MEDICAL BOARD OF CALIFORNIA
LEGISLATIVE ANALYSIS

Bill Number: AB 154
Author: Atkins
Bill Date: March 19, 2013, amended
Subject: Abortion
Sponsor: ACCESS Women's Health Justice
American Civil Liberties Union of California
Black Women for Wellness California
Latinas for Reproductive Justice
NARAL Pro-Choice California
Planned Parenthood Affiliates of California

STATUS OF BILL:

This bill is in Assembly Business, Professions and Consumer Protection Committee.

DESCRIPTION OF CURRENT LEGISLATION:

This bill would eliminate the distinction in existing law between "surgical" and "nonsurgical" abortions and would allow physician assistants (PAs), nurse practitioners (NPs), and certified nurse-midwives (CNMs) to performs an abortion by medication or aspiration techniques in the first trimester of pregnancy, if specified training is completed and clinical competency is validated.

ANALYSIS:

This bill will codify the Health Workforce Pilot Project (HWPP) #171, coordinated through the Office of Statewide Health Planning and Development (OSHPD) and sponsored by the Advancing New Standards in Reproductive Health (ANSIRH) program at the University of California, San Francisco (UCSF). The purpose of the pilot project was to evaluate the safety, effectiveness and acceptability of NPs, NMs, and PAs in providing aspiration abortions, and to evaluate the implementation of a standardized, competency based curriculum in provision of aspiration abortion care.

As part of the pilot, 40 NPs, CNMs and PAs were trained to be competent in aspiration abortion care. Clinicians participated in a comprehensive didactic and supervised clinical training program, which included a written exam and competency-based evaluation process. Trainee competency was evaluated daily and at the end of training on confidence, procedural performance, patient care, communication /interpersonal skills, professionalism, practice-based learning, and clinical knowledge.

This bill would require PAs, NPs, and CNMs to complete specified training and achieve clinical competency, which was also required as a part of the pilot project, before they are allowed to perform abortions by medication or aspiration techniques.

STATISTICS of the HWPP Pilot Project (#171) (Taken from the Peer Reviewed Study published in the American Journal of Public Health):

Patient sample selection, enrollment and consent:

- 5,675 first-trimester aspiration abortion procedures were completed by NPs/CNMs/PAs and 5,812 procedures were completed by physicians, for a total of 11,487 abortion procedures.

Abortion-related complications summary:

- A complication is identified at the time of the procedure (immediate) or after the procedure (delayed) and classified as either major (defined by the DCSMC as "complications requiring abortion-related surgeries, transfusion or hospitalization") or minor.
- Overall abortion-related complication rate: 1.3% of all procedures (152 of 11,487) had abortion-related complication diagnoses.
- Group-specific abortion-related complication rate: 1.8% for NPs, CNMs, and PAs and 0.9% for physicians.
- 96% (146 out of 152) of abortion-related complications were minor; 6 cases have been classified as major complications.
- The most common type of minor abortion-related complication diagnoses reported were incomplete abortion, hematometra, and failed abortion. Major abortion-related complications include hemorrhage, infection, and uterine perforation.
- The peer reviewed study found that abortion complications were clinically equivalent between newly trained NPs, CNMs, and PAs and physicians.

According to the author's office, this bill is needed to ensure that women in California have access to early abortion. According to the author's office early abortion access is a critical public health issue as many women in California do not have sufficient access to aspiration abortion because many counties in California lack an abortion provider, which requires women to travel a significant distance for care. The sponsors believe that increasing the number of providers for aspiration abortions will increase the ability of women to receive safe reproductive health care from providers in their community.

FISCAL: None

SUPPORT: ACCESS Women's Health Justice (sponsor); American Civil Liberties Union of California (Sponsor); Black Women for Wellness California (sponsor); Latinas for Reproductive Justice (sponsor); NARAL Pro-Choice California (sponsor); and Planned Parenthood Affiliates of California (sponsor)

OPPOSITION: None on file

POSITION: Recommendation: Neutral

AMENDED IN ASSEMBLY MARCH 19, 2013

california legislature—2013–14 regular session

ASSEMBLY BILL No. 154

Introduced by Assembly Member Atkins

January 22, 2013

~~An act relating to reproductive health care.~~ *An act to amend Section 2253 of, and to add Sections 734, 2725.4, and 3502.4 to, the Business and Professions Code, and to amend Section 123468 of the Health and Safety Code, relating to healing arts.*

legislative counsel's digest

AB 154, as amended, Atkins. ~~Healing arts: reproductive health care.~~ *Abortion.*

Existing law makes it a public offense, punishable by a fine not exceeding $10,000 or imprisonment, or both, for a person to perform or assist in performing a surgical abortion if the person does not have a valid license to practice as a physician and surgeon, or to assist in performing a surgical abortion without a valid license or certificate obtained in accordance with some other law that authorizes him or her to perform the functions necessary to assist in performing a surgical abortion. Existing law also makes it a public offense, punishable by a fine not exceeding $10,000 or imprisonment, or both, for a person to perform or assist in performing a nonsurgical abortion if the person does not have a valid license to practice as a physician and surgeon or does not have a valid license or certificate obtained in accordance with some other law authorizing him or her to perform or assist in performing the functions necessary for a nonsurgical abortion. Under existing law, nonsurgical abortion includes termination of pregnancy through the use of pharmacological agents.

Existing law, the Nursing Practice Act, provides for the licensure and regulation of registered nurses, including nurse practitioners and certified nurse-midwives, by the Board of Registered Nursing. Existing law, the Physician Assistant Practice Act, provides for the licensure and regulation of physician assistants by the Physician Assistant Committee of the Medical Board of California.

~~Existing law authorizes the Office of Statewide Health Planning and Development to designate experimental health workforce projects as approved projects that, among other things, teach new skills to existing categories of health care personnel. The office has designated a pilot project, known as the Access through Primary Care Project, relating to the provision of health care services involving pregnancy.~~

~~This bill would state that it is the intent of the Legislature to enact legislation that would expand access to reproductive health care in California by allowing qualified health care professionals to perform early abortions.~~

This bill would instead make it a public offense, punishable by a fine not exceeding $10,000 or imprisonment, or both, for a person to perform an abortion if the person does not have a valid license to practice as a physician and surgeon, except that it would not be a public offense for a person to perform an abortion by medication or aspiration techniques in the first trimester of pregnancy if he or she holds a license or certificate authorizing him or her to perform the functions necessary for an abortion by medication or aspiration techniques. The bill would also require a nurse practitioner, certified nurse-midwife, or physician assistant to complete training, as specified, in order to perform an abortion by aspiration techniques, and would indefinitely authorize a nurse practitioner, certified nurse-midwife, or physician assistant who completed a specified training program and achieved clinical competency to continue to perform abortions by aspiration techniques. The bill would delete the references to a nonsurgical abortion and would delete the restrictions on assisting with abortion procedures. The bill would also make technical, nonsubstantive changes.

Because the bill would change the definition of crimes, the bill would impose a state-mandated local program.

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: ~~no~~ *yes*. State-mandated local program: ~~no~~ *yes*.

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

SECTION 1. Section 734 is added to the Business and Professions Code, to read:

734. It is unprofessional conduct for any nurse practitioner, certified nurse midwife, or physician assistant to perform an abortion pursuant to Section 2253, without prior completion of training and validation of clinical competency.

SEC. 2. Section 2253 of the Business and Professions Code is amended to read:

2253. (a) Failure to comply with the Reproductive Privacy Act (Article 2.5 (commencing with Section 123460) of Chapter 2 of Part 2 of Division 106 of the Health and Safety Code) ~~in performing, assisting, procuring or aiding, abetting, attempting, agreeing, or offering to procure an illegal abortion~~ constitutes unprofessional conduct.

(b) (1) ~~A~~ *Except as provided in paragraph (2), a* person is subject to ~~Sections~~ *Section* 2052 ~~and 2053~~ if he or she performs ~~or assists in performing a surgical~~ *an* abortion, and at the time of

so doing, does not have a valid, unrevoked, and unsuspended license to practice as a physician and surgeon ~~as provided in this chapter, or if he or she assists in performing a surgical abortion and does not have a valid, unrevoked, and unsuspended license or certificate obtained in accordance with some other provision of law that authorizes him or her to perform the functions necessary to assist in performing a surgical abortion~~.

(2) A person ~~is~~ *shall not be* subject to ~~Sections~~ *Section* 2052 ~~and 2053~~ if he or she performs ~~or assists in performing a nonsurgical abortion,~~ *an abortion by medication or aspiration techniques in the first trimester of pregnancy,* and at the time of so doing, ~~does not have a valid, unrevoked, and unsuspended license to practice as a physician and surgeon as provided in this chapter, or does not have~~ *has* a valid, unrevoked, and unsuspended license or certificate obtained in accordance with some other provision of law, *including, but not limited to, the Nursing Practice*

Act (Chapter 6 (commencing with Section 2700)) or the Physician Assistant Practice Act (Chapter 7.7 (commencing with Section 3500)), that authorizes him or her to perform ~~or assist in performing~~ the functions necessary for ~~a nonsurgical abortion.~~ *an abortion by medication or aspiration techniques.*

~~(c) For purposes of this section, "nonsurgical abortion" includes termination of the use of pharmacological agents.~~

(c) In order to perform an abortion by aspiration techniques pursuant to paragraph (2) of subdivision (b), a person shall comply with Section 2725.4 or 3502.4.

SEC. 3. Section 2725.4 is added to the Business and Professions Code, to read:

2725.4. (a) In order to perform an abortion by aspiration techniques, a person with a license or certificate to practice as a nurse practitioner or a certified nurse-midwife shall complete training recognized by the Board of Registered Nursing. Beginning January 1, 2014, and until January 1, 2016, the competency-based training protocols established by Health Workforce Pilot Project (HWPP) No. 171 through the Office of Statewide Health Planning and Development shall be used.

(b) A nurse practitioner or certified nurse-midwife who has completed training and achieved clinical competency through HWPP No. 171 shall be authorized to perform abortions by aspiration techniques.

SEC. 4. Section 3502.4 is added to the Business and Professions Code, to read:

3502.4. (a) In order to receive authority from his or her supervising physician and surgeon to perform an abortion by aspiration techniques, a physician assistant shall complete training

either through training programs approved by the Physician Assistant Board pursuant to Section 3513 or by training to perform medical services which augment his or her current areas of competency pursuant to Section 1399.543 of Title 16 of the California Code of Regulations. Beginning January 1, 2014, and until January 1, 2016, the training and clinical competency protocols established by Health Workforce Pilot Project (HWPP) No. 171 through the Office of Statewide Health Planning and Development shall be used as training and clinical competency guidelines to meet this requirement.

(b) The training protocols established by HWPP No. 171 shall be deemed to meet the standards of the Physician Assistant Board. A physician assistant who has completed training and achieved clinical competency through HWPP No. 171 shall be authorized to perform abortions by aspiration techniques.

SEC. 5. Section 123468 of the Health and Safety Code is amended to read:

123468. The performance of an abortion is unauthorized if either of the following is true:

(a) The person performing ~~or assisting in performing~~ the abortion is not a health care provider authorized to perform ~~or assist in performing~~ an abortion pursuant to Section 2253 of the Business and Professions Code.

(b) The abortion is performed on a viable fetus, and both of the following are established:

(1) In the good faith medical judgment of the physician, the fetus was viable.

(2) In the good faith medical judgment of the physician, continuation of the pregnancy posed no risk to life or health of the pregnant woman.

