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# **Health & Human Services Quality Subcommittee**

## **Meeting Packet**

**Tuesday, October 4, 2011  
9:00 - 11:30 AM  
306 HOB**

**Dean Cannon  
Speaker**

**John Wood  
Chair**

# Committee Meeting Notice

## HOUSE OF REPRESENTATIVES

### Health & Human Services Quality Subcommittee

**Start Date and Time:** Tuesday, October 04, 2011 09:00 am

**End Date and Time:** Tuesday, October 04, 2011 11:30 am

**Location:** 306 HOB

**Duration:** 2.50 hrs

Update on the transfer of the Division of Drugs, Devices and Cosmetics from the Department of Health to the Department of Business and Professional Regulation - Department of Business and Professional Regulation

Briefing on Certificate of Need regulation - Agency for Health Care Administration

**NOTICE FINALIZED on 09/27/2011 16:18 by Iseminger.Bobbye**



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Florida Department of  
**Business & Professional  
Regulation**

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License efficiently. Regulate fairly.

**Ken Lawson**  
**Secretary**

# Guiding Principles

- Smart De-Regulation
  - Working to identify and remove rules and business processes that get in the way of businesses.
- Fair But Strong Enforcement
  - The goal is always to get businesses into compliance. Enforcement will be strong but fair, and our licensees deserve to have a voice in the enforcement process.
- Open Door Policy
  - Meeting with and will continue to meet with our licensees on a regular basis.

# Overview

## Mission

- License efficiently. Regulate fairly.

## Vision

- We will make DBPR and Florida great places to do business. To that end we will invest in our employees, treat our licensees as valued customers and partners, and uphold laws that protect the public and Florida's competitive marketplace.

## Structure

- Business Regulation
- Professional Regulation
- Administration, Financial, and Support Services

# Drugs, Devices, and Cosmetics

- Transfer Effective October 1<sup>st</sup>
- Mission – safeguard Florida citizenry from injury by use of adulterated or contaminated drugs, drug ingredients & cosmetics, by administering the Florida Drug and Cosmetic Act (Chapter 499, F.S.)
- 33 Positions – (including 11 drug inspectors (pharmacists) )
- 3 Sub-units
  - Compliance & Enforcement
  - Licensing
  - Legal (supervised by the Office of General Counsel)
- Drug Wholesaler Distribution Advisory Council – provides input to department re: administration of Chapter 499, F.S., including rules.
- Physical transfer of personnel and equipment (9/23/11 – 10/7/11)

# Drugs, Devices, and Cosmetics

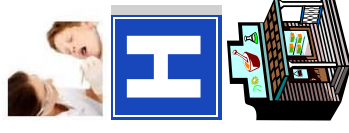
Manufacturer  
Manufacturer  
Manufacturer  
Manufacturer  
Manufacturer



**Patients, Hospitals, Pharmacies, etc. dealing directly w/drug companies.**

Manufacturer  
Manufacturer  
Manufacturer  
Manufacturer  
Manufacturer

Drug Wholesalers



**Wholesale distributors stepped in to serve as lines of distribution between patients, hospital, pharmacies, etc. and drug companies.**

