HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1021 Health Insurance Coverage for Opioids
SPONSOR(S): Health & Human Services Committee; Nuñez
TIED BILLS: **IDEN./SIM. BILLS:** SB 728

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	12 Y, 0 N	McElroy	Poche
2) Insurance & Banking Subcommittee	12 Y, 0 N	Cooper	Cooper
3) Health & Human Services Committee	14 Y, 0 N, As CS	McElroy	Calamas

SUMMARY ANALYSIS

Deaths from drug overdose have steadily increased over the past few decades and are the leading cause of accidental deaths in the United States. Every day in the United States,120 people die as a result of a drug overdose, and another 6,748 are treated in emergency departments for the misuse or abuse of drugs. The vast majority of these deaths and emergency department visits involved an overdose related to opioid analgesics drug products (opioids), which are narcotic pain relievers derived from the opium poppy, or its synthetic analogues.

Opioids can be abused in numerous ways including being swallowed, snorted, smoked, or injected. These delivery methods create a more rapid onset of the effects of the opioid than intended by the manufacturer and a greater euphoria. Abuse-deterrent opioids are formulated to deter this type of abuse by making product alteration more difficult (crush resistant) or by making the altered product less attractive or rewarding (crushing renders the drug essentially ineffective).

CS/HB 1021 permits a health insurance policy providing coverage for opioids to require a prior authorization for an abuse-deterrent opioid only if the policy imposes the same prior authorization requirement for an opioid without an abuse-deterrence labeling claim. The bill also prohibits a policy from requiring the use of an opioid without an abuse-deterrent labeling claim before providing coverage for an abuse-deterrent opioid. The bill expressly states that its provisions do not require a health insurer to provide coverage for opioids or abuse-deterrent opioids.

The bill does not appear to have a fiscal impact on state or local government.

The bill provides an effective date of January 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Opioids

The drug overdose death rate has more than doubled from 1999 through 2013 and has now become the leading cause of accidental deaths in the United States.[1] In 2013, there were 43,982 drug overdose deaths in the United States, of which 22,767, or 51.8 percent, were related to pharmaceuticals.[2] The majority of the pharmaceutical related deaths, 16,235, or 71.3 percent, involved opioid analgesic drug products (opioids).[3]

Opioids also play a prominent role in drug overdose deaths in Florida. In 2013, there were 8,286 drug-related deaths in the state.[4] Opioids were listed as the cause of death in 2,573 cases and were present in an additional 2,730 cases.[5] The four most harmful drugs, found in more than 50 percent of the deaths in which these drugs were present, were all opioids.[6]

Opioids are psychoactive substances derived from the opium poppy or their synthetic analogues.[7] They are commonly used as pain relievers to treat acute and chronic pain. An individual experiences pain as a result of a series of electrical and chemical exchanges among his or her peripheral nerves, spinal cord and brain.[8] Opioid receptors occur naturally and are distributed widely throughout the central nervous system and in peripheral sensory and autonomic nerves.[9] When an individual experiences pain the body releases hormones, such as endorphins, which bind with targeted opioid receptors.[10] This disrupts the transmission of pain signals through the central nervous system and reduces the perception of pain.[11] Opioids function in the same way by binding to specific opioid receptors in the brain, spinal cord and gastrointestinal tract, thereby reducing the perception of pain.[12] Opioids include:[13]

- Buprenorphine (Subutex, Suboxone)
- Codeine
- Fentanyl (Duragesic, Fentora)
- Heroin
- Hydrocodone (Vicodin, Lortab, Norco)
- Hydromorphone (Dilaudid, Exalgo)
- Meperidine

