MEDICAL BOARD OF CALIFORNIA - 2018 TRACKER LIST January 10, 2018

BILL	AUTHOR	TITLE	STATUS	POSITION	AMENDED
AB 148	Mathis	California Physician Corps: Practice Setting	Sen. Approps.	Neutral	7/17/17
AB 182	Waldron	Heroin and Opioid Public Education (HOPE) Act	Sen. Approps.	Support	5/26/17
AB 505	Caballero	Physicians and Surgeons: Probation	Sen. B&P	Oppose	3/27/17
AB 820	Gipson	Emergency Medical Services: Transportation Alternatives	Asm. Health	Reco: Oppose	1/3/18
AB 845	Wood	Cannabidiol	Sen. Approps.	Neutral	7/11/17
AB 1204	Mayes	Public Health: Emergency Prescriptions	Asm. Health	Neutral if Amended	3/28/17
AB 1368	Calderon	Health Professionals: Authorization Forms	Sen. Inactive File	Neutral	6/29/17
AB 1512	McCarty	Opioid Addiction Prevention and Rehabilitation Act	Asm. Rev. and Tax	Support if Amended	5/9/17
AB 1560	Friedman	Nurse Practitioners: Certified Nurse- Midwives: Physician Assistants: Supervision	Sen. Inactive File	Oppose Unless Amended	7/3/17
AB 1612	Burke	Certified Nurse-Midwives: Physician Supervision	Asm. Approps.	Oppose Unless Amended	4/18/17
AB 1650	Maienschein	Emergency Medical Services: Community Paramedicine	Asm. Approps.	Oppose	4/20/17
AB 1751	Low	Controlled Substances: CURES Database	Assembly Desk	Reco: Support	1/3/18
AB 1752	Low	Controlled Substances: CURES Database	Assembly Desk		1/3/18
AB 1753	Low	Controlled Substances: CURES Database	Assembly Desk		1/3/18

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SB 457	Bates	Out-of-Hospital Childbirths	Sen. B&P		4/17/17
SB 641	Lara	CURES: Privacy	Asm. Public Safety	Neutral	4/20/17
SB 790	McGuire	Health Care Providers: Gifts and Benefits	Asm. Inactive File	Support	7/6/17

MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

Bill Number: AB 148

Author: Mathis, E. Garcia, Gonzalez Fletcher, Dahle, and Lackey

Bill Date: July 17, 2017, Amended

Subject: California Physician Corps Program: Practice Setting

Sponsor: Author **Position:** Neutral

DESCRIPTION OF CURRENT LEGISLATION:

This bill would revise the definition of "practice setting" for purposes of eligibility under the Physician Corps Loan Repayment Program (Program), which includes the Steven M. Thompson Loan Repayment Program (STLRP) and the Physician Volunteer Program, for community clinics and physician offices by allowing settings to participate in the program if 30% of their patient population qualifies as medically underserved and if the setting is in a rural area. This bill would sunset the revised definition on January 1, 2020. This bill would require the Health Professions Education Foundation (HPEF) to prepare a study and reports to determine the effect this bill has on funding for loan repayments granted during 2018 and 2019.

BACKGROUND:

The STLRP was created in 2002 via legislation which was co-sponsored by the Medical Board of California (Board). The STLRP encourages recently licensed physicians to practice in underserved locations in California by authorizing a plan for repayment of their student loans (up to \$105,000) in exchange for a minimum three years of service in the underserved area. In 2006, the administration of STLRP was transitioned from the Board to HPEF. Since 1990, HPEF has administered statewide scholarship and loan repayment programs for a wide range of health professions' students and recent graduates, these programs are funded through grants and contributions from public and private agencies, hospitals, health plans, foundations, and corporations, as well as through a surcharge on the renewal fees of various health professionals, including a \$25 fee paid by physicians and surgeons.

ANALYSIS

This bill would revise the definition of a practice setting for the purposes of Program eligibility to allow community clinics and physician offices that are in rural areas to be eligible if 30% of their patient population qualifies as medically underserved. This bill would sunset the revised practice setting definition on January 1, 2020. After January 1, 2020, physician offices would also be required to have a minimum of 50 percent of patients who are uninsured, Medi-Cal beneficiaries, or beneficiaries of another publicly funded program that serves patients who earn less than 250 percent of the federal poverty level.

This bill would define a "rural area" as a medical service study area with a population density of fewer than 250 persons per square mile and no population center in excess of 50,000 with in the area, as determined by the Office of Statewide Health Planning and Development.

The current practice setting definition specifies that community clinics and physician offices are eligible for the Program if 50% of their patient population qualifies as medically underserved. This bill only changes the definition for rural areas, all other areas still must meet the 50% threshold in order to be eligible. This bill would also specify that the revised definition only applies to program participants that enroll in the Program on or after January 1, 2018. After January 1, 2020, the practice setting definition would go back to the original practice setting definition, requiring all areas to meet the 50% medically underserved patient population requirement.

This bill would require HPEF to prepare a study to determine the effect of the revised practice setting definition in this bill on funding for loan repayments granted during the calendar years 2018 and 2019. By March 1, 2019, HPEF would be required to submit a report of the study to the Legislature, including program data for calendar year 2018, as compared to program data for calendar years 2016 and 2017. By March 1, 2020, HPEF would be required to submit a report of the study to the Legislature, including program data for calendar year 2019. The reports, at a minimum, would be required to identify all of the following:

- The name and location of all practice settings with program participants, with the practice settings disaggregated by type.
- The number of patients in a practice setting, disaggregated by type of area, including a rural area, among others, and the number of total patients in that practice setting.
- The number and amount of funding for loan repayments granted under the revised definition, disaggregated by type of program participants.

According to the author, rural areas struggle to incentivize quality physicians to take up residency in these areas, and this bill is designed to give rural areas a greater chance to obtain the benefits of the STLRP and recruit physicians to these areas. According to a report submitted by HPEF, only 15 of the total 126 STLRP awardees were in rural areas in 2015/16. Supporters of this bill state that access to high quality health care in rural areas is dependent upon an adequate supply of health care providers and loan repayment programs are a great way to attract high quality physicians with diverse qualifications. This bill has the potential to expand the number of rural practice settings eligible for this Program.

Although the Board supported the bill in 2013 that originally added the 50% medically underserved patient population requirement for practice settings, AB 565 (Salas, Chapter 378), it appears that some rural areas cannot meet this requirement and as a result are not eligible for the Program. This bill will not increase the funding for the Program, but it will expand eligibility for practice settings in rural areas until January 1, 2020, which may help to incentivize physicians to practice in those areas. For this reason, the Board has taken a neutral position on this bill.

FISCAL: None

SUPPORT: Adventist Health; Alliance of Catholic Health Care; Association of

California Healthcare Districts; California Chapters of the American College of Physicians; California Commission on Aging; California Hospital Association; California Medical Association; Loma Linda University Health; Rural County

Representatives of California; and Tenet Healthcare

OPPOSITION: None on file

AMENDED IN SENATE JULY 17, 2017 AMENDED IN SENATE JUNE 26, 2017 AMENDED IN ASSEMBLY MARCH 27, 2017

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

ASSEMBLY BILL

No. 148

Introduced by Assembly Members Mathis, Eduardo Garcia, Gonzalez Fletcher, Dahle, and Lackey (Coauthors: Assembly Members Caballero, Cunningham, Friedman, Gallagher, Waldron, and Wood)

(Coauthors: Senators Berryhill, Fuller, Galgiani, and Mendoza)

January 10, 2017

An act to amend-Section 128552 of Sections 128552 and 128553 of, and to add and repeal Section 128557.5 of, the Health and Safety Code, relating to physicians and surgeons, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 148, as amended, Mathis. California Physician Corps Program: practice setting.

Existing law establishes the Steven M. Thompson Physician Corps Loan Repayment Program (program) in the California Physician Corps Program within the Health Professions Education Foundation, which provides financial incentives, including repayment of educational loans, to a physician and surgeon who practices in a medically underserved area, as defined. Existing law establishes the Medically Underserved Account for Physicians, a continuously appropriated account, within the Health Professions Education Fund, to primarily provide funding for the ongoing operations of the program. Existing law requires the

foundation and the Office of Statewide Health Planning and Development to develop guidelines using specified criteria for selection and placement of applicants.

Existing law defines "practice setting," for these purposes, to include a community clinic, as defined, a clinic owned or operated by a public hospital and health system, or a clinic owned and operated by a hospital that maintains the primary contract with a county government to fulfill the county's role to serve its indigent population, that is located in a medically underserved area and at least 50% of whose patients are from a medically underserved population. Existing law also defines "practice setting," for these purposes, to include a physician owned and operated medical practice setting that provides primary care located in a medically underserved area and has a minimum of 50% of patients who are uninsured, Medi-Cal beneficiaries, or beneficiaries of another publicly funded program that serves patients who earn less than 250% of the federal poverty level.

This bill would instead require, for purposes of this definition, *only until January 1*, 2020, and only for program participants who enroll in the program on or after January 1, 2018, as specified, and before January 1, 2020, that the clinic or the physician owned and operated medical practice setting have at least 30% of patients, if the area is rural, a rural area, as defined, or at least 50% of patients, if the area is urban, not a rural area, who are from the above-described populations. By expanding the authorization for the use of moneys in the Medically Underserved Account for Physicians, this bill would make an appropriation.

This bill would require the foundation to prepare a study to determine the effect that the revised definition has on funding for loan repayment granted under the program during the calendar years 2018 and 2019. The bill would require the foundation to submit 2 reports of the study by March 1, 2019, and March 1, 2020, respectively, including program data for certain years and identifying specified information.

This bill would also make conforming changes to related provisions. Vote: $\frac{2}{3}$. Appropriation: yes. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 128552 of the Health and Safety Code is amended to read:

1 128552. For purposes of this article, the following definitions 2 apply:

- (a) "Account" means the Medically Underserved Account for Physicians established within the Health Professions Education Fund pursuant to this article.
- (b) "Foundation" means the Health Professions Education Foundation.
 - (c) "Fund" means the Health Professions Education Fund.
- (d) "Medi-Cal threshold languages" means primary languages spoken by limited-English-proficient (LEP) population groups meeting a numeric threshold of 3,000, eligible LEP Medi-Cal beneficiaries residing in a county, 1,000 Medi-Cal eligible LEP beneficiaries residing in a single ZIP Code, or 1,500 LEP Medi-Cal beneficiaries residing in two contiguous ZIP Codes.
- (e) "Medically underserved area" means an area defined as a health professional shortage area in Part 5 of Subchapter A of Chapter 1 of Title 42 of the Code of Federal Regulations or an area of the state where unmet priority needs for physicians exist as determined by the California Healthcare Workforce Policy Commission pursuant to Section 128225.
- (f) "Medically underserved population" means the Medi-Cal program, Healthy Families Program, and uninsured populations.
- (g) "Office" means the Office of Statewide Health Planning and Development (OSHPD).
- (h) "Physician Volunteer Program" means the Physician Volunteer Registry Program established by the Medical Board of California.
- (i) "Practice setting," for the purposes of this article only, means either of the following:
- (1) A community clinic as defined in subdivision (a) of Section 1204 and subdivision (c) of Section 1206, a clinic owned or operated by a public hospital and health system, or a clinic owned and operated by a hospital that maintains the primary contract with a county government to fulfill the county's role pursuant to Section 17000 of the Welfare and Institutions Code, which is located in a medically underserved area and meets the following conditions:
- (A) For program participants who enrolled in the program before January 1, 2018, and who continue to participate in the program on or after that date, the clinic has at least 50 percent of patients who are from a medically underserved population.

- (B) For Until January 1, 2020, for program participants who enroll in the program on or after January 1, 2018, and before January 1, 2020, the clinic has at least 30 percent of patients, if the area is rural, a rural area, or at least 50 percent of patients, if the area is rurban, not a rural area, who are from a medically underserved population.
- (C) Commencing January 1, 2020, for program participants who enroll in the program on or after January 1, 2020, and for program participants described in subparagraph (A) or (B), the clinic has at least 50 percent of patients who are from a medically underserved population.
- (2) A physician owned and operated medical practice setting that provides primary care located in a medically underserved area and meets the following conditions:
- (A) For program participants who enrolled in the program before January 1, 2018, and who continue to participate in the program on or after that date, the medical practice setting has a minimum of 50 percent of patients who are uninsured, Medi-Cal beneficiaries, or beneficiaries of another publicly funded program that serves patients who earn less than 250 percent of the federal poverty level.
- (B) For-Until January 1, 2020, for program participants who enroll in the program on or after January 1, 2018, and before January 1, 2020, the medical practice setting has at least 30 percent of patients, if the area is rural, a rural area, or at least 50 percent of patients, if the area is urban, not a rural area, who are uninsured, Medi-Cal beneficiaries, or beneficiaries of another publicly funded program that serves patients who earn less than 250 percent of the federal poverty level.
- (C) Commencing January 1, 2020, for program participants who enroll in the program on or after January 1, 2020, and for program participants described in subparagraph (A) or (B), the medical practice setting has a minimum of 50 percent of patients who are uninsured, Medi-Cal beneficiaries, or beneficiaries of another publicly funded program that serves patients who earn less than 250 percent of the federal poverty level.
- (j) "Primary specialty" means family practice, internal medicine,pediatrics, or obstetrics/gynecology.
- 38 (k) "Program" means the Steven M. Thompson Physician Corps39 Loan Repayment Program.

(l) "Rural area" means a medical service study area with a population density of fewer than 250 persons per square mile and no population center in excess of 50,000 within the area, as determined by the office.

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- (m) "Selection committee" means a minimum three-member committee of the board, that includes a member that was appointed by the Medical Board of California.
- SEC. 2. Section 128553 of the Health and Safety Code is amended to read:
- 128553. (a) Program applicants shall possess a current valid license to practice medicine in this state issued pursuant to Section 2050 of the Business and Professions Code or pursuant to the Osteopathic Act.
- (b) The foundation and the office shall develop guidelines using the criteria specified in subdivision (c) for selection and placement of applicants. The foundation shall interpret the guidelines to apply to both osteopathic and allopathic physicians and surgeons.
 - (c) The guidelines shall meet all of the following criteria:
- (1) Provide priority consideration to applicants that are best suited to meet the cultural and linguistic needs and demands of patients from medically underserved populations and who meet one or more of the following criteria:
 - (A) Speak a Medi-Cal threshold language.
 - (B) Come from an economically disadvantaged background.
- (C) Have received significant training in cultural and linguistically appropriate service delivery.
- (D) Have three years of experience providing health care services to medically underserved populations or in a medically underserved area, as defined in subdivision (e) of Section 128552.
 - (E) Have recently obtained a license to practice medicine.
- (2) Include a process for determining the needs for physician services identified by the practice setting and for ensuring that the practice setting meets the definition specified in subdivision—(h) (i) of Section 128552.
- (3) Give preference to applicants who have completed a three-year residency in a primary specialty.
- (4) Give preference to applicants who agree to practice in a medically underserved area, as defined in subdivision (e) of Section

- 128552, and who agree to serve a medically underserved population.
- (5) Give priority consideration to applicants from rural communities who agree to practice in a physician owned and operated medical practice setting as defined in paragraph (2) of subdivision (i) of Section 128552.
- (6) Include a factor ensuring geographic distribution of placements.
- (7) Provide priority consideration to applicants who agree to practice in a geriatric care setting and are trained in geriatrics, and who can meet the cultural and linguistic needs and demands of a diverse population of older Californians. On and after January 1, 2009, up to 15 percent of the funds collected pursuant to Section 2436.5 of the Business and Professions Code shall be dedicated to loan assistance for physicians and surgeons who agree to practice in geriatric care settings or settings that primarily serve adults over the age of 65 years or adults with disabilities.
- (d) (1) The foundation may appoint a selection committee that provides policy direction and guidance over the program and that complies with the requirements of subdivision—(l) (m) of Section 128552.
- (2) The selection committee may fill up to 20 percent of the available positions with program applicants from specialties outside of the primary care specialties.
- (e) Program participants shall meet all of the following requirements:
- (1) Shall be working in *in*, or have a signed agreement with with, an eligible practice setting.
- (2) Shall have full-time status at the practice setting. Full-time status shall be defined by the board and the selection committee may establish exemptions from this requirement on a case-by-case basis.
- (3) Shall commit to a minimum of three years of service in a medically underserved area. Leaves of absence shall be permitted for serious illness, pregnancy, or other natural causes. The selection committee shall develop the process for determining the maximum permissible length of an absence and the process for reinstatement.
- Loan repayment shall be deferred until the physician is back to
- 39 full-time status.

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- (f) The office shall adopt a process that applies if a physician is unable to complete his or her three-year obligation.
- (g) The foundation, in consultation with those identified in subdivision (b) of Section 128551, shall develop a process for outreach to potentially eligible applicants.
- (h) The foundation may recommend to the office any other standards of eligibility, placement, and termination appropriate to achieve the aim of providing competent health care services in approved practice settings.
- SEC. 3. Section 128557.5 is added to the Health and Safety Code, to read:
- 128557.5. (a) The foundation shall prepare a study to determine the effect that subparagraph (B) of paragraph (1) of, and subparagraph (B) of paragraph (2) of, subdivision (i) of Section 128552 have on funding for loan repayment granted under this article during the calendar years 2018 and 2019.
- (b) (1) (A) By March 1, 2019, the foundation shall submit a report of the study described in subdivision (a) to the Legislature, including program data for the calendar year 2018 as compared to program data for the calendar years 2016 and 2017.
- (B) By March 1, 2020, the foundation shall submit a report of the study described in subdivision (a) to the Legislature, including program data for the calendar year 2019.
- (2) At a minimum, the reports described in paragraph (1) shall identify all of the following:
- (A) The name and location of all practice settings with program participants, with the practice settings disaggregated by type as defined in paragraphs (1) and (2) of subdivision (i) of Section 128552.
- (B) The number of patients described in subparagraph (B) of paragraph (1) of, or subparagraph (B) of paragraph (2) of, subdivision (i) of Section 128552 in a practice setting, disaggregated by type of area, including a rural area, among others, and the number of total patients in that practice setting.
- (C) The number and amount of funding for loan repayment granted under this article, disaggregated by type of program participants as described in paragraphs (1) and (2) of subdivision (i) of Section 128552.

- 1 (c) A report submitted pursuant to subdivision (b) shall be 2 submitted in compliance with Section 9795 of the Government 3 Code.
- 4 (d) Pursuant to Section 10231.5 of the Government Code, this section shall become inoperative on March 1, 2024, and shall be repealed on January 1, 2025.

MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

Bill Number: AB 182 **Author:** Waldron

Bill Date: May 26, 2017, Amended

Subject: Heroin and Opioid Public Education Act

Sponsor: Author **Position:** Support

DESCRIPTION OF CURRENT LEGISLATION:

This bill would require the California Department of Public Health (CDPH), upon appropriation by the Legislature or receipt of adequate state or federal grant funding, to develop, coordinate, implement and oversee a comprehensive multicultural public awareness campaign, to be known as the Heroin and Opioid Public Education (HOPE) Program, to combat the growing heroin and opioid medication epidemic in California. This bill would sunset the HOPE Program on January 1, 2023.

BACKGROUND:

In 2010, approximately 38,329 unintentional drug overdose deaths occurred in the United States, one death every 14 minutes. Of this number, 22,134 of these deaths were attributed to prescription drugs (16,651 or 75.2% attributed to opioid overdoses). Prescription drug abuse is the fastest growing drug problem in the United States.

According to the California Department of Public Health (CDPH), 2,024 deaths related to pharmaceutical opioids occurred in California in 2014; 4,106 non-fatal ED visits related to all opioids in the same timeframe; 4,482 opioid related hospitalizations in the same timeframe; and 619 opioids were prescribed per 1,000 residents in 2015.

According to the Centers for Disease Control, every day, 44 people in the U.S. die from overdose of prescription painkillers and many more become addicted.

The Medical Board of California (Board) developed a Prescribing Task Force that held multiple meetings to identify best practices, hear from speakers regarding this issue, and update the Board's Guidelines for Prescribing Controlled Substances for Pain. This task force had numerous meetings with interested parties and discussions with experts in the field of pain management to develop this document, which was adopted by the Board in November 2014. These Guidelines are intended to educate physicians on effective pain management in California by avoiding under treatment, overtreatment, or other inappropriate treatment of a patient's pain. The Guidelines' primary objective is improved patient outcomes and reduction of prescription overdose deaths. The Guidelines contain a significant amount of information and are supplemented with as many resources as practical via the appendices and links to websites that further assist a physician when prescribing controlled substances for pain. The Guidelines discuss several areas, including understanding pain, special patient populations, patient evaluation and risk stratification, consultation, treatment plan and objectives, patient

consent, pain management agreements, counseling patient on overdose risk and response, initiating an opioid trial, ongoing patient assessment, and several other areas.

In 2014, the Director of CDPH launched a state agency Prescription Opioid Misuse and Overdose Prevention Workgroup (Workgroup) to share information and develop collaborative strategies to curb prescription drug misuse, abuse, and overdose deaths in California. The Workgroup started as a multi-sector group consisting of more than 10 state agencies, including CDPH, Department of Justice, DHCS, Department of Managed Health Care, Department of Education, Department of Industrial Relations, Department of Corrections and Rehabilitation, Department of Consumer Affairs (including the Board, Dental Board of California, Board of Pharmacy, and Board of Registered Nursing), Emergency Medical Services Authority, and others. The Workgroup initially commenced a multi-phase plan involving enhancement of the state's Prescription Drug Monitoring Program (PDMP), promoting the release and adoption of the Board's revised Guidelines for Prescribing Controlled Substances for Pain, and development of a comprehensive public education campaign to increase public awareness about the potential dangers of opioid medications and to create better understanding and expectations among the public regarding proper prescribing, use, storage and disposal of opioids.

ANALYSIS

This bill makes findings and declarations regarding the epidemic in California stemming from the use of heroin and the abuse of opioid medications and the need for awareness and dissemination of information. This bill would require CDPH, upon appropriation by the Legislature or receipt of adequate state or federal grant funding, to develop, coordinate, implement and oversee a comprehensive multicultural public awareness campaign, to be known as the HOPE Program, to combat the growing heroin and opioid medication epidemic in California. This bill would sunset the HOPE Program on January 1, 2023.

This bill would require the HOPE Program to provide for the coordinated and widespread public dissemination of individual case stories and other generalized information using appropriate types of media, including new technologies in media, print media, television and radio, and Internet and social media. This dissemination of information shall focus on the following:

- Identifying the pathways that can lead to opioid medication abuse and heroin use.
- Showing the many faces of addiction and rebutting the commonly accepted myths and stereotypes about heroin users and opioid medication abusers.
- Educating the public on the negative impact of abuse and diversion of opioid medication, while recognizing the legitimate use of opioids.
- Describing the effects and warning signs of heroin use and opioid medication abuse to enable members of the public to know when help is needed.
- Showing the link that exits between heroin and opioid medication addiction and suicidal behavior.

- Identifying pathways that are available for individuals to seek help, and indicating telephone hotline systems for persons who wish to report cases of drug abuse or engage in substance abuse treatment.
- Highlighting the availability of naloxone hydrochloride as a means to avert death from a heroin or opioid medication overdose, identifying pathways for members of the public to obtain naloxone and training, and promoting the proper use of naloxone.
- Highlighting the benefits of substance abuse treatment.
- Highlighting the benefits of medication-assisted therapy using medications approved by the federal Food and Drug Administration, such as methadone, buprenorphine, extended-release injectable naltrexone, or other similar drugs, and destignatizing the use of the medication-assisted therapy.
- Identifying the methods that can be used by an individual to help finance the costs of substance abuse treatment.
- Identifying the steps that individuals can take to prevent and deter others from misusing opioid medications.
- Identifying the proper methods for safeguarding and disposing of opioid medications.
- Addressing any other issue that CDPH may deem appropriate and necessary to proactively educate the public about the state's heroin or opioid medication addition.

In disseminating this information, the HOPE program shall employ a variety of complementary educational themes and messages that shall be tailored to appeal to different target audiences. At a minimum, the HOPE program shall incorporate all of the following:

- At least one message directed at individuals who are personally at risk of heroin use or opioid medication abuse or who have already started down a pathway of addiction.
- At least one message directed at family members and friends of addicted persons, teachers, school nurses, medical practitioners, and employers.
- At least on message that is directed at the dangers of teen drug pilfering from the household medicine cabinet and how this could be avoided through the use of safe storage products.

This bill would require information under the HOPE Program to be disseminated using culturally and linguistically appropriate means, and when feasible and appropriate, the information shall be made available in a variety of languages.

This bill would allow CDPH to enter into public-private partnerships with pharmaceutical or health care insurance companies, nonprofit social services organizations, mental health service providers and clinics, law enforcement, health care agencies, and school districts, that provide services in the state in order to facilitate the dissemination of information under the HOPE Program.

This bill would require CDPH to submit a report to the Governor and the Legislature on at least an annual basis that summarizes the actions undertaken by CDPH to implement

this bill and to include an assessment of the effectiveness of the HOPE Program, including, but not limited to, effects on the rate of new opioid and heroin addictions by populations, mitigation of the effects of opioid or heroin addiction, crime rates, hospitalization rates, death rates, and other calculable results as determined by CDPH. The report shall provide any recommendations for legislative or executive action that may be necessary to facilitate the ongoing success of the HOPE Program.

According to the author, there is an epidemic in California of heroin use stemming from the abuse of opioid medications and this epidemic demands our attention. The author believes that in order for California to combat this epidemic, citizens must be armed with information that will allow them to recognize and undertake appropriate actions when they or their loved ones are at risk of succumbing to a heroin or opioid medication addiction.

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 will increase awareness and provide education to help prevent heroin use and opioid medication abuse. This bill furthers the Board's mission of consumer protection; as such, the Board supports this bill.

FISCAL: None to the Board

SUPPORT: American Academy of Pediatrics, California

Biocom

California Police Chiefs Association

California State Parent Teacher Association California Special Districts Association

Gatekeeper Innovation

OPPOSITION: None on file

POSITION: Recommendation: Support

AMENDED IN ASSEMBLY MAY 26, 2017 AMENDED IN ASSEMBLY MARCH 23, 2017 AMENDED IN ASSEMBLY MARCH 9, 2017

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

ASSEMBLY BILL

No. 182

Introduced by Assembly Member Waldron (Coauthors: Assembly Members Baker, Mayes, and Wood) (Coauthors: Senators Bates and Glazer)

January 19, 2017

An act to add *and repeal* Article 5 (commencing with Section 11774) to of Chapter 1 of Part 2 of Division 10.5 of the Health and Safety Code, relating to drug abuse.

LEGISLATIVE COUNSEL'S DIGEST

AB 182, as amended, Waldron. Heroin and Opioid Public Education (HOPE) Act.

Existing law vests the State Department of Health Care Services with duties, powers, purposes, functions, responsibilities, and jurisdiction of alcohol and drug programs in the state, including narcotic treatment programs that use narcotic replacement therapy for maintenance or detoxification of opioid medication dependence. Existing law requires the department to develop and implement a statewide prevention campaign designed to deter the abuse of methamphetamine in California, and authorizes the department to develop and implement a mass medical alcohol and other drug education program in order to provide community education, develop public awareness, and motivate community action in alcohol and other drug abuse prevention, treatment, and rehabilitation.

AB 182 -2-

Existing law tasks the State Department of Public Health with certain specified duties related to health information and strategic planning, including opioid misuse and overdose prevention. Among other duties, existing law directs the department, upon appropriation by the Legislature, to award naloxone grant funding to local health departments, local government agencies, or other entities, as specified, in order to reduce the rate of fatal overdose from opioid drugs including heroin and prescription opioids.

This bill would require the department, in consultation with stakeholders, to develop, coordinate, implement, and oversee a comprehensive multicultural public awareness campaign, to be known as "Heroin and Opioid Public Education-(HOPE)." (HOPE)," upon appropriation by the Legislature or receipt of state or federal grant funding, until January 1, 2023. The bill would require the HOPE program to provide for the coordinated and widespread public dissemination of individual case stories and other generalized information that is designed to, focuses on, among other things, describe describing the effects and warning signs of heroin use and opioid medication abuse, so as to better enable members of the public to determine when help is needed and identify the and identifying available pathways-that are available for individuals-to-seek seeking help. The bill would require the HOPE program to effectuate the dissemination of information by using appropriate types of media, as specified, employing a variety of complementary educational themes and messages that are tailored to appeal to different target audiences, and using culturally and linguistically appropriate means.

The bill would require the department to submit a report to the Governor and Legislature on at least an annual basis, that summarizes the actions that have been undertaken by the department to implement the bill and includes an assessment of the effectiveness of the HOPE program, as specified.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. This act shall be known, and may be cited, as the 2 "HOPE Act."

-3- AB 182

SEC. 2. Article 5 (commencing with Section 11774) is added to Chapter 1 of Part 2 of Division 10.5 of the Health and Safety Code, to read:

Article 5. Heroin and Opioid Public Education (HOPE)

- 11774. The Legislature finds and declares all of the following:
- (a) There is an epidemic in this state stemming from the use of heroin and the abuse of opioid medications.
- (b) Prescription drug overdoses now kill more people than car accidents.
- (c) Every day, 2,500 children 12 to 17, inclusive, years of age abuse a prescription painkiller for the first time, and more people are becoming addicted to prescription drugs.
- (d) Data from the federal Centers for Disease Control and Prevention suggests that the nonmedical use of prescription painkillers costs public and private health insurers seventy-two billion eight hundred million dollars (\$72,800,000,000) annually.

(b)

(e) In order for the state to combat this epidemic, citizens in all walks of life shall be alerted to the problem, and shall be armed with information that will allow them to recognize, and undertake appropriate actions, when they or their loved ones are at risk of, or are succumbing to, a heroin or opioid medication addiction.

(e)

- (f) The widespread dissemination of information necessary to combat the state's heroin and opioid medication epidemic could be successfully achieved through the institution and maintenance of a multicultural statewide public awareness campaign, which would be carefully coordinated through all available multimedia channels to reach a wide variety of audiences, including drug users, their family members and friends, medical practitioners and nurses, emergency personnel, and employers.
- (d) Prescription drug overdoses now kill more people than ear accidents.
- (e) Every day, 2,500 children 12 to 17 years of age abuse a prescription painkiller for the first time, and more people are becoming addicted to prescription drugs.
- (f) Data from the federal Centers for Disease Control and Prevention suggests that the nonmedical use of prescription

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painkillers costs public and private health insurers seventy-two billion eight hundred million dollars (\$72,800,000,000) annually.