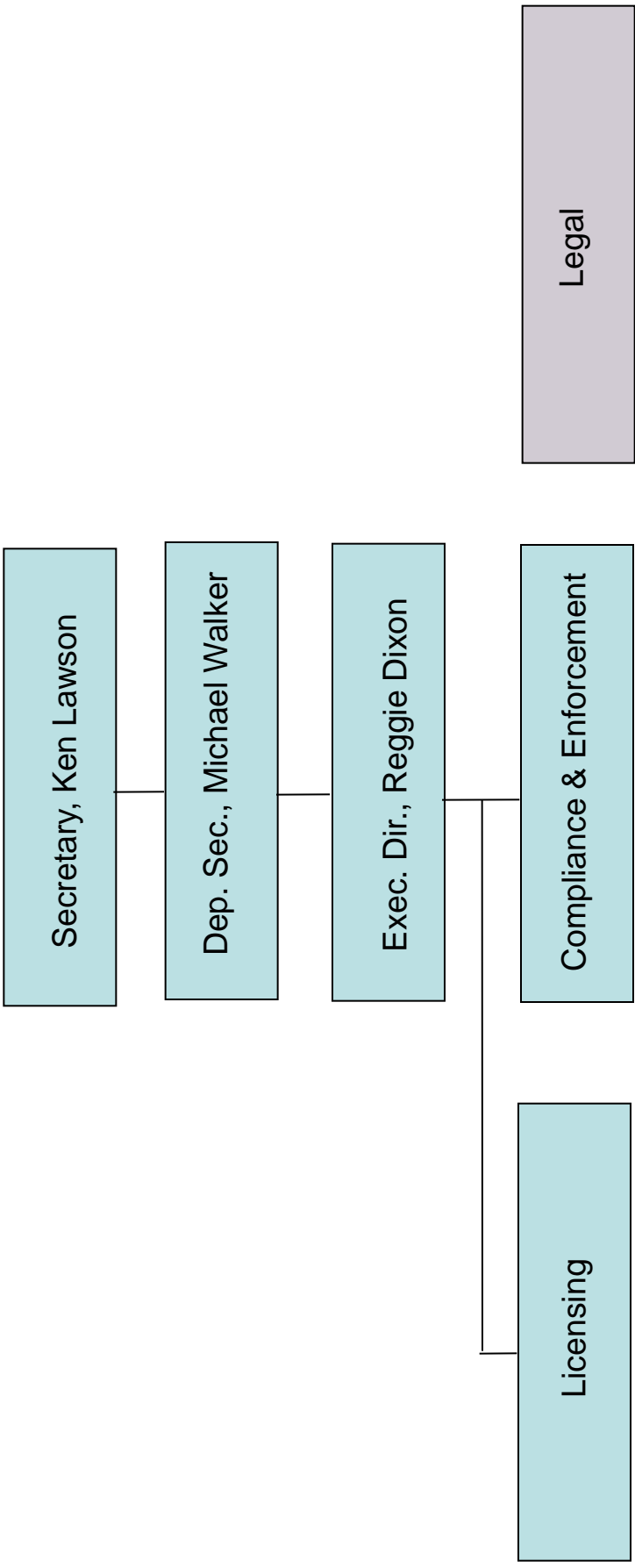


# Drugs, Devices, and Cosmetics

## House Bill 7095

- Mandatory wholesaler reporting of controlled substance distributions
- Sharing information w/FDLE & local Law enforcement agencies
- Internal policies re: credentialing physicians, identifying suspicious orders
- Reporting re: national averages of Hydrocodone, Morphine & Methodone; statewide averages of benzodiazapine distributed by community pharmacy permittees

# Drugs Devices Cosmetics Program



# Licensing

- ApplyNow!
- Licensee Survey
- Opening/Moving Inspections
- Certificate of Free Sales
- Application Review & Approval time
- Paperless Initiative

## **Compliance & Enforcement**

- **Common sense approach to enforcement**
- **Creative problem-solving on volatile issues (e.g., Office use compounding, 340B drugs, etc.)**
- **Risk-based inspections**
- **Flexibility**

Florida Department of  
**Business & Professional  
Regulation**

# Your Bill of Rights

**As a licensee with DBPR, you have the right to:**

- Know the reason for your inspection
- Have knowledgeable, helpful, objective and courteous inspectors
- Have professional inspectors who use safe and minimally disruptive practices in completing your inspection
- Receive a copy of the completed inspection
- Question the findings of your inspection
- Ask for reconsideration of those findings
- Be efficiently and fairly treated in all dealings with DBPR

## **Our Commitment**

We will diligently work to make Florida and DBPR great places to conduct business everyday. In keeping with this purpose, we will treat our licensees as valued customers and partners, invest in our employees, and uphold laws that protect the public and enhance Florida's competitiveness.

