offered in the curricula of accredited colleges or schools of pharmacy. Continuing education may consist of post-baccalaureate degree programs offered by accredited colleges or schools of pharmacy, post-graduate studies, institutes, seminars, lectures, conferences, workshops, correspondence courses, or other such committee-approved educational methods.

(2) All offerings must meet the following standards:

(a) Education Content Development.

1. Continuing education offerings shall involve advance planning that includes a statement of measurable educational goals and behavioral objectives.

2. Continuing education offerings shall be designed to reflect the educational needs of the pharmacist and build on the standards for practice and courses in the curricula of accredited colleges or schools of pharmacy.

3. Each continuing education offering shall be designed to explore one subject or a group of closely related subjects or standards.

(b) Methods of Delivery.

1. The method of delivery of a course shall be determined by giving appropriate consideration to such factors as educational content, objectives, and composition of the audience.

2. The method of delivery must encourage active participation and involvement on the part of the pharmacist.

(c) Program Faculty Qualifications.

1. The program faculty for a particular continuing education offering shall be competent in the subject matter and qualified by experience.

2. An appropriate number of program faculty for each activity shall be utilized.

3. There shall be adequate personnel to assist with administrative matters and personnel with competencies outside content areas in cases where the method of delivery requires technical or other special expertise.

(d) Facilities.

1. The facilities to be utilized shall be appropriate and adequate to the content, method of delivery, size of the audience and promote the attainment of the objectives of the offering.

(e) Evaluation. The provider must make provision for evaluation of the participants' attainment of the stated learner objectives through in-process activities that provide a measurable demonstration of the learner's

achievement(s).

2. The provider must develop and employ an evaluation mechanism for the purpose of allowing the participant to assess his/her achievement of personal objectives.

3. The provider shall develop and employ an evaluation mechanism that will assess the effectiveness of the learning experiences, instructional methods, facilities, and resources used for the offering.

(f) Contact Hour Criteria. The number of contact hours or Continuing Education Units shall be determined by the provider in advance of the offering subject to approval by the committee and awarded upon the successful completion of the entire planned education experience.

(g) Record Keeping.

1. Records of individual offerings shall be maintained by the provider for inspection by the Board. The records shall be adequate to serve the needs of the participants and to permit the Board to monitor for adherence to the standards for continuing education offerings as outlined in the rules.

2. An individual certificate of attendance specifying title of offering, provider number, date of offering, and number of contact hours earned shall be furnished to each participant by the provider.

3. Records shall be maintained by the provider for a minimum of four (4) ~~three (3)~~ years.

(3) Providers seeking board approval shall meet each of the standards outlined herein:

(a) All continuing education offerings conducted by the provider shall meet the standards for continuing education offerings as outlined in these rules.

(b) There shall be a visible, continuous, and identifiable authority charged with administration of continuing education programs. The person or persons in whom the administrative function is vested shall be qualified by virtue of background and experience and approval by the committee.

(4) All programs approved by the Accreditation Council on Pharmacy Education (ACPE) for continuing education for pharmacists may be deemed approved by this Board for general continuing education hours for pharmacists.

(5) Entities or individuals who wish to become approved providers of continuing education must submit an initial approval fee of \$150 and provide information to demonstrate compliance with the requirements of this rule. A provider seeking to renew approved provider status shall pay a renewal fee of \$150.

(6) Entities or individuals applying for approval of an individual program shall submit a fee of \$50 and provide information to demonstrate compliance with this rule.

*Rulemaking Authority 465.005, 465.009 FS. Law Implemented 456.025(7), 465.009 FS. History—New 10-17-79, Amended 7-29-81, Formerly 21S-13.02, 21S-13.002, Amended 1-10-93, Formerly 21S-26.601, 61F10-26.601, 59X-26.601, Amended 1-29-03;*

\_\_\_\_\_.

C. 64B16-26.603 Continuing Education Records Requirements.

Amend or Repeal.

**64B16-26.603 Continuing Education Records Requirements.**

Each pharmacist shall retain documentation of participation in continuing education programs required for license renewal for not less than two years after the license is renewed for audit purposes if and when such audit is undertaken by the Department of Health and the Board of Pharmacy. Such documentation shall consist of statements of credit for lecture attendance, certification forms from instructors, or course completion slips from correspondence courses.

*Rulemaking Authority 465.005 FS. Law Implemented 465.009 FS. History—New 10-17-79, Formerly 21S-13.04, Amended 5-10-89, Formerly 21S-13.004, 21S-26.603, 61F10-26.603, 59X-26.603, Amended 1-11-05; \_\_\_\_\_.*



**D. 64B16-27.210 General Terms and Conditions to Be Followed by a Pharmacist When Ordering and Dispensing Approved Medicinal Drug Products.**

**64B16-27.210 General Terms and Conditions to Be Followed by a Pharmacist When Ordering and Dispensing Approved Medicinal Drug Products.**

Pursuant to the authority of the Formulary Committee in Section 465.186, F.S., a pharmacist may order the medicinal drug products listed in Rule 64B16-27.220, F.A.C., subject to the following terms and limitations:

- (1) Injectable products shall not be ordered by the pharmacist.
- (2) No oral medicinal drugs shall be ordered by a pharmacist for a pregnant patient or nursing mother.
- (3) In any case of dispensing hereunder, the amount or quantity of drug dispensed shall not exceed a 34-day supply or standard course of treatment unless subject to the specific limitations in this rule. Patients shall be advised that they should seek the advice of an appropriate health care provider if their present condition, symptom, or complaint does not improve upon the completion of the drug regimen.
- (4) The directions for use of all prescribed medicinal drugs shall not exceed the manufacturer's recommended dosage.
- (5) The pharmacist may only perform the acts of ordering and dispensing in a pharmacy which has been issued a permit by the Board of Pharmacy.
- (6) The pharmacist shall create a prescription when ordering and dispensing medicinal drug products which shall be maintained in the prescription files of the pharmacy. The pharmacist shall place the trade or generic name and the quantity dispensed on the prescription label, in addition to all other label requirements.
- (7) The pharmacist shall maintain patient profiles, separate from the prescription order, for all patients for whom the pharmacist orders and dispenses medicinal drug products and shall initial and date each profile entry. Such profiles shall be maintained at the pharmacy wherein the ordering and dispensing originated for a period of four ~~(4) two (2)~~ years.
- (8) In the patient profiles, the pharmacist shall record as a minimum the following information if a medicinal drug product is ordered and dispensed.
  - (a) Patient's chief complaint or condition in the patient's own words.
  - (b) A statement regarding the patient's medical history.
  - (c) A statement regarding the patient's current complaint which may include, onset, duration and frequency of the problem.
  - (d) The medicinal drug product ordered and dispensed.
  - (e) The pharmacist ordering and dispensing the medicinal drug product shall initial the profile.
  - (f) The prescription number shall be recorded in the patient's profile.

