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 728
INTRODUCER:	Senator Benacquisto
SUBJECT:	Health Insurance Coverage for Opioids
DATE:	April 8, 2015
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	**Favorable**
2.	Lloyd	Stovall	HP	**Favorable**
3.	McSwain	Kynoch	AP	**Pre-meeting**

I. Summary:

SB 728 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 bill's fiscal impact is indeterminate.

The bill provides an effective date of July 1, 2015.

II. Present Situation:

The abuse of prescription drugs in the United States has been described as an epidemic. Every day in the United States, 120 people die because of drug overdose, and another 6,748 are treated in emergency rooms for the misuse or abuse of drugs.[1] In 2010, 16,651 people in the United States died from a drug overdose involving opioid analgesics, such as oxycodone, hydrocodone, and methadone.

[1] Centers for Disease Control and Prevention, *Prescription Drug Overdose in the United States: Factsheet* (updated March 2, 2015) http://www.cdc.gov/homeandrecreationalsafety/overdose/facts.html (accessed March 7, 2015).

Prescription opioid[2] 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, approximately 4.5 million[3] individuals use prescription pain medications for nonmedical purposes,[4] resulting in more than 16,000 deaths[5] annually. 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[7] was estimated at $55.7 billion.[8]

Food and Drug Administration Guidance on Abuse-Deterrent Opioids

To reduce the misuse and abuse of prescription drugs, the Food and Drug Administration released draft guidance[9] to assist the pharmaceutical industry in developing new formulations of opioid drugs with abuse-deterrent properties. 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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[2] 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, on the other hand, 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 (accessed March 7, 2015).

[3] 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), *available at* http://www.samhsa.gov/data/sites/default/files/NSDUH-SR200-RecoveryMonth-2014/NSDUH-SR200-RecoveryMonth-2014.htm (accessed February 20, 2015).

[4] 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.

[5] Centers for Disease Control and Prevention, *Prescription Drug Overdose in the United States: Factsheet* (updated March 2, 2015) *available at* http://www.cdc.gov/homeandrecreationalsafety/overdose/facts.html .

[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.

[8] The breakout of this estimate is workplace costs $25.6 billion (46 percent), health care costs $25 billion (45 percent), and criminal justice costs $5.1 billion (9 percent). (USD in 2009).

[9] U.S. Food and Drug Administration, Draft Guidance for Industry, *Abuse-Deterrent Opioids-Evaluation and Labeling*, (January 2013) *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm334807.htm

- *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. Physical and chemical barriers can change the physical form of an oral drug rendering it less amenable to abuse.
- *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 combined to produce an unpleasant effect if the dosage form is manipulated prior to ingestion or a higher dosage than directed is used.
- *Delivery System* (including depot injectable formulations and implants) – Certain drug release designs or the method of drug delivery can offer resistance to abuse. For example, a sustained-release depot injectable formulation that is administered intramuscularly or a subcutaneous implant can be more difficult to manipulate.
- *Prodrug* – A prodrug that lacks opioid activity until transformed in the gastrointestinal tract can be unattractive for intravenous injection or intranasal routes of abuse.
- *Combination* – Two or more of the above methods can be combined to deter abuse.

The guidance provides that it is critical that labeling claims regarding abuse-deterrent properties be based on robust, compelling, and accurate data and analysis, and that any characterization of a product's abuse-deterrent properties or potential to reduce abuse be clearly and fairly communicated. Labeling language regarding abuse deterrence should describe the product's specific abuse-deterrent properties as well as the specific routes of abuse that the product has been developed to deter. The FDA provides that there are four general tiers of label claims available to describe the potential abuse-deterrent properties of a product:

- Tier 1: Product is formulated with physiochemical barriers to abuse.
- Tier 2: Product is expected to reduce or block effect of the opioid when it is manipulated.
- Tier 3: Product is expected to reduce abuse.
- Tier 4: Product has demonstrated reduced abuse in the community.

The FDA has approved four extended release opioids with abuse deterrent labels, indicating that they are expected to result in meaningful reductions in abuse.[10] There are approximately twelve products in development.

The increasing use of abuse-deterrent opioids is expected to reduce overall medical costs. One study[11] 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.

[10] These include: Reformulated OxyContin, Embeda, Hysingla, and Targiniq.

[11] 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.

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.[12] 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.[13]

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 first try 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 of time.

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.

In some cases, plans require an insured to try one drug first to treat his or her medical condition before they will cover another drug for that condition. For example, if Drug A and Drug B both treat a medical condition, a plan may require doctors to prescribe Drug A first. If Drug A does not work for a beneficiary, then the plan will cover Drug B. Advocates of step therapy state that a step therapy approach requires the use of a clinically recognized first-line drug before approval of a more complex and often more expensive medication where the safety, effectiveness, and values has been well established before a second-line drug is authorized.

According to a published report by researchers affiliated with the National Institutes of Health, there is mixed evidence on the impact of step therapy policies.[14] A review of the literature by Brenda Motheral found that there is little good empirical evidence,[15] but other studies[16] suggest that step therapy policies have been effective at reducing drug costs without increasing the use of other medical services. However, some studies have found that the policies can increase total utilization costs over the long run because of increased inpatient admissions and emergency department visits.[17] One-step therapy policy for a typical antipsychotic medication in a Medicaid

[12] Section 20.121(3)(a)1., F.S.
[13] Section 641.21(1), F.S.
[14] Rahul K. Nayak and Steven D. Pearson, The Ethics Of "Fail First": Guidelines and Practical Scenarios for Step Therapy Coverage Policies, *Health Affairs,* Vol. 33, No.10, October 2014, pgs. 1779-1785.
[15] Brenda R. Motheral, RPh, MBA, PhD, Pharmaceutical Step Therapy Interventions: A Critical Review of the Literature, *Journal of Managed Care Pharmacy,* Vol. 17, No. 2, March 2011, pgs. 143-155.
[16] See fn. 11 at pg. 1780.
[17] See *id*.

program was associated with a higher rate of discontinuity in medication use, an outcome that was linked to increased risk for hospitalization.[18]

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 July 1, 2015.

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.

[18] See *id*.

B. Private Sector Impact:

The fiscal impact of SB 728 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 of the bill on the government sector is also 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.