# Contact Info

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Secretary

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**AHCA**  
**Certificate of Need**



# Health Care Certificate of Need in Florida

House Health & Human Services  
Quality Subcommittee

October 4, 2011





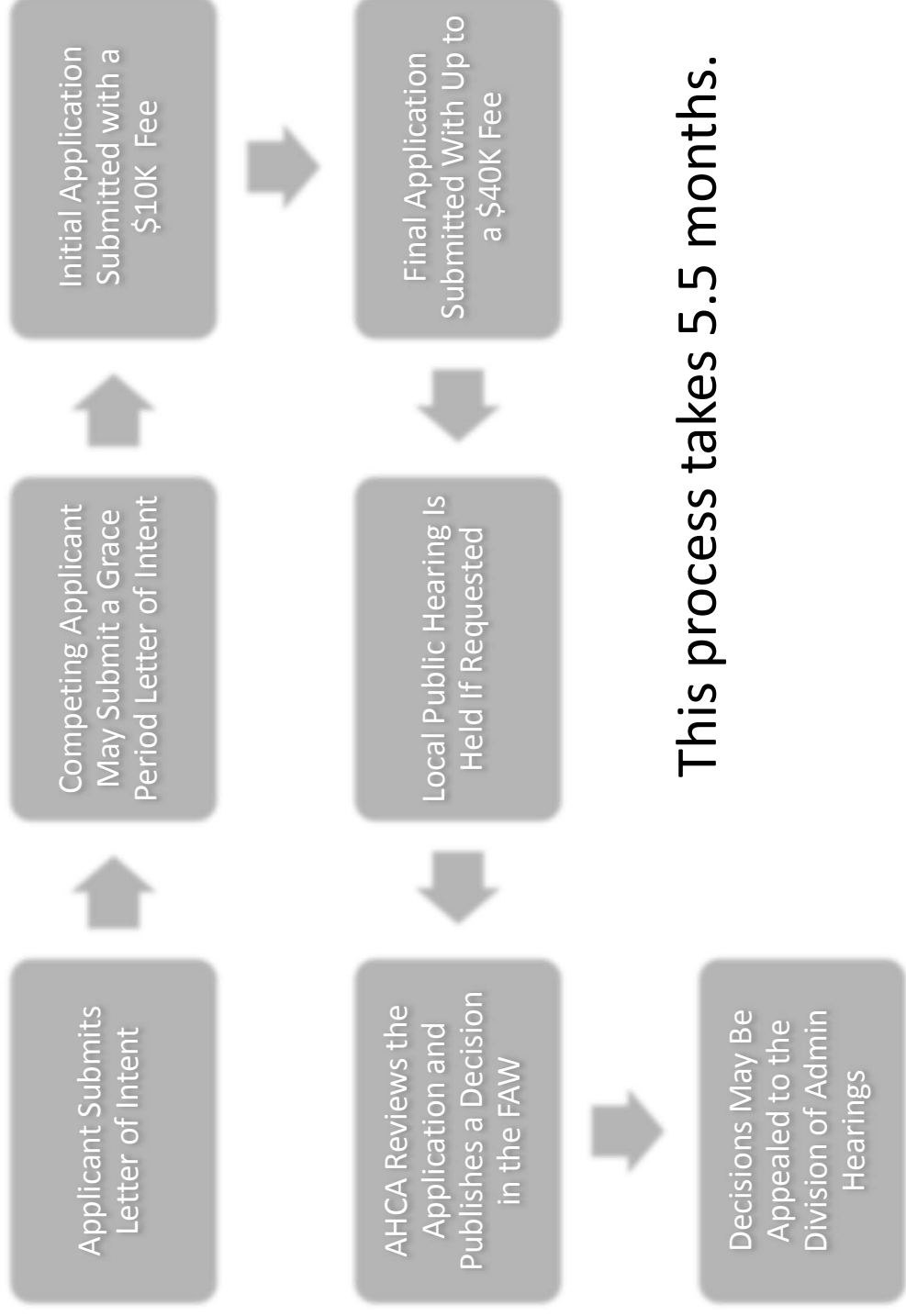
# What Is CON?

