

# Florida Board of Pharmacy

## Pharmacy Inspections and Pharmacists' Responsibilities; Minimizing Disciplinary Violation and Diversion

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



# Objectives

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- 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

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- All Community Pharmacy Permits will need to obtain a new permit by July 1<sup>st</sup> 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

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- 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

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- 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/>

### PHARMACY quicklinks

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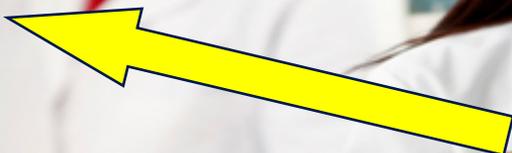
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## Pharmacy

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<a href="#">COMMUNITY PHARMACY RE-PERMITTING</a>			



### hottopics

- > [COMMUNITY PERMITEE: PHARMACY ADMINISTRATIVE ACCOUNT INFORMATION](#)
- > [COMMUNITY RE-PERMITTING INFORMATION...](#)
- > [NEW LEGISLATION REGARDING HEALTH CARE FRAUD AND CONVICTIONS](#)
- > [REGISTERED PHARMACY TECHNICIAN CE HOURS](#)

**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.

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# 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

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- 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

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## Opportunities:

- New and Innovative Practice Settings
- Accountable Care Organizations
- Specialty Opportunities

## Pit Falls:

- Pill Mills
- Medicare Fraud
- Counterfeit Medication

# Tools for Success

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- 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**  
quicklinks

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## BOARD MEETING INFORMATION

BOARD MEETING MINUTES

BOARD MEMBER INFORMATION

AGENDA MATERIALS & AUDIO FILES

### [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.
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# Accessing Public Meeting Materials

FTP directory /pub/bop/ at [ftppub.doh.state.fl.us](ftp://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](#)



10/25/2010 10:37AM	Directory	<a href="#">Audio</a>
10/26/2010 02:53PM	12,599,479	<a href="#">PCF Reconsideration - Board of Pharmacy.zip</a>
04/20/2011 10:54AM	Directory	<a href="#">Public Meeting Materials</a>



Name	Size	Type	Modified
 Public Book February 8-9, 201...	20.6 MB	Adobe Acrobat Doc...	01/21/2011 3:13 PM



The screenshot shows a web browser window with the address bar displaying <ftp://ftppub.doh.state.fl.us/pub/bop/Public%20Meeting%20Materials/Public%20Book%20February%208-9%202011>. The main content area shows a document viewer with a file named "TAB 1 PETITION FOR DECLARATORY STATEMENT / VARIANCE OR WAIVER". The document content includes a list of names and titles:

1. Martin R. Dix, Esquire, Orlando Health Amended Petition
2. Crescent Healthcare, Inc., Warren Phillips, R.Ph.

The document also includes a "File" section with the following details:

**File:**  
Name: November 18, 2010  
To: Orlando Pharmacy Office  
Company: FL Dept. of Health  
Subject: Orlando Health's Amended Petition for Declaratory Statement  
# of Pages: 20  
Created: 2010-11-18 10:10:10 AM  
Created by: [redacted]

The document text continues with a request for a declaratory statement from the Board of Pharmacy and a request for a variance or waiver. It also includes a "Please include a stamped copy" instruction and a "Thank you" note.

# Preparing for Success

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- 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

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- All Community Pharmacy Permits will need to obtain a new permit by July 1<sup>st</sup> 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

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**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

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Questions??????

## Contact Information

Board of Pharmacy  
MQA\_Pharmacy@doh.state.fl.us  
(850) 245-4292