

**HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS**

BILL #:	CS/HB 363	FINAL HOUSE FLOOR ACTION:	
SPONSOR(S):	Insurance & Banking Subcommittee; Nunez	108 Y's	0 N's
COMPANION BILLS:	SB 422	GOVERNOR'S ACTION:	Approved

SUMMARY ANALYSIS

CS/HB 363 passed the House on March 7, 2016, as SB 422.

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 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 involve an overdose related to opioid analgesic drug products (opioids), which are narcotic pain relievers derived from the opium poppy or its synthetic analogues.

Opioids can be abused in numerous ways, such as by swallowing, snorting, smoking, or injecting. 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 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 363 allows a health insurance policy that provides coverage for abuse-deterrent opioids to impose a prior authorization requirement for an abuse-deterrent opioid only if the policy requires prior authorization for opioids 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 authorizing the use of an abuse-deterrent opioid. The bill does not appear to have a fiscal impact on state or local government.

The bill was approved by the Governor on March 25, 2016, ch. 2016-112, L.O.F., and will become effective on January 1, 2017.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Background

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 2014, there were 8,587 drug-related deaths in the state.⁴ Opioids were listed as the cause of death in 2,922 cases and were present in an additional 3,098 cases.⁵ The four most harmful drugs, found in more than 50 percent of the deaths in which 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)

¹ More deaths occur each year due to drug overdose than deaths caused by motor vehicle crashes. Centers for Disease Control and Prevention, *Prescription Drug Overdose Data*, available at: <http://www.cdc.gov/drugoverdose/data/overdose.html> (last visited March 7, 2016).

² Centers for Disease Control and Prevention, *Prescription Drug Overdose Data*, available at: <http://www.cdc.gov/drugoverdose/data/overdose.html> (last visited March 7, 2016).

³ Id.

⁴ Florida Department of Law Enforcement, *Drugs Identified in Deceased Persons by Florida Medical Examiners 2014 Annual Report*, Sept. 2015, available at: <https://www.fdle.state.fl.us/Content/Medical-Examiners-Commission/Drugs-in-Deceased-Persons-Reports.aspx> (last visited March 7, 2016).

⁵ Id. A decedent may have more than one drug listed as the cause of death.

⁶ Id. Heroin (91.3 percent), Fentanyl (73.8 percent), Methadone (63.2 percent), Morphine (59.1 percent).

⁷ World Health Organization, *Information Sheet on Opioid Overdose* (Nov. 2014), available at: http://www.who.int/substance_abuse/information-sheet/en/ (last visited March 7, 2016).

⁸ Riverside, *How You Feel Pain*, http://www.riversideonline.com/health_reference/Nervous-System/PN00017.cfm (last visited February 15, 2016).

⁹ Gjermund Henriksen, Frode Willoch, *Imaging of Opioid Receptors in the Central Nervous System, Brain* (May 2008), available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2367693/> (last visited March 7, 2016).

¹⁰ Id.

¹¹ Id.

¹² Substance Abuse and Mental Health Services Administration *SAMHSA Opioid Overdose Toolkit: Facts for Community Members* (2014), available at: <http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742> (last visited March 7, 2016).

¹³ *Supra*, FN 4.

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

Opioid formulations are classified as either short-acting opioids or long-acting opioids, which relate to the onset and duration of the effects of the drug in the body. Short-acting opioids are typically prescribed for transient pain types, such as acute, breakthrough, or chronic intermittent pain and include the immediate-release formulation of various opioids.¹⁴ The effects of an immediate-release opioid begin shortly after ingestion and generally last between three to four hours. Long-acting opioids are typically prescribed for chronic pain. They are designed to release the drug gradually into the blood stream and include the extended-release formulation of various opioids.¹⁵ The effects of an extended-release opioid generally last between eight to twelve hours with some formulations of long-acting opioids having an 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, 114 people die as a result of drug overdose, and approximately 6,748 are treated in the ED for the misuse or abuse of drugs.¹⁹
- Nearly nine out of ten poisoning deaths are caused by drugs.²⁰
- In 2007, prescription opioid abuse costs were about \$55.7 billion.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 extended-release opioids. Also, abusers may crush extended-release opioids and ingest the drug in a number of ways, including:²²

- Swallowing;

¹⁴ Charles E. Argoff and Daniel I. Silverstein, *A Comparison of Long and Short-Acting Opioids for the Treatment of Chronic Noncancer Pain: Tailoring Therapy to Meet the Patient Need*, Mayo Clin. Proc. (July 2009), available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2704132/> (last visited March 7, 2016).

¹⁵ Id.

¹⁶ Id.

