Tab 1
 SB 422 by Benacquisto; (Identical to H 0363) Health Insurance Coverage For Opioids

The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

BANKING AND INSURANCE Senator Benacquisto, Chair Senator Richter, Vice Chair

Monday, November 2, 2015 **MEETING DATE:**

TIME:

4:00—6:00 p.m. *Toni Jennings Committee Room,* 110 Senate Office Building PLACE:

Senator Benacquisto, Chair; Senator Richter, Vice Chair; Senators Clemens, Detert, Hukill, Lee, Margolis, Montford, Negron, Simmons, and Smith **MEMBERS**:

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	SB 422 Benacquisto (Identical H 363)	Health Insurance Coverage For Opioids; Providing that a health insurance policy that covers opioid analgesic drug products may impose a prior authorization requirement for an abuse-deterrent opioid analgesic drug product only if the insurer imposes the same requirement for each opioid analgesic drug product without an abuse-deterrence labeling claim, etc.	Favorable Yeas 7 Nays 0
		BI 11/02/2015 Favorable HP AP	
	Other Related Meeting Documents		

S-036 (10/2008) Page 1 of 1

The Florida Senate BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

	Prepared I	By: The Prof	essional Staff o	f the Committee on	Banking and Ins	urance
BILL:	SB 422					
INTRODUCER: Senator B		enacquisto				
SUBJECT:	Health Ins	urance Cov	verage For Op	pioids		
DATE:	November	2, 2015	REVISED:			
ANAL	YST	STAFF	DIRECTOR	REFERENCE		ACTION
1. Johnson		Knudson		BI	Favorable	
2.				HP		
3.				AP		

I. Summary:

SB 422 allows a health insurance policy providing coverage for opioid analgesic drug products to impose a prior authorization requirement for an abuse-deterrent opioid analgesic drug product only if the policy imposes the same prior authorization requirement for opioid analgesic drug products without an abuse-deterrence labeling claim. The bill also prohibits a policy from requiring the use of an opioid analgesic without an abuse-deterrent labeling claim before providing coverage for an abuse-deterrent opioid analgesic drug product. Abuse deterrent formulations have characteristics that help prevent widespread abuse by impeding the delivery of their active ingredients, thereby reducing the potential for abuse, diversion, and misuse of the drug.

The fiscal impact of the bill is indeterminate.

The bill provides an effective date of January 1, 2017.

II. Present Situation:

The abuse of prescription drugs in the United States has been described as an epidemic. Every day in the United States, 44 people die because of prescription opioid overdose. In 2013, there were 16,235 deaths involving prescription opioid overdose. In Florida, 2,514 deaths were attributable to prescription opioids in 2014.

¹ Centers for Disease Control and Prevention, Prescription Drug Overdose Data (updated August 16, 2015) http://www.cdc.gov/drugoverdose/data/overdose.html (last accessed October 21, 2015).

² Id.

³ Medical Examiners Commission, Drugs Identified in Deceased Persons by Florida Medical Examiners, 2014 Annual Report (September 2015).

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Prescription opioid⁴ analgesics are a critical component of pain management particularly for treating acute and chronic medical pain, providing humane hospice care for cancer patients, and treating patients in drug treatment programs. When used properly, opioid analgesic drugs provide significant benefits for patients. However, abuse and misuse of these products has created a serious and growing public health problem. In the United States, an estimated 4.5 million⁵ individuals who use prescription pain medications for nonmedical purposes. Recent studies indicate that pharmaceuticals, especially opioid analgesics have driven the increase in drug overdose deaths.⁶ In 2007, the total U.S. societal costs of prescription opioid abuse was estimated at \$55.7 billion.⁷

Food and Drug Administration Guidance on Abuse-Deterrent Opioids

To reduce the misuse and abuse of prescription drugs, the Food and Drug Administration released guidance⁸ to assist the pharmaceutical industry in developing new formulations and labeling of opioid drugs with abuse-deterrent properties.⁹ The goal of abuse-deterrence products is to limit access or attractiveness of the highly desired active ingredient for abusers while assuring the safe and effective release of the medication for patients. The document provides guidance about the studies that should be conducted to demonstrate that a given formulation has abuse-deterrent properties, how the studies will be evaluated, and what labeling clams may be approved based on the results of the studies.