- (g) As abuse rates have risen, the functions of the State Department of Alcohol and Drug Programs have been transferred to the State Department of Health Care Services.
- (h) In order to be more successful in combating drug abuse, while addressing the current opioid and heroin epidemie, the department's current public awareness campaign is being used to combat the state's growing heroin and opioid medication epidemic shall be designed to do all of the following:
- (1) Educate the public as to the reasons why ordinary people may engage in the abuse of opioid medications and the associated use of heroin.
- (2) Rebut the commonly accepted myths and stereotypes associated with heroin use and opioid medication abuse.
- (3) Stigmatize and condemn the abuse and diversion of opioid medication, while still recognizing the legitimate use of those opioid drugs as medications.
- 11774.1. (a) The department, The State Department of Public Health, upon appropriation by the Legislature or receipt of adequate state or federal grant funding, and in consultation with stakeholders, as appropriate, shall develop, coordinate, implement, and oversee a comprehensive multicultural public awareness campaign, to be known as "Heroin and Opioid Public Education (HOPE)," which shall allow for the coordinated and widespread dissemination of information designed to combat the growing heroin and opioid medication epidemic in the state.
- (b) Using the means described in subdivision (c), HOPE shall provide for the coordinated and widespread public dissemination of individual case stories and other generalized information that is designed to do all focuses on any of the following:
- (1) Identify-Identifying the pathways that can lead to opioid medication abuse and heroin use, and the reasons why opioid medication abuse may evolve into heroin use.
- (2) Show Showing the many faces of heroin and opioid medication addiction, and rebut rebutting the commonly accepted myths and stereotypes about heroin users and opioid medication abusers.
- (3) Condemn and stigmatize Educating the public on the 40 negative impact of abuse and diversion of opioid medication, while

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recognizing the legitimate use of those same opioid drugs as medications.

- (4) Describe Describing the effects and warning signs of heroin use and opioid medication abuse, so as to better enable members of the public to determine when help is needed.
- (5) Show Showing the link that exists between heroin and opioid medication addiction and suicidal behavior.
- (6) Identify—Identifying the pathways that are available for individuals to seek help in association with their own, or another person's, heroin or opioid medication addiction, and—indicate indicating the various telephone hotline systems that exist in the state for persons who wish to report a case of drug abuse or engage in substance abuse treatment.
- (7) Highlight—Highlighting the availability of naloxone hydrochloride as a means to avert death from a heroin or opioid medication overdose, identify identifying pathways for members of the public to obtain a prescription for naloxone hydrochloride and training in the emergency administration of naloxone hydrochloride, and promote promoting the proper use of naloxone hydrochloride in crisis situations.
- (8) Highlight–Highlighting the benefits of substance abuse treatment and the potential for treatment to allow for the reclaiming of lives that have been upset by addiction, and—underscore underscoring the fact that relapses occur not because treatment is ineffective, but because of the nature of addiction, which is a recurring and relapsing disorder.
- (9) Highlight-Highlighting the benefits of medication-assisted therapy using medications approved by the federal Food and Drug Administration, such as methadone, buprenorphine, extended-release injectable naltrexone, or other similar drugs, and destigmatize destigmatizing the use of that medication-assisted therapy.
- (10) <u>Identify-Identifying</u> the methods that can be used by an individual to help finance the costs of substance abuse treatment.
- (11) Identify-Identifying the steps that individuals can take to prevent and deter family members, friends, students, patients, coworkers, and others from first experimenting with inappropriately obtained opioid medications, and from misusing or mismanaging lawful opioid medications.

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(12) <u>Identify Identifying</u> the proper methods for safeguarding, and for safely disposing of, legitimate opioid medications.

- (13) Address Addressing any other issues that the department may deem appropriate and necessary to proactively educate the public about the state's heroin and opioid medication epidemic and the actions that can be taken by members of the public to reduce the likelihood of heroin or opioid medication addiction, or to otherwise respond to, or mitigate the effects of, heroin or opioid medication addiction in cases in which it is present.
- (c) (1) The HOPE program shall effectuate the dissemination of information described in subdivision (b) by using appropriate types of media to achieve the goal efficiently and effectively, including new technologies in media, print media, television and radio, *and* Internet and social media.
- (2) In disseminating the information described in subdivision (b), the HOPE program shall employ a variety of complementary educational themes and messages that shall be tailored to appeal to different target audiences in the state. At a minimum, the HOPE program shall incorporate all of the following:
- (A) At least one message that is directed at, and is tailored to influence and resonate with, individuals who are personally at risk of heroin use or opioid medication abuse or who have already started down a pathway to addiction.
- (B) At least one message that is directed at, and is tailored to influence and resonate with, the family members and friends of addicted persons, teachers, school nurses, medical practitioners, and employers.
- (C) At least one message that is directed at the dangers of teen drug pilfering from the household medicine cabinet and how this could be avoided through the use of safe storage products.
- (3) Information under the HOPE program shall be disseminated using culturally and linguistically appropriate means, in a manner that demonstrates respect for individual dignity and cultural differences. Where feasible and appropriate, the information shall be made available in a variety of languages.
- (4) The department may enter into public-private partnerships with pharmaceutical or health care insurance companies, nonprofit social services organizations, mental health services providers and clinics, law enforcement, health care agencies, and school districts,

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that provide services in the state in order to facilitate the dissemination of information under the HOPE program.

- 11774.2. (a) The department shall submit to the Governor and the Legislature on at least an annual basis, a report that summarizes the actions that have been undertaken by the department to implement this article and includes an assessment of the effectiveness of the program, including, but not limited to, effects on the rate of new opioid and heroin addictions by populations, mitigation of the effects of opioid or heroin addiction, crime rates, hospitalization rates, death rates, and other calculable results as determined by the department. The report shall provide any recommendations for legislative or executive action that may be necessary to facilitate the ongoing success of the program.
- (b) A report to be submitted to the Legislature pursuant to this section shall be submitted in compliance with Section 9795 of the Government Code.
- 11774.3. The department may adopt regulations in accordance with the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) as necessary to implement this article.
- 11774.4. This article shall remain in effect only until January 1, 2023, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2023, deletes or extends that date.

MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

Bill Number: AB 505 **Author:** Caballero

Bill Date: March 27, 2017, Amended

Subject: Physicians and Surgeons: Probation **Sponsor:** California Medical Association

Position: Oppose

DESCRIPTION OF CURRENT LEGISLATION:

This bill would prohibit the Medical Board of California (Board) from entering into a stipulation for disciplinary action if the stipulation places a licensee on probation and the operative accusation includes specified charges.

BACKGROUND:

The Board uses its Manual of Model Disciplinary Orders and Disciplinary Guidelines (Disciplinary Guidelines) (16 CCR section 1361) and the Uniform Standards for Substance-Abusing Licensees (Uniform Standards) (16 CCR section 1361.5) as the framework for determining the appropriate penalty for charges filed against a physician. Business and Professions (B&P) Code section 2229 identifies that protection of the public shall be the highest priority for the Board, but also requires that wherever possible, the actions should be calculated to aid in the rehabilitation of the licensee. While the Disciplinary Guidelines and Uniform Standards frame the recommended penalty, the facts of each individual case may support a deviation from the guidelines. After the filing of an accusation and/or petition to revoke probation, a respondent physician must file a notice of defense within 15 days indicating they intend to present a defense to the accusation and/or petition to revoke probation or that they are interested in a settlement agreement. If the individual requests a hearing, existing law (Government Code sections 11511.5 and 11511.7) requires that a prehearing conference be held to explore settlement possibilities and prepare stipulations, as well as schedule a mandatory settlement conference, in an attempt to resolve the case through a stipulated settlement before proceeding to the administrative hearing.

The assigned deputy attorney general (DAG) reviews the case, any mitigation provided, the strengths and weaknesses of the case, the Board's Disciplinary Guidelines, and, when applicable, any prior disciplinary action against the respondent physician, and drafts a settlement recommendation that frames the recommended penalty. In addition, this settlement recommendation takes into account consumer protection and B&P Code section 2229(b). The DAG's recommendation is then reviewed and either approved or edited by the supervising DAG. Once that approval is received, the DAG submits the settlement recommendation to the Board's Executive Director for review and consideration.

The Board's Executive Director reviews the settlement recommendation using the same criteria as the DAG and either approves or changes the settlement recommendation. The

DAG then negotiates with the respondent physician and/or their counsel to settle the case with the recommended penalty. Both the prehearing settlement conference and the mandatory settlement conference have the assistance of an administrative law judge (ALJ). This ALJ reviews the case and hears information from the DAG and the respondent physician and/or their counsel and then assists in negotiating the settlement. During the settlement conference, the Board representative must be available to authorize any change to the previously agreed settlement recommendation.

If a settlement agreement is reached, the stipulated settlement document must be approved by a panel of the Board, unless the settlement is for a stipulated surrender. The Board then has the ability to adopt the settlement as written, request changes to the settlement, or request the matter go to hearing. In the process to settle a case, public protection is the first priority, and must be weighed with rehabilitation of the physician. When making a decision on a stipulation, the panel members are provided the strengths and weaknesses of the case, and weigh all factors.

ANALYSIS

This bill would prohibit the Board from entering into a stipulation for disciplinary action if the stipulation places a licensee on probation and the operative accusation includes any of the following:

- Felony conviction involving harm to patient safety or health.
- Drug or alcohol abuse directly resulting in harm to patient safety or health.
- Sexual act or sexual exploitation as defined in Section 726 and subdivision (a) of Section 729.

Any settlement recommendation stipulated to by the Board must provide an appropriate level of public protection and rehabilitation. Settling cases by stipulations that are agreed to by both sides facilitates consumer protection by rehabilitating the physician in a more expeditious manner. By entering into a stipulation, it puts the individual on probation or restriction sooner and the public is able to see the action taken by the Board more timely than if the matter went to hearing. In addition, the Board may get more terms and conditions through the settlement process than would have been achieved if the matter went to hearing.

If the Board is required to go to hearing for certain cases, there will be a significant fiscal impact to the Board and it will also significantly increase the Board's enforcement timelines. This bill will not enhance consumer protection, as it will result in physicians practicing longer with no monitoring or restrictions by the Board. The Board's primary mission is consumer protection and this bill does not further that mission, as such, the Board opposes this bill.

FISCAL:

Using the categories specified in this bill and comparing them to the categories of discipline in the Board's 15/16 Annual Report, minus the number of proposed decisions in that same time frame with the same categories, Board staff estimates that 95 cases will not be allowed to settle and will have to go to hearing. It is important to note that the Board had to use all cases in those

categories, as the Board will not know beforehand which cases will have the disciplinary outcome of probation. In the probation notification bill from last year, Board staff estimated the cost of going to hearing at \$35,000 per case. With the estimated 95 cases, times the hearing cost, this would result in a cost of \$3,325,000 to the Board. It is possible that a fee increase may be needed if this bill were to be enacted. The Board would have to contract for a fee audit to confirm any possible fee increase.

SUPPORT: California Medical Association (Sponsor)

OPPOSITION: Medical Board of California

AMENDED IN ASSEMBLY MARCH 27, 2017

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

ASSEMBLY BILL

No. 505

Introduced by Assembly Member Caballero

February 13, 2017

An act to add Section 2227.1 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 505, as amended, Caballero. Physicians and surgeons: probation. Under existing law, a physician and surgeon whose matter has been heard by an administrative law judge, or whose default has been entered, and who is found guilty, or who has entered into a stipulation for disciplinary action with the Medical Board of California, is authorized to be subject to, among other things, license revocation, suspension, or probation, as specified. Existing law authorizes the board to discipline a licensee by placing him or her on probation subject to specified conditions.

This bill would prohibit the board from entering into any stipulation for disciplinary action, including placing action if the stipulation places a licensee on probation, if probation and the operative accusation includes specified acts.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 2227.1 is added to the Business and
- 2 Professions Code, to read:

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2227.1. Notwithstanding Sections 2227 and 2228, the board may not enter into any stipulation for disciplinary-action, which includes placing action if the stipulation places a licensee on probation, if probation and the operative accusation includes any of the following:

- (a) Felony conviction involving harm to patient safety or health.
- 7 (b) Drug or alcohol abuse directly resulting in harm to patient 8 safety or health.
 - (c) Sexual act or sexual exploitation as defined in Section 726 and subdivision (a) of Section 729.

MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

Bill Number: AB 820 **Author:** Gipson

Bill Date: January 3, 2018, Amended

Subject:Emergency Medical Services: Transportation AlternativesSponsorLos Angeles County and California Hospital Association

DESCRIPTION OF LEGISLATION:

This bill would allow an emergency medical technician-paramedic (EMT-P) to make a determination at the scene of an emergency to transport the patient to a community care facility or a general acute care hospital (GACH), pursuant to an approved local emergency medical services (EMS) agencies' plan.

BACKGROUND

Under existing law, a paramedic is limited to providing care in emergency situations, during ambulance transports, and while working in a hospital. Beginning in late 2014, thirteen community paramedicine pilot projects began in California, testing six concepts as part of the Health Workforce Pilot Project (HWPP) #173. These HWPP pilot projects are coordinated through the Office of Statewide Health Planning and Development (OSHPD). This bill would authorize one of the original six concepts allowed for in the pilot project.

Board staff, working with a physician Board Member, provided input to OSHPD on HWPP #173 and raised patient safety concerns. One of the concerns raised was related to the transport of a patient to an alternate location, other than a GACH emergency department.

ANALYSIS

This bill would include in the definition of advanced life support, which an EMT-P is authorized to provide, determining transport at the scene of an emergency to a community care facility or an acute care hospital. If transport to a community care facility is determined, the approved local EMS plan must be followed.

This bill would define a community care facility as a mental health urgent care center or sobering center, which is staffed with medical personnel designated by a local EMS agency, as part of an approved local EMS plan.

This bill would allow a local EMS agency to submit, as part of its EMS plan, a plan to transport patients to a community care facility that is not a GACH, based on a determination by an EMT-P that there is no need for emergency health care. This bill would require the plan to

include, without limitation, all of the following:

- Criteria for designating a facility as a community care facility, including appropriate medical staffing and administrative medical oversight, such as a medical director.
- One or more policies for prompt evaluation and treatment of patients within a facility.
- A communication plan between prehospital medical personnel.
- A secondary transport to include criteria for contacting the jurisdictional prehospital provider for transport to an emergency department of a GACH.
- Medical equipment and monitoring protocols.
- Required submission of a quality improvement plan and patient outcome data to the local EMS agency.
- Additional education requirement for paramedics.
- Protocols for handling patient destination considerations, including requests by patients.

This bill would require the Emergency Medical Services Authority to authorize a local EMS agency to add to its scope of practice for an EMT-P those activities necessary for the assessment, treatment, and transport of a patient to a community care facility, upon approval of a plan to transport patient to a community care facility.

As previously stated, Board staff consulted with a physician Board Member and provided input to OSHPD on HWPP #173 and raised patient safety concerns. One of the concerns raised was related to the transport of a patient to an alternate location other than a GACH emergency department. The Board was concerned that transport of a patient to an alternate location other than a GACH emergency department carries the risk of a patient being transported to a facility that is not appropriate to meet the patient's needs, especially in cases where presenting signs and symptoms of life-threatening illnesses may be subtle. In such cases, failure to have transported that patient to a GACH emergency department may jeopardize that patient's well-being and survival. This concern is still relevant to this bill and Board staff recommends that the Board take an oppose position on this bill.

FISCAL: None

SUPPORT: California Hospital Association (Co-Sponsor)

Los Angeles County (Co-Sponsor)

OPPOSITION: American College of Emergency Physicians

California Nurses Association

POSITION: Recommendation: Oppose

AMENDED IN ASSEMBLY JANUARY 3, 2018 AMENDED IN ASSEMBLY MARCH 23, 2017

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

ASSEMBLY BILL

No. 820

Introduced by Assembly Member Gipson

February 15, 2017

An act to add Section 1797.119 to amend Sections 1797.52, 1797.172, and 1797.218 of, and to add Sections 1797.98 and 1797.260 to, the Health and Safety Code, relating to emergency medical services.

LEGISLATIVE COUNSEL'S DIGEST

AB 820, as amended, Gipson. Emergency Medical—Services Authority: task force: Services: transportation alternatives.

Existing law, the Emergency Medical Services System and the Prehospital Emergency Medical Care Personnel Act, governs local emergency medical services (EMS) systems. The aet establishes the Emergency Medical Services Authority, which is responsible for the coordination and integration of all state agencies concerning emergency medical services.

This bill would authorize the authority to establish a task force, as provided, to develop a report evaluating alternative destinations to a general acute care hospital for first responders to transport a patient who may be a danger to himself, herself, or others or gravely disabled as a result of a mental health disorder. The bill would require the report to be published on the authority's Internet Web site. a local emergency medical services agency to transport specified patients to a community care facility, as defined, in lieu of transportation to a general acute care hospital.

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Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1797.52 of the Health and Safety Code 2 is amended to read:

3 1797.52. "Advanced life support" means special services 4 designed to provide definitive prehospital emergency medical care, 5 including, but not limited to, cardiopulmonary resuscitation, cardiac monitoring, cardiac defibrillation, advanced airway management, intravenous therapy, administration of specified drugs and other medicinal preparations, and other specified techniques and 9 procedures administered by authorized personnel under the direct 10 supervision of a base hospital as part of a local EMS system at the scene of an emergency, during transport to an acute care hospital, 11 12 during interfacility transfer, and while in the emergency department 13 of an acute care hospital until responsibility is assumed by the 14 emergency or other medical staff of that hospital. hospital, and at the scene of an emergency for the purpose of determining transport 15 16 to a community care facility or an acute care hospital, and during 17 transport to a community care facility as part of an approved local 18 EMS agency emergency medical services plan. 19

SEC. 2. Section 1797.98 is added to the Health and Safety Code, to read:

1797.98. "Community care facility" means a mental health urgent care center or sobering center staffed with medical personnel that is designated by a local EMS agency, as part of an approved local emergency medical services plan.

SEC. 3. Section 1797.172 of the Health and Safety Code is amended to read:

1797.172. (a) The authority shall develop and, after approval by the commission pursuant to Section 1799.50, adopt minimum standards for the training and scope of practice for EMT-P.

(b) The approval of the director, in consultation with a committee of local EMS medical directors named by the EMS Medical Directors Association of California, is required prior to implementation of any addition to a local optional scope of practice for EMT-Ps proposed by the medical director of a local EMS agency.

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(c) Notwithstanding any other provision of law, the authority shall be the agency solely responsible for licensure and licensure renewal of EMT-Ps who meet the standards and are not precluded from licensure because of any of the reasons listed in subdivision (d) of Section 1798.200. Each application for licensure or licensure renewal shall require the applicant's social security number in order to establish the identity of the applicant. The information obtained as a result of a state and federal level criminal offender record information search shall be used in accordance with Section 11105 of the Penal Code, and to determine whether the applicant is subject to denial of licensure or licensure renewal pursuant to this division. Submission of fingerprint images to the Department of Justice may not be required for licensure renewal upon determination by the authority that fingerprint images have previously been submitted to the Department of Justice during initial licensure, or a previous licensure renewal, provided that the license has not lapsed and the applicant has resided continuously in the state since the initial licensure.

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- (d) The authority shall charge fees for the licensure and licensure renewal of EMT-Ps in an amount sufficient to support the authority's licensure program at a level that ensures the qualifications of the individuals licensed to provide quality care. The basic fee for licensure or licensure renewal of an EMT-P shall not exceed one hundred twenty-five dollars (\$125) until the adoption of regulations that specify a different amount that does not exceed the authority's EMT-P licensure, license renewal, and enforcement programs. The authority shall annually evaluate fees to determine if the fee is sufficient to fund the actual costs of the authority's licensure, licensure renewal, and enforcement programs. If the evaluation shows that the fees are excessive or are insufficient to fund the actual costs of the authority's EMT-P licensure, licensure renewal, and enforcement programs, then the fees shall be adjusted accordingly through the rulemaking process described in the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code). Separate additional fees may be charged, at the option of the authority, for services that are not shared by all applicants for licensure and licensure renewal, including, but not limited to, any of the following services:
 - (1) Initial application for licensure as an EMT-P.

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(2) Competency testing, the fee for which shall not exceed thirty dollars (\$30), except that an additional fee may be charged for the cost of any services that provide enhanced availability of the exam for the convenience of the EMT-P, such as on-demand electronic testing.

- (3) Fingerprint and criminal record check. The applicant shall, if applicable according to subdivision (c), submit fingerprint images and related information for criminal offender record information searches with the Department of Justice and the Federal Bureau of Investigation.
 - (4) Out-of-state training equivalency determination.
 - (5) Verification of continuing education for a lapse in licensure.
- (6) Replacement of a lost licensure card. The fees charged for individual services shall be set so that the total fees charged to EMT-Ps shall not exceed the authority's actual total cost for the EMT-P licensure program.
- (e) The authority may provide nonconfidential, nonpersonal information relating to EMS programs to interested persons upon request, and may establish and assess fees for the provision of this information. These fees shall not exceed the costs of providing the information.
- (f) At the option of the authority, fees may be collected for the authority by an entity that contracts with the authority to provide any of the services associated with the EMT-P program. All fees collected for the authority in a calendar month by any entity designated by the authority pursuant to this section to collect fees for the authority shall be transmitted to the authority for deposit into the Emergency Medical Services Personnel Fund within 30 calendar days following the last day of the calendar month in which the fees were received by the designated entity, unless the contract between the entity and the authority specifies a different timeframe.
- (g) Upon approval of a plan to transport patients to a community care facility submitted pursuant to Section 1797.260, the authority shall authorize a local EMS agency to add to its scope of practice for an EMT-P those activities necessary for the assessment, treatment, and transport of a patient to a community care facility.
- SEC. 4. Section 1797.218 of the Health and Safety Code is amended to read:
- 39 1797.218. Any local EMS agency may authorize an advanced 40 life support or limited advanced life support program which

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provides services utilizing EMT-II or EMT-P, or both, for the delivery of emergency medical care to the sick and injured at the scene of an emergency, during transport to a general acute care 4 hospital, during interfacility transfer, while in the emergency department of a general acute care hospital until care responsibility is assumed by the regular staff of that hospital, and during training within the facilities of a participating general acute care hospital. 8 hospital, and at the scene of an emergency for the purpose of determining transport to a community care facility or an acute 10 care hospital, and during transport to a community care facility 11 as part of an approved local EMS agency emergency medical 12 services plan. 13

SEC. 5. Section 1797.260 is added to the Health and Safety Code, to read:

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1797.260. A local EMS agency may submit, as part of its emergency services plan, a plan to transport patients to a community care facility that is not a general acute care hospital based on a determination that there is no need for emergency health care. This plan shall include, without limitation, all of the following:

- (a) Criteria for designating a facility as a community care facility, including appropriate medical staffing and administrative medical oversight such as a medical director.
- (b) One or more policies for prompt evaluation and treatment of patients within a facility.
- (c) A communication plan between prehospital medical personnel.
- (d) A secondary transport plan to include criteria for contacting the jurisdictional prehospital provider for transport to an emergency department of an acute care hospital.
 - (e) Medical equipment and monitoring protocols.
- (f) Required submission of a quality improvement plan and patient outcome data to the local EMS agency.
 - (g) Additional education requirements for paramedics.
- (h) Protocols for handling patient destination considerations including requests by patients.
- SECTION 1. Section 1797.119 is added to the Health and Safety Code, to read:
- 1797.119. (a) The authority may establish a task force to develop a report evaluating alternative destinations to a general

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acute care hospital for first responders to transport a patient who may be a danger to himself, herself, or others or gravely disabled as a result of a mental health disorder.

- (b) If the authority establishes a task force, the task force shall include representatives from statewide trade associations that represent consumers, physicians, hospitals, law enforcement officers, and public and private first responders.
- (e) If the authority establishes a task force, the report shall be published on the authority's Internet Web site.

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MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

Bill Number: AB 845 **Author:** Wood

Bill Date: July 11, 2017, Amended

Subject: Cannabidiol

Sponsor: Epilepsy Foundation of Greater Los Angeles

Position: Neutral

DESCRIPTION OF CURRENT LEGISLATION:

This bill would allow a physician, pharmacist, or other authorized healing arts licensee acting within his or her scope of practice, to prescribe, furnish, or dispense cannabidiol, if it is excluded from Schedule 1 of the federal Controlled Substances Act (Act) and placed on a schedule other than Schedule I, or if a product composed of cannabidiol is approved by the federal Food and Drug Administration (FDA) and either placed on a schedule of the Act other than Schedule I or is exempted from the Act. If a physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses cannabidiol in accordance with federal law, they shall be deemed to be in compliance with state law. This bill is an urgency statute and will take effect immediately upon being signed into law.

BACKGROUND (taken from the fact sheet):

Existing law, the California Uniform Controlled Substances Act, classifies controlled substances into five designated schedules, with the most restrictive limitations generally placed on controlled substances classified in Schedule I. Existing law places marijuana in Schedule I and cannabidiol is a compound found in marijuana.

Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions. Approximately 1 in 26 Americans will develop epilepsy at some point in their lifetime. There is no "one size fits all" treatment option and about one million people live with uncontrolled or intractable seizures. Access to new treatment is particularly important for these individuals, who live with the continual risk of serious injuries and loss of life.

The FDA is currently reviewing at least one cannabidiol or CBD derived therapy (Epidiolex) that shows promise for the treatment of Dravet and Lennox Gastaut syndromes (LGS), tuberous sclerosis complex (TSC) and potentially other rare epilepsies. This potential treatment option has both Orphan Drug Designation from the FDA for Dravet syndrome and also Orphan Drug Designation for LGS and TSC, other rare types of epilepsy. Given the fast track designation, this potential treatment option could be available as soon as early 2018.

ANALYSIS

This bill would allow a physician, pharmacist, or other authorized healing arts licensee acting within his or her scope of practice, to prescribe, furnish, or dispense cannabidiol, if it is excluded from Schedule 1 of the federal Act and placed on a schedule other than Schedule I, or if a product composed of cannabidiol is approved by the federal Food and Drug Administration (FDA) and either placed on a schedule of the Act other than Schedule I or is exempted from the Act. If a physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses cannabidiol in accordance with federal law, they shall be deemed to be in compliance with state law.

This bill would state that upon the effective date of one of the federal changes specified in this bill, notwithstanding any other state law, a product composed of cannabidiol may be prescribed, furnished, dispensed, transferred, possessed, or used in accordance with federal law and is authorized pursuant to state law. This bill is an urgency statute and will take effect immediately upon being signed into law.

Per the author's office, currently any product that contains any quantity of marijuana is considered a Schedule I controlled substance, unless specifically exempted. Under current law, should a product be derived from cannabidiol, it would still be considered a Schedule I controlled substance and therefore could not be prescribed in California. According to the author, the purpose of this bill is to ensure Californians with uncontrolled seizures will have continued access to FDA approved epilepsy treatments derived from cannabidiol.

This bill would ensure that if the federal government approves cannabidiol treatment, then cannabidiol can be prescribed, furnished and dispensed in California, in accordance with federal law. This bill merely aligns state law with federal law to allow treatments authorized by the federal government in the future. The Board has taken a neutral position on this bill.

FISCAL: None

SUPPORT: Epilepsy Foundation of Greater Los Angeles (Sponsor);

California Life Sciences Association; Dravet Syndrome

Foundation; Epilepsy Foundation of Northern California; LGS Foundation; Tuberous Sclerosis Alliance; and two individuals

OPPOSITION: None on file

AMENDED IN SENATE JULY 11, 2017 AMENDED IN SENATE JUNE 7, 2017 AMENDED IN ASSEMBLY MARCH 28, 2017

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

ASSEMBLY BILL

No. 845

Introduced by Assembly Member Wood

February 16, 2017

An act to add Section 11150.2 to the Health and Safety Code, relating to controlled substances, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 845, as amended, Wood. Cannabidiol.

Existing law, the California Uniform Controlled Substances Act, classifies controlled substances into 5 designated schedules, with the most restrictive limitations generally placed on controlled substances classified in Schedule I, and the least restrictive limitations generally placed on controlled substances classified in Schedule V. Existing law places marijuana cannabis in Schedule I. Cannabidiol is a compound found in marijuana. cannabis.

Existing law restricts the prescription, furnishing, possession, sale, and use of controlled substances, including marijuana cannabis and synthetic cannabinoid compounds, and makes a violation of those laws a crime, except as specified.

This bill, if one of specified changes in federal law regarding the controlled substance cannabidiol occurs, would provide that a physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses a product composed of cannabidiol, in

AB 845 -2-

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accordance with federal law, is in compliance with state law governing those acts. The bill would also provide that upon the effective date of one of those changes in federal law regarding cannabidiol, the prescription, furnishing, dispensing, transfer, possession, or use of that product in accordance with federal law is for a legitimate medical purpose and is authorized pursuant to state law.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: $\frac{2}{3}$. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds and declares that both children and adults with epilepsy are in desperate need of new treatment options and that cannabidiol is showing potential as one 4 of these treatments. If federal laws prohibiting the prescription of 5 medications composed of cannabidiol are repealed or if an 6 exception from the general prohibition is enacted permitting the prescription of drugs composed of cannabidiol, patients should have rapid access to this treatment option. The availability of this new prescription medication is intended to augment, not to restrict or otherwise amend, other cannabinoid treatment modalities 10 11 currently available under state law. 12

SEC. 2. Section 11150.2 is added to the Health and Safety Code, to read:

11150.2. (a) Notwithstanding any other law, if cannabidiol is removed excluded from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I, or if a product composed of cannabidiol is approved by the federal Food and Drug Administration and either placed on a schedule of the act other than Schedule I, or exempted from one or more provisions of the act, so as to permit a physician, pharmacist, or other authorized healing arts licensee acting within his or her scope of practice, to prescribe, furnish, or dispense that product, the physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses that product in accordance with federal law shall be deemed to be in compliance with state law governing those acts.

—3— AB 845

(b) For purposes of this chapter, upon the effective date of one of the changes in federal law described in subdivision (a), notwithstanding any other state law, a product composed of cannabidiol may be prescribed, furnished, dispensed, transferred, possessed, or used in accordance with federal law and is authorized pursuant to state law.

SEC. 3. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the California Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to ensure that patients are able to obtain access to a new treatment modality as soon as federal law makes it available, it is necessary that this act take effect immediately.

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MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

Bill Number: AB 1204 **Author:** Mayes

Bill Date: March 28, 2017, Amended

Subject: Public Health: Emergency Prescriptions

Sponsor: Author

Position: Neutral if Amended

DESCRIPTION OF CURRENT LEGISLATION:

This bill would allow a physician to prescribe a one-month supply of a life-saving medication, as defined, to a patient to be stored for the use of that patient in case of a natural disaster or other emergency.

