lkDate of Hearing: June 20, 2017

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
SB 554(Stone) – As Amended April 17, 2017

SENATE VOTE: 36-0

SUBJECT: Nurse practitioners: physician assistants: buprenorphine

SUMMARY: Clarifies that nurses may furnish or order buprenorphine when done in compliance with the provisions of the Comprehensive Addiction Recovery Act (CARA). This bill also clarifies that physician assistants may administer or provide buprenorphine to a patient, or transmit orally, or in writing on a patient's record or in a drug order, an order for buprenorphine to a person who may lawfully furnish buprenorphine when done in compliance with the provisions of the CARA.

EXISTING LAW:

Business and Professions Code (BPC):

1) Establishes the Board of Registered Nursing (BRN) within the Department of Consumer Affairs (DCA) to administer and enforce the Nursing Practice Act. (BPC § 2701)

2) Establishes a nurse practitioner (NP) certificate, which may be issued to an individual with an active registered nursing license and a master's degree who has completed a NP program approved by the BRN. (BPC § 2835.5)

3) Defines "standardized procedures" as either policies and protocols developed by a health facility through collaboration among administration and health professionals or policies and protocols developed through collaboration among administrators and health professionals by an organized health care system which is not a health care facility. (BPC § 2725 (c))

4) Permits NPs to furnish and order Schedule II – V drugs pursuant to standardized procedures developed by the NP and the supervising physician and surgeon when the drugs or devices are consistent with the practitioner's educational preparation or for which clinical competency has been established and maintained. (BPC § 2836.1)

5) Requires physician and surgeon supervision of prescribing NPs, but no more than four NPs at a time.
(BPC §§ 2836.1(d)-(e))

6) Establishes the Physician Assistant Board (PAB) to administer the Physician Assistant Act. (BPC §§ 3504, 3509)

7) Authorizes a physician assistant (PA) to perform those medical services set forth in regulations and when supervised by a physician and surgeon and operating under written guidelines, such as the delegation of services agreement or protocols. (BPC § 3502)

8) Requires a PA's supervising physician available to the PA for consultation in person or by electronic communication. (California Code of Regulations, tit. 16, §1399.545)

9) Authorizes a PA to issue a drug order for a Schedule II – V drug as determined by the supervising physician and surgeon, as specified. (BPC § 3502.1 (a))

Federal law:

1) Expands prescribing privileges to NPs and PAs for all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention until October 1, 2021. (Public Law (P.L.) 114-198, §303)

2) Requires NPs and PAs to complete 24 hours of training to be eligible for a waiver to prescribe buprenorphine and must be supervised by or work in collaboration with a qualifying physician, as specified. (P.L. 114-198, §303)

3) Allows the United States Secretary of Health and Human Services (HHS) 18 months to issue updated regulations governing office-based opioid addiction treatment to include NPs and PAs. (P.L. 114-198, §303)

THIS BILL:

1) Declares that the Nursing Practice Act nor any other provision of law shall be construed to prohibit a nurse practitioner from furnishing or ordering buprenorphine when done in compliance with the provisions of the CARA, as enacted on July 22, 2016, including the following:

    a. The requirement that the nurse practitioner complete not fewer than 24 hours of initial training provided by an organization listed in the specified provision of the USC, or any other organization that the United States Secretary of Health and Human Services determines is appropriate for the purposes of that provision that addresses the following:

        i. Opioid maintenance and detoxification.

        ii. Appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder.

        iii. Initial and periodic patient assessments, including substance use monitoring.

        iv. Individualized treatment planning, overdose reversal, and relapse prevention.

        v. Counseling and recovery support services.

vi. Staffing roles and considerations.

vii. Diversion control.

viii. Other best practices, as identified by the United States Secretary of Health and Human Services.

b. The alternative requirement that the nurse practitioner have other training or experience that the United States Secretary of Health and Human Services determines will demonstrate the ability of the nurse practitioner to treat and manage opiate-dependent patients.

c. The requirement that the nurse practitioner be supervised by, or work in collaboration with, a licensed physician and surgeon.

2) Declares that the Physician Assistant Act nor any other provision of law shall be construed to prohibit a physician assistant from administering or providing buprenorphine to a patient, or transmitting orally, or in writing on a patient's record or in a drug order, an order to a person who may lawfully furnish buprenorphine when done in compliance with the provisions of the CARA, including the following:

a. The requirement that the physician assistant complete not fewer than 24 hours of initial training provided by an organization listed in the specified provision of the USC, or any other organization that that the United States Secretary of Health and Human Services determines is appropriate for the purposes of that provision that addresses the following:

i. Opioid maintenance and detoxification.

ii. Appropriate clinical use of all drugs approved by the Federal Drug Administration for the treatment of opioid use disorder.

iii. Initial and periodic patient assessments, including substance use monitoring.

iv. Individualized treatment planning, overdose reversal, and relapse prevention.

v. Counseling and recovery support services.

vi. Staffing roles and considerations.

vii. Diversion control.

viii. Other best practices, as identified by the United States Secretary of Health and Human Services.

b. The alternative requirement that the physician assistant to have other training or experience that the United States Secretary of Health and Human Services determines will demonstrate the ability of the nurse practitioner to treat and manage opiate-

dependent patients.

c. The requirement that the physician assistant be supervised by, or work in collaboration with, a licensed physician and surgeon.

