

The Florida Senate
COMMITTEE MEETING EXPANDED AGENDA

HEALTH REGULATION
Senator Garcia, Chair
Senator Sobel, Vice Chair

MEETING DATE: Tuesday, September 20, 2011

TIME: 10:45 a.m.—12:45 p.m.

PLACE: *Pat Thomas Committee Room, 412 Knott Building*

MEMBERS: Senator Garcia, Chair; Senator Sobel, Vice Chair; Senators Diaz de la Portilla, Fasano, Gaetz, Jones, and Norman

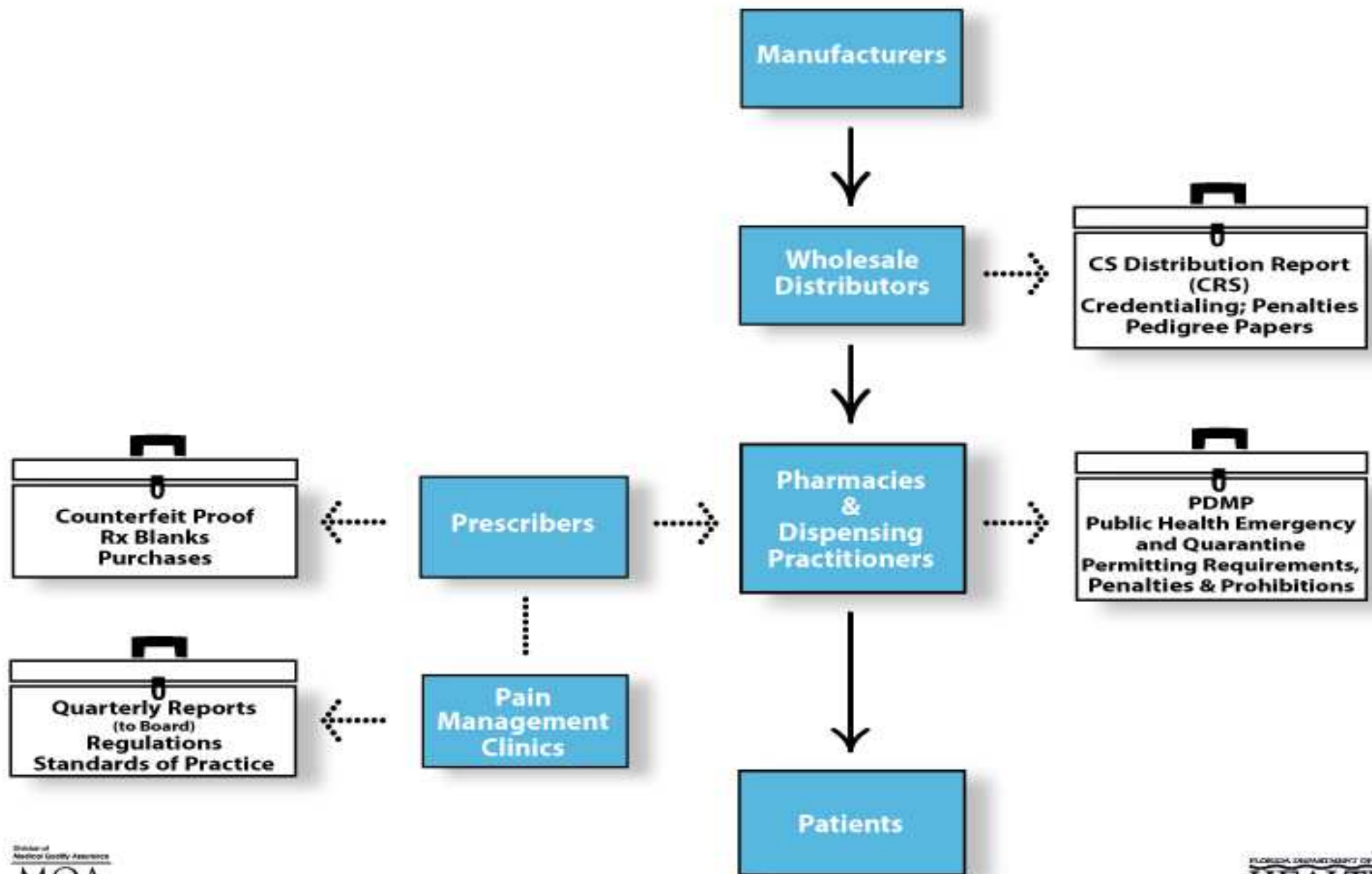
TAB		BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1		Status Report on Implementation of CS/CS/HB 7095 (2011) relating to Prescription Drugs		Discussed
2		Update on Renewal of the Section 1115 Medicaid Reform Pilot Waiver and Status Report on Implementation of the 2011 Medicaid Reform Bills (CS/HB 7107 and CS/HB 7109)		Discussed

Implementation of
House Bill 7095
Relating to Prescription Drugs
Florida Department of Health

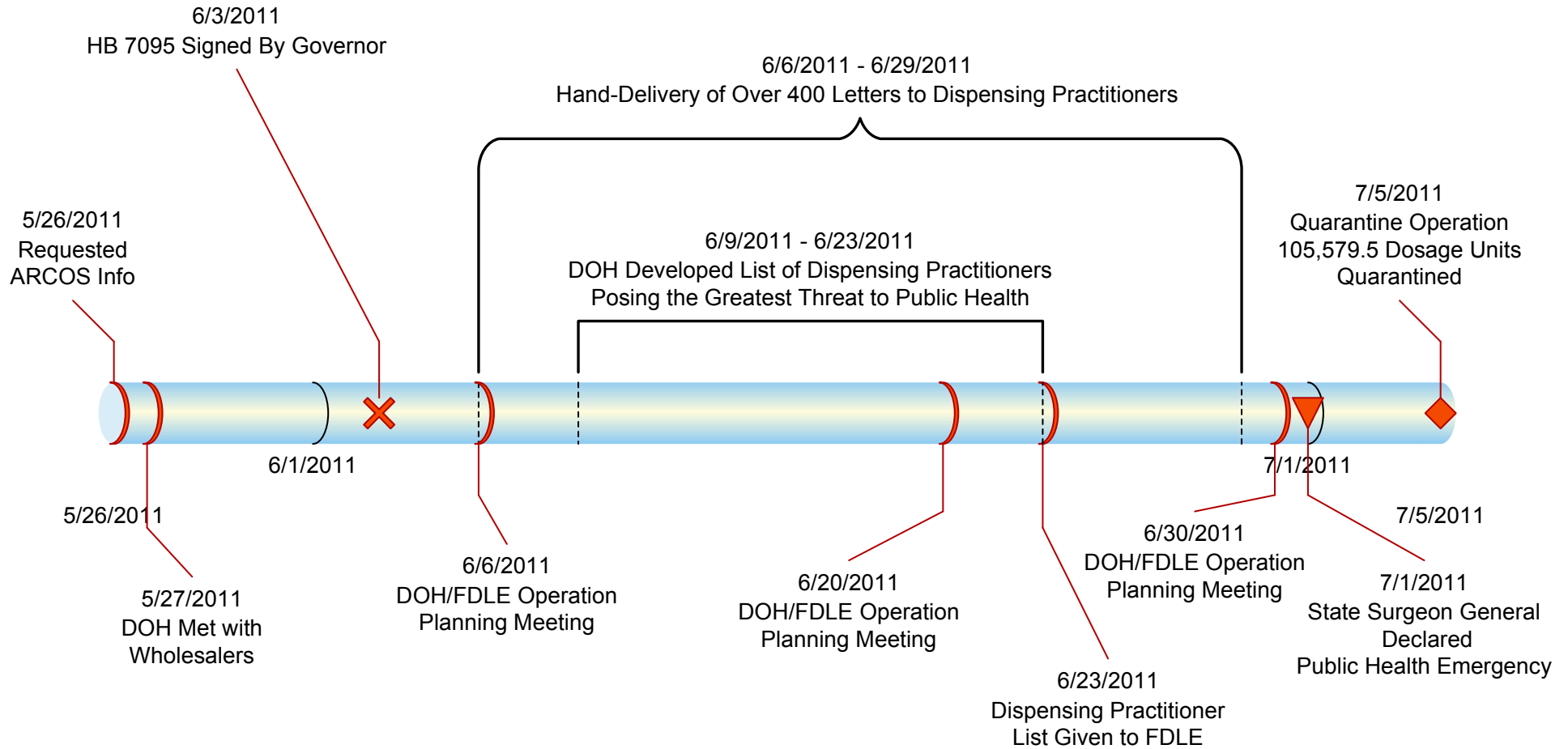
**Florida Senate
Health Regulation Committee**
September 20, 2011



FLORIDA'S DRUG DISTRIBUTION SYSTEM TOOLBOX



Public Health Emergency & Controlled Substance Quarantine Operation Timeline

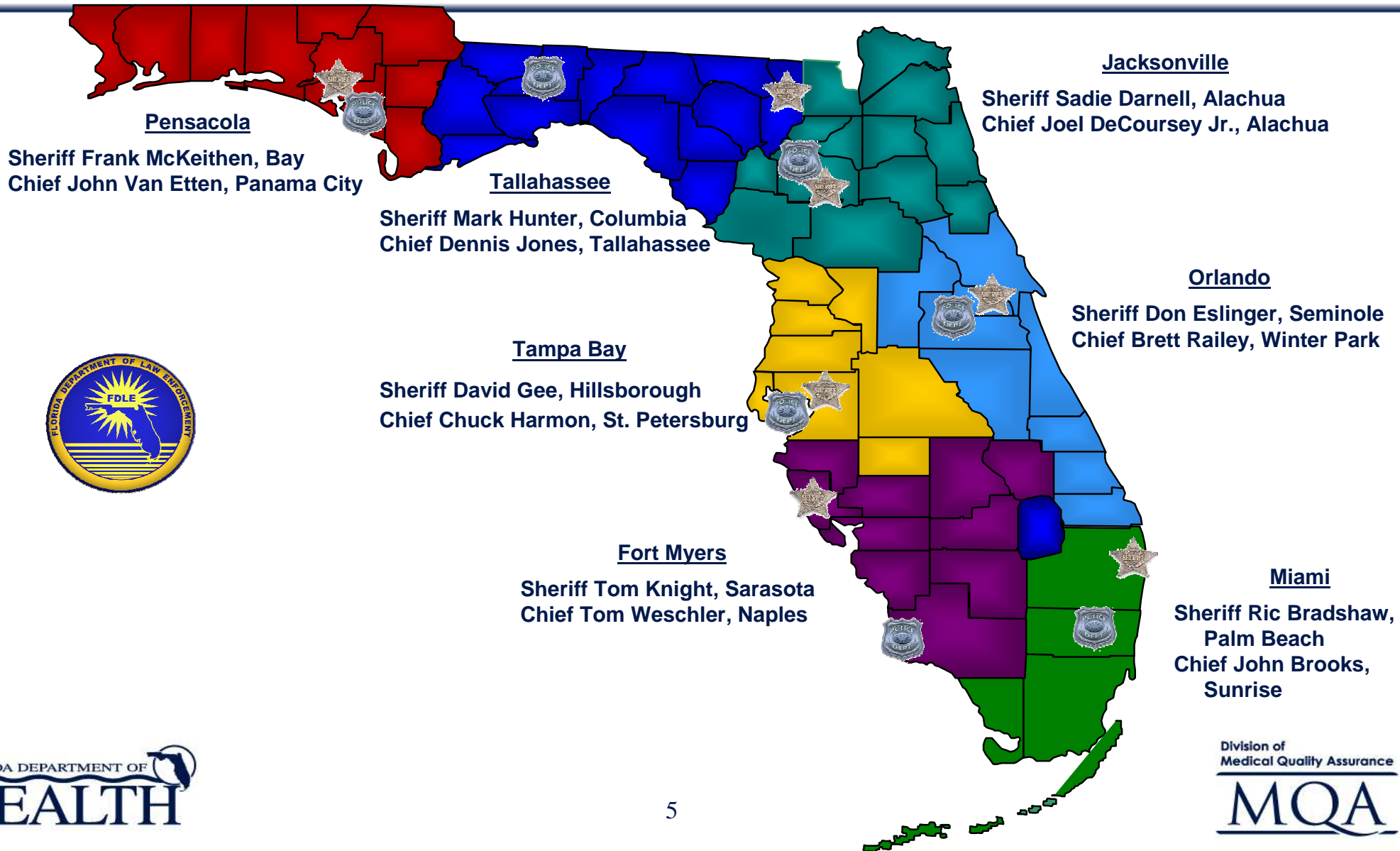


Public Health Emergency & Controlled Substance Quarantine Operation

Criteria for Identification of Dispensing Practitioners

- Risk of Non-Compliance
- Purchase Amounts
- Manner of Medical Services
- Other Factors:
 - Complaint history of controlled substance prescribing or dispensing violations
 - Wholesaler reports of suspicious purchasing
 - Law enforcement reports of suspicious behavior
 - Dispensing practitioner inspection information