According to the guidance, opioid analgesics can be abused in a number of ways. For example, they can be swallowed whole, crushed and swallowed, crushed and snorted, crushed and smoked, or crushed, dissolved and injected. Abuse-deterrent formulations should target known or expected routes of abuse for the opioid drug substance for that formulation. As a general framework, the FDA guidance provides that abuse-deterrent formulations are categorized in one of the following groups:

⁴ Medications that fall within this class include hydrocodone (e.g., Vicodin), oxycodone (e.g., OxyContin, Percocet), morphine (e.g., Kadian, Avinza), codeine, and related drugs. Hydrocodone products are the most commonly prescribed for a variety of painful conditions, including dental and injury-related pain. Morphine is often used before and after surgical procedures to alleviate severe pain. Codeine is often prescribed for mild pain. See National Institute on Drug Abuse at http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/what-are-opioids (last accessed October 25, 2015).

⁵ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, The NSDUH Report, *Substance and Use and Mental Health Estimates from the 2013 National Survey on Drug Use and Health: Overview of Findings* (September 4, 2014). "Nonmedical use" is defined as the use of prescription-type drugs that were not prescribed for the respondent or use only for the experience or feeling they caused. Nonmedical use of any prescription type drug does not include over-the-counter drugs.

⁶ Christopher Jones, et al., Pharmaceutical Overdose, United States, 2010, *Journal of American Medical Association*. 2013;309:657.

⁷ Birnbaum, H.G., et al., Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States. Pain *Medicine*. 12:657-667. The breakout of this estimate includes the following costs: workplace \$25.6 billion (46 percent), health care \$25 billion (45 percent), and criminal justice \$5.1 billion (9 percent). (USD in 2009).

⁸ U.S. Department of Health and Human Services, *Abuse-Deterrent Opioids-Evaluation and Labeling*, Guidance for Industry (April 2015).

⁹ The FDA has approved four extended release opioids with abuse deterrent labels (Reformulated OxyContin, Embeda ER, Hysingla ER, and Targiniq ER).

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• *Physical/Chemical barriers* – Physical barriers can prevent chewing, crushing, cutting, grating, or grinding. Chemical barriers can resist extraction of the opioid using common solvents like water, alcohol, or other organic solvents.

- Agonist/Antagonist combinations An opioid antagonist can be added to interfere with, reduce, or defeat the euphoria associated with abuse. The antagonist can be sequestered and released only upon manipulation of the product. For example, a drug product may be formulated such that the substance that acts as an antagonist is not clinically active when the product is swallowed but becomes active if the product is crushed and injected or snorted.
- Aversion Substances can be added to a product to produce an unpleasant effect if the dosage form is manipulated prior to ingestion or is used at a higher dosage than directed.
- *Delivery System* (including depot injectable formulations and implants) Certain drug release designs or the method of drug delivery can offer resistance to abuse.
- *New Molecular entities (NME) and prodrugs* The properties of a NME or a prodrug could include the need for enzymatic activation or other novel effects.
- *Combination* Two or more of the above methods can be combined to deter abuse.
- Novel approaches Novel approaches or technologies that are not captured in the previous categories.

The increasing use of abuse-deterrent opioids is expected to reduce overall medical costs. One study¹⁰ estimated the potential cost savings from introducing abuse-deterrent opioids may be in the range of \$0.6 billion to \$1.6 billion per year in the United States. The study notes that cost data was extrapolated from claims data of privately insured national employers. The study also states that privately insured population accounts for approximately 60 percent of the U.S. population, and the costs and abuse patterns for Medicaid, uninsured individuals, and small employers could be different.

Regulation of Insurers and Health Maintenance Organizations

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, health maintenance organizations, and other risk-bearing entities. ¹¹ The Agency for Health Care Administration (agency) regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from the agency pursuant to part III of ch. 641, F.S. ¹²

Cost Containment Measures Used by Insurers and HMOs

Insurers use many cost containment strategies to manage medical and drug spending and utilization. For example, plans may place utilization management requirements on the use of certain drugs on their formulary, such as requiring enrollees to obtain prior authorization from their plan before being able to fill a prescription, requiring enrollees to try first a preferred drug to treat a medical condition before being able to obtain an alternate drug for that condition, or limiting the quantity of drugs that they cover over a certain period.