ANALYSIS

This bill would define life-saving medication to include, but is not limited to, medication necessary to save the life of a patient whose life is at risk due to illnesses such as cancer, heart disease, diabetes, stroke, and other illnesses in which the failure to administer the medication can result in the death of the patient. A life-saving medication does not include medications that are primarily prescribed to relieve pain.

According the author's office this bill is a district bill and the purpose is to ensure that once a year a doctor can prescribe a life-saving medication, over and above what is normally prescribed, so the patient can store that medication at home in case of a natural disaster or other emergency that prevents the individual from going to the pharmacy and having their prescription filled.

Ensuring that patients have access to life-saving medications is important and will ensure that these patient's lives are not at risk. However, the bill as written does not make it clear that the 30-day supply is in addition to their regularly prescribed dosage. In addition, although this bill does say that life-saving medications do not include medications that are primarily prescribed to relieve pain, this bill should specifically prohibit controlled substances used for pain management. The Board will be neutral on this bill if it is amended to address these issues and to ensure that expired drugs are disposed of properly.

FISCAL: None

SUPPORT: None on file

OPPOSITION: None on file

AMENDED IN ASSEMBLY MARCH 28, 2017

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

ASSEMBLY BILL

No. 1204

Introduced by Assembly Member Mayes

February 17, 2017

An act to-amend Section 1797.1 of add Chapter 13 (commencing with Section 1799.300) to Division 2.5 of the Health and Safety Code, relating to emergency medical services.

LEGISLATIVE COUNSEL'S DIGEST

AB 1204, as amended, Mayes. Public health: emergency—medical services. prescriptions.

Existing law governs the practice of medicine and the issuance of prescription drugs.

Existing law, the Emergency Medical Services System and the Prehospital Emergency Medical Care Personnel Act, states that it is the policy of the State of California to ensure the provision of effective and efficient emergency medical care.

This bill would authorize a licensed physician to prescribe a one-month supply of a life-saving medication, as described, to a patient to be stored for the use of that patient in case of a natural disaster or other emergency.

Existing law, the Emergency Medical Services System and the Prehospital Emergency Medical Care Personnel Act, makes findings and declarations regarding the establishment of the Emergency Medical Services Authority.

This bill would make a technical, nonsubstantive change to these provisions.

AB 1204 -2-

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Chapter 13 (commencing with Section 1799.300) is added to Division 2.5 of the Health and Safety Code, to read:

CHAPTER 13. EMERGENCY PRESCRIPTIONS

1799.300. For purposes of this chapter, a "life-saving medication" includes, but is not limited to, medication necessary to save the life of a patient whose life is at risk due to illnesses such as cancer, heart disease, diabetes, stroke, and other illnesses in which the failure to administer the medication can result in the death of the patient. A life-saving medication does not include medications that are primarily prescribed to relieve pain.

1799.301. Notwithstanding any other law, a licensed physician may prescribe a one-month supply of a life-saving medication to a patient to be stored for the use of that patient in case of a natural disaster or other emergency.

SECTION 1. Section 1797.1 of the Health and Safety Code is amended to read:

1797.1. The Legislature finds and declares that it is the intent of this act to provide the state with a statewide system for emergency medical services by establishing within the California Health and Human Services Agency, the Emergency Medical Services Authority, which is responsible for the coordination and integration of all state activities concerning emergency medical services.

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MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

Bill Number: AB 1368 **Author:** Calderon

Bill Date: June 29, 2017, Amended

Subject: Health Professionals: Authorization Forms

Sponsor: California Academy of Physician Assistants (CAPA)

Position: Neutral

DESCRIPTION OF CURRENT LEGISLATION:

This bill would authorize the Department of Health Care Services (DHCS) to allow a physician assistant (PA) or a nurse practitioner (NP) to sign any authorization form required by DHCS for benefits and services under the Medi-Cal Program, the Genetically Handicapped Persons Program, and the Child Health Disability Prevention Program, provided the PA or NP is authorized by the supervising physician, or by the NP's standardized procedures or protocols, and if the physician and the PA or NP are each enrolled as Medi-Cal providers.

BACKGROUND:

The Physician Assistant Practice Act authorizes a PA to perform specified medical services when the services are rendered under the supervision of a licensed physician and surgeon. A PA may only provide those medical services which he or she is competent to perform and which are consistent with his or her education, training, and experience. A physician and PA must establish written guidelines or protocols for the adequate supervision of PAs.

Under the Nurse Practice Act, NPs hold a valid and active registered nursing license, possess a master's degree in a clinical field related to nursing or a graduate degree in nursing and have completed a nurse practitioner program approved by the Board of Registered Nursing. Generally, standardized procedures and protocols, developed in collaboration with physicians and surgeons and other health professionals, govern the types of medical services that can be provided by NPs.

PAs and NPs provide a wide breath of health care services in a variety of settings, including hospitals, community clinics, and private practice settings.

ANALYSIS

According to the sponsor, current law recognizes PAs as licensed health care providers that practice medicine under the supervision of a physician and act as an agent of the supervising physician when performing any authorized medical services. Specifically, Medi-Cal recognizes PAs as non-physician providers that render medical services under the general

supervision of a physician. PAs must be enrolled with the Department of Health Care Services Provider Enrollment Division for reimbursement, ordering, referring and prescribing purposes. Further, the Medi-Cal program recognizes PAs as primary care providers. However, there are many forms that require a physician (M.D. or D.O) signature, even when a PA has performed the medical services. Requiring a physician signature on authorization forms creates delays in access to care and supplies to meet basic health care needs such as: incontinence supplies, non-urgent medical transport, physical therapy and other critical patient needs.

Allowing PAs and NPs to sign off on authorization forms for benefits and services under the Medi-Cal Program, the Genetically Handicapped Persons Program, and the Child Health Disability Prevention Program seems reasonable, as PAs and NPs are already recognized as primary care providers in Medi-Cal. This bill would only allow PAs or NPs to sign off on authorization forms if their physician supervisor or their standardized protocols and procedures has designated them to do so. This may prevent delays in access to care for California patients and will not compromise consumer protection. The Board has taken a neutral position on this bill.

FISCAL: None

SUPPORT: CAPA (sponsor)

California Academy of Family Physicians California Association for Nurse Practitioners

California Council of Community Behavioral Health Agencies

California Health +Advocates

OPPOSITION: None on File

AMENDED IN SENATE JUNE 29, 2017

AMENDED IN SENATE JUNE 19, 2017

AMENDED IN ASSEMBLY APRIL 20, 2017

AMENDED IN ASSEMBLY MARCH 30, 2017

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

ASSEMBLY BILL

No. 1368

Introduced by Assembly Member Calderon

February 17, 2017

An act to add Sections 123823, 124037, 124037 and 125186 to the Health and Safety Code, and to add Section 14133.91 to the Welfare and Institutions Code, relating to health professionals.

LEGISLATIVE COUNSEL'S DIGEST

AB 1368, as amended, Calderon. Health professionals: authorization forms.

Existing law establishes the Medi-Cal program, which is administered by the State Department of Health Care Services, under which qualified low-income individuals receive health care services. Existing law provides for a schedule of benefits and services under the Medi-Cal program, subject to utilization controls. Existing law provides that specified utilization controls may be applied to any specific service or group of services that are subject to utilization controls, including prior authorization requirements. Existing law also requires the department to administer other health programs, including the California Children's Services Program, the Genetically Handicapped Persons—Program, Program and the Child Health and Disability Prevention Program.

AB 1368 -2-

This bill would require the department to allow a physician assistant or a nurse practitioner to sign any authorization form required by the department for benefits and services under the Medi-Cal program, the Genetically Handicapped Persons Program, or the Child Health and Disability Prevention Program, and to allow a nurse practitioner to sign any required authorization form, as specified, under the California Children's Services Program, subject to specified criteria, including, among others, that the physician and the designated physician assistant or nurse practitioner are each enrolled as a Medi-Cal provider.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 123823 is added to the Health and Safety Code, to read:

123823. The department shall allow a nurse practitioner to sign any authorization form required by the department for benefits and services under this article, subject to both of the following:

- (a) The nurse practitioner is a CCS-paneled provider who is authorized by the supervising physician, or the nurse practitioner's standardized procedure or protocol, to provide the service pursuant to his or her scope of practice.
- (b) The physician and the designated nurse practitioner are each enrolled as a Medi-Cal provider pursuant to Article 1.3 (commencing with Section 14043) of Chapter 7 of Part 3 of Division 9 of the Welfare and Institutions Code.

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- SECTION 1. Section 124037 is added to the Health and Safety Code, to read:
- 124037. The department shall allow a physician assistant or a nurse practitioner to sign any authorization form required by the department for benefits and services under this article, subject to both of the following:
- (a) The physician assistant or the nurse practitioner is authorized by the supervising physician, or the nurse practitioner's standardized procedure or protocol, to provide the service pursuant to his or her scope of practice.
- 25 (b) The physician and the designated physician assistant or nurse 26 practitioner are each enrolled as a Medi-Cal provider pursuant to

-3- AB 1368

1 Article 1.3 (commencing with Section 14043) of Chapter 7 of Part
2 3 of Division 9 of the Welfare and Institutions Code.

SEC. 3.

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- SEC. 2. Section 125186 is added to the Health and Safety Code, to read:
- 125186. The department shall allow a physician assistant or a nurse practitioner to sign any authorization form required by the department for benefits and services under this article, subject to both of the following:
- (a) The physician assistant or the nurse practitioner is authorized by the supervising physician, or the nurse practitioner's standardized procedure or protocol, to provide the service pursuant to his or her scope of practice.
- (b) The physician and the designated physician assistant or nurse practitioner are each enrolled as a Medi-Cal provider pursuant to Article 1.3 (commencing with Section 14043) of Chapter 7 of Part 3 of Division 9 of the Welfare and Institutions Code.

SEC. 4.

- SEC. 3. Section 14133.91 is added to the Welfare and Institutions Code, immediately following Section 14133.9, to read:
- 14133.91. The department shall allow a physician assistant or a nurse practitioner to sign any authorization form required by the department for benefits and services under this chapter, subject to both of the following:
- (a) The physician and the designated physician assistant or nurse practitioner are each enrolled as a Medi-Cal provider pursuant to Article 1.3 (commencing with Section 14043).
- (b) The physician assistant or the nurse practitioner is authorized by the supervising physician, or the nurse practitioner's standardized procedure or protocol, to provide the service pursuant to his or her scope of practice.

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MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

Bill Number: AB 1512 **Author:** McCarty

Bill Date: May 9, 2017, Amended

Subject: Opioid Addiction Prevention and Rehabilitation Act

Sponsor: California Council of Community Behavioral Health Agencies

Position: Support if Amended

DESCRIPTION OF CURRENT LEGISLATION:

This bill would create the Opioid Addiction Prevention and Rehabilitation Act, which will be funded through a one cent per milligram surcharge on opioid distribution in California, effective July 1, 2018.

BACKGROUND:

In 2010, approximately 38,329 unintentional drug overdose deaths occurred in the United States, one death every 14 minutes. Of this number, 22,134 of these deaths were attributed to prescription drugs (16,651 or 75.2% attributed to opioid overdoses). Prescription drug abuse is the fastest growing drug problem in the United States.

According to the California Department of Public Health (CDPH), 2,024 deaths related to pharmaceutical opioids occurred in California in 2014; 4,106 non-fatal ED visits related to all opioids in the same timeframe; 4,482 opioid related hospitalizations in the same timeframe; and 619 opioids were prescribed per 1,000 residents in 2015.

According to the Centers for Disease Control, every day, 44 people in the U.S. die from overdose of prescription painkillers and many more become addicted.

The Medical Board of California (Board) developed a Prescribing Task Force that held multiple meetings to identify best practices, hear from speakers regarding this issue, and update the Board's Guidelines for Prescribing Controlled Substances for Pain. This task force had numerous meetings with interested parties and discussions with experts in the field of pain management to develop this document, which was adopted by the Board in November 2014. These Guidelines are intended to educate physicians on effective pain management in California by avoiding under treatment, overtreatment, or other inappropriate treatment of a patient's pain. The Guidelines' primary objective is improved patient outcomes and reduction of prescription overdose deaths. The Guidelines contain a significant amount of information and are supplemented with as many resources as practical via the appendices and links to websites that further assist a physician when prescribing controlled substances for pain. The Guidelines discuss several areas, including understanding pain, special patient populations, patient evaluation and risk stratification, consultation, treatment plan and objectives, patient consent, pain management agreements, counseling patient on overdose risk and response, initiating an opioid trial, ongoing patient assessment, and several other areas.

In 2014, the Director of CDPH launched a state agency Prescription Opioid Misuse and Overdose Prevention Workgroup (Workgroup) to share information and develop collaborative strategies to curb prescription drug misuse, abuse, and overdose deaths in California. The Workgroup started as a multi-sector group consisting of more than 10 state agencies, including CDPH, Department of Justice, DHCS, Department of Managed Health Care, Department of Education, Department of Industrial Relations, Department of Corrections and Rehabilitation, Department of Consumer Affairs (including the Board, Dental Board of California, Board of Pharmacy, and Board of Registered Nursing), Emergency Medical Services Authority, and others. The Workgroup initially commenced a multi-phase plan involving enhancement of the state's Prescription Drug Monitoring Program (PDMP), promoting the release and adoption of the Board's revised Guidelines for Prescribing Controlled Substances for Pain, and development of a comprehensive public education campaign to increase public awareness about the potential dangers of opioid medications and to create better understanding and expectations among the public regarding proper prescribing, use, storage and disposal of opioids.

ANALYSIS

This bill would create the Opioid Prevention and Rehabilitation Program Fund (Fund) in the State Treasury. This bill would state the intent of the Legislature is to enact legislation that would provide for distribution of the moneys in the fund for addiction prevention and rehabilitation programs.

This bill would, on and after July 1, 2018, impose a tax upon the distribution of opioids by a manufacturer to a wholesaler, at the rate of one cent per milligram of active opioid ingredient. The wholesaler shall collect the tax from the manufacturer and shall separately state the amount of the tax imposed under this part on the purchase order, which shall be given by the wholesaler to the manufacturer at the time of sale. The wholesaler shall remit the tax to the Board of Equalization (BOE), who would collect the tax pursuant to existing law. The tax imposed would be due and payable to the BOE on or before the last day of the month next succeeding each calendar quarter. Returns shall be filed with BOE using electronic media. All taxes, interest, penalties, and other amounts collected, less refunds and BOE's cost of administration, shall be deposited in the Fund.

According to the author, addiction is an issue that affects all types of people regardless of their ethnicity, age, social class, gender, or where they live. The barriers of access to treatment are unique to every patient and every county. Despite the high level of need, California's capacity for treatment services is not keeping pace. From 2010-2014, more than 87% of those dependent on or abusing illicit drugs did not have access to the care they needed. Despite more Californians enrolled in healthcare programs, millions go unserved and cannot access drug treatment programs.

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 will impose a tax upon the distribution of opioids by a manufacturer to a wholesaler, which seems to be a reasonable funding source to contribute to the

growing opioid abuse epidemic. This bill will help collect funding for addiction prevention and rehabilitation programs, which is much needed in California. This bill will increase awareness and furthers the Board's mission of consumer protection. The Board will support this bill if it is amended to ensure that the tax is not passed on to the consumers.

FISCAL: None to the Board

SUPPORT: California Council of Community Behavioral Health Agencies

(Sponsor); California Consortium of Addiction Programs and Professionals; California Society of Addiction Medicine; County Behavioral Health Directors Association of California; Medical Board of California (if amended); and Transitions Clinic

OPPOSITION: California Taxpayers Association

Healthcare Distribution Alliance

AMENDED IN ASSEMBLY MAY 9, 2017

AMENDED IN ASSEMBLY APRIL 25, 2017

AMENDED IN ASSEMBLY APRIL 17, 2017

AMENDED IN ASSEMBLY MARCH 28, 2017

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

ASSEMBLY BILL

No. 1512

Introduced by Assembly Member McCarty

February 17, 2017

An act to add Division 10.4 (commencing with Section 11740) to the Health and Safety Code, and to add Part 14.3 (commencing with Section 33001) to Division 2 of the Revenue and Taxation Code, relating to taxation, *and making an appropriation therefor*, to take effect immediately, tax levy.

LEGISLATIVE COUNSEL'S DIGEST

AB 1512, as amended, McCarty. Opioid Addiction Prevention and Rehabilitation Act.

Existing law imposes various fees and taxes, including taxes on the privilege of engaging in certain activities. The Fee Collection Procedures Law, the violation of which is a crime, provides procedures for the collection of certain fees and surcharges.

Under this bill, the Opioid Addiction Prevention and Rehabilitation Act would impose a tax on and after—January July 1, 2018, upon the distribution of opioids by—every person including, but not limited to, a manufacturer or wholesaler, that makes the first sale in this state of opioids, where the sale is for the purpose of resale in the regular course of business, a manufacturer to a wholesaler from the manufacturer, as

AB 1512 -2-

those terms are defined, at the rate of \$0.01 per milligram of active opioid ingredient. The bill would require the wholesaler to collect the tax and remit it to the State Board of Equalization. The tax would be administered by the State Board of Equalization and would be collected pursuant to the procedures set forth in the Fee Collection Procedures Law, which sets forth requirements for registration, returns, payments, penalties, interest, determinations and redeterminations, collections, overpayments and refunds, administration and confidentiality, and violations. By expanding the application of the Fee Collection Procedures Law, the violation of which is a crime, this bill would impose a state-mandated local program.

This bill would require the board to deposit all taxes, interest, penalties, and other amounts collected, less-refunds, refunds and the board's costs of administration, into the Opioid Prevention and Rehabilitation Program Fund, which this bill would create. By authorizing the use of moneys collected pursuant to this bill for these purposes, the bill would make an appropriation. The bill would state the intent of the Legislature to enact legislation that would provide for distribution of the moneys in the fund for addiction prevention and rehabilitation programs.

This bill would include a change in state statute that would result in a taxpayer paying a higher tax within the meaning of Section 3 of Article XIII A of the California Constitution, and thus would require for passage the approval of $\frac{2}{3}$ of the membership of each house of the Legislature.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would take effect immediately as a tax levy.

Vote: ²/₃. Appropriation: no-yes. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Division 10.4 (commencing with Section 11740)
- 2 is added to the Health and Safety Code, to read:

-3- AB 1512

DIVISION 10.4. OPIOID PREVENTION AND REHABILITATION PROGRAM FUND

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- 11740. (a) There is hereby created in the State Treasury the Opioid Prevention and Rehabilitation Program Fund.
- (b) It is the intent of the Legislature to enact legislation that would provide for distribution of the moneys in the fund for addiction prevention and rehabilitation programs.
- SEC. 2. Part 14.3 (commencing with Section 33001) is added to Division 2 of the Revenue and Taxation Code, to read:

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PART 14.3. OPIOID ADDICTION PREVENTION AND REHABILITATION ACT

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- 33001. This part shall be known and may be cited as the Opioid Addiction Prevention and Rehabilitation Act.
 - 33002. For purposes of this part:
- (a) "Active opioid ingredient" means that portion of a product that is an opioid.
- (b) "Distribution" means the sale of untaxed opioids in this state.
- (c) "In this state" means within the exterior limits of the State of California and includes all territory within these limits owned by or ceded to the United States.
- (d) "Manufacturer" means any person, whether or not located in this state, who manufactures opioids for distribution in this state.

(d)

(e) "Opiate" means the dried, condensed juice of a poppy, Papaver somniferum, that has a narcotic, soporific, analgesic, and astringent effect.

(e)

(f) "Opioid" means an opiate or any synthetic or semisynthetic narcotic that has opiatelike activities but is not derived from opium and has effects similar to natural opium alkaloids, and any derivatives thereof.

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38 (g) "Person" means person as defined in Section 55002.

39 (g)

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(h) "Sale" means any transfer of title or possession for a consideration, exchange, or barter, in any manner or by any means.

(h)

- (i) "Untaxed opioid" means any opioid which has not yet been distributed in a manner as to result in a tax liability under this part.
- (j) "Wholesaler" means any person who engages in this state in the making of sales for resale of opioids.
- 33003. (a) On and after January July 1, 2018, a tax is hereby imposed upon the distribution of opioids by every person including, but not limited to, a manufacturer or wholesaler, that makes the first sale in this state of opioids, where the sale is for the purpose of resale in the regular course of business, a manufacturer to a wholesaler, at the rate of one cent (\$0.01) per milligram of active opioid ingredient.
- (b) The wholesaler shall collect the tax from the manufacturer and shall separately state the amount of the tax imposed under this part on the purchase order, which shall be given by the wholesaler to the manufacturer at the time of sale. The wholesaler shall remit the tax to the board.
- 33004. There shall be exempt from the taxes imposed by this part the distribution to a person if the state is prohibited from taxing that sale under the Constitution or laws of the United States or under the Constitution of this state.
- 33005. (a) The board shall collect the tax pursuant to the Fee Collection Procedures Law (Part 30 (commencing with Section 55001) of Division 2 of the Revenue and Taxation Code). For purposes of administration of the tax pursuant to this part, references in the Fee Collection Procedures Law to "feepayer" and "fee" shall include "taxpayer" and "tax."
- (b) The board may adopt any regulations necessary or appropriate to carry out the purposes of this part.
- (c) The tax imposed by this part shall be due and payable to the board on or before the last day of the month next succeeding each calendar quarter, together with a return for that calendar quarter. Returns shall be filed with the board using electronic media and authenticated in a form or pursuant to methods as may be prescribed by the board.
- 33006. All taxes, interest, penalties, and other amounts collected pursuant to this part, less refunds, refunds and the board's costs of administration, shall be deposited into the Opioid

-5- AB 1512

Prevention and Rehabilitation Program Fund established by Section 11740 of the Health and Safety Code.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIIIB of the California Constitution.

SEC. 4. This act provides for a tax levy within the meaning of Article IV of the California Constitution and shall go into immediate effect.

MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

Bill Number: AB 1560 **Author:** Friedman

Bill Date: July 3, 2017, Amended

Subject: Nurse Practitioners: Certified Nurse-Midwives: Physician Assistants;

Physician and Surgeon Supervision

Sponsor: California Association for Nurse Practitioners (CANP)

Position: Oppose Unless Amended

DESCRIPTION OF CURRENT LEGISLATION:

This bill would allow a physician to supervise up to 12 furnishing nurse practitioners (NPs), certified nurse-midwives (CNMs), and physician assistants (PAs) at any one time.

ANALYSIS:

Existing law, limits the number of NPs who are furnishing or ordering drugs, PAs, and CNMS that may be supervised by a physician, to four for each category of mid-level practitioner. This means a physician could supervise four NPs, four PAs and four CNMS for a total of 12 mid-level practitioners. This bill would allow a physician to supervise 12 mid-level practitioners total, but does not limit the type of mid-level practitioner, so a physician could supervise 12 NPs, 12 PAs, or 12 CNMs, instead of four of each type of mid-level practitioner.

According to the author's office, in many clinic systems where there are multiple clinic sites, but only one medical director on staff, this severely limits the number of NPs who can provide patient care. The author's office believes this bill will increase essential health care availability and improve efficiency.

Increasing the supervision ratio from four to 12 for the individual categories of mid-level practitioners may result in insufficient supervision. The current limit for physician supervision for each mid-level practitioner category is four, with a total limit of 12. These mid-level practitioners are well qualified to provide medical care when practicing under physician supervision. The standardized procedures and physician supervision, collaboration, and consultation are in existing law to ensure that the patient care provided includes physician involvement and oversight, as physicians should be participating in the patient's care in order to ensure consumer protection. Board staff suggests that raising the limit from four to six for each category of mid-level practitioner seems reasonable. The total limit could still be 12 as it is currently, but allowing a physician to supervise two more PAs, NPs, or CNMs would not negatively impact patient care, and would still maintain the current limit of 12. Board staff suggests the Board oppose this bill unless it is amended to cap the number of PAs, NPs, and CNMS a physician can supervise at six for each category of mid-level practitioner, and keep

the total cap at 12 mid-level practitioners total that a physician can supervise.

FISCAL: None

SUPPORT: CANP (Sponsor); Association of California Healthcare Districts; Bay

Area Council; California Academy of PAs; California Council of Community Behavioral Health Agencies; and California Health

Advocates

OPPOSITION: California Chapter of American College of Cardiology

California Society of Plastic Surgeons

Union of American Physicians and Dentists

POSITION: Recommendation: Oppose Unless Amended

AMENDED IN SENATE JULY 3, 2017 AMENDED IN ASSEMBLY MAY 8, 2017 AMENDED IN ASSEMBLY MARCH 21, 2017

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

ASSEMBLY BILL

No. 1560

Introduced by Assembly Member Friedman

February 17, 2017

An act to amend Sections 2746.51, 2836.1, 3516, and 3516.5 of, and to add Sections 2746.54 and 2836.4 to, the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 1560, as amended, Friedman. Nurse practitioners: eertified-nurse midwives: certified nurse-midwives: physician assistants: physician and surgeon supervision.

The Nursing Practice Act provides for the licensure and regulation of the practice of nursing by the Board of Registered Nursing. The act authorizes a nurse practitioner to, among other things, furnish or order drugs or devices under specified circumstances subject to physician and surgeon supervision. The act prohibits a physician and surgeon from supervising more than 4 nurse practitioners at one time for purposes of furnishing drugs or devices.

Existing law authorizes the Board of Registered Nursing to issue a certificate to practice nurse-midwifery to any person licensed under the Nursing Practice Act that meets certain qualifications. Existing law authorizes a certified-nurse midwife certified nurse-midwife to, among other things, furnish or order drugs and devices under specified circumstances subject to physician and surgeon supervision. Existing

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law prohibits a physician and surgeon from supervising more than 4 eertified-nurse midwives certified nurse-midwives at one time for purposes of furnishing or ordering drugs or devices.

The Physician Assistance Practice Act provides for the licensure and regulation of physician assistants by the Physician Assistant Board, which is within the jurisdiction of the Medical Board of California. The act authorizes a physician assistant licensed by the Physician Assistant Board to be eligible for employment or supervision by any physician and surgeon who is not subject to a disciplinary condition imposed by the Medical Board of California prohibiting that employment or supervision. The act prohibits a physician and surgeon from supervising more than 4 physician assistants at any one time, except as specified.

This bill would instead prohibit a physician and surgeon from supervising more than 12 nurse practitioners, eertified-nurse midwives, certified nurse-midwives, and physician assistants at any one time. time, as specified.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

- SECTION 1. Section 2746.51 of the Business and Professions 1 Code is amended to read:
- 2746.51. (a) Neither this chapter nor any other law shall be construed to prohibit a certified nurse-midwife from furnishing or ordering drugs or devices, including controlled substances classified in Schedule II, III, IV, or V under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 8 11000) of the Health and Safety Code), when all of the following 9 apply:
- 10 (1) The drugs or devices are furnished or ordered incidentally 11 to the provision of any of the following:

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- (A) Family planning services, as defined in Section 14503 of the Welfare and Institutions Code.
 - (B) Routine health care or perinatal care, as defined in subdivision (d) of Section 123485 of the Health and Safety Code.
- (C) Care rendered, consistent with the certified nurse-midwife's 16 educational preparation or for which clinical competency has been established and maintained, to persons within a facility specified 18 in subdivision (a), (b), (c), (d), (i), or (j) of Section 1206 of the 19

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Health and Safety Code, a clinic as specified in Section 1204 of the Health and Safety Code, a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code, a licensed birth center as defined in Section 1204.3 of the Health and Safety Code, or a special hospital specified as a maternity hospital in subdivision (f) of Section 1250 of the Health and Safety Code.

- (2) The drugs or devices are furnished or ordered by a certified nurse-midwife in accordance with standardized procedures or protocols. For purposes of this section, standardized procedure means a document, including protocols, developed and approved by the supervising physician and surgeon, the certified nurse-midwife, and the facility administrator or his or her designee. The standardized procedure covering the furnishing or ordering of drugs or devices shall specify all of the following:
- (A) Which certified nurse-midwife may furnish or order drugs or devices.
- (B) Which drugs or devices may be furnished or ordered and under what circumstances.
 - (C) The extent of physician and surgeon supervision.
- (D) The method of periodic review of the certified nurse-midwife's competence, including peer review, and review of the provisions of the standardized procedure.
- (3) If Schedule II or III controlled substances, as defined in Sections 11055 and 11056 of the Health and Safety Code, are furnished or ordered by a certified nurse-midwife, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician and surgeon. For Schedule II controlled substance protocols, the provision for furnishing the Schedule II controlled substance shall address the diagnosis of the illness, injury, or condition for which the Schedule II controlled substance is to be furnished.
- (4) The furnishing or ordering of drugs or devices by a certified nurse-midwife occurs under physician and surgeon supervision. For purposes of this section, no physician and surgeon shall supervise more certified nurse-midwives than allowed by Section 2746.54 at one time. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include all of the following:

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1 (A) Collaboration on the development of the standardized 2 procedure or protocol.

- (B) Approval of the standardized procedure or protocol.
- (C) Availability by telephonic contact at the time of patient examination by the certified nurse-midwife.
- (b) (1) The furnishing or ordering of drugs or devices by a certified nurse-midwife is conditional on the issuance by the board of a number to the applicant who has successfully completed the requirements of paragraph (2). The number shall be included on all transmittals of orders for drugs or devices by the certified nurse-midwife. The board shall maintain a list of the certified nurse-midwives that it has certified pursuant to this paragraph and the number it has issued to each one. The board shall make the list available to the California State Board of Pharmacy upon its request. Every certified nurse-midwife who is authorized pursuant to this section to furnish or issue a drug order for a controlled substance shall register with the United States Drug Enforcement Administration.
- (2) The board has certified in accordance with paragraph (1) that the certified nurse-midwife has satisfactorily completed a course in pharmacology covering the drugs or devices to be furnished or ordered under this section. The board shall establish the requirements for satisfactory completion of this paragraph.
- (3) A physician and surgeon may determine the extent of supervision necessary pursuant to this section in the furnishing or ordering of drugs and devices.
- (4) A copy of the standardized procedure or protocol relating to the furnishing or ordering of controlled substances by a certified nurse-midwife shall be provided upon request to any licensed pharmacist who is uncertain of the authority of the certified nurse-midwife to perform these functions.
- (5) Certified nurse-midwives who are certified by the board and hold an active furnishing number, who are currently authorized through standardized procedures or protocols to furnish Schedule II controlled substances, and who are registered with the United States Drug Enforcement Administration shall provide documentation of continuing education specific to the use of Schedule II controlled substances in settings other than a hospital based on standards developed by the board.