Regional Strike Force Co-Chairs



Regional Drug Enforcement Strike Force

Regional Activity

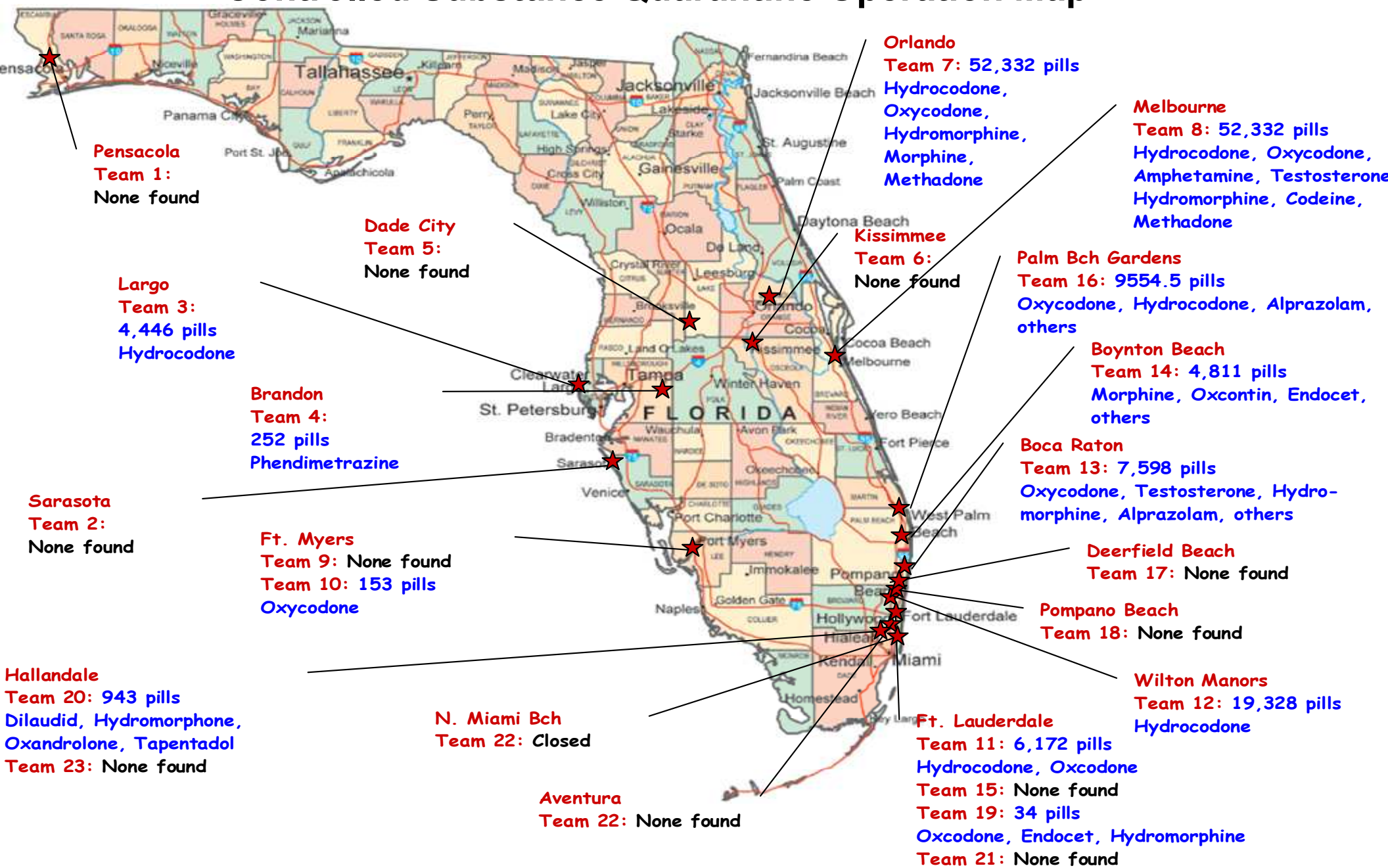
September 15, 2011

Region	Arrests	Pills	Vehicles	Weapons	Currency	Clinics Closed	Doctors Arrested
PROC	64	4,516	1	0	31,129	1	0
TROC	51	5,619.5	1	9	34,919	0	0
JROC	86	5,934.5	3	3	14,418	0	1
OROC	435	76,606.5	3	17	1,275,906	4	9
TBROC	243	20,511	11	7	82,251	20	2
FMROC	65	2,593	0	3	3,500	0	1
MROC	155	154,859.25	16	12	815,486	0	5
TOTAL	1,099	270,639.75	35	51	2,257,609	25	18

HB 7095 General Revenue Allocations & Federal Justice Assistance Grants

	Justice Assistance Grant Allocation	General Revenue Allocation	Total
Local Reserve Funds	0	500,000	500,000
Ft. Myers	91,668	254,316	345,984
Jacksonville	104,056	222,189	326,245
Miami	201,470	987,344	1,188,813
Orlando	135,026	330,290	465,316
Pensacola	64,640	125,128	189,768
Tallahassee	56,757	107,101	163,858
Tampa	174,442	473,633	648,074
Total	828,059	3,000,000	3,828,059

Controlled Substance Quarantine Operation Map



FLORIDA DEPARTMENT OF
HEALTH

Division of
Medical Quality Assurance
MQA

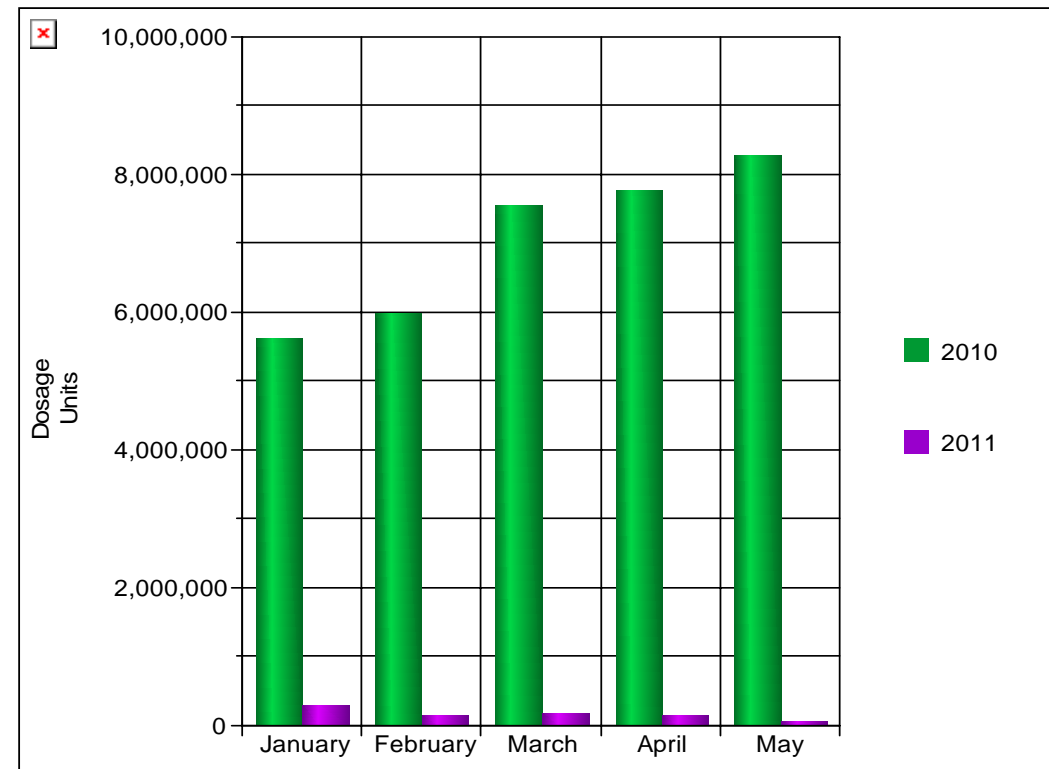
Public Health Emergency & Controlled Substance Quarantine Operation

- 105,579.5 Pills Found
 - 6,172 Transported to UPS by FDLE for Reverse Distributor
 - 99,407.5 Quarantined Off Site by FDLE

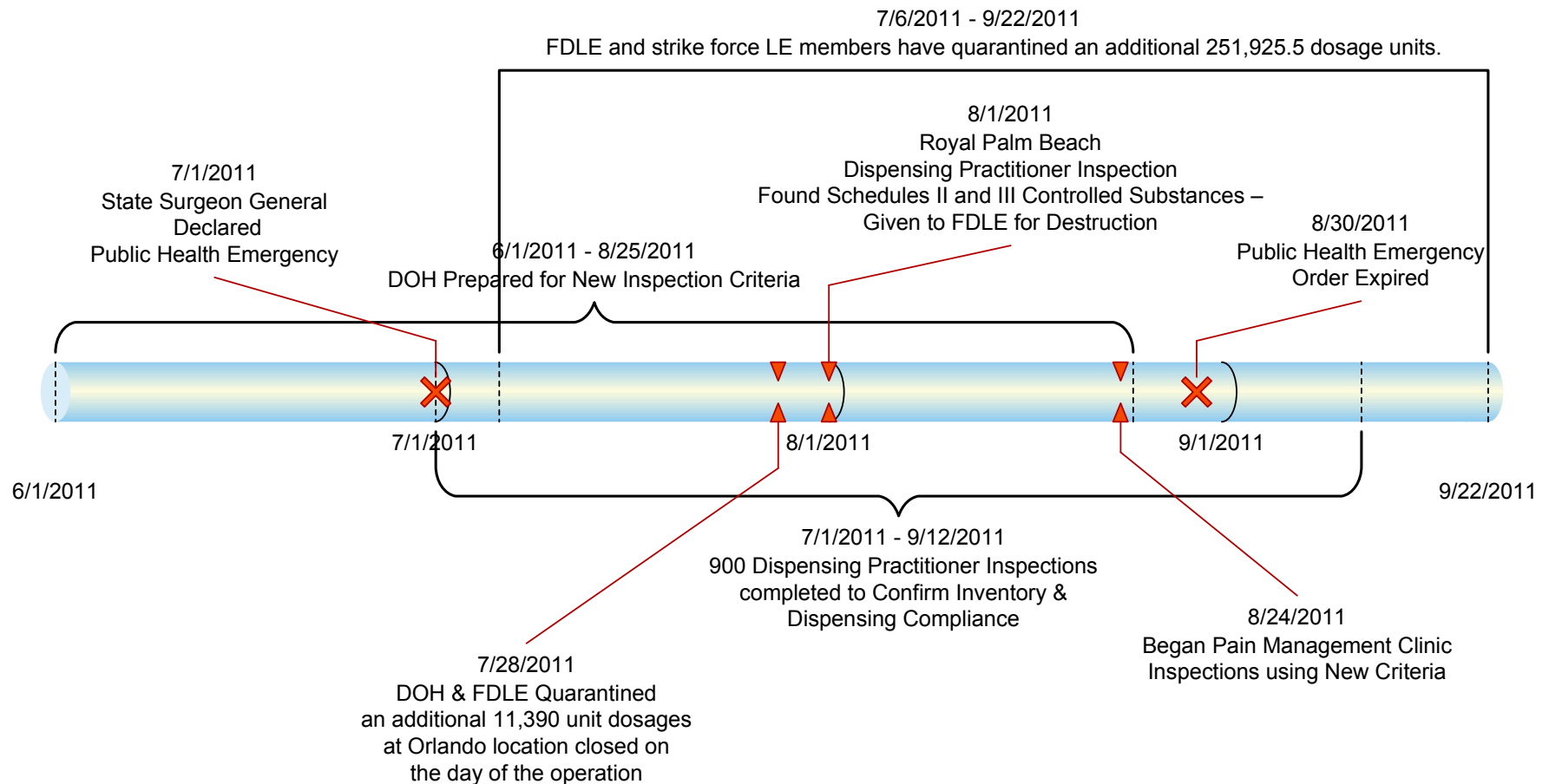
Florida Practitioners

Trends~Monthly Purchases of Oxycodone

MDs, DOs, Podiatrists, & Dentists		
Month	2010	2011
Jan	5,629,672	307,670
Feb	5,994,694	177,780
March	7,568,606	197,674
April	7,787,033	163,350
May	8,283,396	78,800
	35,263,401	925,274

