Date of Hearing: April 18, 2017

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Rudy Salas, Chair
AB 1048 (Arambula) – As Amended March 21, 2017

NOTE: *This bill is double referred, and if passed by this Committee, it will be referred to the Assembly Committee on Health.*

SUBJECT: Health care: pain management and Schedule II drug prescriptions.

SUMMARY: Authorizes a pharmacist to dispense opioids as partial fills if requested by the prescribing physician or patient; removes the requirement that pain be assessed at the same time as vital signs; and, prohibits hospitals from basing executive compensation to chief officers, executives, managers and administrators on patient satisfaction measurements for pain management.

EXISTING LAW:

1) Establishes the Board of Pharmacy, within the Department of Consumer Affairs, to regulate the practice of pharmacy (Business and Professions Code (BPC) § 4000 et seq.)

2) Classifies controlled substances in five schedules according to their danger and potential for abuse. Schedule I controlled substances have the greatest restrictions and penalties, including prohibiting the prescribing of a Schedule I controlled substance. (Health & Safety Code §§ 11054 to 11058.)

THIS BILL:

1) Permits a pharmacist to dispense a Schedule II controlled substance as a partial fill if requested by the patient or the prescribing physician.

2) Specifies if a pharmacist dispenses a partial fill on a prescription, the pharmacy shall retain the original prescription, with a notation of how much of the prescription has been filled, until the prescription has been fully dispensed. The total quantity dispensed shall not exceed the total quantity prescribed.

3) Further specifies, subsequent fills, until the original prescription is completely dispensed, shall occur at the pharmacy where the original prescription was partially filled. The full prescription shall be dispensed not more than 30 days after the first partial fill. Thirty-one days after the initial partial fill on a prescription, the prescription shall expire and no more of the drug shall be dispensed without a subsequent prescription.

4) Require the pharmacist to record in the state prescription drug monitoring program only the actual amounts of the drug dispensed.

5) Specifies that the pharmacist shall notify the prescriber that the prescription was partially filled and the amount of the drug that was dispensed in one of the following ways:

a) A notation in the patient's interoperable electronic health record.

b) An electronic or facsimile transmission.

c) A notation in the patient's record at the pharmacy that is available to the prescriber upon request.

6) Directs pharmacies to collect the copayment, if any, for the entire prescription at the time of the first partial fill. No additional money shall be collected for later dispensing, up to the full prescription amount.

7) Specifies that a pharmacist shall not charge an additional fee, service fee, or a higher rate or copayment for prescriptions that are dispensed as partial fills.

8) Establishes the following definitions:

a) "Original prescription" means the prescription presented by the patient to the pharmacy or submitted electronically to the pharmacy.

b) "Partial fill" means a part of a prescription filled that is of a quantity less that the entire prescription.

9) Mandates that a licensed health facility include pain as an item to be assessed. The health facility shall ensure that pain assessment is performed in a consistent manner that is appropriate to the patient. The pain assessment shall be noted in the patient's chart.

10) Prohibits a health facility from basing executive compensation on patient satisfaction measurements for pain management.

11) Defines "executive compensation" as compensation or any tangible employment benefit to chief executive officers, executives, managers, and administrators of hospitals, including, but not limited to, wages; salary; paid time off; bonuses; incentive payments; lump-sum cash payments; below market rate loans or loan forgiveness; payments for transportation, travel, meals, or other expenses in excess of actual documented expenses incurred in the performance of duties; payments or reimbursement for entertainment or social club memberships; housing, automobiles, parking, or similar benefits; scholarships or fellowships; payment for dependent care or adoption assistance; payment of personal legal or financial services; stock options or awards; and deferred compensation earned or accrued, even if not yet vested or paid.

12) Specifies that "executive compensation" does not include a benefit or remuneration to the extent that the inclusion of that benefit or remuneration is preempted by federal law or violates the state or federal constitution.

13) Defines "pain management" as the prevention, diagnosis, and treatment of pain.

14) Defines "patient satisfaction measurement" as a survey, questionnaire, poll, audit, or other instrument or process that collects or measures patient-reported outcomes or patient feelings

about the medical care provided at the hospital, including, but not limited to, satisfaction with professional staff, service, and facilities.

FISCAL EFFECT: Unknown. This bill is keyed fiscal by the Legislative Counsel.

COMMENTS:

Purpose. This bill is sponsored by the **California Medical Association**. According to the author, "Opioid addiction and overdosing is a multi-faceted issue that is growing in the United States and in California specifically. With over 2,000 opioid overdose deaths in California in 2014 alone, there are steps that California Legislature can take to prevent the over prescription of opioids and minimize the number of pills available for unintentional or intentional diversion. The three-pronged approach to attack the opioid overdosing epidemic are as follows:

1) Authorize a pharmacist to dispense opioids as partial fills to limit the supply of opioids from the pharmacy to partial amounts so that intake of opioids can be monitored.