(9) A medicinal drug product may be ordered, and dispensed only by the pharmacist so ordering.

(10) Only legend medicinal drugs may be prescribed by a pharmacist. Over-the-counter drugs are exempt from the requirements of this rule and shall be recommended as over-the-counter products.

(11) Pharmacy interns and technicians may not be involved in the ordering of the medicinal drugs permitted in this rule.

*Rulemaking Authority 465.186(2) FS. Law Implemented 465.186 FS. History—New 5-1-86, Formerly 21S-18.002, 21S-27.210, 61F10-27.210, 59X-27.210, Amended 11-18-07; \_\_\_\_\_.*

E. 64B16-27.300 Standards of Practice - Continuous Quality Improvement Program.

**64B16-27.300 Standards of Practice - Continuous Quality Improvement Program.**

(1) "Continuous Quality Improvement Program" means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.

(2) "Quality-Related Event" means the inappropriate dispensing or administration of a prescribed medication including:

(a) A variation from the prescriber's prescription order, including, but not limited to:

1. Incorrect drug;
2. Incorrect drug strength;
3. Incorrect dosage form;
4. Incorrect patient; or
5. Inadequate or incorrect packaging, labeling, or directions.

(b) A failure to identify and manage:

1. Over-utilization or under-utilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;
4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions; or
7. Clinical abuse/misuse.

(3)(a) Each pharmacy shall establish a Continuous Quality Improvement Program which program shall be described in the pharmacy's policy and procedure manual and, at a minimum shall contain:

1. Provisions for a Continuous Quality Improvement Committee that may be comprised of staff members of the pharmacy, including pharmacists, registered pharmacy interns, registered pharmacy technicians, clerical staff, and other personnel deemed necessary by the prescription department manager or the consultant pharmacist of record;

2. Provisions for the prescription department manager or the consultant pharmacist of record to ensure that the committee conducts a review of Quality Related Events at least every three months.

3. A planned process to record, measure, assess, and improve the quality of patient care; and

4. The procedure for reviewing Quality Related Events.

(b) As a component of its Continuous Quality Improvement Program, each pharmacy shall assure that, following a Quality-Related Event, all reasonably necessary steps have been taken to remedy any problem for the patient.

(c) At a minimum, the review shall consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.

(4) Each Quality-Related Event that occurs, or is alleged to have occurred, as the result of activities in a pharmacy, shall be documented in a written record or computer database created solely for that purpose. The Quality-Related Event shall be initially documented by the pharmacist to whom it is described, and it shall be recorded on the same day of its having been described to the pharmacist. Documentation of a Quality-Related Event shall include a description of the event that is sufficient to permit categorization and analysis of the event. Pharmacists shall maintain such records at least until the event has been considered by the committee and incorporated in the summary required in subsection (5) below.

(5) Records maintained as a component of a pharmacy Continuous Quality Improvement Program are confidential under the provisions of Section 766.101, F.S. In order to determine compliance the Department may review the policy and procedures and a Summarization of Quality-Related Events. The summarization document shall analyze remedial measures undertaken following a Quality-Related Event. No patient name or employee name shall be included in this summarization. The summarization shall be maintained for four (4)~~two~~ years. Records are considered peer-review documents and are not subject to discovery in civil litigation or administrative actions.

*Rulemaking Authority 465.0155 FS. Law Implemented 465.0155 FS. History—New 7-15-99, Amended 1-2-02, 6-16-03, 11-18-07, 1-1-10; \_\_\_\_\_.*

## F. 64B16-27.800 Requirement for Patient Records.

### **64B16-27.800 Requirement for Patient Records.**

(1) A patient record system shall be maintained by all pharmacies for patients to whom new or refill prescriptions are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing. The pharmacist shall ensure that a reasonable effort is made to obtain, record and maintain the following information:

(a) Full name of the patient for whom the drug is intended;

(b) Address and telephone number of the patient;

(c) Patient's age or date of birth;

(d) Patient's gender;

(e) A list of all new and refill prescriptions obtained by the patient at the pharmacy maintaining the patient record during the ~~four~~ four (4) two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and

(f) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) The pharmacist shall ensure that a reasonable effort is made to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review. The pharmacist shall record any related information indicated by a licensed health care practitioner.

(3) A patient record shall be maintained for a period of not less than ~~four~~ four (4) two years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

(4) Patient records shall be maintained for prescriptions dispensed subsequent to the effective date of this regulation.

*Rulemaking Authority 465.022, 465.0155 FS. Law Implemented 465.0155 FS. History—New 8-18-93, Formerly 21S-27.800, 61F10-27.800, 59X-27.800, Amended 6-15-98; \_\_\_\_\_.*

## G. 64B16-27.851 Record-Keeping for Orthotics and Pedorthics.

**64B16-27.851 Record-Keeping for Orthotics and Pedorthics.**

(1) The pharmacist or supportive personnel shall prepare and maintain in a timely manner patient records which include, at a minimum, the following:

- (a) The patient name, address and telephone number;
- (b) The location and dates of all treatment, evaluation or consultation;
- (c) The name of the prescribing physician;
- (d) All prescriptions pertaining to services provided to the patient;
- (e) A treatment or service plan;
- (f) Progress notes for each session;

(2) The licensee may charge a fee for the reproduction of records, which shall be no greater than \$ 1.00 per page for the first 25 pages, and \$0.50 per page for every page after 25. In addition, the actual cost of postage may be added. Reasonable costs of reproducing radiographs and such other kinds of records shall be the actual costs. "Actual costs" means the cost of the material and supplies used to duplicate the record and the labor and overhead costs associated with the duplication.