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[1] More deaths occur each year due to drug overdose than deaths caused by motor vehicle crashes. *Prescription Drug Overdose in the United States: Fact Sheet*, Centers for Disease Control and Prevention. http://www.cdc.gov/homeandrecreationalsafety/overdose/facts.html (last viewed April 2, 2015).
[2] *Prescription Drug Overdose in the United States: Fact Sheet*, Centers for Disease Control and Prevention. http://www.cdc.gov/homeandrecreationalsafety/overdose/facts.html (last viewed April 2, 2015).
[3] Id.
[4] *Drugs Identified in Deceased Persons by Florida Medical Examiners 2013 Report,* Florida Department of Law Enforcement, October 2014.
[5] Id. A decedent may have more than one drug listed as the cause of death.
[6] Id. Heroin (97%), Methadone (67%), Fentanyl (63.4%), Morphine (59.9%).
[7] *Information Sheet on Opioid Overdose*, World Health Organization, November 2014. http://www.who.int/substance_abuse/information-sheet/en/ (last viewed April 2, 2015).
[8] Mayo Clinic Health Library, http://www.riversideonline.com/health_reference/Nervous-System/PN00017.cfm (last viewed March 13, 2015).
[9] *Imaging of Opioid Receptors in the Central Nervous System,* Gjermund Henriksen, Frode Willoch; Brain (2008) 131 (5): 1171-1196.
[10] Id.
[11] Id.
[12] *SAMHSA Opioid Overdose Toolkit: Facts for Community Members*, Department of Health and Human Services- Substance Abuse and Mental Health Services Administration. http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742 (last viewed April 2, 2015).
[13] *Supra* at footnote 4.

- Methadone
- Morphine
- Oxycodone (OxyContin, Percodan, Percocet)
- Oxymorphone
- Tramadol

Opioid formulations are classified as either short-acting opioids (SAOs) or long-acting opioids (LAOs), which relate to the onset and duration of the effects of the drug in the body. SAOs are typically prescribed for transient pain types, such as acute, breakthrough or chronic intermittent pain and include immediate release (IR) formulation of various opioids.[14] The effects of an IR opioid begin shortly after ingestion and generally last between three to four hours. LAOs are typically prescribed for chronic pain and are designed to gradually release the drug in the blood stream and include the extended release (ER) formulation of various opioids.[15] The effects of an ER opioid generally last between eight to twelve hours with some formulations of LAOs having effect for up to seventy-two hours.[16]

Opioid Abuse and Misuse

The abuse and misuse of opioids is a serious and growing public health concern. In the United States:

- Approximately 4.5 million individuals use prescription pain medications for nonmedical purposes.[17]
- In 2011, approximately 1.4 million emergency departments (ED) visits involved nonmedical use of pharmaceuticals.[18]
- Every day 120 people die as a result of drug overdose, and another 6,748 are treated in ED for the misuse or abuse of drugs.[19]
- Nearly 9 out of 10 poisoning deaths are caused by drugs.[20]
- Prescription opioid abuse costs were about $55.7 billion in 2007.[21]

Opioids can be abused and misused in a variety of ways. For example, an abuser may swallow a greater quantity of the unaltered drug than what is prescribed. This typically occurs with IR opioids. Also, abusers may crush ER opioids and ingest the drug in a number of ways, including:[22]

- Swallowing;
- Snorting;
- Smoking; and
- Dissolving and injecting.

Opioids are commonly abused due to the euphoric effect created by their use.[23] ER opioids hold a greater attraction for abusers than IR opioids because of their higher concentrations of the drug.[24]

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[14] *A Comparison of Long and Short-Acting Opioids for the Treatment of Chronic Noncancer Pain: Tailoring Therapy to Meet the Patient Need*, Charles E. Argoff and Daniel I. Silverstein, Mayo Clin Proc. Jul; 84(7): 602-621. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2704132/ (last viewed April 2, 2015).
[15] Id.
[16] Id.
[17] *The NSDUH Report: Substance and Use and Mental Health Estimates from the 2013 National Survey on Drug Use and health: Overview of Findings*, Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, September 4, 2014. http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&ved=0CB4QFjAA&url=http%3A%2F%2Fstore.samhsa.gov%2Fshin%2Fcontent%2FNSDUH14-0904%2FNSDUH14-0904.pdf&ei=WwQDVY2ZMsuXNobrgNAH&usg=AFQjCNEFZtjCu4cxzFBucykETY7MMsY2Fg (last viewed April 2, 2015).
[18] *Prescription Drug Overdose in the United States: Factsheet*, Centers for Disease Control. http://www.cdc.gov/homeandrecreationalsafety/overdose/facts.html (last viewed April 2, 2015).
[19] Id.
[20] Id.
[21] Id. Of this amount, 46% was attributable to workplace costs (e.g., lost productivity), 45% to healthcare costs (e.g., abuse treatment), and 9% to criminal justice costs.
[22] *Abuse-Deterrent Opioids-Evaluation and Labeling*, *Guidance for Industry*, U.S. Food and Drug Administration, April 2015. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm (last viewed April 2, 2015).

