

# Inspecting Pharmacies for Compliance to Florida Laws.



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Division of Medical Quality Assurance  
Florida Dept of Health, St Petersburg

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## Speaker Disclosure

- I do not have (nor does any immediate family member have):
  - a vested interest in or affiliation with any corporate organization offering financial support or grant monies for this continuing education activity
  - any affiliation with an organization whose philosophy could potentially bias my presentation



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## Have you experienced an inspection

Yes

No



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**Learning Objectives**



- Describe**  
Describe the role of the Department of Health Inspectors
- Illustrate**  
Illustrate the steps necessary for Pharmacies to take to ensure a compliant inspection
- Explain**  
Explain common issues that Pharmacy Inspectors encounter when visiting a Pharmacy.
- Identify**  
Identify different types of citations.
- Discuss**  
Discuss the role of the pharmacist and the technician in the inspection process.

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**Learning Objectives**

**Describe**

Describe the role of the Department of Health Inspectors



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**Learning Objectives**



- Describe**  
Describe the role of the Department of Health Inspectors
- A. Enforce rules**
- B. Give fines**
- C. Scare people**
- D. Protect the public**

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F.S.Chapter  
465  
Pharmacy



Florida Statutes are the statutory laws of Florida.

465.005 Authority to make rules.

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F.A.C.  
64B16-27  
64B16-28



Florida Rules and Regulations.

Board of Pharmacy authority to adopt rules.

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Statutes and Rules

Florida Statutes  
[Chapter 465](#): Pharmacy  
[Chapter 456](#): Health Professions and Occupations: General Provisions  
[Chapter 120](#): Administrative Procedure Act  
[Chapter 499](#): Florida Drug and Cosmetic Act  
[Chapter 893](#): Drug Abuse Prevention and Control

Florida Administrative Code  
Rules: [Chapter 64B16](#): Board of Pharmacy



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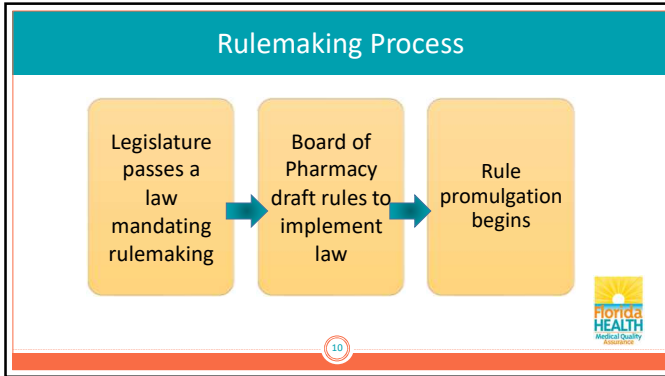
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### Role of Florida Department of Health

- Enforce the rules to: Protect the public  
Protect the Pharmacist  
The Department of Health, Division of Medical Quality Assurance, serves as the principal administrative unit for the Board
- Important to review Statutes and Rules and understand



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### Learning Objectives

**Illustrate**

Illustrate the steps necessary for Pharmacies to take to ensure a compliant inspection.



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### Requirements for compliant inspection

- Understand statutes and rules
- Documentation readily retrievable
- Understand pharmacist and technician requirements.



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### Audience Poll

- How many Community Pharmacists
- Institutional Class II or III
- Consultant Class I or ALF
- Special Closed System
- Other



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### Community Pharmacy Inspection

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**Technician requirements**

- Name badge
- Active license
- Proof of training in tasks performed
- Acknowledgement of Review of Policy and Procedure Manual within 90 days of hire



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**Pharmacist requirements**

- Active license
- Understanding of Technician duties-delegable and non delegable
- Signed certified daily log
- Number of pharmacy technicians and their positions



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**Pharmacist requirements**

- Controlled Substance Prescription requirements
- HB21 : Acute pain, acute pain exception and chronic pain.
- CSOS and DEA 222
- Controlled substance Rx records
- Biennial Inventory of controlled substances



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### Pharmacist Requirements

- Policy and procedure to prevent fraudulent dispensing of controlled substances
- Continuous Quality Improvement Minutes/Proof of meetings
- Unit dose packing logs
- Compounding records



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### Pharmacist : Controlled substances

Section 456.42(3), Florida Statutes, requires prescribing health care practitioners to electronically transmit prescriptions for medicinal drugs upon renewal of license or by July 1, 2021, whichever is earlier, unless a specific exception applies.



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### Class I Institutional and ALF Inspection

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**Class I Institutional and ALF**

- Consultant Pharmacist of record
- Monthly inspection documentation
- Quarterly Continuous Quality Improvement Minutes

*Since Consultant Pharmacist is not usually on site at time of inspection, please ensure documents are in a binder/ electronic folder and Director of Nursing has access to them.*

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**Class I Institutional and ALF**

- Class I - INV 360
- ALF – INV 414




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**Class I Institutional and ALF**

64B16-28.301 Destruction of Controlled Substances – Institutional Class I Pharmacies (Nursing Homes).