- Certificate of Need (CON) is a population based health planning program that tries to direct new development to areas of greatest population need.
- CON began as a required federal program in 1974
- Florida CON became state-only in 1982.
- 36 states have CON

# What Is CON?

- CONs are required for new hospitals, nursing homes, hospices and intermedicate care facilities for the developmentally disabled.
- CON includes
  - Competitive batched reviews
  - Expedited reviews
  - Exemptions
  - Annual monitoring of CON conditions

# Competitive Batched Reviews



This process takes 5.5 months.



# CON Appeals

This process takes 1 to 2 years.

# Other CON Processes

- Expedited reviews
  - Expedited reviews follow the same process as batched reviews except the applicant chooses when the process starts.
  - Examples of expedited reviews:
    - Transferring a CON for a nursing home or a hospice that is not yet licensed to a new organization,
    - Adding sheltered nursing home beds in continuing care retirement communities,
    - Moving existing community nursing home beds short distances under certain circumstances.

# Other CON Processes

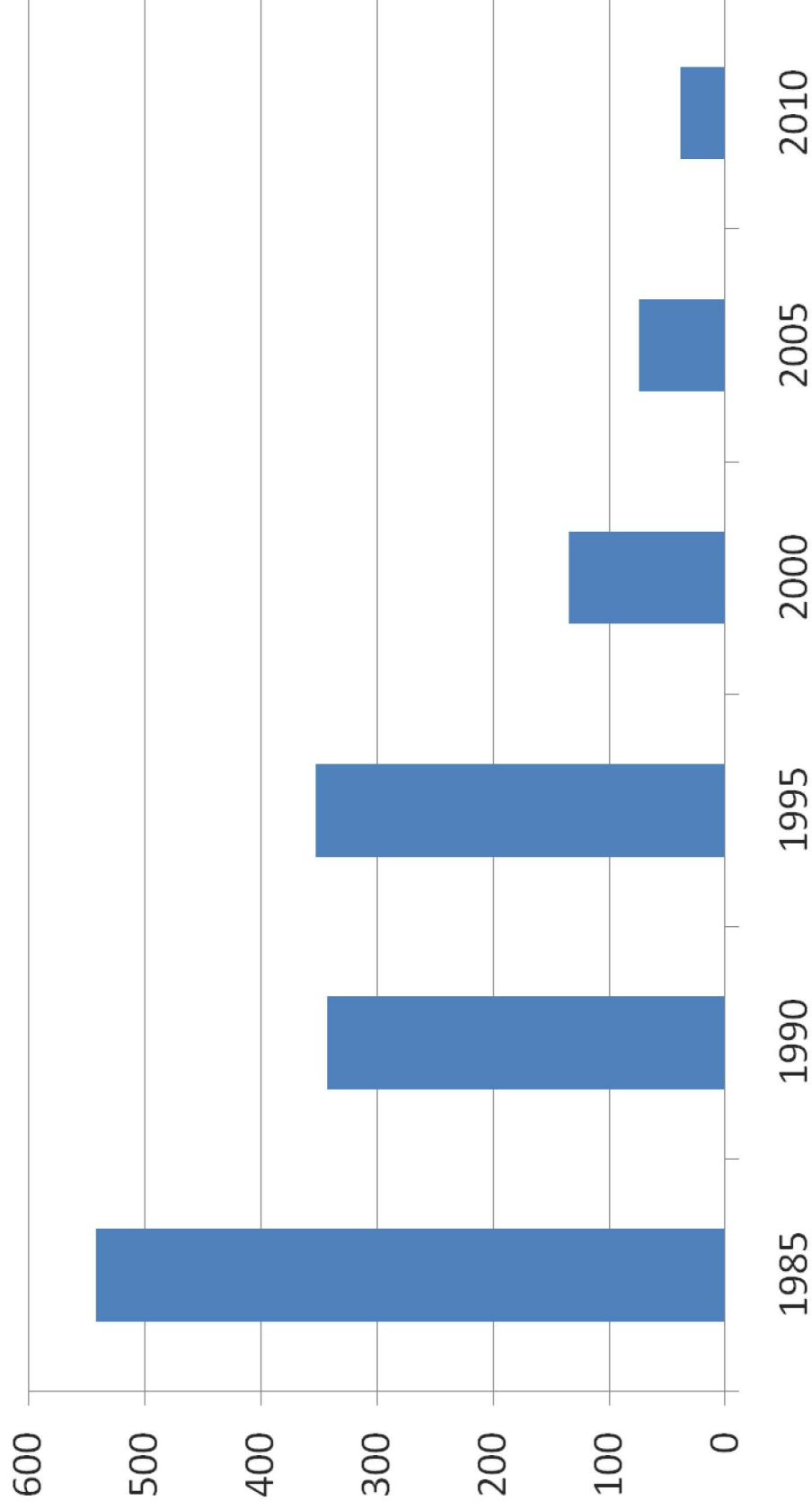
- CON exemptions
  - Exemption applications receive a brief review for a \$250 fee.
  - Examples of projects that need CON exemptions:
    - Adding mental health beds in acute care hospitals
    - Adding NICUs in hospitals with relatively large numbers of births
    - Authorizing emergency-only angioplasty programs in hospitals that do not have open heart surgery programs
    - Adding inpatient rehab beds in hospitals with highly utilized rehab units
    - Replacing a nursing home within 3 miles of its existing site