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(c) Drugs or devices furnished or ordered by a certified nurse-midwife may include Schedule II controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) under the following conditions:

- (1) The drugs and devices are furnished or ordered in accordance with requirements referenced in paragraphs (2) to (4), inclusive, of subdivision (a) and in paragraphs (1) to (3), inclusive, of subdivision (b).
- (2) When Schedule II controlled substances, as defined in Section 11055 of the Health and Safety Code, are furnished or ordered by a certified nurse-midwife, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician and surgeon.
- (d) Furnishing of drugs or devices by a certified nurse-midwife means the act of making a pharmaceutical agent or agents available to the patient in strict accordance with a standardized procedure or protocol. Use of the term "furnishing" in this section shall include the following:
- (1) The ordering of a drug or device in accordance with the standardized procedure or protocol.
- (2) Transmitting an order of a supervising physician and surgeon.
- (e) "Drug order" or "order" for purposes of this section means an order for medication or for a drug or device that is dispensed to or for an ultimate user, issued by a certified nurse-midwife as an individual practitioner, within the meaning of Section 1306.03 of Title 21 of the Code of Federal Regulations. Notwithstanding any other law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician; (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by certified nurse-midwives; and (3) the signature of a certified nurse-midwife on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.
- 38 SEC. 2. Section 2746.54 is added to the Business and 39 Professions Code, to read:

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2746.54. A physician and surgeon shall not supervise more than 18 certified-nurse midwives, 12 certified nurse-midwives functioning under Section 2746.51, nurse practitioners, practitioners functioning under Section 2836.1, and physician assistants licensed under Chapter 7.7 (commencing with Section 3500) at any one time.

- SEC. 3. Section 2836.1 of the Business and Professions Code is amended to read:
- 2836.1. Neither this chapter nor any other law shall be construed to prohibit a nurse practitioner from furnishing or ordering drugs or devices when all of the following apply:
- (a) The drugs or devices are furnished or ordered by a nurse practitioner in accordance with standardized procedures or protocols developed by the nurse practitioner and the supervising physician and surgeon when the drugs or devices furnished or ordered are consistent with the practitioner's educational preparation or for which clinical competency has been established and maintained.
- (b) The nurse practitioner is functioning pursuant to standardized procedure, as defined by Section 2725, or protocol. The standardized procedure or protocol shall be developed and approved by the supervising physician and surgeon, the nurse practitioner, and the facility administrator or the designee.
- (c) (1) The standardized procedure or protocol covering the furnishing of drugs or devices shall specify which nurse practitioners may furnish or order drugs or devices, which drugs or devices may be furnished or ordered, under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the nurse practitioner's competence, including peer review, and review of the provisions of the standardized procedure.
- (2) In addition to the requirements in paragraph (1), for Schedule II controlled substance protocols, the provision for furnishing Schedule II controlled substances shall address the diagnosis of the illness, injury, or condition for which the Schedule II controlled substance is to be furnished.
- (d) The furnishing or ordering of drugs or devices by a nurse practitioner occurs under physician and surgeon supervision. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include (1)

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collaboration on the development of the standardized procedure, (2) approval of the standardized procedure, and (3) availability by telephonic contact at the time of patient examination by the nurse practitioner.

- (e) (1) Drugs or devices furnished or ordered by a nurse practitioner may include Schedule II through Schedule V controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) and shall be further limited to those drugs agreed upon by the nurse practitioner and physician and surgeon and specified in the standardized procedure.
- (2) When Schedule II or III controlled substances, as defined in Sections 11055 and 11056, respectively, of the Health and Safety Code, are furnished or ordered by a nurse practitioner, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician. A copy of the section of the nurse practitioner's standardized procedure relating to controlled substances shall be provided, upon request, to any licensed pharmacist who dispenses drugs or devices, when there is uncertainty about the nurse practitioner furnishing the order.
- (f) (1) The board has certified in accordance with Section 2836.3 that the nurse practitioner has satisfactorily completed a course in pharmacology covering the drugs or devices to be furnished or ordered under this section.
- (2) A physician and surgeon may determine the extent of supervision necessary pursuant to this section in the furnishing or ordering of drugs and devices.
- (3) Nurse practitioners who are certified by the board and hold an active furnishing number, who are authorized through standardized procedures or protocols to furnish Schedule II controlled substances, and who are registered with the United States Drug Enforcement Administration, shall complete, as part of their continuing education requirements, a course including Schedule II controlled substances based on the standards developed by the board. The board shall establish the requirements for satisfactory completion of this subdivision.
- (g) Use of the term "furnishing" in this section, in health facilities defined in Section 1250 of the Health and Safety Code, shall include (1) the ordering of a drug or device in accordance

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 with the standardized procedure and (2) transmitting an order of a supervising physician and surgeon.

- (h) "Drug order" or "order" for purposes of this section means an order for medication which is dispensed to or for an ultimate user, issued by a nurse practitioner as an individual practitioner, within the meaning of Section 1306.03 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician; (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by nurse practitioners; and (3) the signature of a nurse practitioner on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.
- SEC. 4. Section 2836.4 is added to the Business and Professions Code, to read:
- 2836.4. A physician and surgeon shall not supervise more than 18 12 nurse practitioners, certified-nurse midwives, practitioners functioning under Section 2836.1, certified nurse-midwives functioning under Section 2746.51, and physician assistants licensed under Chapter 7.7 (commencing with Section 3500) at any one time.
- SEC. 5. Section 3516 of the Business and Professions Code is amended to read:
- 3516. (a) Notwithstanding any other law, a physician assistant licensed by the board shall be eligible for employment or supervision by any physician and surgeon who is not subject to a disciplinary condition imposed by the Medical Board of California prohibiting that employment or supervision.
- (b) A physician and surgeon shall not supervise more than—18 12 physician assistants, nurse practitioners licensed under Chapter 6 (commencing with Section—2700), 2700) and functioning under Section—2836.1, and—certified-nurse—midwives—certified nurse-midwives—certified under Article 2.5 (commencing with Section—2746)of 2746) of Chapter 6 and functioning under Section 2746.51 at any one time, except as provided in Section 3502.5.
- 38 (c) The Medical Board of California may restrict a physician 39 and surgeon to supervising specific types of physician assistants 40 including, but not limited to, restricting a physician and surgeon

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from supervising physician assistants outside of the field of specialty of the physician and surgeon.

- SEC. 6. Section 3516.5 of the Business and Professions Code is amended to read:
- 3516.5. (a) Notwithstanding any other law and in accordance with regulations established by the Medical Board of California, the director of emergency care services in a hospital with an approved program for the training of emergency care physician assistants, may apply to the Medical Board of California for authorization under which the director may grant approval for emergency care physicians on the staff of the hospital to supervise emergency care physician assistants.
- (b) The application shall encompass all supervising physicians employed in that service.
- (c) A violation of this section by the director of emergency care services in a hospital with an approved program for the training of emergency care physician assistants constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000).
- (d) A violation of this section shall be grounds for suspension of the approval of the director or disciplinary action against the director or suspension of the approved program under Section 3527.

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MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

Bill Number: AB 1612 **Author:** Burke

Bill Date: April 18, 2017, Amended

Subject: Certified Nurse Midwives: Supervision

Sponsor: California Nurse Midwives Association (CNMA)

United Nurses Association of California (UNAC)

Position: Oppose Unless Amended

DESCRIPTION OF CURRENT LEGISLATION:

This bill would remove the physician supervision requirement for certified nurse midwives (CNMs) allowing CNMs to attend cases of normal childbirth and to provide prenatal, intrapartum, and postpartum care, including family planning care, for the mother, and immediate care for the newborn in a variety of settings, including the home setting.

BACKGROUND:

CNMs are registered nurses with a certificate to practice midwifery, who have acquired additional training in the field of obstetrics and are certified by the American College of Nurse Midwives. Like licensed midwives (LMs), CNMS can practice in homes, birth centers and clinics; however, CNMs can also practice in hospital settings. In 2012, CNMs attended approximately 8.5 percent of all births in California, the majority of these births took place in a hospital, and the remainder took place in free-standing birthing centers. It is estimated that ninety percent of CNM attended births take place in a hospital setting. CNMs are required to practice under the supervision of a physician; California is one of the six states that require physician supervision of CNMs.

Existing law authorizes a CNM, under physician supervision, to attend cases of normal childbirth and to provide prenatal, intrapartum, and postpartum care, including family-planning care for the mother, and immediate care for the newborn. Existing law authorizes a CNM to furnish and order drugs or devices incidental to the provision of family planning services, routine health care or perinatal care, and care rendered consistently with the CNM's education, and in accordance with standardized procedures and protocols with the supervising physician. Existing law also authorizes a CNM to perform and repair episiotomies and repair first-degree and second degree lacerations of the perineum in a licensed acute care hospital and licensed alternate birth center, if performed pursuant to protocols developed and approved by the supervising physician.

AB 1308 (Bonilla, Chapter 665) was signed into law in 2013 and removed the physician supervision requirement for LMs. There were specific requirements on what type of patients LMs can accept, those that meet the criteria for normal pregnancy and childbirth, as specified.

If a potential client does not meet the criteria for normal pregnancy and childbirth, then the LM must refer that client to a physician trained in obstetrics and gynecology for examination; the LM can only accept the client if the physician examines the client and determines that the risk factors are not likely to significantly affect the course of pregnancy and childbirth. AB 1308 also allowed LMs to directly obtain supplies and devices, obtain and administer drugs and diagnostic tests, order testing, and receive reports that are necessary to the practice of midwifery and consistent with the LMs scope of practice. AB 1308 was very narrow on what services could be provided and what patients LMs could accept. It also included other provisions related to hospital transfers and education program requirements.

ANALYSIS

This bill would authorize a CNM provide the same range of services they are now authorized to provide, but without physician supervision. This bill would allow CNMs to practice in a variety of settings, including the home setting. This bill would allow a CNM to consult, refer, or transfer care to a physician, as indicated by the health status of the patient and the resources and medical personnel available in the setting of care. This bill would specify that nurse-midwifery care emphasizes informed consent, preventive care, and early detection and referral of complications. This bill would state that the furnishing or ordering of drugs or devices by a CNM occurs under standardized procedures and protocols, but does not necessarily require physician supervision. This bill would allow a CNM to directly procure supplies and devices, to obtain and administer drugs and diagnostic tests, to order laboratory and diagnostic testing, and to receive reports that are necessary to his or her practice as a CNM and consistent with nurse-midwifery education preparation.

This bill would authorize a CNM to perform and repair episiotomies and to repair first degree and second degree lacerations of the perineum in the settings currently allowed, and in a birth center accredited by a national accrediting body approved by the Board of Registered Nursing and in a home setting. This bill would delete all requirements that those procedures be performed pursuant to protocols developed and approved by the supervising physician. This bill would require a CNM to provide emergency care to a patient when a physician is not available.

This bill removes physician supervision for CNMs. Although the Board was supportive of the bill in 2013 that removed physician supervisions for LMs, it was because the bill was very restricted and clear on what types of patients LMs could accept, and required physician consultation and approval for patients that did not meet the requirements. High risk patients cannot be accepted by an LM. This bill would allow a CNM to accept all patients, there are no clear limits on what types of patients a CNM could accept. This bill would provide that the practice of nurse-midwifery emphasizes informed consent, preventive care and early detection and referral of complications. However, this bill does not define informed consent or when a CNM has to refer a patient to a physician and for what types of complications. In addition, it is also unknown how this bill would affect corporate practice, as the bill does not address this issue.

The Board's primary mission is consumer protection and this bill does not currently include parameters on independent CNM practice that would ensure consumer protection. As such, the Board is opposed to this bill unless it is amended to address the Board's concerns.

FISCAL: None to the Board

SUPPORT: CNMA (Sponsor)

UNAC (Sponsor)

California Hospital Association

California Association of Nurse Anesthetists

Maternal and Child Health Access American Nurses Association California California Families for Access to Midwives

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OPPOSITION: California Medical Association

Medical Board of California (Unless Amended)

AMENDED IN ASSEMBLY APRIL 18, 2017 AMENDED IN ASSEMBLY MARCH 20, 2017

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

ASSEMBLY BILL

No. 1612

Introduced by Assembly Member Burke

February 17, 2017

An act to amend—Section 2746.2 Sections 2746.5, 2746.51, and 2746.52 of the Business and Professions Code, relating to nursing.

LEGISLATIVE COUNSEL'S DIGEST

AB 1612, as amended, Burke. Nursing: nurse-midwives. certified nurse-midwives: supervision.

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(1) The Nursing Practice Act provides for the licensure and regulation of nurse practitioners by the Board of Registered Nursing, which is within the Department of Consumer Affairs, and requires the board to issue a certificate to practice nurse-midwifery to a licensee who meets specified qualifications. That act requires each applicant for a certificate to show evidence satisfactory to the board that the applicant has met educational standards established by the board or has at least the equivalent thereof and authorizes the board to appoint a committee of qualified physicians and nurses to develop the necessary standards relating to educational requirements, ratios of nurse-midwives to supervising physicians, and associated matters. authorizes a certified nurse-midwife, under the supervision of a licensed physician and surgeon, to attend cases of normal childbirth and to provide prenatal, intrapartum, and postpartum care, including family planning care, for the mother, and immediate care for the newborn, and provides that the

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practice of nurse-midwifery constitutes the furthering or undertaking by a certified person, under the supervision of a licensed physician and surgeon who has current practice or training in obstetrics, to assist a woman in childbirth so long as progress meets criteria accepted as normal. The act makes the violation of any of its provisions punishable as a misdemeanor, as specified.

This bill would specify that evidence satisfactory to the board includes evidence of current advanced level national certification by a certifying body that meets standards established and approved by the board and would remove from the authority of the committee the development of standards relating to ratios of nurse-midwives to supervising physicians. repeal the requirement that a certified nurse-midwife be under the supervision of a licensed physician and surgeon. The bill would authorize a certified nurse-midwife to consult, refer, or transfer care to a physician and surgeon as indicated by the health status of the patient and the resources and medical personnel available in the setting of care. The bill would provide that a certified nurse-midwife practices within a variety of settings, including, but not limited to, the home setting. The bill would specify that nurse-midwifery care emphasizes informed consent, preventive care, and early detection and referral of complications.

(2) The act authorizes a certified nurse-midwife to furnish and order drugs or devices incidentally to the provision of family planning services, routine health care or perinatal care, and care rendered consistent with the certified nurse-midwife's educational preparation in specified facilities and clinics, and only in accordance with standardized procedures and protocols, including physician and surgeon supervision.

This bill additionally would authorize a certified nurse-midwife to furnish and order drugs and devices related to care rendered in a home and only would require physician and surgeon supervision for the furnishing and ordering of drugs and devices if the standardized procedures and protocols require supervision. The bill would authorize a certified nurse-midwife to directly procure supplies and devices, to obtain and administer drugs and diagnostic tests, to order laboratory and diagnostic testing, and to receive reports that are necessary to his or her practice and consistent with nurse-midwifery education preparation.

(3) The act also authorizes a certified nurse-midwife to perform and repair episiotomies and to repair first-degree and 2nd-degree

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lacerations of the perineum in a licensed acute care hospital and a licensed alternative birth center, if certain requirements are met, including, but not limited to, that episiotomies are performed pursuant to protocols developed by the supervising physician and surgeon.

This bill would also authorize a certified nurse-midwife to perform and repair episiotomies and to repair first-degree and 2nd-degree lacerations of the perineum in a home setting and in a birth center accredited by a national accrediting body approved by the board. The bill would delete all requirements that those procedures be performed pursuant to protocols developed and approved by the supervising physician and surgeon. The bill would require a certified nurse-midwife when performing those procedures to ensure that all complications are referred to a physician and surgeon immediately and to ensure immediate care of patients who are in need of care beyond the scope of practice of the certified nurse-midwife or emergency care for times when a physician and surgeon is not available. By placing new requirements on a certified nurse-midwife, this bill would expand an existing crime and would, therefore, result in a state-mandated local program.

(4) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no-yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 2746.5 of the Business and Professions 2 Code is amended to read:
- 3 2746.5. (a) The certificate to practice nurse-midwifery
- 4 authorizes the holder, under the supervision of a licensed physician
- 5 and surgeon, holder to attend cases of normal childbirth and to
- 6 provide prenatal, intrapartum, and postpartum care, including
- family-planning care, for the mother, and immediate care for the newborn. newborn in a variety of settings, including, but not limited
- 9 to, the home setting.

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(b) As used in this chapter, the practice of nurse-midwifery constitutes the furthering or undertaking by any certified person, under the supervision of a licensed physician and surgeon who has current practice or training in obstetries, person to assist a woman in childbirth so long as progress meets criteria accepted as normal. All complications shall be referred to a physician and surgeon immediately. The practice of nurse-midwifery does not include the assisting of childbirth by any artificial, forcible, or mechanical means, nor the performance of any version.

- (c) As used in this article, "supervision" shall not be construed to require the physical presence of the supervising physician. A certified nurse-midwife may consult, refer, or transfer care to a physician and surgeon as indicated by the health status of the patient and the resources and medical personnel available in the setting of care. Nurse-midwifery care emphasizes informed consent, preventive care, and early detection and referral of complications.
- (d) A certified nurse-midwife is not authorized to practice medicine and surgery by the provisions of this chapter.
- (e) Any regulations promulgated by a state department that affect the scope of practice of a certified nurse-midwife shall be developed in consultation with the board.
- SEC. 2. Section 2746.51 of the Business and Professions Code is amended to read:
- 2746.51. (a) Neither this chapter nor any other—provision of law shall be construed to prohibit a certified nurse-midwife from furnishing or ordering drugs or devices, including controlled substances classified in Schedule II, III, IV, or V under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code), when all of the following apply:
- (1) The drugs or devices are furnished or ordered incidentally *related* to the provision of any of the following:
- (A) Family planning services, as defined in Section 14503 of the Welfare and Institutions Code.
- (B) Routine health care or perinatal care, as defined in subdivision (d) of Section 123485 of the Health and Safety Code.
- (C) Care rendered, consistent with the certified nurse-midwife's educational preparation or for which clinical competency has been established and maintained, to persons within a facility specified in subdivision (a), (b), (c), (d), (i), or (j) of Section 1206 of the

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Health and Safety Code, a clinic as specified in Section 1204 of the Health and Safety Code, a general acute care hospital as defined 3 in subdivision (a) of Section 1250 of the Health and Safety Code, 4 a licensed birth center as defined in Section 1204.3 of the Health and Safety Code, or a special hospital specified as a maternity hospital in subdivision (f) of Section 1250 of the Health and Safety 6 Code.

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- (D) Care rendered in a home pursuant to subdivision (a) of Section 2746.5.
- (2) The drugs or devices are furnished or ordered by a certified nurse-midwife in accordance with standardized procedures or protocols. For purposes of this section, standardized procedure means a document, including protocols, developed and approved by the supervising a physician and surgeon, the certified nurse-midwife, and the facility administrator or his or her designee. The standardized procedure covering the furnishing or ordering of drugs or devices shall specify all of the following:
- (A) Which certified nurse-midwife may furnish or order drugs or devices.
- (B) Which drugs or devices may be furnished or ordered and under what circumstances.
- (C) The extent of physician and surgeon supervision. supervision required, if any.
- (D) The method of periodic review of the certified nurse-midwife's competence, including peer review, and review of the provisions of the standardized procedure.
- (3) If Schedule II or III controlled substances, as defined in Sections 11055 and 11056 of the Health and Safety Code, are furnished or ordered by a certified nurse-midwife, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating-or supervising physician and surgeon. For Schedule II controlled substance protocols, the provision for furnishing the Schedule II controlled substance shall address the diagnosis of the illness, injury, or condition for which the Schedule II controlled substance is to be furnished.
- (4) The furnishing or ordering of drugs or devices by a certified nurse-midwife occurs under physician and surgeon supervision. For purposes of this section, no physician and surgeon shall supervise more than four certified nurse-midwives at one time.

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Physician standardized procedures and protocols. If the standardized procedures and protocols require physician and surgeon supervision, supervision shall not be construed to require 4 the physical presence of the physician, but does include all of the following:

- (A) Collaboration on the development of the standardized procedure or protocol.
 - (B) Approval of the standardized procedure or protocol.
- (C) Availability by telephonic contact at the time of patient examination by the certified nurse-midwife.
- (b) (1) The furnishing or ordering of drugs or devices by a certified nurse-midwife is conditional on the issuance by the board of a number to the applicant who has successfully completed the requirements of paragraph (2). The number shall be included on all transmittals of orders for drugs or devices by the certified nurse-midwife. The board shall maintain a list of the certified nurse-midwives that it has certified pursuant to this paragraph and the number it has issued to each one. The board shall make the list available to the California State Board of Pharmacy upon its request. Every certified nurse-midwife who is authorized pursuant to this section to furnish or issue a drug order for a controlled substance shall register with the United States Drug Enforcement Administration.
- (2) The board has certified in accordance with paragraph (1) that the certified nurse-midwife has satisfactorily completed a course in pharmacology covering the drugs or devices to be furnished or ordered under this section. The board shall establish the requirements for satisfactory completion of this paragraph.
- (3) A physician and surgeon may determine the extent of supervision necessary pursuant to this section in the furnishing or ordering of drugs and devices.
- (4) A copy of the standardized procedure or protocol relating to the furnishing or ordering of controlled substances by a certified nurse-midwife shall be provided upon request to any licensed pharmacist who is uncertain of the authority of the certified nurse-midwife to perform these functions.
- (5) Certified nurse-midwives who are certified by the board and hold an active furnishing number, who are currently authorized through standardized procedures or protocols to furnish Schedule II controlled substances, and who are registered with the United

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States Drug Enforcement Administration shall provide documentation of continuing education specific to the use of Schedule II controlled substances in settings other than a hospital based on standards developed by the board.

- (c) Drugs or devices furnished or ordered by a certified nurse-midwife may include Schedule II controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) under the following conditions:
- (1) The drugs and devices are furnished or ordered in accordance with requirements referenced in paragraphs (2) to (4), inclusive, of subdivision (a) and in paragraphs (1) to (3), inclusive, of subdivision (b).
- (2) When Schedule II controlled substances, as defined in Section 11055 of the Health and Safety Code, are furnished or ordered by a certified nurse-midwife, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising *a* physician and surgeon.
- (d) Furnishing of drugs or devices by a certified nurse-midwife means the act of making a pharmaceutical agent or agents available to the patient in strict accordance with a standardized procedure or protocol. Use of the term "furnishing" in this section—shall include the following: includes
- (1) The the ordering of a drug or device in accordance with the standardized procedure or protocol.
- (2) Transmitting an order of a supervising physician and surgeon.
- (e) "Drug order" or "order" for purposes of this section means an order for medication or for a drug or device that is dispensed to or for an ultimate user, issued by a certified nurse-midwife as an individual practitioner, within the meaning of Section 1306.03 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising *a* physician; (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by certified nurse-midwives; and (3) the signature of a certified nurse-midwife on a drug order issued in accordance with

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this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

- (f) Notwithstanding any other law, a certified nurse-midwife is authorized to directly procure supplies and devices, to obtain and administer drugs and diagnostic tests, to order laboratory and diagnostic testing, and to receive reports that are necessary to his or her practice as a certified nurse-midwife and consistent with nurse-midwifery education preparation.
- SEC. 3. Section 2746.52 of the Business and Professions Code is amended to read:
- 2746.52. (a) Notwithstanding Section 2746.5, the certificate to practice nurse-midwifery authorizes the holder to perform and repair episiotomies, and to repair first-degree and second-degree lacerations of the perineum, in a licensed acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, and a licensed alternate alternative birth center, as defined in paragraph (4) of subdivision (b) of Section 1204 of the Health and Safety Code, but only if all of the following conditions are met: a birth center accredited by a national accrediting body approved by the board, and in a home setting.
- (a) The supervising physician and surgeon and any backup physician and surgeon is credentialed to perform obstetrical care in the facility.
- (b) The episiotomies are performed pursuant to protocols developed and approved by all of the following:
 - (1) The supervising physician and surgeon.
 - (2) The certified nurse-midwife.
- (3) The director of the obstetries department or the director of the family practice department, or both, if a physician and surgeon in the obstetries department or the family practice department is a supervising physician and surgeon, or an equivalent person if there is no specifically identified obstetries department or family practice department.
 - (4) The interdisciplinary practices committee, if applicable.
 - (5) The facility administrator or his or her designee.
- (e) The protocols, and the procedures which shall be developed pursuant to the protocols, shall relate to the performance and repair of episiotomies and the repair of first-degree and second-degree lacerations of the perineum, and shall do all of the following:

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(b) A certified nurse-midwife performing and repairing episiotomies and repairing first-degree and second-degree lacerations of the perineum, shall do both of the following:

- (1) Ensure that all complications are referred to a physician and surgeon immediately.
- (2) Ensure immediate care of patients who are in need of care beyond the scope of practice of the certified nurse midwife, nurse-midwife, or emergency care for times when the supervising a physician and surgeon is not on the premises. available.
- (3) Establish the number of certified nurse-midwives that a supervising physician and surgeon may supervise.
- SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

SECTION 1. Section 2746.2 of the Business and Professions Code is amended to read:

2746.2. Each applicant shall show by evidence satisfactory to the board that he or she has met the educational standards established by the board or has at least the equivalent thereof, including evidence of current advanced level national certification by a certifying body that meets standards established and approved by the board. The board is authorized to appoint a committee of qualified physicians and nurses, including, but not limited to, obstetricians and nurse-midwives, to develop the necessary standards relating to educational requirements and associated matters.

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MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

Bill Number: AB 1650 **Author:** Maienschein

Bill Date: April 20, 2017, Amended

Subject: Emergency Medical Services: Community Paramedicine

Sponsor: California Ambulance Association

Position: Oppose

DESCRIPTION OF LEGISLATION:

This bill would create the Community Paramedic Program (Program) in the Emergency Medical Services Authority (EMSA). This bill would sunset the Program on January 1, 2022.

BACKGROUND

Under existing law, a paramedic is limited to providing care in emergency situations, during ambulance transports, and while working in a hospital. Beginning in late 2014, thirteen community paramedicine pilot projects began in California, testing six concepts as part of the Health Workforce Pilot Project (HWPP) #173. These HWPP pilot projects are coordinated through the Office of Statewide Health Planning and Development (OSHPD). This bill would authorize four of the original six concepts allowed for in the pilot project.

ANALYSIS

This bill would allow the Program to authorize a local emergency medical services (EMS) agency that opts to participate in the Program to provide, through a local community paramedic program, any of the following services:

- Post-discharge follow up services for targeted and eligible patients recently discharged from a hospital participating in the Program, which is intended to provide short-term assistance in order to reduce hospital admission and shall not replace home health care or any other services available.
- Directly observed therapy for eligible patients undergoing tuberculosis treatment in partnership with a county public health department. This therapy service is intended as a supplement to provide for after-hours availability or to reach patients who are difficult to serve, and shall not replace community health workers or public health nurses.
- Hospice rapid response service for eligible and enrolled patients to administer comfort care, coordinate services with the hospice nurse, and, as appropriate, avoid patient transport to an acute care hospital emergency department.
- Case management services and linkage to non-emergency services for frequent EMS system users, for the purpose of reducing dependence of those users on the EMS system and acute care hospital emergency departments to provide primary medical care.

This bill would require EMSA to develop criteria that qualifies local community paramedic services to participate in the Program. The criteria must include minimum training and certification requirements for a community paramedic, including, but not limited to, the following:

- Four years of job experience as an EMT-P.
- At least 48 hours of classroom-based instruction.
- At least four hours of clinical, hands-on training.
- At least 56 hours of study outside the classroom.

EMSA would also be required to develop regulations for the initiation, operation, and evaluation of a local community paramedic program. This bill would require EMSA to develop an application and application process to be used by a local EMS agency that seeks to participate in the Program and to review and approve these applications. EMSA would be required to consult with OSHPD on the implementation of this Program. This bill would require EMSA to provide OSHPD with an annual report regarding all local community paramedic programs that shall include, but not be limited to, information regarding program effectiveness, cost-savings, and patient safety, including details regarding any adverse patient outcomes. OSHPD would be required to publish the report on its website.

This bill would specify that a local EMS agency can opt to participate in the Program as long as they meet the criteria and submit an application to EMSA. This bill would require a community paramedic service plan developed by a local EMS agency that seeks to participate in the Program to demonstrate it will be able to meet all the requirements of the Program and include specified information.

This bill would sunset the Program on January 1, 2022.

According to the author, a report published in January 2017 concluded that the HWPP pilot projects resulted in improved health care for the targeted patients, as well as a reduction in health care costs. The intent of this bill, according to the author, is to permanently authorize the expanded role of paramedics and to establish parameters for community paramedicine programs.

Board staff, working with a Board Member who is a physician, provided input to OSHPD on HWPP #173 and raised patient safety concerns. One of these concerns being that persons recently discharged from the hospital should be seen by their primary care physician for follow up care. The additional training that would be required would not be sufficient enough to teach paramedics the basics of disease management or how to diagnose and treat medical conditions. The other concern raised was that the pilot project did not specifically delineate what services will be allowed to be performed by community paramedics as part of the post-discharge follow up services and case management services; the same is true for this bill. This bill could have a negative impact on consumer protection; as such, the Board opposes this bill.

FISCAL: None

SUPPORT: California Ambulance Association (Sponsor)

California Hospital Association

County Behavioral Health Director's Association

Assisted Hospice Care

OPPOSITION: American College of Emergency Physicians (Unless Amended)

California Association for Health Services at Home California Hospice and Palliative Care Association

California Nurses Association/National Nurses Association

Medical Board of California

AMENDED IN ASSEMBLY APRIL 20, 2017 AMENDED IN ASSEMBLY APRIL 6, 2017 AMENDED IN ASSEMBLY MARCH 29, 2017

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

ASSEMBLY BILL

No. 1650

Introduced by Assembly Member Maienschein (Coauthors: Assembly Members Chávez and Mathis)

(Coauthor: Senator Wilk)

February 17, 2017

An act to add *and repeal* Chapter 13 (commencing with Section 1800) to of Division 2.5 of the Health and Safety Code, relating to emergency medical services.

LEGISLATIVE COUNSEL'S DIGEST

AB 1650, as amended, Maienschein. Emergency medical services: community paramedicine.