FISCAL EFFECT: According to the Senate Appropriations Committee, pursuant to Senate rule 28.8, this bill will result in negligible state costs.

COMMENTS:

Purpose. This bill is sponsored by the author. According to the author, "opioid addiction is a growing problem that must be medically addressed during recovery. The more professionals that have the ability to treat this addiction the better we can bring access to those in need. The Comprehensive Addiction and Recovery Act (CARA) passed by the federal government that allows NPs and PAs to prescribe opioid addiction treatment with buprenorphine. Many NPs and PAs may not be aware of the process and opportunity that is needed to gain authority to prescribe buprenorphine to treat opioid addiction. SB 554 looks to codify this federal law in state law under the Nurse Practitioners Act which will bring awareness of the availability and process for NPs and PAs interested in gaining this privilege."

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 abuse deterrent 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 Services Agency (SAMHSA), 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, 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.

Buprenorphine. According to the SAMHSA, buprenorphine is a drug utilized in medication assisted treatment to assist individuals who desire to reduce of quit their use of opiates. Buprenorphine is an opioid partial agonist that produces euphoria and respiratory depression. As a result of the Drug Addiction treatment Act of 2000, buprenorphine is permitted to be prescribed or dispensed in various settings such as a physician's office, hospital, health department or correctional facility.

Use of buprenorphine may result in psychological and or physical dependence. Its onset is slow, the drug has a mild effect, and is very long acting with a half-life of 24 to 60 hours. Once a patient has stabilized on the drug, treatment options include continual use/maintenance, or medically supervised withdrawal from the physical dependence to the drug (SAMHSA, *About Buprenorphine Therapy*, 2014).

CARA. On July 22, 2016, President Obama signed into law the CARA which has been lauded as the first major federal addiction legislation in 40 years and the most comprehensive effort undertaken to address the opioid epidemic. The CARA utilizes grant funding to increase prevention and education efforts by expanding:

- Prevention and educational efforts for teens, parents and other caretakers, and aging populations in an effort to address the abuse of methamphetamines, opioids and heroin, and promote treatment and recovery.

- Availability of naloxone to law enforcement agencies and other first responders to help in the reversal of overdoses.

- Resources to identify and treat incarcerated individuals suffering from addiction disorders promptly.

- Disposal sites for unwanted prescription medications.

- An evidence-based opioid and heroin treatment and intervention program to expand best practices throughout the country.

- Launching a medication-assisted treatment and intervention demonstration program.

- Strengthening prescription drug monitoring programs to help states monitor and track prescription drug diversion and to help at-risk individuals access services.

This measure will codify the provisions of CARA relating to NPs and PAs into state law.

Prior Related Legislation. AB 1535 (Bloom) Chapter 326, Statutes of 2014 permitted a pharmacist to furnish naloxone hydrochloride pursuant to standardized procedures or protocols developed and approved by the California Board of Pharmacy and the Medical Board of California.

ARGUMENTS IN SUPPORT:

The **California Association for Nurse Practitioners** writes, "SB 554 will aid the fight against opioid abuse by prohibiting the state from preventing NPs and PAs from prescribing buprenorphine to patients…. As the state grapples with the challenges associated with the insufficient supply of physicians and the worsening opioid epidemic, NPs are trained, able and ready to treat those suffering from opioid use disorders, especially in underserved communities."

The **California Hospital Association** writes in support, "This bill would allow improved access to overdose treatment by authorizing NPs and PAs to prescribe buprenorphine to help combat the opioid-related overdose abuse and death epidemic in California. NPs and PAs must be allowed to prescribe buprenorphine consistent with CARA to comprehensively combat opioid abuse."

The **Medical Board of California** also writes in support, "The growing opioid abuse epidemic remains a matter of concern for the Board and it is a priority for the Board to help prevent inappropriate prescribing and misuse and abuse of opioids. This bill would conform California law to federal law… and allow NPs and PAs to administer of provide buprenorphine… This expansion seems reasonable and is in line with federal law."

ARGUMENTS IN OPPOSITION:

None on file.

REGISTERED SUPPORT:

California Association for Nurse Practitioners
California Hospital Association
Medical Board of California

REGISTERED OPPOSITION:

None on file.

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