2) Remove pain assessment as a fifth vital sign due to the overtreatment of pain with opioid painkillers – instead it is highly encouraged for practitioners to assess pain in a manner that allows organizations and hospitals to set their own policies regarding which patient should have pain assessed based on the population served and services delivered.

3) Prohibit hospitals from basing compensations for hospital executives on patient satisfaction surveys for pain management. In efforts to have higher ratings for a hospital, high survey scores can encourage inappropriate medical practices. In some cases, hospital executives may be incentivized through compensations to increase their hospital ratings, and thereby increase unnecessary prescriptions of opioids."

Background. *The Opioid Epidemic.* Opioids are a class of narcotic drugs that include medications such as hydrocodone (e.g. Vicodin), oxycodone (e.g., OxyContin, Percocet), morphine (e.g., Kadian, Avinza) codeine, and other related drugs. Through the Controlled Substances Act of 1970 (CSA), the Drug Enforcement Administration (DEA) regulates the manufacture, distribution and dispensing of controlled substances. The CSA ranks into five schedules those drugs known to have potential for physical or psychological harm, based on three considerations: 1) their potential for abuse, 2) their accepted medical use, and 3) their accepted safety under medical supervision. Presently, the ADF formulations on the market and pending FDA approval are Schedule II drugs.

Schedule I controlled substances have a high potential for abuse and have no generally accepted medical use such as heroin, ecstasy, and LSD.

Schedule II controlled substances have a currently accepted medical use in treatment, or a currently accepted medical use with severe restrictions, and have a high potential for abuse and psychological or physical dependence. Schedule II drugs can be narcotics or non-narcotic. Examples of Schedule II controlled substances include morphine, methadone, Ritalin, Demerol, Dilaudid, Percocet, Adderall, and Oxycontin. In October of 2014, the DEA as a response to the rising prescription drug abuse epidemic promulgated a rule rescheduling hydrocodone

containing prescriptions (e.g., Vicodin) into this more tightly controlled category (21 Code of Federal Regulations 1308).

Schedule III and IV controlled substances have a currently accepted medical use in treatment, less potential for abuse but are known to be mixed in specific ways to achieve a narcotic-like end product. Examples include drugs include Tylenol with Codeine, Ambien, Xanax, and other anti-anxiety drugs.

Schedule V drugs have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. Examples include Robitussin with Codeine and Lomotil.

Prescription Drug Abuse. According the Drug Abuse Warning Network, a division of the Substance Abuse and Mental Health Agency, prescription drug misuse and abuse is the intentional or unintentional use of medication without a prescription, in a way other than prescribed, or for the experience or feeling it causes. Abuse can stem from the fact that prescription drugs are legal and potentially more easily accessible, as they can be found at home in a medicine cabinet. Data shows that individuals who misuse prescription drugs, particularly teens, believe these substances are safer than illicit drugs because they are prescribed by a health care professional and thus are safe to take under any circumstances.

According to the Centers for Disease Control and Prevention (CDC), drug overdoses are the top cause of accidental deaths in the United States. Overdose deaths involving prescription opioids have quadrupled since 1999, as well as sales of these prescription drugs. Additionally, approximately 20 percent of prescribers prescribe 80 percent of all prescription painkillers.

In the years spanning 1999 to 2014, over 165,000 people died in the United States from overdoses related to prescription opioids. During this time period, overdose rates were highest among people age 25 to 54 years. Overdose rates were higher among non-Hispanic whites and American Indian or Alaskan Natives, compared to non-Hispanic blacks and Hispanics. In addition, men were more likely to die from overdose, but the mortality gap between men and women is closing.

Pain as the 5th Vital Sign. The phrase "pain as the 5th vital sign" was initially promoted by the American Pain Society in the late 1990's to elevate awareness of pain treatment among healthcare professionals. The thinking was that if pain were assessed with the same zeal as other vital signs, it would have a much better chance of being treated properly.

In 2001, the Joint Commission on Accreditation of Healthcare Organization (JCAHO) introduced standards for pain assessment and management relevant to multiple health care disciplines and settings. These standards stress patients' rights to appropriate assessment and management of pain (JCAHO Standard RI1.2.8, 2000) and emphasize that pain should be assessed in all patients (JCAHO Standard PE1.4, 2000).

Since then, health care providers have engaged in screening, assessing, and documenting pain routinely. As with any other vital sign, a positive pain score should trigger further assessment of the pain, prompt intervention, and follow-up evaluation of the pain and the effectiveness of

treatment. However, in recent years, the practice of screening for pain has been scrutinized. Many believe that the pain as the 5th vital sign movement has done more harm than good as some believe that pain assessment has fueled the opioid crisis. Some physicians nationwide have said they felt pressure to prescribe opioid painkillers to achieve higher scores in patient satisfaction for themselves and their hospitals. According to the global news site Medscape, the American Medical Association House of Delegates took a stand in June opposing that classification, and the American Academy of Family Physicians' Congress of Delegates did so in the fall.