Existing law, the Emergency Medical Services System and the Prehospital Emergency Medical Care Personnel Act, governs local emergency medical services (EMS) systems. The act establishes the Emergency Medical Services Authority, which is responsible for the coordination and integration of all state agencies concerning emergency medical services. Among other duties, the authority is required to develop planning and implementation guidelines for emergency medical services systems, provide technical assistance to existing agencies, counties, and cities for the purpose of developing the components of emergency medical services systems, and receive plans for the implementation of emergency medical services and trauma care systems from local EMS agencies.

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This bill-would, until January 1, 2022, create the Community Paramedic Program in the authority. The bill would authorize the authority to authorize a local EMS agency that opts to participate in the program to provide specified services, such as case management services and linkage to nonemergency services for frequent EMS system users, through a local community paramedic program. The bill would require the authority, in consultation with the Office of Statewide Health Planning and Development, to develop criteria to qualify services for participation in the program, develop an application and application process for local EMS agencies seeking to participate in the program, and to review and approve applications for participation in the program as a component of the local EMS agency's EMS plan. The bill would authorize a local EMS agency to opt to participate in the program if it meets the criteria established by the authority and completes the application process developed by the criteria. The bill would specify the necessary components of a community paramedic service plan to be included in the local EMS agency's application. The bill would require the medical director of the local EMS agency to oversee the local community paramedic program. The bill would require the authority to annually report specified information related to local community paramedic programs to the office, and require the office to publish the report on its Internet Web site.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Chapter 13 (commencing with Section 1800) is added to Division 2.5 of the Health and Safety Code, to read: 3 4 CHAPTER 13. COMMUNITY PARAMEDIC PROGRAM 5 6 Article 1. General Provisions 7 1800. This chapter shall be known, and may be cited, as the 9 Community Paramedic Program Act. 1802. Unless the context requires otherwise, the following 10 11 definitions shall apply to this chapter: 12 (a) "Community paramedic" means an individual who is educated and trained in community paramedicine, whose scope of 13

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practice is in accordance with standards established by the authority, who holds a current certification as a mobile integrated health community paramedic by the International Board of Specialty Certification or equivalent, who has a valid license issued pursuant to this chapter, and who is accredited by a local EMS agency.

- (b) "Program" means the Community Paramedic Program established by this chapter.
- 1804. Within the authority there is the statewide Community Paramedic Program. The program may authorize a local EMS agency that opts to participate in the program to provide, through a local community paramedic program, *and notwithstanding Sections 1797.52 and 1797.218*, any of the following services:
- (a) (1) Postdischarge followup services for targeted and eligible patients recently discharged from a hospital participating in the program.
- (2) A postdischarge service authorized pursuant to this subdivision is intended to provide short-term assistance in order to reduce hospital admissions and shall not replace home health care or any other services available to patients.
- (b) (1) Directly observed therapy for eligible patients undergoing tuberculosis treatment in partnership with a county public health department.
- (2) A directly observed therapy service authorized pursuant to this subdivision is intended as a supplement to provide for after-hours availability or to reach patients who are difficult to serve, and shall not replace home community health workers or public health nurses.
- (c) Hospice rapid response service for eligible and enrolled patients to administer comfort care, coordinate services with the hospice nurse, and, as appropriate, avoid patient transport to an acute care hospital emergency department.
- (d) Case management services and linkage to nonemergency services for frequent EMS system users, for the purpose of reducing dependence of those users on the EMS system and acute care hospital emergency departments to provide primary medical care.

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Article 2. Duties and Powers of the Authority

- 1810. (a) To implement the program, the authority shall do all of the following:
- (1) Develop criteria that qualify local community paramedic services to participate in the program.
- (2) Develop an application and application process to be used by a local EMS agency that seeks to participate in the program. The application process shall provide for the submission of a local community paramedic service plan described in Section 1820 that shall be a component of the local EMS agency's local EMS plan.
- (3) Review and approve applications for the implementation of local community paramedic services as a component of the local EMS agency's EMS plan in accordance with Section 1797.105.
- (b) Criteria described in paragraph (1) of subdivision (a) shall include, but not be limited to, the following:
- (1) Training-Minimum training and certification requirements for a community-paramedic. paramedic, including, but not limited to, the following:
 - (A) Four years of job experience as an EMT-P.
 - (B) At least 48 hours of classroom-based instruction.
 - (C) At least four hours of clinical, hands-on training.
 - (D) At least 56 hours of study outside of the classroom.
- (2) Regulations for the initiation, operation, and evaluation of a local community paramedic program.
- 1812. (a) The authority shall consult with the Office of Statewide Health Planning and Development in performing its duties required by this chapter.
- (b) The authority shall provide the Office of Statewide Health Planning and Development with an annual report regarding all local community paramedic programs that shall include, but not be limited to, information regarding program effectiveness, cost-savings, and patient safety, including details regarding any adverse patient outcomes. The Office of Statewide Health Planning and Development shall publish the report on its Internet Web site.

Article 3. Local EMS Agency Participation

1820. (a) A local EMS agency may opt to participate in the program by meeting the criteria and completing the application

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1 and application process established by the authority pursuant to 2 Section 1810.

- (b) A community paramedic service plan developed by a local EMS agency that seeks to participate in the program shall demonstrate that the local EMS agency will be able to meet the requirements of the program and shall include, but not be limited to, all of the following:
- (1) Agreements between local agencies and service providers participating or partnering in the local community paramedic program.
 - (2) A description of the local community paramedic program.
- (3) A description of existing problems that the local community paramedic program is intended to address.
- (4) Criteria for the enrollment or inclusion of patients in the local community paramedic program.
- (5) Goals and intended results of the local community paramedic program.
 - (6) Criteria for patient and provider safety.

- (7) Estimated costs and savings attributable to the local community paramedic program.
- (8) Data to be collected for the purpose of evaluating the effectiveness of the local community paramedic program.
- (9) Criteria and processes for evaluating the effectiveness of the local community paramedic program.
- (10) Protocols, policies, and procedures for the implementation and operation of local community paramedic program services by a community paramedic.
- (11) Protocols for the assessment of patients served by the local community paramedic program.
- (12) Any other information or plan component required by the authority pursuant to Section 1810.
- 1822. The local EMS agency medical director shall oversee a local community paramedic program participating in the program.
- 1823. This chapter shall remain in effect only until January 1, 2022, and as of that date is repealed, unless a later enacted statute that is enacted before January 1, 2022, deletes or extends that date.

MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

Bill Number: AB 1751 **Author:** Low

Bill Date: January 3, 2018, Introduced

Subject: Controlled Substances: CURES Database

Sponsor: California State Board of Pharmacy

DESCRIPTION OF CURRENT LEGISLATION:

This bill would allow for information sharing between California's prescription drug monitoring program (PDMP), the Controlled Substances Utilization Review and Evaluation System (CURES), and other states' PDMPs.

BACKGROUND:

The CURES Program is currently housed in the Department of Justice (DOJ) and is a state database of dispensed prescription drugs that have a high potential for misuse and abuse. CURES provides for electronic transmission of specified prescription data to DOJ. In September 2009, DOJ launched the CURES Prescription Drug Monitoring Program (PDMP) allowing pre-registered users, including licensed health care prescribers eligible to prescribe controlled substances, pharmacists authorized to dispense controlled substances, law enforcement, and regulatory boards, to access patient controlled substance history information through a secure website. SB 809 (DeSaulnier, Chapter 400) was signed into law in 2013 and included a provision to collect funds from boards that license individuals who prescribe and dispense, for purposes of funding and upgrading the CURES system. This bill also required all prescribers to register with CURES by January 1, 2016, but the law was amended to extend the registration deadline to July 1, 2016. The new CURES 2.0 system, which is a modernized system that has been updated to more efficiently serve prescribers, pharmacists and other entities, is now operational and available online, as long as the prescriber uses a compliant browser.

According to the Centers for Disease Control and Prevention, drug overdose deaths and opioid-involved deaths continue to increase in the United States. Since 1999, the number of overdose deaths involving opioids quadrupled. From 2000 to 2015, more than half a million people died from drug overdoses. Opioids killed more than 42,000 people in 2016, more than any year on record.

According to the author's office, 48 other states have their own PDMPs like CURES. Use of PDMPs is recognized as one of the most effective ways to combat the growing opioid abuse crisis.

ANALYSIS

This bill would allow DOJ to enter into an agreement with an entity operating an interstate data share hub for purposes of participating in inter-jurisdictional information

sharing between PDMPs across state lines. This bill would require any agreement entered into by DOJ to ensure that all access of data within CURES complies with California law and meets the same patient privacy and data security standards employed and required for direct access of CURES.

According to the author, several entities offer interstate data share hubs to allow doctors to review prescriptions dispensed in other states, and many state PDMPs are already participating. The author believes this bill will provide health professionals in California with state-of-the-art tools to combat the opioid abuse crisis.

The Medical Board of California (Board) believes CURES is a very important enforcement tool and an effective aid for physicians to use to prevent doctor shopping. This bill will give physicians access to prescription drug information from other states, which will help to further the Board's mission of consumer protection. Board staff recommends that the Board support this bill.

FISCAL: None to the Board

SUPPORT: California State Board of Pharmacy

OPPOSITION: None on file

POSITION: Recommendation: Support

Introduced by Assembly Member Low

January 3, 2018

An act to amend Section 11165 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 1751, as introduced, Low. Controlled substances: CURES database.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by a health care practitioner authorized to prescribe, order, administer, furnish, or dispense a Schedule II, Schedule III, or Schedule IV controlled substance.

This bill would authorize the Department of Justice to enter into an agreement with an entity operating an interstate data share hub for the purposes of participating in interjurisdictional information sharing between prescription drug monitoring programs across state lines. The bill would require any agreement entered into by the Department of Justice for those purposes to ensure that all access to data within CURES complies with California law and meets the same patient privacy and data security standards employed and required for direct access of CURES.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

AB 1751 -2-

The people of the State of California do enact as follows:

SECTION 1. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

- (b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.
- (c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.
- (2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party, unless authorized by, or pursuant to, state and

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federal privacy and security laws and regulations. The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

- (B) Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.
- (3) In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data is provided and keep a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.
- (d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:
- (1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.
- (2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
- (3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.
- (4) National Drug Code (NDC) number of the controlled substance dispensed.
 - (5) Quantity of the controlled substance dispensed.

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1 (6) International Statistical Classification of Diseases, 9th 2 revision (ICD-9) or 10th revision (ICD-10) Code, if available.

- (7) Number of refills ordered.
- (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
 - (9) Date of origin of the prescription.
 - (10) Date of dispensing of the prescription.
 - (e) The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.
 - (f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).
 - (g) The Department of Justice may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.
 - (h) (1) The Department of Justice may enter into an agreement with an entity operating an interstate data share hub for purposes of participating in interjurisdictional information sharing between prescription drug monitoring programs across state lines.
 - (2) Any agreement entered into by the Department of Justice for purposes of interstate data sharing shall ensure that all access to data within CURES complies with California law and meets the same patient privacy and data security standards employed and required for direct access of CURES.

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MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

Bill Number: AB 1752 **Author:** Low

Bill Date: January 3, 2018, Introduced

Subject: Controlled Substances: CURES Database

Sponsor: California State Board of Pharmacy

DESCRIPTION OF CURRENT LEGISLATION:

This bill would add Schedule V drugs to the Controlled Substances Utilization Review and Evaluation System (CURES) database, would allow for other drugs to be added to CURES, and would shorten the timeline for pharmacists to report dispensed prescriptions.

BACKGROUND:

The CURES Program is currently housed in the Department of Justice (DOJ) and is a state database of dispensed prescription drugs that have a high potential for misuse and abuse. CURES provides for electronic transmission of specified prescription data to DOJ. In September 2009, DOJ launched the CURES Prescription Drug Monitoring Program (PDMP) allowing pre-registered users, including licensed health care prescribers eligible to prescribe controlled substances, pharmacists authorized to dispense controlled substances, law enforcement, and regulatory boards, to access patient controlled substance history information through a secure website. SB 809 (DeSaulnier, Chapter 400) was signed into law in 2013 and included a provision to collect funds from boards that license individuals who prescribe and dispense, for purposes of funding and upgrading the CURES system. This bill also required all prescribers to register with CURES by January 1, 2016, but the law was amended to extend the registration deadline to July 1, 2016. The new CURES 2.0 system, which is a modernized system that has been updated to more efficiently serve prescribers, pharmacists and other entities, is now operational and available online, as long as the prescriber uses a compliant browser.

According to the Centers for Disease Control and Prevention, drug overdose deaths and opioid-involved deaths continue to increase in the United States. Since 1999, the number of overdose deaths involving opioids quadrupled. From 2000 to 2015, more than half a million people died from drug overdoses. Opioids killed more than 42,000 people in 2016, more than any year on record.

ANALYSIS

This bill would add Schedule V drugs to CURES and would authorize the California State Board of Pharmacy (BOP) to add additional medications to CURES through regulations if a medication is determined to pose a substantial risk of abuse or diversion. This bill would also shorten the timeframe for pharmacists to report dispensed controlled

substances to CURES, from the current seven days, to one working day after the date a controlled substance is dispensed.

According to the author, the recent rise in street use of cough syrups containing the opioid codeine has led to a spike in theft and abuse of Schedule V drugs. Adding Schedule V drugs to CURES will help to curb the abuse and diversion of all controlled substances. Changing the 7-day reporting timeline to one-day will allow for more real-time access to data used to prevent prescription drug abuse.

This bill will not add Schedule V drugs to the section of law that requires physicians to check the CURES database. Therefore, adding Schedule V drugs to CURES will have a significant impact on dispensers, not prescribers. In addition, changing the reporting deadline for dispensers will result in up-to-date information in CURES and will make it even more of an effective aid for physicians to use to prevent doctor shopping. The Board may want to discuss and consider the language that would authorize the BOP to add additional medications to CURES through regulations if a medication is determined to pose a substantial risk of abuse or diversion.

FISCAL: None to the Board

SUPPORT: California State Board of Pharmacy

OPPOSITION: None on file

Introduced by Assembly Member Low

January 3, 2018

An act to amend Sections 11165 and 11165.1 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 1752, as introduced, Low. Controlled substances: CURES database.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by a health care practitioner authorized to prescribe, order, administer, furnish, or dispense a Schedule II, Schedule III, or Schedule IV controlled substance. Existing law requires a dispensing pharmacy, clinic, or other dispenser to report specified information to the Department of Justice as soon as reasonably possible, but not more than 7 days after the date a controlled substance is dispensed.

This bill would add Schedule V controlled substances to the CURES database. The bill would additionally authorize the California State Board of Pharmacy, through regulation, to add additional medications to be tracked in the CURES database. The bill would require a dispensing pharmacy, clinic, or other dispenser to report the information required by the CURES database no more than one working day after a controlled substance is dispensed. The bill would change what

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information is required to be reported by deleting references to classification codes and adding the date of sale of the prescription.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 11165 of the Health and Safety Code is 2 amended to read:

3 11165. (a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV IV, and Schedule V controlled substances, and for statistical analysis, education, and research, the Department of 10 Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization 11 12 Review and Evaluation System (CURES) for the electronic 13 monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and 14 Schedule-IV IV, and Schedule V controlled substances by all 15 practitioners authorized to prescribe, order, administer, furnish, or 16 17 dispense these controlled substances. The California State Board 18 of Pharmacy may add through regulation additional medications 19 determined to pose a substantial risk of abuse or diversion that 20 shall be tracked in CURES.

- (b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.
- (c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.
- (2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the

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Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations. The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

(B) Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.

- (3) In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data is provided and keep a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.
- (d) For each prescription for a Schedule II, Schedule III, or Schedule IV, or Schedule V controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, and 1308.15, respectively, of Title 21 of the Code of Federal Regulations, and for any additional medications of concern added by the California State Board of Pharmacy through regulation, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days one working day after the date a controlled substance is dispensed, in a format specified by the Department of Justice:
- (1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of

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Health and Human Services, and the gender, and date of birth of the ultimate user.

- (2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
- (3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.
- (4) National Drug Code (NDC) number of the controlled substance dispensed.
 - (5) Quantity of the controlled substance dispensed.
- (6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.
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- 16 (6) Number of refills ordered.
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- 18 (7) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
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- 21 (8) Date of origin of the prescription.
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- (9) Date of dispensing of the prescription.
- (10) Date of sale of the prescription.
- (e) The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.
- (f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying

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desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).

- (g) The Department of Justice may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.
- SEC. 2. Section 11165.1 of the Health and Safety Code is amended to read:
- 11165.1. (a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule—IV IV, or Schedule V controlled substances pursuant to Section 11150 shall, before July 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to that practitioner the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).
- (ii) A pharmacist shall, before July 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to that pharmacist the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES PDMP.
- (B) An application may be denied, or a subscriber may be suspended, for reasons which include, but are not limited to, the following:
- (i) Materially falsifying an application to access information contained in the CURES database.
- (ii) Failing to maintain effective controls for access to the patient activity report.
- (iii) Having his or her federal DEA registration suspended or revoked.
- 38 (iv) Violating a law governing controlled substances or any 39 other law for which the possession or use of a controlled substance 40 is an element of the crime.

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(v) Accessing information for a reason other than to diagnose or treat his or her patients, or to document compliance with the law.

- (C) An authorized subscriber shall notify the department within 30 days of any changes to the subscriber account.
- (D) Commencing no later than October 1, 2018, an approved health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist pursuant to subdivision (b) of Section 209 of the Business and Professions Code may use the department's online portal or a health information technology system that meets the criteria required in subparagraph (E) to access information in the CURES database pursuant to this section. A subscriber who uses a health information technology system that meets the criteria required in subparagraph (E) to access the CURES database may submit automated queries to the CURES database that are triggered by predetermined criteria.
- (E) Commencing no later than October 1, 2018, an approved health care practitioner or pharmacist may submit queries to the CURES database through a health information technology system if the entity that operates the health information technology system can certify all of the following:
- (i) The entity will not use or disclose data received from the CURES database for any purpose other than delivering the data to an approved health care practitioner or pharmacist or performing data processing activities that may be necessary to enable the delivery unless authorized by, and pursuant to, state and federal privacy and security laws and regulations.
- (ii) The health information technology system will authenticate the identity of an authorized health care practitioner or pharmacist initiating queries to the CURES database and, at the time of the query to the CURES database, the health information technology system submits the following data regarding the query to CURES:
 - (I) The date of the query.
- 34 (II) The time of the query.
- 35 (III) The first and last name of the patient queried.
- 36 (IV) The date of birth of the patient queried.
- (V) The identification of the CURES user for whom the systemis making the query.

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(iii) The health information technology system meets applicable patient privacy and information security requirements of state and federal law.

- (iv) The entity has entered into a memorandum of understanding with the department that solely addresses the technical specifications of the health information technology system to ensure the security of the data in the CURES database and the secure transfer of data from the CURES database. The technical specifications shall be universal for all health information technology systems that establish a method of system integration to retrieve information from the CURES database. The memorandum of understanding shall not govern, or in any way impact or restrict, the use of data received from the CURES database or impose any additional burdens on covered entities in compliance with the regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations.
- (F) No later than October 1, 2018, the department shall develop a programming interface or other method of system integration to allow health information technology systems that meet the requirements in subparagraph (E) to retrieve information in the CURES database on behalf of an authorized health care practitioner or pharmacist.
- (G) The department shall not access patient-identifiable information in an entity's health information technology system.
- (H) An entity that operates a health information technology system that is requesting to establish an integration with the CURES database shall pay a reasonable fee to cover the cost of establishing and maintaining integration with the CURES database.
- (I) The department may prohibit integration or terminate a health information technology system's ability to retrieve information in the CURES database if the health information technology system fails to meet the requirements of subparagraph (E), or the entity operating the health information technology system does not fulfill its obligation under subparagraph (H).
- (2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV, or Schedule V controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied

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with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

- (b) A request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the department.
- (c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule—IV IV, or Schedule V controlled substances, the department may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.
- (d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the department pursuant to this section is medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.
- (e) Information concerning a patient's controlled substance history provided to a practitioner or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 1308.14, and 1308.15 of Title 21 of the Code of Federal Regulations.
- (f) A health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, is not subject to civil or administrative liability arising from any false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for any resulting failure of the CURES database to accurately or timely report that information.
- (g) For purposes of this section, the following terms have the following meanings:
- (1) "Automated basis" means using predefined criteria to trigger an automated query to the CURES database, which can be attributed to a specific health care practitioner or pharmacist.
 - (2) "Department" means the Department of Justice.

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(3) "Entity" means an organization that operates, or provides or makes available, a health information technology system to a health care practitioner or pharmacist.

- (4) "Health information technology system" means an information processing application using hardware and software for the storage, retrieval, sharing of or use of patient data for communication, decisionmaking, coordination of care, or the quality, safety, or efficiency of the practice of medicine or delivery of health care services, including, but not limited to, electronic medical record applications, health information exchange systems, or other interoperable clinical or health care information system.
- (5) "User-initiated basis" means an authorized health care practitioner or pharmacist has taken an action to initiate the query to the CURES database, such as clicking a button, issuing a voice command, or taking some other action that can be attributed to a specific health care practitioner or pharmacist.

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MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

Bill Number: AB 1753 **Author:** Low

Bill Date: January 3, 2018, Introduced

Subject: Controlled Substances: CURES Database

Sponsor: California State Board of Pharmacy

DESCRIPTION OF CURRENT LEGISLATION:

This bill would allow require the Department of Justice (DOJ) to reduce the number of approved vendors for the security Printers Program and would require each prescription pad to be serialized and include specified information.

BACKGROUND:

DOJ operates the Security Printers Program that regulates the manufacturing of prescription pads. Existing law requires prescribers of Schedule II through V controlled substances to use tamper-resistant prescription forms obtained from a DOJ-approved vendor.

The Medical Board of California (Board) has recently received inquiries from physicians regarding some pharmacies refusing to fill prescriptions written on non-compliant prescription forms. The Board has put information on its website urging physicians to verify their prescription forms are compliant with state law prior to using the form. Existing law requires 14 elements to appear on California Security Prescription Forms.

ANALYSIS

This bill would require DOJ, beginning January 1, 2020, to limit the number of approved security printers to three. This bill would require DOJ to establish policies governing the selection of the three approved vendors based on ability to meet demand and prevent fraud and theft of prescription pads and the process of revoking approval for currently authorized printers (in excess of three).

This bill would require the printed prescription forms for controlled substances to include the following:

- A uniquely serialized number, in a manner prescribed by DOJ
- The security printer to submit via web-based application, within the next working day following delivery, all of the following information for all prescription forms delivered:
 - o Serial number of all prescription forms delivered
 - All prescriber names and Drug Enforcement Administration Controlled Substance Registration Certificate numbers displayed on the prescription forms
 - o The delivery and shipment recipient names.

According to the author, this bill tightens the existing regulation of prescription pad manufacturers to prevent fraud and diversion and requires each pad to be uniquely serialized so that stolen pads can be easily identified and neutralized by regulators and law enforcement.

FISCAL: None to the Board

SUPPORT: California State Board of Pharmacy

OPPOSITION: None on file

Introduced by Assembly Member Low

January 3, 2018

An act to amend Sections 11161.5, 11162.1, and 11165 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 1753, as introduced, Low. Controlled substances: CURES database.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by a health care practitioner authorized to prescribe, order, administer, furnish, or dispense a Schedule II, Schedule III, or Schedule IV controlled substance. Existing law requires prescription forms for controlled substance prescriptions to be obtained from security printers approved by the Department of Justice, as specified. Existing law requires a dispensing pharmacy, clinic, or other dispenser to report specified information to the Department of Justice.

This bill would, beginning January 1, 2020, require the Department of Justice to limit the number of approved printers to 3, as specified. The bill would require prescription forms for controlled substance prescriptions to have a uniquely serialized number, in a manner prescribed by the Department of Justice, and would require a printer to submit specified information to the Department of Justice for all prescription forms delivered. The bill would require the information

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submitted by a dispensing pharmacy, clinic, or other dispenser to the Department of Justice to include the serial number for the corresponding prescription pad, if applicable.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares the following:

- (a) The prevailing use of paper prescription pads to prescribe controlled substances leads to significant instances of theft and fraud each year, contributing to the prescription drug abuse crisis and fueling criminal enterprises engaged in drug diversion.
- (b) Prescribing controlled substances by means of electronic transmission prescription, or e-prescribing, has long been considered the most effective way to combat prescription pad theft and fraud.
- (c) Many states have begun to require that all controlled substances must be prescribed electronically as a means of addressing the public health and public safety crises associated with prescription drug abuse and diversion.
- (d) Until mandatory e-prescribing is established in California, it is critical that tighter restrictions be placed on the manufacturing and tracking of prescription pads used within the state.
- SEC. 2. Section 11161.5 of the Health and Safety Code is amended to read:
- 11161.5. (a) Prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Department of Justice.
- (b) The department may approve security printer applications after the applicant has provided the following information:
 - (1) Name, address, and telephone number of the applicant.
- (2) Policies and procedures of the applicant for verifying the identity of the prescriber ordering controlled substance prescription forms.
- (3) Policies and procedures of the applicant for verifying delivery of controlled substance prescription forms to prescribers.
- 30 (4) (A) The location, names, and titles of the applicant's agent 31 for service of process in this state; all principal corporate officers, 32 if any; all managing general partners, if any; and any individual

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owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms.

- (B) A report containing this information shall be made on an annual basis and within 30 days after any change of office, principal corporate officers, managing general partner, or of any person described in subparagraph (A).
- (5) (A) A signed statement indicating whether the applicant, any principal corporate officer, any managing general partner, or any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms, has ever been convicted of, or pled no contest to, a violation of any law of a foreign country, the United States, or any state, or of any local ordinance.
- (B) The department shall provide the applicant and any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms, with the means and direction to provide fingerprints and related information, in a manner specified by the department, for the purpose of completing state, federal, or foreign criminal background checks.
- (C) Any applicant described in subdivision (b) shall submit his or her fingerprint images and related information to the department, for the purpose of the department obtaining information as to the existence and nature of a record of state, federal, or foreign level convictions and state, federal, or foreign level arrests for which the department establishes that the applicant was released on bail or on his or her own recognizance pending trial, as described in subdivision (*l*) of Section 11105 of the Penal Code. Requests for federal level criminal offender record information received by the department pursuant to this section shall be forwarded to the Federal Bureau of Investigation by the department.
- (D) The department shall assess against each security printer applicant a fee determined by the department to be sufficient to cover all processing, maintenance, and investigative costs generated from or associated with completing state, federal, or foreign background checks and inspections of security printers pursuant

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to this section with respect to that applicant; the fee shall be paid by the applicant at the time he or she submits the security printer application, fingerprints, and related information to the department.

- (E) The department shall retain fingerprint impressions and related information for subsequent arrest notification pursuant to Section 11105.2 of the Penal Code for all applicants.
- (c) The department may, within 60 calendar days of receipt of the application from the applicant, deny the security printer application.
- (d) The department may deny a security printer application on any of the following grounds:
- (1) The applicant, any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms, has been convicted of a crime. A conviction within the meaning of this paragraph means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action which a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4 of the Penal Code.
- (2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another.
- (3) The applicant committed any act that would constitute a violation of this division.
- (4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms.
- (5) The department determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms.
- (6) The department determines that the applicant has submitted an incomplete application.
- (7) As a condition for its approval as a security printer, an applicant shall authorize the Department of Justice to make any examination of the books and records of the applicant, or to visit

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and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce this section.

- (e) An approved applicant shall submit an exemplar of a controlled substance prescription form, with all security features, to the Department of Justice within 30 days of initial production.
- (f) The department shall maintain a list of approved security printers and the department shall make this information available to prescribers and other appropriate government agencies, including the Board of Pharmacy.
- (g) Before printing any controlled substance prescription forms, a security printer shall verify with the appropriate licensing board that the prescriber possesses a license and current prescribing privileges which permits the prescribing of controlled substances with the federal Drug Enforcement Administration (DEA).
- (h) Controlled substance prescription forms shall be provided directly to the prescriber either in person, by certified mail, or by a means that requires a signature signifying receipt of the package and provision of that signature to the security printer. Controlled substance prescription forms provided in person shall be restricted to established customers. Security printers shall obtain a photo identification from the customer and maintain a log of this information. Controlled substance prescription forms shall be shipped only to the prescriber's address on file and verified with the federal Drug Enforcement Administration or the Medical Board of California.
- (i) Security printers shall retain ordering and delivery records in a readily retrievable manner for individual prescribers for three years.
- (j) Security printers shall produce ordering and delivery records upon request by an authorized officer of the law as defined in Section 4017 of the Business and Professions Code.
- (k) Security printers shall report any theft or loss of controlled substance prescription forms to the Department of Justice via fax or e-mail within 24 hours of the theft or loss.
- (1) (1) The department shall impose restrictions, sanctions, or penalties, subject to subdivisions (m) and (n), against security printers who are not in compliance with this division pursuant to regulations implemented pursuant to this division and shall revoke its approval of a security printer for a violation of this division or

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action that would permit a denial pursuant to subdivision (d) of this section.

- (2) When the department revokes its approval, it shall notify the appropriate licensing boards and remove the security printer from the list of approved security printers.
- (m) The following violations by security printers shall be punishable pursuant to subdivision (n):
- (1) Failure to comply with the Security Printer Guidelines established by the Security Printer Program as a condition of approval.
- (2) Failure to take reasonable precautions to prevent any dishonest act or illegal activity related to the access and control of security prescription forms.
- (3) Theft or fraudulent use of a prescriber's identity in order to obtain security prescription forms.
- (n) A security printer approved pursuant to subdivision (b) shall be subject to the following penalties for actions leading to the denial of a security printer application specified in subdivision (d) or for a violation specified in subdivision (m):
- (1) For a first violation, a fine not to exceed one thousand dollars (\$1,000).
- (2) For a second or subsequent violation, a fine not to exceed two thousand five hundred dollars (\$2,500) for each violation.
- (3) For a third or subsequent violation, a filing of an administrative disciplinary action seeking to suspend or revoke security printer approval.
- (o) Beginning January 1, 2020, the Department of Justice shall limit the number of approved printers to three. The Department of Justice shall establish policies governing the selection of the three approved vendors based on ability to meet demand and prevent fraud and theft of prescription pads and the process of revoking approval for currently authorized printers in excess of three.
- 34 SEC. 3. Section 11162.1 of the Health and Safety Code is amended to read:
- 36 11162.1. (a) The prescription forms for controlled substances 37 shall be printed with the following features:
- 38 (1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned

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or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.