(3) The licensee shall retain the patient record for at least four (4)~~two~~ years from the date of last entry, unless otherwise provided by law.

*Rulemaking Authority 468.802, 468.812(3) FS. Law Implemented 456.057(16), 465.0155, 465.022, 468.802, 468.812(3) FS. History-New 5-2-07; \_\_\_\_\_.*

## H. 64B16-28.2021 Change of Ownership.

### **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 ~~four (4) to (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; \_\_\_\_\_.*





## I. 64B16-28.503 Transmission of Starter Dose Prescriptions for Patients in Class I Institutional or Modified II B Facilities.

### **64B16-28.503 Transmission of Starter Dose Prescriptions for Patients in Class I Institutional or Modified II B Facilities.**

#### (1) Definitions.

(a) "Vendor pharmacy" means a community pharmacy or special closed system pharmacy which has a contract to dispense a medicinal drug to a patient in a facility holding a Class I Institutional Permit or Modified II B Permit.

(b) "Starter dose pharmacy" means a pharmacy that dispenses a medicinal drug pursuant to a starter dose prescription to a patient in a facility served by the vendor pharmacy.

(c) "Starter dose prescription" means a prescription transmitted by a vendor pharmacy to a starter dose pharmacy for the purpose of initiating drug therapy for a patient in a facility served by the vendor pharmacy.

(2) A vendor pharmacy may transmit a starter dose prescription to a starter dose pharmacy if the vendor pharmacy:

(a) Has written authorization from the facility to utilize a starter dose pharmacy.

(b) Has a written contract with the starter dose pharmacy.

(c) Has written authorization from a prescribing practitioner to act as the practitioner's agent for the purpose of transmitting a starter dose prescription.

(d) Possess a valid prescription from the prescribing practitioner prior to transmitting the starter dose prescription.

(e) Maintains a record of each starter dose prescription.

(f) Maintains a policy and procedure manual that references starter dose prescriptions.

(3) A starter dose pharmacy may dispense a medicinal drug pursuant to a starter dose prescription for a patient in a facility that holds a Class I Institutional Permit or Modified II B Permit if the starter dose pharmacy:

(a) Has a written contract with the vendor pharmacy.

(b) Maintains a record of each starter dose prescription.

(c) Maintains a policy and procedure manual that references starter dose prescriptions.

(4) The contract between a vendor pharmacy and a prescribing practitioner shall:

(a) Be in writing.

(b) Identify each facility served by the vendor pharmacy for which the authorization is valid.

(c) Authorize the vendor pharmacy to transmit, as an agent of the practitioner, a starter dose prescription to a

starter dose pharmacy.

(d) Be on file at the vendor pharmacy, at the facility served by the vendor pharmacy, and with the prescribing practitioner.

(e) Be available for inspection by agents of the Department of Health or the Board of Pharmacy.

(5) The contract between the vendor pharmacy and the starter dose pharmacy shall:

(a) Be in writing.

(b) Identify each facility served by the vendor pharmacy.

(c) Assign the responsibility for prospective drug use review required by Rule 64B16-27.810, F.A.C., to the vendor pharmacy.

(d) Assign the responsibility for patient counseling required by Rule 64B16-27.820, F.A.C., to the vendor pharmacy.

(e) Be referenced in the Policy and Procedure Manual of the vendor pharmacy and of the starter dose pharmacy.

(f) Be updated as necessary to identify facilities or practitioners.

(g) Be on file at the vendor pharmacy, at the starter dose pharmacy, and at the facility.

(h) Be available for inspection by authorized agents of the Department of Health and the Board of Pharmacy.

(6) A record of each starter dose prescription shall be:

(a) Readily retrievable.

(b) Maintained for four (4)~~two~~ years.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.018, 465.019, 465.022 FS. History—New 11-29-04; \_\_\_\_\_.*

## J. 64B16-28.605 Class II Institutional Pharmacies – Automated Distribution and Packaging.

### **64B16-28.605 Class II Institutional Pharmacies – Automated Distribution and Packaging.**

(1) Definitions.

(a) “Automated medication system” means a robotic, mechanical or computerized device that is not used for medication compounding and is designed to:

1. Distribute medications in a licensed health care facility; or

2. Package medications for final distribution by a pharmacist.

(b) “Centralized automated medication system” means an automated medication system located in a pharmacy department from which medication is distributed or packaged for final distribution by a pharmacist.

(c) “Decentralized automated medication system” means an automated medication system that is located outside of a pharmacy department but within the same institution.

(d) “Distribute” or “Distribution” means the process of providing a drug to an individual authorized to administer medications and licensed as a health care provider in the state of Florida pursuant to an order issued by an authorized prescriber.

(e) “Medication” means a medicinal drug or proprietary preparation.

(f) “Override medication” means a single dose of medication that may be removed from a decentralized automated medication system prior to pharmacist review because a practitioner licensed pursuant to Chapter 458, 459 or 466, F.S., determined that the clinical status of the patient would be significantly compromised by delay.

(g) “Low risk override medication” is a medication determined by a practitioner licensed pursuant to Chapter 458, 459, or 466, F.S., to have a low risk of drug allergy, drug interaction, dosing error, or adverse patient outcome, and may be removed from a decentralized automated medication system independent of a pharmacist’s review of the medication order or clinical status of the patient.

(h) “Physician controlled medication” is medication distributed in an environment where a practitioner controls the order, preparation and administration of the medication.

(2) General Requirements for the Use of Automated Medication Systems.

(a) The consultant pharmacist of record shall be responsible for:

1. Maintaining a record of each transaction or operation;

2. Controlling access to the system;

3. Maintaining policies and procedures for;

a. Operation of the automated medication system;

b. Training personnel who use the automated medication system;

c. Maintaining patient services whenever the automated medication system is not operating; and

d. Defining a procedure for a pharmacist to grant or deny access to the medication in the system.