When ER opioids are altered, the higher concentrations of the drug are immediately absorbed in the bloodstream rather than the gradual release and absorption of the drug as originally designed. This creates a more rapid onset of the effects of the opioids than the manufacturer intended and a greater euphoria.[25] This is the effect the abusers seek; however, this commonly can lead to overdose and death.

Continued use or abuse of opioids can lead to the development of tolerance and psychological and physical dependence.[26] This dependence is characterized by a strong desire to take opioids, impaired control over opioid use, persistent opioid use despite harmful consequences, a higher priority given to opioid use than to other activities and obligations, and a physical withdrawal reaction when opioids are discontinued.[27] This issue is widespread as an estimated 15 million people worldwide suffer from opioid dependence.[28]

Abuse-Deterrent Opioids

Abuse-deterrent opioids are formulated to deter abuse and misuse of the drug.[29] The goal of abuse-deterrent opioids 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.[30]

In 2015, the Food and Drug Administration (FDA) released guidance to assist the pharmaceutical industry in developing new formulations of opioid drugs with abuse-deterrent properties. The document provides guidance on 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 claims may be approved based on the results of the studies.[31]

The FDA guidance provides that abuse-deterrent formulations are categorized in one of the following groups:[32]

- **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**– 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;

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[23] Opioids affect the regions of the brain involved with pleasure and reward and can thereby create a euphoric effect. *How Do Opioids Affect the Brain and Body?,* National Institute on Drug Abuse. http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/how-do-opioids-affect-brain-body (last viewed April 2, 2015).
[24] *A Review of Abuse-Deterrent Opioids for Chronic Nonmalignant Pain*, Robin Moorman-Li, Carol Motycka, et al., P.T. 2012 Jul; 37(7): 412-418. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3411218/ (last viewed April 2, 2015).
[25] Id.
[26] *Supra* at footnote 9.
[27] *Supra* at footnote 7.
[28] Id.
[29] The National Addictions Vigilance Intervention and Prevention Program (NAVIPPRO) database was created to track drugs of abuse, their current popularity and their preferred method of use by abusers. Pharmaceutical companies can review this database to determine the drugs of abuse the most concern and to identify the routes of delivery that new formulations should specifically strive to deter. *Supra* at footnote 24.
[30] Id.
[31] *Supra* at footnote 22.
[32] Id.

- **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; and
- **Novel approaches** – This category encompasses novel approaches or technologies that are not captured in the previous categories.

Abuse Deterrence Studies and Labeling

The FDA recommends premarket and post-market studies which evaluate the known routes of abuse of opioids and anticipate new routes which could develop due to the development of abuse-deterrent opioids. These studies fall into four categories:[33]

- **Category 1- Laboratory-based in vitro manipulation and extraction studies**- The goal of laboratory-based studies is to evaluate the ease with which the potentially abuse-deterrent properties of a formulation can be defeated or compromised. This information should be used when designing Category 2 and Category 3 studies;
- **Category 2- Pharmacokinetic studies**- The goal of the clinical pharmacokinetic studies is to understand the in vivo properties of the formulation by comparing the pharmacokinetic profiles of the manipulated formulation with the intact formulation and with manipulated and intact formulations of the comparator drugs through one or more routes of administration.
- **Category 3- Clinical abuse potential studies**- The goal of clinical studies of abuse potential is to assess the impact of potentially abuse-deterrent properties.
- **Category 4- Post-market**- The goal of post-market studies is to determine whether the marketing of a product with abuse-deterrent properties results in meaningful reductions in abuse, misuse, and related adverse clinical outcomes, including addiction, overdose, and death in the post-approval setting.