- (2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."
- (3) A chemical void protection that prevents alteration by chemical washing.
 - (4) A feature printed in thermochromic ink.
- (5) An area of opaque writing so that the writing disappears if the prescription is lightened.
- (6) A description of the security features included on each prescription form.
- (7) (A) Six quantity check off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box where the following quantities shall appear:
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- 17 25-49
- 18 50–74
- 19 75–100
- 20 101–150
- 21 151 and over.
 - (B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.
 - (8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."
 - (9) The preprinted name, category of licensure, license number, federal controlled substance registration number, and address of the prescribing practitioner.
- 31 (10) Check boxes shall be printed on the form so that the 32 prescriber may indicate the number of refills ordered.
 - (11) The date of origin of the prescription.
 - (12) A check box indicating the prescriber's order not to substitute.
- 36 (13) An identifying number assigned to the approved security 37 printer by the Department of Justice.
- 38 (14) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.

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(B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by his or her name.

- (15) (A) A uniquely serialized number, in a manner prescribed by the Department of Justice.
- (B) Within the next working day following delivery, a security printer shall submit via Web-based application, as specified by the Department of Justice, all of the following information for all prescription forms delivered:
 - (i) Serial numbers of all prescription forms delivered.
- (ii) All prescriber names and Drug Enforcement Administration Controlled Substance Registration Certificate numbers displayed on the prescription forms.
 - (iii) The delivery shipment recipient names.
- (b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.
- (c) (1) A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a) or paragraph (3) of this subdivision.
- (2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility the clinic specified in Section 1200, or the clinic specified in Section 1206 that has 25 or more physicians or surgeons preprinted on the form. Licensed health care facilities or clinics exempt under Section 1206 are not required to preprint the category of licensure and license number of their facility or clinic.
- (3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.

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(4) (A) Except as provided in subparagraph (B), the designated prescriber shall maintain a record of the prescribers to whom the controlled substance prescription forms are issued, that shall include the name, category of licensure, license number, federal controlled substance registration number, and quantity of controlled substance prescription forms issued to each prescriber. The record shall be maintained in the health facility for three years.

- (B) Forms ordered pursuant to this subdivision that are printed by a computerized prescription generation system shall not be subject to subparagraph (A) or paragraph (7) of subdivision (a). Forms printed pursuant to this subdivision that are printed by a computerized prescription generation system may contain the prescriber's name, category of professional licensure, license number, federal controlled substance registration number, and the date of the prescription.
- (d) This section shall become operative on January 1, 2012. Prescription forms not in compliance with this division shall not be valid or accepted after July 1, 2012.
- SEC. 4. Section 11165 of the Health and Safety Code is amended to read:
- 11165. (a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.
- (b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.

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38 39 (c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.

- (2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations. The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.
- (B) Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.
- (3) In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data is provided and keep a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.
- (d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not

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more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

- (1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.
- (2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
- (3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.
- (4) National Drug Code (NDC) number of the controlled substance dispensed.
 - (5) Quantity of the controlled substance dispensed.
- (6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.
 - (7) Number of refills ordered.

- (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
 - (9) Date of origin of the prescription.
 - (10) Date of dispensing of the prescription.
- (11) The serial number for the corresponding prescription pad, if applicable.
- (e) The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.
- (f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder

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identified by the department, for the purpose of identifying

- desirable capabilities and upgrades to the CURES Prescription
- Drug Monitoring Program (PDMP).
- (g) The Department of Justice may establish a process to educate authorized subscribers of the CURES PDMP on how to access and 4
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- use the CURES PDMP.

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AMENDED IN SENATE APRIL 17, 2017 AMENDED IN SENATE MARCH 20, 2017

SENATE BILL

No. 419

Introduced by Senator Portantino

February 15, 2017

An act to add Section 2242.3 to the Business and Professions Code, relating to controlled substances. An act to amend Section 2241.6 of, and to add Section 4075.7 to, the Business and Professions Code, and to add Section 11167.7 to the Health and Safety Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 419, as amended, Portantino. Oxycodone: prescriptions. *Medical practice: pain management*.

Existing law, the Controlled Substances Act, prohibits a person other than a physician, dentist, podiatrist, veterinarian, or certain other health care practitioners, in specified circumstances, from writing or issuing a prescription. That act requires a prescription for specified controlled substances to be made on a specified controlled substance prescription form, to be signed and dated by the prescriber in ink, and to contain specified information. That act requires a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance to consult the Controlled Substance Utilization Review and Evaluation System database to review a patient's controlled substance history before prescribing specified controlled substances to the patient for the first time, and at least once every 4 months thereafter if the substance remain part of the treatment of the patient, except as specified. That act prohibits a person from prescribing, administering, or dispensing a controlled substance to an addict or any person

representing himself or herself as an addict, except as specified. That act defines "addict" for this purpose, and excludes from the definition a person whose drug-seeking behavior is primarily due to the inadequate control of pain. Existing law, the Pharmacy Law, imposes various requirements on the dispensing by prescription of dangerous drugs, including controlled substances. That law prohibits furnishing a prescription for a controlled substance transmitted by means of an oral or electronically transmitted order to any person unknown and unable to properly establish his or her identity. Existing law makes a violation of these provisions a crime.

This bill would require a specified health care practitioner, before prescribing, ordering, or furnishing specified narcotic pain medications, including controlled substances, to a minor, as defined, to educate the guardian of the minor on all other available medical treatments, specified nonopioid treatment alternatives to be tried before and alongside opioid therapy, the risks and benefits of narcotic medications and alternatives to narcotic medications, the safe storage of opioid medications, the proper disposal of unused medications, and the illegality of sharing or misusing prescribed medications. The bill would also require this discussion and counseling to be memorialized in a document printed on a secure prescription pad and signed by the minor, if he or she was counseled, the guardian, and the prescriber. The bill would require a pharmacist to review and verify the document before dispensing the medication. The bill would prohibit a subsequent prescription of those medications from being made until the minor is reevaluated by a pain management specialist or a pediatrician. By adding these new requirements to the Controlled Substances Act and the Pharmacy Law, the violation of which would be a crime, this bill would impose a state-mandated local program.

Existing law establishes the Medical Board of California within the Department of Consumer Affairs. Existing law, among other things, required the board to develop standards before June 1, 2002, to ensure the competent review in cases concerning the management, including, but not limited to, the undertreatment, undermedication, and overmedication of a patient's pain.

This bill would require the board, on or before July 1, 2018, to update those standards. The bill would also require the board to update those standards on or before July 1 each 5th year thereafter. The bill would require the board to convene a task force to develop and recommend the updated standards to the board. The bill would require the task

force, in developing the updated standards, to consult with specified entities.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Existing law, the California Uniform Controlled Substances Act, classifies controlled substances into 5 designated schedules, with the most restrictive limitations generally placed on controlled substances classified in Schedule I, and the least restrictive limitations generally placed on controlled substances classified in Schedule V. Existing law places oxycodone within Schedule II. Existing law requires a prescription for a controlled substance to only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.

Existing law, the Medical Practice Act, provides for the licensing and regulation of physicians and surgeons by the Medical Board of California. Among other things, the act regulates the prescribing, dispensing, or furnishing of dangerous drugs, including oxycodone, by a licensee, and provides, under certain circumstances, for the imposition of an administrative fine pursuant to a citation by the board, or the imposition of a civil penalty for a violation of these provisions. A violation of designated provisions of the act is a crime.

This bill would prohibit a person from prescribing oxycodone, by whatever official, common, usual, chemical, or trade name designated, to a patient under 21 years of age, except as specified. The bill would make a violation of this prohibition subject to a civil penalty, as specified. The bill would also authorize a patient who was prescribed oxycodone in violation of the prohibition, and who sustained economic loss or personal injury as a result of that violation, to bring a civil action to recover compensatory damages, reasonable attorney's fees, and litigation costs.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no-yes.

The people of the State of California do enact as follows:

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- SECTION 1. Section 2241.6 of the Business and Professions Code is amended to read:
- 2241.6. The Division of Medical Quality shall develop standards before June 1, 2002, to assure the competent review in eases concerning the management, including, but not limited to, the undertreatment, undermedication, and overmedication of a patient's pain. The division
- 2241.6. (a) (1) The board shall develop standards before June 1, 2002, to ensure the competent review in cases concerning the management, including, but not limited to, the undertreatment, undermedication, and overmedication of a patient's pain.
- (2) The board may consult with entities such as the American Pain Society, the American Academy of Pain Medicine, the California Society of Anesthesiologists, the California Chapter of the American College of Emergency Physicians, and any other medical entity specializing in pain control therapies to develop the standards utilizing, to the extent they are applicable, current authoritative clinical practice guidelines.
- (b) The board shall update the standards adopted pursuant to subdivision (a) on or before July 1, 2018, and on or before July 1 each fifth year thereafter.
- (c) The board shall convene a task force to develop and recommend the updated standards to the board. The task force, in developing the updated standards, shall consult with the entities specified in paragraph (2) of subdivision (a), the American Cancer Society, and specialists in pharmacology and addiction medicine.
- SEC. 2. Section 4075.7 is added to the Business and Professions Code, to read:
- 4075.7. (a) Before dispensing a prescription for a minor for a pain medication listed in Section 11167.7 of the Health and Safety Code, the pharmacist shall review and verify the disclosure and counseling document described in subdivision (c) of Section 11167.7 of the Health and Safety Code.
- (b) For purposes of this section, "minor" shall have the same meaning as in Section 11167.7 of the Health and Safety Code.
- meaning as in Section 11167.7 of the Health and Safety Code.
 SEC. 3. Section 11167.7 is added to the Health and Safety
 Code, to read:

- 11167.7. (a) For purposes of this section, the following definitions shall apply:
- (1) "Minor" means a person under 18 years of age who is not any of the following:
 - (A) A cancer patient.

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- (B) A patient in hospice or palliative care.
- (C) A patient who has been diagnosed with a terminal illness.
 - (2) "Guardian" means the legal guardian of the minor.
- (b) A health care practitioner, except a veterinarian, authorized to prescribe, order, administer, or furnish oxycodone, hydrocodone, hydromorphone, morphine, codeine, oxymorphone, fentanyl, methadone, tramadol, or tapentadol to a minor shall, before prescribing, ordering, administering, or furnishing those medications, educate the guardian on all of the following:
- (1) All other available medical treatments, other than the medication to be prescribed.
- (2) Nonopioid treatment alternatives to be tried before and alongside opioid therapy, unless there is a specific adverse reaction or contraindication.
- 20 (3) The risks and benefits of narcotic medications and 21 alternatives.
 - (4) The safe storage of opioid medications.
 - (5) The proper disposal of unused medications.
 - (6) The illegality of sharing or misusing prescribed medications.
 - (c) The discussion and counseling provided in subdivision (b) shall be memorialized in a document printed on a secure prescription pad and signed by the minor, if he or she was counseled, the guardian, and the prescriber.
 - (d) A subsequent prescription for the pain medications listed in subdivision (b) shall not be made until the minor is reevaluated by a pain management specialist or a pediatrician.
 - SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty
- 37 for a crime or infraction, within the meaning of Section 17556 of
- 38 the Government Code, or changes the definition of a crime within
- 39 the meaning of Section 6 of Article XIIIB of the California
- 40 Constitution.

SECTION 1. Section 2242.3 is added to the Business and Professions Code, to read:

2242.3. (a) (1) Notwithstanding any other law, a person shall not prescribe oxycodone, by whatever official, common, usual, chemical, or trade name designated, to a patient under 21 years of age.

- (2) Paragraph (1) does not apply with respect to a patient of any age who is any of the following:
 - (A) A cancer patient.

- (B) A patient in hospice or palliative care.
- (C) A patient who has been diagnosed with a terminal illness.
- (b) (1) Notwithstanding Section 2314 or any other law, a violation of this section may subject the person who has committed the violation to either a fine of up to five thousand dollars (\$5,000) per violation pursuant to a citation issued by the board or a civil penalty of up to five thousand dollars (\$5,000) per violation.
- (2) The Attorney General may bring an action to enforce this section and to collect the fines or civil penalties authorized by paragraph (1).
- (e) In addition to the penalties described in paragraph (1) of subdivision (b), a patient who was prescribed oxygodone in violation of subdivision (a), and who sustained economic loss or personal injury as a result of that violation, may bring an action to recover compensatory damages, as well as reasonable attorney's fees and costs.

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No. 457

Introduced by Senator Bates

February 16, 2017

An act to amend Section 1248 of the Health and Safety Code, relating to health facilities. An act to amend Section 2507 of, to add Section 2746.54 to, to add Article 17 (commencing with Section 880) to Chapter 1 of Division 2 of, and to repeal Sections 2508, 2510, 2516 of, the Business and Professions Code, and to amend Section 1204.3 of the Health and Safety Code, relating to out-of-hospital childbirths.

LEGISLATIVE COUNSEL'S DIGEST

SB 457, as amended, Bates. Health facilities: outpatient settings. Out-of-Hospital Childbirths: physicians and surgeons: licensed midwives: certified nurse-midwives.

(1) Existing law, the Medical Practice Act, provides for the licensure and regulation of physicians and surgeons by the Medical Board of California.

Existing law, the Licensed Midwifery Practice Act of 1993, provides for the licensure and regulation of midwives by the Medical Board of California. A violation of the act is a crime. Existing law authorizes a licensed midwife to attend cases of normal pregnancy and childbirth, but requires a midwife to immediately refer or transfer a client to a physician and surgeon if there are complications. Under the act, if a client of a licensed midwife is transferred to a hospital, the licensed midwife is required to provide records and speak with the receiving physician and surgeon about labor up to the point of the transfer. The act requires a hospital to report each transfer of a planned out-of-hospital birth to the Medical Board of California and the

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California Maternal Quality Care Collaborative using a standardized form developed by the board. Under existing law, a midwife is authorized to directly obtain supplies and devices, obtain and administer drugs and diagnostic tests, order testing, and receive reports that are necessary to his or her practice of midwifery and consistent with his or her scope of practice.

Existing law, the Nursing Practice Act, provides for the licensure and regulation of certified nurse-midwives by the Board of Registered Nursing. A violation of the act is a crime. Existing law authorizes a certified nurse-midwife, under the supervision of a licensed physician and surgeon, to attend cases of normal childbirth and to provide prenatal, intrapartum, and postpartum care, including family planning care, for the mother, and immediate care for the newborn, and provides that the practice of nurse-midwifery constitutes the furthering or undertaking by a certified person, under the supervision of a licensed physician and surgeon who has current practice or training in obstetrics, to assist a woman in childbirth so long as progress meets criteria accepted as normal. Existing law authorizes a certified nurse-midwife to furnish and order drugs or devices incidentally to the provision of family planning services, routine health care or perinatal care, and care rendered consistent with the certified nurse-midwife's educational preparation or clinical competence to specified persons, and only in accordance with standardized procedures and protocols developed and approved by, among others, the supervising physician and surgeon.

Existing law establishes the Office of Statewide Health Planning and Development in state government and it has jurisdiction over health planning and research development.

This bill would revise and recast these provisions by requiring that a licensed physician and surgeon, a licensed midwife, and a certified nurse-midwife only attend cases of pregnancy and out-of-hospital childbirth, as defined, when specified conditions are met. For purposes of determining whether a patient or client satisfies these conditions, the bill would require the licensed physician and surgeon, licensed certified nurse midwife, or licensed midwife to use a self-screening form to identify patient or client risk factors for out-of-hospital childbirth. The bill would specify those circumstances when a medical examination by a licensed physician and surgeon is required, when a licensed physician and surgeon, a licensed midwife, and a certified nurse-midwife is prohibited from attending cases of pregnancy and out-of-hospital childbirth, and when a licensed physician and surgeon, a licensed

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midwife, and a certified nurse-midwife would be required to initiate appropriate interventions, including transfer to a hospital, when a patient or client's health status changes. The bill would make it unprofessional conduct for a licensed physician and surgeon, licensed midwife, or licensed certified nurse-midwife to attend to a case of out-of-hospital childbirth after a licensed physician and surgeon determines that the patient or client is at an increased risk due to her health status, as provided.

This bill would require licensed physician and surgeon, licensed midwife, or a licensed certified nurse-midwife attending to cases of out-of-hospital childbirths to make specified disclosures to a prospective patient or client and obtain consent, as provided. The bill would also require these licensees to provide the patient or client with the most recent versions of specified documents concerning out-of-hospital childbirths. The bill would also require the Medical Board of California and the Board of Registered Nursing to make those same documents publicly available on their Internet Web sites.

If a patient or client is transferred to a hospital, this bill would require the licensee to provide specified records and speak with the receiving physician and surgeon about the labor up to the point of the transfer. The bill would provide that the failure to comply with this requirement shall constitute unprofessional conduct. The bill would also require the hospital, within a specified period of time, to report to the Office of Statewide Health Planning and Development each transfer of a patient, as specified. The bill would require the Office of Statewide Health Planning and Development to develop a form, subject to specified criteria, including that patient identifying information is protected, for purposes of implementing the hospital reporting requirement.

This bill would require each licensee caring for a patient or client planning an out-of-hospital birth to submit, within a specified period of time, a form to the Office of Statewide Health Planning and Development indicating the initiation of care. The bill would also require each licensee who attends an out-of-hospital childbirth to annually submit a specified report to the Office of Statewide Health Planning and Development. The bill would require the Office of Statewide Health Planning and Development to, among other things, maintain the confidentiality of this information.

For consistency with the above provisions governing out-of-hospital childbirths, the bill would make conforming changes to the Licensed Midwifery Practice Act of 1993 and the Nursing Practice Act. The bill

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would specify that a certified nurse-midwife is authorized to attend cases of out-of-hospital childbirth without physician and surgeon supervision when the provisions governing out-of-hospital childbirths are complied with. The bill would also authorize a licensed midwife and a certified nurse-midwife to administer, order, or use certain drugs and equipment. Because a violation of these requirements by a licensed midwife or certified nurse-midwife would be a crime under their respective acts, the bill would impose a state-mandated local program.

(2) Under existing law, an alternative birth center that is licensed as an alternative birth center specialty clinic is required to, as a condition of licensure, and a primary care clinic providing services as an alternative birth center is required to, meet specified certain requirements including requiring the presence of at least 2 attendants at all times during birth, one of whom is required to be a licensed physician and surgeon, licensed midwife, or a certified nurse-midwife.

This bill would require the client to be informed orally and in writing when no licensed physician and surgeon is present.

(3) Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

(4) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Existing law provides for the licensure and regulation of health facilities by the State Department of Public Health. Existing law prohibits the operation, management, conduct, or maintenance of an outpatient setting unless the outpatient setting is accredited by an accreditation agency that is approved by the Medical Board of California, licensed by the State Department of Public Health, as specified, or meets other criteria. Existing law defines an outpatient setting, in part, as a facility, clinic, unlicensed clinic, center, office, or other setting that is not part of a general acute care facility, as defined, that uses anesthesia, as specified.

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This bill would make technical, nonsubstantive changes to those provisions.

Vote: majority. Appropriation: no. Fiscal committee: no-yes. State-mandated local program: no-yes.

The people of the State of California do enact as follows:

SECTION 1. Article 17 (commencing with Section 880) is added to Chapter 1 of Division 2 of the Business and Professions Code, to read:

Article 17. Out-of-Hospital Childbirths

- 880. (a) Notwithstanding any other law and except as provided in subdivisions (c) and (d), a licensed physician and surgeon, a licensed midwife, and a certified nurse-midwife shall only attend cases of pregnancy and out-of-hospital childbirth when all of the following conditions are met:
- (1) There is no increased risk to the patient or client because of a disease or condition that could adversely affect the pregnancy and childbirth.
- (2) The patient or client has not had prior uterine or abdominal surgery, including, but not limited to, myomectomy, hysterotomy, or prior caesarian section.
 - (3) There is a singleton fetus.
- (4) There is a cephalic presentation by 36° /₇ completed weeks of pregnancy.
- (5) The gestational age of the fetus is greater than 37° /₇ weeks and less than 42° /₇ completed weeks of pregnancy.
- (6) Labor is spontaneous or manually induced after 39 weeks gestation.
- (7) Transfer to a hospital setting can occur within 20 minutes from the initiation of the transfer.
- (b) The licensed physician and surgeon, licensed certified nurse midwife, or licensed midwife, acting within their scope of practice, shall use a self-screening form to identify patient or client risk factors for out-of-hospital childbirth.
- (c) If the patient or client meets the conditions specified in paragraphs (3) to (7), inclusive, of subdivision (a), but fails to meet the conditions specified in paragraph (1) or (2) of subdivision

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(a) based on the risk factors identified by the self-screening form, the patient or client shall obtain a medical examination by a licensed physician and surgeon with privileges to practice obstetrics or gynecology. Under these circumstances, the licensed physician and surgeon, licensed midwife, or certified nurse midwife may only attend cases of out-of-hospital childbirth if a licensed physician and surgeon with privileges to practice obstetrics or gynecology determines, at the time of the examination, that the patient or client is not at an increased risk due to a disease or condition, that could adversely affect the pregnancy and childbirth.

- (d) The licensed physician and surgeon, licensed midwife, or licensed certified nurse-midwife attending cases of pregnancy and out-of-hospital childbirth under this article shall continuously assess the patient or client for any evidence of a disease or condition that could adversely affect the pregnancy and childbirth. If any evidence of a disease or condition that could adversely affect the pregnancy and childbirth arise, the patient or client shall obtain a medical examination by a licensed physician and surgeon with privileges to practice obstetrics or gynecology or the licensed physician and surgeon, licensed midwife, or licensed certified nurse-midwife, shall initiate appropriate interventions, including transfer, first-responder emergency care or emergency transport.
- (e) For the purposes of this article, "out-of-hospital childbirth" means childbirth in the home setting, an alternative birth center pursuant to pursuant to paragraph (4) of subdivision (b) of Section 1204 of the Health and Safety Code, or any other setting other than a facility as described in Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, or a facility as described in Chapter 2.5 (commencing with Section 1440) of Division 2 of the Health and Safety Code.
- (f) It shall constitute unprofessional conduct for a licensed physician and surgeon, licensed midwife, or licensed certified nurse-midwife to attend to a case of out-of-hospital childbirth after a licensed physician and surgeon with privileges in obstetrics or gynecology, pursuant to a medical examination under subdivision (c) or (d), determines that the patient or client is at an increased risk due to a disease or condition, that could adversely affect the pregnancy and childbirth. Notwithstanding any other law, a violation of this section shall not be a crime.

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880.2. (a) A licensed physician and surgeon, licensed midwife, or a licensed certified nurse-midwife authorized to attend to cases of out-of-hospital childbirths pursuant to this article shall disclose in oral and written form to a prospective patient or client seeking care for a planned out-of-hospital childbirth, and obtain consent for, all of the following:

(1) All of the provisions of Section 880.

- (2) The type of license held by the licensee and licensee number.
- (3) A licensed midwife or certified nurse-midwife who attends cases of out-of-hospital childbirth without physician and surgeon supervision shall provide notice that the care being provided is not being supervised by a physician and surgeon.
 - (4) The practice settings in which the licensee practices.
- (5) If the licensee does not have professional liability coverage for the care being provided in an out-of-hospital birth setting, he or she shall disclose that fact.
- (6) The acknowledgment that if the patient or client is required to obtain an examination with a licensed physician and surgeon pursuant to subdivision (c) or (d) of Section 880, failure to do so may affect the patient or client's legal rights in any professional negligence actions against a physician and surgeon, a healing arts licensee, or hospital.
- (7) There are conditions that will result in an examination from, or transfer of care to, a licensed physician and surgeon and if these conditions exist, the licensee will no longer be able to care for the patient or client in an out-of-hospital setting, beyond continuing care during the transition period to the physician and surgeon.
- (8) The specific arrangements for examination by a physician and surgeon with privileges in obstetrics or gynecology for examination. The licensee shall not be required to identify a specific physician and surgeon.
- (9) The specific arrangements for the transfer of care during the prenatal period, hospital transfer during the intrapartum and postpartum periods, and access to appropriate emergency medical services for patient or client and newborn, if necessary, and recommendations for preregistration at a hospital that has obstetric emergency services and is most likely to receive the transfer.

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(10) If, during the course of care, the patient or client has or may have a condition indicating the need for a transfer to a hospital, that the licensee shall initiate the transfer.

- (11) The availability of the text of laws regulating out-of-hospital childbirth and the procedure for reporting complaints to the appropriate licensing entity.
- (12) Consultation by a licensee with a consulting physician and surgeon does not alone create a physician-patient relationship or any other relationship with the consulting physician and surgeon. The licensee shall inform the patient or client that he or she is an independent healing arts licensee and is solely responsible for the services he or she provides.
- (b) The disclosure and consent form shall be signed by both the licensee and patient or client and a copy of the signed disclosure and consent form shall be placed in the patient or client's medical record.
- (c) (1) The licensee shall provide the patient or client with the most recent versions of the following documents:
- (A) The American College of Nurse-Midwives Clinical Bulletin entitled "Midwifery Provision of Home Birth Services."
- (B) The American College of Obstetricians and Gynecologists on Obstetric Practice Committee Opinion #669: Planned Home Birth.
- (C) Society of Maternal Fetal Medicine and the American College of Obstetricians and Gynecologists document entitled "Obstetrics Care Consensus: Levels of Maternal Care."
- (2) The Medical Board of California and the Board of Registered Nursing shall make the most recent version of the documents specified in paragraph (1) publicly available on their Internet Web sites.
- 880.4. (a) If a patient or client is transferred to a hospital, the licensee shall provide records, including prenatal records, and speak with the receiving physician and surgeon about the labor up to the point of the transfer. The failure to comply with this section shall constitute unprofessional conduct. Notwithstanding any other law, a violation of this section shall not be a crime.
- (b) The hospital shall report, in writing on a form developed by the Office of Statewide Health Planning and Development, within 30 days, each transfer of a patient who attempted a planned

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out-of-hospital childbirth to the Office of Statewide Health Planning and Development. The standardized form shall include:

- (1) Name and license number of the licensed physician and surgeon, certified nurse-midwife, or licensed midwife who attended the patient's planned out-of-hospital childbirth or out-of-hospital childbirth attempt.
- (2) Name and license number of the accepting or admitting physician and surgeon or certified nurse midwife who assumed care of the patient.
 - (3) Name of the patient and patient identifying information.
- (4) Name of the hospital or emergency center where the patient was transferred.
- (5) Date of report.

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- (6) Whether the person or persons admitted was pregnant, the delivered mother, or newborn newborns.
- (7) Whether there was a verbal handoff or if any prenatal records were obtained from the out-of-hospital childbirth attendant.
- (8) Gestational age of the fetus or newborn in weeks and method of determination.
- (9) Events triggering transfer including, but not limited to, pain management, excessive bleeding, fetal intolerance of labor, prolonged or nonprogressive labor with time in labor, maternal request for transfer, or the clinical judgment of the out-of-birth childbirth attendant.
- (10) Presence of significant history and risk factors including, but not limited to, preterm less than $37\%_7$, postterm greater than $42\%_7$, prior uterine or abdominal surgery including prior cesarean section, Group B strep, multiple births, IUGR, IUFD, chorioamnionitis, bleeding, noncephalic presentation, gestational diabetes, morbid obesity (BMI >40), or preeclampsia.
- 31 (11) Method of delivery.
- 32 (12) Whether a caesarian section was performed.
- 33 (13) Place of delivery.
- 34 (14) FHR tracing on admission.
- 35 (15) Fetal presentation on admission.
- 36 (16) APGAR score of the newborn.
- *37* (17) Cord gases.
- 38 (18) Whether the newborn suffered any complications and was
- 39 placed in the NICU.

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(19) Whether the mother suffered any complications and was placed in the ICU.

- (20) Duration of hospital stay for the mother and the newborn and newborns as of the date of the report and final disposition or status, if not released from the hospital, of the mother and newborn or newborns.
- (c) The form described in subdivision (b) shall be constructed in a format to enable the hospital to transmit the information in paragraphs (4) to (20), inclusive, to the Office of Statewide Health Planning and Development in a manner that the licensees and the patient are anonymous and their identifying information is not transmitted to the office. The entire form containing information described in paragraphs (1) to (20), inclusive, of subdivision (b) shall be placed in the patient's medical record.
- (d) The Office of Statewide Health Planning and Development may revise the reporting requirements for consistency with national and standards, as applicable.
- 880.6. (a) Each licensee caring for a patient or client planning an out-of-hospital birth shall submit, within 30 days of initial acceptance of a patient or client, a form indicating the initiation of care to the Office of Statewide Health Planning and Development. The office shall develop a standardized form.
- (b) Each licensee who attends an out-of-hospital childbirth, including supervising a student midwife, shall annually report to the Office of Statewide Health Planning and Development. The report shall be submitted no later than March 30, for the prior calendar year, in a form specified by the office and shall contain all of the following:
 - (1) The licensee's name and license number.
 - (2) The calendar year being reported.
- (3) The following information with regard to cases in California in which the licensee, or the student midwife supervised by a licensee, attended or assisted during the previous year when the intended place of birth at the onset of care was an out-of-hospital setting:
- (A) The total number of patients or clients served as primary caregiver at the onset of prenatal care.
- *(B) The number by county of live births attended as primary* 39 *caregiver.*

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(C) The number, by county, of cases of fetal demise, infant deaths, and maternal deaths attended as primary caregiver at the discovery of the demise or death.

- (D) The number of patients or clients whose primary care was transferred to another health care practitioner during the antepartum period, and the reason for each transfer.
- (E) The number, reason, and outcome for each elective hospital transfer during the intrapartum or postpartum period.
- (F) The number, reason, and outcome for each urgent or emergency transport of an expectant mother in the antepartum period.
- (G) The number, reason, and outcome for each urgent or emergency transport of an infant or mother during the intrapartum or immediate postpartum period.
- (H) The number of planned out-of-hospital births at the onset of labor and the number of births completed in an out-of-hospital setting.
- (I) The number of planned out-of-hospital births completed in an out-of-hospital setting that were any of the following:
 - (i) Twin births.

- (ii) Multiple births other than twin births.
- (iii) Presentations other than cephalic.
- (iv) Vaginal births after cesarean section (VBAC).
- (J) A brief description of any complications resulting in the morbidity or mortality of a mother or a neonate.
- (K) Any other information prescribed by the Office of Statewide Health Planning and Development in regulations.
- (c) The Office of Statewide Health Planning and Development shall maintain the confidentiality of the information submitted pursuant to this section, and shall not permit any law enforcement or regulatory agency to inspect or have copies made of the contents of any reports submitted pursuant to subdivisions (a) and (b) for any purpose, including, but not limited to, investigations for licensing, certification, or any other regulatory purposes.
- (d) The Office of Statewide Health Planning and Development shall report to the appropriate board, by April 30, those licensees who have met the requirements of this section for that year.
- (e) The Office of Statewide Health Planning and Development shall report the aggregate information collected pursuant to this section to the appropriate board by July 30 of each year. The

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Medical Board of California and the Board of Registered Nursing
 shall include this information in its annual report to the
 Legislature.