¹⁰ Birnbaum HG, White, AG, et al. Development of a Budget-Impact Model to Quantify Potential Cost Savings from Prescription Opioids Designed to Deter Abuse or Ease of Extraction. Appl Health Econ Health Policy. 2009; 7(1); 61-70.

¹¹ Section 20.121(3)(a)1., F.S.

¹² Section 641.21(1), F.S.

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Under prior authorization, a health care provider is required to seek approval from an insurer before a patient may receive a specified diagnostic or therapeutic treatment or specified prescription drugs under the plan. A preferred drug list (PDL) is an established list of one or more prescription drugs within a therapeutic class deemed clinically equivalent and cost effective. In order to obtain another drug within the therapeutic class, not part of the PDL, prior authorization is required. Prior authorization for emergency services is not required. Preauthorization for hospital inpatient services is generally required

III. **Effect of Proposed Changes:**

Section 1 creates s. 627.64194, F.S., which provides requirements for opioid analysis drug coverage. The terms "abuse-deterrent opioid analgesic drug product" and "opioid analgesic drug product" are defined. An "abuse-deterrent opioid analgesic drug product" means a brand or generic opioid analgesic drug product approved by the U.S. Food and Drug Administration with an abuse-deterrence labeling claim that indicates the drug product is expected to deter abuse. The term, "opioid analgesic drug product" means a drug product in the opioid analgesic drug class prescribed to treat moderate to severe pain or other conditions in immediate-release, extended release, or long-acting form regardless of whether or not combined with other drug substances to form a single drug product or dosage form.

The bill allows a health insurance policy that provides coverage for opioid analgesic drug products to impose a prior authorization for an abuse-deterrent opioid analysesic drug product only if the policy imposes the same prior authorization requirement for opioid analgesic drug products without an abuse-deterrence labeling claim. The bill also prohibits a health insurance policy from requiring the use of an opioid analgesic without an abuse-deterrent labeling claim before providing coverage for an abuse-deterrent opioid analgesic drug product. Abuse deterrent formulations have characteristics that help prevent widespread abuse by impeding the delivery of their active ingredients thereby reducing the potential for abuse and misuse of the drug.

Section 2 provides an effective date of January 1, 2017.

IV. Constitutional Issues:

A.	Municipality/County Mandates Restrictions:
	None.
B.	Public Records/Open Meetings Issues:

C. Trust Funds Restrictions:

None.

None.

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V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The fiscal impact on the private sector is indeterminate. The bill will provide patients with greater access to abuse-deterrent opioid analgesic drug products, which is expected to reduce opioid drug misuse, abuse, and diversion. The increased use of abuse deterrent drugs is expected to reduce emergency room and drug treatment costs associated with the misuse or abuse of opioids without such abuse deterrent formulations.

C. Government Sector Impact:

The fiscal impact on the government sector is indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 627.64194 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

Florida Senate - 2016 SB 422

By Senator Benacquisto

30-00436A-16 2016422 A bill to be entitled

An act relating to health insurance coverage for

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opioids; creating s. 627.64194, F.S.; defining terms; providing that a health insurance policy that covers opioid analgesic drug products may impose a prior authorization requirement for an abuse-deterrent opioid analgesic drug product only if the insurer imposes the same requirement for each opioid analgesic drug product without an abuse-deterrence labeling claim; prohibiting such health insurance policy from requiring use of an opioid analgesic drug product without an abuse-deterrence labeling claim before providing coverage for an abuse-deterrent opioid analgesic drug product; providing an effective date.

WHEREAS, the Legislature finds that the abuse of opioids is a serious problem that affects the health, social, and economic welfare of this state, and

WHEREAS, the Legislature finds that an estimated 2.1 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers in 2012,

WHEREAS, the Legislature finds that the number of unintentional overdose deaths from prescription pain relievers has more than quadrupled since 1999, and

WHEREAS, the Legislature is convinced that it is imperative for people suffering from pain to obtain the relief they need while minimizing the potential for negative consequences, NOW, THEREFORE,

Page 1 of 2

CODING: Words stricken are deletions; words underlined are additions.