Abuse-deterrent labeling is important to inform health care professionals, the patient community, and the public about a product's abuse potential.[34] The FDA encourages labeling that sets forth the results of in vitro, pharmacokinetic, clinical abuse potential and formal post-market studies and appropriately characterizes the abuse-deterrent properties of a product.[35] Category 1 studies should be described in general terms to avoid creating a road map for defeating the product's abuse-deterrent properties.[36] However, the design, conduct, and results of Category 2 and 3 studies should be described in sufficient detail to support clear labeling regarding a product's abuse-deterrent properties.[37]

Health Insurer Prior Authorization

Insurers use 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.[38]

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.[39] A preferred drug list (PDL) is an established list of one or more prescription drugs

[33] Id.
[34] Id.
[35] Id
[36] Id.
[37] Id.
[38] *Prescription for Prior Authorizations: A Better Way*, Leah Krieger, Policy Matters Journal, Fall 2014- Special Edition. http://www.policymattersjournal.org/krieger.html (last viewed April 2, 2015).
[39] *Administrative Simplification and Fair Contracting*, American Medical Association. http://www.ama-assn.org/ama/pub/advocacy/state-advocacy-arc/state-advocacy-campaigns/private-payer-reform/admin-simp-fair-contracting.page (last viewed March 13, 2015).

within a therapeutic class deemed clinically equivalent and cost effective.[40] In order to obtain another drug within the therapeutic class, not part of the PDL, prior authorization is required.[41]

Health insurers are increasingly turning to step therapy (or "fail first") policies in pharmacy benefit design.[42] This designation requires an insured to try one drug first to treat his or her medical condition before the insurer will cover another drug for that condition.[43] 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.

Effect of the Proposed Changes

CS/HB 1021 permits a health insurance policy providing coverage for opioids to require a prior authorization for an abuse-deterrent opioid only if the policy imposes the same prior authorization requirement for the corresponding opioid without an abuse-deterrence labeling claim. The bill defines "abuse-deterrent opioid analgesic drug product" as 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 bill defines "opioid analgesic drug product" as 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 prohibits a policy from requiring the use of an opioid without an abuse-deterrent labeling claim before providing coverage for an abuse-deterrent opioid. As a result, a physician may prescribe an abuse-deterrent opioid for a patient as an initial treatment, rather than waiting for failure of a non-abuse deterrent opioid to meet the patient's needs.

The bill expressly states that its provisions do not require a health insurer to provide coverage for opioids or abuse-deterrent opioids.

The bill provides an effective date of January 1, 2016.

B. SECTION DIRECTORY:

Section 1: Creates s. 627.64194, F.S., relating to abuse-deterrent opioid analgesic drug products.
Section 2: Provides an effective date of January 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

[40] *Health Cost Containment and Efficiencies, NCSL Briefs for State Legislators*, National Conference of State Legislatures, No.9, June 2010. www.ncsl.org/documents/health/IntroandBriefsCC-16.pdf (last viewed April 2, 2015).
[41] Id.
[42] *The Ethics Of 'Fail First': Guidelines And Practical Scenarios For Step Therapy Coverage Policies*, Rahul K. Nayak and Steven D. Pearson, Health Aff October 2014, vol. 33, no. 10, 1779-1785.
[43] Id.

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Insurers may pay higher costs for abuse-deterrent opioids prescribed by a physician as an initial treatment, rather than paying for lower cost opioids without an abuse deterrence claim.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On April 9, 2015, the Health & Human Services Committee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The amendment:

- Removed references to “coverage” to clarify that the bill does not require health insurers to provide coverage for abuse-deterrent opioid analgesic drug products;
- Changed the effective date of the bill to January 1, 2016, to coincide with the next plan year;
- Prohibited health insurers from utilizing step therapy policies for abuse-deterrent opioid analgesic drug product; and

- Expressly stated that the provisions of the bill do not require coverage of an opioid analgesic drug product or an abuse-deterrent opioid analgesic drug product.

The analysis is drafted to the committee substitute as passed by the Health & Human Services Committee.