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 By: The Professional Staff of the Committee on Appropriations

BILL:	SB 422
INTRODUCER:	Senator Benacquisto
SUBJECT:	Health Insurance Coverage For Opioids
DATE:	February 17, 2016
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	**Favorable**
2.	Lloyd	Stovall	HP	**Favorable**
3.	Betta	Kynoch	AP	**Favorable**

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.

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.[1] In 2013, there were 16,235 deaths involving prescription opioid overdose.[2] In Florida, 2,922 deaths were attributable to prescription opioids in 2014.[3]

[1] Centers for Disease Control and Prevention, *Prescription Drug Overdose Data* (updated August 16, 2015) http://www.cdc.gov/drugoverdose/data/overdose.html (last visited Nov. 19, 2015).
[2] *Id.*
[3] Medical Examiners Commission, *Drugs Identified in Deceased Persons by Florida Medical Examiners*, 2014 Annual Report (September 2015), https://www.fdle.state.fl.us/Content/Medical-Examiners-Commission/MEC-Publications-and-Forms/Documents/2014-Annual-Drug-Report-FINAL.aspx (last visited Nov. 20, 2015).

Prescription opioid[4] 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 million[5] individuals 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 United States 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 (FDA) released guidance[8] 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:

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[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 Nov. 19, 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), https://store.samhsa.gov/shin/content/NSDUH14-0904/NSDUH14-0904.pdf (lasted visited Nov. 20, 2015). "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, http://jama.jamanetwork.com/article.aspx?articleid=1653518 (last visited: Nov. 20, 2015).

[7] Birnbaum, H.G., et al., *Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States*, PAIN MEDICINE. 12:657-667, http://onlinelibrary.wiley.com/doi/10.1111/j.1526-4637.2011.01075.x/epdf (last visited Nov. 20, 2015). 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), http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.pdf (last visited Nov. 20, 2015).

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

- *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 study[10] 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 United States 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 (AHCA) 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 AHCA 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.

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 drug 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 analgesic 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 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 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:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The fiscal impact on the private sector is indeterminate. SB 422 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.

The OIR notes that the bill does not require health insurance plans to have equivalent cost sharing to the policyholder. As a result, the policyholders may incur additional cost sharing if they switch to the abuse-deterrent opioids.[13]

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.

[13] Office of Insurance Regulation, *Senate Bill 422 Analysis* (Oct. 19, 2015) (on file with the Senate Committee on Health Policy).