(1) Controlled substances that have been dispensed and not used by the patient shall not be returned to the pharmacy and shall be securely stored by the nursing home until destroyed.

Records of destruction and requirements

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**Class I Institutional**

- Emergency Drug Kits:
  - Inventory list on outside of kit
  - Sealed and available for use
  - Contents must be correctly labeled
  - Documentation of use of any of the contents



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Special Closed System Inspection

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**Special Closed System**

- Customized medication packages :
  - 120 days from date of packing unless expiration date of one of the components is less.
- Unit dose packing records
- Certified daily log
- INV-406



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**Special Closed System**

- Quarterly continuous quality improvement meetings
- Controlled substances documents
- Dispensing to individuals as allowed by rule



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Class II and III Permit Inspection

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**Class II and III Permits**

64B16-28.750 Class III Institutional Pharmacies.  
(1)(a) Class III Institutional Pharmacies are those Institutional Pharmacies authorized by section 465.019(2)(d), F.S.  
All Class III Institutional Pharmacies must be affiliated with a hospital



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### Class II and III Permits-Differences

- Transfer of medications allowed between Class III Permits under common control
- Compounded sterile preparations- must be patient specific
- Records of transfer of medications



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### Class II Permits

- Main hospital – INV 361
- Modified Institutional – INV 362
- Two different inspection forms



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### Class III Permits

- Main hospital – INV 361
- Stand alone ED or Surgery Center – INV456
- Two different inspection forms



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### Technician requirements

- Name badge
- Active license
- Proof of training in tasks performed
- Acknowledgement of Review of Policy and Procedure Manual within 90 days of hire



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### Pharmacist requirements

- Active license
- Understanding of Technician duties-delegable and non-delegable
- Number of pharmacy technicians and their positions
- Biennial inventory of controlled substances
- Controlled substances records maintained for 4 years
- CSOS/DEA 222 forms



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### Pharmacist requirements

- Automated dispensing machines:
  - Policies to ensure accurate stocking of ADM's
  - Policies for medications that are approved as overrides
  - Quality assurance program to review overrides



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## Pharmacist requirements

- SPE Contract- documentation requirements
- Policies for remote order entry
- Unit Dose Packing logs
- Compounding records



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## Pharmacist : Discharge

Senate Bill 262, Dispensing Medicinal Drugs, was signed into law by Governor DeSantis. The effective date is July 1, 2021. The bill authorizes medicinal drugs to be dispensed by a hospital that operates a Class II or Class III institutional pharmacy to any inpatient upon discharge or patient discharged from an emergency department if the prescribing practitioner determines that the medicinal drug is warranted, and community pharmacy services are not readily accessible to the patient. The drug may be dispensed up to a 48-hour supply or through the end of the next business day. During a declared state of emergency, a 72-hour supply may be dispensed by a hospital located in an area affected by the emergency



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## Learning Objectives

**Explain**

Explain common issues that Pharmacy Inspectors encounter when visiting a Pharmacy.



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**Issues seen by inspectors**

- Signage missing in community pharmacy
- Technicians not identified
- Documents cannot be retrieved
- Continuous Quality Improvement minutes
- No training documents for Technicians in job description
- No certified daily log




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**Issues seen by Inspectors**

- Incorrect BUD on custom medication packages
- Unit dose packing records

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**Issues seen by Inspectors**

- No access to documents in a Class I –nursing director cannot help.
- Controlled substances in Class I- no system to reconcile the waste, stored in unlocked cabinets with no documentation
- Consultant unaware of requirements related to controlled substances

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### Issues seen by inspectors

- Documents unavailable in a Class III stand alone when no pharmacist on duty
- No documents of transfer of medications between Class III
- Pharmacists and Technicians unaware of rules.



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### Issues seen by inspectors

- What do you want me to do?
- The previous inspector told me I could do this.
- How come the previous inspector didn't tell me that?



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### Issues seen by inspectors

- An inspection is a snapshot in time, different inspectors notice different things and we may not see everything!
- We are enforcing the rules.



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**Learning Objectives**

**Identify**

Identify different types of citations.

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**Citable Offenses**

A. 64B16-30.003(2)(e) FAC, Failure to display any sign, license or permit required by statute or rule. \$500

B. 64B16-30.003(2)(k) FAC, Failure to correct minor violation as listed in rule 64B16-30.002, FAC \$250

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**Citations Violation A**



64B16-30.003(2)(e) FAC

Failure to display any sign, license or permit required by statute or rule

Sign stating the hours the pharmacy department is open each day

"Prescription Department Closed" sign when applicable

"Patient Consultation Area" sign

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### Citations Violation B

- 64B16-30.003(2)(k) FAC
- Outdated pharmaceuticals; rule 64B16-28.110, F.A.C.
- Failure to meet regulation of daily operating hours; rule 64B16-28.1081, F.A.C.
- Information required on controlled substance prescriptions: practitioner’s address, practitioner’s DEA registration number, patient’s address; section 893.04, F.S.