SEC. 6. 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. It is the intent of the Legislature to enact legislation that would expand access to reproductive health care in California by allowing qualified health care professionals to perform early abortions, provided that the functions are within the scope of their licenses.~~

http://blog.ansirh.org/2013/01/roe-v-wade-california-abortion-law-hwpp-171-and-the-future-of-access/

Roe v Wade, California abortion law, HWPP #171, and the future of access

Posted January 17, 2013 By Tracy Weitz

A newly published landmark study by ANSIRH demonstrates that trained nurse practitioners, certified nurse midwives, and physician assistants match physicians in the safety of aspiration abortions they provide. We hope that these results will give policymakers the evidence they need to move beyond physician-only restrictions in order to enable more women to have their reproductive health care needs met in their local communities by health care providers they know and trust.

January 22, 2013 marks the 40th anniversary of the *Roe v. Wade* Supreme Court decision that legalized abortion nationwide. While abortion in California had been legal under more limited circumstances since 1967, *Roe* did have an effect on our law. It eliminated the need for a psychiatrist to approve a woman's abortion, negated the requirement that abortions be performed in hospitals, and extended when a woman could have an abortion. But the law on the books didn't change.

It wasn't until 2000, when the FDA was poised to approve mifepristone (the "abortion pill"), that advocates considered asking the legislature to modernize the abortion law. Legal research in California confirmed that the state's physician-only law would prohibit nurse practitioners (NPs), certified nurse midwives (CNMs), and physician assistants (PAs) from being able to offer women the abortion pill, thereby limiting the benefit of this new abortion option. Although they knew it wouldn't be easy, advocates took on the challenge of reforming California's abortion law. A lot of hard work paid off, and on January 1, 2003, California enacted a contemporary abortion law. Known as the Reproductive Privacy Act, SB1301 codified the *Roe v. Wade* standards and affirmed the legal right of NPs, CNMs, and PAs to perform abortions using medications.

One of the unsettled parts of the discussion over SB1301 was whether non-physician clinicians should be allowed to offer other types of low-risk abortion procedures. At the time, there were two published studies on the provision of aspiration abortion by PAs in Vermont and New Hampshire. While the authors found no difference in safety, the studies included both a small number of patients and only a few clinicians. For many stakeholders, the evidence was insufficient to give them comfort opening up California's law in this way. What was needed was a more comprehensive study of the safety of aspiration abortion provision by NPs, CNMs, and PAs.

This is where UCSF entered the picture

After a few years of research design and fundraising, ANSIRH researchers were prepared to study the safety and competency of NPs, CNMs, and PAs performing aspiration abortions. In order to conduct the study, we utilized the Health Workforce Pilot Project (HWPP) mechanism within the Office of Statewide Health Planning and Development (OSHPD), which provides legal waivers for demonstration projects to test and evaluate new or expanded roles for health care professionals to improve access to health care and encourage workforce development. In 2007, UCSF obtained a legal waiver from the State and the HWPP #171 study began.

HWPP #171 was designed to answer two questions:

1. Can NPs, CNMs, and PAs be trained to competence in aspiration abortion?
2. Can they perform those procedures with outcomes comparable to those of their physician colleagues?

There were three principal investigators on the application to the state: Tracy A. Weitz, PhD, MPA; Diana Taylor, PhD, FNP, and Philip Darney, MD, MSc. There is also a principal investigator for each of the five partner organizations where clinicians were trained and offered services (four Planned Parenthood affiliates and Kaiser Permanente of Northern California).

Today, the results of our study were released in the *American Journal of Public Health*, one of the nation's most prestigious peer-reviewed journals.

The study results are relatively simple. A total of 5,675 women had their abortions performed by an NP, CNM, or PA and 5,812 by a licensed physician. The first major conclusion is that abortion is incredibly safe no matter who performed it. Fewer than 2% of all patients required any additional care after the initial abortion; only 6 patients (less than .05%) needed any hospital-based care (3 of those patients were seen by physicians and 3 by an NP, CNM, or PA); and all of those women recovered without any long-term physical harm.

The study was designed to assess the equivalence between the two groups of providers. The goal of the study was not to show that one group was better than the other, rather to see if they are the same. To do this, we set a margin of difference of 2%. In the physician group, 0.9% of women had a complication, compared to 1.8% of women in the NP/CNM/PA group. This slightly higher number among newly trained providers was expected and is not clinically significant. The risk difference for complications between the two groups fell within the predetermined margin of non-inferiority. As a result, we conclude that NPs, CNMs, and PAs can perform aspiration abortions as safely as their physician colleagues.

So why does all this matter?

Nationally, 92% of abortions take place in the first trimester—but black, uninsured, rural, and low-income women continue to have less access to this care. In California, 13% of women using state Medicaid insurance obtain abortions after the first trimester. Because the average cost of a second-trimester abortion is substantially higher than a first-trimester procedure and abortion complications increase as the pregnancy advances, shifting the population distribution of abortions to earlier gestations would result in safer, less costly care.

In addition, NPs, CNMs, and PAs provide the majority of well-woman care in primary care settings and are key health access points for low-income and rural women. Allowing a larger group of health care professionals to offer early aspiration abortion care is one way to reduce this health care disparity and increase continuity of care. The evidence to support this policy option is now in hand.

In 2013, policy advocates in Sacramento will once again work with the California legislature to modernize California's abortion law and allow NPs, CNMs, and PAs to perform early aspiration abortions. By utilizing these skilled health care professionals, perhaps many more California women will have their reproductive health care needs met in their local communities by health care providers they know and trust.

Safety of Aspiration Abortion Performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under a California Legal Waiver

Tracy A. Weitz, PhD, Diana Taylor, PhD, Sheila Desai, MPH, Ushma D. Upadhyay, PhD, Jeff Waldman, MD, Molly F. Battistelli, BA, and Eleanor A. Drey, MD

Objectives. We examined the impact on patient safety if nurse practitioners (NPs), certified nurse midwives (CNMs), and physician assistants (PAs) were permitted to provide aspiration abortions in California.

Methods. In a prospective, observational study, we evaluated the outcomes of 11 487 early aspiration abortions completed by physicians (n = 5812) and newly trained NPs, CNMs, and PAs (n = 5675) from 4 Planned Parenthood affiliates and Kaiser Permanente of Northern California, by using a noninferiority design with a predetermined acceptable risk difference of 2%. All complications up to 4 weeks after the abortion were included.

Results. Of the 11 487 aspiration abortions analyzed, 1.3% (n = 152) resulted in a complication: 1.8% for NP-, CNM-, and PA-performed aspirations and 0.9% for physician-performed aspirations. The unadjusted risk difference for total complications between NP–CNM–PA and physician groups was 0.87 (95% confidence interval [CI] = 0.45, 1.29) and 0.83 (95% CI = 0.33, 1.33) in a propensity score–matched sample.

Conclusions. Abortion complications were clinically equivalent between newly trained NPs, CNMs, and PAs and physicians, supporting the adoption of policies to allow these providers to perform early aspirations to expand access to abortion care. (*Am J Public Health.* Published online ahead of print January 17, 2013: e1–e8. doi:10.2105/AJPH.2012.301159)

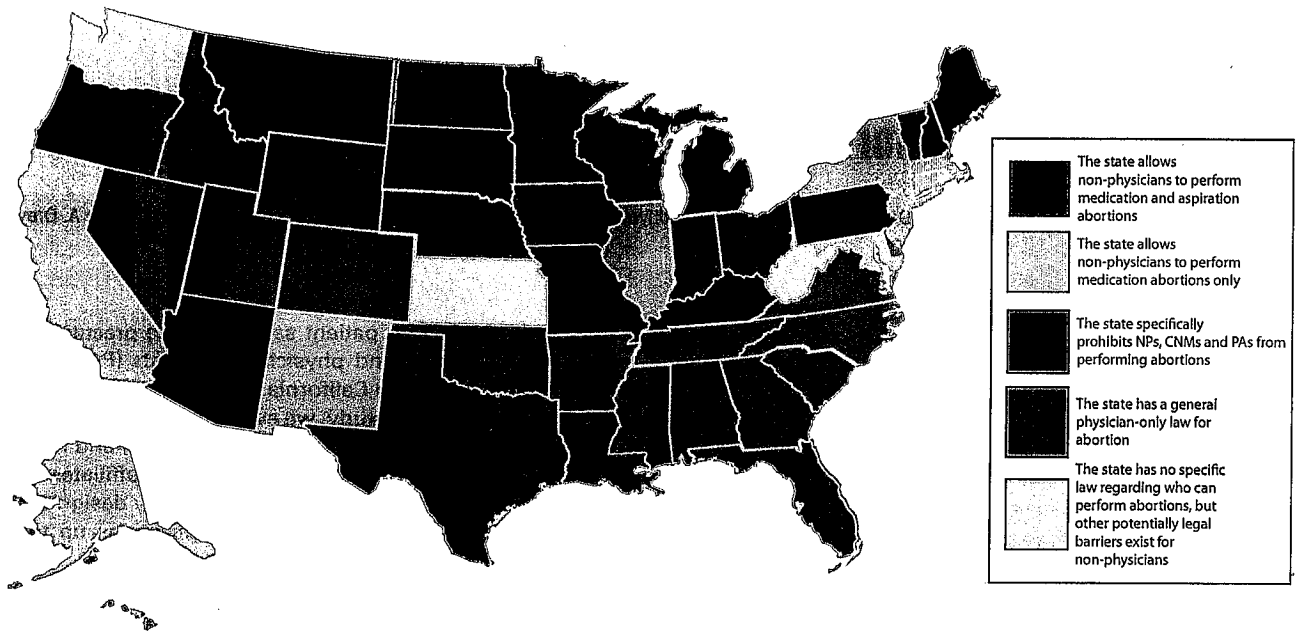
Increased access to early abortion is a pressing public health need. By 2005, the number of abortion care facilities in the United States had decreased 38% from its peak in 1982.[1] Although the number has since remained stable, the proportion of US counties with no facility remains high at 87%; more than one third of women aged 15 to 44 years live in these counties.[2] Additionally, a large proportion of US facilities are hospitals that perform abortions only in cases of serious medical and fetal indications or facilities that offer medical abortions only up to 9 weeks of pregnancy.[2]

Many women face difficulties finding a facility, resulting in delayed care.[3] Increasing access is critical because abortions at later gestations are associated with a higher risk of complications[4] and higher costs.[2] Research has also found that many women would prefer to obtain their abortions earlier[5] Finally, traditionally underserved populations experience the greatest barriers to abortion care, resulting in higher rates of procedures after the first trimester.[6,7]

In California, more than half of the 58 counties lack a facility that provides 400 or more abortions (R. K. Jones, personal communication). Low-income and minority women are most likely to be served by public health departments or community health centers,[8] most of which do not provide abortions. These women are also more likely to be cared for by nurse practitioners (NPs) and physician assistants (PAs) than by obstetricians and gynecologists.[9]

One potential solution to improve access is to increase the number and types of health care professionals who offer early abortion care.[10–12] Increased emphasis has been placed on task sharing to better meet women's health needs in the context of health care workforce shortages.[13] In the United States, health professions are regulated through a patchwork of state regulations[14,15] that determine who can perform abortions, a power reaffirmed by several US Supreme Court decisions.[16–18] Currently, nonphysician clinicians can perform aspiration abortions legally in only 4 states—Montana, Oregon, New Hampshire, and Vermont. Two additional states (Kansas and West Virginia) do not limit the performance of abortions to physicians, but nonphysician clinicians have never tried to provide abortion care. Of the remaining 44 states (Figure 1), some allow nonphysician clinicians to perform medical (but not aspiration) abortions under decisions by attorneys general or health departments, and 1 state—California—passed statutory authority for that care. As part of a larger effort to limit abortion access, several states have recently promulgated laws that specifically prohibit nonphysician clinicians from performing abortions.[19] For example, a 2009 Arizona law (HB 2564 and SB 1175) that precluded NPs from providing abortions resulted in the discontinuation of abortion care at several facilities that had previously been staffed exclusively by NPs.[20]

Limited clinical evidence is available to inform policymakers about whether physician-only legal restrictions on abortion are evidence-based.[21–24] Our study was designed to provide this evidence to policymakers; it answers the question "What would be the impact on patient safety if NPs, PAs, and certified nurse midwives (CNMs) were permitted to provide aspiration abortions in California?" (We use the term *aspiration abortion* to refer to what is commonly called *surgical abortion* because the technique does not meet the technical definition of surgery.[25]) We used a noninferiority design to compare the incidence of abortion-related complications between groups because we anticipated a slightly higher number of complications among newly trained NPs, CNMs, and PAs than among the experienced physicians.