Previous Related Legislation. ACR 26 (Levine), Chapter 16, Statutes of 2015, proclaimed the month of March 2015 as Prescription Drug Abuse Awareness Month and encourages all citizens to actively participate in prevention programs and activities, and to safely store and dispose of their medications on a continual basis.

AB 73 (Waldron), Chapter 548, Statutes of 2016, provides that drugs in specified therapeutic drug classes that are prescribed by a Medi-Cal beneficiary's treating provider are covered Medi-Cal benefits and requires that a Medi-Cal managed care plan cover the drug upon demonstration by the provider that the drug is medically necessary and consistent with federal rules and regulations for labeling and use.

AB 1535 (Bloom), Chapter 326, Statutes of 2014, authorizes a pharmacist to furnish naloxone hydrochloride (opioid overdose antidote) in accordance with standardized procedures or protocols developed and approved by both the BOP and the Medical Board of California.

AB 1814 (Waldron) of 2014, would have established that a prescriber's reasonable professional judgment prevails over the policies and utilization controls of the Medi-Cal program, including the utilization controls of a Medi-Cal managed care plan, in prescribing a pharmaceutical from specified therapeutic drug classes. *(NOTE: This bill was held in the Assembly Appropriations Committee.)*

AB 831 (Bloom) of 2013, would have required, until January 1, 2016, the California Health and Human Services Agency (CHHSA) to convene a temporary working group to develop a state plan to reduce the rate of fatal drug overdoses and appropriates $500,000 from the General Fund to CHHSA to provide grants to local agencies to implement drug overdose prevention and response programs. *(NOTE: This bill was held in the Assembly Appropriations Committee.)*

AB 889 (Frazier) of 2013, would have prohibited a plan and insurer that provides coverage for medications pursuant to step therapy or fail first protocol from requiring an enrollee or insured to try and fail more than two medications before allowing the enrollee or insured access to the medication originally prescribed by their provider, and would have required plans and insurers to have an expeditious process in place for step therapy exceptions and that the duration of step therapy be consistent with up-to-date evidence-based outcomes and current published peer-reviewed medical and pharmaceutical literature. *(NOTE: This bill was held in the Senate Appropriations Committee.)*

AB 369 (Huffman) of 2012, would have prohibited plans and insurers that restrict medications for the treatment of pain from requiring a patient to try and fail on more than two pain medications before allowing the patient access to the pain medication, or its generic equivalent,

prescribed by his or her physician. *(NOTE: This bill was vetoed by Governor Brown with a veto message stating that a doctor's judgment and a health plan's clinical protocols have a role in ensuring prudent prescribing of pain medications, and any limitations on the practice of step therapy should better reflect a health plan or insurer's legitimate role in determining the allowable steps.)*

AB 1826 (Huffman) of 2010, would have required a plan or insurer that covers prescription drug benefits to provide coverage for a drug that has been prescribed for the treatment of pain without first requiring the enrollee or insured to use an alternative drug or product. *(NOTE: This bill was held in the Senate Appropriations Committee.)*

AB 1144 (Price) of 2009, would have required plans and insurers to report to DMHC and CDI specified information related to chronic pain medication management, including when the plan or insurer requires an enroll to use of more than two formulary alternative medications prior to providing access to a pain medication prescribed by a provider, or to use pain medication other than what was prescribed for more than seven days prior to providing access to the prescribed pain medication. *(NOTE: This bill was held in the Assembly Appropriations Committee.)*

ARGUMENTS IN SUPPORT:

The **California Medical Association (sponsor)** writes in support, "California, like other states across the country, is looking for ways [to] reduce overdose deaths related to the nonmedical use of opioids. This is a complicated problem that requires a multi-faceted approach. California physicians have been active participants in the effort supporting a public health strategy to address the issues surrounding addiction while balancing the need for patients [to] get appropriate treatment."

ARGUMENTS IN OPPOSITION:

The **California Hospital Association** has a support if amended position and writes, "We are working with hospitals and pharmacies to determine how the requirements of this bill will interface with existing hospital software pharmacy programs. This mandate may create additional workload and information system updates, if available, for hospital pharmacies that are not currently offering partial fill prescriptions. As such, we anticipate requesting amendments in the future to addresses operational and payment issues that are being identified.

CHA appreciates the time Assemblymember Arambula spent discussing the bill with us and from our understanding his willingness to eliminate section [three] of the bill which would have limited the use of various patient satisfaction tools/surveys to improve hospital quality and patient care. This is critical to CHA's support of the bill."

REGISTERED SUPPORT:

California Medical Association (sponsor)

REGISTERED OPPOSITION:

California Hospital Association

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