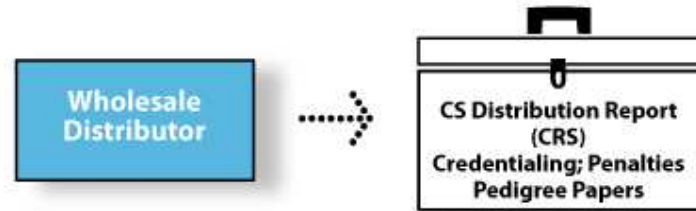


Post-Quarantine Timeline

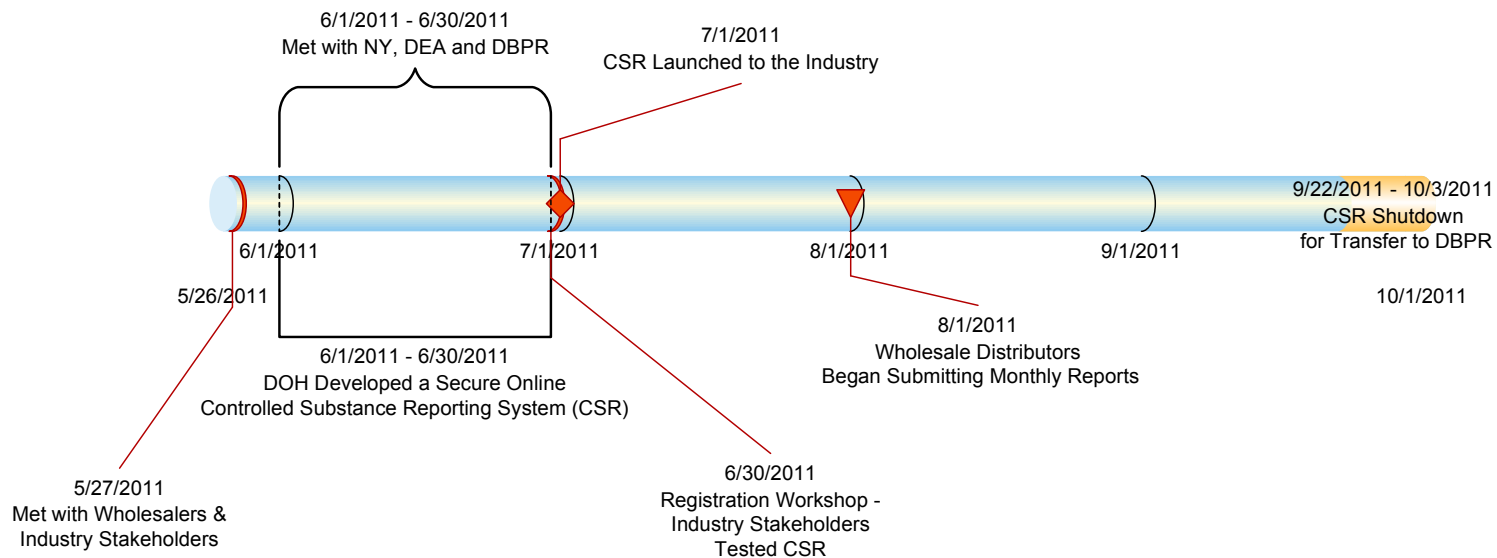


Wholesale Distributors

- Document credentialing policies and procedures with application
- Report receipts and distributions of Schedules II-V controlled substances
 - DEA number
 - National drug code
 - Quantity
 - Unit
 - Recipient DEA number
 - Transaction date
 - Strength



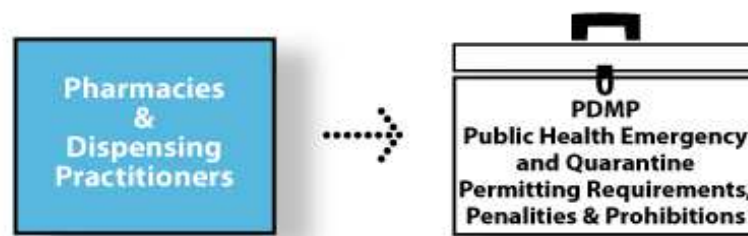
Wholesale Distributor Controlled Substance Reporting Timeline



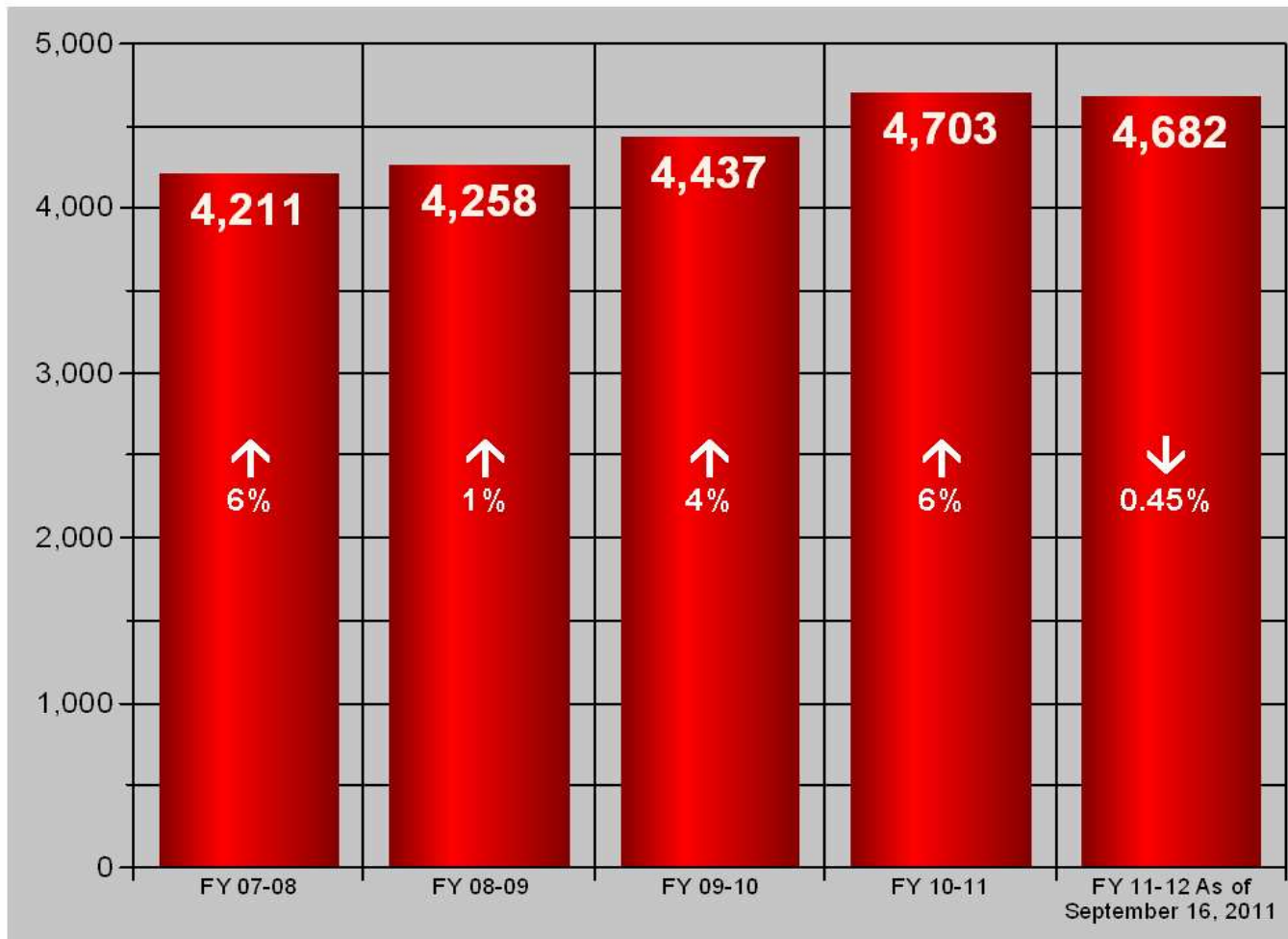
Community Pharmacies

As of July 1, 2012, community pharmacies must be permitted under new requirements to dispense controlled substances listed in Schedules II or III

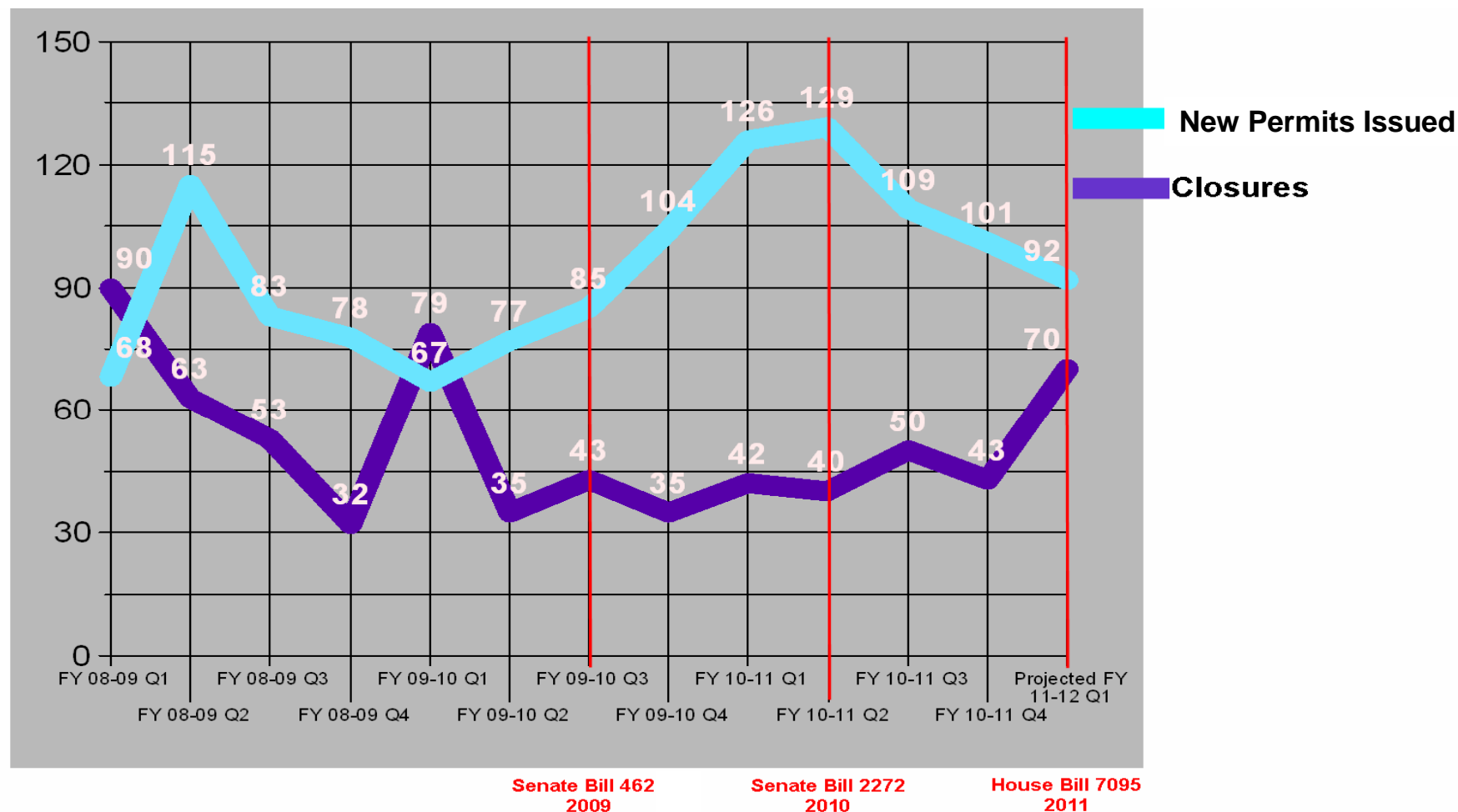
- Requires fingerprints and background screens
- Requires on-site inspection within 90 days
- Prohibits pharmacy permit transfer
- Grants authority to deny or revoke a permit for prescription processing errors
- Establishes additional grounds for denying a permit
- Requires pharmacists to report to law enforcement within 24 hours any attempt to obtain a controlled substance from a pharmacy by fraud.