4. Security of the system;

5. Assuring that a patient receives the pharmacy services necessary for good pharmaceutical care in a timely manner;

6. Assuring that the system maintains the integrity of the information in the system and protects patient confidentiality;

7. Establishing a comprehensive Quality Assurance program;

8. Establishing a procedure for stocking or restocking the automated medication system; and

9. Ensuring compliance with all requirements for packaging and labeling.

(b) A pharmacist shall perform prospective drug use review and approve each medication order prior to administration of a medication except an override medication, a low risk override medication or a physician controlled medication.

(c) A pharmacist shall perform retrospective drug use review for an override medication.

(3) Multidisciplinary Committee for Decentralized Automated Medication Systems.

(a) The consultant pharmacist of record shall convene or identify a multidisciplinary committee, which is charged with oversight of the decentralized automated medication system.

(b) The Multidisciplinary Committee shall:

1. Include at least one pharmacist;

2. Establish the criteria and process for determining which medication qualifies as an override medication or a low risk override medication in a decentralized automated medication system;

3. Develop policies and procedures regarding the decentralized automated medication system; and

4. Have its decisions reviewed and approved by the consultant pharmacist of record.

(4) Stocking or Restocking of a Decentralized Automated Medication System.

(a) Medications in a decentralized Automated Medication System shall be stocked or restocked by a pharmacist, registered pharmacy intern, or by a registered pharmacy technician supervised by a pharmacist.

(b) The stocking or restocking of a decentralized automated medication system shall follow one of the following procedures to assure correct medication selection:

1. A pharmacist shall conduct a daily audit of medications placed or to be placed into an automated medication system that includes random sampling.

2. A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of medication placed or to be placed into an automated medication system. The utilization of a bar code, electronic, or similar verification technology shall require an initial quality assurance validation followed by a monthly quality assurance review by a pharmacist.

(5) Centralized Automated Medication Systems. A pharmacist utilizing a centralized medication system may distribute patient specific medications within the licensed health care facility without checking each individual medication selected or packaged by the system, if:

(a) The initial medication order has been reviewed and approved by a pharmacist; and

(b) The medication is distributed for subsequent administration by a health care professional permitted by Florida law to administer medication; and

(c) A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of medication placed or to be placed into an automated medication system. The utilization of a

bar code, electronic verification, or similar verification technology shall require an initial quality assurance validation, followed by monthly quality assurance review by a pharmacist.

(6) Quality Assurance Program. The consultant pharmacist of record shall be responsible for establishing a quality assurance program for the automated medication system. The program shall provide for:

- (a) Review of override and low risk override medication utilization;
- (b) Investigation of a medication error related to the automated medication system;
- (c) Review of a discrepancy or transaction reports and identify patterns of inappropriate use or access;
- (d) Review of the operation of the system;
- (e) Integration of the automated medication system quality assurance program with the overall continuous quality improvement of the pharmacy as defined in Rule 64B16-27.300, F.A.C.; and
- (f) Assurance that individuals working with the automated medication system receive appropriate training on the operation of the system and procedures for maintaining pharmacy services when the system is not in operation.

(7) Record Keeping.

(a) The consultant pharmacist of record shall maintain records related to the automated medication system in a readily retrievable manner.

(b) The following records shall be maintained for at least 60 days:

1. Daily audits of stocking or restocking, if applicable;
2. Daily audits for the output of centralized automated medication system, if applicable; and
3. Transaction records for all non-controlled medications or devices distributed by the automated medication system.

(c) The following records shall be maintained for at least four (4)~~two (2)~~ years:

1. Any report or analysis generated as part of the quality assurance program;
2. A report or database related to access to the system or any change in the access to the system or to medication in the system; and
3. Transaction records from the automated medication system for all controlled substances dispensed or distributed.

(8) Compliance. The consultant pharmacist of record shall assure compliance with all requirements of Chapter 465, F.S., and the rules of Chapter 64B16, F.A.C.

(9) Security. A decentralized automated medication system that contains controlled substances shall prohibit simultaneous access to multiple drug entities, drug strengths, or dosage forms of controlled substances, unless otherwise contained in labeled patient-specific form.



**K. 64B16-28.606 Remote Medication Order Processing for Class II Institutional Pharmacies.**

**64B16-28.606 Remote Medication Order Processing for Class II Institutional Pharmacies.**

(1) Definitions.

(a) "Remote Medication Order Processing" includes any of the following activities performed for a Class II Institutional Pharmacy from a remote location:

1. Receiving, interpreting, or clarifying medication orders.
2. Entering or transferring medication order data.
3. Performing prospective drug use review.
4. Obtaining substitution authorizations.
5. Interpreting and acting on clinical data.
6. Performing therapeutic interventions.
7. Providing drug information.
8. Authorizing the release of a medication for administration.

(b) "Medication" means a medicinal drug or proprietary preparation.

(c) "Prospective drug use review" means an evaluation of medication orders and patient medication records for:

1. Over-utilization or under-utilization of medication.
2. Therapeutic duplication of medication.
3. Drug-disease contraindications.
4. Drug interactions.
5. Incorrect drug dosage or duration of drug treatment.
6. Clinical abuse or misuse of medication.

(2) General requirements.

(a) All pharmacists participating in remote medication order processing shall be Florida licensed pharmacists.

(b) A Class II Institutional pharmacy may utilize remote medication order processing if the pharmacist performing the remote medication order processing has access to sufficient patient information necessary for prospective drug use review and approval of medication orders.

(c) A pharmacist shall perform the final check of a medication order.

(d) If the pharmacist performing remote order processing is not an employee of the Class II Institutional pharmacy, the Class II Institutional pharmacy must have a written agreement or contract with the pharmacist or entity employing the pharmacist. The written agreement or contract shall:

1. Outline the services to be provided.

2. Delineate the responsibilities of each party including compliance with federal and state laws and regulations governing the practice of pharmacy as well as state and federal medical privacy requirements.