Note. CNM = certified nurse midwife; NP = nurse practitioner; PAs = physician assistants.

FIGURE 1—Landscape of health professional regulation of abortion provision in the United States.

METHODS

In 2005, study investigators applied to the California Office of Statewide Health Planning and Development (OSHPD) for a waiver of legal statutes that limit the completion of surgical abortion to physicians.[26–28] Following a public meeting, hearing, and extensive input from stakeholders, the State of California granted approval for Health Workforce Pilot Project No. 171 in March 2007, followed by approval of 4 subsequent extensions. The study received institutional review board approvals from the University of California, San Francisco; Ethical and Independent Review Services; and Kaiser Permanente of Northern California (KPNC).

In this prospective, observational cohort study, NPs, CNMs, and PAs from 5 partner organizations (4 Planned Parenthood affiliates and KPNC) were trained to competence in the provision of aspiration abortion (a minimum of 40 procedures over 6 clinical days, with competence assessed by an authorized physician trainer). To be qualified for training, NPs, CNMs, and PAs had to have a California professional license, basic life support certification, and 12 months or more of clinical experience, including 3 months or more experience in medication abortion provision. Physicians employed by the facility served as the comparison group. A total of 28 NPs, 5 CNMs, and 7 PAs (n = 40) and 96 physicians (with training in either family medicine or obstetrics and gynecology) completed procedures during the study period. Physicians had a mean of 14 years of experience providing abortions compared with a mean of 1.5 years among NPs, CNMs, and PAs. This analysis did not include procedures performed by NPs, CNMs, and PAs during their training phase.

Patients were enrolled at 22 clinical facilities between August 2007 and August 2011. Patients were eligible for the study if they were aged 16 years or older (18 years at Planned Parenthood affiliates), were seeking a first-trimester aspiration abortion (facilities self-defined this as ≤ 12 or ≤ 14 weeks' gestation by ultrasound), and could speak English or Spanish. Patients were excluded if they requested general anesthesia or did not meet the health-related criteria (unexplained historical, physical, or laboratory findings or known or suspected cervical or uterine abnormalities).

Study Procedures

Eligible patients reviewed a consent form with a facility staff member. If a patient agreed to participate, she was asked whether she was willing to have her abortion done by an NP, CNM, or PA; if so, the aspiration was performed by the NP, CNM, or PA on duty. Patients in this group were routed to a physician if clinical flow necessitated reorganizing patients. Patients were also routed to a physician if they were unwilling to have their abortions performed by an NP, CNM, or PA or arrived for care when only a physician was present.

Each patient received $5 and a follow-up survey about medical problems after the abortion to capture any delayed postprocedure complications. If patients did not return the survey, clinic staff made at least 3 attempts to administer the survey by phone. If the patient experienced postabortion problems, she was asked a defined set of questions to obtain medical details. Additionally, staff conducted patient chart abstractions 2 to 4 weeks after abortion to ensure delayed complications were

captured. For all outcomes other than an uncomplicated recovery, an incident report was generated and reviewed by the site medical director, study investigators, and the study's Data and Clinical Safety Monitoring Committee. Additional monitoring of outcomes and study procedures included annual Office of Statewide Health Planning and Development–sponsored site visits; quarterly reviews of participant recruitment, patient experience, and clinical outcomes; and routine communication between facility and UCSF study staff.

Study Outcomes

Unlike a superiority analysis, a noninferiority study design determines whether the effect of a new treatment is not worse than that of an active control by more than a specified clinically acceptable margin.[29–32] We selected a noninferiority design because we were seeking not to replace physicians as abortion providers or to determine whether NPs, CNMs, and PAs were better than current providers of care but to identify additional, comparably safe providers to supplement the provider pool. Because NPs, CNMs, and PAs who are newly trained in aspiration abortion have less experience, we expected to find a statistically significant higher rate of complications among this group than among more experienced physicians. However, we also anticipated a low overall incidence of complications from procedures across both groups. Therefore, a noninferiority design provided a more clinically relevant analysis. Given a low expected complication rate in both provider groups, we prespecified the margin of noninferiority as a change of 2%, which was determined before the start of the study by a panel of researchers and clinicians and approved by the Data and Clinical Safety Monitoring Committee, who considered ethical and clinical issues and previous US-based studies, which showed abortion-related complication rates ranging from 1.3% to 4.4%.[21,22,33–38]

The primary outcome was the difference in incidence of complications within 4 weeks of the aspiration abortion between NPs, CNMs, and PAs and physicians. Complications were categorized as immediate (occurring before leaving the facility) and delayed (occurring ≤ 4 weeks after the procedure). Additionally, complications were classified as major if the patient required hospital admission, surgery, or a blood transfusion and minor if they were treated at home or in an outpatient setting. This classification schema is consistent with that used in other studies of abortion-related morbidity.[34–37]

Statistical Analysis

We based sample size calculations for this study on an expected complication rate of 2.5%, which was based on mean complication rates cited in the published literature[21,22,33–38] and powered at 90% to detect a 1.0% or greater difference in complication incidence between groups ($\alpha = .025$, 1-tailed test). The study was powered specifically for a noninferiority analysis. Although we set a clinically acceptable margin of difference at 2.0%, we took a conservative approach and powered the study to detect an even smaller difference. We then further increased the sample size per group by 15% to adjust for clustering effects at the provider and clinic levels.

We compared sociodemographic characteristics of patients seen by NPs, CNMs, and PAs and those seen by physicians using mixed-effects logistic regression for dichotomous variables, mixed-effects multinomial logistic regression for categorical variables, and mixed-effects linear regression for continuous variables, all of which included random effects for facility. Incidence of a complication was coded as a dichotomous variable. Complication incidence was calculated by provider group. We fit a mixed-effects logistic regression model with crossed random effects to obtain odds ratios that account for the lack of independence between abortions performed by the same clinician and within the same facility and cross-classification of providers across facilities. We included variables associated with complications in bivariate analyses at $P < .05$ in the multivariate model in addition to other clinically relevant covariates to adjust for potential confounders.

To mitigate selection bias resulting from the lack of randomization, we replicated the analysis in a propensity score–matched sample, a method used to achieve balance between study groups in observational or nonrandomized studies using the predicted probability of group membership (NP, CNM, or PA vs physician group) on the basis of observed predictors.[39–41] We used the Stata module pscore to develop the propensity scores based on a logistic regression model that included patient characteristics that potentially influenced to which provider type the patient was assigned (age, race/ethnicity, insurance type, gestational age, parity, history of cesarean delivery, history of miscarriages, history of abortions, screening for sexually transmitted infections, positive test for a sexually transmitted infection, selection of a clinical contraceptive method, and presence of risk factors). Patients with similar propensity scores in the 2 provider groups were matched using nearest neighbor matching. After testing that the balancing property of the propensity score was satisfied, we selected a matched sample composed of 78.3% of the original sample, among which we replicated our mixed-effects analysis. We used predictive probabilities to calculate risk differences and 95% confidence intervals (CIs) for all models. We used STATA version 12 (StataCorp LP, College Station, TX) for all analyses.

RESULTS

A total of 21 095 women were screened for eligibility. Of these, 3837 did not meet the eligibility criteria, most commonly because of patient age and gestational age. Among the 17 258 eligible women, 13 807 agreed to participate in the study. Of these, 2320 had procedures performed by NPs, CNMs, and PAs during their training phase and were therefore not included in this analysis. As a result of a protocol violation at 1 site, 79 patients in the physician group were excluded. Follow-up data were available for 69.5% of patients, and follow-up rates were nondifferential between provider groups. Patients who did not return the follow-up survey were retained in the analytic sample because we found that they contacted the facility when they did experience a complication (n = 41), which we also discovered via medical chart abstraction, suggesting a low likelihood of missing complications among this group. Additionally, in a sensitivity analysis, complication incidence and risk differences were similar when we excluded patients who did not return the

TABLE 1—Baseline Characteristics of Patient Study Participants by Provider Type at 22 California Clinical Facilities: August 2007–August 2011

Patient Characteristic	Physicians (n = 5812), % or Mean ±SD	NPs-CNMs-PAs (n = 5675), % or Mean ±SD	P[a]
Age, y	25.7 ±6.1	25.6 ±5.9	.01
16-19	12.9	13.5	.73
20-24 (Ref)	39.0	39.0	
25-34	36.9	37.4	.83
≥35	11.2	10.1	.06
Race/ethnicity[b]			
White, non-Hispanic (Ref)	29.3	29.5	
Black, non-Hispanic	12.1	13.8	.03
Hispanic	40.6	40.4	.87
Asian, non-Hispanic	8.3	6.6	.01
Other, non-Hispanic	8.7	8.5	.83
Insurance type			
No coverage (Ref)	24.7	26.5	
Medi-Cal[c]	56.3	54.1	.68
Private	11.9	14.1	.67
Other	7.1	5.3	<.001
Gestational age, d			
<36 (Ref)	2.5	2.7	
36-49	31.5	33.3	.26
50-63	32.1	33.1	.36
≥64	33.9	30.9	.93
Gravidity			
≤1 (Ref)	27.2	26.9	
2	20.6	21.5	.25
3	18.3	17.4	.55
≥4	33.9	34.1	.59
Parity[d]			
0 (Ref)	44.2	44.9	
1	24.8	24.1	.63
≥2	30.8	30.7	.97
Previous cesarean deliveries			
0 (Ref)	86.5	86.7	
≥1	13.5	13.3	.21
Previous miscarriages[e]			
0 (Ref)	82.3	82.7	
1	13.9	13.2	.2
≥2	3.5	3.6	.99
Previous induced abortions[f]			
0 (Ref)	52.3	51.5	
1	28.0	28.6	.46
≥2	19.5	19.6	.7
Tested positive for an STI	3.6	3.4	.77

Continued

follow-up survey. Patients without follow-up data were more likely to have no insurance, have fewer risk factors, be multigravida, and be at less than 5 weeks gestation than were those with follow-up data ($P<.05$; not shown). The final analytic sample size was 11 487; of these procedures, 5812 were performed by physicians and 5675 were performed by NPs, CNMs, or PAs.

Patient Characteristics

The majority of women in both groups had had 3 or more pregnancies; no previous cesarean deliveries, miscarriages, or induced abortions; and no history of medical risk factors (Table 1). Women in the NP–CNM–PA group were more likely to be younger ($P<.01$), less likely to be Asian than White ($P<.01$), and more likely to be non-Hispanic Black than White ($P<.03$). Women were similar on all other sociodemographic characteristics across provider groups.

