

CHAPTER 2

REGULATORY OVERVIEW

MILESTONES IN CONSULTANT PHARMACY

1965 Medicare/Medicaid Conditions for Participation

The Federal government creates standards for the operation of hospitals and nursing homes that accept Federal money

1969 American Society of Consultant Pharmacists (ASCP)

A small group of pharmacists from around the country who want to focus on servicing nursing homes meets in Chicago and creates an association that specializes in institutional pharmacy issues.

1970 Florida Institutional Drug Bill

The state of Florida creates the position of Consultant Pharmacist and requires additional training for this license. The state also creates new pharmacy permits that include those for hospital pharmacies and nursing homes.

1974 Drug Regimen Review mandated (Federal requirement)

The Federal government mandates that all patients in nursing homes and ICF-DD's have drug regimen reviews by a pharmacist. Unfortunately, this mandate does not define what the pharmacist should evaluate during this review.

1980 GAO Report critiques D.R.R. results

The Government Accounting Office (GAO) evaluates the effectiveness of drug regimen reviews (implemented in 1974) and states these reviews have not improved patient care. GAO also states the pharmacist is not to blame since the original regulations lacked guidance on what should be evaluated.

1982 Federal Indicators go into effect

The federal government establishes the first set of criteria for doing a drug regimen review. These "indicators" were written for the surveyors to help them determine if the consultant pharmacist was doing an adequate job. Consultant Pharmacists use these indicators to enhance the way drug regimen reviews are conducted

1984 Med. Error Detection method created

Studies in the 70's & 80's indicated that error rates in nursing homes were in the 20-40% range. Each author had their own definition of what constituted a medication error which accounts for these high error rates. These new federal regulations define a medication error, establish a method to determine medication error rates, and suggest methods that can help reduce medication errors. These new regulations established that a facility's error rate must fall below 5% in order to avoid citation. Actual rates are closer to 1.5%.

1986 Outcome Survey Process

The federal survey shifts from a focus on paper documentation to a patient care evaluation. While documentation is still important, the main focus becomes patient outcomes. Are patients eating, drinking, free from decubitus ulcers, free from restraints and free from pain.

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1987 Omnibus Budget Reconciliation Act (OBRA 1990)

OBRA represents the annual budget act which includes health care, finance, defense, social programs etc. What makes this OBRA significant is a it includes the “Nursing Home Standards Reform Act” which significantly raises the bar on patient care in the nursing home.

1992 Unnecessary Drug Regulations

These regulations represent the most significant change in the Drug Regimen Review process since 1982. These regulations establish that each medication in a nursing home must have a supporting diagnosis. They also establish:

- 1) when it is appropriate to use psychoactive drugs,
- 2) normal dosage ranges for the elderly and patients with dementia
- 3) when dosage reductions should be attempted and
- 4) how to quantitatively measure and reduce the risk of adverse effects.

1998 MEDICARE Begins “Prospective Payment System” (PPS)

The Federal Medicare program changes the way nursing homes are reimbursed for Medicare A patients. “Medicare A” pays for those patients who move from a hospital to a nursing home for rehabilitation. The PPS system changes nursing home reimbursement from a “pass-through” approach to a set price per day (i.e. capitated rate) based on a rating scale called the RUGS score (i.e. resource utilization groups). Despite the fact that Medicare A patients represent only 10% of nursing home patients, this reimbursement change has a tremendous effect on nursing homes and long term care pharmacies.

1998 OSCAR REPORT (Online Survey & Certification Activity Report) begins tracking facility data nationally

The Federal government creates a process to compare nursing homes across the county on many characteristics including patient types, rates of infection patient falls, drug usage etc. This data is consolidated from the Minimum Data Set (MDS) submitted by the facility. The OSCAR report allows each facility (and their Consultant Pharmacist) to compare their practices against other facility in the state, region and nationally.

1999 Quality Indicators and BEER’S List of High Risk Drugs in the Elderly

These new regulations are the third installment in guidance to the prescriber and consultant pharmacist since 1982 on appropriate therapy in the elderly.

These changes raise the bar again on the requirements for a Drug Regimen Review. The new regulations incorporate information published by Dr. Beers on high risk medications in the elderly. The new guidelines establish a list of drugs that should not be used in the elderly and a second list of drugs that have a higher risk of causing side effects in the elderly if used inappropriately.

MILESTONES IN CONSULTANT PHARMACY (page 3)

2001 MEDICARE.GOV web site expands to include Quality Measures for all nursing homes in the country

The Medicare program creates a web site for the public that allows them to compare nursing homes in their community, based on criteria called "Quality Measures". This web site uses data collected from the Minimum Data Set transmitted from the facility to Medicare. The web site also includes survey deficiencies taken from the most recent state survey.

2004 Hospital quality indicators released and revisions to hospital pharmacy conditions of participation standards

The Medicare program expands their public web site that compares nursing home quality measures to the hospital market. The goal is to provide consumers with a method of choosing a hospital based on service data.

2006 CMS releases new guidelines for Pharmaceutical Services, Medication Regimen Review, and Unnecessary Medications (Effective Date December 18, 2006)

The Federal government (CMS) revises the Interpretive Guidelines for pharmacy services in the nursing home. While the underlying law remains unchanged, the rewrite of interpretive guidelines increases the role of the consultant pharmacist. These changes consolidate several F Tags, require much more specific policies for handling the initiation of new orders, require the consultant pharmacist to be available between monthly visits and move away from the Beers criteria in favor of current standards of practice.

2010 October 1st, 2010 - MDS 3.0 goes live changing the assesment of all residents living in Nursing Homes in the Country

2012 CMS roles out the "Partnership to Improve Dementia Care in Nursing Homes. They set the standard to reduce Antipsychotic use by 15%

2013 January 1st, 2013 – CMS implements short cycle dispensing requirements for Brand name drugs in all nursing Homes in the U.S.

2013 CMS has proposed a split between Consulting services and Vendor Pharmacy services.

2014 The National Partnership for the Treatment of Dementia has set further reductions in Antopsychotic use to 25% (from baseline) by the end of 2015 and 30% (from baseline) by the end of 2016

Regulatory Overview

Federal

- HHS (*via* CMS –Formerly HCFA) - Conditions for participation in hospitals accepting Medicare/Medicaid payment
SNF, ICF/DD, hospice, home health care
- DEA
- FDA
- Joint Commission accreditation (VOLUNTARY) - hospitals have deemed status - means that hospital can substitute accreditation for HHS certification
- Joint Commission does have accreditation program for nursing homes but HHS does not recognize it as a substitute for HHS certification for Medicaid/Medicare

State

<u>Statute</u>	<u>Rules & Regs</u>
465 Pharmacy Practice Act	64B-16
400 Nursing Homes & related facilities	59A-4 AHA (DMQA)
Intermediate Care Facility (DD)	10D-38 ICF/DD (MR)
Assisted Living Facility (ALF)	58A-5
395 Hospital Licensing	59A-3
499 Drug & Cosmetic Act	61N-1
893 Controlled Substances Act	
409 Social and Economic Assist	59G4.250, 59G-4.280

Types of Facilities

Facilities Requiring Pharmacy licenses (and a Consultant Pharmacist)

Hospitals
Skilled Nursing Facilities (SNF/nursing home)
Intermediate Care Facility – Developmentally Disabled (ICF/DD)
ALF's (if they wish to return discontinued unit dose medications)
Correctional Facilities
Surgical Centers
Alcohol Detox Centers

Facilities without Pharmacy licenses (that may use a Consultant Pharmacist)

ALF (Assisted Living Facility)
Developmentally Delayed Group Homes
Psychiatric Group Homes
ADT (Adult Day Treatment Center)
Geriatric Residential Treatment Centers
FACT (Florida Assertive Community Treatment Team)
Correctional Facilities including Juvenile Detention Centers
Healthcare Clinic Establishment Permit (FS 499.01 2) (t)

Society and Association Information

ASCP

American Society of Consultant Pharmacists
1321 Duke Street
Alexandria, VA 22314-3563
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fax (703) 739-1321
www.ascp.com

APhA

American Pharmaceutical Association
2215 Constitution Avenue, NW
Washington, DC 20037
(202) 628-4410
www.aphanet.org

ASHP

American Society of Health-System Pharmacists
7272 Wisconsin Avenue
Bethesda, MD 20814
(301) 657-3000
www.ashp.org

FPA

Florida Pharmacy Association
610 N. Adams Street
Tallahassee, FL 32301
(850) 222-2400
www.pharmview.com

FSHP

Florida Society of Health-System Pharmacists (FSHP)
2910 Kerry Forest Pkwy D4 Suite 376
Tallahassee, FL 32309
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PHARMACY PERMITS

INSTITUTIONAL PERMITS (FS 465.019)

COMMUNITY PERMITS (FS 465)

SPECIAL PERMITS (FS 465)

TCU - TRANSITIONAL CARE UNIT

HEALTHCARE CLINIC ESTABLISHMENT PERMIT (FS 499.01 (2) (t))

WHOLESALE PERMITS

I. INSTITUTIONAL PERMITS (FS 465.019)

a. Institutional Class I (64B-16 28.501)

- i. Consultant Pharmacist required. Inspect and provide a written report at least monthly. The Board will consider petitions to perform inspections on a less frequent basis.
- ii. Nursing homes and Intermediate Care Facility/Developmentally Disabled (ICF/DD).
- iii. **Allows storage of validly ordered and dispensed legend drugs on the premises.**
- iv. No medication stock permitted, except in emergency box.
- v. Stock of OTC.
- vi. Conduct medication regimen review as required by law.

b. Institutional Class II (64B-16 28.602)

- i. Consultant Pharmacist required.
- ii. **Hospital practice setting.**
- iii. Dispensing of medications and consulting on the premises.
- iv. **Open "sufficient hours to provide quality services".**
- v. Emergency department dispensing (465.019(4) F.S., 64B16-28.6021).
 1. Dispensing by individuals licensed to prescribe.
 2. Consultant pharmacist responsible for maintaining records created by prescriber/dispenser.
 3. Pharmacy services were not readily accessible.
 4. Limited to 24 hour or minimal dispensable quantity.
- vi. **"Nurse in charge" may obtain a single dose when the Pharmacy is closed.**
- vii. May outsource IV compounding (64B16-28.860).
- viii. May utilize remote medication order processing (64B16-28.606).
- ix. **Recurring practice activities of the Consultant Pharmacist include documentation of employee competency, renewal of permits, assuring license renewal for all pharmacists in the department, and biennial controlled substance inventory count.**
- x. Class II Institutional Pharmacies – Automated Distribution and Packaging (64B16-28.605).

c. **Modified Institutional Class II Type A, B, and C (64B-16 28.702)**

i. **Common requirements**

1. Restricted in scope of practice. Short term treatment centers.
2. Consultant Pharmacist required.
3. **Consultant Pharmacist inspects at least monthly.** Maintain records of consultations for not less than four (4) years at the facility which shall be stored on-site and available for inspection by the Department of Health.
4. **Medication regimen reviews are NOT required by Federal or State regulations.**
5. Policy and procedure manual available onsite and available for inspection by the Department of Health.
 - a. Required with permit application and any changes approved by the Board of Pharmacy.
6. Medicinal drugs may not be dispensed, except to patients of the institution for use on the premises.
7. Pharmacy Services Committee meets at least annually.

ii. **Modified Institutional II A (for example - Alcohol De-Tox Center)**

1. 15 medicinal drugs may be stocked excluding those in the emergency box.
2. Control drugs shall be stocked in unit size not exceed 100 doses unless an exception is granted by the Board.
3. Proof of use record for all drugs.

iii. **Modified Institutional II B (for example – urgent care center; outpatient surgery center; correctional institution, multi-doctor practice with centralized medication stock, ambulatory dialysis, freestanding ED)**

1. Expanded formulary may be any medications needed to meet the medical objectives of the facility.
2. Medications stored in patient specific form and bulk form.
3. A perpetual inventory system for all controlled medications. Injectables and other medicinal drugs controlled as required by the pharmacy services committee.

iv. **Modified Institutional II C (for example - Custodial Setting, Jails with low inmate population)**

1. Drugs in patient specific prescription containers, self administered under supervision.

II. COMMUNITY PERMITS (FS 465)

a. Community Pharmacy

- i. Pharmacist manager of the prescription department.
- ii. No more than one permit per pharmacist.
- iii. Petition Board for exemption for limited workload and proximity of permits (64B16-27.104)
- iv. Community pharmacies that dispense controlled substances must maintain a record of all controlled substance dispensing consistent with the requirements of s. 893.07, F.S., and must make the record available to the department and law enforcement agencies upon request.
- v. 465.0181. Community pharmacy permit required to dispense Schedule II or Schedule III controlled substances. Permitting requirements that must be met for a pharmacy to dispense Schedule II or Schedule III prescriptions after July 1, 2012 include, but are not limited to, fingerprinting requirements and written policies and procedures for preventing controlled substance dispensing based upon fraudulent representations or invalid practitioner-patient relationships.
- vi. A permit holder must notify the department, on a form approved by the board, within 10 days after any change in prescription department manager or consultant pharmacist of record.
- vii. A permit holder must notify the department of the identity of the prescription department manager within 10 days after employment.
- viii. The prescription department manager must comply with the following requirements:
 1. The prescription department manager of a permit holder must obtain and maintain all drug records required by any state or federal law to be obtained by a pharmacy, including, but not limited to, records required by or under this chapter, chapter 499, or chapter 893.
 2. The prescription department manager must ensure the security of the prescription department. The prescription department manager must notify the board of any theft or significant loss of any controlled substances within 1 business day after discovery of the theft or loss.
- ix. All required records documenting prescription drug distributions shall be readily available or immediately retrievable during an inspection by the department and must be maintained for 4 years after the creation or receipt of the record, whichever is later.
- x. A pharmacist may not serve as the prescription department manager in more than one location unless approved by the board.

- b. **Special closed system pharmacy (64B16-28.830)**
 - i. Utilizes closed delivery systems to facilities where prescriptions are prepared for the ultimate consumers, including nursing homes, jails, ACLF's, ICF/DD's, or other custodial care facilities.
 - ii. Policy and procedure manual required.
 - iii. 24 hour emergency and on call service.
 - iv. May dispense sterile product preparations with approval.
 - v. Pharmacist manager (one permit) with experience in IV therapy.

- c. **Special Limited Community (64B16-28.800)**
 - i. Issued ONLY to a Institutional Class II pharmacy (hospital).
 - ii. Dispense to employees, medical staff and their dependents for a personal use.
 - iii. Dispense to patients who are under a continuation of therapy not to exceed 3 days.
 - iv. Dispense to patients receiving treatment in the facilities emergency room, etc.
 - v. Discharged patients of the hospital who are under a continuation of a course of therapy using multi-dose medicinal drugs.
 - 1. Must be labeled consistent with Community Pharmacy permit requirements.
 - 2. A specific order is written by the patient's physician to authorize that the multi-dose medicinal drug is appropriate to dispense upon discharge.
 - 3. A "multi-dose medicinal drug" as used in this rule means, but is not limited to, commercially available multi-dose packages such as inhalers, ocular products, insulin vials or pens, otic products, bulk antibiotic suspensions, topical agents, and methylprednisolone dose packets dispensed to inpatients, provided in containers that may exceed a three (3) day supply, and are intended to be continued by the patient on an outpatient basis but not to be re-filled by the hospital. Controlled substances are not considered multi-dose medicinal drugs as defined in this rule.
 - vi. Must provide offer to counsel.

III. SPECIAL PERMITS (FS 465)

- a. **Special Sterile Compounding (64B16-28.802)**
 - i. A special sterile compounding permit is a type of special permit, which is required before any permitted pharmacy may engage in the preparation of compounding sterile products.
 - ii. The compounding of sterile products must be in strict compliance with the standards set forth in Rules 64B16-27.797 and 64B16-27.700, F.A.C. *Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History—New 6-18-13.*

- b. **Sterile Products and Special Parenteral/Enteral Compounding (64B16-28.820)**
 - i. Allows dispensing of sterile compounded products pursuant to a valid patient prescription.
 - ii. Policy and procedure manual required.
 - iii. Environment set apart, designed and equipped to facilitate controlled aseptic conditions.
 - iv. Prescription department manager (only 1 per permit).
 - v. Patient profile shall be maintained for each patient.
 - vi. Special handling and delivery.
 - vii. Quality assurance program.
 - viii. Special handling of cytotoxic drugs.
 - ix. Exempt from requirement to obtain Special Sterile Compounding permit.