3. Require that the parties adopt a policies and procedures manual.

4. Provide that the parties have access to or share a common electronic file such that the pharmacist performing remote medication order processing has sufficient patient information necessary for prospective drug use review and approval of medication orders.

(3) Policy and Procedures. A policy and procedures manual shall:

(a) Be accessible to each party involved in remote medication order processing.

(b) Be available for inspection by the Board or an authorized agent of the Department.

(c) Outline the responsibilities of each party involved in remote medication order processing.

(d) Include a current list of the name, address, telephone number, and license number of each pharmacist involved in remote medication order processing.

(e) Include policies and procedures for:

1. Protecting the confidentiality and integrity of patient information.

2. Ensuring that a pharmacist performing prospective drug use review has access to appropriate drug information resources.

3. Ensuring that medical and nursing staff understand how to contact a pharmacist.

4. Maintaining records to identify the name, initials, or identification code of each person who performs a processing function for a medication order.

5. Complying with federal and state laws and regulations.

6. Operating or participating in a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

7. Reviewing the written policies and procedures and documenting the review every year.

(4) Records.

(a) A Class II Institutional Pharmacy involved in remote medication order processing shall maintain a record that identifies the name, initials, or identification code of each person who performed a processing function for every medication order. The record shall be available by medication order or by patient name.



(b) The record may be maintained in a common electronic file if the record is maintained in such a manner that the data processing system can produce a printout which identifies every person who performed a processing function for a medication order.

(c) The record shall be readily retrievable for at least the past four (~~two~~) years.

(d) The record shall be available for inspection by the Board or an authorized agent of the Department.

*Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.019, 465.022, 465.026 FS. History—New 11-29-04;*

\_\_\_\_\_.

## L. 64B16-28.607 Automated Pharmacy System – Long Term Care, Hospice, and Prison.

### **64B16-28.607 Automated Pharmacy System – Long Term Care, Hospice, and Prison.**

#### (1) Definitions.

(a) “Automated pharmacy system” means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and delivery of a medicinal drug, and which collects, controls, and maintains a record of each transaction.

(b) “Provider pharmacy” means a pharmacy that provides pharmacy services by using an automated pharmacy system at a remote site.

(c) “Remote site” means a long term care facility or hospice licensed under Chapter 400, F.S., or a state correctional institution operated under Chapter 944, F.S., that is not located at the same location as the provider pharmacy, at which pharmacy services are provided using an automated pharmacy system.

(d) “Controlled substance” means a substance listed in Chapter 893, F.S., or 21 CFR Part 1308.

#### (2) Provider Pharmacy Requirements.

(a) A provider pharmacy may provide pharmacy services to a long term care facility or hospice licensed under Chapter 400, F.S., or a state correctional institution operated under Chapter 944, F.S., through the use of an automated pharmacy system.

(b) An automated pharmacy system shall only be used to provide pharmacy services to an inpatient or a resident of the remote site.

(c) Supervision of the automated pharmacy system shall be the responsibility of a Florida pharmacist employed by the provider pharmacy.

(d) Every medicinal drug stored in the automated pharmacy system shall be owned by the provider pharmacy.

(e) An automated pharmacy system shall be under the supervision of a pharmacist employed by the provider pharmacy. The pharmacist need not be physically present at the remote site if the system is supervised electronically.

(f) A provider pharmacy shall have policies and procedures to ensure adequate security.

#### (3) Prescription Department Manager Requirements.

(a) The prescription department manager shall ensure that the automated pharmacy system complies with Chapter 893, F.S., and 21 C.F.R., relating to the regulation of controlled substances, for each automated pharmacy system that contains a controlled substance.

(b) The prescription department manager shall ensure that the use of an automated pharmacy system does not compromise patient confidentiality.

(c) The prescription department manager or a designee shall:

1. Authorize or deny access to the data from an automated pharmacy system or to a drug stored inside the automated pharmacy system.

2. Document the training of each person who has access to the data from an automated pharmacy system or to a drug stored inside the automated pharmacy system.

(4) Automated Pharmacy System Requirements.

(a) A medicinal drug stored in bulk or unit-of-use in an automated pharmacy system is part of the inventory of the provider pharmacy and is not part of the inventory of any other pharmacy permit for the facility.

(b) A medicinal drug may be removed from an automated pharmacy system for administration to a patient only after a prescription or order has been received and approved by a pharmacist at the provider pharmacy. This provision does not apply to a medication designated as an emergency medication if the automated pharmacy system is also used as an emergency medication kit in compliance with Section 400.142, F.S. and Rule 59A-4.112, F.A.C.

(c) A pharmacist at the provider pharmacy shall control all operations of the automated pharmacy system and approve release of the initial dose of a prescription or order. A subsequent dose from an approved prescription or order may be released without additional approval of a pharmacist. However, any change made in a prescription or order shall require a new approval by a pharmacist to release the drug.

(d) A pharmacist at the provider pharmacy shall comply with the patient record requirements in Rule 64B16-27.800, F.A.C., and prospective drug use review requirements in Rule 64B16-27.810, F.A.C., for every medicinal drug delivered through an automated pharmacy system.

(e) If the facility where pharmacy services are being provided maintains a medication administration record that includes directions for use of the medication, a unit dose medication may be utilized if the provider pharmacy or the automated pharmacy system identifies and records the dispensing pharmacy, the prescription or order number, the name of the patient, and the name of the prescribing practitioner for each medicinal drug delivered.

(f) Stocking or Restocking of an Automated Pharmacy System.

1. The stocking or restocking of a medicinal drug in an automated pharmacy system at the remote site shall be completed by a pharmacist or other licensed personnel, except as provided in subparagraph 2. below of this section.

2. If the automated pharmacy system uses removable cartridges or containers to store the drug, the stocking or restocking of the cartridges or containers may occur at the provider pharmacy and be sent to the remote site to be loaded by personnel designated by the pharmacist if:

a. A pharmacist verifies the cartridge or container has been properly filled and labeled.

b. The individual cartridge or container is transported to the remote site in a secure, tamper-evident container.

c. The automated pharmacy system uses bar code verification, electronic verification, or similar process to assure that the cartridge or container is accurately loaded into the automated pharmacy system.