Outcomes

Overall, complications were rare (Table 2). Out of 11 487 aspiration abortions, 1.3% (n = 152; 95% CI = 1.11, 1.53) resulted in a complication; 1.8% of NP-, CNM-, and PA-performed aspirations and 0.9% of physician-performed aspirations resulted in a complication. The majority of complications (146/152, or 96%) were minor (1.3% of all abortions) and included cases of incomplete abortion (n = 9 among physicians, n = 24 among NPs, CNMs, and PAs), failed abortion (n = 7 among physicians, n = 11 among NPs, CNMs, and PAs), bleeding not requiring transfusion (n = 2 among NPs, CNMs, and PAs), hematometra (n = 3 among physicians, n = 16 among NPs, CNMs, and PAs), infection (n = 7 among physicians, n = 7 among NPs, CNMs, and PAs), endocervical injury (n = 2 among physicians, n = 2 among NPs, CNMs, and PAs), anesthesia-related reactions (n = 1 among physicians, n = 1 among NPs, CNMs, and PAs), and uncomplicated uterine perforation (n = 3 among NPs, CNMs, and PAs). We classified complications without clear etiology but accompanied by patient symptoms as symptomatic intrauterine material (n = 16 among physicians, n = 24 among NPs, CNMs, and PAs). We classified 11 minor complications as "other"; 4 were from physician-performed procedures

TABLE 1—*Continued*

Risk factors[g]			
Extreme obesity (BMI > 40 kg/m^2)	2.3	2.2	.33
Existing chronic illness	5.0	4.9	.72
Placenta previa (16-18 wk)	0.0	0.0	.32
Psychiatric condition	3.3	3.2	.61

Note. BMI = body mass index; CNM = certified nurse midwife; NP = nurse practitioner; PA = physician assistant; STI = sexually transmitted infection. Physicians had completed a residency in either obstetrics and gynecology or family medicine. Missing data on age (n = 18), patient insurance (n = 35), cesarean delivery history (n = 82), and gravidity (n = 7) were recoded to mean age, no insurance, no history of cesarean delivery, and median gravidity, respectively. Missing data on gestational age by ultrasound (n = 85) were recoded to gestational age by last menstrual period; where those data were also missing, they were recoded to the mean gestational age by ultrasound. For other missing variables, we created a new variable for missing.
[a]*P* values are based on a significance level of .05 and were calculated using mixed-effects logistic regression for dichotomous variables, mixed-effects multinomial logistic regression for categorical variables, and mixed-effects linear regression models for continuous variables, all of which included random effects for facility.
[b]Data missing for 70 women in the NP-CNM-PA group and 56 in the physician group.
[c]California's Medicaid program.
[d]Data missing for 11 women in each provider group.
[e]Data missing for 25 women in the NP-CNM-PA group and 20 in the physician group.
[f]Data missing for 17 women in the NP-CNM-PA group and 18 in the physician group.
[g]All risk factor variables are dichotomous (no-yes). "No" is the reference category (not shown in table).

(1 urinary tract infection, 1 possible false passage, 1 probable gastroenteritis, 1 unspecified allergic reaction), and 7 were from NP-, CNM-, or PA-performed procedures (1 fever of unknown origin, 1 intrauterine device–related bleeding, 3 sedation drug errors, 1 inability to urinate, 1 vaginitis).

Only 6 major complications occurred (3 in each provider group), which included 2 uterine perforations, 3 infections, and 1 hemorrhage. We found no difference in risk of major complications between provider groups: 0.001% (95% CI = –0.08, 0.09).

The overall unadjusted risk difference for total complications between NPs, CNMs, and PAs and physicians was 0.87% (95% CI = 0.45, 1.29). The risk difference in immediate complications (n = 9 for physicians; n = 20 for NPs, CNMs, and PAs) was 0.20% (95% CI = 0.01, 0.38); for delayed complications (n = 43 for physicians; n = 80 for clinicians), it was 0.67% (95% CI = 0.29, 1.10).

Abortions by NPs, CNMs, and PAs were 1.92 (95% CI = 1.36, 2.72) times as likely to result in a complication as those performed by physicians after adjusting for potential confounders (see table available as a supplement to the online version of this article at http://www.ajph.org). Among the propensity score–matched sample, complications were 2.12 (95% CI = 1.33, 3.37) times as likely to result from abortions by NPs, CNMs, and PAs as by physicians. The corresponding risk differences were 0.70% (95% CI = 0.29, 1.10) in overall complications between provider groups in the adjusted model and 0.83% (95% CI = 0.33, 1.33) in the propensity score–matched sample. The estimated 95% CIs for risk differences in unadjusted, adjusted, and propensity score–matched analyses all fell well within the predetermined margin of noninferiority, and therefore complication rates from aspiration abortions performed by recently trained NPs, CNMs, and PAs were statistically no worse than those from those performed by the more experienced physician group (Figure 2).

DISCUSSION

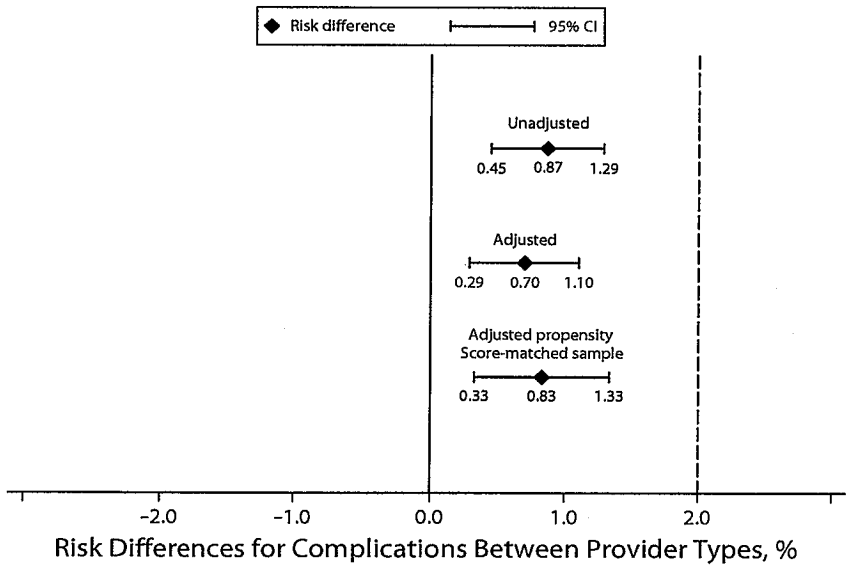
In 2008, 1.21 million abortions took place in the United States, with more 200 000 (18%) in the State of California.[2] Nationally, 92% of abortions take place in the first trimester,[7] but Black, uninsured, and low-income women have less access to this care.[6] In California, only 87% of women using state Medicaid insurance obtain abortions in the first trimester.[42] Because the average cost of a second-trimester abortion is substantially higher than that of a first-trimester procedure, shifting the population distribution of abortions to earlier gestations would result in safer, less costly care. Increasing the types of health care professionals involved in abortion care is one way to reduce this health care disparity.

Our study was designed to examine the effect of removing the physician-only requirement for aspiration abortion provision in California. We found that the care provided by newly trained NPs, CNMs, and PAs was not inferior to that provided by experienced physicians. We estimate that only 1 additional complication would occur for every 120 procedures as a consequence of having an NP, CNM, or PA as the abortion provider. Additionally, the 0.83% risk difference was mainly

TABLE 2—Overall and Major and Minor Complication Rates by Provider Type at 22 California Clinical Facilities: August 2007–August 2011

	Physicians (n = 5812)		NPs-CNMs-PAs (n = 5675)		Total (n = 11 487)		Risk Difference Between Provider Groups (n = 11 487)
Complication Type	Rate/100 (95% CI)	No.	Rate/100 (95% CI)	No.	Rate/100 (95% CI)	No.	Difference in Rate/100 (95% CI)
Major	0.05 (-0.01, 0.11)	3	0.05 (-0.01, 0.11)	3	0.05 (0.01, 0.09)	6	0.001 (-0.08, 0.09)
Minor	0.84 (0.61, 1.08)	49	1.71 (1.37, 2.05)	97	1.27 (1.07, 1.48)	146	0.87 (0.46, 1.28)
Total	0.89 (0.65, 1.14)	52	1.76 (1.42, 2.10)	100	1.32 (1.11, 1.53)	152	0.87 (0.45, 1.29)

Note. CI = confidence interval; CNM = certified nurse midwife; NP = nurse practitioner; PA = physician assistant. Physicians had completed a residency in either obstetrics and gynecology or family medicine.



Note. CI = confidence interval. Both adjusted models included patient age, race/ethnicity, insurance type, gestational age, gravidity, history of cesarean section, positive test for a sexually transmitted infection, an indicator for extreme obesity, an indicator for chronic illness, and an indicator for psychiatric conditions. 2.0 is also the delta.

FIGURE 2—Unadjusted, adjusted, and adjusted propensity score–matched risk differences in overall complication rates of first-trimester aspiration abortion by nurse practitioner, certified nurse midwife, and physician assistant providers compared with physician providers in California.

the result of higher incidence of minor complications, the majority of which were from diagnoses easily treated and without consequential sequelae. Moreover, on the basis of findings in other studies, we expect this risk difference to narrow further over time.[43–45] The comparison of newly trained NPs, CNMs, and PAs with more experienced physician abortion providers suggests that the small difference found would represent the maximum variation in outcomes that might be expected immediately after a policy change.

Both provider groups had extremely low numbers of complications, less than 2% overall—well below published rates—and only 6 complications out of 11 487 procedures required hospital-based care. Because the effect size is minimal compared with the published data and within the prespecified margin of noninferiority, we conclude that the difference between the 2 groups of providers is not clinically significant.

While the reported odds ratios comparing complication rates from procedures performed by NPs, CNMs, and PAs with those from procedures performed by physicians were statistically significant, these results should be interpreted cautiously. The study was powered specifically for a noninferiority analysis, which necessitated a larger sample size than a superiority analysis would. Therefore the significance we see may be a result of the study being overpowered.

These findings support the adoption of policies that increase access to abortion by expanding the number and type of health care professionals who can perform early aspiration abortions. The benefits of expanding access to abortion for California's women outweigh the small initial difference in risk, particularly because it would likely move many secondnd-trimester abortions into the first trimester, significantly decreasing the overall risk of complications, which increases with gestational age.[4] Expanded access is also likely to afford more women the opportunity to obtain care without the additional indirect costs associated with traveling to a geographically distant abortion provider.

The strengths of this study are its statistical power, the large number of providers, and its setting in multiple facilities. A limitation of the study is its nonrandomized design, although the use of propensity score matching allowed for statistical adjustments to address this limitation. Additionally, this study had a low follow-up rate (70%), but this was not unexpected because of the sensitive nature of abortion, which may have deterred women from continuing participation in the study after the procedure. This follow-up rate is also similar to those in other US abortion-related studies with comparable follow-up periods (14–28 days).[22,37,46] Although postprocedure complications may have been missed among patients for whom we did not have follow-up data, given the nondifferential follow-up rates between provider groups, we would expect unidentified complications to be equally distributed between groups, leaving the risk difference unaffected. A further limitation of the study is that the health care provider who initially identified a complication was not blinded to the type of provider who performed the abortion. However, we hypothesize that complaints from patients cared for by newly trained NPs, CNMs, and PAs would be more aggressively evaluated if the provider type was known to the health care provider evaluating the patient. Therefore, any bias caused by lack of blinding would have resulted in an overestimate of the risk difference.

Our results confirm existing evidence from smaller studies that the provision of abortion by NPs, CNMs, and PAs is safe[21,22] and from larger international[13] and national[47] reviews that have found these clinicians to be safe and qualified health care providers. The value of this study extends beyond the question of who can safely perform aspiration abortion services in California because it provides an example of how research can be used to answer relevant health workforce policy issues. As the demand for health care providers increases under US health care reform,[48] one part of the solution for all health care, including abortion care, is to allow all

qualified professionals to perform clinical care to the fullest extent of their education and competency.[49,50] ■

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This article was accepted November 26, 2012.