# Other CON Processes

- Condition monitoring
  - CON holders commit to providing certain services or certain levels of a service.
  - The most common CON condition is an agreement by a nursing home to serve a certain level of Medicaid residents.
    - Penalties for failure to meet nursing home Medicaid conditions were eliminated last session in CS/HB 7109.
  - CON holders report annually.
  - Failure to meet a CON condition can result in an annual fine of up to \$365,000.



# Number of Applications Reviewed





# CON Reforms Timeline

- 1974 Federal program established. Required for all states.
- 1982 Federal program eliminated. Federal health systems agencies eliminated and replaced by Florida's local health councils. Local role in CON becomes voluntary.
- 1987 Capital expenditure thresholds for hospitals eliminated for outpatient services and modified for major medical equipment.  
Review of hospital-based obstetrical programs eliminated.  
Fining authority added for failure to meet CON conditions.
- 1997 Review of major medical equipment eliminated.
- 2000 Small bed additions at hospitals and nursing homes were eliminated from batched review and converted to CON exemptions.  
Review of Medicare certified home health agencies eliminated.
- 2001 5-year moratorium on the addition of community nursing home beds.
- 2003 CON requirements eliminated for rural hospitals.



# CON Reforms Timeline

- 2004 Eliminated review of most kinds of hospital bed additions or conversions from one type of bed to another.
- 2006 Moratorium on the addition of community nursing home beds extended until 2011.
- 2007 Established a process to replace the CON review of adult open heart surgery programs and burn units with hospital licensure programs.
- 2008 Streamlined the process for the review and appeal of new general hospitals.
- 2011 Moratorium on the addition of community nursing home beds extended until 2016 or when the statewide implementation of Medicaid long term care managed care is complete.

# Which Facilities and Services Are Subject to CON Review in 2011?

- New hospitals (general and specialty)
- Hospital tertiary services
  - Organ transplant programs
  - New inpatient rehab units
  - Neonatal intensive care units (NICUs)
  - Pediatric organ transplant and cardiovascular programs
- New nursing homes (moratorium since 2001)
  - Nursing home bed additions
- New hospice programs
  - New hospice inpatient facilities
- New ICF-DDs