(g) A medicinal drug that has been removed from the automated pharmacy system shall not be replaced into the system unless a pharmacist has examined the medication, the packaging, and the labeling and determined that reuse of the medication is appropriate.

(h) Medication to be returned to the provider pharmacy's stock shall meet the requirements of Rule 64B16-28.118, F.A.C.

(5) Security Requirements.

(a) If a provider pharmacy intends to store a controlled substance in an automated pharmacy system:

1. It shall maintain a separate DEA registration for each remote site at which a controlled substance is stored.
2. It may utilize one DEA registration to include multiple automated pharmacy systems located at a single address.

(b) A provider pharmacy shall only store a medicinal drug at a remote site within an automated pharmacy system which is locked by a mechanism that prevents access to a drug or to data by unauthorized personnel.

(c) Access to the drugs shall be limited to a pharmacist or a registered pharmacy technician employed by the provider pharmacy or licensed personnel in the facility or institution who are authorized to administer medication.

(d) An automated pharmacy system that contains a controlled substance shall prohibit simultaneous access to multiple drug entities, drug strengths, or dosage forms of controlled substances.

(6) Emergency medication. If an automated pharmacy system is utilized for both a medication ordered for a specific patient and an emergency medication for which the review of a pharmacist is not required:

- (a) The emergency medication shall be stored separately from other patient medications.
- (b) The record shall identify the storage location from which the medication was released.
- (c) The record shall include the name of the medication, the patient, the prescriber, the person who accessed the automated pharmacy system, and the date and time of the release.

(7) Record Keeping Requirements.

(a) The record of transactions with the automated pharmacy system shall be maintained in a readily retrievable manner.

(b) The record shall be available to an authorized agent of the Department of Health or the Board of Pharmacy.

(c) The record shall include:

1. Name or identification of the patient or resident.
2. Name, strength and dosage form of the drug product released.
3. Quantity of drug released.
4. Date and time of each release of a drug.
5. Name of provider pharmacy.
6. Prescription number or order number.
7. Name of prescribing practitioner.

8. Identity of the pharmacist who approved the prescription or order.

9. Identity of the person to whom the drug was released.

(d) A record of every transaction with the automated pharmacy system shall be maintained for four (4)~~two (2)~~ years.

*Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.019, 465.022, 465.0235 FS. History—New 4-22-07, Amended 1-1-10; \_\_\_\_\_.*

## M. 64B16-28.702 Modified Class II Institutional Pharmacies.

### **64B16-28.702 Modified Class II Institutional Pharmacies.**

(1) Modified Class II Institutional Pharmacies are those Institutional Pharmacies which provide specialized pharmacy services restricted in scope of practice and designed to provide certain health care pharmacy services that are not generally obtainable from other pharmacy permittees. These specialized institutional pharmacy practices are generally identifiable with short-term or primary care treatment modalities in entities such as primary alcoholism treatment centers, free-standing emergency rooms, rapid in/out surgical centers, certain county health programs, and correctional institutions. Medicinal drugs may not be administered, except to patients of the institution for use on the premises of the institution, in any facility which has been issued a Modified Class II Institutional Pharmacy Permit. All medicinal drugs as defined by Section 465.003(7), F.S., which are stocked in these pharmacies are only to be administered on premises as defined by Section 465.003(1), F.S., to inpatients on an inpatient or in-program basis. In-program patients are defined as those patients who have met program admission criteria required by the institution.

(2) Modified Class II Institutional Pharmacies are categorized according to the type of specialized pharmaceutical delivery system utilized and the following criteria (Categories are designated as Type "A", Type "B" and Type "C"):

(a) The type of the medicinal drug delivery system utilized at the facility, either a patient-specific or bulk drug system, and, the quantity of the medicinal drug formulary at the facility,

(b) Type "A" Modified Class II Institutional Pharmacies provide pharmacy services in a facility which has a formulary of not more than 15 medicinal drugs, excluding those medicinal drugs contained in an emergency box, and in which the medicinal drugs are stored in bulk and in which the consultant pharmacist shall provide on-site consultations not less than once every month, unless otherwise directed by the Board after review of the policy and procedure manual.

(c) Type "B" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and in bulk form and which has an expanded drug formulary, and in which the consultant pharmacist shall provide on-site consultations not less than once per month, unless otherwise directed by the Board after review of the policy and procedure manual.

(d) Type "C" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and which has an expanded drug formulary, and in which the consultant pharmacist shall provide on-site consultations not less than once per month, unless otherwise directed by the Board after review of the policy and procedure manual.

(3) All Modified Class II Institutional Pharmacies shall be under the control and supervision of a certified consultant pharmacist.

(4) The consultant pharmacist of record for the Modified Class II Institutional Pharmacy shall be responsible for establishing a written protocol and a policy and procedure manual for the implementation of a drug delivery system to be utilized and the requirements of this rule.

(5) A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit

application. The original policy and procedure manual shall be kept within the Modified Class II Institutional Pharmacy and shall be available for inspection by the Department of Health.

(6) Drugs as defined in Section 465.003(7), F.S., stocked in Modified Class II Institutional Pharmacies, Type "A" and Type "B" as provided herein, shall be those drugs generally utilized in the treatment modalities encompassed within the health care scope of the particular institutional care entity. The protocol and the policy and procedure manual for Type "A" and Type "B" Modified Class II Institutional Pharmacies shall contain definitive information as to drugs and strengths thereof to be stocked.

(a) The policy and procedure manual of facilities which are issued Type A Modified Class II Institutional Permits shall provide the following:

1. Definitive information as to drugs and strengths to be stored.
2. The establishment of a Pharmacy Services Committee which shall meet at least annually.
3. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.
4. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.
5. Provisions for the utilization of proof-of-use forms for all medicinal drugs within the facility.
6. A diagram of the facility and the security and storage of the medicinal drugs.
7. Provisions for maintaining the records of consultations for not less than ~~two (2)~~ four (4) years at the facility which shall be stored on-site and available for inspection by the Department of Health.