Contributors

T. A. Weitz and D. Taylor developed the study concept and design. T. A. Weitz, D. Taylor, and E. A. Drey supervised the overall study and analyzed the interpretation of results. S. Desai oversaw the acquisition of data. U. D. Upadhyay and S. Desai analyzed the data and provided statistical expertise. T. A. Weitz, U. D. Upadhyay, S. Desai, and E. A. Drey drafted the article, and J. Waldman advised on critical revision of the article for intellectual content. M. F. Battistelli provided administrative, technical, and material support.

Acknowledgments

This research was supported by grants from private foundations including the John Merck Foundation, the Educational Foundation of America, the David & Lucile Packard Foundation, and the Susan Thompson Buffet Foundation. In addition, the research was conducted under a legal waiver from the California Health Workforce Pilot Project Program, a division of the Office of Statewide Health Planning and Development.

We are grateful for the work of the partner organization principal investigators: Mary Gatter, MD, Katharine Sheehan, MD, Dick Fischer, MD, Debbie Postlethwaite, NP, MPH, and Amanda Calhoun, MD. Additional gratitude is extended to two former University of California, San Francisco (UCSF)-based research managers, Deborah Karasek, MPH, and Kristin Nobel, MPH; UCSF-based project manager Patricia Anderson, MPH; former UCSF-based legal team Jennifer Dunn, JD, and Erin Schultz, JD; clinical education consultant Amy Levi, PhD, CNM; statistical consultant John Boscardin, PhD, through the UCSF Clinical and Translational Science Institute; health regulation consultant Barbara Safriet, JD; and the site-specific research coordinators. Finally, Maureen Paul, MD, MPH, and Suzan Goodman, MD, MPH, were instrumental in the early design of this project.

Human Participant Protection

Study protocol and procedures received institutional review board approvals from the University of California, San Francisco; Ethical and Independent Review Services; and Kaiser Permanente of Northern California.

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MEDICAL BOARD OF CALIFORNIA
LEGISLATIVE ANALYSIS

Bill Number: AB 635
Author: Ammiano
Bill Date: February 20, 2013, Introduced
Subject: Drug Overdose Treatment: Liability
Sponsor: Harm Reduction Coalition
California Society of Addiction Medicine

STATUS OF BILL:

This bill is in the Assembly Judiciary Committee.

DESCRIPTION OF CURRENT LEGISLATION:

This bill would amend the civil code to allow a licensed health care provider that is authorized by law to prescribe an opioid antagonist, to prescribe and subsequently dispense or distribute an opioid antagonist to a person at risk of on opioid-related overdose or a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose. This bill would allow the licensed health care provide to issue standing orders for the administration of the opioid antagonist. This bill would specify that if health care provider or person who possesses, distributes, or administers an opioid antagonist pursuant to a prescription or order acts with reasonable care, they shall not be subject to professional review, be found liable in a civil action, or be subject to criminal prosecution for issuing a prescription or order or possessing, distributing, or administering the opioid antagonist.

BACKGROUND (taken from the fact sheet)

Naloxone is used in opioid overdoses to counteract life-threatening depression of the central nervous system and respiratory system, allowing an overdosing person to breathe normally. Naloxone is a non-scheduled, inexpensive prescription medication with the same level of regulation as ibuprofen. Naloxone only works if a person has opioids in their system, and has no effect if opioids are absent.

In 2008, SB 797 (Ridley-Thomas, Chapter 477, Statutes of 2007) established a three-year overdose prevention pilot project. This bill granted immunity from civil and criminal penalties to licensed health care providers in seven counties (Alameda, Fresno, Humboldt, Los Angeles, Mendocino, San Francisco, and Santa Cruz) who worked with opioid overdose prevention and treatment training programs, if the provider acted with reasonable care when prescribing, dispensing, or distributing naloxone. The pilot was extended in 2010 and extended liability protection to third party administrators of naloxone. This pilot is now scheduled to sunset on January 1, 2016.

California's longest running naloxone prescription program in San Francisco has

provided over 3,600 take-home naloxone prescriptions since 2003 through collaboration with the San Francisco Department of Public Health. To date, 916 lives have been saved by laypersons trained by this program who administered the take-home naloxone during an overdose. According to the most recent data released by the Centers for Disease Control and Prevention (CDC), in 2008 there were 36,450 drug overdose deaths in the United States. According to CDC, overdose prevention programs in the United States distributing naloxone have trained over 50,000 lay persons to revive someone during an overdose, resulting in over 10,000 overdose reversals using naloxone

ANALYSIS

This bill will allow health care providers to prescribe, dispense, and issue standing orders for an opioid antagonist to persons at risk of overdose, or their family member, friend, or other person in a position to assist persons at risk, without making them professionally, civilly or criminally liable, if acting within reasonable care. It would also extend this same liability protection to individuals assisting in dispensing, distributing, or administering the opioid antagonist during an overdose.

Language in existing law for the pilot project only provides civil and criminal liability, it does not exclude health care providers from "professional review". Board staff is unsure of what the reasoning behind including professional review is, and would like to work with the author's office on this point and bring this bill back to the Board at the April Board Meeting.

Drug overdoses are now the leading cause of injury death in the United States, surpassing motor vehicle crash deaths. According to the author's office, this bill will protect licensed health care providers and encourage them to begin prescribing naloxone to patients on chronic opioid pain medications in order to help address the prescription drug overdose epidemic, as well as make it easier for providers to participate in comprehensive drug overdose prevention programs that prescribe opioid antagonists. This is one element of many to address the issue of drug related overdose deaths in California.

This bill will help to further the Board's mission of consumer protection, staff is suggesting that the Board support this bill in concept, but continue to work with the author's office.

FISCAL: None

SUPPORT: Harm Reduction Coalition (sponsor)
California Society of Addiction Medicine (sponsor)

OPPOSITION: None on file

POSITION: Recommendation: Support in Concept

ASSEMBLY BILL No. 635

Introduced by Assembly Member Ammiano

February 20, 2013

An act to amend Section 1714.22 of the Civil Code, relating to drug overdose treatment.

legislative counsel's digest

AB 635, as introduced, Ammiano. Drug overdose treatment: liability.

Existing law authorizes a physician and surgeon to prescribe, dispense, or administer prescription drugs, including prescription-controlled substances, to an addict under his or her treatment, as specified. Existing law prohibits, except in the regular practice of his or her profession, any person from knowingly prescribing, administering, dispensing, or furnishing a controlled substance to or for any person who is not under his or her treatment for a pathology or condition other than an addiction to a controlled substance, except as specified.

Existing law authorizes, until January 1, 2016, and only in specified counties, a licensed health care provider, who is already permitted pursuant to existing law to prescribe an opioid antagonist, as defined, and who is acting with reasonable care, to prescribe and subsequently dispense or distribute an opioid antagonist in conjunction with an opioid overdose prevention and treatment training program, as defined, without being subject to civil liability or criminal prosecution. Existing law requires a local health jurisdiction that operates or registers an opioid overdose prevention and treatment training program to collect prescribed data and report it to the Senate and Assembly Committees on Judiciary by January 1, 2015.

Existing law authorizes, until January 1, 2016, and only in specified counties, a person who is not licensed to administer an opioid antagonist to do so in an emergency without fee if the person has received specified training information and believes in good faith that the other person is experiencing a drug overdose. Existing law prohibits that person, as a result of his or her acts or omissions, from being liable for any violation of any professional licensing statute, or subject to any criminal prosecution arising from or related to the unauthorized practice of medicine or the possession of an opioid antagonist.

This bill would revise and recast these provisions to instead authorize a licensed health care provider who is permitted by law to prescribe an opioid antagonist and is acting with reasonable care to prescribe and subsequently dispense or distribute an opioid antagonist for the treatment of an opioid overdose to a person at risk of an opioid-related overdose or a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose. The bill would authorize these licensed health care providers to issue standing orders for the

distribution of an opioid antagonist to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist the person at risk. The bill would authorize these licensed health care providers to issue standing orders for the administration of an opioid antagonist by a family member, friend, or other person in a position to assist a person experiencing or suspected of experiencing an opioid overdose. The bill would provide that a person who acts with reasonable care and issues a prescription for, or an order for the administration of, an opioid antagonist to a person experiencing or suspected of experiencing an opioid overdose is not subject to professional review, liable in a civil action, or subject to criminal prosecution for issuing the prescription or order. The bill would also delete the repeal date and reporting requirements and expand the applicability of these provisions statewide.

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 1714.22 of the Civil Code is amended to read:

1714.22. (a) For purposes of this ~~section:~~

~~(1) "Opioid~~ *section, "opioid* antagonist" means naloxone hydrochloride that is approved by the federal Food and Drug Administration for the treatment of ~~a drug~~ *an opioid* overdose.

~~(2) "Opioid overdose prevention and treatment training program" or "program" means any program operated by a local health jurisdiction or that is registered by a local health jurisdiction to train individuals to prevent, recognize, and respond to an opiate overdose, and that provides, at a minimum, training in all of the following:~~

~~(A) The causes of an opiate overdose.~~

~~(B) Mouth to mouth resuscitation.~~

~~(C) How to contact appropriate emergency medical services.~~

~~(D) How to administer an opioid antagonist.~~

(b) A licensed health care provider who is ~~permitted~~ *authorized* by law to prescribe an opioid antagonist may, if acting with reasonable care, prescribe and subsequently dispense or distribute an opioid antagonist ~~in conjunction with an opioid overdose prevention and treatment training program, without being subject to civil liability or criminal prosecution. This immunity shall apply to the licensed health care provider even when the opioid antagonist is administered by and to someone other than the person to whom it is prescribed~~ *to a person at risk of an opioid-related overdose*

or a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose.

(c) (1) A licensed health care provider who is authorized by law to prescribe an opioid antagonist may issue standing orders for the distribution of an opioid antagonist to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose.

(2) A licensed health care provider who is authorized by law to prescribe an opioid antagonist may issue standing orders for the administration of an opioid antagonist to a person at risk of an opioid-related overdose by a family member, friend, or other person in a position to assist a person experiencing or reasonably suspected of experiencing an opioid overdose.

(d) A licensed health care provider who acts with reasonable care shall not be subject to professional review, be found liable in a civil action, or be subject to criminal prosecution for issuing a prescription or order pursuant to subdivision (b) or (c).

~~(c) A person who is not otherwise licensed to administer an opioid antagonist may administer an opioid antagonist in an emergency without fee if the person has received the training information specified in paragraph (2) of subdivision (a) and believes in good faith that the other person is experiencing a drug overdose. The person shall not, as a result of his or her acts or omissions, be liable for any violation of any professional licensing statute, or subject to any criminal prosecution arising from or related to the unauthorized practice of medicine or the possession of an opioid antagonist.~~

~~(d) Each local health jurisdiction that operates or registers an opioid overdose prevention and treatment training program shall, by January 1, 2015, collect, and report to the Senate and Assembly Committees on Judiciary, all of the following data on programs within the jurisdiction:~~

~~(1) Number of training programs operating in the local health jurisdiction.~~

~~(2) Number of individuals who have received a prescription for, and training to administer, an opioid antagonist.~~

~~(3) Number of opioid antagonist doses prescribed.~~

~~(4) Number of opioid antagonist doses administered.~~

~~(5) Number of individuals who received opioid antagonist injections who were properly revived.~~

~~(6) Number of individuals who received opioid antagonist injections who were not revived.~~

~~(7) Number of adverse events associated with an opioid antagonist dose that was distributed as part of an opioid overdose~~

~~prevention and treatment training program, including a description of the adverse events.~~

~~(e) This section shall apply only to the Counties of Alameda, Fresno, Humboldt, Los Angeles, Mendocino, San Francisco, and Santa Cruz.~~

~~(f) This section shall remain in effect only until January 1, 2016, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2016, deletes or extends that date.~~

(e) Notwithstanding any other law, a person who possesses or distributes an opioid antagonist pursuant to a prescription or standing order shall not be subject to professional review, be found liable in a civil action, or be subject to criminal prosecution for this possession or distribution. Notwithstanding any other law, a person who acts with reasonable care and administers an opioid antagonist to a person who is experiencing or is suspected of experiencing an overdose shall not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution for this administration.