- c. **Special Parenteral/Enteral Extended Scope (SPEES) (64B16-28.860)**
 - i. Providing sterile products/enterals to an Institutional II Pharmacy permit (Hospital) – reference 64B16-28.602.
 - ii. Policy and Procedure manual required - delineates duties and responsibilities of each entity.
 - iii. Hospital maintains records to ensure provision of proper patient care.
 - iv. Hospital inspects and logs in products prepared by SPEES pharmacy.
 - v. Hospital pharmacists review drug order prior to sending Rx to SPEES pharmacy
 - vi. Prescription department manager (only 1 per permit).
 - vii. Exempt from requirement to obtain Special Sterile Compounding permit.

- d. **Special Permit – ALF (Assisted Living Facility) 64B16-28.870 – optional**
 - i. Consultant Pharmacist required.
 - ii. Unit dose may be returned (except controlled substances).
 - iii. Policy and procedure manual.
 - iv. Inspect monthly and prepare written report.
 - v. Discontinued controlled drugs disposed according to 64B16-28.301.

- e. **Special pharmacy-ESRD (64B16-28.850)**
 - i. Limited in scope for persons with chronic kidney failure for self-administration in person's home.
 - ii. Limited formulary.
 - iii. For home use the following is required:
 - 1. Rx ordering drug for use at a specific address.
 - 2. Pharmacy must have records that the patient has been properly trained in administering.
 - 3. If requested by the physician a list will be furnished to the physician of all drugs and supplies that were provided.
 - 4. The prescription may indicate that the patient may order refills.
 - 5. Maintain a list of drugs sent by quantity, product name, and product code number.
 - 6. Products will be removed from the shelf if less than 3 months remain on the expiration date.

7. 24 hour on-call service required.
8. Consultant pharmacist inspect monthly.
9. Consultant pharmacists required.
10. Policy and Procedure manual required.

f. **Nuclear Pharmacy permit (64B16-28.900).**

- i. Certified nuclear pharmacist as manager.
- ii. Nuclear pharmacy area secured from access by unauthorized people.

g. **Animal Control Shelter permits (64B16-29)**

- i. Consultant RPh. Not required.
- ii. Registered as a modified II permit.
- iii. Registration with DEA required.
- iv. May stock only sodium pentothal and sodium pentothal with lidocaine.

h. **Non-Resident Mail Service permit (64B16-28.840)**

- i. For mail order pharmacies outside the state.
- ii. Pharmacy and prescription department manager are licensed in the state of location.
- iii. Changes of locations, managers, or corporate officers must be reported to the Board.
- iv. Must have regular hours of 6 day per week and 40 hours per week.
- v. Must have a toll free telephone number.

IV. TCU - TRANSITIONAL CARE UNIT (also called SKILLED NURSING UNITS OR SNU)

- a. Separately licensed that may be within hospital facility.
- b. Consultant Pharmacist Required.
- c. Joint Commission Accreditation Standards and CMS nursing home standards apply.

V. HEALTHCARE CLINIC ESTABLISHMENT PERMIT (FS 499.01 (2) (t))

- a. Required for purchase of prescription drugs by a place of business at one physical location.
 - i. Owned and operated by a professional corporation or professional limited liability company as referenced in FS 621.
- b. "Qualifying Practitioner" is responsible for complying with all legal and regulatory requirements related to purchasing, recordkeeping, storage, and handling of prescription drugs. Records are under the qualifying practitioner's license. Qualifying Practitioner = MD, DO, PA, ARNP, DPM, DDS, DMD, DVM, DC.
- c. Notify the DOH within 10 business days of any changes to the qualifying practitioner.
- d. A healthcare clinic establishment that meets the criteria of a modified Class II Institutional Pharmacy Permit under FS 465.019 is not eligible to be permitted as a Healthcare Clinic Establishment Permit.
- e. Consultant Pharmacist NOT required.

VI. WHOLESALER PERMITS – reference FL Statutes chapter 499, 61N-1

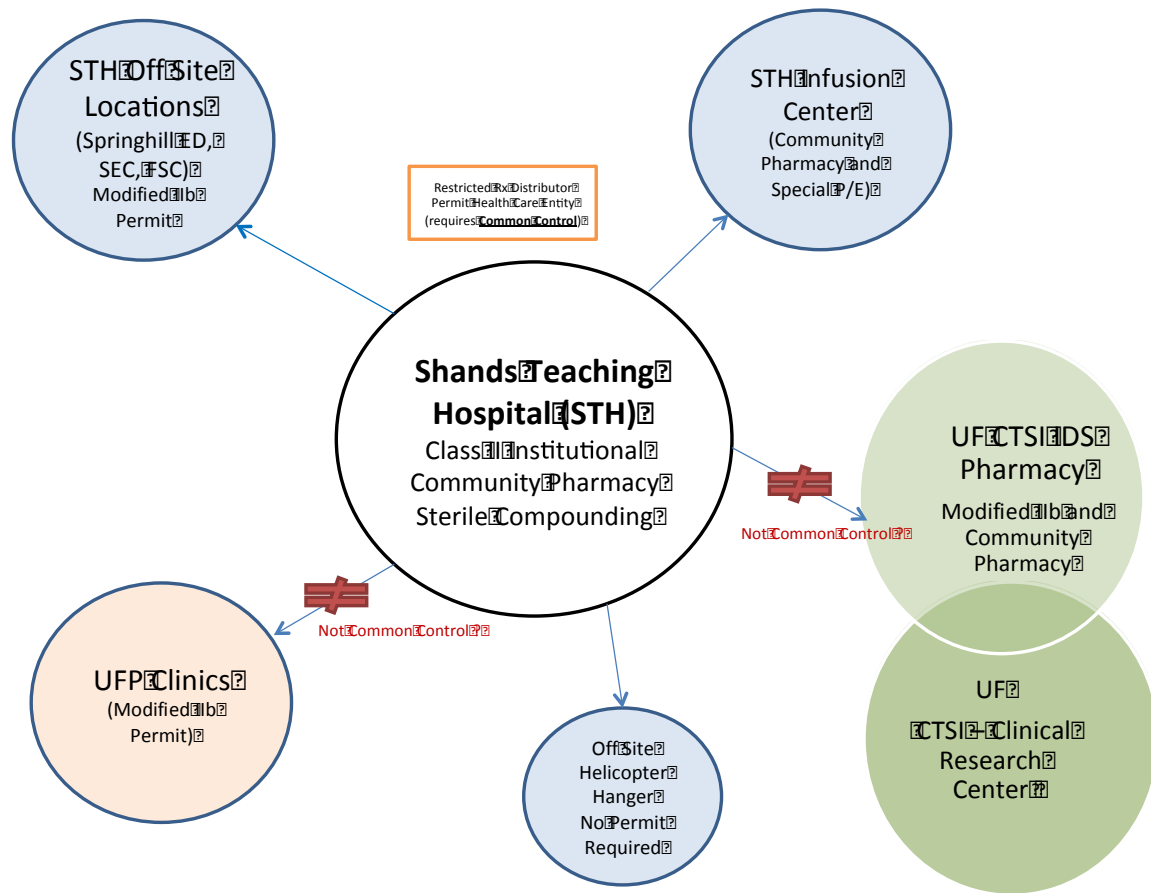
- a. Requires policy and procedures with specific record keeping requirements.
- b. Records readily retrievable.
- c. Policies focus on drug security and storage.
- d. Controlled room temperature measured between 2-4 pm daily.
- e. Permit types:

i. Restricted Rx Drug Distributor – Health Care Entity

- 1. Required for a hospital or health care entity as defined in Section 499.003(15), F.S., for the limited purpose of transferring prescription drugs among hospitals or other health care entities that are:
 - a. Under common control as provided in Section 499.012(1)(a)3., F.S.
 - b. Members of a group purchasing organization as provided for in Section 499.012(1)(a)1., F.S.

ii. Retail Drug Distributor - See page 2.14 for summary

EXAMPLE HEALTH SYSTEM PHARMACY PERMIT RELATIONSHIPS



REQUIREMENTS OF A RETAIL PHARMACY WHOLESALER'S PERMIT

- This license applies to a retail Pharmacy only that purchases drugs at “fair market” prices. Therefore a retail Pharmacy with a Sterile Products and Special Parenteral/Enteral Compounding license OR a closed door Pharmacy cannot apply for this wholesale permit
- This license allows the licensed retail Pharmacy to sell prescription drugs to other Pharmacies, facilities with Modified Class II licenses and health care practitioners licensed in Florida to prescribe medications.
- A Policy & Procedure manual is required that will address:
 - Receipt of Drugs
 - Security of drugs (must have a security system)
 - Storage of Medication (includes recording of temp & humidity in storage areas)
 - Procedures for identifying, recording, and reporting losses
 - Procedures for rotating stock
 - Procedure for handling recalls
 - Disaster Plans in the event of a fire, hurricane etc.
 - Designated area for non-saleable products “ Quarantine Area” must be clearly marked
- Records for all wholesale activities must be kept separate & distinct from the Pharmacy prescription activities. The sales cannot be processed in your computer system as if filling a prescription since this would intermingle your records.
- All invoices must be kept on site for a period of 3 years
- Wholesale activities cannot exceed 30% of the Pharmacy's total annual purchases
- Annual inventory must be item specific (Either drug name, strength, quantity or NDC # and quantity).
- The Florida Dept of Health will inspect the Pharmacy prior to issuing a license to review the site, purchasing activities, storage conditions, P&P manuals etc.
- Pedigree Papers for all purchases and sales (effective 7/1/2006)

C. Special circumstances:

1. Emergency borrowing of pharmaceuticals

61N-1.011 Wholesale Distribution of Prescription Drugs – Exceptions and Specific Distributions Authorized.

(1) The exemption from the definition of wholesale distribution in Section 499.003(53)(b)2., F.S., for “emergency medical reasons” includes:

(a) Transfers of a prescription drug between health care entities or from a health care entity to a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules, and should not occur between the parties so as to amount to the health care entity regularly and systematically supplying that drug;

(b) Transfers of prescription drugs by a health care entity to an emergency transport vehicle which is under the direction of a medical director of an emergency medical service provider licensed under Chapter 401, F.S., for use in the treatment of persons transported to that health care entity to immediately restock a licensed vehicle or an emergency medical kit for prescription drugs used on that person or to immediately restock prescription drugs on the vehicle which have become unsuitable for use. This exception does not extend to the stocking of supply inventory or for warehousing of prescription drugs used by emergency medical service providers;

(c) Emergency transfers of prescription drugs as authorized in Rule 59A-4.112, F.A.C., for nursing homes or Rule 64B16-28.6021, F.A.C., of the Florida Board of Pharmacy; or

(d) Transfers of prescription drugs by a retail pharmacy to another retail pharmacy or to a health care entity to alleviate a temporary shortage, but not for the regular and systematic supplying of that prescription drug;

(e) Transfers of prescription drugs in an emergency declared pursuant to Section 252.36, F.S., until the state of emergency is lifted, under the following conditions:

1. The manufacturer, wholesaler, or other person supplying the prescription drugs is authorized by Florida law to distribute prescription drugs in or into Florida; and

2. The prescription drugs are delivered to a temporary emergency medical station, officially designated by the state emergency operation center as a Disaster Medical Assistance Team or State Medical Response Team site;

3. The prescription drugs are delivered to a Pharmacy licensed under Chapter 465, F.S.;

(f) Transfers of prescription drugs from a health care entity to a pharmacy or other end-user practitioner for a named patient to treat or prevent a serious medical condition when a shortage of the product is documented by the manufacturer;

but does not include regular and systematic sales of prescription drugs to licensed practitioners that will be used for routine office procedures.

(g) Transfers of prescription drugs by or on behalf of the Department of Health to the medical director of an advanced life support service provider, licensed under Chapter 401, Part III, F.S., and for further distribution to an emergency transport vehicle operated by the advanced life support services provider, for use in the treatment of persons in need of emergency medical services;

(h) Transfers of prescription drugs by or on behalf of the Department of Health to a health care entity authorized to purchase prescription drugs, for storage and use in the treatment of persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health;

(i) Transfers of prescription drugs by or on behalf of the Department of Health to the licensed medical director of a government agency health care entity, authorized to purchase prescription drugs, for storage and use in the treatment of persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health.

(j) Transfers of prescription drugs by or on behalf of the Department of Health to a community pharmacy authorized to purchase prescription drugs, for dispensing to persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health.

(2) The revocation of a sale or the return of a prescription drug purchased by a hospital or other health care entity, or acquired at a reduced price by or donated to a charitable institution to the manufacturer or the wholesale

distributor that sold, donated, or supplied the prescription drug, is not a wholesale distribution prohibited by Section 499.005(21), F.S., provided:

(a) The hospital, health care entity or charitable institution forwards a copy of the documentation for the return to the manufacturer of the product. This documentation must at a minimum comply with the requirements of Rule 61N-1.012, F.A.C.; and

(b) The value of any credit, refund, or exchange for the returned product does not exceed the purchase price or, if a donation, the fair market price of the returned product.

(c) Prescription drugs returned or to be returned to a manufacturer or wholesale distributor must be kept under proper conditions for storage, handling, and shipping as set forth in Section 499.0121, F.S.; and written documentation showing that these conditions were or were not maintained must be provided to the manufacturer or wholesale distributor to which the prescription drugs are returned.

(3) A person authorized to possess non-dispensed prescription drugs can donate prescription drugs that are not misbranded or adulterated to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs provided the transfer is not for sale or trade and the donor receives no financial benefit (except for tax benefits related to charitable contributions) either directly or indirectly. Records to document the transfer must comply with Section 499.0121(6), F.S., and paragraph 61N-1.008(2)(c), F.A.C.

(4) A person who uses prescription drugs for lawful research, teaching, or testing may obtain a registration number from the department to authorize acquisition of the requisite prescription drugs for this activity. The person must submit correspondence to the department explaining the conditions of the lawful research, teaching, or testing, along with a statement signed by the individual who will be responsible for the prescription drugs that the drugs will be secured, access will be restricted to authorized individuals, and that the prescription drugs are not for resale. If applicable, this correspondence should also identify the name in which purchases will be made, the specific prescription drug(s) required for the activity, the quantity which will ordinarily be purchased, the frequency of the purchases, and the name and state permit or license or permit number of suppliers of the prescription drugs. A letter and registration number will be assigned to the person which authorizes the purchase or other acquisition and possession of prescription drugs. This registration number must be included on invoices as required by Section 499.0121(6)(a), F.S.

Rulemaking Authority 499.003(53)(b), 499.012, 499.03, 499.05 FS. Law Implemented 499.003(53)(b), 499.012, 499.03, 499.05 FS. History—New 7-1-96, Formerly 10D-45.0525, Amended 1-26-99, 4-17-01, 1-1-04, 10-4-07, 12-13-09, 6-8-10, Formerly 64F-12.011.

2. In the case of Emergency as Declared by the Governor

465.019 Institutional pharmacies; permits.--

(1) Any institution desiring to operate an institutional pharmacy shall apply to the department. If the board certifies that the application complies with the laws of the state and the rules of the board governing pharmacies, the department shall issue the permit.

(2) The following classes of institutional pharmacies are established:

(a) "Class I institutional pharmacies" are those institutional pharmacies in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises, except that nursing homes licensed under part II of chapter 400 may purchase medical oxygen for administration to residents. No medicinal drugs may be dispensed in a Class I institutional pharmacy.

(b) "Class II institutional pharmacies" are those institutional pharmacies which employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, shall provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution. However, an institutional pharmacy located in an area or county included in an emergency order or proclamation of a state of emergency declared by the Governor may provide dispensing and consulting services to individuals who are not patients of the institution. However, a single dose of a medicinal drug may be obtained and administered to a patient on a valid physician's drug order under the supervision of a

physician or charge nurse, consistent with good institutional practice procedures. The obtaining and administering of such single dose of a medicinal drug shall be pursuant to drug-handling procedures established by a consultant pharmacist. Medicinal drugs may be dispensed in a Class II institutional pharmacy, but only in accordance with the provisions of this section.

(c) "Modified Class II institutional pharmacies" are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements.

(3) Medicinal drugs shall be stocked, stored, compounded, dispensed, or administered in any health care institution only when that institution has secured an institutional pharmacy permit from the department.

(4) Medicinal drugs shall be dispensed in an institutional pharmacy to outpatients only when that institution has secured a community pharmacy permit from the department. However, an individual licensed to prescribe medicinal drugs in this state may dispense up to a 24-hour supply of a medicinal drug to any patient of an emergency department of a hospital that operates a Class II institutional pharmacy, provided that the physician treating the patient in such hospital's emergency department determines that the medicinal drug is warranted and that community pharmacy services are not readily accessible, geographically or otherwise, to the patient. Such dispensing from the emergency department must be in accordance with the procedures of the hospital. For any such patient for whom a medicinal drug is warranted for a period to exceed 24 hours, an individual licensed to prescribe such drug must dispense a 24-hour supply of such drug to the patient and must provide the patient with a prescription for such drug for use after the initial 24-hour period. The board may adopt rules necessary to carry out the provisions of this subsection.