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### Citations Violation B

- Failure to have certified by dispensing pharmacists the daily hard-copy printout or daily log; paragraph 64B16-28.140(3)(c) or (e), F.A.C.
- Failure to have pharmacy minimally equipped i.e. references, compounding equipment, and a current copy of the laws and rules governing the practice of pharmacy in the State of Florida; rule 64B16-28.102, F.A.C.



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### Citations Violation B

- Failure to properly identify pharmacy technicians; rule 64B16-27.100, F.A.C.
- Improper storage of legend drugs; rule 64B16-28.120, F.A.C.
- Improper documentation of destruction of controlled substances; rules 64B16-28.301, 64B16-28.303, F.A.C.
- Generic Equivalent sign not posted; F.S. 465.025(7)



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## Citation Amounts

Maximum Amount = \$750 Total

If several minor violations exist, fine is \$250

If several required signs are not posted, fine is \$500



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## Learning Objectives

Discuss

Discuss the role of the pharmacist and the technician in the inspection process.



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## Inspection Process

- Arrival:
  - Notify PDM
  - Don't panic
  - Patient care must continue
  - Provide inspector with an area to work
  - Decide who will work with inspector to provide documents



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# Inspection Process

- Understand the statutes and rules
- Understand what is required for pharmacist, technician
- All apply, even if there is not a specific question
- Review inspection form and keep documents in a binder
- Be always inspection ready



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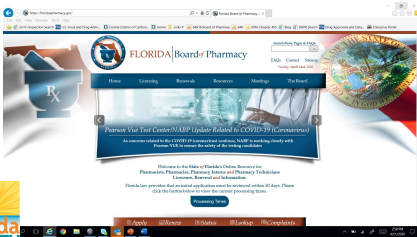
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# Board of Pharmacy Website



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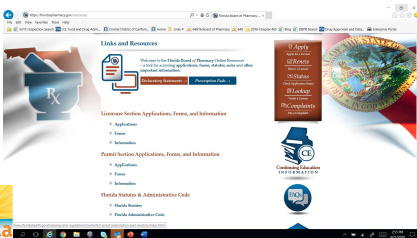
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# Board of Pharmacy Website



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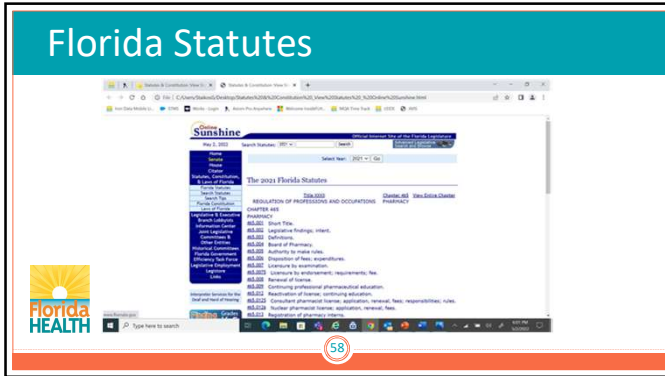
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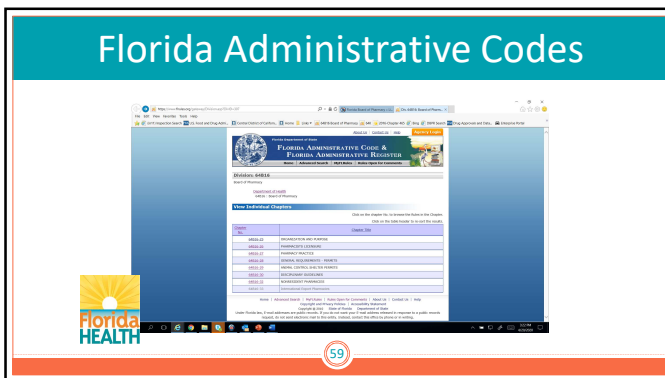
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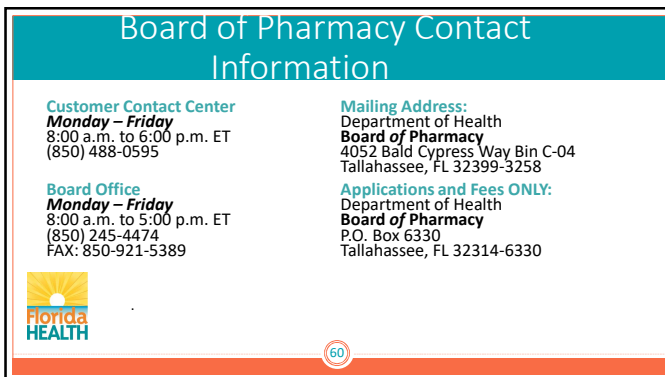
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Questions?

**Contact**  
Gillian Staikos, Senior Pharmacist  
(850) 841 0256  
[Gillian.Staikos@flhealth.gov](mailto:Gillian.Staikos@flhealth.gov)



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