- (f) The Office of Statewide Health Planning and Development, with input from the appropriate licensing boards, may adjust the data elements required to be reported to better coordinate with other reporting systems, including the reporting system of the Midwives Alliance of North America (MANA), while maintaining the data elements unique to California. To better capture data needed for the report required by this section, the concurrent use of systems, including MANA's, by licensed midwives is encouraged.
- (g) A failure to report under this section shall constitute unprofessional conduct. Notwithstanding any other law, a violation of this section shall not be a crime.
- SEC. 2. Section 2507 of the Business and Professions Code is amended to read:
- 2507. (a) The Notwithstanding any other law, the license to practice midwifery authorizes the holder to attend cases of normal pregnancy and childbirth, as defined in paragraph (1) of subdivision (b), out-of-hospital childbirth pursuant to Article 17 (commencing with Section 880), and to provide prenatal, intrapartum, and postpartum eare, including family-planning eare, for the mother, care related to the out-of-hospital childbirth for the client and immediate care for the newborn.
- (b) As used in this article, the practice of midwifery constitutes the furthering or undertaking by any licensed midwife to assist a woman in childbirth as long as progress meets criteria accepted as normal. client in an out-of-hospital childbirth pursuant to pursuant to Article 17 (commencing with Section 880).
- (1) Except as provided in paragraph (2), a licensed midwife shall only assist a woman in normal pregnancy and childbirth, which is defined as meeting all of the following conditions:
 - (A) There is an absence of both of the following:
- (i) Any preexisting maternal disease or condition likely to affect the pregnancy.
 - (ii) Significant disease arising from the pregnancy.
- 37 (B) There is a singleton fetus.
 - (C) There is a cephalic presentation.
- 39 (D) The gestational age of the fetus is greater than 37 %, weeks 40 and less than 42 %, completed weeks of pregnancy.

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(E) Labor is spontaneous or induced in an outpatient setting.

(2) If a potential midwife client meets the conditions specified in subparagraphs (B) to (E), inclusive, of paragraph (1), but fails to meet the conditions specified in subparagraph (A) of paragraph (1), and the woman still desires to be a client of the licensed midwife, the licensed midwife shall provide the woman with a referral for an examination by a physician and surgeon trained in obstetrics and gynecology. A licensed midwife may assist the woman in pregnancy and childbirth only if an examination by a physician and surgeon trained in obstetrics and gynecology is obtained and the physician and surgeon who examined the woman determines that the risk factors presented by her disease or condition are not likely to significantly affect the course of pregnancy and childbirth.

- (3) The board shall adopt regulations pursuant to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part of 1 of Division 3 of Title 2 of the Government Code) specifying the conditions described in subparagraph (A) of paragraph (1).
- (c) (1) If at any point during pregnancy, childbirth, or postpartum—eare a client's condition deviates from normal, the licensed midwife shall immediately refer or transfer the client to a physician and surgeon. care, there is any evidence of a disease or condition that could adversely affect the pregnancy and childbirth arise, the client shall obtain a medical examination by a licensed physician and surgeon with privileges to practice obstetrics or gynecology pursuant to paragraph (b) of Section 880, or the licensed midwife shall initiate appropriate interventions, including immediate transfer, first-responder emergency care, or emergency transport. The licensed midwife may consult and remain in consultation with the physician and surgeon after the referral or transfer.
- (2) If a physician and surgeon determines that the client's condition or concern has been resolved such that the risk factors presented by a woman's disease or condition are not likely to significantly affect the course of pregnancy or childbirth, client is not at an increased risk due to a disease or condition, that could adversely affect the pregnancy and childbirth, the licensed midwife may resume primary care of the client and resume assisting the client during her the pregnancy, childbirth, or postpartum care.

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(3) If a physician and surgeon determines the client's condition or concern has not been resolved as specified in paragraph—(2), (2) and is at an increased risk due to a disease or condition, that could adversely affect the pregnancy and childbirth, the licensed midwife may provide concurrent care with a physician and surgeon and, if authorized by the client, be present during the labor and childbirth, and resume postpartum care, if appropriate. A licensed midwife shall not resume primary care of the client. attend an out-of-hospital childbirth of the client.

- (d) A licensed midwife shall not provide or continue to provide midwifery care to a woman with a risk factor that will significantly affect the course of client if a licensed physician and surgeon with privileges to practice obstetrics or gynecology determines, at the time of the examination, that the client is at an increased risk due to a disease or condition, that could adversely affect the pregnancy and childbirth as described in Article 17 (commencing with Section 880) pregnancy and childbirth, regardless of whether the woman client has consented to this care or refused care by a physician or surgeon, except as provided in paragraph (3) of subdivision (c).
- (e) The practice of midwifery does not include the assisting of childbirth by any artificial, forcible, or mechanical means, nor the performance of any version of these means.
- (f) A midwife is authorized to directly obtain supplies and devices, obtain and administer drugs and diagnostic tests, order testing, and receive reports that are necessary to his or her practice of midwifery and consistent with his or her scope of practice.
- (f) A licensed midwife may administer, order, or use any of the following:
- (1) Postpartum antihemorrhagic drugs.
 - (2) Prophylactic opthalmic antibiotics.
- *(3) Vitamin K.*
- *(4) RhoGAM*.
 - (5) Local anesthetic medications.
 - (6) Intravenous fluids limited to lactated ringers, 5 percent dextrose with lactated ringers, and heparin and 0.9 percent sodium chloride for use in intravenous locks.
- 37 (7) Epinephrine for use in maternal anaphylaxis pending 38 emergency transport.
- 39 (8) HBIG and GBV for neonates born to hepatitis B mothers, 40 per current Centers for Disease Control guidelines.

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(9) Antibiotics for intrapartum prophylaxis of Group B Betahemolytic Streptococcus (GBBS), per current Centers For Disease Control guidelines.

- (10) Equipment incidental to the practice of out-of-hospital childbirth, specifically, dopplers, syringes, needles, phlebotomy equipment, suture, urinary catheters, intravenous equipment, amnihooks, airway suction devices, neonatal and adult resuscitation equipment, glucometer, and centrifuge.
- (11) Equipment incidental to maternal care, specifically, compression stockings, maternity belts, breast pumps, diaphragms, and cervical caps.
- (g) This article does not authorize a midwife to practice medicine or to perform surgery.
- SEC. 3. Section 2508 of the Business and Professions Code is repealed.
- 2508. (a) A licensed midwife shall disclose in oral and written form to a prospective client as part of a client care plan, and obtain informed consent for, all of the following:
 - (1) All of the provisions of Section 2507.
- (2) The client is retaining a licensed midwife, not a certified nurse-midwife, and the licensed midwife is not supervised by a physician and surgeon.
- (3) The licensed midwife's current licensure status and license number.
 - (4) The practice settings in which the licensed midwife practices.
- (5) If the licensed midwife does not have liability coverage for the practice of midwifery, he or she shall disclose that fact. The licensed midwife shall disclose to the client that many physicians and surgeons do not have liability insurance coverage for services provided to someone having a planned out-of-hospital birth.
- (6) The acknowledgment that if the client is advised to consult with a physician and surgeon, failure to do so may affect the client's legal rights in any professional negligence actions against a physician and surgeon, licensed health care professional, or hospital.
- (7) There are conditions that are outside of the scope of practice of a licensed midwife that will result in a referral for a consultation from, or transfer of care to, a physician and surgeon.

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(8) The specific arrangements for the referral of complications to a physician and surgeon for consultation. The licensed midwife shall not be required to identify a specific physician and surgeon.

- (9) The specific arrangements for the transfer of care during the prenatal period, hospital transfer during the intrapartum and postpartum periods, and access to appropriate emergency medical services for mother and baby if necessary, and recommendations for preregistration at a hospital that has obstetric emergency services and is most likely to receive the transfer.
- (10) If, during the course of care, the client is informed that she has or may have a condition indicating the need for a mandatory transfer, the licensed midwife shall initiate the transfer.
- (11) The availability of the text of laws regulating licensed midwifery practices and the procedure for reporting complaints to the Medical Board of California, which may be found on the Medical Board of California's Internet Web site.
- (12) Consultation with a physician and surgeon does not alone ereate a physician-patient relationship or any other relationship with the physician and surgeon. The informed consent shall specifically state that the licensed midwife and the consulting physician and surgeon are not employees, partners, associates, agents, or principals of one another. The licensed midwife shall inform the patient that he or she is independently licensed and practicing midwifery and in that regard is solely responsible for the services he or she provides.
- (b) The disclosure and consent shall be signed by both the licensed midwife and the client and a copy of the disclosure and consent shall be placed in the client's medical record.
- (c) The Medical Board of California may prescribe the form for the written disclosure and informed consent statement required to be used by a licensed midwife under this section.
- SEC. 4. Section 2510 of the Business and Professions Code is repealed.
- 2510. If a client is transferred to a hospital, the licensed midwife shall provide records, including prenatal records, and speak with the receiving physician and surgeon about labor up to the point of the transfer. The hospital shall report each transfer of a planned out-of-hospital birth to the Medical Board of California and the California Maternal Quality Care Collaborative using a standardized form developed by the board.

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SEC. 5. Section 2516 of the Business and Professions Code is repealed.

- 2516. (a) Each licensed midwife who assists, or supervises a student midwife in assisting, in childbirth that occurs in an out-of-hospital setting shall annually report to the Office of Statewide Health Planning and Development. The report shall be submitted no later than March 30, for the prior calendar year, in a form specified by the board and shall contain all of the following:
 - (1) The midwife's name and license number.
 - (2) The calendar year being reported.

- (3) The following information with regard to eases in California in which the midwife, or the student midwife supervised by the midwife, assisted during the previous year when the intended place of birth at the onset of care was an out-of-hospital setting:
- (A) The total number of clients served as primary caregiver at the onset of care.
- (B) The number by county of live births attended as primary earegiver.
- (C) The number, by county, of cases of fetal demise, infant deaths, and maternal deaths attended as primary caregiver at the discovery of the demise or death.
- (D) The number of women whose primary care was transferred to another health care practitioner during the antepartum period, and the reason for each transfer.
- (E) The number, reason, and outcome for each elective hospital transfer during the intrapartum or postpartum period.
- (F) The number, reason, and outcome for each urgent or emergency transport of an expectant mother in the antepartum period.
- (G) The number, reason, and outcome for each urgent or emergency transport of an infant or mother during the intrapartum or immediate postpartum period.
- (H) The number of planned out-of-hospital births at the onset of labor and the number of births completed in an out-of-hospital setting.
- (I) The number of planned out-of-hospital births completed in an out-of-hospital setting that were any of the following:
- 38 (i) Twin births.
- 39 (ii) Multiple births other than twin births.
- 40 (iii) Breech births.

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(iv) Vaginal births after the performance of a cesarean section.

- (J) A brief description of any complications resulting in the morbidity or mortality of a mother or a neonate.
- (K) Any other information prescribed by the board in regulations.
- (b) The Office of Statewide Health Planning and Development shall maintain the confidentiality of the information submitted pursuant to this section, and shall not permit any law enforcement or regulatory agency to inspect or have copies made of the contents of any reports submitted pursuant to subdivision (a) for any purpose, including, but not limited to, investigations for licensing, certification, or regulatory purposes.
- (e) The office shall report to the board, by April 30, those licensees who have met the requirements of subdivision (a) for that year.
- (d) The board shall send a written notice of noncompliance to each licensee who fails to meet the reporting requirement of subdivision (a). Failure to comply with subdivision (a) will result in the midwife being unable to renew his or her license without first submitting the requisite data to the Office of Statewide Health Planning and Development for the year for which that data was missing or incomplete. The board shall not take any other action against the licensee for failure to comply with subdivision (a).
- (e) The board, in consultation with the office and the Midwifery Advisory Council, shall devise a coding system related to data elements that require coding in order to assist in both effective reporting and the aggregation of data pursuant to subdivision (f). The office shall utilize this coding system in its processing of information collected for purposes of subdivision (f).
- (f) The office shall report the aggregate information collected pursuant to this section to the board by July 30 of each year. The board shall include this information in its annual report to the Legislature.
- (g) The board, with input from the Midwifery Advisory Council, may adjust the data elements required to be reported to better ecordinate with other reporting systems, including the reporting system of the Midwives Alliance of North America (MANA), while maintaining the data elements unique to California. To better capture data needed for the report required by this section, the

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eoneurrent use of systems, including MANA's, by licensed midwives is encouraged.

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- (h) Notwithstanding any other law, a violation of this section shall not be a crime.
- SEC. 6. Section 2746.54 is added to the Business and Professions Code, to read:
- 2746.54. (a) Notwithstanding Section 2746.5 or any other law, a certified nurse-midwife may attend cases of out-of-hospital childbirth pursuant to Article 17 (commencing with Section 880), and to provide prenatal, intrapartum, and postpartum care, related to the out-of-hospital childbirth, for the client and immediate care for the newborn without physician and surgeon supervision.
- (b) (1) If at any point during pregnancy, childbirth, or postpartum care there is any evidence of a disease or condition that could adversely affect the pregnancy and childbirth arise, the client shall obtain a medical examination by a licensed physician and surgeon with privileges to practice obstetrics or gynecology as described in Article 17 (commencing with Section 880), or the certified nurse midwife shall initiate appropriate interventions, including immediate transfer, first-responder emergency care, or emergency transport. The certified nurse-midwife may consult and remain in consultation with the physician and surgeon after the referral or transfer.
- (2) If a physician and surgeon determines that the client's condition or concern has been resolved such that the risk factors presented by a client's disease or condition does not adversely affect the pregnancy or childbirth, the certified nurse midwife may resume care of the client and resume assisting the client during the pregnancy, out-of-hospital childbirth, or postpartum care.
- (3) If a physician and surgeon determines the client's condition or concern has not been resolved as specified in paragraph (2), and is at an increased risk due to a disease or condition, that could adversely affect the pregnancy and childbirth, the certified nurse-midwife may provide concurrent care with a physician and surgeon and, if authorized by the client, be present during the labor and childbirth, and resume postpartum care, if appropriate.
- Notwithstanding any other law, under the circumstances described in this paragraph, a certified nurse-midwife shall not attend an
- 39 out-of-hospital birth of the client unless under the supervision of
- 39 out-of-hospital birth of the client unless under the supervision of
- 40 a physician and surgeon pursuant to Section 2746.5.

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(c) A certified nurse-midwife shall not provide or continue to provide care to a client if a licensed physician and surgeon with privileges to practice obstetrics or gynecology determines, at the time of the examination, that there is an increased risk to the client because of a disease or condition that could adversely affect the pregnancy and childbirth, as described in Article 17 (commencing with Section 880), regardless of whether the client has consented to this care or refused care by a physician or surgeon, except as provided in paragraph (3) of subdivision (b).

- (d) This section does not include the assisting of childbirth by any artificial, forcible, or mechanical means, nor the performance of any version of these means.
- (e) For purposes of attending an out-of-hospital childbirth pursuant to this section, and notwithstanding Section 2746.51, a certified nurse-midwife may administer, order, or use any of the following:
- 17 (1) Postpartum antihemorrhagic drugs.
 - (2) Prophylactic opthalmic antibiotics.
- *(3) Vitamin K.*
- 20 (4) RhoGAM.
 - (5) Local anesthetic medications.
 - (6) Intravenous fluids limited to lactated ringers, 5 percent dextrose with lactated ringers, and heparin and 0.9 percent sodium chloride for use in intravenous locks.
 - (7) Epinephrine for use in maternal anaphylaxis pending emergency transport.
 - (8) HBIG and GBV for neonates born to hepatitis B mothers, per current Centers for Disease Control guidelines.
 - (9) Antibiotics for intrapartum prophylaxis of Group B Betahemolytic Streptococcus (GBBS), per current Centers For Disease Control guidelines.
 - (10) Equipment incidental to the practice of out-of-hospital childbirth, specifically, dopplers, syringes, needles, phlebotomy equipment, suture, urinary catheters, intravenous equipment, amnihooks, airway suction devices, neonatal and adult resuscitation equipment, glucometer, and centrifuge.
- 37 (11) Equipment incidental to maternal care, specifically, 38 compression stockings, maternity belts, breast pumps, diaphragms, 39 and cervical caps.

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(f) This section does not authorize a nurse midwife to practice medicine or to perform surgery.

- SEC. 7. Section 1204.3 of the Health and Safety Code is amended to read:
- 1204.3. (a) An alternative birth center that is licensed as an alternative birth center specialty clinic pursuant to paragraph (4) of subdivision (b) of Section 1204 shall, as a condition of licensure, and a primary care clinic licensed pursuant to subdivision (a) of Section 1204 that provides services as an alternative birth center shall, meet all of the following requirements:
- (1) Be a provider of comprehensive perinatal services as defined in Section 14134.5 of the Welfare and Institutions Code.
 - (2) Maintain a quality assurance program.

- (3) Meet the standards for certification established by the American Association of Birth Centers, or at least equivalent standards as determined by the state department.
- (4) In addition to standards of the American Association of Birth Centers regarding proximity to hospitals and presence of attendants at births, meet both of the following conditions:
- (A) Be located in proximity, in time and distance, to a facility with the capacity for management of obstetrical and neonatal emergencies, including the ability to provide cesarean section delivery, within 30 minutes from time of diagnosis of the emergency.
- (B) Require the presence of at least two attendants at all times during birth, one of whom shall be a physician and surgeon, a licensed midwife, or a certified nurse-midwife. If no licensed physician and surgeon is present, the client shall be informed orally and in writing that no licensed physician and surgeon is present.
- (5) Have a written policy relating to the dissemination of the following information to patients:
- (A) A summary of current state laws requiring child passenger restraint systems to be used when transporting children in motor vehicles.
- (B) A listing of child passenger restraint system programs located within the county, as required by Section 27362 of the Vehicle Code.

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(C) Information describing the risks of death or serious injury associated with the failure to utilize a child passenger restraint system.

- (b) The state department shall issue a permit to a primary care clinic licensed pursuant to subdivision (a) of Section 1204 certifying that the primary care clinic has met the requirements of this section and may provide services as an alternative birth center. Nothing in this section shall be construed to require that a licensed primary care clinic obtain an additional license in order to provide services as an alternative birth center.
- (c) (1) Notwithstanding subdivision (a) of Section 1206, no place or establishment owned or leased and operated as a clinic or office by one or more licensed health care practitioners and used as an office for the practice of their profession, within the scope of their license, shall be represented or otherwise held out to be an alternative birth center licensed by the state unless it meets the requirements of this section.
- (2) Nothing in this subdivision shall be construed to prohibit licensed health care practitioners from providing birth related services, within the scope of their license, in a place or establishment described in paragraph (1).
- SEC. 8. The Legislature finds and declares that Section 1 of this act, which adds Section 880.6 to the Business and Professions Code, imposes a limitation on the public's right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:

In order to allow the Office of Statewide Health Planning and Development to fully accomplish its goals, it is imperative to protect the interests of those persons submitting information to the office to ensure that any personal or sensitive information that this act requires those persons to submit is protected as confidential information.

SEC. 9. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or — 23 — SB 457

infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIIIB of the California Constitution.

SECTION 1. Section 1248 of the Health and Safety Code is amended to read:

1248. For purposes of this chapter, the following definitions shall apply:

- (a) "Division" means the Medical Board of California. All references in this chapter to the division, the Division of Licensing of the Medical Board of California, or the Division of Medical Quality shall be deemed to refer to the Medical Board of California pursuant to Section 2002 of the Business and Professions Code.
- (b) (1) "Outpatient setting" means a facility, elinic, unlicensed elinic, center, office, or other setting that is not part of a general acute care facility, as defined in Section 1250, that uses anesthesia, except local anesthesia or peripheral nerve blocks, or both, in compliance with the community standard of practice, in doses that, when administered, have the probability of placing a patient at risk for loss of the patient's life-preserving protective reflexes.
- (2) "Outpatient setting" also means a facility that offers in vitro fertilization, as defined in subdivision (b) of Section 1374.55.
- (3) "Outpatient setting" does not include, among other settings, a setting where anxiolytics and analgesies are administered, when done so in compliance with the community standard of practice, in doses that do not have the probability of placing the patient at risk for loss of the patient's life-preserving protective reflexes.
- (e) "Accreditation agency" means a public or private organization that is approved to issue certificates of accreditation to outpatient settings by the board pursuant to Sections 1248.15 and 1248.4.

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MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

Bill Number: SB 641 Author: Lara

Bill Date: April 20, 2017, Amended

Subject: CURES: Privacy

Sponsor: California Medical Association

Position: Neutral

DESCRIPTION OF CURRENT LEGISLATION:

This bill would specify that the Department of Justice (DOJ) shall only provide data obtained from the Controlled Substance Utilization Review and Evaluation System (CURES) to a federal, state, or local law enforcement agency pursuant to a warrant based on probable cause and issued at the request of the law enforcement agency engaged in an open and active criminal investigation regarding prescription drug abuse or diversion of controlled substances involving the individual to whom the requested information pertains.

BACKGROUND:

The CURES Program is currently housed in DOJ and is a state database of dispensed prescription drugs that have a high potential for misuse and abuse. CURES provides for electronic transmission of specified prescription data to DOJ. In September 2009, DOJ launched the CURES Prescription Drug Monitoring Program (PDMP) system allowing pre-registered users, including licensed health care prescribers eligible to prescribe controlled substances, pharmacists authorized to dispense controlled substances, law enforcement, and regulatory boards, to access patient controlled substance history information through a secure website.

SB 809 (DeSaulnier, Chapter 400) was signed into law in 2013 and included a provision to collect funds from boards that license individuals who prescribe and dispense, for purposes of funding and upgrading the CURES system. This bill also required all prescribers to register with CURES by January 1, 2016, but the law was amended to extend the registration deadline to July 1, 2016. The new CURES 2.0 system, which is a modernized system that has been updated to more efficiently serve prescribers, pharmacists and other entities, is now operational and available online, as long as the prescriber uses a compliant browser.

SB 482 (Lara, Chapter 708) was signed into law in 2016 and requires a health care practitioner that is authorized to prescribe, order, administer or furnish a controlled substance to consult the CURES database to review a patient's controlled substance history before prescribing a Schedule II, III or IV controlled substance for the first time to that patient and at least once every four months thereafter, if the prescribed controlled substance remains part of the patient's treatment, with specified exceptions. This bill requires a health care practitioner to obtain a patient's controlled substance history from the CURES database no earlier than 24 hours before the medication is prescribed,

ordered, administered, furnished or dispensed. If a health care practitioner is exempted from checking CURES before prescribing a controlled substance for the first time pursuant to this bill, they are required to consult CURES before subsequently prescribing a controlled substance to the patient at least every four months thereafter if the substance remains part of the treatment of the patient. This bill specifies that it is not operative until six months after DOJ certifies that the CURES database is ready for statewide use and that DOJ has adequate staff, which, at a minimum, shall be consistent with the appropriation authorized in the Budget Act of 2016. This bill requires DOJ to notify the Secretary of State and the Office of Legislative Counsel of the date of that certification. DOJ has not yet certified that the CURES database is ready for statewide use and the DOJ has adequate staff.

ANALYSIS

This bill would not change the Medical Board of California's (Board) access to CURES, although the original version of this bill would have. Now this bill only affects law enforcement agencies. Although the Department of Consumer Affairs, Health Quality Investigation Unit (HQIU) investigators that perform the Board's investigations are peace officers, they are performing the investigations on behalf of a regulatory board, so this bill would not apply to the Board's administrative investigations. However, there are a small portion of criminal investigations performed by HQIU investigators on behalf of the Board. This bill would impact those investigations, but there are only approximately 20 criminal investigations per year conducted on behalf of the Board.

Board staff did request a technical amendment to make it clear this bill only applies to criminal investigations. This technical amendment was made, as such, the Board is now neutral on this bill.

FISCAL: Minimal and absorbable fiscal impact

SUPPORT: California Medical Association (Sponsor)

American Academy of Pediatrics, California

American College of Physicians – California Services Chapter

California Dental Association

County Behavioral Health Directors Association

OPPOSITION: California Narcotics Officers Association

California Teamsters Public Affairs Council

Center for Public Interest Law, University of San Diego

Consumer Attorneys of California Consumer Federation of California

Consumer Watchdog

Shatterproof

Troy and Alana Pack Foundation

AMENDED IN SENATE APRIL 20, 2017 AMENDED IN SENATE MARCH 28, 2017

SENATE BILL

No. 641

Introduced by Senator Lara

February 17, 2017

An act to amend Section 11165 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 641, as amended, Lara. Controlled Substance Utilization Review and Evaluation System: privacy.

Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. Existing law requires the operation of CURES to comply with all applicable federal and state privacy and security laws and regulations. Under existing law, data obtained from CURES may only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the department, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Existing law allows data obtained from CURES to be provided to public or private entities for statistical or research purposes, as approved by the department.

This bill would prohibit the release of data obtained from CURES to a law enforcement agency except pursuant to a valid court order, warrant based on probable cause, as specified.

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Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 11165 of the Health and Safety Code is amended to read:

- 11165. (a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.
- (b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.
- (c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.
- (2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised.

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Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations.

- (B) The Department of Justice shall only provide data obtained from CURES to a federal, state, or local law enforcement agency pursuant to a valid court order or warrant based on probable cause and issued at the request of a federal, state, or local law enforcement agency engaged in an open and active *criminal* investigation regarding prescription drug abuse or diversion of prescription of controlled substances involving the individual to whom the requested information pertains.
- (C) The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with Section 11165.1.
- (D) Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.
- (3) In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data is provided and keep a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.
- (d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:
- (1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of

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Health and Human Services, and the gender, and date of birth of the ultimate user.

- (2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
- (3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.
- (4) National Drug Code (NDC) number of the controlled substance dispensed.
 - (5) Quantity of the controlled substance dispensed.
- (6) International Statistical Classification of Diseases, 10th revision (ICD-10) Code, if available.
 - (7) Number of refills ordered.
- (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
 - (9) Date of origin of the prescription.
 - (10) Date of dispensing of the prescription.
- (e) The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.
- 28 (f) The Department of Justice shall, prior to upgrading CURES, 29 consult with prescribers licensed by one of the boards or 30 committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or 31 32 committees identified in subdivision (d) of Section 208 of the 33 Business and Professions Code, and any other stakeholder 34 identified by the department, for the purpose of identifying 35 desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).

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- 1 (g) The Department of Justice may establish a process to educate authorized subscribers of the CURES PDMP on how to access and
- 3 use the CURES PDMP.

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MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

Bill Number: SB 790 **Author:** McGuire

Bill Date: July 6, 2017 Amended

Subject: Health Care Providers: Gifts and Benefits

Sponsor: Author **Position:** Support

DESCRIPTION OF CURRENT LEGISLATION:

This bill would, on and after January 1, 2019, prohibit a manufacturer of a prescribed product from offering or giving a gift to a health care provider. This bill would prohibit a manufacturer of a prescribed product or an entity on behalf of a manufacturer of a prescribed product from providing a fee, payment, subsidy, or other economic benefit to a health care provider in connection with the provider's participation in research.

BACKGROUND:

The Physician Payments Sunshine Act is a 2010 federal healthcare law to increase transparency of financial relationships between health care providers and pharmaceutical manufacturers. The Sunshine Act requires manufacturers of drugs, medical devices, and biological and medical supplies, covered by the three federal health care programs Medicare, Medicaid, and State Children's Health Insurance Program, to collect and track all financial relationships with physicians and teaching hospitals and to report this data to the federal Centers for Medicare and Medicaid Services. The goal of the law is to increase the transparency of financial relationships between health care providers and pharmaceutical manufacturers and to uncover potential conflicts of interest.

Data from 2014 shows that California physicians received the highest number of payments from pharmaceutical companies than any state (\$1.44B) compared to the second and third ranking states, New York (\$517M) and Texas (\$435M), with Alaska at the bottom, receiving the lowest amount (\$1.8M). 2014 data also revealed almost 280,000 doctors received a total of more than 60,000 payments associated with four target drugs.

Nationally, about three quarters of doctors across five common medical specialties received at least one payment from a company in 2014. In Nevada, that number was over 90 percent. In Vermont, the state with the strictest gift regulations, the number fell below 24 percent.

The Office of the Inspector General of the U.S. Department of Health and Human Services cautioned drug companies about making excessive payments to physicians for consulting and offering inappropriate gifts.

California's largest hospitals such as Kaiser, the University of California Medical Centers, and Stanford have implemented policies restricting pharma gifts to doctors.

Eight other states and the District of Columbia have also adopted gift bans and restrictions.

ANALYSIS

This bill would define an allowable expenditure as any of the following:

- A payment by a manufacturer of a prescribed product to the sponsor of a significant educational, medical, scientific, or policy making conference or seminar, provided that the payment is not made directly to a health care professional or pharmacist. The funding must be used solely for bona fide educational purposes (can be used for meals and other food for conference participants), and all program content is objective, free from industry control, and does not promote specific products.
- Honoraria and payment of the expenses of a health care professional who serves
 on the faculty at a bona fide educational, medical, scientific, or policy making
 conference or seminar, if the honoraria or payment is governed by an explicit
 contract with specific deliverables that are restricted to medical issues and the
 content of the presentation is determined or at a minimum is reviewed and
 approved by the health care professional.
- For a bona fide clinical trial or a research project that constitutes a systematic investigation, is designed to develop or contribute to general knowledge, and reasonably can be considered to be of significant interest or value to scientists or health care professionals working in the particular field of inquiry. It can include compensation for services provided by investigators, health care professionals, or health care providers in connection with the bona fide clinical trial or research project; expenses paid on behalf of investigators, health care professionals, or health care providers in connection with the bona fide clinical trial or research project; and materials and supplies used in connection with the bona fide clinical trial or research project.
- Payment or reimbursement for reasonable expenses, including travel and lodging-related expenses, necessary for technical training of individual health care professionals on the administration of a prescribed product, if the commitment to provide those expenses and the amounts or categories of reasonable expenses to be paid are described in a written agreement between the health care provider and the manufacturer.
- Public health initiatives to develop replicable and sustainable model programs that embody best practices in disease screening and linages to care.
- Royalties and licensing fees paid to health care providers in return for contractual
 rights to use or purchase a patented or otherwise legally recognized discovery for
 which the provider holds an ownership right. This also includes royalties,
 licensing fees, and financial transactions related to joint ventures and
 partnerships with health care providers.
- A payment to a health care provider for participation in bona fide marketing research conducted by a third party, only if the payments are made by that third party and the sponsoring manufacturer is not informed of the identity of the participating health care provider.
- Other reasonable fees, payments, subsidies, or other economic benefits provided by a manufacturer of a prescribed product at fair market value.