¹(5) All institutional pharmacies shall be under the professional supervision of a consultant pharmacist, and the compounding and dispensing of medicinal drugs shall be done only by a licensed pharmacist. Every institutional pharmacy that employs or otherwise utilizes pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions which a pharmacy technician is allowed to perform.

(6) In a Class II institutional pharmacy, an institutional formulary system may be adopted with approval of the medical staff for the purpose of identifying those medicinal drugs and proprietary preparations that may be dispensed by the pharmacists employed in such institution. A facility with a Class II institutional permit which is operating under the formulary system shall establish policies and procedures for the development of the system in accordance with the joint standards of the American Hospital Association and American Society of Hospital Pharmacists for the utilization of a hospital formulary system, which formulary shall be approved by the medical staff.

History.--ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; s. 2, ch. 83-101; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 29, ch. 93-211; s. 244, ch. 98-166; s. 36, ch. 99-397; s. 79, ch. 2001-277; s. 6, ch. 2008-216.

¹**Note.**--Section 6, ch. 2008-216, amended subsection (5), effective January 1, 2010, to read:

(5) All institutional pharmacies shall be under the professional supervision of a consultant pharmacist, and the compounding and dispensing of medicinal drugs shall be done only by a licensed pharmacist. Every institutional pharmacy that employs or otherwise uses registered pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions that a registered pharmacy technician is allowed to perform.

PRESCRIPTION DEPARTMENT MANAGERS

Whenever there is a change in Prescription Department Manager, the permittee must notify the Department within 10 days of the change.

To reflect compliance with this requirement, a copy of the document furnished to the Board Office must be posted with the license(s) of the facility and pharmacists.

A Registered Pharmacist can only be the Prescription Department Manager Of 1 Pharmacy unless approved by the Board (see 64B16.27-104)

The attached form or a letter may be used to provide us with notice of the change. It should state the following:

1. Name and license number(s) of the pharmacist
2. Facility name and license number(s)
3. Address of the facility
4. Effective date of change

If you should have any questions regarding this matter, please contact the Board Office.

CONSULTANT PHARMACISTS OF RECORD

Whenever there is a change in Consultant Pharmacist of Record, you must notify the Board within 10 days.

To reflect compliance with this requirement, a copy of the documentation furnished to the Board Office must be posted with the license(s) of the facility and pharmacists.

The attached form or letter may be used to provide us with notice of the change. The notice should state the following:

1. Name and license number(s)
2. Facility name and license number(s)
3. Address of the facility
4. Effective date of change

If you should have any questions regarding this matter, please contact the Board Office.

A Consultant Pharmacist can be the Consultant of Record of multiple facilities. There is no maximum number of facilities for a Consultant. A Pharmacist can also be the Prescription Department Manager of a single Pharmacy and the Consultant of Record of multiple facilities.



FLORIDA BOARD OF PHARMACY
4052 Bald Cypress Way, Bin C-04 • Tallahassee, FL 32399
Phone: (850) 245-4292 • Fax: (850) 413-6982
www.doh.state.fl.us/mqa/pharmacy

CHANGE OF CONSULTANT PHARMACIST OF RECORD

Rule 64B16-28.501, *Florida Administrative Code*, requires each facility holding a Class I, a Class II, or a Modified Class II Institutional permit to designate a consultant pharmacist of record to ensure compliance with the laws and rules governing the permit. The Board office shall be notified in writing within 10 days of any change in the consultant pharmacist of record.

Once completed, return the signed form to the Florida Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, FL 32399-3254 ATTN: Permitting or by fax (850) 413-6982 or email (MQA_Pharmacy@doh.state.fl.us Feedback). Please contact our office at (850) 245-4292 if you have any questions.

This section must be completed by the Pharmacy Permit Establishment	
PHARMACY PERMIT ESTABLISHMENT NAME: _____	Print Establishment Name
PHARMACY PERMIT ESTABLISHMENT LICENSE NUMBER: _____	
FORMER CONSULTANT PHARMACIST NAME: _____	
AND LICENSE NUMBER: _____	
SIGNATURE: _____	DATE: _____
PRINT NAME: _____	POSITION: _____

This section must be completed by the IN-COMING Consultant Pharmacist of Record	
CONSULTANT PHARMACIST NAME: _____	Print Consultant Pharmacist of Record Name
CONSULTANT PHARMACIST OF RECORD SIGNATURE: _____	Signature
CONSULTANT PHARMACIST OF RECORD LICENSE NUMBER WITH PREFIX: _____	
DATE BEGINNING AS CONSULTANT PHARMACIST OF RECORD: ____/____/____	

This section must be completed by the OUT-GOING Consultant Pharmacist of Record	
CONSULTANT PHARMACIST OF RECORD NAME: _____	Print Consultant Pharmacist of Record Name
CONSULTANT PHARMACIST OF RECORD SIGNATURE: _____	Signature
CONSULTANT PHARMACIST OF RECORD LICENSE NUMBER WITH PREFIX: _____	
DATE ENDING AS CONSULTANT PHARMACIST OF RECORD: ____/____/____	









FLORIDA NURSING HOME REGULATIONS REGARDING PHARMACY SERVICES












59A-4.112 Pharmacy Services

1. The facility shall adopt procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals, to meet the needs of each resident.
2. The facility shall employ, or obtain, the services of a state licensed consultant pharmacist. A consultant pharmacist is a pharmacist who is licensed by the Department of Business and Professional Regulation and certified as a consultant pharmacist by the Board of Pharmacy in accordance with Rule 61F10-26.300, F.A.C. and who provides consultation on all aspects of the provision of pharmacy services in the facility.
3. The consultant pharmacist shall establish a system to accurately record the receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation.
4. The pharmacist shall determine that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.
5. Drugs and biologicals used in the facility shall be labeled in accordance with currently accepted professional principles, Chapter 499, F.S. and Chapter 61F10, F.A.C.
6. Drugs and non-prescription medications requiring refrigeration shall be stored in a refrigerator. When stored in a general-use refrigerator, they shall be stored in a separate, covered, waterproof, and labeled receptacle.
7. All controlled substances shall be disposed of in accordance with State and federal laws. All non-controlled substances may be destroyed in accordance with the facility's policies and procedures. Records of the disposition of all substances shall be maintained in sufficient detail to enable an accurate reconciliation.
8. Non-controlled substances, in unit dose containers, may be returned to the dispensing pharmacy.
9. If ordered by the resident's physician, the resident may, upon discharge, take all current prescription drugs with him. An inventory of the drugs released shall be completed, shall be dated, and signed by both the person releasing the drugs and the person receiving the drugs, and shall be placed in the resident's record.
10. The facility shall maintain an Emergency Medication Kit, the contents of which shall be determined in consultation with the Medical Director, Director of Nursing and Pharmacist, and it shall be in accordance with facility policies and procedures. The kit shall be readily available and shall be kept sealed. All items in the kit shall be properly labeled. The facility shall maintain an accurate log of receipt and disposition of each item in the Emergency Medication Kit. An inventory of the contents of the Emergency Medication Kit shall be attached to the outside of the kit. If the seal is broken, the kit must be resealed the next business day after use.

Medicare State Operations Manual Appendix

- Each Appendix is a separate file that can be accessed directly from the SOM Appendices Table of Contents, as applicable.
- The appendices are in PDF format, which is the format generally used in the IOM to display files. Click on the red button in the 'Download' column to see any available file in PDF.
- To return to this page after opening a PDF file on your desktop. use the browser "back" button. This is because closing the file usually will also close most browsers

App. No.	Description	PDF File
A	Hospitals	 <u>2,185 KB</u>
AA	Psychiatric Hospitals	 <u>606 KB</u>
B	Home Health Agencies	 <u>761 KB</u>
C	Laboratories and Laboratory Services	 <u>3,868 KB</u>
D	Portable X-Ray Service	 <u>82 KB</u>
E	Outpatient Physical Therapy or Speech Pathology Services-Interpretive Guidelines	 <u>234 KB</u>
F	Physical Therapists in Independent Practice	Deleted
G	Rural Health Clinics (RHCs)	 <u>382 KB</u>
H	End-Stage Renal Disease Facilities	 <u>1,669 KB</u>

I	Life Safety Code	 140 KB
J	Intermediate Care Facilities for Persons With Mental Retardation	 1,810 KB
K	Comprehensive Outpatient Rehabilitation Facilities	 202 KB
L	Ambulatory Surgical Services Interpretive Guidelines and Survey Procedures	 263 KB
M	Hospice	 720 KB
N	Pharmaceutical Service Requirements in Long-Term Care Facilities	Deleted
P	Survey Protocol for Long-Term Care Facilities	 929 KB
PP	Interpretive Guidelines for Long-Term Care Facilities	 1,440 KB
Q	Determining Immediate Jeopardy	 326 KB
R	Resident Assessment Instrument for Long-Term Care Facilities	 38 KB
S	Mammography Suppliers	Deleted
T	Swing-Beds	 363 KB
U	Responsibilities of Medicare Participating Religious Nonmedical Healthcare Institutions	 452 KB
V	Responsibilities of Medicare Participating Hospitals In Emergency Cases	 393 KB
W	Critical Access Hospitals (CAHs)	 1,597 KB

465.018 Community pharmacies; permits.--Any person desiring a permit to operate a community pharmacy shall apply to the department. If the board office certifies that the application complies with the laws of the state and the rules of the board governing pharmacies, the department shall issue the permit. No permit shall be issued unless a licensed pharmacist is designated as the prescription department manager responsible for maintaining all drug records, providing for the security of the prescription department, and following such other rules as relate to the practice of the profession of pharmacy. The permittee and the newly designated prescription department manager shall notify the department within 10 days of any change in prescription department manager.
History.--ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 3, ch. 88-172; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.019 Institutional pharmacies; permits.--

(1) Any institution desiring to operate an institutional pharmacy shall apply to the department. If the board certifies that the application complies with the laws of the state and the rules of the board governing pharmacies, the department shall issue the permit.

(2) The following classes of institutional pharmacies are established:

(a) "Class I institutional pharmacies" are those institutional pharmacies in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises, except that nursing homes licensed under part II of chapter 400 may purchase medical oxygen for administration to residents. No medicinal drugs may be dispensed in a Class I institutional pharmacy.

(b) "Class II institutional pharmacies" are those institutional pharmacies which employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, shall provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution. However, an institutional pharmacy located in an area or county included in an emergency order or proclamation of a state of emergency declared by the Governor may provide dispensing and consulting services to individuals who are not patients of the institution. However, a single dose of a medicinal drug may be obtained and administered to a patient on a valid physician's drug order under the supervision of a physician or charge nurse, consistent with good institutional practice procedures. The obtaining and administering of such single dose of a medicinal drug shall be pursuant to drug-handling procedures established by a consultant pharmacist. Medicinal drugs may be dispensed in a Class II institutional pharmacy, but only in accordance with the provisions of this section.

(c) "Modified Class II institutional pharmacies" are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements.

(3) Medicinal drugs shall be stocked, stored, compounded, dispensed, or administered in any health care institution only when that institution has secured an institutional pharmacy permit from the department.

(4) Medicinal drugs shall be dispensed in an institutional pharmacy to outpatients only when that institution has secured a community pharmacy permit from the department. However, an individual licensed to prescribe medicinal drugs in this state may dispense up to a 24-hour supply of a medicinal drug to any patient of an emergency department of a hospital that operates a Class II institutional pharmacy, provided that the physician treating the patient in such hospital's emergency department determines that the medicinal drug is warranted and that community pharmacy services are not readily accessible, geographically or otherwise, to the patient. Such dispensing from the emergency department must be in accordance with the procedures of the hospital. For any such patient for whom a medicinal drug is warranted for a period to exceed 24 hours, an individual licensed to prescribe such drug must dispense a 24-hour supply of such drug to the patient and must provide the patient with a prescription for such drug for use after the initial 24-hour period. The board may adopt rules necessary to carry out the provisions of this subsection.

(5) All institutional pharmacies shall be under the professional supervision of a consultant pharmacist, and the compounding and dispensing of medicinal drugs shall be done only by a licensed pharmacist. Every institutional pharmacy that employs or otherwise utilizes pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions which a pharmacy technician is allowed to perform.

(6) In a Class II institutional pharmacy, an institutional formulary system may be adopted with approval of the medical staff for the purpose of identifying those medicinal drugs and proprietary preparations that may be dispensed by the pharmacists employed in such institution. A facility with a Class II institutional permit which is operating under the formulary system shall establish policies and procedures for the development of the system in accordance with the joint standards of the American Hospital Association and American Society of Hospital Pharmacists for the utilization of a hospital formulary system, which formulary shall be approved by the medical staff. **History.**--ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; s. 2, ch. 83-101; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 29, ch. 93-211; s. 244, ch. 98-166; s. 36, ch. 99-397s. 79, ch. 2001-277; s. 6, ch. 2008-216.

¹**Note.**--Section 6, ch. 2008-216, amended subsection (5), effective January 1, 2010, to read:

(5) All institutional pharmacies shall be under the professional supervision of a consultant pharmacist, and the compounding and dispensing of medicinal drugs shall be done only by a licensed pharmacist. Every institutional pharmacy that employs or otherwise uses registered pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions that a registered pharmacy technician is allowed to perform.

465.0193 Nuclear pharmacy permits.--Any person desiring a permit to operate a nuclear pharmacy shall apply to the department. If the board certifies that the application complies with applicable law, the department shall issue the permit. No permit shall be issued unless a duly licensed and qualified nuclear pharmacist is designated as being responsible for activities described in s. 465.0126. The permittee shall notify the department within 10 days of any change of the licensed pharmacist responsible for the compounding and dispensing of nuclear pharmaceuticals. **History.**--ss. 33, 118, ch. 83-329; ss. 15, 26, 27, ch. 86-256; s. 4, ch. 88-172; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.0196 Special pharmacy permits.--Any person desiring a permit to operate a pharmacy which does not fall within the definitions set forth in s. 465.003(11)(a)1., 2., and 3. shall apply to the department for a special pharmacy permit. If the board certifies that the application complies with the applicable laws and rules of the board governing the practice of the profession of pharmacy, the department shall issue the permit. No permit shall be issued unless a licensed pharmacist is designated to undertake the professional supervision of the compounding and dispensing of all drugs dispensed by the pharmacy. The licensed pharmacist shall be responsible for maintaining all drug records and for providing for the security of the area in the facility in which the compounding, storing, and dispensing of medicinal drugs occurs. The permittee shall notify the department within 10 days of any change of the licensed pharmacist responsible for such duties. **History.**--ss. 34, 118, ch. 83-329; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch.

64B16-28.501 Institutional Permit - Consultant Pharmacist of Record.

Each facility holding a Class I, a Class II, or a Modified Class II Institutional permit shall designate a consultant pharmacist of record to ensure compliance with the laws and rules governing the permit. The Board office shall be notified in writing within 10 days of any change in the consultant pharmacist of record. The consultant pharmacist of record for a Class I, Modified Class II, or a Special ALF permit shall conduct Drug Regimen Reviews as required by Federal or State law, inspect the facility and prepare a written report to be filed at the permitted facility at least monthly. In addition, the consultant pharmacist of record must monitor monthly the facility system for providing medication administration records and physician order sheets to ensure that the most current record of medications is available for the monthly drug regimen review. The consultant pharmacist of record may utilize additional consultant pharmacists to assist in this review and or in the monthly facility inspection.

Specific Authority 465.005, 465.0125, 465.022 FS. Law Implemented 465.0125, 465.019, 465.022 FS. History--New 7-18-94, Formerly 61F10-28.501, 59X-28.501, Amended 1-2-02, 12-30-07.

64B16-28.602 Institutional Class II Dispensing.

(1) Pharmaceutical preparations which are administered to patients of a hospital by the personnel of such institution shall only be taken from the original container, or from a container which has been prepared by a Florida licensed pharmacist. Only single doses of such preparations shall be removed from the container, and then only after the preparation has been prescribed for a specific patient, and the order has been duly recorded upon the records of the institution. This requirement shall not apply to nor be construed as preventing the administration of treatment in bona fide emergency cases, or further as prohibiting any person who is a duly licensed physician from dispensing medicinal drugs as defined in Chapter 465, F.S. A single dose of medicinal drugs based upon a valid physician's drug order may also be obtained and administered under the supervision of the nurse in charge consistent with good institutional practice procedures as established by the consultant pharmacist of record and written in the policy and procedure manual which shall be available within the pharmacy.

(2) A 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.

3. A pharmacist for the institutional pharmacy shall provide drug utilization review and shall review each prescription order prior to transmission to 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)(b), 465.0196, 465.022(1) FS. History—Amended 5-19-72, Repromulgated 12-18-74, Amended 10-10-78, Formerly 21S-1.11, 21S-1.011, Amended 7-31-91, Formerly 21S-28.602, 61F10-28.602, Amended 9-4-96, Formerly 59X-28.602, Amended 8-16-10.