(b) The policy and procedure manual of facilities which are issued Type B Modified Class II Institutional Permits shall provide the following:

1. The establishment of a Pharmacy Services Committee which shall meet at least annually.
2. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.
3. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.
4. Provisions for the utilization of a perpetual inventory system for all controlled substances, injectables and other medicinal drugs as required by the Pharmacy Services Committee.
5. A diagram of the facility and the security and storage of the medicinal drugs.
6. Provisions for maintaining the records of consultations for not less than ~~two (2)~~ four (4) years at the facility which shall be stored on-site and available for inspection by the Department of Health.

(c) The policy and procedure manual of facilities which are issued Type C Modified Class II Institutional Permit shall provide the following:

1. The establishment of a Pharmacy Services Committee which shall meet at least annually.
2. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.

3. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.

4. Provisions for the utilization of a Medication Administration Record (MAR) for all medicinal drugs administered to patients of the facility.

5. A diagram of the facility and the security and storage of the medicinal drugs.

6. Provisions for maintaining the records of consultations for not less than ~~two (2)~~ four (4) years at the facility which shall be stored on-site and available for inspection by the Department of Health.

(7) Controlled drugs as defined in Chapter 893, F.S., stocked as provided herein within a Type "A" Modified Class II Institutional Pharmacy shall be stocked in unit size not to exceed 100 dosage units unless an exception thereto is granted by the Board of Pharmacy. Proof of use record sheets showing patient's name, date of administration, initials of person administering drug, and other pertinent control requirements are required for both controlled and noncontrolled substance medicinal drugs in Type "A" Modified Class II Institutional Pharmacies.

(8) A Modified Class II institutional pharmacy may contract with a Special Parenteral/Enteral Extended Scope pharmacy for the pharmacy services provided for by Rule 64B16-28.860, F.A.C.

(a) Special Parenteral/Enteral Extended Scope pharmacies and institutional pharmacy permits shall create and comply with Policy and Procedure Manuals that delineate duties and responsibilities of each entity including the following provisions:

1. The institutional pharmacy permit shall maintain records appropriate to ensure the provision of proper patient care.

2. The institutional pharmacy permit designee shall inspect and log in all medicinal drugs provided by the Special Parenteral/Enteral Extended Scope pharmacy.

(b) Such Policy and Procedure manuals shall be made available to the Board or Department upon request.

(c) Prior to contracting for such services the institutional pharmacy shall ensure that the Special Parenteral/Enteral Extended Scope pharmacy is licensed under the provisions of Rule 64B16-28.860, F.A.C.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019(2)(c) FS. History—New 4-22-82, Amended 11-5-85, Formerly 21S-1.37, Amended 4-16-86, Formerly 21S-1.037, Amended 7-31-91, Formerly 21S-28.702, 61F10-28.702, Amended 9-4-96, Formerly 59X-28.702, Amended 10-15-01; \_\_\_\_\_.*



## N. 64B16-29.0041 Record Maintenance Systems for Animal Shelter Permits.

### **64B16-29.0041 Record Maintenance Systems for Animal Shelter Permits.**

(1) General requirements for records maintained in an electronic system.

(a) If a permitted animal shelter's data processing system is not in compliance with the Board's data processing requirements, the facility must maintain a manual recordkeeping system meeting the requirements of Rule 64B16-29.004, F.A.C.

(b) Requirements for back-up systems. The facility shall maintain a back-up copy of information stored in the data processing system using disk, tape, or other electronic back-up and up-date this back-up copy on a regular basis, at least monthly, to assure that data is not lost due to system failure.

(c) Change or discontinuance of a data processing system.

1. Records of dispensed and returned medicinal drugs. A permitted animal shelter that changes or discontinues use of a data processing system must:

a. Transfer the records to the new data processing system; or

b. Purge the records to a printout which contains the same information as required on the audit trail printout as specified in Rule 64B16-29.004, F.A.C.

2. Other records. A pharmacy that changes or discontinues use of a data processing system must:

a. Transfer the records to the new data processing system; or

b. Purge the records to a printout which contains all of the information required on the original document.

3. Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for four (4) two years from the date of initial entry into the data processing system.

(d) Loss of data. The shelter manager for permitted animal shelters shall report to the Board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(2) The permitted animal shelter shall maintain a system(s) which can produce the information required in Rule 64B16-29.004, F.A.C., for the preceding four (4) two years. The information required in this paragraph shall be supplied by the permitted animal shelter within seven working days if requested.

(3) Failure to maintain records. Failure to provide records set out in this subsection, either on site or within 7 working days for whatever reason, constitutes failure to keep and maintain records.

(4) Data processing system downtime. In the event that a permitted animal shelter which uses a data processing system experiences system downtime, the permitted animal shelter must have an auxiliary procedure which will ensure that all data is retained.



## **TAB 4. 64B16-28.101 Prescription Area Accessible to Inspection.**

Review of Inspection Frequency and Violation-Free Periods to be consistent with 4 year records retention requirements.

### **64B16-28.101 Prescription Area Accessible to Inspection.**

(1) The prescription department compounding room or any other place where prescriptions are compounded, filled, processed, accepted, dispensed, or stored in each pharmacy shall be so situated and located that authorized agents and employees of the Department or other persons authorized by law to enter and inspect, can observe and survey the confines of said department, room or area and can enter into said department, room or area after identifying themselves, for the purpose of inspection at a reasonable hour or when the practice of the profession of pharmacy is being carried on, as defined in Section 465.003, F.S., without having been previously detained or announced. Such inspection may be routinely conducted at any time by authorized agents of the Department to determine whether Chapter 465, F.S., or provisions of these rules have been violated or for other lawful purposes, and need not be in response to a complaint filed with the Department. There shall be a minimum of one (1) inspection per year except as otherwise provided herein or directed by the Board.

(a) A pharmacy shall be inspected twice during the first year of operation.

(b) A pharmacy which has had passing inspections for the most current three years, and no discipline during the most current three years shall be inspected every two years.