Centers for Disease Control and Prevention
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Morbidity and Mortality Weekly Report (*MMWR*)

Community-Based Opioid Overdose Prevention Programs Providing Naloxone — United States, 2010

Weekly
February 17, 2012 / 61(06);101-105

Drug overdose death rates have increased steadily in the United States since 1979. In 2008, a total of 36,450 drug overdose deaths (i.e., unintentional, intentional [suicide or homicide], or undetermined intent) were reported, with prescription opioid analgesics (e.g., oxycodone, hydrocodone, and methadone), cocaine, and heroin the drugs most commonly involved (*1*). Since the mid-1990s, community-based programs have offered opioid overdose prevention services to persons who use drugs, their families and friends, and service providers. Since 1996, an increasing number of these programs have provided the opioid antagonist naloxone hydrochloride, the treatment of choice to reverse the potentially fatal respiratory depression caused by overdose of heroin and other opioids (*2*). Naloxone has no effect on non-opioid overdoses (e.g., cocaine, benzodiazepines, or alcohol) (*3*). In October 2010, the Harm Reduction Coalition, a national advocacy and capacity-building organization, surveyed 50 programs known to distribute naloxone in the United States, to collect data on local program locations, naloxone distribution, and overdose reversals. This report summarizes the findings for the 48 programs that completed the survey and the 188 local programs represented by the responses. Since the first opioid overdose prevention program began distributing naloxone in 1996, the respondent programs reported training and distributing naloxone to 53,032 persons and receiving reports of 10,171 overdose reversals. Providing opioid overdose education and naloxone to persons who use drugs and to persons who might be present at an opioid overdose can help reduce opioid overdose mortality, a rapidly growing public health concern.

Overdose is common among persons who use opioids, including heroin users. In a 2002–2004 study of 329 drug users, 82% said they had used heroin, 64.6% had witnessed a drug overdose, and 34.6% had experienced an unintentional drug overdose (*4*). In 1996, community-based programs began offering naloxone and other opioid overdose prevention services to persons who use drugs, their families and friends, and service providers (e.g., health-care providers, homeless shelters, and substance abuse treatment programs). These services include education regarding overdose risk factors, recognition of signs of opioid overdose, appropriate responses to an overdose, and administration of naloxone.

To identify local program locations and assess the extent of naloxone distribution, in October 2010 the Harm Reduction Coalition e-mailed an online survey to staff members at the 50 programs then known to distribute naloxone. Follow-up e-mails and telephone calls were used to encourage participation, clarify responses, and obtain information on local, community-based programs. The survey included questions about the year the program began distributing naloxone, the number of persons trained in overdose prevention and naloxone administration, the number of overdose reversals reported, and whether the totals were estimates or based on program data. The survey also asked questions regarding the naloxone formulations currently distributed, any recent difficulties in obtaining naloxone, and the program's experience with naloxone distribution.

Staff members at 48 (96%) of the 50 programs completed the online survey. Since the first program began distributing naloxone in 1996, through June 2010, the 48 responding programs reported providing training and distributing naloxone to an estimated 53,032 persons (program range: zero to 16,220; median: 102.5; mean: 1,104.8).* From the first naloxone distribution in 1996 through June 2010, the programs received reports of 10,171 overdose reversals using naloxone (range: zero to 2,385; median: 32; mean: 211.9).† During a recent 12-month period, respondents distributed an estimated 38,860 naloxone vials (Table).§ Using data from the survey, the number of programs beginning naloxone distribution each year during 1996–2010 was compared with the annual crude rates of unintentional drug overdose deaths per 100,000 population from 1979 to 2008 (Figure 1) (*1*).

The 48 responding programs were located in 15 states and the District of Columbia. Four responding programs provided consolidated data for multiple local, community-based programs. Three state health departments, in New York, New Mexico, and Massachusetts, provided data for 129 local programs (65, 56, and eight, respectively); a nongovernmental organization in Wisconsin provided data on a statewide operation with 16 local programs. In all, the 48 responding programs provided data for 188 local opioid overdose prevention programs that distributed naloxone (Figure 2). Nineteen (76.0%) of the 25 states with 2008 drug overdose death rates higher than the median and nine (69.2%) of the 13 states in the highest quartile (*1*) did not have a community-based opioid overdose prevention program that distributed naloxone (Figure 2).

For a recent 12-month period, the 48 responding programs reported distributing 38,860 naloxone vials, including refills (range: zero to 12,070; median: 97; mean: 809.6).¶ Overdose prevention programs were characterized as small, medium, large, or very large, based on the number of naloxone vials distributed during that period. The six responding programs in the large and very large categories distributed 32,812 (84.4%) of the naloxone vials (Table).

Twenty-one (43.7%) responding programs reported problems obtaining naloxone in the "past few months" before the survey. The most frequently reported reasons for difficulties obtaining naloxone were the cost of naloxone relative to available funding and the inability of suppliers to fill orders.**

Reported by

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Editorial Note

The findings in this report suggest that distribution of naloxone and training in its administration might have prevented numerous deaths from opioid overdoses. Syringe exchange and harm reduction programs for injection-drug users were early adopters of opioid overdose prevention interventions, including providing naloxone (*5,6*). More noninjection opioid users might be reached by opioid overdose prevention training and (where feasible) provision of naloxone in jails and prisons, substance abuse treatment programs, parent support groups, and physician offices (Maya Doe-Simkins, MPH, Boston Medical Center, personal communication, 2011). Reaching users of prescription opioid analgesics is important because a large proportion of drug overdose deaths have been associated with these drugs (*1,7*).

Widespread concern about the substantial increases in opioid drug overdose deaths has prompted adoption of various other prevention measures, including 1) education of patients, clinicians, pharmacists, and emergency department staff members; 2) issuing opioid prescribing guidelines; 3) prescription drug monitoring programs; 4) legal and administrative efforts to reduce illegal

prescribing; 5) prescription drug take-back programs; and 6) improved access to substance abuse treatment (*8,9*). Programs such as Project Lazarus and Operation OpioidSAFE in North Carolina include clinicians prescribing naloxone to patients receiving opioid analgesic prescriptions who meet criteria for higher overdose risk (*8*) (Anthony Dragovich, MD, Womack Army Medical Center, Fort Bragg, North Carolina, personal communication, 2011).

In the United States, naloxone is provided to participants in different ways, including through onsite medical professionals and the use of standing orders. Recognizing the potential value of providing naloxone to laypersons, some states (e.g., California, Illinois, New Mexico, New York, and Washington) have passed laws and changed regulations to provide limited liability for prescribers who work with programs providing naloxone to laypersons. In addition, Washington, Connecticut, New Mexico, and New York have enacted Good Samaritan laws providing protection from arrest in an effort to encourage bystanders at a drug overdose to call 911 and use naloxone when available (*9*). Because of high overdose mortality among persons who use drugs, the Global Fund to Fight AIDS, Tuberculosis, and Malaria recommends naloxone distribution as a component of comprehensive services for drug users (*10*).

In this analysis, the majority (76.0%) of the 25 states with 2008 age-adjusted drug overdose death rates higher than the median did not have a community-based opioid overdose prevention program that distributed naloxone. High death rates provide one measure of the extent of drug overdoses; however, the number of deaths also should be considered. For example, in 2008, West Virginia had the highest drug overdose death rate (25.8) in the United States, and Texas (8.6) had one of the lowest. However, the West Virginia rate was based on 459 deaths, whereas the Texas rate was based on 2,053 deaths. States might consider both death rates and number of deaths in their intervention planning.

The findings in this report are subject to at least three limitations. First, other naloxone distribution programs might exist that were unknown to the Harm Reduction Coalition. Second, all data are based on unconfirmed self-reports from the 48 responding programs. Finally, the numbers of persons trained in naloxone administration and the number of overdose reversals involving naloxone likely were underreported because of incomplete data collection and unreported overdose reversals. However, because not all untreated opioid overdoses are fatal, some of the persons with reported overdose reversals likely would have survived without naloxone administration (*2*).

In this report, nearly half (43.7%) of the responding opioid overdose programs reported problems obtaining naloxone related to cost and the supply chain. Price increases of some formulations of naloxone appear to restrict current program activities and the possibility of new programs. Economic pressures on state and local budgets could decrease funding of opioid overdose prevention activities (Daniel Bigg, Chicago Recovery Alliance, personal communication, 2011). To address the substantial increases in opioid-related drug overdose deaths, public health agencies could consider comprehensive measures that include teaching laypersons how to respond to overdoses and administer naloxone to those in need.

Acknowledgments

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* The number of participants to whom naloxone was distributed was estimated by 29 responding programs (26.5% of total) and based on program data for 19 respondents (73.5%).

† The number of opioid overdose reversals was estimated by 26 responding programs (25.4% of total) and based on program data for 22 respondents (74.6%).

§ The number of vials distributed to participants during 2009 or July 2009–June 2010 was estimated by 21 program respondents (6.5% of total) and based on program data for 27 respondents (93.5%).

¶ Responding programs provide naloxone for injection in multidose (10 mL) and single-dose (1 mL) vials with concentrations of 0.4 mg/mL. Vials that are adapted for intranasal use (using a mucosal atomization device) are single-dose 2 mL vials with concentration of 1 mg/mL. Typically, respondents provide 1 multidose or 2 single-dose vials in an overdose rescue kit. Forty-two (87.5%) of 48 reported providing only injectable naloxone (63.0% of total vials), four (8.3%) provided only intranasal naloxone (33.1%), and four (8.3%) provided both injectable and intranasal naloxone (3.9%).

** The two most commonly reported reasons for difficulties obtaining naloxone were the cost of naloxone relative to available funding (seven responding programs) and inability of suppliers to fill orders (13 respondents). Four respondents reported interruptions because they did not have a qualified medical provider to either order naloxone from suppliers or prescribe naloxone to users. Five reported two of the three reasons for interruptions.

What is already known on this topic?

From 1990 to 2008, drug overdose death rates increased threefold in the United States, and the number of annual deaths increased to 36,450. Opioids (including prescription opioid medications and heroin) are major causes of drug overdose deaths. Naloxone is the standard of care for treatment of potentially fatal respiratory depression caused by opioid overdose.

What is added by this report?

In October 2010, at least 188 local opioid overdose prevention programs that distributed naloxone existed. During 1996–2010, these programs in 15 states and the District of Columbia reported training and providing naloxone to 53,032 persons, resulting in 10,171 drug overdose reversals using naloxone. However, many states with high drug overdose death rates have no opioid overdose prevention programs that distribute naloxone.

What are the implications for public health practice?

To address the high rates of opioid drug overdose deaths, public health agencies could, as part of a comprehensive prevention program, implement community-based opioid drug overdose prevention programs, including training and providing naloxone to potential overdose witnesses, and systematically assess the impact of these programs.