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) 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.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019, 465.022, 465.0235, 465.026 FS. History—New 4-22-07, Amended 1-1-10, 7-14-14.

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 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 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 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), 465.022 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, 7-14-14.

64B16-28.800 Special Pharmacies.

(1) Special pharmacies are pharmacies providing miscellaneous specialized pharmacy service functions. The Board of Pharmacy, by this rule, provides for the establishment of the following special pharmacy permits:

- (a) Special-Limited Community.
- (b) Special-Parenteral and Enteral.
- (c) Special-Closed System Pharmacy.
- (d) Special-Non Resident (Mail Service).
- (e) Special-End Stage Renal Disease.
- (f) Special-Parenteral/Enteral Extended Scope.
- (g) Special-ALF.
- (h) Special Sterile Compounding.

(2) An applicant for any special pharmacy permit shall provide the Board of Pharmacy with a Policy and Procedure Manual which sets for a detailed description of the type of pharmacy services to be provided

within the special pharmacy practice. The Policy and Procedures Manual shall contain detailed provisions for compliance with the provision of Section 465.0196, F.S., and other applicable requirements contained in the chapter.

(3) The Policy and Procedure Manual shall be prepared, maintained, and will be reviewed and is subject to approval by the Board of Pharmacy or its designee prior to the issuance of the permit and the initiation of the operation of the permittee. The policy and procedure manual is reviewed to determine if the operation of the facility will be in compliance with Chapters 465 and 893, F.S., and Chapter 64B16, F.A.C. The Policy and Procedure Manual shall be made available upon request of the Board or its agents. The applicant who requests a special permit shall be subject to inspection prior to the issuance of the permit.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196, 456.022 FS. History—New 2-21-84, Formerly 21S-1.39, 21S-1.039, Amended 7-31-91, 10-14-91, Formerly 21S-28.800, 61F10-28.800, Amended 3-10-96, 6-4-97, Formerly 59X-28.800, Amended 11-11-98, 10-15-01, 7-2-13.

64B16-28.802 Special Sterile Compounding Permits.

A special sterile compounding permit is a type of special permit, which is required before any permitted pharmacy may engage in the preparation of compounding sterile products. The compounding of sterile products must be in strict compliance with the standards set forth in Rules 64B16-27.797 and 64B16-27.700, F.A.C.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History—New 6-18-13.

64B16-28.810 Special Pharmacy – Limited Community Permit.

A Special-Limited Community Permit shall be obtained by a Class II Institutional Pharmacy that dispenses medicinal drugs, including controlled substances to:

- (1) Employees, medical staff and their dependents for their personal use,
- (2) Patients of the hospital who are under a continuation of a course of therapy not to exceed a three (3) day supply,
- (3) Patients obtaining medical services in the facility's emergency room and, whenever it is otherwise appropriate, as indicated in the applicant's policy and procedure manual, and
- (4) Discharged patients of the hospital who are under a continuation of a course of therapy using multi-dose medicinal drugs if the following requirements are met:
 - (a) The label affixed to a container used in dispensing multi-dose medicinal drugs contains at least the following information:
 1. The name of and contact information of the pharmacy;
 2. The name of the prescriber;
 3. The name of the patient;
 4. The date of the original filling and any applicable expiration date;
 5. The prescription number or other prescription identification adequate to readily identify the prescription;
 6. The directions for use;
 7. The name, strength, and size of the medicinal drug dispensed; and
 8. The quantity of the drug in the container.
 - (b) The patient is deemed competent to handle and administer the multi-dose medicinal drug.
 - (c) A specific order is written by the patient's physician to authorize that the multi-dose medicinal drug is appropriate to dispense upon discharge.
 - (d) Before the hospital dispenses a multi-dose medicinal drug as specified in paragraph (4) of this section, the hospital shall establish protocols to ensure the following:
 1. Infection control during transport and handling of multi-dose medicinal drug containers that have been in contact with a patient;
 2. Patient or caregiver education on administration of the multi-dose medicinal drug if necessary on an individual basis.
 - (e) A "multi-dose medicinal drug" as used in this rule means, but is not limited to, commercially available multi-dose packages such as inhalers, ocular products, insulin vials or pens, otic products, bulk antibiotic suspensions, topical agents, and methylprednisolone dose packets dispensed to inpatients, provided in containers that may exceed a three (3) day supply, and are intended to be continued by the patient on an outpatient basis but not to be re-filled by the hospital. Controlled substances are not considered multi-dose medicinal drugs as defined in this rule.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History—New 7-31-91, Formerly 21S-28.810, 61F10-28.810, 59X-28.810, Amended 7-17-05, 2-10-14.

64B16-28.830 Special - Closed System Pharmacy.

(1) A Special – Closed System Pharmacy permit is a type of special pharmacy as provided for by Section 465.0196, F.S., which dispenses medicinal drugs, utilizing closed delivery systems, to facilities where prescriptions are individually prepared for the ultimate consumer, including nursing homes, jails, ALF's (Adult Congregate Living Facilities), ICF-MR's (Intermediate Care Facility/Mentally Retarded) or other custodial care facilities when defined by AHCA rules which the Board may approve.

(2) A special – closed system pharmacy permittee shall maintain a policy and procedure manual including drug procurement, storage, handling, compounding, dispensing, record keeping and disposition.

(3) A special – closed system pharmacy permittee shall provide twenty-four hour emergency and on-call service.

(4) A special – closed system pharmacy permittee may dispense parenteral and enteral medications as provided by rule.

(5) A special – closed system pharmacy permittee shall be under the supervision of a prescription department manager who is responsible for maintaining all drug records, providing security of the prescription department and following other rules as relate to the practice of pharmacy. The prescription department manager of a closed system pharmacy shall not be the prescription department manager of any other pharmacy permit except when the permit is within the premises of a community pharmacy permit.

(6) The utilization of registered pharmacy interns and registered pharmacy technicians is subject to the rules as provided by Rule 64B16-26.400, F.A.C.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196, 465.022 FS. History—New 7-31-91, Amended 10-1-92, Formerly 21S-28.830, 61F10-28.830, 59X-28.830, Amended 1-1-10.

64B16-28.850 Special Pharmacy - ESRD.

(1) An ESRD Pharmacy is a type of special pharmacy as provided by Section 465.0196, F.S., which is limited in scope of pharmacy practice to the provision of dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address. Pharmacy services and dialysis supplies and products provided by an ESRD pharmacy shall be limited to the distribution and delivery of legend drugs included in schedule (3) below; or legend devices included in schedule (4) below; which are ordered by a physician for administration or delivery to a person with chronic kidney failure for self-administration at the person's home or specified address. All dialysis supplies and products provided by an ESRD pharmacy shall be prepackaged and shall be covered by an approved NDA or 510 (k) application issued by the Federal Food and Drug Administration.

(2) Prior to engaging in an ESRD pharmacy practice an entity shall obtain a special ESRD pharmacy permit as provided herein.

(3) Schedule of legend drugs:

(a) Saline Solutions.

(b) Porcine Heparin.

(c) Beef Heparin.

(d) Dextrose Solutions.

(e) Doxercalciferol.

(f) Epoetin Alfa.

(g) NAACL INJ 50 MEQ/20 ML.

(h) Levocarnitine.

(i) Lidocaine.

- (j) Vitamin Preparations (dialysate use only).
- (k) Paricalcitol.
- (l) Peritoneal Dialysate Solutions.
- (m) Protamine Sulfate.
- (n) Potassium 20 MEQ/10ML (dialysate use only).
- (o) Sodium Ferric Gluconate Complex or equivalent.
- (p) Sterile Water for Irrigation.

(4) The schedule of legend devices includes:

- (a) Hemodialyzers.
- (b) Hemodialysis solutions.
- (c) Bloodlines and Associated Connectology.
- (d) Peritoneal Dialysis Tubing and Connectology.

(5) The provision of legend drugs and devices included in the schedule necessary to perform dialysis to a person with chronic kidney failure for self-administration at the person's home or specified address shall be under the professional supervision of an appropriate practitioner licensed under Florida law. The consultant pharmacist shall assure that the following occurs:

(a) The ESRD pharmacy receives a prescription from the prescribing practitioner directing the pharmacist to dispense and deliver to a person with chronic kidney failure (or such person's designee) any legend drugs and/or devices included in the formulary necessary for the self-administration of dialysis at such person's home or specified address.

(b) That no dispensing shall occur unless the person with chronic kidney failure has been trained in the proper use and administration of such products. Further, the consulting pharmacist shall ensure that the ESRD pharmacy has received records confirming the completion of such training.

(c) After the delivery of such products by the ESRD pharmacy, the ESRD pharmacy shall upon request therefor, make available to the prescribing practitioner documentation describing, in sufficient detail, the types and quantities of products dispensed and delivered by the ESRD pharmacy. The ESRD pharmacy shall also, upon request, make available to the prescribing practitioner documentation confirming shipment of such products and receipt thereof by the person with chronic kidney failure.

(6) The licensed ESRD pharmacy shall comply with all applicable state and federal regulatory requirements and shall maintain in effect all applicable permits and licenses required to dispense and deliver legend drugs and/or devices included in the formulary described in this Section.

(7) The ESRD pharmacy shall deliver products to a person with chronic kidney failure only upon receipt of a valid prescription from a prescribing practitioner specifying or including:

(a) Documentation that the intended recipient of the products has been trained in home dialysis therapy and will require such products;

(b) The duration of prescribing practitioner's order; and

(c) The name and product code of each product prescribed and the quantity prescribed.

(d) The prescription may indicate the person with chronic kidney failure shall have the right to request refills of legend drugs, devices or both, included in the schedule and described in the order for a period of one year.

(8) The ESRD pharmacy shall assemble the products to be delivered pursuant to the prescribing practitioner's prescription. In assembling such products for delivery, the ESRD pharmacy shall take steps necessary to assure the following:

(a) The code numbers and quantities of the products assembled match the code numbers identified in the prescribing practitioner's prescription;

(b) With respect to any dated products, a minimum of three (3) full months of shelf-life remain; and

(c) All cartons and other packaging are properly labeled as noted below:

1. "Use as Directed" statement;
2. The name and address of the person to whom the products will be delivered;
3. The name of the prescribing practitioner;
4. The name and address of the ESRD pharmacy location from which the products were shipped;
5. The prescription number identifying the shipment to the order created by the prescribing practitioner; and
6. Any special instructions regarding delivery dates or locations.

7. The date after which the drug(s) and/or device(s) must be discarded. Notwithstanding any other rule, the ESRD pharmacy may use, in lieu of a discard after date, the manufacturer's expiration date when such is displayed in an unopened sealed package.

(d) All cartons and related packaging shall be visually inspected to confirm compliance with the specifications in paragraph

(8)(c). Compliance with the requirements set forth in paragraph (8)(c) shall be conducted by the consulting pharmacist or independently by not less than two employees of the ESRD pharmacy trained in the performance of the foregoing activities, each of whom shall acknowledge in writing their completion of such activities with respect to each group of products assembled for delivery.

(9) The ESRD pharmacy permit holder shall assure through visual inspection and comparison of records that products assembled for delivery to persons with chronic kidney failure are consistent with the prescribing practitioner's order therefor.

(10) The products ordered by the prescribing practitioner under this Rule shall be delivered by either the ESRD pharmacy or a carrier authorized by the ESRD pharmacy.

(11) Upon delivery of the products by the ESRD pharmacy or its carrier to the person identified on the prescribing practitioner's order, the ESRD pharmacy or its carrier shall confirm receipt by the patient or the patient's designee that the number of units delivered equals the number of units identified on the appropriate documentation. Compliance with the foregoing requirements set forth above shall be conducted by an employee or agent of the ESRD pharmacy trained in the performance of such activities, who shall acknowledge in writing the delivery of the products and the completion of such activities with respect to each delivery.

(12) In addition to the foregoing operation requirements, an ESRD pharmacy shall comply with the following:

(a) The ESRD pharmacy license shall be displayed at each ESRD pharmacy location.

(b) The Board of Pharmacy shall be notified in writing of the Consulting Pharmacist responsible, at the time of application for the permit, for supervising the ESRD pharmacy operations and within 10 days, if the Consultant Pharmacist of record changes.

(c) The ESRD pharmacy's hours of business shall be posted. The ESRD pharmacy shall be open such hours as are necessary to safely and effectively dispense and deliver supplies to those persons designated by the applicable prescribing practitioner. An ESRD pharmacy shall provide twenty-four hour emergency and on-call service.

(d) The ESRD pharmacy shall have sufficient space and storage capabilities as are necessary to carry out its operation.

(e) All legend drugs and/or legend devices included in the formulary subject to this Rule shall be properly identified.

(f) The ESRD pharmacy shall maintain a current copy of the Florida pharmacy laws and rules.

(g) The ESRD pharmacy shall comply with patient counseling requirements of Rules 64B16-27.800-.810 and 64B16-27.820, F.A.C.

(13) ESRD Pharmacy Application Requirements. An applicant for an ESRD pharmacy permit shall provide the Board of Pharmacy with a Policy and Procedure Manual setting forth in detail the operational guidelines of the applicant. The Policy and Procedure Manual shall include a Quality Assurance Program which monitors personnel qualifications, training and performance.

(14) An ESRD pharmacy shall be under the control and supervision of licensed Consultant Pharmacist licensed under Section 465.0125, F.S. The Consulting Pharmacist shall be responsible for the drug/device delivery system.

(15) The Consultant Pharmacist of record for the ESRD Pharmacy shall be responsible for establishing a written protocol and Policy and Procedure Manual for the implementation of a delivery system to be utilized in compliance with the requirements of this Rule.

(16) The Consultant Pharmacist shall inspect the permitted ESRD pharmacy on a monthly basis.

(17) A copy of the ESRD pharmacy's Policy and Procedure Manual as provided above shall accompany the permit application, shall be kept within the ESRD Pharmacy, and shall be available for inspection by the Department of Health. Changes in the Policy and Procedure Manual shall be approved by the Consulting Pharmacist.

Specific Authority 465.005, 465.0125 FS. Law Implemented 465.0196, 465.022 FS. History—New 10-2-94, Formerly 59X-28.850, Amended 9-20-99, 7-17-05, 6-24-08.

64B16-28.870 Special-ALF.

The Special-ALF permit is an optional facility license for those Assisted Living Facilities providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging. All medicinal drugs must be maintained in individual prescription containers for the individual patient. Medicinal drugs may not be dispensed on the premises. Medicinal drugs dispensed to patients of Special-ALF permits may be returned to the dispensing pharmacy's stock under the provisions of Section 64B16-28.118, F.A.C. Dispensed controlled substances that have been discontinued shall be disposed of under the provisions of Section 64B16-28.301, F.A.C. Medicinal drugs dispensed to the residents of a Special-ALF permit shall meet the labeling requirements of Sections 64B16-28.502 and 64B16-28.402(1)(h), F.A.C. Each facility holding a Special-ALF permit shall designate a consultant pharmacist of record to ensure compliance with the laws and rules governing the permit. The Board office shall be notified in writing within 10 days of any change in the consultant pharmacist of record. The consultant pharmacist of record shall be responsible for the preparation of the Policy and Procedure Manual required by Section 64B16-28.800(2), F.A.C. Policy and Procedure Manuals must provide for the appropriate storage conditions and security of the medicinal drugs stored at the facility. The consultant pharmacist of record shall inspect the facility and prepare a written report to be filed at the permitted facility at least monthly.

Specific Authority 465.022 FS. Law Implemented 465.0196 FS. History—New 2-23-98.

64B16-28.900 Definitions - Nuclear Pharmacy.

- (1) A “nuclear pharmacy” is a pharmacy which provides radiopharmaceutical services.
- (2) A “nuclear pharmacist” is a pharmacist who has met the training qualifications as described in Rule 64B16-28.903, F.A.C., and has been licensed by the Board of Pharmacy.
- (3) A “radiopharmaceutical service” shall include, but shall not be limited to, the procurement, storage, preparation, labeling, quality assurance testing, distribution, record keeping and disposal of radiopharmaceuticals.
- (4) A “radiopharmaceutical” is any substance defined as a drug by section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.
- (5) “Radiopharmaceutical quality assurance” includes, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals, and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records.
- (6) “Authentication of product history” includes, but is not limited to, identifying the purchasing source, the ultimate fate, and intermediate handling of any component of a radiopharmaceutical or other drug.

Specific Authority 465.005 FS. Law Implemented 465.003(14), 465.022(1)(e) FS. History—New 1-7-76, Formerly 21S-3.01, Amended 4-4-88, Formerly 21S-3.001, Amended 7-31-91, 4-15-92, 10-1-92, Formerly 21S-28.900, 61F10-28.900, 59X-28.900, Amended 4-5-05.