(c) A pharmacy which fails to obtain a passing inspection or which is disciplined during the two year inspection cycle will be inspected annually until it achieves passing inspections for the most current three years, and no discipline during the most current three years as set forth in this subsection.

(2) Authorized agents and employees of the Department or other persons authorized by law shall have the right to inspect invoices, shipping tickets, or any other document pertaining to the transfer of drugs or drug preparations, from or to all pharmacies and a reasonable amount of time shall be allowed for said information to be made available.

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.017, 465.022 FS. History—Amended 5-19-72, 11-2-81, Formerly 21S-1.01, 21S-1.001, Amended 7-31-91, Formerly 21S-28.101, 61F10-28.101, 59X-28.101, Amended 5-4-05, 2-2-12.*

**Statutory Authority and Laws Implemented:**

### **465.017 Authority to inspect; disposal.—**

(1) Duly authorized agents and employees of the department shall have the power to inspect in a lawful manner at all reasonable hours any pharmacy, hospital, clinic, wholesale establishment, manufacturer, physician's office, or any other place in the state in which drugs and medical supplies are manufactured, packed, packaged, made, stored, sold, offered for sale, exposed for sale, or kept for sale for the purpose of:

(a) Determining if any of the provisions of this chapter or any rule promulgated under its authority is being violated;

(b) Securing samples or specimens of any drug or medical supply after paying or offering to pay for such sample or specimen; or

(c) Securing such other evidence as may be needed for prosecution under this chapter.

(2)(a) Except as permitted by this chapter, and chapters 406, 409, 456, 499, and 893, records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs shall not be furnished to any person other than to the patient for whom the drugs were dispensed, or her or his legal representative, or to the department pursuant to existing law, or, in the event that the patient is incapacitated or unable to request said records, her or his spouse except upon the written authorization of such patient. Such records may be furnished in any civil or criminal proceeding, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or her or his legal representative by the party seeking such records.

(b) The board shall adopt rules to establish practice guidelines for pharmacies to dispose of records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs. Such rules shall be consistent with the duty to preserve the confidentiality of such records in accordance with applicable state and federal law.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 1, 2, ch. 85-151; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 125, ch. 94-218; s. 245, ch. 97-103; s. 127, ch. 2000-160; s. 1, ch. 2003-166.

#### **465.022 Pharmacies; general requirements; fees.—**

**(12)** The board shall adopt rules that require the keeping of such records of prescription drugs as are necessary for the protection of public health, safety, and welfare.

(a) All required records documenting prescription drug distributions shall be readily available or immediately retrievable during an inspection by the department.

(b) The records must be maintained for 4 years after the creation or receipt of the record, whichever is later.

## **TAB 5. 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.

### **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)~~ two 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 6. 64B16-26.2032 Pharmacy Intern Registration Internship Requirements (U.S. Pharmacy Students/Graduates) and 64B16-26.2033 Pharmacy Intern Registration and Internship Requirements (Foreign Pharmacy Graduates).**

Discussion of expiration of intern registration.

### **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.

(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. 09/09), 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.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, which includes significant aspects of the practice of pharmacy as defined in Section 465.003(13), F.S.

(6) An internship program at college or school of pharmacy accredited by the ACPE shall 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 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 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.*

**64B16-26.2033 Pharmacy Intern Registration and Internship Requirements (Foreign Pharmacy Graduates).**

A foreign pharmacy 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.

(1) All applicants for intern registration must be made on form DH-MQA 102, "Pharmacy Intern Application for Foreign Graduates and Instructions," effective September 2009, which is incorporated by reference. Contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254 or (850) 488-0595 to request a form or download the form from the board's website at <http://www.doh.state.fl.us/mqa/pharmacy>.

(2) An applicant for foreign pharmacy graduate intern registration in Florida must submit proof of:

(a) Eligibility by the Foreign Pharmacy Graduate Equivalency Committee to sit for the Foreign Pharmacy Graduate Equivalency Examination, or

(b) A passing score on the Foreign Pharmacy Graduate Equivalency Examination to be considered a graduate of an accredited college or school of pharmacy.

(3) Upon the receipt of proof satisfactory to the Board that the intern applicant meets the requirements of either paragraph (a) or (b) of subsection (1), and submitted a completed application as required in subsection (2) unless there exists good cause for the Board's refusal to certify an applicant as set forth in Section 465.013, F.S., the Board shall certify the applicant to the Department for registration as an intern.

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

(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, which includes significant aspects of the practice of pharmacy as defined in Section 465.003(13), F.S.

(6) An internship program at an accredited college or school of pharmacy shall 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.

(e) No pharmacist may be responsible for the supervision of more than one intern at any one time.

(7) The program shall 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 (2) 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 1580 hours; or

(c) Licensure in another state and work performed as a pharmacist for a sufficient number of hours to total 1580 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 assure compliance with these rules.

(14) Proof of current licensure in another state and work as a pharmacist for up to 1580 hours may substitute for all or part of the internship hours requirement.

(15) Governmental and private radiopharmacy internship programs shall not apply to the pharmacy internship required under subsection (1) of this rule.

(16) All foreign pharmacy graduates must complete 500 hours of supervised work activity within the state of Florida as provided by Section 465.007(1)(b)2., F.S. The supervised work activity program experience shall be documented on form DH-MQA 1153, "Foreign Graduate Registered Intern Work Activity Manual," effective 01/10. Contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254 or (850)488-0595 to request a form or download the form from the board's website at <http://www.doh.state.fl.us/mqa/pharmacy>. Further, this 500 hours of work activity program shall not be recognized for any applicant until said applicant has obtained the passing score on the Foreign Pharmacy Graduate Equivalency Exam as provided in Section 465.007, F.S.

*Rulemaking Authority 465.005 FS. Law Implemented 456.013(1), 465.002, 465.007, 465.0075, 465.013 FS. History—New 5-27-10.*

## **TAB 7. 64B16-28.203 Transfer of Medicinal Drugs; Change of Ownership; Closing of a Pharmacy.**

### **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.*