TABLE. Number of opioid overdose programs/local programs, naloxone vials provided in a recent 12-month period, program participants overall, and overdose reversals, by program size — United States, 1996–2010

Program size (by no. of vials of naloxone provided during a recent 12-month period)	No. of program respondents	No. of local programs	No. of naloxone vials provided to participants during a recent 12-month period*		No. of program participants from beginning of program through June 2010†		Reported opioid overdose reversals from beginning of program through June 2010§	
			No.	(%)	No.	(%)	No.	(%)
Small <100	24	24	754	(1.9)	1,646	(3.1)	371	(3.6)
Medium 101–1,000	18	18	5,294	(13.6)	13,214	(24.9)	3,241	(31.9)
Large 1,001–10,000	4	74	9,792	(25.3)	26,213	(49.4)	5,648	(55.5)
Very large >10,000	2	72	23,020	(59.2)	11,959	(22.6)	1,091	(10.7)
Total	**48**	**188**	**38,860**	**(100.0)**	**53,032**	**(100.0)**	**10,171**	**(100.0)**

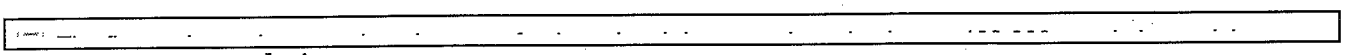
* Units of naloxone (including number of vials or intranasal doses and refills) distributed to participants during 2009 or July 2009–June 2010. Estimated by 21 program respondents (2,524 units, 6.5% of total) and based on program data for 27 respondents (36,336 units, 93.5%).

EXEC 4-27

† Number of participants to whom naloxone was distributed from the start of program through June 2010. Estimated by 29 respondents (14,066 participants, 26.5% of total) and based on program data for 19 respondents (38,966 participants, 73.5%).

§ Number of opioid overdose reversals reported using the naloxone provided by the program from the start of the program through June 2010. Estimated by 26 respondents (2,582 reversals, 25.4% of total) and based on program data for 22 respondents (7,589 reversals, 74.6%).

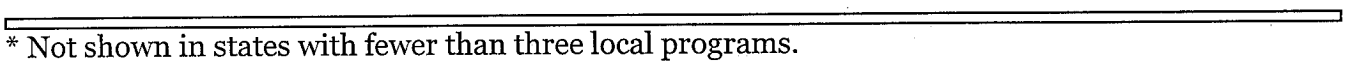
FIGURE 1. Annual crude rates* of unintentional drug overdose deaths and number of overdose prevention programs distributing naloxone — United States, 1979–2010



* Per 100,000 population.

Alternate Text: The figure above shows the annual crude rates of unintentional drug overdose deaths per 100,000 population and the number of overdose prevention programs distributing naloxone in the United States during 1979-2010.

FIGURE 2. Number (N = 188) and location* of local drug overdose prevention programs providing naloxone in 2010 and age-adjusted rates† of drug overdose deaths§ in 2008 — United States



* Not shown in states with fewer than three local programs.

† Per 100,000 population.

§ **Source:** National Vital Statistics System. Available at http://www.cdc.gov/nchs/nvss.htm. Includes intentional, unintentional, and undetermined.

Alternate Text: The figure above shows the number (N = 188) and location of local overdose prevention programs providing naloxone in 2010 and age-adjusted rates of drug overdose deaths, by state, in the United States during 2008. In all, the 48 responding programs provided data for 188 local opioid overdose prevention programs that distributed naloxone. Nineteen (76.0%) of the 25 states with 2008 drug overdose death rates higher than the median and nine (69.2%) of the 13 states in the highest quartile did not have a community-based opioid overdose prevention program that distributed naloxone.

Page last reviewed: February 17, 2012
Page last updated: February 17, 2012

MEDICAL BOARD OF CALIFORNIA
LEGISLATIVE ANALYSIS

Bill Number: AB 831
Author: Bloom
Bill Date: March 18, 2013, Amended
Subject: Drug Overdoses
Sponsor: Drug Policy Alliance

STATUS OF BILL:

This bill is in the Assembly Health Committee.

DESCRIPTION OF CURRENT LEGISLATION:

This bill would require the California Health and Human Services Agency (CHHS) to convene a temporary working group to develop a state plan to reduce the rate of fatal drug overdose in California. This bill would also appropriate $500,000 from the General Fund to fund a grants program to local governments and community based organizations to implement overdose prevention efforts suited to local needs.

ANALYSIS

This would require CHHS to convene a temporary working group to develop a plan to reduce the rate of fatal drug overdoses in California. The bill would allow experts and staff from the Office of Emergency Services, State Department of Alcohol and Drug Programs, State Department of Public Health, Office of AIDS, and any other staff that the Secretary of CHHS designates may participate in the working group. This bill would also allow staff from the Medical Board of California (Board) and the Board of Pharmacy to participate for the purpose of identifying promising practices to reduce accidental drug overdose among patients and other at-risk groups. This bill would require the working group to make recommendations to the Chair of the Senate Committee on Health and the Chair of the Assembly Committee on Health on or before January 1, 2015. This bill would sunset the working group on January 1, 2016.

This bill would appropriate $500,000 from the General Fund for fiscal year 2014/15 and in later years if included in CHHS' budget. This bill would require CHHS to make grants to local agencies from the $500,000 appropriation for the following purposes:

- Drug overdose prevention, recognition, and response education projects in jails, prisons, drug treatment centers, syringe exchange programs, clinics, and other organizations that work with or have access to drug users, their families, and communities.
- Drug overdose prevention, recognition, and response training for patients and their families when the patient is prescribed opiate-based medications for which there is a

significant risk of overdose.

- Naloxone hydrochloride prescription or distribution projects.
- Development and implementation of policies and projects to encourage people, including drug users, to call the 911 emergency response system when they witness potentially fatal drug overdoses.
- Programs to educate Californians over 65 years of age about the risks associated with using opiate-based medications, ways to prevent overdose, or how to respond if they witness an overdose.
- The production and distribution of targeted or mass media materials on drug overdose prevention and response.
- Education and training projects on drug overdose response and treatment for emergency services and law enforcement personnel, including, but not limited to, volunteer fire and emergency services.
- Parent, family, and survivor education and mutual support groups, distributing, or administering the opioid antagonist during an overdose.

This bill would allow CHHS to set guidelines regarding the prioritization of applications and the types of organizations or entities that may apply in a given year. This bill would allow CHHS to adopt emergency regulations needed to implement this bill.

Drug overdoses are now the leading cause of injury death in the United States, surpassing motor vehicle crash deaths. According to the author's office, California should implement evidence-based interventions to reduce the rate of fatal drug overdoses. This bill would make a small investment in reducing the suffering of California families, and the Author's office believes this bill will significantly reduce hospitalization and emergency room costs.

This bill will help to protect consumers and save lives in California, which will further the Board's mission of consumer protection; staff is suggesting that the Board support this bill.

FISCAL: None

SUPPORT: Drug Policy Alliance (Sponsor)

OPPOSITION: None on file

POSITION: Recommendation: Support

AMENDED IN ASSEMBLY MARCH 18, 2013

california legislature—2013–14 regular session

ASSEMBLY BILL No. 831

Introduced by Assembly Member Bloom

February 21, 2013

~~An act to amend Section 1797.5 of the Health and Safety Code, relating to emergency medical services.~~ *An act to add Section 11758.08 to, and to add and repeal Section 11758.07 of, the Health and Safety Code, relating to drugs, and making an appropriation therefor.*

legislative counsel's digest

AB 831, as amended, Bloom. ~~Emergency medical services.~~ *Drug overdoses.*

Existing law establishes various programs for the control of illegal drugs in California and requires the State Department of Alcohol and Drug Programs to place on its Internet Web site specified information on drug overdose trends in California, including county and state death rates, from existing data, in order to ascertain changes in the causes or rates of fatal and nonfatal drug overdoses for the preceding 5 years.

This bill, until January 1, 2016, would establish within the California Health and Human Services Agency, a temporary working group, as specified, to develop a plan to reduce the rate of fatal drug overdoses in the state. The bill would require the temporary working group to make recommendations to the Chair of the Senate Committee on Health and the Chair of Assembly Committee on Health on or before January 1, 2015.

This bill would establish a grant program within the California Health and Human Services Agency to provide funds for programs related to drug overdose prevention, recognition, and response education, as

specified. The bill would appropriate $500,000 from the General Fund for this purpose in the 2014–15 fiscal year.

~~Existing law declares the intent of the Legislature to promote the development, accessibility, and provision of emergency medical services, and the policy of this state that people shall be encouraged and trained to assist others at the scene of a medical emergency.~~

~~This bill would make technical, nonsubstantive changes to these provisions.~~

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

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

SECTION 1. Section 11758.07 is added to the Health and Safety Code, to read:

11758.07. (a) The California Health and Human Services

Agency shall convene a temporary working group within the agency to develop a plan to reduce the rate of fatal drug overdoses in the state. Experts and staff from the Office of Emergency Services, State Department of Alcohol and Drug Programs, State Department of Public Health, Office of AIDS, and any other staff that the Secretary of California Health and Human Services designates may participate in the temporary working group. Additionally, staff from the Medical Board of California and California State Board of Pharmacy may also participate for the purpose of identifying promising practices to reduce accidental drug overdose among patients and other at-risk groups.

(b) The secretary may invite other experts to participate in the temporary working group. Their participation shall be uncompensated.

(c) The temporary working group shall make recommendations to the Chair of the Senate Committee on Health and the Chair of the Assembly Committee on Health on or before January 1, 2015.

(d) This section shall remain in effect only until January 1, 2016, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2016, deletes or extends that date.

SEC. 2. Section 11758.08 is added to the Health and Safety Code, to read:

11758.08. (a) The California Health and Human Services Agency shall make grants to local agencies from funds

appropriated pursuant to this section for any of the following purposes:

(1) Drug overdose prevention, recognition, and response education projects in jails, prisons, drug treatment centers, syringe exchange programs, clinics, and other organizations that work with or have access to drug users, their families, and communities.

(2) Drug overdose prevention, recognition, and response training for patients and their families when the patient is prescribed opiate-based medications for which there is a significant risk of overdose.

(3) Naloxone hydrochloride prescription or distribution projects.

(4) Development and implementation of policies and projects to encourage people, including drug users, to call the 911 emergency response system when they witness potentially fatal drug overdoses.

(5) Programs to educate Californians over 65 years of age about the risks associated with using opiate-based medications, ways to prevent overdose, or how to respond if they witness an overdose.

(6) The production and distribution of targeted or mass media materials on drug overdose prevention and response.

(7) Education and training projects on drug overdose response

and treatment for emergency services and law enforcement personnel, including, but not limited to, volunteer fire and emergency services.

(8) Parent, family, and survivor education and mutual support groups.

(b) In order to control budgets and appropriately limit the number of possible applications, the agency may set guidelines regarding the prioritization of applications and the types of organizations or entities that may apply in a given year.

(c) The adoption and one readoption of regulations to implement this section shall be deemed to be an emergency necessary for the immediate preservation of public peace, health, and safety, or the general welfare for purposes of Sections 11346.1 and 11349.6 of the Government Code, and the agency is hereby exempted from the requirement that it describe specific facts showing the need for immediate action and from review by the Office of Administrative Law.

(d) There is hereby appropriated from the General Fund, in the 2014–15 fiscal year, five hundred thousand dollars ($500,000) for

the purpose of funding the grants provided in subdivision (a). Additional funds necessary for the implementation of this section in the 2014–15 fiscal year and in later fiscal years may be included in the budget appropriation for the California Health and Human Services Agency.