64B16-28.840 Special - Non Resident (Mail Service).

- (1) A Special – Non Resident (Mail Service) pharmacy is provided for by Section 465.0156, F.S. It is a pharmacy located outside this state delivering a dispensed medicinal drug in any manner into this state.
- (2) The pharmacy and the pharmacist designated as the prescription department manager or equivalent, for dispensing into Florida, must be licensed in the state of location.
- (3) Changes of location, corporate officers, and prescription department managers must be reported to the Board as required by Section 465.0156(1)(b), F.S.
- (4) The pharmacy must have regular hours of operation of not less than six (6) days per week and not less than forty (40) hours per week. A toll-free telephone number must be available to patients.

Specific Authority 465.005, 465.022, 465.0156 FS. Law Implemented 465.0156 FS. History—New 10-14-91, Formerly 21S-28.840, 61F10-28.840, 59X-28.840.

64B16-27.104 Conduct Governing Pharmacists and Pharmacy Permittees.

- (1) A pharmacist or pharmacy shall be permitted to advertise medicinal drugs other than those controlled substances specified in Chapter 893, F.S., and patent and proprietary preparations so long as such advertising is not false, misleading or deceptive.
- (2) No pharmacist, employer or employee of a pharmacy shall maintain a location, other than a pharmacy for which a permit has been issued by the Florida Board of Pharmacy, from which to solicit, accept or dispense prescriptions.
- (3) No pharmacist or pharmacy, or employee or agent thereof, shall enter into or engage in any agreement or arrangement with any physician or other practitioner or nursing home or extended care facility for the payment or acceptance of compensation in any form or type for the recommending of the professional services of either; or enter into a rebate or percentage rental agreement of any kind, whereby in any way a patient's free choice of a pharmacist or pharmacy is or may be limited.
- (4) No pharmacist, employer or employee of a pharmacy may knowingly place in stock of any pharmacy any part of any prescription compounded for, or dispensed to, any customer of any pharmacy and returned by said customer, unless otherwise permitted by Rule 64B16-28.118, F.A.C.
- (5) Pursuant to Section 465.018, F.S., that requires that a permit for a community pharmacy may not be issued unless a licensed pharmacist is designated as the prescription department manager responsible for maintaining all drug records, providing for the security of the prescription department and following such other rules as relate to the practice of the profession of pharmacy. The Board shall not register a prescription department manager as the manager of more than one pharmacy. The Board may grant an exception to this requirement upon application by the permittee and the prescription department manager showing circumstances such as proximity of permits and limited pharmacist workload that would allow the manager to carry out all duties and responsibilities required of a prescription department manager.

Specific Authority 465.005, 465.0155, 465.018, 465.022 FS. Law Implemented 465.018, 465.022, 465.024 FS. History—New 10-20-81, Formerly 21S-1.20, 21S-1.020, Amended 7-30-91, Formerly 21S-27.104, 61F10-27.104, 59X-27.104, Amended 11-18-07.

64B16-27.100 Display of Current License; Pharmacist, Registered, Intern, and Registered Pharmacy Technician Identification.

- (1) The current license of each pharmacist engaged in the practice of the profession of pharmacy as defined by Section 465.003(13), F.S., in any pharmacy shall be displayed, when applicable, in a conspicuous place in or near the prescription department, and in such manner that said license can be easily read by patrons of said establishment. Pharmacists employed in secondary practice sites shall present a valid wallet license as evidence of licensure upon request.
- (2) No pharmacist shall display, cause to be displayed or allow to be displayed, their license in any pharmacy where said pharmacist is not engaged in the practice of the profession as defined in Section 465.003(13), F.S.
- (3) A pharmacist and registered pharmacy intern must be clearly identified by a means such as an identification badge or monogrammed smock showing their name and if they are a pharmacist or a registered pharmacy intern.
- (4) The current registration of each registered pharmacy technician shall be displayed, when applicable, in a conspicuous place in or near the prescription department, and in such a manner that can be easily read by patrons of said establishment. Registered pharmacy technicians employed in a secondary practice site shall present a valid wallet registration as evidence of registration upon request.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022 FS. History—Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.06, 21S-1.006, Amended 7-30-91, Formerly 21S-27.100, 61F10-27.100, Amended 1-30-96, Formerly 59X-27.100, Amended 11-18-07, 1-1-10.

64B16-27.1001 Practice of Pharmacy.

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

- (1) A pharmacist or registered pharmacy intern must:
 - (a) Supervise and be responsible for the controlled substance inventory.
 - (b) Receive verbal prescriptions from a practitioner.
 - (c) Interpret and identify prescription contents.
 - (d) Engage in consultation with a practitioner regarding interpretation of the prescription and date in patient profile.
 - (e) Engage in professional communication with practitioners, nurses or other health professionals.
 - (f) Advise or consult with a patient, both as to the prescription and the patient profile record.
- (2) When parenteral and bulk solutions of all sizes are prepared, regardless of the route of administration, the pharmacist must:
 - (a) Interpret and identify all incoming orders.
 - (b) Mix all extemporaneous compounding or be physically present and give direction to the registered pharmacy technician for reconstitution, for addition of additives, or for bulk compounding of the parenteral solution.
 - (c) Physically examine, certify to the accuracy of the final preparation, thereby assuming responsibility for the final preparation.
 - (d) Systemize all records and documentation of processing in such a manner that professional responsibility can be easily traced to a pharmacist.
- (3) Only a pharmacist may make the final check of the completed prescription thereby assuming the complete responsibility for its preparation and accuracy.
- (4) The pharmacist, as an integral aspect of dispensing, shall be directly and immediately available to the patient or the patient's agent for consultation and shall not dispense to a third party. No prescription shall be deemed to be properly dispensed unless the pharmacist is personally available.
- (5) The pharmacist performing in this state any of the acts defined as "the practice of the profession of pharmacy" in Section 465.003(13), F.S., shall be actively licensed as a pharmacist in this state, regardless of whether the practice occurs in a permitted location (facility) or other location.
- (6) The pharmacist may take a meal break, not to exceed 30 minutes in length, during which the pharmacy department of a permittee shall not be considered closed, under the following conditions:
 - (a) The pharmacist shall be considered present and on duty during any such meal break if a sign has been prominently posted in the pharmacy indicating the specific hours of the day during which meal breaks may be taken by the pharmacist and assuring patients that a pharmacist is available on the premises for consultation upon request during a meal break.
 - (b) The pharmacist shall be considered directly and immediately available to patients during such meal breaks if patients to whom medications are delivered during meal breaks are verbally informed that they may request that a pharmacist contact them at the pharmacist's earliest convenience after the meal break, and if a pharmacist is available on the premises during the meal break for consultation regarding emergency matters. Only prescriptions with the final certification by the pharmacist may be delivered.
 - (c) The activities of registered pharmacy technicians during such a meal break shall be considered to be under the direct and immediate personal supervision of a pharmacist if the pharmacist is available on the premises during the meal break to respond to questions by the technicians, and if at the end of the meal break the pharmacist certifies all prescriptions prepared by the registered pharmacy technicians during the meal break.
- (7) The delegation of any duties, tasks or functions to registered pharmacy interns and registered pharmacy technicians must be performed subject to a continuing review and ultimate supervision of the pharmacist who instigated the specific task, so that a continuity of supervised activity is present between one pharmacist and one registered pharmacy technician. In every pharmacy, the pharmacist shall retain the professional and personal responsibility for any delegated act performed by registered pharmacy interns and registered pharmacy technicians in the licensee's employ or under the licensee's supervision.

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

64B16-27.700 Definition of Compounding.

64B16-27.700 Definition of Compounding.

“Compounding” is the professional act by a pharmacist or other practitioner authorized by law, employing the science or art of any branch of the profession of pharmacy, incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or the practitioner’s agent; and shall specifically include the professional act of preparing a unique finished product containing any ingredient or device defined by Sections 465.003(7) and (8), F.S. The term also includes the preparation of nuclear pharmaceuticals and diagnostic kits incident to use of such nuclear pharmaceuticals. The term “commercially available products,” as used in this section, means any medicinal product as defined by Sections 465.003(7) and (8), F.S., that are legally distributed in the State of Florida by a drug manufacturer or wholesaler.

(1) Compounding includes:

- (a) The preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns.
 - (b) The preparation pursuant to a prescription of drugs or devices which are not commercially available.
 - (c) The preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist. The reconstitution of commercially available products pursuant to the manufacturer’s guidelines is permissible without notice to the practitioner.
- (2) The preparation of drugs or devices for sale or transfer to pharmacies, practitioners, or entities for purposes of dispensing or distribution is not compounding and is not within the practice of the profession of pharmacy, except that the supply of patient specific compounded prescriptions to another pharmacy under the provisions of Section 465.0265, F.S., and Rule 64B16-28.450, F.A.C., is authorized.
- (3) Office use compounding, “Office use” means the provision and administration of a compounded drug to a patient by a practitioner in the practitioner’s office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy. A pharmacist may dispense and deliver a quantity of a compounded drug to a practitioner for office use by the practitioner in accordance with this section provided:
- (a) The quantity of compounded drug does not exceed the amount a practitioner anticipates may be used in the practitioner’s office before the expiration date of the drug;
 - (b) The quantity of compounded drug is reasonable considering the intended use of the compounded drug and the nature of the practitioner’s practice;
 - (c) The quantity of compounded drug for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.
 - (d) The pharmacy and the practitioner enter into a written agreement. The agreement shall specifically provide:
 1. That the compounded drug may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity;
 2. That the practitioner shall include on the patient’s chart, medication order, or medication administration record the lot number and the beyond-use-date of any compounded drug administered to the patient that was provided by the pharmacy;
 3. That the practitioner will provide notification to the patient for the reporting of any adverse reaction or complaint in order to facilitate any recall of batches of compounded drugs.
 - (e) The pharmacy shall maintain readily retrievable records of all compounded drugs ordered by practitioners for office use. The records must be maintained for a minimum of four (4) years and shall include:
 1. The name, address and phone number of the practitioner ordering the compounded drug for office use and the date of the order;
 2. The name, strength, and quantity of the compounded drug provided, including the number of containers and quantity in each;
 3. The date the drug was compounded;
 4. The date the compounded drug was provided to the practitioner;
 5. The lot number and beyond use date.

(f) The pharmacy shall affix a label to any compounded drug that is provided for office use. The label shall include:

1. The name, address, and phone number of the compounding pharmacy;
2. The name and strength of the preparation of a list of active ingredients and strengths;
3. The pharmacy's lot number and beyond-use-date;
4. The quantity or amount in the container;
5. The appropriate ancillary instructions such as storage instructions, cautionary statements, or hazardous drug warning labels were appropriate; and
6. The statement "For Institutional or Office Use Only – Not for Resale," or if the drug is provided to a veterinarian the statement "Compounded Drug."

(g) In the case of compounded sterile products intended for human use, the pharmacy must be in full compliance with 21 U.S.C. § 353b, including being registered as an Outsourcing Facility. 21 U.S.C. § 353b (eff. Nov. 27, 2013) is hereby adopted and incorporated by reference and available at

<http://www.flrules.org/Gateway/reference.asp?No=Ref-04180>.

Rulemaking Authority 465.005 FS. Law Implemented 465.003, 465.0155, 465.0265 FS. History—New 10-1-92, Formerly 21S-27.700, 61F10-27.700, 59X-27.700, Amended 11-2-03, 10-7-08, 3-21-13, 6-22-14.

A-0490

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.25 Condition of Participation: Pharmaceutical Services

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

Interpretive Guidelines §482.25

Provision of pharmaceutical services must meet the needs of the patients' therapeutic goal by promoting a safe medication use process that ensures optimal selection of medications, dose, dosage form, frequency, route, duration of therapy and that substantially reduces or eliminates adverse drug events and duplication of treatment.

The hospital's pharmacy must be directed by a registered pharmacist. If a drug storage area is used instead of a pharmacy at any location providing pharmacy services, that storage area must be under competent supervision in accordance with State and Federal law.

Pharmaceutical Services would include:

- ξ The procuring, manufacturing, compounding, packaging, dispensing, ordering, distributing, disposition, use, and administering of all medications, biologicals, chemicals and the use of medication related devices.
- ξ Provision of medication-related information to hospital health care professionals and patients necessary to optimize therapeutic outcomes.
- ξ Provision of pharmaceutical care. Pharmaceutical care is defined as the direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient's quality of life while minimizing patient risk.

Functions of Pharmaceutical Care are the:

- ξ Collection and organization of patient-specific information;
- ξ Determination of the presence of medication-therapy problems both potential and actual;

- ξ Summary of the patient's medication related health care needs;
- ξ Identification and specification of pharmacotherapeutic goals;
- ξ Development of a pharmacotherapeutic regimen;
- ξ Implementation of a monitoring plan in collaboration with the patient, if applicable, and other health care professionals;
- ξ Monitoring the effects of the pharmacotherapeutic regimen; and
- ξ Redesigning the regimen and monitoring plan as indicated.

Medication errors are a substantial source of morbidity and mortality in the hospitalized setting. Therefore, the development of policies and procedures to minimize medication errors should be based on accepted professional principles; external alerts and proactive review of facility reported and reviewed adverse drug events. It is important to flag new types of mistakes and continually improve and refine things, based on what went wrong.

The hospital's medical staff must develop policies and procedures to minimize drug errors, but may delegate this function to the hospital's organized pharmaceutical service.

Policies and procedures to minimize drug errors should include:

- ξ High-alert medications - dosing limits, administration guidelines, packaging, labeling and storage;
- ξ Limiting the variety of medication-related devices and equipment. For Example limit the types of general-purpose infusion pumps to one or two;
- ξ Availability of up-to-date medication information;
- ξ Availability of pharmacy expertise. Pharmacist available on-call when pharmacy does not operate 24 hours a day;
- ξ Standardization of prescribing and communication practices to include:
 - Avoidance of dangerous abbreviations;
 - All elements of the order - dose, strength, units (metric), route, frequency, and rate;
 - Alert systems for look-like and sound-alike drug names;
 - Use of facility approved pre-printed order sheets whenever possible.

- ξ That orders to “resume previous orders” are prohibited;
- ξ A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);
- ξ The preparation, distribution, administration and proper disposal of hazardous medications;
- ξ Drug recalls;
- ξ That patient-specific information is readily accessible to all individuals involved in provision of pharmaceutical care. The patient information must be sufficient to properly order, prepare, dispense, administer and monitor medications as appropriate;
- ξ Identification of when weight-based dosing for pediatric populations is required; and
- ξ Requirements for review and revision based on facility-generated reports of adverse drug events and QAPI activities.

The hospital should have policies and procedures to actively identify potential and actual adverse drug events. Proactive identification could include; direct observation of medication administration, review of patient’s clinical records, identification of patient signals that would warrant immediate review of patient’s medication therapy and implementation of medication use evaluation studies.

The hospital should have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration. National associations could include Institute for Safe Medications Practice, National Coordination Council for Medication Error Reporting and Prevention and Joint Commission for Accreditation of Health Care Facilities, Sentinel Event Reports. Governmental agencies may include: Food and Drug Administration, Med Watch Program, and Agency for Health Care Research and Quality.

The hospital’s pharmacy services must be integrated into its hospital-wide QAPI program.

Survey Procedures §482.25

- ξ Interview the chief pharmacist or the individual delegated to fulfill the chief pharmacist’s functions. Determine that either the medical staff has developed policies and procedures regarding the management of pharmaceuticals or that this function is fulfilled by the pharmacy service.

- ξ Verify that the purpose of pharmaceutical policies and procedures is to minimize drug errors. Review the pharmaceutical policies and procedures, the hospital's formulary and, if there is a pharmacy and therapeutic committee, the minutes of the committee meetings.
- ξ Does a multidisciplinary committee composed of representatives from nursing, pharmacy, administration and medicine develop policies and procedures?
- ξ Are there policies and procedures to minimize drug errors?
- ξ Are policies and procedures reviewed and amended based on:
 - Facility-generated reports of adverse drug events;
 - o Facility QAPI activities pertaining to pharmaceutical care;
 - o Evaluation of external alerts and/or recommendations from national associations;
 - o Evaluation of literature for new technologies or successful practices that have demonstrated enhanced medication safety in other organizations.
- ξ Is the staff familiar with the medication-related policies and procedures?
- ξ Is there a method to periodically review and evaluate the actual implementation of pharmaceutical policies and procedures by staff?
- ξ Upon review of patient clinical record are issues with regard to provision of pharmaceutical services identified? Is the facility aware of the issues? Was there a failure to implement a policy and procedure?
- ξ Are pharmacists an integral component of pharmaceutical care?
- ξ Verify that the hospital's pharmacy services is integrated into its hospital-wide QAPI program.