of Community Pharmacies Permitted with DOH
% Increase and Decrease
July 1, 2008 – September 16, 2011



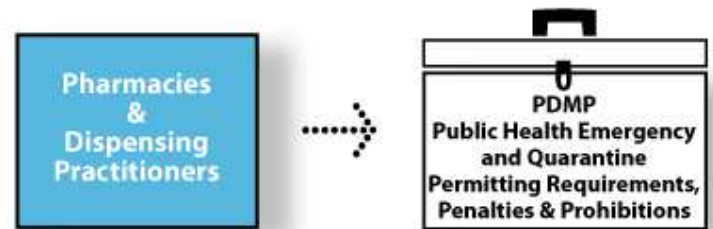
of New Community Pharmacy Permits Issued & # of Community Pharmacy Permits Closed July 1, 2007 – June 30, 2011 Quarterly



Dispensing Practitioners

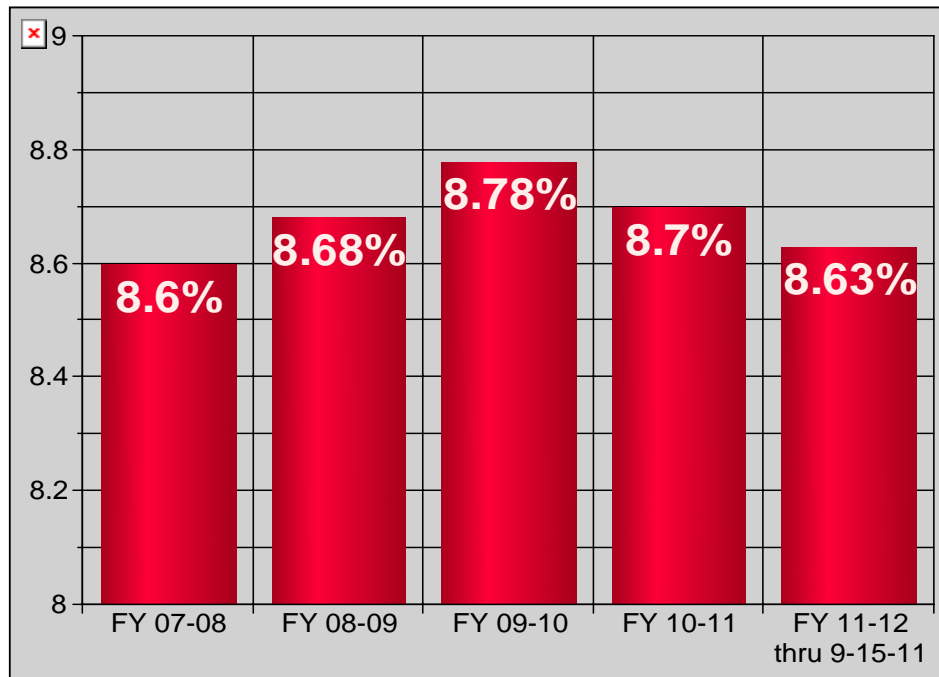
HB 7095 prohibits dispensing of Schedules II or III controlled substances by practitioners except:

- Complimentary packages of medicinal drugs
- Department of Corrections
- Surgical Procedures
- Clinical Trials
- Methadone Facilities
- Hospices

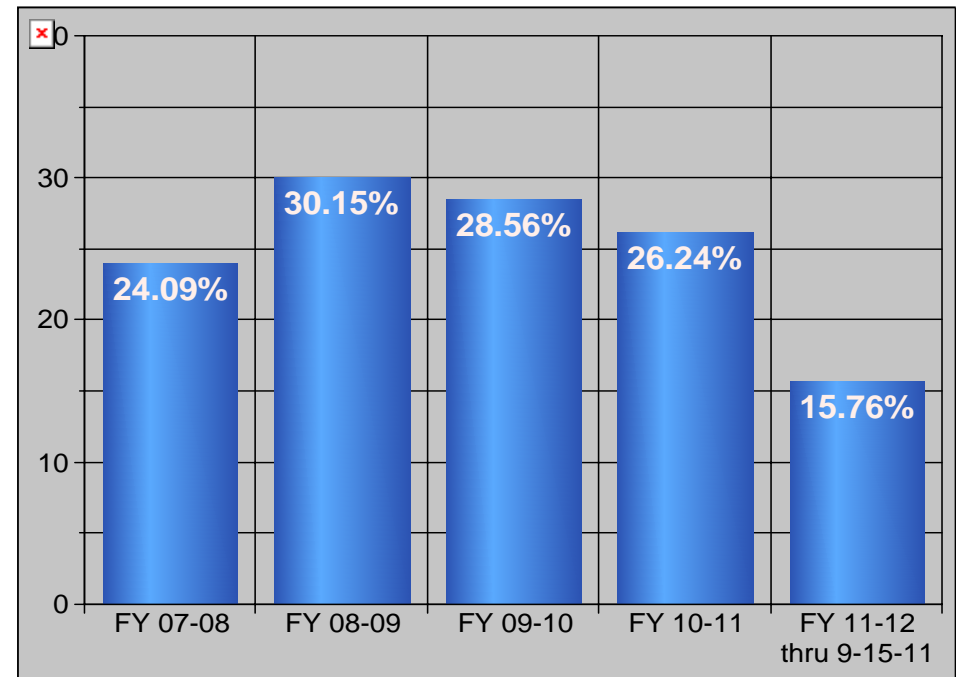


Dispensing Practitioner Trends

% of total licensed physicians that are dispensing practitioners by fiscal year



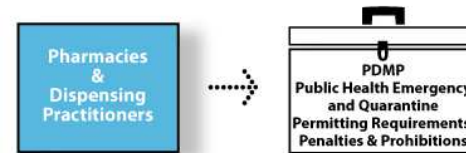
% of new physician applications requesting to be dispensing practitioner by fiscal year



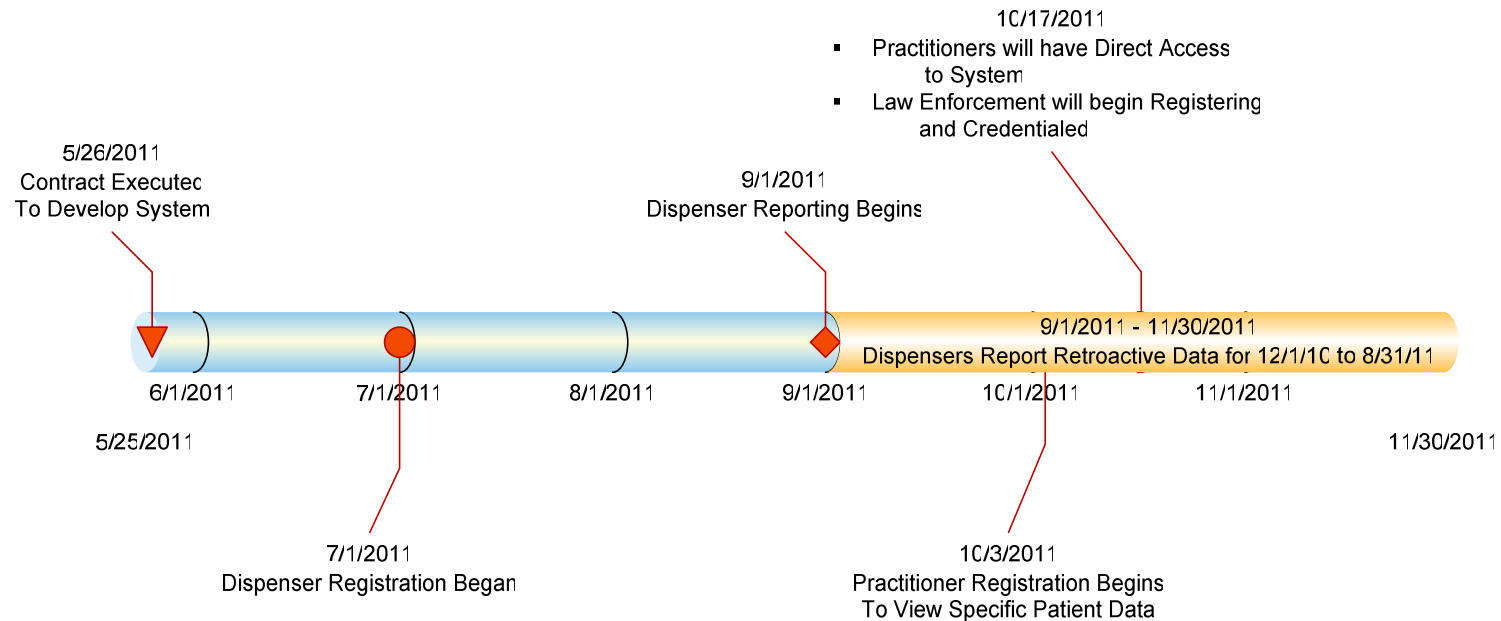
Prescription Drug Monitoring Program



- Must report within 7 days
- Comply with state and federal privacy laws and regulations
- Required to report weekly
- Requests that dispensers report retroactive data by November 30, 2011, from December 1, 2010 to August 31, 2011.



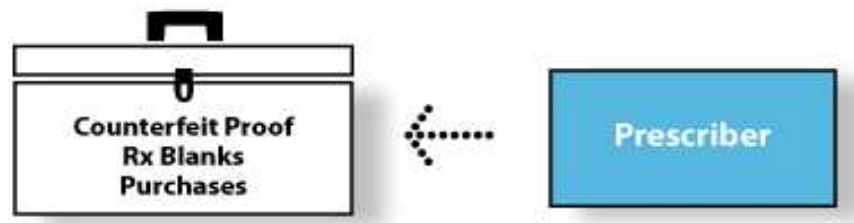
Prescription Drug Monitoring Program Timeline



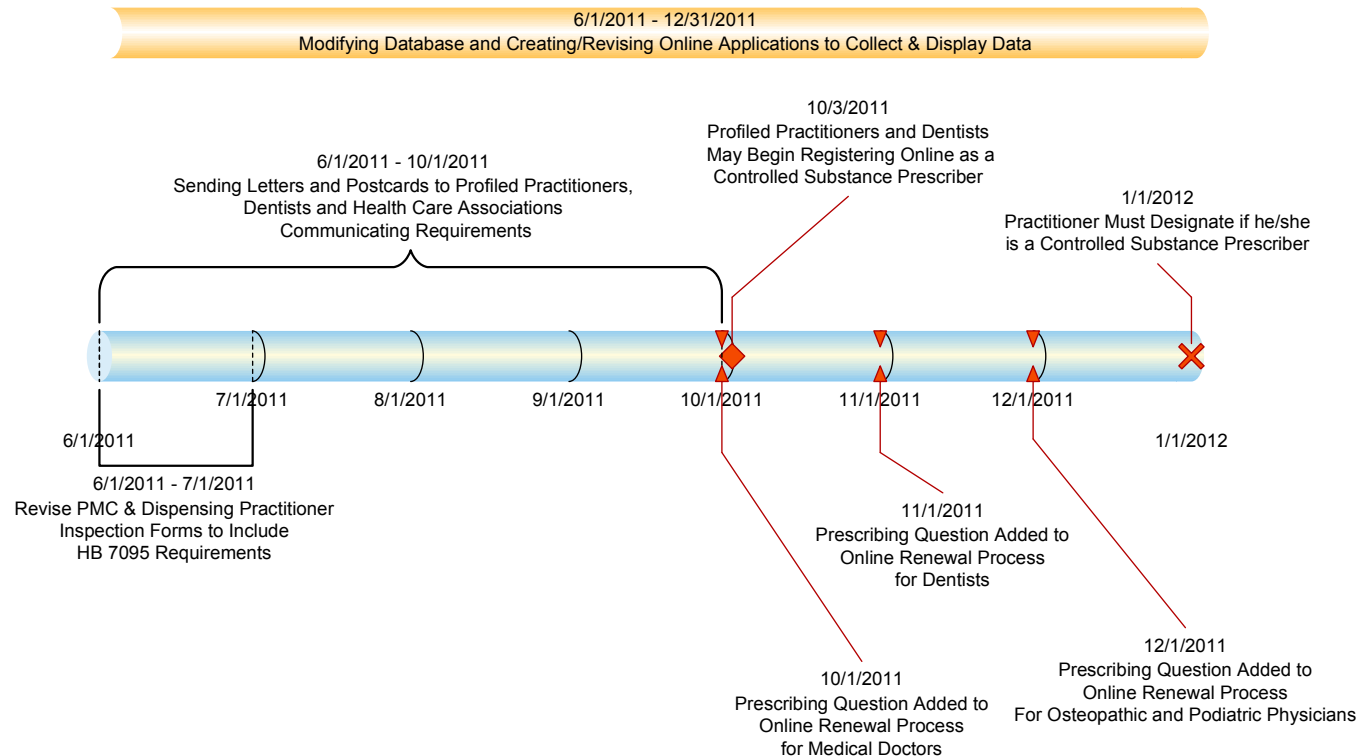
Controlled Substance Prescriber Registration

By January 1, 2012, practitioners who prescribe controlled substances for the treatment of chronic nonmalignant pain are required to:

- Register with the Department
- Comply with new standards of practice




Controlled Substance Prescriber Registration Timeline



Controlled Substance Prescribers Displayed on Practitioner Profile


floridashea

Practitioner Profile

Printer Friendly Version 

TEST PHYSICIAN LICENSE NUMBER: PO327

Profession: **Podiatric Physician**
Year Began Practicing: **1/1/1960**
Expiration Date: **3/31/2012**
Status: **CLEAR/ACTIVE**

Controlled Substance Prescriber: **YES** 

General Information | Education and Training | Academic Appointments | Speciality Certification | Financial Responsibility | Proceedings and Actions | Optional Information | License Verification

Information in this profile has been verified by the practitioner.