Florida Senate - 2016 SB 422

2016422

20-004267-16

	30-00436A-10
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31	Be It Enacted by the Legislature of the State of Florida:
32	
33	Section 1. Section 627.64194, Florida Statutes, is created
34	to read:
35	627.64194 Requirements for opioid coverage.
36	(1) DEFINITIONS.—As used in this section, the term:
37	(a) "Abuse-deterrent opioid analgesic drug product" means a
38	brand or generic opioid analgesic drug product approved by the
39	United States Food and Drug Administration with an abuse-
40	deterrence labeling claim that indicates the drug product is
41	expected to deter abuse.
42	(b) "Opioid analgesic drug product" means a drug product in
43	the opioid analgesic drug class prescribed to treat moderate to
44	severe pain or other conditions in immediate-release, extended-
45	release, or long-acting form regardless of whether or not
46	combined with other drug substances to form a single drug
47	<pre>product or dosage form.</pre>
48	(2) COVERAGE REQUIREMENTS.—A health insurance policy that
49	<pre>provides coverage for opioid analgesic drug products:</pre>
50	(a) May impose a prior authorization requirement for an
51	abuse-deterrent opioid analgesic drug product only if the policy
52	$\underline{\text{imposes}}$ the same prior authorization requirement for each opioid
53	analgesic drug product without an abuse-deterrence labeling
54	<pre>claim which is covered by the policy.</pre>
55	(b) May not require use of an opioid analgesic drug product
56	without an abuse-deterrence labeling claim before providing
57	coverage for an abuse-deterrent opioid analgesic drug product.
58	Section 2. This act shall take effect January 1, 2017.

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CODING: Words stricken are deletions; words underlined are additions.

APPEARANCE RECORD

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(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date **Topic** Amendment Barcode (if applicable) Address Phone Street **Email** City State Speaking: For **Against** Information Waive Speaking: In Support (The Chair will read this information into the record.) + Drug Abuse Appearing at request of Chair: Lobbyist registered with Legislature:

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

APPEARANCE RECORD



(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

mooting bato	Bill Number (if applicable)
TOPIC HEALTH INSURANCE COVERGEE FOR C	P101155 Amendment Barcode (if applicable)
Name STEPHEN R. WIND	
Job Title EXECUTIVE DIRECTOR	
Address 2544 BLAIRSTONE PINES DR	Phone <u>878-7463</u>
Street [AUAHASSE] FL	3230/ Email
Speaking: State Speaking: Against Information	Waive Speaking: In Support Against (The Chair will read this information into the record.)
Representing FLORIDA OSTEOPATH CIMEDIGA	•
Appearing at request of Chair: Yes No	Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

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APPEARANCE RECORD

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Name Vice President of Government Relations Job Title (850) 321-6489 537 East Park Avenue Phone Address Street 32301 darrick@teamjb.com Tallahassee **Florida** Zip City State Waive Speaking: In Support Information Speaking: Against (The Chair will read this information into the record.)

Appearing at request of Chair: Yes No Lobbyist registered with Legislature: Yes No

Florida Society of Interventional Pain Physicians (FSIPP)

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

APPEARANCE RECORD

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(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date	Bill Number (if applicable)
Topic	
Name Chris Mand	
Job Title	
Address 1000 Riverside Ave	Phone 904-233-3051
Address 1000 Riverside Ave Street Tropischille, R 32204 City State	Email n land lan packem
Speaking: For Against Information	Waive Speaking: In Support Against (The Chair will read this information into the record.)
Representing Planda Chapter, America	can College of Physicians
	Lobbyist registered with Legislature: Yes No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.



Tallahassee, Florida 32399-1100

COMMITTEES: Ethics and Elections, Chair Banking and Insurance, Vice Chair Appropriations

Appropriations Subcommittee on Health and Human Services Commerce and Tourism Regulated Industries

SENATOR GARRETT RICHTER

President Pro Tempore 23rd District

October 28, 2015

The Honorable Lizbeth Benacquisto, Chair Committee on Banking and Insurance 320 Knott Building 404 South Monroe Street Tallahassee, FL 32399

Dear Madam Chair:

I respectfully ask to be excused from the Banking and Insurance Committee meeting scheduled for Monday November 2nd, 2015.