¹⁷ 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*, Sept. 4, 2014, available at:

<http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&ved=0CB4QFjAA&url=http%2F%2Fstore.samhsa.gov%2Fshin%2Fcontent%2FNSDUH14-0904%2FNSDUH14-0904.pdf&ei=WwQDVY2ZMsuXNobrgNAH&usq=AFQjCNEFZtjCu4cxzFBucykETY7MMsY2Fg> (last visited March 7, 2016).

¹⁸ Centers for Disease Control, *Prescription Drug Overdose in the United States: Factsheet*, available at:

http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=7&ved=0CDYQFjAGahUKEwjWueOGz_fIAhVImx4KHdz1CtY&url=http%2F%2Fwww.mayorsinnovation.org%2Fimages%2Fuploads%2Fpdf%2F1_-_Prescription_Drug_Overdose_in_the_United_States.pdf&usq=AFQjCNG4txlr2GiqmkMxlcpaigqZ6MguNA (last visited March 7, 2016).

¹⁹ Id.

²⁰ Id.

²¹ Id. Of this amount, 46 percent was attributable to workplace costs (e.g., lost productivity), 45 percent to healthcare costs (e.g., abuse treatment), and 9 percent to criminal justice costs.

²² U.S. Food and Drug Administration, *Abuse-Deterrent Opioids-Evaluation and Labeling: Guidance for Industry*, April 2015, available at: <http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&ved=0CB4QFjAA&url=http%2F%2Fwww.fda.gov%2Fdownloads%2Fdrugs%2Fguidancecomplianceregulatoryinformation%2Fguidances%2Fucm334743.pdf&ei=HykDVaWHDpLRggTlgoT4Cg&usq=AFQjCNHvX1Wg3qdmw6C3Jz97t3uJ5-bxw&bvm=bv.88198703.d.eXY> (last viewed March 7, 2016).

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

Opioids are commonly abused for their euphoric effect.²³ Extended-release opioids hold a greater attraction for abusers than immediate-release opioids because of their higher concentrations of the drug.²⁴ When extended-release opioids are altered, the higher concentrations of the drug are immediately absorbed into the bloodstream as contrasted with 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: 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 to or attractiveness of the active ingredient that is highly attractive to abusers, while still 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 into 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

²³ Opioids affect the regions of the brain involved with pleasure and reward and can thereby create a euphoric effect. National Institute on Drug Abuse, *How Do Opioids Affect the Brain and Body?*, <http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/how-do-opioids-affect-brain-body> (last visited March 7, 2016).

²⁴ Robin Moorman-Li, Carol Motycka, et al., *A Review of Abuse-Deterrent Opioids for Chronic Nonmalignant Pain*, P.T. (July 2012), available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3411218/> (last visited March 7, 2016).

²⁵ Id.

²⁶ Supra, FN 9.

²⁷ Supra, FN 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, FN 24.

³⁰ Id.

³¹ Supra, FN 22.

³² Id.

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.
- **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.
- **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 pre-market and post-market studies which evaluate the known routes of abuse of opioids and anticipate new routes that 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 vitro 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 that 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 try a preferred drug to treat a medical condition before allowing

³³ Id.

³⁴ Id.

³⁵ Id.

³⁶ Id.

³⁷ Id.

them to obtain an alternate drug for that condition; or limiting the quantity of drugs that the plan will cover during a certain period of time.³⁸

Prior authorization is a requirement for a health care provider to obtain approval from an insurer before a patient may receive a specified diagnostic or therapeutic treatment or specified prescription drugs.³⁹ A preferred drug list is an established list of one or more prescription drugs 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 preferred drug list, 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 363 allows a health insurance policy that provides coverage for abuse-deterrent opioids to impose a prior authorization requirement for an abuse-deterrent opioid only if the policy imposes the same prior authorization requirement for opioids 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 authorizing the use of 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 a patient to fail in the use of a non-abuse deterrent opioid.

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

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

³⁸ Policy Matters Journal, Leah Krieger, *Prescription for Prior Authorizations: A Better Way*, (Fall 2014- Special Edition), available at: <http://www.policymattersjournal.org/krieger.html> (last visited March 7, 2016).

³⁹ American Medical Association, *Administrative Simplification and Fair Contracting*, available at: <http://www.ama-assn.org/ama/pub/advocacy/state-advocacy-arc/state-advocacy-campaigns/private-payer-reform/admin-simp-fair-contracting.page> (last visited March 7, 2016).

⁴⁰ National Conference of State Legislatures, *Health Cost Containment and Efficiencies, NCSL Briefs for State Legislators* (June 2010), available at: <http://www.ncsl.org/documents/health/IntroandBriefsCC-16.pdf> (last visited March 7, 2016).

⁴¹ Id.

⁴² Rahul K. Nayak and Steven D. Pearson, *The Ethics Of ‘Fail First’: Guidelines And Practical Scenarios For Step Therapy Coverage Policies*, Health Aff October 2014, vol. 33, no. 10, 1779-1785.

⁴³ Id.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

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.