Primary Practice Address

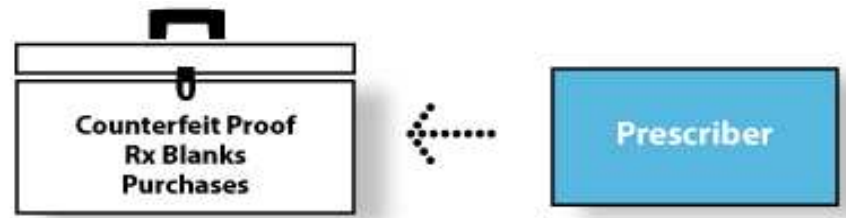
TEST PHYSICIAN
111 CARLETON AVE
SUITE 5
ISLIP TERRACE, NY 11752-2236
UNITED STATES

ATTN: DONNA

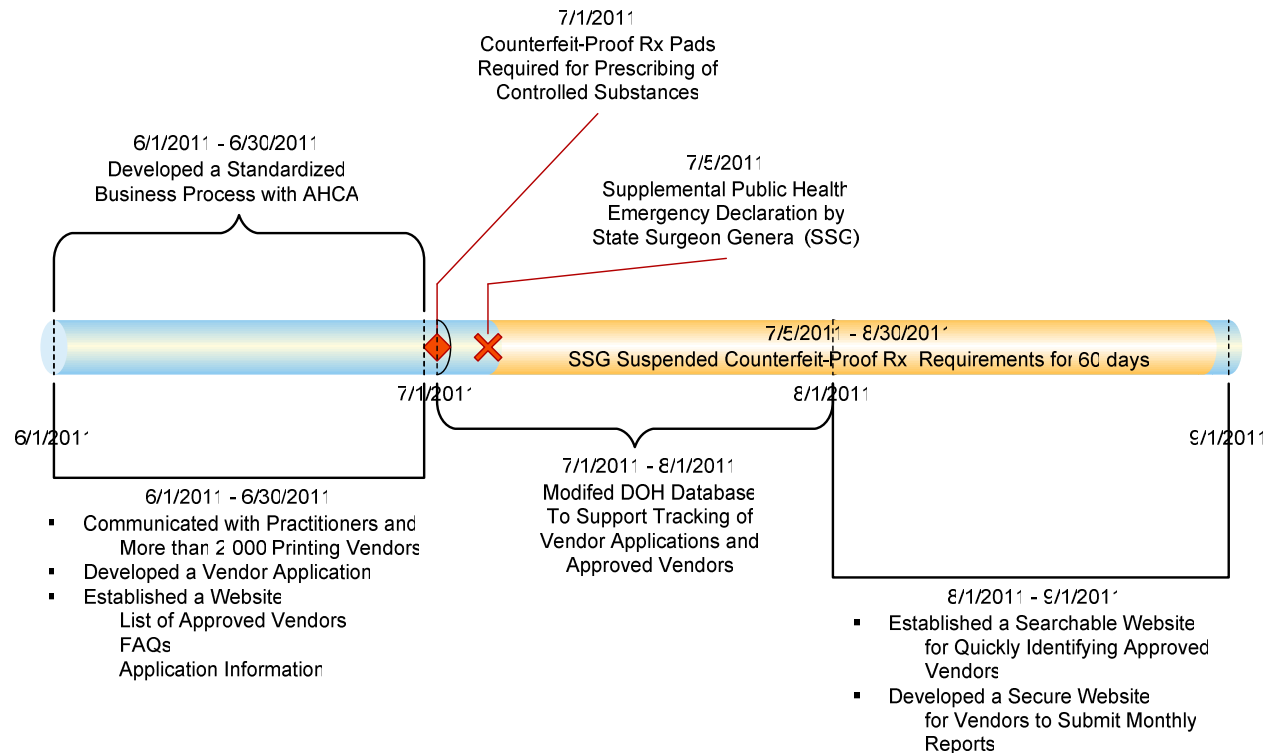
Medicaid

Counterfeit-Proof Prescription Pad Vendors & Reporting

- A written prescription for controlled substances must have certain information, be on a counterfeit-proof prescription pad and be produced by an approved vendor or electronically prescribed
- The approved vendor must also submit monthly reports that include the number of pads printed and to whom it is provided



Counterfeit Proof Prescription Pads Timeline



Counterfeit-Proof Prescription Sample

SPECIFICATIONS FOR **FRONT** OF RX PAD

NAME OF PRACTITIONER OR HOSPITAL OR FACILITY

ADDRESS | CITY, STATE ZIP | TELEPHONE

DEA #

NAME: _____

ADDRESS: _____ DATE: _____

R_x

SIGNATURE

CATEGORY OF LICENSURE

0000YRMMDDYBATCH

SPECIFICATIONS FOR **BACK** OF RX PAD

SECURITY FEATURES HERE:

- Resist erasures and reproductions.
- The blank must be printed on official watermarked paper.
- Contain blue or green background ink that resists reproduction.
- Ink changes color when rubbed with a coin.
- Display the word "VOID" or "ILLEGAL" if the prescription pad is copied.

DETAILS OF EACH SPECIFICATION BELOW

- 1) The name of the healthcare practitioner or hospital or facility
- 2) Physical address of the healthcare practitioner or hospital or facility
- 3) A space for the DEA number (this information can also be printed on the script)
- 4) A space for patient information and the date the prescription was written
- 5) Blue or Green background ink that resists reproduction
- 6) Category of Licensure for prescribing practitioner
(may be abbreviated or spelled out e.g. MD or Medical Doctor)

- 7) The print vendor's unique tracking number must include three subsets:
 1. a unique alphabetic prefix that readily identifies the vendor
 2. the date of printing (YRMMDDY)
 3. a batch number assigned by the vendor
- 8) List of security features, which must be printed on back of prescription pad
(features listed on sample above are the minimum requirements)

Pain Management Clinic Registration

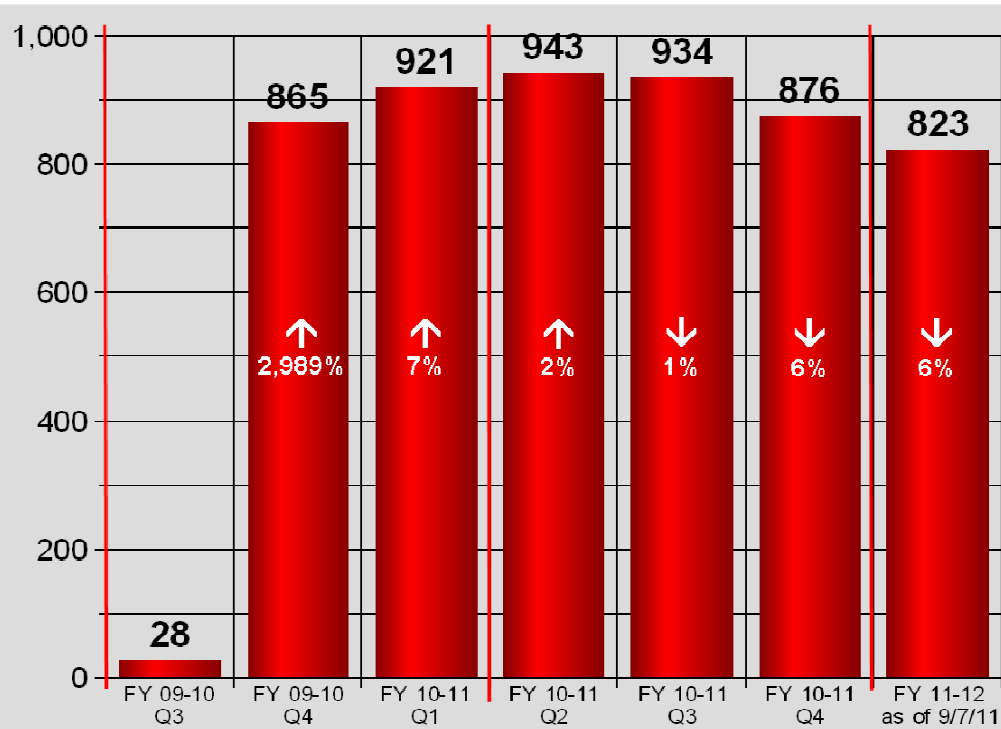
- New requirements for practicing in and registration of pain management clinics
- Definitions
- Added exemptions from registration
- Designated physician responsible for compliance with quality assurance requirements, data collection and reporting