A-0491

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.25(a) Standard: Pharmacy Management and Administration

The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

Interpretive Guidelines §482.25(a)

The hospital may utilize a unit dose system, individual prescription, floor stock system or a combination of these systems, properly stored.

Pharmaceutical services must be administered in accordance with accepted professional principles. Accepted professional principles includes compliance with applicable Federal and State laws, regulations, and guidelines governing pharmaceutical services, as well as, standards or recommendations promoted by nationally recognized professional organizations. Agencies and organizations could include FDA, NIH, American Society of Health-System Pharmacists, etc.

A fundamental purpose of pharmaceutical services is to ensure the safe and appropriate use of medications and medication-related devices. The pharmacy director, with input from appropriate hospital staff and committees, develops, implements and periodically reviews and revises policies and procedures governing provision of pharmaceutical services.

Methods a hospital may use to maintain professional principles include:

- ξ Policies and procedures have been developed and are being followed;
- ξ Drugs and biologicals are stored in accordance with manufacturer's directions and State and Federal requirements;
- ξ Employees provide pharmaceutical services within their scope of license and education;
- ξ Pharmacy records have sufficient detail to follow the flow of pharmaceuticals from their entry into the hospital through dispensation/administration;
- ξ Maintaining controls over drugs and medications including the floor stock and those of the pharmacy or drug room;
- ξ Maintaining pharmacy and accounting records pertaining to the requisitioning and dispensing of drugs and pharmaceutical supplies;
- ξ Ensuring that drugs are being dispensed only by a licensed pharmacist;
- ξ Only pharmacists or pharmacy-supervised personnel compound, label and dispense drugs or biologicals.

Survey Procedures §482.25(a)

- ξ Are the policies and procedures consistent with accepted professional principles?

- ξ Determine that professional principles are maintained by verifying that:
 - Policies and procedures have been developed and are being followed;
 - Drugs and biologicals are stored in accordance with manufacturers directions and State and Federal requirements;
 - Records have sufficient detail to follow the flow of control from entry through dispensation; and
 - Employees provide pharmaceutical services within their scope of license and education.

- ξ Does the hospital have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration?

- ξ Are policies developed to promote consistent application of pharmaceutical services and care throughout the hospital?

- ξ Is the pharmacy director periodically monitoring implementation of policies and procedures?

- ξ Are policies and procedures reviewed and revised as warranted?

- ξ Are services provided in a manner consistent with accepted professional principles?

- ξ Is the pharmacy responsible for the procurement, distribution and control of all medication products used in the hospital (including medication-related devices) for inpatient and outpatient care?

A-0492

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.25(a)(1) - A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

Interpretive Guidelines §482.25(a)(1)

Direction of pharmaceutical services may not require continuous on-premise supervision at the hospital's single pharmacy or at any pharmacy location but may be accomplished through regularly scheduled visits, and/or telemedicine in accordance with Federal and State law and regulation and accepted professional principles.

A single pharmacist must be responsible for the overall administration of the pharmacy service and must be responsible for developing, supervising, and coordinating all the activities of the hospital wide pharmacy service.

The job description or the written agreement for the responsibilities of the pharmacist should be clearly defined and include development, supervision and coordination of all the activities of pharmacy services.

A professional, competent, legally qualified pharmacist must manage the pharmacy. The Director of pharmacy service must be thoroughly knowledgeable about hospital pharmacy practice and management.

Pharmacists and pharmacy technicians must perform their duties within scope of their license and education.

The Pharmacy Director should be actively involved in those committees responsible for establishing medication-related policies and procedures.

Survey Procedures §482.25(a)(1)

- ξ Determine whether the pharmacist is a full-time, or part-time employee or employed on a consultative basis.
- ξ Review the implementation of the chief pharmacist's responsibilities by:
 - Reviewing written status reports;
 - Reviewing minutes of meetings (if any) with facility staff regarding pharmaceutical services;
 - Reviewing schedules, time logs, etc.;
 - Reviewing the job description or the written agreement to see that the responsibilities of the pharmacist are clearly defined and include development supervision and coordination of all the activities of pharmacy services;

- Determining whether the Pharmacy Director routinely evaluates the performance and competency of pharmacy personnel? Do performance evaluations include high-risk activities such as the compounding of hazardous medications, pharmacy-based prescriptive activities (e.g. aminoglycoside protocols) and pharmaceutical care for high-risk patients (pediatric, ICU, geriatric etc)?
- ξ Determine whether the pharmacy director is actively involved in those committees responsible for establishing medication-related policies and procedures?

A-0493

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.25(a)(2) - The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

Interpretive Guidelines §482.25(a)(2)

There must be sufficient personnel to respond to the pharmaceutical needs of the patient population being served.

The pharmaceutical services staff must be sufficient in types, numbers, and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.

The number of pharmacists and/or the number of hours of services provided by pharmacists at the hospital, or at each location of the hospital that provides pharmaceutical services, must meet and be in accordance with the needs of its patients and accepted professional principles (as previously defined), and reflect the scope and complexity of the hospital's pharmaceutical services.

There must be sufficient numbers and types of personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.

Survey Procedures §482.25(a)(2)

- ξ Determine that the pharmaceutical services staff is sufficient in number and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.
- ξ Determine if there are sufficient personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.

A-0494

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.25(a)(3) - Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

Interpretive Guidelines §482.25(a)(3)

Components of a record system to maintain current and accurate records of the receipt and disposition of scheduled drugs would include:

- ξ Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs.
- ξ Records of the receipt and disposition of all scheduled drugs must be current and must be accurate.
- ξ Records trace the movement of scheduled drugs throughout the service.
- ξ The pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled.
- ξ The record system, delineated in policies and procedures, tracks movement of all scheduled drugs from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacture. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.
- ξ All drug records are in order and an account of all scheduled drugs is maintained and any discrepancies in count are reconciled promptly.

- ξ The hospital system is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion?
- ξ Facility policies and procedures should minimize scheduled drug diversion.

Survey Procedures §482.25(a)(3)

- ξ Determine if there is a record system in place that provides information on controlled substances in a readily retrievable manner.
- ξ Review the records to determine that they trace the movement of scheduled drugs throughout the service.
- ξ Determine if there is a system, delineated in policies and procedures, that tracks movement of all scheduled drugs from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacture. Determine if this system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.
- ξ Determine if the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled.
- ξ Is the hospital system capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion?
- ξ Determine if facility policy and procedures minimize scheduled drug diversion.

A-0500

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.25(b) Standard: Delivery of Services

In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

Interpretive Guidelines §482.25(b)

Drugs and biologicals must be controlled and distributed in accordance with applicable Federal and State laws and regulations, and in accordance with applicable standards of practice. Applicable standards of practice include compliance with all Federal and State laws, regulations, and guidelines, as well as, standards and recommendations promoted by nationally recognized professional organizations that apply to pharmaceutical care and the control and distribution of drugs and biologicals.

The procedures established to prevent unauthorized usage and distribution must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.

The pharmacist, in consultation with appropriate hospital staff and committees, is to develop and implement guidelines, protocols, policies and procedures for the provision of pharmaceutical services that ensure patient safety through the appropriate control and distribution of medications, medication-related devices and biologicals.

For high risk medications and high-risk patients (pediatric, geriatric or patients with renal or hepatic impairment) there should be systems in place to minimize adverse drug events. Such systems could include but not limited to; checklists, dose limits, pre-printed orders, special packaging, special labeling, double-checks and written guidelines. “**High risk medications**” are those medications involved in a high percentage of medication errors and/or sentinel events and medications that carry a higher risk for abuse, errors, or other adverse outcomes. Lists of high-risk or high-alert drugs are available from such organizations as the Institute for Safe Medication Practices (ISMP) and the United States Pharmacopoeia (USP). Examples of high-risk drugs may include investigational drugs, controlled medications, medications not on the approved FDA list, medications with a narrow therapeutic range, psychotherapeutic medications and look-alike/sound-alike medications and those new to the market or new to the hospital.

All medication orders (except in emergency situations) should be reviewed for appropriateness by a pharmacist before the first dose is dispensed.

Review of medication orders should include:

- ξ Therapeutic appropriateness of a patient’s medication regimen;
- ξ Therapeutic duplication in the patient’s medication regimen;
- ξ Appropriateness of the drug, dose, frequency, route and method of administration;
- ξ Real or potential medication-medication, medication-food, medication-laboratory test and medication-disease interactions;
- ξ Real or potential allergies or sensitivities;

ξ Variation from organizational criteria for use

ξ Other contraindications;

The effects of medication(s) on patients are monitored to assure medication therapy is appropriate and minimizes the occurrence of adverse events. That monitoring process includes:

- ξ Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects;
- ξ Physical signs and clinical symptoms relevant to the patient's medication therapy;
- ξ Assessing the patient's own perceptions about side effects, and, when appropriate, perceived efficacy.

Sterile products should be prepared and labeled in a suitable environment by appropriately trained and qualified personnel.

The pharmacy should participate in hospital decisions about emergency medication kits. The supply and provision of emergency medications stored in the kits must be consistent with standards of practice and appropriate for a specified age group or disease treatment as well as consistent with applicable Federal and State laws.

The pharmacy should be involved in the evaluation, use and monitoring of drug delivery systems, administration devices and automated drug-dispensing machines? The evaluation and monitoring should include the potential for medication errors.

There must be a process to report serious adverse drug reactions to the FDA in accordance with the MedWatch program?

There is a policy that addresses the use of medications brought into the hospital by patients or their families.

There is a process and policy to ensure that investigational medications are safety controlled and administered. Procedures for the use of investigational medications include the following: A written process for reviewing, approving, supervising and monitoring investigational medications specifying that when pharmacy services are provided, the pharmacy controls the storage, dispensing, labeling, and distribution of the investigational medication.

Medications dispensed by the hospital are retrieved when recalled or discontinued by the manufacturer or the Food and Drug Administration (FDA) for safety reasons.

The hospital pharmacy must ensure that medication orders are accurate and that medications are administered as ordered. The pharmacy should have a system to reconcile medications that are not administered, that remain in the patient's medication drawer, slot, etc., when the pharmacy inventories patient medications or restocks patient medications. The pharmacy should determine the reason the medications were not used. For example, did the patient refuse the medication, was there a clinical or treatment reason the medication was not used, or was the medication not used due to an error?

Survey Procedures §482.25(b)

- ξ Are there limits on the number of possible concentrations for a medication, particularly high-alert drugs like morphine and heparin?
- ξ Is access to concentrated solutions (e.g. potassium chloride, sodium chloride solutions greater than 0.9%) restricted?
- ξ Are questions regarding the order resolved with the prescriber and a written notation of these discussions documented in the patient's medical record or pharmacy copy of the prescriber's order?
- ξ Identify and assess the quality assurance procedures for the preparation of sterile products.
- ξ Is appropriate monitoring of medication therapy being conducted?
- ξ Is the pharmacy involved in the evaluation, use and monitoring of drug delivery systems, administration devices and automated drug dispensing machines? The evaluation and monitoring should include the potential for medication errors.
- ξ Is there a process to report serious adverse drug reactions to the Federal MedWatch program?
- ξ Review the procedures established to prevent unauthorized usage and distribution. These procedures must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.
- ξ Are medication storage areas periodically inspected to make sure medications are properly stored?
- ξ Does the hospital retrieve and remove medications available or patient use when the hospital has been informed of a drug recall? Does the recall include notification of patients that have been impacted and those that would order, dispense or administer the medication?

A-0501

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.25(b)(1) - All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

Interpretive Guidelines §482.25(b)(1)

All compounding, packaging, and dispensing of drugs and biologicals must be conducted by a registered pharmacist or under the supervision of a registered pharmacist and performed consistent with State and Federal laws.

Medications must be prepared safely. Safe preparation procedures could include:

- ξ Only the pharmacy compounds or admixes all sterile medications, intravenous admixtures, or other drugs except in emergencies or when not feasible (for example, when the product's stability is short).
- ξ Whenever medications are prepared, staff uses safety materials and equipment while preparing hazardous medications.
- ξ Wherever medications are prepared, staff uses techniques to assure accuracy in medication preparation.
- ξ Whenever medications are prepared, staff uses appropriate techniques to avoid contamination during medication preparation, which include but are not limited to the following:
 - Using clean or sterile technique as appropriate;
 - Maintaining clean, uncluttered, and functionally separate areas for product preparation to minimize the possibility of contamination;
 - Using a laminar airflow hood or other appropriate environment while preparing any intravenous (IV) admixture in the pharmacy, any sterile product made from non-sterile ingredients, or any sterile product that will not be used with 24 hours; and
 - Visually inspecting the integrity of the medications.

Medications should be dispensed in a manner that is safe and meets the needs of the patient:

- ξ Quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of the patient;
- ξ Medications are dispensed in a timely manner. The hospital must have a system that ensures that medication orders get to the pharmacy and medications get back to patients promptly.
- ξ Whenever possible, medications are dispensed in the most ready to administer form available from the manufacturer or, if feasible, in unit dose that have been repackaged by the pharmacy;
- ξ The hospital consistently uses the same dose packaging system, or, if a different system is used, provides education about the use of the dose packaging system; and
- ξ All concerns, issues or questions are clarified with the individual prescriber before dispensing.

Survey Procedures §482.25(b)(1)

- ξ Determine that only pharmacists or pharmacy supervised personnel compound, label and dispense drugs or biologicals in accordance with State and Federal laws and regulations and as accepted national principles by:
 - Reviewing policies and procedures;
 - Interviewing pharmacy and hospital staff to determine how drugs and biologicals are prepared and dispensed;
 - Observing on site dispensing and compounding operations (if applicable);
 - Reviewing records of drugs and biologicals removed from the pharmacy by non-pharmacy personnel; and
 - Inspecting drug storage areas.
- ξ Verify through interviews of pharmacy and hospital staff, observation of on-site dispensing operations, inspection and review of hospital records that compounding, dispensing and packaging of drugs and biologicals are performed under the supervision of a pharmacist, in accordance with applicable laws and in a manner to promote patient safety.

A-0502

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.25(b)(2)(i) - All drugs and biologicals must be kept in a secure area, and locked when appropriate.

Interpretive Guidelines §482.25(b)(2)(i)

A secure area means that drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. For example, if medications are kept in a private office, or other area where patients and visitors are not allowed without the supervision or presence of a health care professional (for example, ambulatory infusion), they are considered secure. Areas restricted to authorized personnel only would generally be considered “secure areas.” If there is evidence of tampering or diversion, or if medication security otherwise becomes a problem, the hospital is expected to evaluate its current medication control policies and procedures, and implement the necessary systems and processes to ensure that the problem is corrected, and that patient health and safety are maintained. (71 FR 68689)

All controlled substances must be locked. Hospitals are permitted flexibility in the storage of non-controlled drugs and biologicals when delivering care to patients, and in the safeguarding of drugs and biologicals to prevent tampering or diversion. An area in which staff are actively providing care to patients or preparing to receive patients, i.e., setting up for procedures before the arrival of a patient, would generally be considered a secure area. When a patient care area is not staffed, **both** controlled and non-controlled substances are expected to be locked.

Generally labor and delivery suites and critical care units are staffed and actively providing patient care around the clock, and, therefore, considered secure. However, hospital policies and procedures are expected to ensure that these areas are secure, with entry and exit limited to appropriate staff, patients and visitors.

The operating room suite is considered secure when the suite is staffed and staff are actively providing patient care. When the suite is not in use (e.g., weekends, holidays and after hours), it would not be considered secure. A hospital may choose to lock the entire suite, lock non-mobile carts containing drugs and biologicals, place mobile carts in a locked room, or otherwise lock drugs and biologicals in a secure area. If an individual operating room is not in use, the hospital is expected to lock non-mobile carts, and ensure mobile carts are in a locked room. (71FR 68689)

This regulation gives hospitals the flexibility to integrate patient self-administration of non-controlled drugs and biologicals into their practices as appropriate. When a hospital allows a patient to self-administer selected drugs and biologicals, the hospital authorizes the patient to have access to these medications. This regulation is consistent with the current practice of giving patients access at the bedside to urgently needed medications, such as nitroglycerine tablets and inhalers. It supports the current practice of placing selected nonprescription medications at the bedside for the patient's use, such as lotions and creams, and rewetting eye drops. Hospitals are expected to address patient self-administration of non-controlled drugs and biologicals in their policies and procedures. This regulation supports hospital development, in collaboration with the medical staff and the nursing and pharmacy departments, of formal patient medication self-administration programs for select populations of patients, including hospital policies and procedures necessary to ensure patient safety and security of medications. The policies and procedures are expected to include measures to ensure the security of bedside drugs and biologicals. They are also expected to address both the competence of the patient to self-administer drugs and biologicals as well as patient education regarding self-administration of drugs and biologicals. (71FR 68689)

Due to their mobility, mobile nursing medication carts, anesthesia carts, epidural carts and other medication carts containing drugs or biologicals (hereafter, all referred to as "carts") must be locked in a secure area when not in use. Hospital policies and procedures are expected to address the security and monitoring of carts, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage and to ensure patient safety. (71 FR 68689)

Medication automated distribution units with security features, such as logon and password or biometric identification, are considered to be locked, since they can only be accessed by authorized personnel who are permitted access to the medications. Such units must be stored in a secure area.