- The payment of reasonable expenses of an individual related to the interview of the individual by a manufacturer in connection with a bona fide employment opportunity or for health care services on behalf of an employee of the manufacturer.
- Provision of meals for a health care provider that do not exceed \$250 per person, per year in value in addition to payments otherwise permitted under this subdivision.

This bill would define a gift as a payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided at no cost or less than full market value to a health care provider. A "gift" does not include any allowable expenditure defined in this bill, any payment, food, entertainment, travel, subscription, advance, service, or anything else of value for which the health care provider reimburses the cost at fair market value, or any payment made in compliance with the Political Reform Act of 1974 except a gift made under that act.

This bill would specify that a health care professional shall not be construed to include individuals employed by a manufacturer, working as a full-time contractor for a manufacturer or working as a full-time employee or contractor of a clinical research organization or business service firm, regardless of licensure, provided that the individual does not treat or otherwise render health care services to patients or hold a position to recommend prescribed products for a formulary, organization, or individuals.

This bill would define a health care provider as a health care professional, hospital, nursing home, pharmacist, health benefit plan administrator, hospital foundation that is organized as a nonprofit entity separate from a hospital, or any other person authorized to dispense, or purchase for distribution, prescribed products in California.

This bill would define a manufacturer as a pharmaceutical manufacturer, biological product manufacturer, or any other person who is engaged in the production, preparation, propagation, compounding, processing, marketing, packaging, repacking, distributing, or labeling of prescribed products. This bill would specify that it does not include a wholesaler, a pharmacist, or a pharmacy.

This bill would expressly prohibit a manufacturer of a prescribed product from offering or giving a gift to a health care provider. This bill would also prohibit a manufacturer or an entity on behalf of a manufacturer from providing a fee, payment, subsidy, or other economic benefit, with the exception of allowable expenditures, to a health care provider in connection with the provider's participation in research. This bill would specify that these prohibitions do not apply to the following:

- Samples of a prescribed product or reasonable quantities of an over-the-counter drug, an item of non-prescription durable medical equipment, an item of medical food as defined in federal law, or infant formula, that are provided to a health care provider for free distribution to patients.
- The provision, distribution, dissemination, or receipt of peer-reviewed academic, scientific, or other clinical articles or journals and other items that serve an educational function for the benefit of patients.

- Scholarship or other support for medical students, residents and fellows to attend a significant educational, scientific, or policy making conference or seminar.
- Rebates and discounts for prescribed products provided in the normal course of business.
- The provision to a free clinic of financial donations or of free prescription drugs, over-the-counter drugs, biological products, combination products, medical food or infant formula.
- Prescribed products distributed free of charge or at a discounted price pursuant to a manufacturer-sponsored or manufacturer-funded patient assistance program.
- Fellowship salary support provided to fellows through grants from manufacturers of prescribed products, if the following apply: the grants are applied for by an academic institution or hospital or clinical research site; the institution, hospital or clinical research site selects the recipient fellows; the manufacturer imposes no further demands or limits on the use of the funds; and the fellowships are not named for a manufacturer, and no individual recipient's fellowship is attributed to a particular manufacturer.
- The provision of coffee or other snacks or refreshments at a booth at a conference or seminar.

Although the language was amended out of this bill that would have allowed the AG to bring an action seeking injunctive relief, costs, attorney's fees, and imposition of a civil penalty of up to \$10,000, the AG would still be responsible for enforcing the provisions of this bill and ensuring that manufacturers of prescribed products are not violating the restrictions in this bill.

This bill would state that it is the intent of the Legislature that the requirements and prohibitions in this bill would complement and operate in conjunction with the federal Physician Payments Sunshine Act. If the Physician Payments Sunshine Act is repealed or becomes inoperative, it is the intent of the Legislature to enact similar legislation requiring manufacturers to disclose payments or other transfers of value made to health care providers in California.

According to the author, studies have shown that interaction with the pharmaceutical industry is associated with substantially negative consequences that include risks to patient safety associated with unnecessary drug prescriptions, drug cost increases borne by the patient, less availability of generic drugs, and less attention paid to evidence-based prescribing. The author believes that the pervasive use of gifts is of special concern to vulnerable populations and that physicians prescribing in the California's foster care system in recent years have received, on average, more than twice the amount in payments and incentives from drug companies when compared with the typical California physician. The author introduced this bill because he believes the time has come for California to join the largest hospitals, eight other states and the District of Columbia in providing regulations on pharma gifts.

The Medical Board of California's (Board) primary mission is consumer protection. This bill would ensure that physicians are not influenced by gifts or economic benefits when deciding what brand of drug to prescribe, but would still allow for some

reasonable expenditures. This bill would further the Board's mission of consumer protection and the Board is supportive of this bill.

FISCAL: None to the Board

SUPPORT: AIDS Healthcare Foundation; California Health + Advocates;

California Labor Federation; California Professional Firefighters; CALPIRG; Consumers Union; Health Access California; Medical Board of California; School Employers Association of California;

and Small School Districts' Association

OPPOSITION: American College of Private Physicians

California Access Coalition

California Chapter of the American College of Cardiology

Infectious Disease Association of California

Sanofi

AMENDED IN ASSEMBLY JULY 6, 2017
AMENDED IN ASSEMBLY JUNE 22, 2017
AMENDED IN ASSEMBLY JUNE 13, 2017
AMENDED IN SENATE MAY 2, 2017
AMENDED IN SENATE APRIL 17, 2017
AMENDED IN SENATE MARCH 29, 2017

SENATE BILL

No. 790

Introduced by Senator McGuire (Coauthor: Senator Monning)

February 17, 2017

An act to add Division 117 (commencing with Section 150300) to the Health and Safety Code, relating to health care providers.

LEGISLATIVE COUNSEL'S DIGEST

SB 790, as amended, McGuire. Health care providers: gifts and benefits.

The Sherman Food, Drug, and Cosmetic Law, administered by the State Department of Public Health, regulates the packaging, labeling, and advertising of drugs and devices, and requires a manufacturer of any drug or device in the state to be licensed by the department. Existing law imposes various requirements on persons engaged in the provision of health care services in the state.

This bill would, on and after January 1, 2019, prohibit a manufacturer of a prescribed product from offering or giving a gift to a health care provider. The bill would further prohibit a manufacturer of a prescribed product or an entity on behalf of a manufacturer of a prescribed product

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from providing a fee, payment, subsidy, or other economic benefit to a health care provider in connection with the provider's participation in research, except as specified. The bill would define terms of its purposes, including, among others, the term "gift." The bill would specify circumstances to which these prohibitions do not apply.

Existing federal law, the Physician Payments Sunshine Act (Sunshine Act), requires manufacturers of specified drugs, devices, biologicals, or medical supplies to disclose to the federal Centers for Medicare and Medicaid Services payments or other transfers of value made to physicians or teaching hospitals.

This bill would state the intent of the Legislature that the prohibitions and requirements described above complement and operate in conjunction with the Sunshine Act. The bill would state the intent of the Legislature to enact legislation similar to the Sunshine Act if the Sunshine Act is repealed or becomes inoperative.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Division 117 (commencing with Section 150300) is added to the Health and Safety Code, to read:

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DIVISION 117. EXPENDITURES BY MANUFACTURERS OF PRESCRIBED PRODUCTS

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18 19 150300. For the purposes of this division, the following definitions shall apply:

- (a) "Allowable expenditure" means any of the following:
- (1) Payment by a manufacturer of a prescribed product to the sponsor of a significant educational, medical, scientific, or policymaking conference or seminar, provided that all of the following conditions are satisfied:
- (A) The payment is not made directly to a health care professional or pharmacist.
- (B) Funding is used solely for bona fide educational purposes, except that the sponsor may, in the sponsor's discretion, apply some or all of the funding to provide meals and other food for all conference participants.

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(C) All program content is objective, free from industry control, and does not promote specific products.

- (2) Honoraria and payment of the expenses of a health care professional who serves on the faculty at a bona fide educational, medical, scientific, or policymaking conference or seminar, only if all of the following conditions are satisfied:
- (A) The honoraria or payment is governed by an explicit contract with specific deliverables that are restricted to medical issues, not marketing activities.
- (B) Consistent with federal law, the content of the presentation, including slides and written materials, is determined or at a minimum is reviewed and approved by the health care professional.
- (3) For a bona fide clinical trial or a research project that constitutes a systematic investigation, is designed to develop or contribute to general knowledge, and reasonably can be considered to be of significant interest or value to scientists or health care professionals working in the particular field of inquiry, all of the following:
- (A) Compensation for services provided by investigators, health care professionals, or health care providers in connection with the bona fide clinical trial or research project.
- (B) Expenses paid on behalf of investigators, health care professionals, or health care providers in connection with the bona fide clinical trial or research project.
- (C) Expenses paid by the investigators, health care professionals, or health care providers in connection with the bona fide clinical trial or research project.
- (D) Materials and supplies used in connection with the bona fide clinical trial or research project.
- (4) Payment or reimbursement for reasonable expenses, including travel and lodging-related expenses, necessary for technical training of individual health care professionals on the administration of a prescribed product, if the commitment to provide those expenses and the amounts or categories of reasonable expenses to be paid are described in a written agreement between the health care provider and the manufacturer.
- (5) Public health initiatives to develop replicable and sustainable model programs that embody best practices in disease screening and linkages to care.

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(6) Royalties and licensing fees paid to health care providers in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the health care provider holds an ownership right. This also includes royalties, licensing fees, and financial transactions related to joint ventures and partnerships with health care providers.

- (7) A payment to a health care provider for participation in bona fide marketing research conducted by a third party, only if the payments are made by that third party and the sponsoring manufacturer is not informed of the identity of the participating *health care* provider.
- (8) Other reasonable fees, payments, subsidies, or other economic benefits provided by a manufacturer of a prescribed product at fair market value.
- (9) The payment of reasonable expenses of an individual related to the interview of the individual by a manufacturer of prescribed products in connection with a bona fide employment opportunity or for health care services on behalf of an employee of the manufacturer.
- (10) Provision of meals for a health care provider that do not exceed two hundred fifty dollars (\$250) per person, per year in value in addition to payments otherwise permitted under this subdivision.
- (b) "Bona fide clinical trial" means an FDA-reviewed clinical trial that constitutes research as defined in Section 46.102 of Title 45 of the Code of Federal Regulations that can be reasonably considered to be of interest to scientists or health care professionals working in the particular field of inquiry.
- (c) "Bona fide marketing research" means the collection and analysis of data regarding opinions, needs, awareness, knowledge, views, experiences, and behaviors of a population, through the development and administration of surveys, interviews, focus groups, polls, observation, or other research methodologies, in which no sales, promotional, or marketing efforts are involved and through which there is no attempt to influence a participant's attitudes or behavior.
- 37 (d) "Clinical trial" means a study that does either of the 38 following:

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(1) Assesses the safety, efficacy, or effectiveness of prescribed products administered alone or in combination with other prescribed products or other therapies.

- (2) Assesses the relative safety or efficacy of prescribed products in comparison with other prescribed products or therapies.
- (e) "Free clinic" means a health care facility operated by a nonprofit private entity that satisfies all of the following conditions:
- (1) In providing health care, the health care facility does not accept reimbursement from any third-party payer, including reimbursement from any insurance policy, health plan, or federal or state health benefits program that is individually determined.
- (2) In providing health care, the health care facility either does not impose charges on patients to whom service is provided, or imposes charges on patients according to their ability to pay.
- (3) The health care facility may accept voluntary donations from patients for the provision of health care services.
- (4) The health care facility is licensed or certified to provide health services under applicable law.
- (f) "Gift" means a payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided at no cost or less than full market value to a health care provider. Notwithstanding the foregoing, "gift" does not include any allowable expenditure as defined in subdivision (a), any payment, food, entertainment, travel, subscription, advance, service, or anything else of value for which the health care provider reimburses the cost at fair market value, or any payment made in compliance with the Political Reform Act of 1974 (Title 9 (commencing with Section 81000) of the Government Code) except a gift made under that act.
- (g) "Health benefit plan administrator" means the person or entity who sets formularies on behalf of an employer or health insurer
 - (h) (1) "Health care professional" means any of the following:
- (A) A person who is authorized by law to prescribe or to recommend prescribed products, who regularly practices in the state, and who is either licensed by the state to provide or is otherwise lawfully providing health care in the state.
- 38 (B) A partnership or corporation made up of the persons described in subparagraph (A).

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(C) An officer, employee, agent, or contractor of a person described in subparagraph (A). who is acting in the course and scope of employment, of an agency, or of a contract related to or supportive of the provision of health care to individuals.

- (2) A "health care professional" shall not be construed to include individuals employed by a manufacturer, working as a full-time contractor for a manufacturer or working as a full-time employee or contractor of a clinical research organization or business services firm, regardless of licensure, provided that the individual does not treat or otherwise render health care services to patients or hold a position to recommend prescribed products for a formulary, organization, or individuals.
- (i) "Health care provider" means a health care professional, hospital, nursing home, pharmacist, health benefit plan administrator, hospital foundation that is organized as a nonprofit entity separate from a hospital, or any other person authorized to dispense or purchase for distribution prescribed products in the state. A health care provider is not a veterinarian.
- (j) "Investigator" means any individual who is involved in conducting a bona fide clinical trial or research project.
- (k) "Manufacturer" means a pharmaceutical manufacturer, biological product manufacturer, or any other person who is engaged in the production, preparation, propagation, compounding, processing, marketing, packaging, repacking, distributing, or labeling of prescribed products. "Manufacturer" does not include a wholesaler, as defined in Section 4043 of the Business and Professions Code, a pharmacist, as defined in Section 4036 of the Business and Professions Code, or a pharmacy, as defined in Section 4037 of the Business and Professions Code.
- (*l*) "Marketing" means promoting, detailing, or any activity that is intended to be used or is used to influence sales or market share or to evaluate the effectiveness of a professional sales force.
- (m) "Pharmaceutical manufacturer" means either of the following:
- (1) An entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, whether directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.

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(2) An entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs.

- (n) "Prescribed product" means a drug as defined in Section 321 of Title 21 of the United States Code, a compounded drug or drugs, a biological product as defined in Section 262 of Title 42 of the United States Code for human use, or a combination product as defined in subdivision (e) of Section 3.2 of Title 21 of the Code of Federal Regulations.
- (o) "Sample" means a unit of a prescription drug or biological product that is not intended to be sold and is intended to promote the sale of the drug or product and includes starter packs and coupons or other vouchers that enable an individual to receive a prescribed product free of charge or at a discounted price. "Sample" does not include prescribed products distributed free of charge or at a discounted price pursuant to a manufacturer-sponsored or manufacturer-funded patient assistance program.
- (p) "Research" or "research project" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge, whether or not it is conducted or supported under a program that is considered research for other purposes.
- (q) "Significant educational, scientific, or policymaking conference or seminar" means a nonmarketing educational, scientific, or policymaking conference or seminar that is national, regional, or within the State of California and that satisfies either of the following:
- (1) The conference or seminar is accredited by the Accreditation Council for Continuing Medical Education or a comparable organization or is presented by an approved sponsor of continuing education, only if the sole sponsor is not a manufacturer of prescribed products.
- (2) The conference or seminar offers continuing education credit, features multiple presenters on scientific research, or is authorized by the sponsor to recommend or make policy.
- 150302. A manufacturer of a prescribed product or an agent thereof shall not offer or give a gift to a health care provider.
- 150304. Except as described in paragraph (3) of subdivision (a) of Section 150300, a manufacturer or an entity on behalf of a manufacturer shall not provide a fee, payment, subsidy, or other

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economic benefit to a health care provider in connection with the provider's participation in research.

150306. Sections 150302 and 150304 shall not apply to the following:

- (a) Samples of a prescribed product or reasonable quantities of an over-the-counter drug, an item of medical food as defined in Section 360ee of Title 21 of the United States Code, or infant formula as defined in Section 321 of Title 21 of the United States Code, that are provided to a health care provider for free distribution to patients.
- (b) The provision, distribution, dissemination, or receipt of peer-reviewed academic, scientific, or clinical articles or journals and other items that serve a genuine educational function provided to a health care provider for the benefit of patients.
- (c) Scholarship or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policymaking conference or seminar of a national, regional, or specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association.
- (d) Rebates and discounts for prescribed products provided in the normal course of business.
- (e) The provision to a free clinic of financial donations or of free prescription drugs, over-the-counter drugs, biological products, combination products, medical food, or infant formula.
- (f) Prescribed products distributed free of charge or at a discounted price pursuant to a manufacturer-sponsored or manufactured-funded patient assistance program.
- (g) Fellowship salary support provided to fellows through grants for from manufacturers of prescribed products, provided that all of the following conditions are satisfied:
- (1) The grants are applied for by an academic institution or hospital or clinical research site.
- (2) The institution, hospital, or clinical research site selects the recipient fellows.
- (3) The manufacturer imposes no further demands or limits on the institution's, hospital's, clinical research site's, or fellow's use of the funds.
- (4) Fellowships are not named for a manufacturer and no individual recipient's fellowship is attributed to a particular manufacturer of prescribed products.

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(h) The provision of coffee or other snacks or refreshments at a booth at a conference or seminar.

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150308. It is the intent of the Legislature that the requirements and prohibitions of this division complement and operate in conjunction with the federal Physician Payments Sunshine Act (42 U.S.C. Sec. 1320a-7h). If the Physician Payments Sunshine Act is repealed or becomes inoperative, it is the intent of the Legislature to enact similar legislation requiring manufacturers to disclose payments or other transfers of value made to health care providers in the state.

150310. This division shall become operative on January 1, 12 2019.

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BILL	AUTHOR	TITLE	STATUS	AMENDED
AB 11	McCarty	Early and Periodic Screening, Diagnosis, and Treatment Program	Asm. Health	01/03/18
AB 12	Cooley	State Government: Administrative Regulations: Review	Asm. Approps.	
AB 64	Bonta	Cannabis: Licensure and Regulation	Sen. Approps.	06/27/17
AB 77	Fong	Regulations: Effective Dates and Legislative Review	Asm. Approps.	02/07/17
AB 110	Ting	Cannabis: Medicinal and Adult Use	Sen. Inactive	06/12/17
AB 183	Lackey	Bill of Rights for State Excluded Employees	Asm. Inactive	05/25/17
AB 186	Eggman	Controlled Substances: Safer Drug Consumption Program	Sen. Inactive	09/08/17
AB 207	Arambula	California State University: Doctor of Medicine Degrees	Asm. Higher Ed.	02/22/17
AB 224	Thurmond	Dentistry: Anesthesia and Sedation	Sen. B&P	05/30/17
AB 244	Cervantes	Maternal Mental Health	Asm. Health	03/21/17
AB 251	Bonta	Health and Care Facilities: Dialysis Clinics	Sen. Inactive	06/29/17
AB 254	Thurmond	Local Educational Agency Behavioral Health Pilot Program	Sen. Approps.	06/28/17
AB 259	Gipson	Medical Cannabis and Nonmedical Marijuana	Asm. Inactive	03/28/17
AB 263	Rodriguez	Emergency Medical Services Workers	Senate	06/21/17
AB 389	Salas	Cannabis: Consumer Guide	Sen. Approps.	07/05/17
AB 444	Ting	Medical Waste: Home Generated Medical Waste	Sen. Env. Quality	04/18/17
AB 451	Arambula	Health Facilities: Emergency Services and Care	Sen. Approps.	07/05/17
AB 479	Gonzalez Fletcher	Workers' Compensation: Permanent Disability	Asm. Insurance	01/03/18
AB 514	Salas	Medical Waste: Pharmaceuticals	Sen. Env. Quality	04/17/17
AB 613	Nazarian	Healing Arts: Clinical Laboratories	Sen. Inactive	08/29/17
AB 632	Acosta	Small Business Procurement and Contract Act	Asm. Approps.	03/21/17
AB 635	Harper	Department of Consumer Affairs	Assembly	
AB 650	Dahle	Director of Technology: State Baseline Security Controls	Asm. Priv. & Cons. Prot.	
AB 654	Maienschein	Pediatric Home Health Care	Asm. Approps.	03/13/17
AB 703	Flora	Professions and Vocations: Licenses: Fee Waivers	Asm. B&P	

BILL	AUTHOR	TITLE	STATUS	AMENDED
AB 710	Wood	Department of Consumer Affairs: Boards: Meetings	Sen. B&P	04/27/17
AB 728	Waldron	Health Care Coverage: Duchenne Muscular Dystrophy	Asm. Health	04/19/17
AB 750	Gallagher	Criminal Law: Competency: Department of State Hospitals	Asm. Health	03/30/17
AB 767	Quirk-Silva	Master Business License Act	Asm. Approps.	05/03/17
AB 826	Brough	Professions and Vocations	Assembly	
AB 827	Rubio	Department of Consumer Affairs: Task Force: Foreign-Trained Professionals	Sen. Approps.	04/03/17
AB 835	Dababneh	Consumer Affairs: Licenses: Prohibited Acts	Asm. B&P	03/27/17
AB 876	Acosta	State Agency Databases	Assembly	
AB 893	Garcia, E.	Public Health: Graduate Medical Education	Sen. Health	05/11/17
AB 937	Eggman	Health Care Decisions: Order of Priority	Sen. Health	05/03/17
AB 963	Gipson	Taxation: Marijuana	Asm. Inactive	05/30/17
AB 966	Chau	Public Health: Medication Assistance	Assembly	
AB 1003	Bloom	Healthy California Fund	Assembly	04/19/17
AB 1005	Calderon	Professions and Vocations: Fines: Relief	Asm. Approps.	05/02/17
AB 1098	McCarty	Child Death Investigations: Review Teams	Sen. Approps.	05/26/17
AB 1116	Grayson	Peer Support and Crisis Referral Services Act	Sen. Inactive	09/08/17
AB 1349	Daly	Diabetes: Strategy for Awareness and Prevention	Asm. Health	03/30/17
AB 1353	Waldron	Health Care Coverage: Prescription Drugs: Continuity of Care	Asm. Health	03/23/17
AB 1372	Levine	Crisis Stabilization Units: Psychiatric Patients	Sen. Inactive	06/13/17
AB 1445	Reyes	Public Contracting: Small Business Goal	Senate	04/18/17
AB 1466	Patterson	Patient Records	Assembly	
AB 1485	Rubio	California Health and Human Services Agency	Asm. Human Svcs	03/20/17
AB 1539	Chen	Mental Health	Asm. Health	04/04/17
AB 1643	Bonta	Health Care for All Commission	Asm. Approps.	03/28/17
AB 1658	Frazier	State Agencies: Accountability	Asm. Approps.	03/21/17

BILL	AUTHOR	TITLE	STATUS	AMENDED
AB 1659	Low	Healing Arts Boards: Inactive Licenses	Asm. B&P	01/03/18
AB 1685	Maienschein	Children's Mental Health	Assembly	
SB 21	Hill	Law Enforcement Agencies: Surveillance: Policies	Asm. Approps.	08/21/17
SB 22	Hill	Firearms: Law Enforcement Agencies: Accounting	Sen. Approps.	03/28/17
SB 23	Portantino	Public Health: Umbilical Cord Blood Collection	Sen. Approps.	04/17/17
SB 27	Morrell	Professions and Vocations: Licenses: Military Service	Sen. Approps.	04/17/17
SB 32	Moorlach	Public Employees Pension Reform Act of 2018	Sen. P.E. &R	03/02/17
SB 43	Hill	Antimicrobial-Resistant Infection: Reporting	Asm. Health	04/05/17
SB 76	Nielsen	Excluded Employees: Arbitration	Asm. Inactive	06/29/17
SB 162	Allen	Cannabis: Marketing	Asm. Approps.	08/21/17
SB 172	Portantino	Health Care Coverage: Fertility Preservation	Sen. Approps.	05/01/17
SB 191	Beall	Pupil Health: Mental Health and Substance Use Disorder Svcs.	Sen. Approps.	03/28/17
SB 198	Galgiani	Hearing Aid Dispensers: Cerumen Management: Tympanometry	Sen. B&P	04/17/17
SB 199	Hernandez	The California Health Care Cost, Quality, and Equity Atlas	Asm. Approps.	03/30/17
SB 200	Morrell	Public Employees' Retirement Benefits: Final Compensation	Senate	
SB 212	Jackson	Medical Waste	Asm. E.S.&T.M.	
SB 244	Lara	Privacy: Agencies: Personal Information	Asm. Inactive	09/08/17
SB 350	Galgiani	Incarcerated Persons: Health Records	Sen. Approps.	04/25/17
SB 392	Bates	Dentistry: Report: Access to Care: Pediatric Dental Patients	Asm. B&P	05/26/17
SB 399	Portantino	Health Care Coverage: Pervasive Developmental Disorder/Autism	Sen. Health	01/03/18
SB 454	Moorlach	Public Employees' Health Benefits	Sen. P.E. &R	04/06/17
SB 456	Pan	Medi-Cal Managed Care: FQHCs and Rural Health Clinics	Asm. Approps.	06/19/17
SB 487	Pan	Practice of Medicine: Hospitals	2-year Bill	
SB 501	Glazer	Dentistry: Anesthesia and Sedation: Report	Asm. Approps.	05/01/17
SB 538	Monning	Hospital Contracts	Asm. Health	05/26/17

BILL	AUTHOR	TITLE	STATUS	AMENDED
SB 555	Morrell	Regulations: 5-year Review and Report	Sen. G.O.	
SB 562	Lara	The Healthy California Act	Assembly	05/26/17
SB 572	Stone	Healing Arts Licensees: Violations: Grace Period	Sen. B&P	03/27/17
SB 648	Mendoza	Health and Care Facilities: Private Referral Agencies	Sen. Approps.	04/27/17
SB 657	Bates	California Public Records Act: Reverse Public Records Actions	Sen. Judiciary	
SB 762	Hernandez	Healing Arts Licensee: License Activation Fee: Waiver	Asm. B&P	04/17/17
SB 783	Pan	State Employment: Unused Leave Buy-Back	Sen. P.E. &R	
SCA 8	Moorlach	Public Employee Retirement Benefits	Senate	
SCA 10	Moorlach	Public Employee Retirement Benefits	Sen. P.E. &R	

2018 TENTATIVE LEGISLATIVE CALENDAR

COMPILED BY THE OFFICE OF THE SECRETARY OF THE SENATE

Revised 11/16/16

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DEADLINES

- Statutes take effect (Art. IV, Sec. 8(c)).
- Legislature Reconvenes (J.R. 51(a)(4)).
- Jan. 10 Budget must be submitted by Governor (Art. IV, Sec. 12(a)).
- Jan. 12 Last day for policy committees to hear and report to fiscal committees fiscal bills introduced in their house in the odd-numbered year (J.R. 61(b)(1)).
- Jan. 15 Martin Luther King, Jr. Day.
- Jan. 19 Last day for any committee to hear and report to the floor bills introduced in that house in the odd-numbered year (J.R. 61(b)(2)). Last day to submit bill requests to the Office of Legislative Counsel.
- Jan. 31 Last day for each house to pass bills introduced in that house in the odd-numbered year (J.R. 61(b)(3), (Art. IV, Sec. 10(c)).
- Feb. 16 Last day for bills to be introduced (J.R. 61(b)(4), (J.R. 54(a)).
- Feb. 19 Presidents' Day.
- Mar. 22 Spring Recess begins upon adjournment of this day's session (J,R, 51(b)(1)).
- Mar. 30 Cesar Chavez Day observed.

- Apr. 2 Legislature Reconvenes from Spring Recess (J.R. 51(b)(1)).
- Apr. 27 Last day for policy committees to hear and report to fiscal committees fiscal bills introduced in their house (J.R. 61(b)(5)).
- May 11 Last day for policy committees to hear and report to the floor nonfiscal bills introduced in their house (J.R. 61(b)(6)).
- May 18 Last day for policy committees to meet prior to June 4 (J.R. 61(b)(7)).
- May 25 Last day for fiscal committees to hear and report to the floor bills introduced in their house (J.R. 61(b)(8)). Last day for fiscal committees to meet prior to June 4 (J.R. 61(b)(9)).
- May 28 Memorial Day.
- May 29- June 1 Floor Session only. No committees, other than conference or Rules committees, may meet for any purpose (J.R. 61 (b)(10)).

^{*}Holiday schedule subject to Senate Rules committee approval

2018 TENTATIVE LEGISLATIVE CALENDAR

COMPILED BY THE OFFICE OF THE SECRETARY OF THE SENATE

Revised 11/16/16

JUNE							
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June 1	Last day for each house to pass bills introduced in that house
	(f.R. 61(b)(11)).

Committee meetings may resume (J.R. 61(b)(12)).

June 15 Budget Bill must be passed by midnight (Art. IV, Sec. 12(c)(3)).

Last day for a legislative measure to qualify for the Nov. 6 General Election bailot (Elections code Sec. 9040).

June 29 Last day for policy committees to hear and report fiscal bills to fiscal committees (J.R. 61(b)(13)).

July 4	Independence Day.	

Last day for policy committees to meet and report bills (J.R. 61(b)(14)). July 6 Summer Recess begins upon adjournment provided Budget Bill has been passed (J.R. 51(b)(2)).

Legislature Reconvenes (J.R. 51(b)(2)).

Last day for fiscal committees to meet and report bills (J.R. 61(b)(15)).

Aug. 20-31 Floor Session only. No committees, other than Conference and Rules Committees, may meet for any purpose (J.R. 61(b)(16)).

Last day to amend on the floor (J.R. 61(b)(17)).

Last day for each house to pass bills, except bills that take effect immediately or bills in Extraordinary Session (Art. IV, Sec. 10(c), (J.R. 61(b)(18)). Final Recess begins upon adjournment (J.R. 51(b)(3)).

IMPORTANT DATES OCCURRING DURING INTERIM STUDY RECESS

Sept. 30 Last day for Governor to sign or veto bills passed by the Legislature before Sept. 1 and in the Governor's possession on or after Sept. 1 (Art. IV, Sec. 10(b)(2)). Nov. 6 General Election Nov. 30 Adjournment Sine Die at midnight (Art. IV, Sec. 3(a)). Dec. 3 12 Noon convening of the 2019-20 Regular Session (Art. IV, Sec. 3(a)). <u> 2019</u> Jan, 1 Statutes take effect (Art. IV, Sec. 8(c)).

^{*}Holiday schedule subject to Senate Rules committee approval