Pain Management Clinic Registrations

January 1, 2010 – September 7, 2011

Total # of Registered Pain Management Clinics by Fiscal Year
% ↑ or ↓

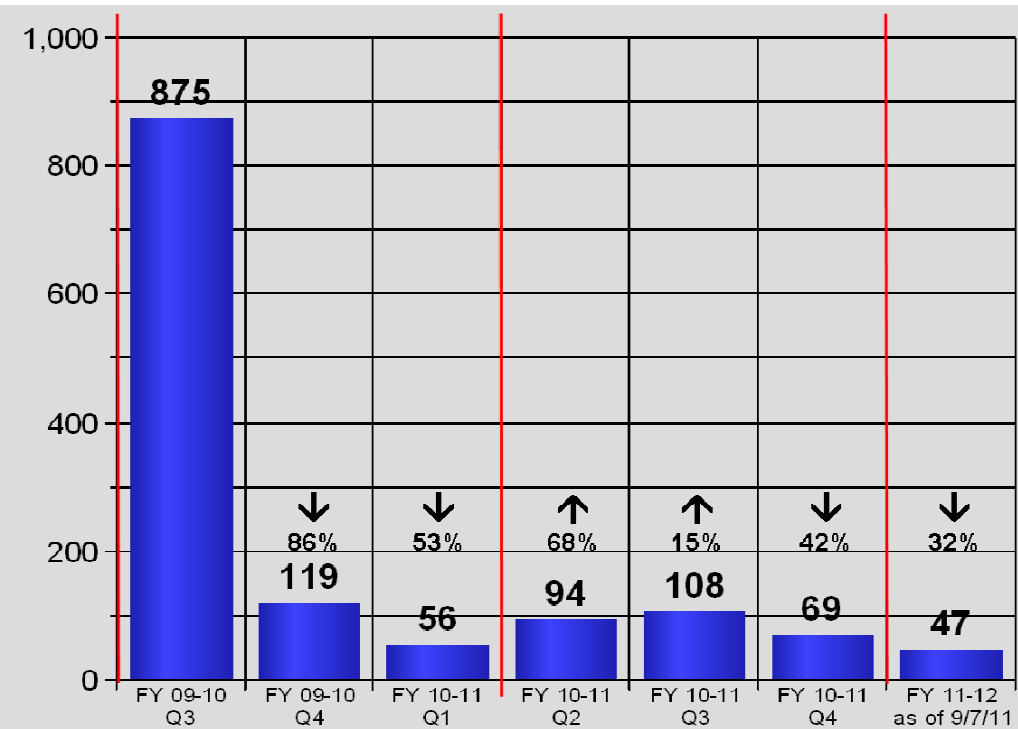


Senate Bill 462
2009

Senate Bill 2272
2010

House Bill 7095
2011

Total # of Approved Pain Management Clinic Applications by Fiscal Year
% ↑ or ↓



Senate Bill 462
2009

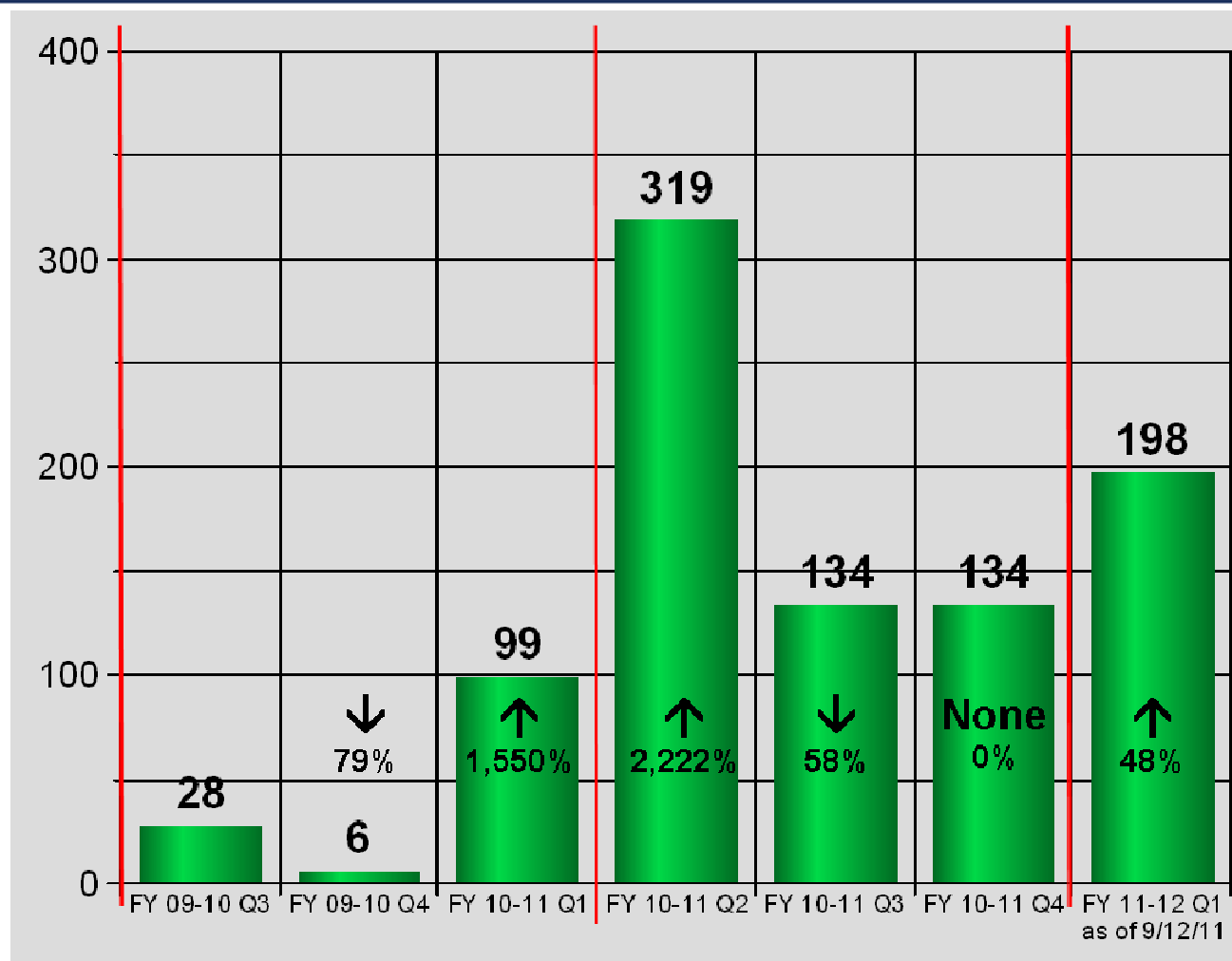
Senate Bill 2272
2010

House Bill 7095
2011

of Pain Management Clinic Closures by Quarter

% ↑ or ↓

January 1, 2010 – September 12, 2011



Senate Bill 462
2009

Senate Bill 2272
2010

House Bill 7095
2011

Pain Management Clinic Closures by Fiscal Year

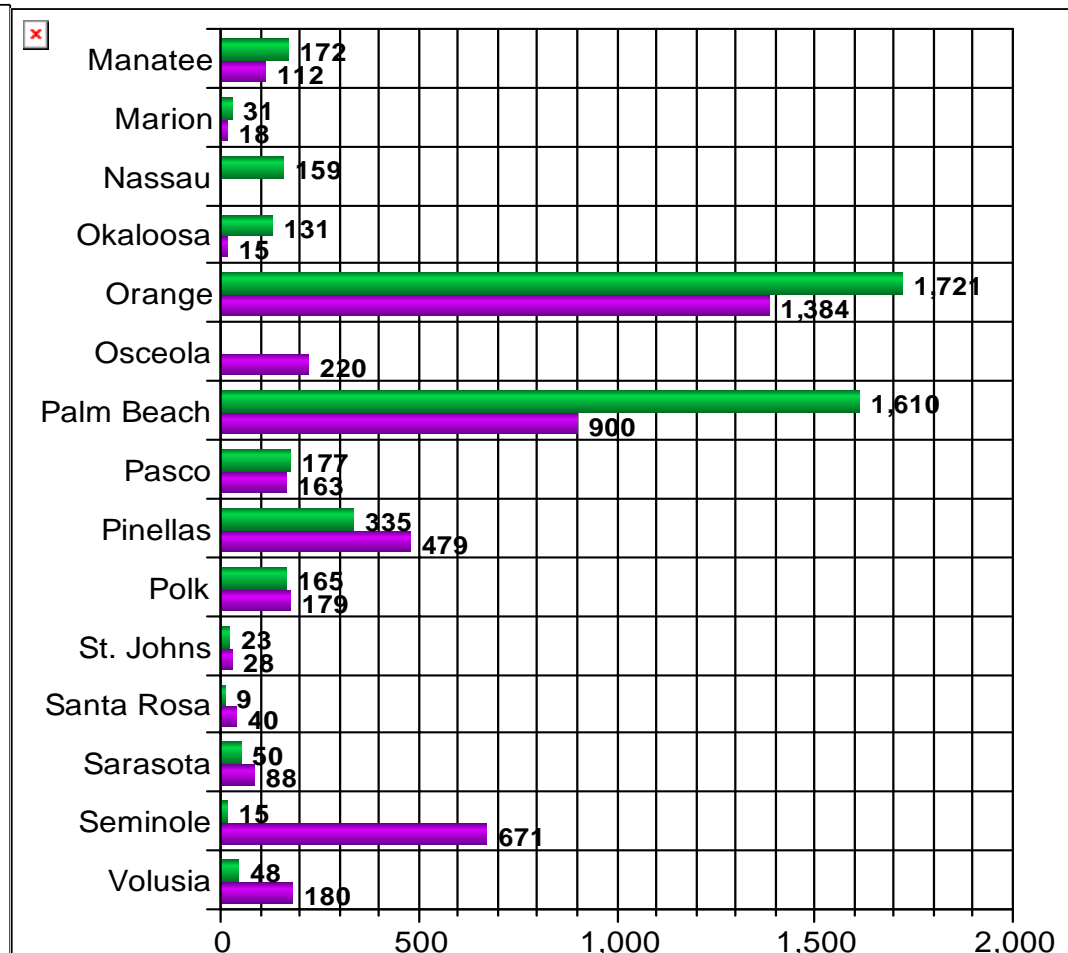
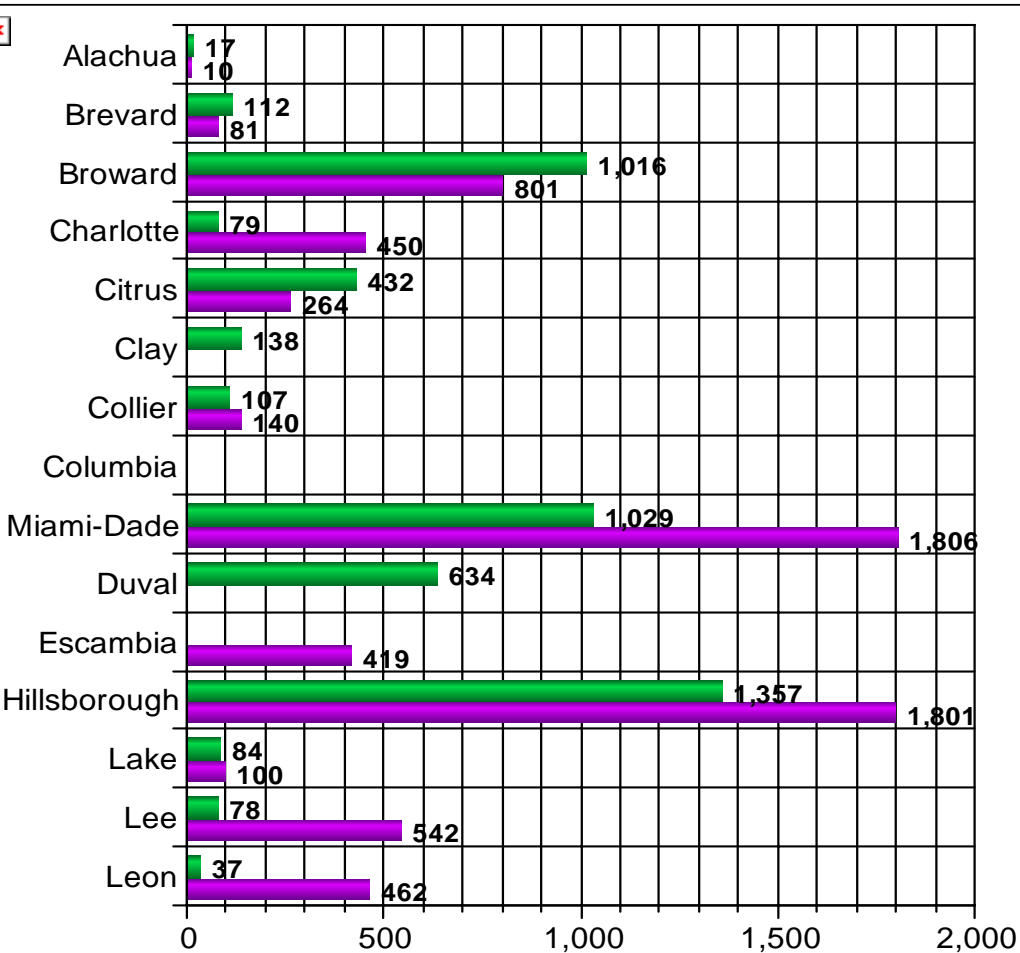
Reason for Closure	FY 09-10 Q3	FY 09-10 Q4	FY 10-11 Q1	FY 10-11 Q2	FY 10-11 Q3	FY 10-11 Q4	FY 11-12 to 9/12/11	Total
Voluntary Relinquishment	0	0	0	1	7	0	128	134
Disciplinary Relinquishment	0	0	0	1	0	4	4	9
Administratively Revoked	28	6	6	2	15	6	5	68
Closed	0	0	93	90	101	121	62	467
Intent to Administratively Revoke	0	0	0	225	11	3	1	240
Totals	28	6	99	319	134	134	198	918

