Florida Board of Pharmacy
Pharmacy Inspections and Pharmacists’ Responsibilities; Minimizing Disciplinary Violation and Diversion

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Past Chair, Florida Board of Pharmacy

Pharmacy Diversion Awareness Conference
March 17, 2012 & March 18, 2012
West Palm Beach, Florida Marriott Hotel
Objectives

• Discuss a permit’s regulatory accountability as related to the Profession of Pharmacy
• Discuss Prescription Department Manager and Consultant of Record Responsibilities
• Describe the Inspection Process and Expectations
• Discuss tools, preparations and resources that promote successful inspection outcomes and minimize exposure to violations and diversion
Pre-Assessment Check
True or False

• All Community Pharmacy Permits will need to obtain a new permit by July 1\textsuperscript{st} 2012 in order to continue to dispense CII’s and CIII’s
• The requirement for Prescription Department Managers and Consultants of Record are just paper work formalities
• Legislative and Community concerns have minimal impact on the practice of pharmacy
Permit Requirements

• Need Consultant of Record or Prescription Manager
• Responsible for basic requirements outlined by law and rule
• No Professional expertise required
• Corporate shield
• SB 1986: HB7095: New Accountability
Professional Oversight

• Prescription Department Manager
  • Inspection readiness
  • General & Site Specific compliance

• Consultant of Record
  • Inspection readiness
  • General & Site Specific compliance

• Pharmacist
  • Practice standards
  • Medication control
Prescription Department Manager

- Responsibilities of the PDM
  - Numbers of locations - limits
  - Continuous Quality Improvement (CQI) Programs
  - Policies and Procedures
    - Tech utilization, registration and training
    - Physical requirements, operating procedures, references, diversion prevention, etc
  - Record Keeping
    - Medications
    - Patient
    - Prescription
    - Permit
  - Automation
    - Quality Assurance – performance and maintenance
    - Record keeping
    - Security
  - Closing
  - Compliance to statutes and rules governing the practice of pharmacy
Re-permitting July 2012

• Section 465.018, Florida Statutes was amended during the 2011 legislative session to require a community permittee to be re-permitted in order to dispense controlled substances listed in Schedule II and III on or after July 1, 2012.

• Required Policy and Procedure
  • Procedures for the dispensing of controlled substances to minimize dispensing based on fraudulent representations or invalid practitioner-patient relationships

• Board of Pharmacy Website:
  http://www.doh.state.fl.us/mqa/pharmacy/
Steps For Re-Permit Process

• 1st Step:
   Establish or Update Officers and Owners Online via Online Services using your pharmacy administrator account user id and password. If you do not have a user id or password, please see the Pharmacy Administrator Account information

• 2nd Step:
   Fingerprints - All owners, officers and prescription department managers are required to submit a set of fingerprints unless the corporation is exempt under the Section 465.022, Florida Statutes for corporations having more than $100 million of business taxable assets in this state. If your corporation is exempt only the prints of the prescription department manager is required. If the manager prints are on file with DOH or AHCA and they are less than one year old then they will not have to be resubmitted. The manager must provide proof of them being on file
   The Department of Health accepts electronic fingerprinting service offered by Livescan device vendors that are approved by the Florida Department of Law Enforcement. For additional information on the submission of fingerprints please review the pdf documents on the “Fingerprint Information” drop-down box above or our FAQs
   The ORI number for the pharmacy profession is FL924190Z

• 3rd Step:
   Apply for the new permit (on or after January 18, 2012) via Online Services using the Pharmacy user id and password. Your User ID and Password were mailed with your physical license. Look in the center section and refer to the Online Services Instructions, item #5
Consultant of Record

• Various Practice Settings
  • Hospital - Institutional II, Long Term Care-Institutional I, Modified II, Special Pharmacies – ALF etc.
• Compliance
  • Permit Records, Licensing, Inspections, Policy and Procedures, Joint Commission, Medicaid, Medicare etc.
  • Medication Records, Security, Storage, Formulary and Distribution management
  • Patient – Reviews, CMS and other agencies
• Monthly Reports
Changing Practices: Good News / Bad News

Opportunities:
• New and Innovative Practice Settings
• Accountable Care Organizations
• Specialty Opportunities

Pit Falls:
• Pill Mills
• Medicare Fraud
• Counterfeit Medication
Tools for Success

- Know the Law
  - Consultant Certification and Recertification
  - Continuing Education and Seminars
  - Professional Association participation
- Use the New and Improved Board of Pharmacy Website
  - Laws and Rules
    - Rule Drafts and Declaratory Statements
  - Applications
  - Licensure and Tech Registration “Look – Up”
  - Hot Topics
  - Board Meetings and Minutes
Pharmacy

BOARD MEETING INFORMATION

2011 Board of Pharmacy Meeting Dates and Locations

Dates and locations are subject to change. The board will notify applicants and licensees of a required appearance.

2012 Board of Pharmacy Meeting Dates and Locations

Dates and locations are subject to change. The board will notify applicants and licensees of a required appearance.

Agenda Request

Note: Under Florida law, e-mail addresses are public records. If you do not want your e-mail address released in response to a public records request, do not send electronic mail to this entity. Instead, contact this office by phone or in writing.

You may submit an email request to be placed on the Board’s Interested Parties List. The board routinely sends out Agenda Outlines to interested parties 7–10 days prior to an upcoming board meeting. Copies of the full “public” agenda are also available, but are subject to a duplication fee.

Agendas and Notices

MISSION: To protect and promote the health of all residents and visitors in the state through organized state and community efforts, including cooperative agreements with counties.

VISION: A healthier future for the people of Florida.

PURPOSE: To protect the public through health care licensure, enforcement and information.

FOCUS: To be the nation's leader in quality health care regulation.

VALUES: Integrity, Commitment, Respect, Excellence, Accountability, Teamwork, & Empowerment.
Accessing Public Meeting Materials

FTP directory /pub/bop/ at ftppub.doh.state.fl.us

To view this FTP site in Windows Explorer, click Page, and then click Open FTP Site in Windows Explorer.

Up to higher level directory

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Florida Department of Health

Division of Medical Quality Assurance

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Preparing for Success

• Embrace Management Skills
  • People: Communication styles, Effective delegation
  • Automation: Process Management, Expectations, Metrics

• Organize Inspection Materials
  • User friendly procedures, Checklists, Quick view protocols

• Communicate With All Involved

• Regularly Scheduled Dry Runs

• Recap, Review, Revise
Post Assessment Review
True or False

• All Community Pharmacy Permits will need to obtain a new permit by July 1\textsuperscript{st} 2012 in order to continue to dispense CII’s and CIII’s (TRUE)
• The requirement for Prescription Department Managers and Consultants of Record are just paper work formalities (FALSE)
• Legislative and Community concerns have minimal impact on the practice of pharmacy (FALSE)
2012 Meeting Dates

**February 7-8, 2012**  
St. Augustine, FL  
Agenda Material Deadline: January 6, 2012

**April 10-11, 2012**  
Tampa, FL  
Agenda Material Deadline: March 16, 2012

**June 5-6, 2012**  
Boca Raton, FL  
Agenda Material Deadline: May 11, 2012

**August 14-15, 2012**  
Orlando, FL  
Agenda Material Deadline: July 20, 2012

**October 9-10, 2012**  
Tallahassee, FL  
Agenda Material Deadline: September 14, 2012

**December 11-12, 2012**  
Gainesville, FL  
Agenda Material Deadline: November 9, 2012
Thank You

Questions??????

Contact Information

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