Thank you for your consideration.

Sincerely,

Garrett S. Richter

cc: James Knudson, Staff Director Sheri Green, Administrative Assistant

REPLY TO:

☐ 3299 E. Tamlami Trail, Suite 203, Naples, Florida 34112-4961 (239) 417-6205
☐ 404 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5023
☐ 25 Homestead Road North, Suite 42 B, Lehigh Acres, Florida 33936 (239) 338-2777

Senate's Website: www.flsenate.gov

Tallahassee, Florida 32399-1100

COMMITTEES: COMMITTEES:
Appropriations, Chair
Appropriations Subcommittee on
General Government
Banking and Insurance
Reapportionment Rules
Joint Legislative Budget Commission,
Alternating Chair

SENATOR TOM LEE

Deputy Majority Leader 24th District

November 2, 2015

The Honorable Senator Lizbeth Benacquisto, Chair Senate Banking and Insurance Committee 404 South Monroe Street 320 Knott Building Tallahassee, FL 32399

Dear Chair Benacquisto:

I respectfully request to be excused from today's meeting of the Senate Committee on Banking and Insurance.

Sincerely,

Tom Lee

Florida State Senator

24th District



Tallahassee, Florida 32399-1100

COMMITTEES:
Appropriations Subcommittee on Health and Human Services, Vice Chair
Appropriations
Banking and Insurance
Environmental Preservation and Conservation Ethics and Elections

JOINT COMMITTEE: Joint Committee on Public Counsel Oversight, Alternating Chair

SENATOR CHRISTOPHER L. SMITH 31st District

November 2, 2015

The Honorable Lizbeth Benacquisto, Chair Senate Committee on Banking and Insurance 320 Knott Tallahassee, Florida 32399-1100

Dear Chair Benacquisto:

Please excuse Senator Christopher Smith from Committee on Banking and Insurance that will be held on Monday November 2, 2015 at 4:00 PM. Due to inclement weather conditions Senator Smith's flight plans were delayed by the airline causing his arrival time to Tallahassee to fall after the scheduled committee meeting.

Thank you in advance for your consideration.

Sincerely

Sharonda Wright-Placide Legislative Assistant to

Senator Chris Smith, District 31



Tallahassee, Florida 32399-1100

COMMITTEES:

Commerce and Tourism, *Chair*Commerce and Tourism, *Chair*Education Pre-K - 12, *Vice Chair*Appropriations Subcommittee on Transportation,
Tourism, and Economic Development

Banking and Insurance

Children, Families, and Elder Affairs

JOINT COMMITTEE:
Joint Administrative Procedures Committee

SENATOR NANCY C. DETERT 28th District

November 2, 2015

The Honorable Lizbeth Benacquisto Chair Senate Banking and Insurance Committee 404 S. Monroe Street 320 Knott Building Tallahassee, FL 32399-1100

Dear Madame Chair:

I respectfully request that I be excused from today's Senate Banking and Insurance Committee meeting as I had car trouble on my way to Tallahassee this morning. My tire blew out and my car had to be towed all the way back to Tampa to get it repaired. I have just picked up a loaner car and am currently driving back to Tallahassee.

Thank you for your consideration of this request.

Nancy C. Detert

NCD/ca

Cc: James Knudson, Staff Director

Trancy Detect

Sheri Green, Administrative Assistant

REPLY TO:

☐ 417 Commercial Court, Suite D, Venice, Florida 34292 (941) 480-3547 FAX: (941) 480-3549 ☐ 416 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5028

Senate's Website: www.flsenate.gov

CourtSmart Tag Report

Room: EL 110 Case No.: Type:

Caption: Senate Banking and Insurance **Judge:**

Started: 11/2/2015 4:00:33 PM

Ends: 11/2/2015 4:04:43 PM Length: 00:04:11

4:00:42 PM Meeting call to order by Chairman--quorum present

4:01:03 PM Chair turned over to Senator Simmons

4:01:36 PM Senator Benacquisto recognized to explain SB 422/Health Ins. Coverage

4:04:02 PM roll call on SB 422 - Favorable

4:04:25 PM Meeting adjourned.