Pain Management Clinic Quarterly Report

of New Patients by Quarter by County

January 1, 2011 – March 31, 2011 |

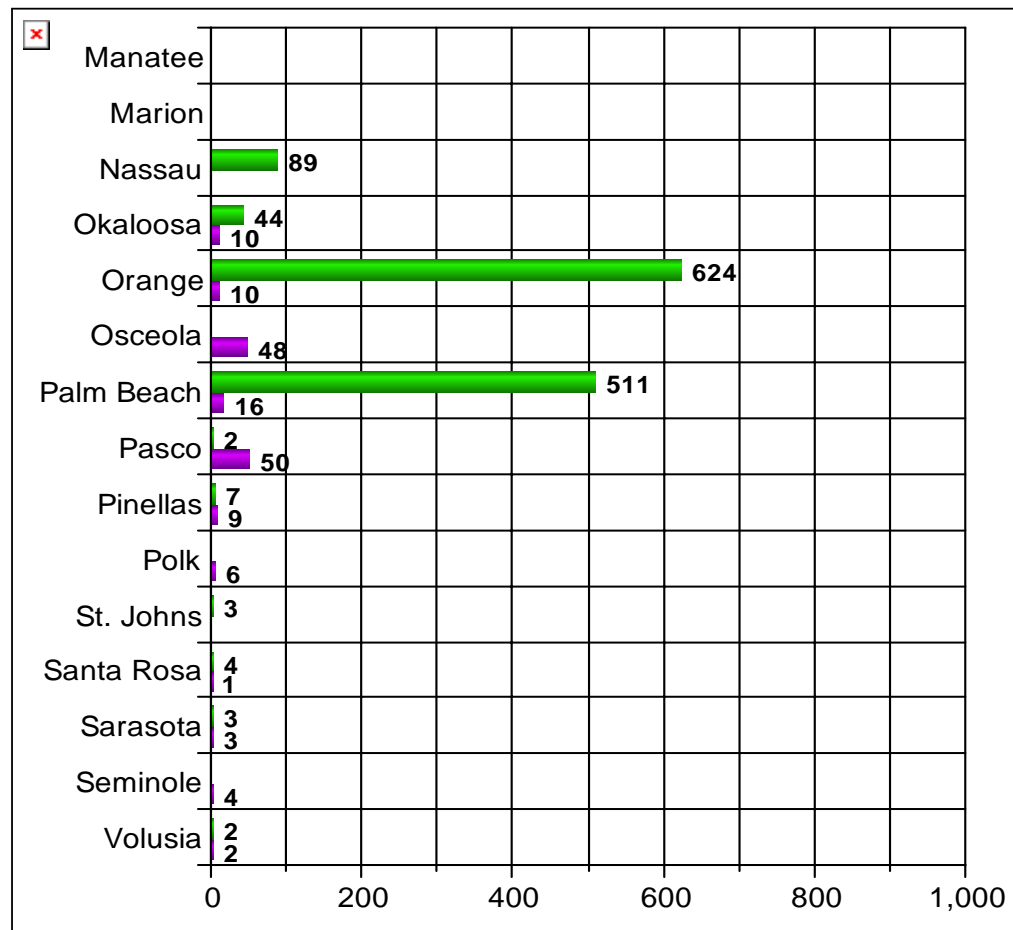
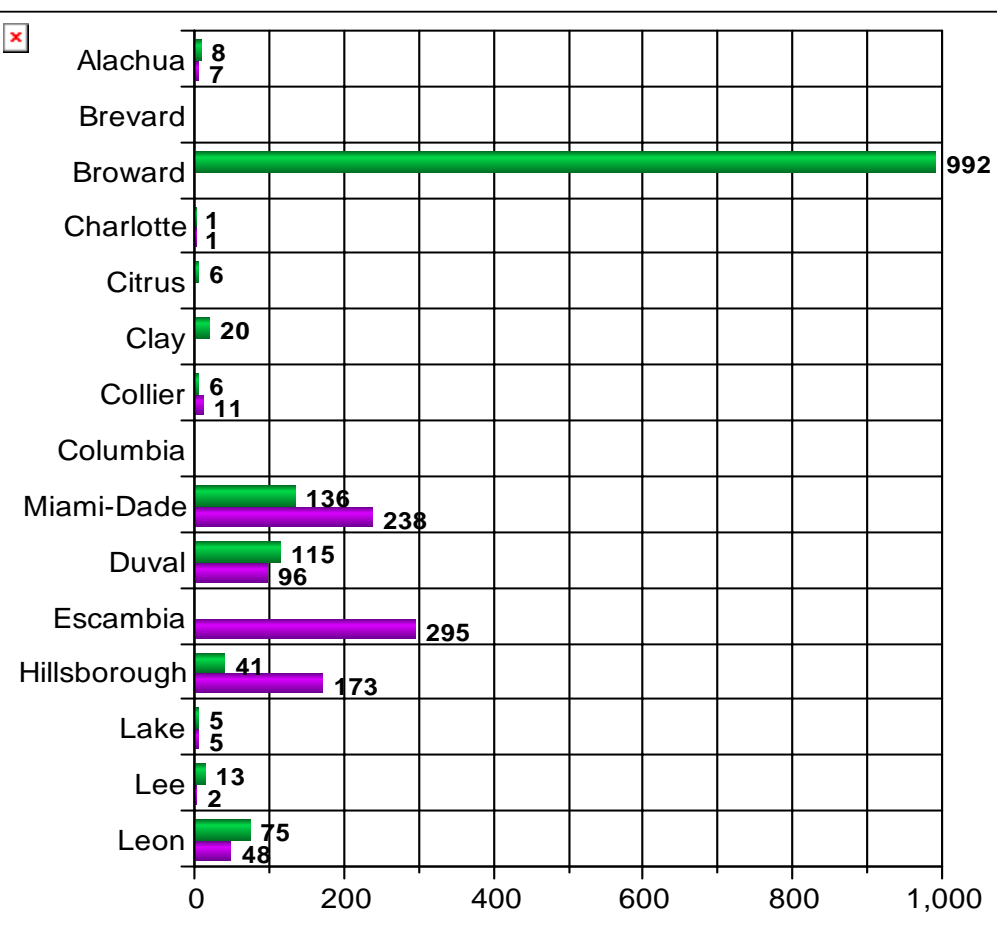
April 1, 2011 – June 30, 2011



Pain Management Clinic Quarterly Report

of Out-of-State Patients by Quarter by County

January 1, 2011 – March 31, 2011 | April 1, 2011 – June 30, 2011

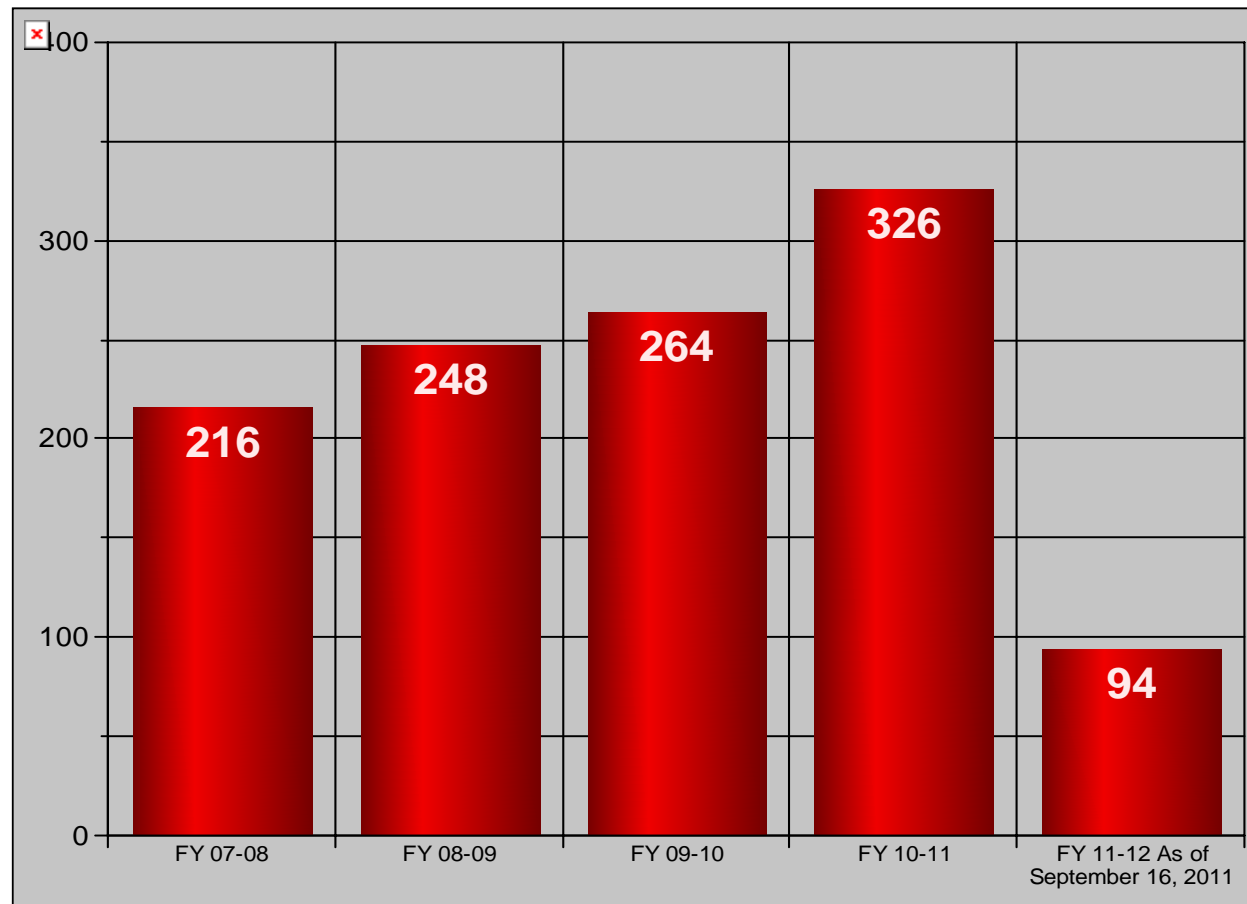


Emergency Action Improvement Target

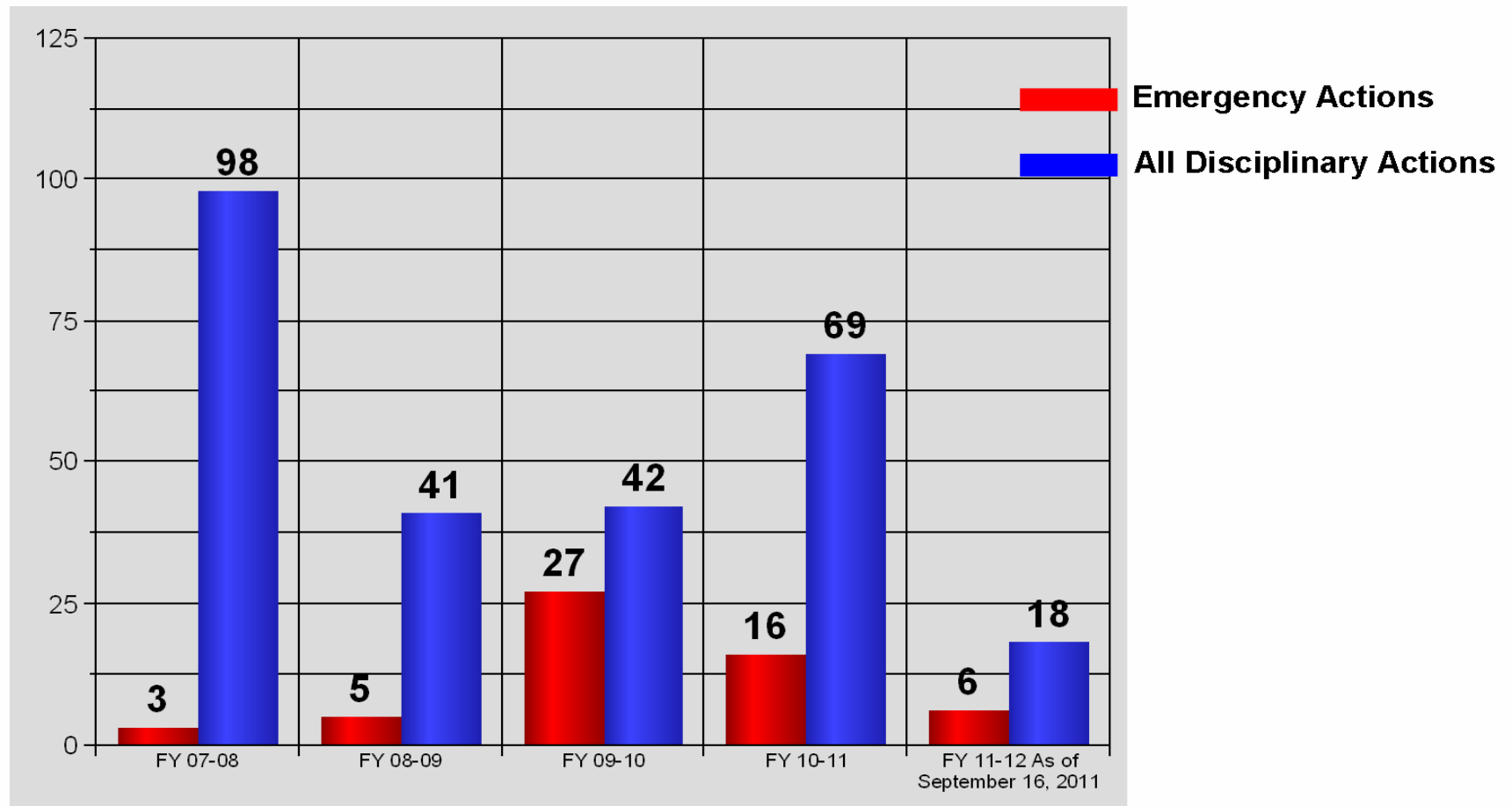
Priority 1 Cases That Do Not Require Supplemental Investigation, Expert Witness, or Order to Compel Mental and Physical Examination