Survey Procedures §482.25(b)(2)(i)

- Review hospital policies and procedures governing the security of drugs and biologicals to determine whether they provide for securing and locking as appropriate.
- ξ Review hospital policies and procedures governing patient self-administration of drugs and biologicals.
- ξ Observe whether medications in various areas of the hospital are stored in a secure area, and locked when appropriate.

- Determine that security features in automated medication distribution units are implemented and actively maintained, e.g., that access authorizations are regularly updated to reflect changes in personnel, assignments, etc.
- Interview staff to determine whether policies and procedures to restrict access to authorized personnel are implemented and effective.
- ξ Interview patients and staff to determine whether policies and procedures regarding patient self-administration of drugs and biologicals are implemented and effective.

A-0503

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.25(b)(2)(ii) - Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.

Interpretive Guidelines §482.25(b)(2)(ii)

All Schedule II, III, IV, and V drugs must be kept locked within a secure area. A secure area means the drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals. Medication automated distribution units with logon and password/biometric identification are considered to be locked, since they can only be accessed by authorized personnel who are permitted access to Schedule II - V medications.

Mobile nursing medication carts, anesthesia carts, epidural carts and other medication carts containing Schedule II, III, IV, and V drugs must be locked within a secure area.

Survey Procedures §482.25(b)(2)(ii)

- Determine whether there is a hospital policy and procedure that requires Schedule II, III, IV, and V drugs to be kept in a locked storage area.
- Observe in various parts of the hospital whether Schedule II, III, IV and V drugs are locked and stored in a secure area..
- Determine whether security features in automated medication distribution units are implemented and actively maintained, e.g., that access authorizations are regularly updated to reflect changes in personnel, assignments, etc.
- Interview staff to determine whether policies and procedures to restrict access to authorized personnel are implemented and effective.

A-0504

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.25(b)(2)(iii) - Only authorized personnel may have access to locked areas.

Interpretive Guidelines §482.25(b)(2)(iii)

The hospital must assure that only authorized personnel may have access to locked areas where drugs and biologicals are stored.

A hospital has the flexibility to define which personnel have access to locked areas, based on the hospital's needs as well as State and local law. For example, a hospital could include within its definition of "authorized personnel" ancillary support personnel, such as engineering, housekeeping staff, orderlies and security personnel as necessary to perform their assigned duties. The hospital's policies and procedures must specifically address how "authorized personnel" are defined for purposes of this section. It is not necessary for the policy to name specific authorized individuals, but the policy should be clear in describing the categories of personnel who have authorized access, as well as whether there are different levels of access authorized in different areas of the hospital, or at different times of day, or for different classes of drugs and biologicals, etc.

The hospital's policies and procedures must also address how it prevents unauthorized personnel from gaining access to locked areas where drugs and biologicals are stored. Whenever unauthorized personnel have access, or could gain access, to those locked areas, the hospital is not in compliance with this requirement and is expected to reevaluate and tighten its security measures.

Survey Procedures §482.25(b)(2)(iii)

- Determine whether there is a hospital policy and procedure defining authorized personnel that are permitted access to locked areas where drugs and biologicals are stored.
- ξ Determine whether there is a hospital policy and procedure for limiting access to locked storage areas to authorized personnel only.
- Observe whether or not access to locked storage areas is limited to personnel authorized by the hospital's policy.

A-0505

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.25(b)(3) - Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

Interpretive Guidelines §482.25(b)(3)

The hospital must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable drugs and biologicals are not available for patient use.

Survey Procedures §482.25(b)(3)

- ξ Spot-check the labels of individual drug containers to verify that they conform to State laws, and/or contain the following minimal information:
 - Each patient's individual drug container bears his/her full name, the prescriber's name, and strength and quantity of the drug dispensed. Appropriate accessory and cautionary statements are included as well as the expiration date.
 - Each floor stock container bears the name and strength of the drug, lot and control number of equivalent, expiration date.
- ξ If the unit dose system is utilized, verify that each single unit dose package bears name and strength of the drug, lot and control number equivalent, and expiration date.
- ξ Inspect patient-specific and floor stock medications to identify expired, mislabeled or unusable medications.

A-0506

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.25(b)(4) - When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

Interpretive Guidelines §482.25(b)(4)

Routine after-hours access to the pharmacy by non-pharmacists for access to medication should be minimized and eliminated as much as possible. The use of well-designed night cabinets, after-hours medication carts, and other methods may preclude the need for nonpharmacist to enter the pharmacy. Policies and procedures should be consistent with Federal and State Law.

If an urgent or emergent patient need occurs, the hospital must be able to provide medications to the patients in its facility.

The hospital must have a process for providing medications to meet patient needs when the pharmacy is closed.

When non-pharmacist health care professionals are allowed by law and regulation to obtain medications after the pharmacy is closed, the following safeguards are applied:

- ξ Access is limited to a set of medications that has been approved by the hospital. These medications can be stored in a night cabinet, automated storage and distribution device, or a limited section of the pharmacy.
- ξ Only trained, designated prescribers and nurses are permitted access to medications.
- ξ Quality control procedures (such as an independent second check by another individual or a secondary verification built into the system, such as bar coding) are in place to prevent medication retrieval errors.
- ξ The hospital arranges for a qualified pharmacist to be available either on-call or at another location (for example, at another organization that has 24-hour pharmacy service) to answer questions or provides medications beyond those accessible to non-pharmacy staff.
- ξ This process is evaluated on an on-going basis to determine the medications accessed routinely and the causes of accessing the pharmacy after hours.
- ξ Changes are implemented as appropriate to reduce the amount of times non-pharmacist health care professionals are obtaining medications after the pharmacy is closed.

Survey Procedures §482.25(b)(4)

- ξ Determine through pharmacy records that when the pharmacist is not available, drugs are removed from the pharmacy (drug storage area) only by a designated individual (in accordance with State law if applicable) and only in amounts sufficient for immediate therapeutic needs.
- ξ Review policies and procedures to determine who is designated to remove drugs and biologicals from the pharmacy or storage area and the amount a non-pharmacist may remove in the absence of a pharmacist. The individual(s) designated should be identified by name and qualifications.
- ξ Determine that a system is in place that accurately documents the removal of medications (type and quantity) from either the pharmacy or the after hours supply.
- ξ Determine that the pharmacist reviews all medication removal activity and correlates the removal with current medication orders in the patient medication profile.

ξ Determine if the pharmacist routinely reviews the contents of the after-hours supply to determine if it is adequate to meet the after-hours needs of the hospital.

A-0507

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.25(b)(5) - Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

Interpretive Guidelines §482.25(b)(5)

In accordance with accepted standards of practice, the medical staff, in coordination and consultation with the pharmacy service, determines and establishes the reasonable time to automatically stop orders for drugs and biologicals not specifically prescribed as to time or number of doses. The hospital must implement, monitor, and enforce this automatic stop system.

Survey Procedures §482.25(b)(5)

Review policies and procedures to determine that there is a protocol established by the medical staff to discontinue and review patients' medical records to determine compliance with stop-order policy.

A-0508

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§482.25(b)(6) - Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital's quality assessment and performance improvement program .

Interpretive Guidelines §482.25(b)(6)

Hospitals are required to ensure that the attending physician is made immediately aware of drug administration errors, adverse drug reactions, and incompatibilities. When the attending physician is unavailable, the covering physician must be notified. When the covering physician must be notified, the patient's attending physician must be notified as soon as he/she is available. In addition, when appropriate, such events must also be reported to the hospital-wide Quality Assessment and Performance Improvement (QAPI) program.

The hospital must adopt policies and procedures that identify the types of events that must be reported immediately to the attending physician, as well as those to be reported to the QAPI program.

ξ Drug administration error:

The National Coordinating Council Medication Error Reporting and Prevention definition of a medication error is “Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.” In the context of this regulation, however, “drug administration error” is limited to those errors in administration that actually reach the patient, i.e., a medication actually is administered to a patient when it should not be, or the wrong dose is administered, or the wrong route of administration is used, etc., or a medication that should have been administered to the patient has not been administered in a timely manner, as discussed in the medication administration standard at 42 CFR 482.23(c).

ξ Adverse drug reaction:

The American Society of Health-System Pharmacists (ASHP) defines an adverse drug reaction (ADR) as “Any unexpected, unintended, undesired, or excessive response to a drug that:

1. Requires discontinuing the drug (therapeutic or diagnostic)
2. Requires changing the drug therapy
3. Requires modifying the dose (except for minor dosage adjustments)
4. Necessitates admission to a hospital
5. Prolongs stay in a health care facility
6. Necessitates supportive treatment
7. Significantly complicates diagnosis
8. Negatively affects prognosis, or
9. Results in temporary or permanent harm, disability, or death.

Consistent with the definition, an allergic reaction (an immunologic hypersensitivity occurring as the result of unusual sensitivity to a drug) and an idiosyncratic reaction (an abnormal susceptibility to a drug that is peculiar to the individual) are also considered ADRs.”

ξ Drug incompatibilities

A drug incompatibility occurs when drugs interfere with one another chemically or physiologically. Drugs known to be incompatible must not be mixed, administered together, or administered within a timeframe where they will interfere with each other.

When IV medications are administered with known incompatibilities, an error has occurred and it needs to be reported to the attending physician immediately. Any unexpected reaction that occurs between IV medications not previously identified as incompatible also needs to be reported.

Hospitals can minimize the risk of administering incompatible medications by making available pertinent resources, such as drug incompatibility charts and online incompatibility references. The incompatibility information needs to be readily available to staff administering medications. The information needs to be kept up-to-date as the information is frequently updated by drug manufacturers.

The immediate reporting requirement applies to drug administration errors, adverse drug reactions or incompatibilities that have harmed or have the potential to harm the patient. If the outcome of the drug administration error is unknown, the physician must also be notified without delay.

Drug administration errors that result in no or insignificant harm to the patient must also be documented in the medical record but do not require immediate reporting to the attending physician. For example, if an analgesic dose is missed during the night shift, it can be reported first thing in the morning. Hospital staff is expected to use their clinical judgment, based on patient presentation and assessment in accordance with hospital policy and procedures, to determine whether immediate reporting is required.

On the other hand, for purposes of reporting to the hospital's QAPI program, hospitals must, in accordance with the requirements of the QAPI CoP at 42 CFR 482.21(c)(2), track and report not only the errors that cause or risk harm to the patient, but also those which do not. Such "near misses" and suspected ADRs may reveal important information about systems vulnerabilities that the hospital should address in order to avoid events that result in harm.

Hospitals must establish policies and procedures for reporting of medication errors, ADRs, and incompatibilities, and ensure that staff is aware of the reporting process. For those events that require immediate reporting, the hospital's policies must establish timeframes for reporting that are based on the clinical effect of the error on the patient.

To improve staff willingness to report medication error incidents, hospitals are encouraged to adopt a non-punitive approach that focuses on system issues rather than individual health care professionals. A non-punitive approach is likely to encourage reporting by those who otherwise may fear retribution or hospital disciplinary action.

In addition to employing broad definitions of medication errors and ADRs for QAPI tracking purposes and encouraging the reporting of medication errors, ADRs and drug incompatibilities, the hospital must take additional steps to identify these events as part of its QAPI program where medical errors and adverse patient events are measured, analyzed and tracked. Reliance solely on incident reporting fails to identify the majority of errors and adverse reactions. Proactive identification includes observation of medication passes, concurrent and retrospective review of a patient's clinical records, ADR surveillance team, implementation of medication usage evaluations for high-alert drugs, and identification of indicator drugs that, when ordered, automatically generate a drug regimen review for a potential adverse drug event.

The hospital must have a method by which to measure the effectiveness of its systems for identifying and reporting to the QAPI program medication errors and ADRs. Such methods could include use of established benchmarks for the size and scope of services provided by the hospital, or studies on reporting rates published in peer-reviewed journals. Hospitals are encouraged, and may be required by State law, to participate in statewide and national reporting of drug administration errors, adverse drug reactions, and incompatibilities. National organizations include, but are not limited to, the Food and Drug Administration's (FDA) MedWatch Reporting Program and the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program.

Survey Procedures §482.25(b)(6)

- ξ Does the hospital have policies and procedures that define medications errors, ADRs, and drug incompatibilities? Do they address the circumstances under which they must be reported immediately to the attending physician, as well as to the hospital's QAPI program? Do they address how reporting is to occur?
- ξ Are all medication errors and suspected ADRs promptly recorded in the patient's medical record, including those not subject to immediate reporting?
- ξ If upon review of a sample of records, a suspected ADR or medication error is identified, determine if it was reported immediately to the attending or covering physician, in accordance with the hospital's written policies and procedures. If it is reported to a covering physician, determine if it was also reported to the attending physician when he/she became available.
- ξ Ask hospital staff what they do when they become aware of a medication error, ADR or drug incompatibility. Are staff aware of and do they follow the hospital's policy and procedures?

- ξ Ask hospital staff how they manage drug incompatibilities. What tools do they use in the clinical setting to minimize the risk of incompatibilities? How is the information related to drug incompatibilities made available to the clinical staff administering IV medications (posters, online tools, etc.)? How often is the information updated to ensure accuracy?
- ξ Interview hospital staff to ascertain awareness of the hospital's policy on reporting and documentation of medication errors and adverse drug reactions.
- ξ How does information regarding medication errors, adverse drug reactions, and incompatibilities get reported to the hospital QAPI program? Ask staff to speak to the process.
- ξ For QAPI reporting purposes, is the hospital's definition of an ADR and medication error based on national standards?

A-0509

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.25(b)(7) - Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

Survey Procedures §482.25(b)(7)

- ξ Interview the pharmacists, or pharmacy employees to determine their understanding of the controlled drug policies.
- ξ Conduct a spot check of drug use and other inventory records to ensure that drugs are properly accounted for.
- ξ Review reports of pharmaceutical services to determine if there are reported problems with controlled drugs and what actions have been taken to correct the situation.
- ξ Interview the Pharmacy Director, pharmacist and pharmacy employees to determine their understanding of the controlled drug policies. Is there a policy and procedure for handling controlled drug discrepancies?
- ξ Review reports of pharmaceutical services to determine if there are reported problems with controlled drugs and what actions have been taken to correct the situation.
- ξ Determine if controlled drug losses were reported to appropriate authorities in accordance with State and Federal laws.

A-0510

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.25(b)(8) - Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.
Interpretive Guidelines §482.25(b)(8)

The facility has immediately available sufficient texts and other resources on drug therapy. The pharmacist also should be readily available by telephone or other means to discuss drug therapy, interactions, side effects, dosage etc., with practitioners to assist in drug selection and with nursing personnel to assist in the identification of drug-induced problems.

Survey Procedures §482.25(b)(8)

- ξ Examine the sources of drug information available at the nursing station and/or drug storage area and determine if they are current.
- ξ Determine whether staff development programs on drug therapy are available to facility staff to cover such topics as new drugs added to the formulary, how to resolve drug therapy problems, and other general information as the need arises.

A-0511

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.25(b)(9) - A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.

Interpretive Guidelines §482.25(b)(9)

The medical staff must establish a formulary system. The formulary lists medications for dispensing or administration that the hospital maintains or that are readily available. In accordance with accepted standards of practice, the medical staff, in consultation with the pharmacy service, should develop written criteria for determining what medications are available for dispensing or administration. At a minimum, the criteria include the indication for use, effectiveness, risks (including propensity for medication errors, abuse potential, and sentinel events), and costs.

Processes and mechanisms should be established to monitor patient responses to a newly added medication before the medication is made available for dispensing or administration within the hospital.

Medications designated as available for dispensing or administration are reviewed periodically based on emerging safety and efficacy information.

The hospital should have processes to approve and procure medications that are not on the hospital's medication list.

The hospital should have processes to address medication shortages and outages, including the following:

ξ Communicating with appropriate prescribers and staff; ξ Developing approved substitution protocols;

ξ Educating appropriate LIPs, appropriate health care professionals, and staff about these protocols; and

ξ Obtaining medications in the event of a disaster. **Survey Procedures §482.25(b)(9)**

ξ Interview the pharmacist to determine that the medical staff has established a formulary that lists drugs that actually are available in the hospital.

ξ Interview the Pharmacy Director to determine that there is a process for creation and periodic review of a formulary system.