Current	Target	Time Savings
115.9 days	19 – 25 Days	91.9 – 97.9 days

of All Emergency Actions by Fiscal Year



of Disciplinary & Emergency Actions Related to Over- and Inappropriate-Prescribing of Controlled Substances by Fiscal Year



Tool Box Report Card

Complaints with HB 7095 related allegations

- # of complaints received
- # of disciplinary actions
- # of emergency actions

Dispensing Practitioners

- # of new registrations issued
- # of new registration requests denied

Community Pharmacies

- # of new permits issued
- # of applications denied
- # of complaints received
- # of disciplinary actions
- # of emergency actions
- # of reports to law enforcement for theft or fraudulent prescriptions

Pain Management Clinics

- # of new registrations
- # of applications denied
- # closed
- # of complaints
- # of disciplinary actions
- # of emergency actions
- # of Inspections

Counterfeit-Proof Prescription Pads

- # of orders by purchaser

HB 7095 Related Websites

- DOH HB 7095 General Information:
www.floridashealth.com/mqa/HB7095.html
 - Public Health Emergency Orders
 - Correspondence to Licensees
 - Frequently Asked Questions
- DOH Counterfeit-Proof Pad Vendors:
www.floridashealth.com/mqa/counterfeit-proof.html
 - Vendor Reporting
 - Approved Vendor Search
 - Vendor Applications
 - Frequently Asked Questions
- Press Releases:
<http://esetappsdo.h.doh.state.fl.us/pressreleasesearch/search.aspx>
- Prescription Drug Monitoring Program (E-FORCSE): www.eforcse.com
- Controlled Substance Reporting System:
<https://ww2.doh.state.fl.us/CSR/login.aspx>

Questions?

Lucy C. Gee, M.S., Director
Florida Department of Health
Division of Medical Quality Assurance
(850) 245-4224
Lucy_Gee@doh.state.fl.us

2010 SB 1484: Extension of the 1115 Reform Demonstration Waiver

Overview:

The 2005 Florida Legislature directed the Agency for Health Care Administration (Agency), through Section 409.91211, Florida Statutes, to implement a Medicaid Managed Care Pilot Program. This statute directs the Agency to implement the pilot program in five Florida counties: Baker, Broward, Clay, Duval, and Nassau.

Pursuant to this statute, the Agency requested an 1115 Demonstration Waiver to implement the program. The federal government approved the request for a five year period from July 1, 2006 through June 30, 2011. Under an 1115 waiver, states have the option to request a 3 year extension after the initial 5 year approval period.

On April 30, 2010 the Florida Legislature passed Senate Bill 1484. Within this bill, the Florida Legislature directed the Agency to seek approval of a 3 year waiver extension to continue operation of the pilot program in Baker, Broward, Clay, Duval and Nassau Counties. The Legislature directed the Agency to submit the extension request by no later than July 1, 2010.

Request for Extension:

The Agency submitted a request to extend the pilot program to the federal Centers for Medicare and Medicaid Services (CMS) on June 30, 2010, as well as several follow up extension requests. The Agency currently has authority to continue the pilot program through September 30, 2011.

On August 17, 2010, CMS advised the Agency that they would review and process the State's request to renew the Reform Demonstration under section 1115(a) authority, rather than under section 1115(e) authority as originally requested by the State. By this decision, CMS notified the state that they will request changes/ amendments to the terms and conditions of the waiver. In addition, while there are timelines for CMS to respond to a state waiver requested under the 1115(e) authority, no timelines exist for CMS to respond under section 1115(a). Since that time, the Agency has been involved in ongoing discussion, provision of information and negotiation with CMS with regard to the waiver extension.

Key outstanding issues include:

- Whether or not CMS will require a medical loss ratio for participating managed care plans; and
- Changes to the requirements of the State's Low Income Pool (LIP) program.

Of particular concern is that CMS indicated that the federal Office of Management and Budget is evaluating an early sunset date for Florida's Low Income Pool program. CMS noted that they and OMB are considering a sunset date of December 31, 2013. The changes in the effective date would provide a partial year funding for LIP of \$500 million during the last year of the renewal period instead of the \$1 billion annual allotment currently authorized.

Additional details regarding the waiver extension and the Agency's interaction with CMS are available on the Agency's website: <http://ahca.myflorida.com/Medicaid/index.shtml#reform>

**2011 House Bill 7107: Florida Statewide Medicaid Managed Care Program
Status Update**

Overview:

On May 6, 2011, the Florida Legislature passed House Bill (HB) 7107, relating to Medicaid Managed Care. The bill outlines a comprehensive expansion of managed care for most Medicaid recipients throughout Florida. This program is known as the Statewide Medicaid Managed Care (SMMC) program.

The SMMC program had two main components: (1) the Long-Term Care Managed Care program and (2) the Managed Medical Assistance program. HB 7107 directed the Agency for Health Care Administration (Agency) to apply for state plan amendments and federal waivers necessary to implement the program.

The Legislation contained timelines for implementation of the SMMC, including deadlines for public meetings, for submission of requests for federal authority, for release of invitations to negotiate to secure health plans, and for actual program implementation.

Deadlines:

<i>Statutorily Mandated SMMC Deadlines</i>		
	LTC Component	MMA Component
Public Meetings	Allow for 30 day comment period after meeting/ before submission of requests for federal authority	Allow for 30 day comment period after meeting/ before submission of requests for federal authority
Submission of Requests for Federal Authority	August 1, 2011	August 1, 2011
Release of Invitations to Negotiate	July 1, 2012	January 1, 2013
Program Implementation	July 1, 2012 - October 1, 2013	January 1, 2013 - October 1, 2014

Public Meetings:

The Agency held a public meeting in each of the 11 regions created by the legislation between June 10 and June 17, 2011.

The opportunity for public comment will continue throughout the implementation process. The Florida Medicaid program is open to feedback from any stakeholder, including recipients, providers, advocates and researchers. Based on feedback, Florida Medicaid has taken advantage of opportunities to adapt and improve and will continue to do so.

**2011 House Bill 7107: Florida Statewide Medicaid Managed Care Program
Status Update**

Submission of Requests for Federal Authority

On August 1, 2011, the Agency submitted the required documents requesting various authorities to implement the program. An overview of those authorities follows:

Managed Medical Assistance Program	
Amendment Vehicle	Subject
1115 Medicaid Reform Demonstration Waiver	<ul style="list-style-type: none"> • Request for authority to mandatorily enroll the vast majority of individuals in managed care plans statewide. This includes children with chronic conditions, children in foster care and children who receive an adoptive subsidy, as well as Medicare/Medicaid dual eligible recipients. • Request for authority to allow health plans to develop customized benefit packages targeted to specific populations. • Request for authority to implement an Employer Sponsored Insurance program in which maximum payment will be the Medicaid authorized premium.
1115 Medicaid Reform Demonstration Waiver	Requests the authority to impose a \$10 monthly premium on recipients enrolling in the SMMC program.
1115 Medicaid Reform Demonstration Waiver	Requests the authority to require a \$100 copayment for non-emergency ER visits.
1115 MEDS AD Demonstration Waiver	<ul style="list-style-type: none"> • Premium option for Medically Needy population • Seeking 1115 authority to require a premium not to exceed share of cost after the first month of qualifying as a medically needy recipient and enrolling in a plan. The recipient would pay a portion of the monthly premium equal to the enrollee's share of the cost. • Continuous Enrollment –seeking 1115 authority to provide Medically Needy recipients with continuous enrollment for up to six months.
	<ul style="list-style-type: none"> • Seeking state plan authority relating to cost effective methods for employer-based group health plans • The Health Insurance Premium Payment Program (HIPP) program will enable Medicaid recipients to participate in employer-sponsored insurance. • The Medicaid MCO capitation payment that would have been paid for a Medicaid recipient will be used to pay the recipient's share of their employer-sponsored health insurance. • Medical services that are not covered by the recipient's employer-sponsored health insurance will be submitted to Medicaid by the Medicaid provider. Medicaid will pay the provider up to its allowable amounts. This is known as wrap-around services.

Long Term Managed Care Program	
Amendment Vehicle	Subject
New Waiver (1915 b/c combo)	The Agency is seeking a 1915(c) waiver from federal CMS for the authority to identify and allow qualified individuals to receive home and community based care services in lieu of nursing home care services. AHCA will also be seeking a 1915(b) wavier for the authority to enroll individuals in managed care plans statewide, and to allow for selective contracting of those plans.

**2011 House Bill 7107: Florida Statewide Medicaid Managed Care Program
Status Update**

Timeline for Requests for Federal Authority to Implement the SMMC program

1915(b)/(c) and state plan amendment have three 90 day periods:

- The Agency submitted its 1915(b)/(c) waiver application and state plan amendment on August 1, 2011. Starting on that date, CMS has 90 days to review these materials and approve, deny or request clarification
- Upon receiving CMS' response, the Agency has 90 days to respond.
- Once CMS receives the Agency's completed responses, they have 90 days to make a final decision.
- CMS must approve state plan amendments that comply with federal Medicaid law.

1115 waivers have no time periods to which either CMS or the Agency must comply.

THE FLORIDA SENATE

COMMITTEE APPEARANCE RECORD

(Submit to Committee Chair or Administrative Assistant)

9-20-11

Date

Barcode

Name JEFF BEASLEY

Phone 410-7084

Address 2331 PHILLIPS RD

E-mail jeffbeasley@flda.state.fl.us

Street

TALLAHASSEE

FL

32308

City

State

Zip

Job Title SPECIAL AGENT SUPERVISOR

Speaking: ☐ For ☐ Against ☒ Information

Appearing at request of Chair ☐

Subject HB 7095 IMPLEMENTATION / REQUEST FROM CHAIR

Representing FDL

Lobbyist registered with Legislature: ☐ Yes

☒ No

Pursuant to s. 11.061, *Florida Statutes*, state, state university, or community college employees are required to file the first copy of this form with the Committee, unless appearance has been requested by the Chair as a witness or for informational purposes.

If designated employee: Time: from _____ .m. to _____ .m.



THE FLORIDA SENATE

COMMITTEE APPEARANCE RECORD

(Submit to Committee Chair or Administrative Assistant)

9/20/11
Date

Presenter
Bill Number

Barcode

Name Justin Senior

Phone

Address 2727 Mahan Drive

E-mail

Street

Tallahassee

FL

State

32308

Zip

Job Title Dep. Secretary

Speaking: ☐ For ☐ Against ☒ Information

Appearing at request of Chair ☒

Subject

Representing AHCA

Lobbyist registered with Legislature: ☒ Yes ☐ No

Pursuant to s. 11.061, *Florida Statutes*, state, state university, or community college employees are required to file the first copy of this form with the Committee, unless appearance has been requested by the Chair as a witness or for informational purposes.

If designated employee: Time: from _____ .m. to _____ .m.

THE FLORIDA SENATE

COMMITTEE APPEARANCE RECORD

(Submit to Committee Chair or Administrative Assistant)

9/20/11

Date

Presenter

7095

Bill Number

Barcode

Name

Lucy Gee

Phone

Address

2085 Merchants Row Blvd

E-mail

Street

Tallahassee

FL

32399

City

State

Zip

Job Title

Division

Director

Speaking:

☐

For

☐

Against

☒

Information

Appearing at request of Chair

☒

Subject

Representing

Florida Department of Health

Lobbyist registered with Legislature:

☐

Yes

☒

No

Pursuant to s. 11.061, *Florida Statutes*, state, state university, or community college employees are required to file the first copy of this form with the Committee, unless appearance has been requested by the Chair as a witness or for informational purposes.

If designated employee:

Time:

from

____.m.

to

____.m.