ξ Determine that the formulary lists drugs that are available.

A-0528

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.26 Condition of Participation: Radiologic Services

The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.



**STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
COMMUNITY PHARMACY**



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File # _____
Insp # _____

ROUTINE CHANGE LOC NEW CURRENTLY NOT OPERATING CHANGE OWNER
INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 466, FLORIDA STATUTES

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION							
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER							
STREET ADDRESS		TELEPHONE #	EXT.								
CITY	COUNTY	STATE/ZIP		PRESCRIPTION DEPARTMENT MANAGER LICENSE #							
PRESCRIPTION DEPARTMENT HOURS				REGISTERED PHARMACIST/INTERM/TECHNICIAN	LICENSE #						
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	1.			
Open								2.			
Close								3.			
								SATISFACTORY	N/A	YES	NO
1	Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]										
2	Pharmacy technicians properly identified and supervised. [64B16-27.410, F.A.C.]										
3	Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]										
4	Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]										
5	A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]										
6	Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]										
7	Prescription department clean and safe. [64B16-28.102(4), F.A.C.]										
8	Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]										
9	Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]										
10	Expired medications removed from the shelves. [64B16-28.110, F.A.C.]										
11	CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]										
12	Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]										
13	Prescriptions have the date dispensed and dispensing pharmacist. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]										
14	Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]										
15	All controlled substance prescriptions contain information required. [893.04, F.S.]										
16	Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.]							<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
17	Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]										
18	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]										
19	DEA 222 order forms properly completed. [893.07, F.S.]										
20	Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]										
21	Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]										
22	Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]										
23	Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]							<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
24	Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]										
25	Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]										
26	Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]							<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
27	Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]										
28	Compounding records properly maintained. [64B16-27.797, F.A.C.]*										
29	Unit dose records properly maintained. [465.016(1)(i), F.S.] [64B16-28.118, F.A.C.]										
30	Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]										

* Note: If establishment is engaged in parenteral/ventral compounding, a separate inspection form should be completed.

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT _____

ID _____

Institutional Representative _____
INV 359 Revised 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

Date _____ Investigator/Sr. Pharmacist Signature _____

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**STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES**



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CLASS I INSTITUTIONAL PHARMACY

Insp # _____

ROUTINE CHANGE LOC NEW CURRENTLY NOT OPERATING CHANGE OWNER

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION
DOING BUSINESS AS		DEA NUMBER		CONSULTANT PHARMICIST
STREET ADDRESS		TELEPHONE #	EXT.	
CITY	COUNTY	STATE/ZIP		CONSULTANT PHARMICIST LICENSE #
				N/A YES NO
1	Consultant pharmacist of record inspecting monthly and providing written report. [64B16-28.501, F.A.C.]			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2	Prepackaged medication properly labeled. [64B16-28.108(3)] [64F12.006 (1) (a) 5., F.A.C.]			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3	Medication requiring refrigeration stored in a refrigerator. [59A-4.112(6), F.A.C.]			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
4	Medication properly labeled and has quantity of the drug placed in the container. [64B16-28.502(1)(h), F.A.C.]			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
5	Unit dose medication properly labeled. [64B16-28.108(4)] [64F-12.006 (1) (a)] [59A-4.112(5), F.A.C.]			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
6	Adequate sanitation and space to protect the health of the public served. [64B16-28.102(4), F.A.C.]			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7	Medicinal drugs stored in emergency kits are those medications deemed by Medical Director, Director of Nursing, and Consultant Pharmacist as necessary. [59A-4.112(10), F.A.C.]			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
8	Emergency kit is readily available and kept sealed. [59A-4.112(10), F.A.C.]			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
9	Inventory of emergency kit attached to outside of kit. [59A-4.112(10), F.A.C.]			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
10	Drugs in emergency kits are labeled consistent with Chapter 499 requirements. [59A-4.112(10), F.A.C.]			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
11	Medication administered from emergency kits properly accounted for through procedural controls. [59A-4.112(10), F.A.C.]			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
12	P & P manual delineates procedure for disposition of unused controlled substances. [64B16-28.301, F.A.C.]			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
13	Records exist for receipt and disposition of all controlled drugs. [59A-4.112(3)(7)][64B16-28.301, F.A.C.]			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
14	Account of controlled drugs is reconciled periodically. [59A-4.112(4), F.A.C.]			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
15	Starter dose contracts provided. [64B16-28.503(2)(c), F.A.C.]*			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
16	CQI Policy and Procedures and quarterly meetings. [64B16-27.300, F.A.C.] [766.101, F.S.]			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Questions with () may be answered n/a (not applicable)				
Remarks:				

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME _____

ID _____

Institutional Representative

Date

Investigator/Sr. Pharmacist Signature

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**STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES**



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CLASS II INSTITUTIONAL PHARMACY

File # _____

ROUTINE CHANGE LOC NEW CURRENTLY NOT OPERATING CHANGE OWNER

Insp # _____

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION							
DOING BUSINESS AS		DEA NUMBER		CONSULTANT PHARMACIST							
STREET ADDRESS		TELEPHONE #	EXT.								
CITY	COUNTY	STATE/ZIP		LICENSE #							
PRESCRIPTION DEPARTMENT HOURS											
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #		
Open								1.			
Close								2.			
								3.			
				Satisfactory		N/A		YES NO			
				Satisfactory		N/A		YES NO			
1	Current Class II Institutional Pharmacy permit. [465.019(2)(b), F.S.]			<input type="checkbox"/>	<input type="checkbox"/>	17	Controlled substance records readily retrievable. [893.07(4), F.S.]			<input type="checkbox"/>	<input type="checkbox"/>
2	Current professional supervision of a consultant pharmacist. [465.019(5), F.S.]			<input type="checkbox"/>	<input type="checkbox"/>	18	Controlled substance records maintained for 2 years. [CFR 1304.04 & 1306.22] [893.07(4)(b), F.S.]			<input type="checkbox"/>	<input type="checkbox"/>
3	Current consultant pharmacist supervisor of record. [465.019(5), F.S.]			<input type="checkbox"/>	<input type="checkbox"/>	19	DEA 222 order forms properly completed. [893.07(2), F.S.]			<input type="checkbox"/>	<input type="checkbox"/>
4	Current DEA registration. [21 CFR 1301.11] & [465.023(1)(c), F.S.]			<input type="checkbox"/>	<input type="checkbox"/>	20	Controlled substance inventory taken on biennial basis and available for inspection. [893.07(1)(a), F.S.]			<input type="checkbox"/>	<input type="checkbox"/>
5	Sufficient daily operating hours to adequately serve patients of institution. [64B16-28.603, F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	21	Policy and procedures for removal of a single dose of medication for administration to a patient when no pharmacist is on duty. [64B16-28.602(1), F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>
6	Current pharmacists' licenses displayed. [64B16-27.100(1), F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	22	Prepacking of medication either unit dose or multiple dose according to policy and procedures by consultant pharmacist. [64B16-28.120(3), F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>
7	Pharmacy interns properly registered and supervised. [465.013, F.S.] [64B16-26.400(4), F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	23	Unit dose medication properly labeled. [64F-12.006, F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>
8	Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410(3), F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	24	Prepacking and labeling of unit dose or multiple dose medication checked by Florida licensed pharmacist. [64B16-27.410(1), F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>
9	Visible identification badge worn by pharmacy technician(s). [64B16-27.420(4)(a), F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	25	Pharmaceutical stock examined at least every four months and deteriorated or outdated items removed. [64B16-28.110, F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>
10	Policy and procedures available describing utilization of pharmacy technicians. [64B16-27.440, F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	26	Florida licensed pharmacist doing the compounding or is physically present and certifies the accuracy of the finished product. [64B16-27.1001(2), F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>
11	Prescription area has sink and running water. [64B16-28.102(1), F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	27	Florida licensed pharmacist certifying the final parenterals and bulk solutions. [64B16-27.1001(2), F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>
12	Prescription area has refrigeration for storing pharmaceuticals. [64B16-28.102(3), F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	28	Records indicate the pharmacist that reviewed and certified the appropriateness and accuracy of medication orders. [64B16-27.1001(3), F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>
13	Prescription area clean and sanitary with no overcrowded/unhealthy conditions. [64B16-28.102(4), F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	29	Medication administration record (MAR) attached with unit dose system when delivering or administering drugs to patients. [64B16-28.108(1)(c), F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>
14	Prescription balance and weights or electronic balance, counting tray graduates, spatulas, mortars, and pestles. [64B16-28.102(5)(b), F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	30	Emergency Department dispensing records properly maintained. [64B16-28.6021, F.A.C.]*			<input type="checkbox"/>	<input type="checkbox"/>
15	Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format [64B16-28.102(5)(a), F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	31	Continuous Quality Improvement Program described in Pharmacy policy and procedure manual and summarization of Quality - Related Events which have been reviewed by the Continuous Quality Improvement Committee quarterly. [64B16-27.300, F.A.C.], [766.101(1)(a), F.S.]			<input type="checkbox"/>	<input type="checkbox"/>
16	Policy and procedures for destruction of unusable controlled substances. [64B16-28.303, F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>						
* Questions with (*) may be answered n/a (not applicable).											
Remarks:											

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT _____

ID _____

Institutional Representative
INV 361 Revised 03/11, 01/07, 06/02

Date _____

Investigator/Sr. Pharmacist Signature _____

Save



**STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES**

4052 Bald Cypress Way, BIN # C70 • Tallahassee, FL 32399-3270



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File# _____
Insp # _____
Next Insp # _____

SPECIAL-CLOSED SYSTEM PHARMACY

ROUTINE CHANGE LOC NEW CURRENTLY NOT OPERATING CHANGED OWNER

INSPECTION AUTHORITY – CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION		
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER		
STREET ADDRESS		TELEPHONE #				
CITY		COUNTY		STATE/ZIP		
				LICENSE #		
PRESCRIPTION DEPARTMENT HOURS				REGISTERED PHARMACIST/INTERN/TECHNICIAN		
	Monday	Tuesday	Wednesday	Thursday	Friday	
Open						
Close						
				LICENSE #		
				1		
				2		
				3		
SATISFACTORY			YES	NO		
1	Current pharmacy permit displayed. [465.015(1)(a),F.S.]				23	Pharmacy maintains patient profile records. [64B16-27.800,F.A.C.]
2	Board of Pharmacy office notified in writing of current pharmacy manager. [64B16-28.830(5),F.A.C.]				24	Controlled substance records readily available. [893.07,F.S.]
3	Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]				25	Initials of pharmacist filling cont. sub. Rx on the Rx. [893.04(1)(c)6,F.S.]
4	Interns properly registered and supervised. [465.013,F.S.] [64B16-26.400,F.A.C.]				26	Date controlled substance Rx was filed on the Rx. [893.04(1)(c),F.S.]
5	Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410] [64B16-27.420,F.A.C.]				27	Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]
6	Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]				28	Prescriber's name/address/DEA# on all controlled substance prescriptions. [893.04(1)(c)2,F.S.]
7	Written policy/procedure manual for pharmacy technicians. [64B16-27.440,F.A.C.]				29	All controlled substance prescriptions must have drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]
8	Pharmacist license/renewal certificate displayed. [64B16-27.100(1),F.A.C.]				30	Date of refills on controlled substance prescriptions. [893.04(1)(c)6,F.S.]
9	Pharmacist on duty when Rx department open. [64B16-28.1,F.A.C.]				31	Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]
10	Written offer to counsel when appropriate. [64B16-27.B2,F.A.C.]*				32	Controlled substance refills limited to 5 in 6 months from original date of prescription. [893.04(1)(g),F.S.]
11	Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]				33	Controlled substance inventory taken on biennial basis and available for inspection. [893.07(1)(a),F.S.]
12	Prescription department has drug refrigeration storage. [64B16-28.104,F.A.C.]				34	DEA 222 order forms properly completed. [893.07(2),F.S.]
13	Prescription department clean and safe. [64B16-28.105,F.A.C.]				35	Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07,F.S.] [64B16-28.140,F.A.C.]
14	Prescription balance and weights, counting tray, graduates, spatulas, mortars, and pestles. [64B16-28.107(2)(a) b)(c)(d),F.A.C.]				36	Controlled substance records maintained for 2 years. [893.07(4)(e),F.S.] [CFR 1304.04 & 1306.22]
15	Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format. [64B16-28.107(1),F.A.C.]				37	Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) or (e),F.A.C.]*
16	CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S.] [64B16-27.300,F.A.C.]				38	Provides 24-hour emergency and on-call service. [64B16-28.830(3),F.A.C.]
17	Medication properly labeled. [64B16-27.101,F.A.C.]				39	Prepackaged medication with proper expiration date. [64B12.006(1)(a),F.A.C.]
18	Outdated pharmaceuticals removed from active stock. [64B16-28.110,F.A.C.]				40	Log of prepacking. [64B16-27.410(1),F.A.C.]
19	"Discard After" date on prescription label or provided in other written form. [64B16-28.402(1)(h),F.A.C.]				41	Dispensing only to individuals as allowed by rule for Special-Closed Systems Pharmacy permit. [64B16-28.830,F.A.C.]
20	All medicinal drug prescriptions require date dispensed. [64B16-28.140(3)(b)2,F.A.C.]				42	Appropriate records of returned/unused unit dose medicinal drugs maintained/available. [64B16-28.830(2),F.A.C.] [64B16-28.118,F.A.C.] [64B-12.012(1)(a),F.A.C.] [465.016(1)(f),F.S.]
21	All medicinal drug prescriptions require initials of pharmacist and date of refill. [64B16-28.140(3)(b),F.A.C.]					
22	Complete prescription records of pharmacy. [64B16-28.140,F.A.C.]					
* QUESTIONS WITH (*) MAY BE ANSWERED N/A (NOT APPLICABLE).						

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form completed.

Remarks: _____

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Pharmacist _____ Date _____ Investigator/Sr. Pharmacist Signature/ID Number _____

INV 406 Revised 05/02, Replaces 02/02

White Copy: Field Yellow Copy: Headquarters Pink Copy: Licensee



STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
WWW.DOH.STATE.FL.US



CLASS I INSTITUTIONAL PHARMACY

FILE#: _____

INSPECTION #: _____

NAME OF ESTABLISHMENT		DATE OF INSPECTION	DATE NOTIFIED BOARD OFFICE		
DOING BUSINESS AS		TELEPHONE NUMBER	EXTENSION		
STREET ADDRESS		CITY	COUNTY	STATE ZIP	
PERMIT NUMBER			EXPIRATION DATE		
CONSULTANT PHARMACIST NAME		LICENSE NUMBER			
VENDOR PHARMACY PERMIT					
		SATISFACTORY	NA	YES	NO
1. Consultant pharmacist of record inspecting monthly and providing written report. [64B16-28.501, F.A.C.]					
2. Prepackaged medication properly labeled. [64B16-28.108(3)] [64F12.006 (1) (a), F.A.C.]					
3. Medication requiring refrigeration stored in a refrigerator. [59A-4.112(6), F.A.C.]					
4. Medication properly labeled and has quantity of the drug placed in the container. [64B16-28.502(3), F.A.C.]					
5. Unit dose medication properly labeled. [64B16-28.108(3)] [64F-12.006 (1) (a), F.A.C.] [59A-4.112(5)]					
6. Adequate sanitation and space to protect the health of the public served. [64B16-28.102(4), F.A.C.]					
7. Medicinal drugs stored in emergency kits are those medications deemed by Medical Director, Director of Nursing and Consult Pharmacist as necessary. [59A-4.112(10), F.A.C.]					
8. Emergency kit is readily available and kept sealed. [59A-4.112(10), F.A.C.]					
9. Inventory of emergency kit attached to outside of kit. [59A-4.112(10), F.A.C.]					
10. Drugs in emergency kits are labeled consistent with Chapter 499 requirements. [59A-4.112(10), F.A.C.]					
11. Medication administered from emergency kits properly accounted for through procedural controls. [59A-4.112(10), F.A.C.]					
12. P & P manual delineates procedure for disposition of unused medications, both controlled substances and non-controlled substances. [64B16-28.301, F.A.C.]					
13. Records exist for receipt and disposition of all controlled drugs. [59A-4.112(3)] [64B16-28.301, F.A.C.]					
14. Account of controlled drugs is reconciled periodically. [59A-4.112(4), F.A.C.]					
15. Starter dose contracts provided. [64B16-28.503, F.A.C.]*					
16. CQI Policy and Procedures and quarterly meetings. [64B16-27.300, F.A.C. [766.101, F.S.]					
* Questions with (*) may be answered n/a (not applicable)					

Remarks: _____

I have read and have had this inspection report and the laws and regulations concerned explained, and the information given is true and correct to the best of my knowledge.

Signature of Institutional Representative _____

Date _____

Investigator/Sr. Pharmacist Signature/ID Number _____

Print Name _____