~~SECTION 1. Section 1797.5 of the Health and Safety Code is amended to read:~~

~~1797.5. (a) It is the intent of the Legislature to promote the development, accessibility, and provision of emergency medical services to the people of this state.~~

~~(b) Further, it is the policy of this state that people shall be encouraged and trained to assist others at the scene of a medical emergency. Local governments, agencies, and other organizations shall be encouraged to offer training in cardiopulmonary resuscitation and lifesaving first aid techniques so that people may be adequately trained, prepared, and encouraged to assist others immediately.~~

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MEDICAL BOARD OF CALIFORNIA
LEGISLATIVE ANALYSIS

Bill Number: AB 916
Author: Eggman
Bill Date: February 22, 2013, Introduced
Subject: Healing Arts: False or Misleading Advertising
Sponsor: California Society of Plastic Surgeons

STATUS OF BILL:

This bill is in the Assembly Business, Professions and Consumer Protection Committee.

DESCRIPTION OF CURRENT LEGISLATION:

This bill would prohibit physicians from using the terms "board", "certified" or "certification" when advertising unless the terms are used in connection to a specific certifying board and that board has been approved by the American Board of Medical Specialties (ABMS), is a board or association with equivalent requirements approved by the Medical Board of California (Board), or is a board or association with an Accreditation Council for Graduate Medical Education (ACGME)-approved postgraduate training program that provides complete training in that specialty or subspecialty.

ANALYSIS

Existing law prohibits physicians from advertising in public communications that they are "board certified" unless the board advertised is a member of ABMS, or the board or association with equivalent requirements is approved by the Board, or a board or association with an Accreditation Council for Graduate Medical Education (ACGME)-approved postgraduate training program that provides complete training in that specialty or subspecialty.

According to the author's office, there are some physicians misrepresenting themselves and their qualifications by providing misleading statements in public communications. Physicians can imply that they are "board certified", by using the terms "board", "certified", or "certification" in their advertising. When these terms are used, it circumvents the prohibition in existing law, because they aren't using the term "board certified".

This bill would prohibit physicians from using the terms "board", "certified" or "certification" when advertising unless the terms are used in connection to a specific certifying board and that board has been approved by the American Board of Medical Specialties (ABMS), is a board or association with equivalent requirements approved by the Medical Board of California (Board), or is a board or association with an Accreditation Council for Graduate Medical Education (ACGME)-approved postgraduate training program that provides

complete training in that specialty or subspecialty.

According to the author's office, some patients may choose a physician based on misleading terms, believing that the physician is "board certified" when that is not the case. This bill clarifies existing law to further protect the public and to ensure that patients better understand the training and qualifications of physicians from whom they are seeking care. This bill does not address the proposal included in the Board's sunset report that would remove the provision in existing law that requires the Board to recognize equivalent boards or associations.

This bill will allow patients to make informed decisions when choosing a health care provider and tighten existing law related to advertising, which will help to ensure consumer protection. Staff suggests that the Board support this bill.

FISCAL: None

SUPPORT: California Society of Plastic Surgeons (Sponsor)

OPPOSITION: None on file

POSITION: Recommendation: Support

ASSEMBLY BILL No. 916

Introduced by Assembly Member Eggman

February 22, 2013

An act to amend Section 651 of the Business and Professions Code, relating to healing arts.

legislative counsel's digest

AB 916, as introduced, Eggman. Healing arts: false or misleading advertising.

Existing law provides for the licensure and regulation of the practice of various healing arts practitioners by boards within the Department of Consumer Affairs. Existing law makes it unlawful for those practitioners to disseminate a false, fraudulent, misleading, or deceptive statement and defines those terms for its purposes. Existing law prohibits a physician and surgeon from making a statement in public communications that he or she is board certified unless that board meets certain requirements.

This bill would further prohibit the use of additional terms by a physician or surgeon with respect to board of certification, except as provided. The bill would also make findings and declarations regarding the need for legislation pertaining to misleading advertisements and statements by physicians and surgeons.

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. The Legislature finds and declares all of the following:

(a) Existing law prohibits a physician and surgeon from advertising in public communications that he or she is board certified unless that board is a member of the American Board of Medical Specialties, a board or association with equivalent requirements approved by the Medical Board of California, or a board or association with an Accreditation Council for Graduate Medical Education-approved postgraduate training program that provides complete training in that specialty or subspecialty.

(b) The intent of these laws is to protect the public from being misled or endangered as a result of false or misleading advertisements by practitioners who claim board certification by boards not meeting the above requirements, and to enhance the quality of care and safety afforded to patients.

(c) Unfortunately, these laws have been widely circumvented

by the dissemination of public communications by physicians and surgeons, or on their behalf by boards that do not meet the above requirements, that do not include the exact phrase "board certified" but contain similar terms that strongly imply board certification.

(d) Further clarification of existing law is needed to further protect the public and to ensure that patients better understand the training and qualifications possessed by physicians and surgeons from whom they are seeking care.

SEC. 2. Section 651 of the Business and Professions Code is amended to read:

651. (a) It is unlawful for any person licensed under this division or under any initiative act referred to in this division to disseminate or cause to be disseminated any form of public communication containing a false, fraudulent, misleading, or deceptive statement, claim, or image for the purpose of or likely to induce, directly or indirectly, the rendering of professional services or furnishing of products in connection with the professional practice or business for which he or she is licensed. A "public communication" as used in this section includes, but is not limited to, communication by means of mail, television, radio, motion picture, newspaper, book, list or directory of healing arts practitioners, Internet, or other electronic communication.

(b) A false, fraudulent, misleading, or deceptive statement, claim, or image includes a statement or claim that does any of the following:

(1) Contains a misrepresentation of fact.

(2) Is likely to mislead or deceive because of a failure to disclose material facts.

(3) (A) Is intended or is likely to create false or unjustified expectations of favorable results, including the use of any photograph or other image that does not accurately depict the results of the procedure being advertised or that has been altered in any manner from the image of the actual subject depicted in the photograph or image.

(B) Use of any photograph or other image of a model without clearly stating in a prominent location in easily readable type the fact that the photograph or image is of a model is a violation of subdivision (a). For purposes of this paragraph, a model is anyone other than an actual patient, who has undergone the procedure being advertised, of the licensee who is advertising for his or her services.

(C) Use of any photograph or other image of an actual patient that depicts or purports to depict the results of any procedure, or

presents “before” and “after” views of a patient, without specifying in a prominent location in easily readable type size what procedures were performed on that patient is a violation of subdivision (a). Any “before” and “after” views (i) shall be comparable in presentation so that the results are not distorted by favorable poses, lighting, or other features of presentation, and (ii) shall contain a statement that the same “before” and “after” results may not occur for all patients.

(4) Relates to fees, other than a standard consultation fee or a range of fees for specific types of services, without fully and specifically disclosing all variables and other material factors.

(5) Contains other representations or implications that in reasonable probability will cause an ordinarily prudent person to misunderstand or be deceived.

(6) Makes a claim either of professional superiority or of performing services in a superior manner, unless that claim is relevant to the service being performed and can be substantiated with objective scientific evidence.

(7) Makes a scientific claim that cannot be substantiated by reliable, peer reviewed, published scientific studies.

(8) Includes any statement, endorsement, or testimonial that is likely to mislead or deceive because of a failure to disclose material facts.

(c) Any price advertisement shall be exact, without the use of phrases, including, but not limited to, “as low as,” “and up,” “lowest prices,” or words or phrases of similar import. Any advertisement that refers to services, or costs for services, and that uses words of comparison shall be based on verifiable data substantiating the comparison. Any person so advertising shall be prepared to provide information sufficient to establish the accuracy of that comparison. Price advertising shall not be fraudulent, deceitful, or misleading, including statements or advertisements of bait, discount, premiums, gifts, or any statements of a similar nature. In connection with price advertising, the price for each product or service shall be clearly identifiable. The price advertised for products shall include charges for any related professional services, including dispensing and fitting services, unless the advertisement specifically and clearly indicates otherwise.

(d) Any person so licensed shall not compensate or give anything of value to a representative of the press, radio, television, or other communication medium in anticipation of, or in return for, professional publicity unless the fact of compensation is made known in that publicity.

(e) Any person so licensed may not use any professional card, professional announcement card, office sign, letterhead, telephone

directory listing, medical list, medical directory listing, or a similar professional notice or device if it includes a statement or claim that is false, fraudulent, misleading, or deceptive within the meaning of subdivision (b).

(f) Any person so licensed who violates this section is guilty of a misdemeanor. A bona fide mistake of fact shall be a defense to this subdivision, but only to this subdivision.

(g) Any violation of this section by a person so licensed shall constitute good cause for revocation or suspension of his or her license or other disciplinary action.

(h) Advertising by any person so licensed may include the following:

(1) A statement of the name of the practitioner.

(2) A statement of addresses and telephone numbers of the offices maintained by the practitioner.

(3) A statement of office hours regularly maintained by the practitioner.

(4) A statement of languages, other than English, fluently spoken by the practitioner or a person in the practitioner's office.

(5) (A) A statement that the practitioner is certified by a private or public board or agency or a statement that the practitioner limits his or her practice to specific fields.

(B) A statement of certification by a practitioner licensed under Chapter 7 (commencing with Section 3000) shall only include a statement that he or she is certified or eligible for certification by a private or public board or parent association recognized by that practitioner's licensing board.

(C) A physician and surgeon licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California may include a statement that he or she limits his or her practice to specific fields, but shall not include a statement that he or she is certified or eligible for certification by a private or public board or parent association, including, but not limited to, a multidisciplinary board or association, unless that board or association is (i) an American Board of Medical Specialties member board, (ii) a board or association with equivalent requirements approved by that physician and surgeon's licensing board, or (iii) a board or association with an Accreditation Council for Graduate Medical Education approved postgraduate training program that provides complete training in that specialty or subspecialty. A physician and surgeon licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California who is certified by an organization other than a board or association referred to in clause (i), (ii), or (iii) shall not use the term "board certified" in reference to that certification, unless the

physician and surgeon is also licensed under Chapter 4 (commencing with Section 1600) and the use of the term "board certified" in reference to that certification is in accordance with subparagraph (A). A physician and surgeon licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California who is certified by a board or association referred to in clause (i), (ii), or (iii) shall not use *any of* the ~~term~~ *terms "board," "certified," "certification," or* "board certified" unless the full

name of the certifying board is also used and given comparable prominence with the ~~term~~ *terms "board," "certified," "certification," or* "board certified" in the statement *and unless the term or terms are used in reference to a certifying board meeting at least one of the criteria described in clause (i), (ii), or (iii).*

For purposes of this subparagraph, a "multidisciplinary board or association" means an educational certifying body that has a psychometrically valid testing process, as determined by the Medical Board of California, for certifying medical doctors and other health care professionals that is based on the applicant's education, training, and experience.

~~For purposes of the term "board certified," as used in this subparagraph, the terms "board" and "association" mean an organization that is an American Board of Medical Specialties member board, an organization with equivalent requirements approved by a physician and surgeon's licensing board, or an organization with an Accreditation Council for Graduate Medical Education approved postgraduate training program that provides complete training in a specialty or subspecialty.~~

The Medical Board of California shall adopt regulations to establish and collect a reasonable fee from each board or association applying for recognition pursuant to this subparagraph. The fee shall not exceed the cost of administering this subparagraph. Notwithstanding Section 2 of Chapter 1660 of the Statutes of 1990, this subparagraph shall become operative July 1, 1993. However, an administrative agency or accrediting organization may take any action contemplated by this subparagraph relating to the establishment or approval of specialist requirements on and after January 1, 1991.

(D) A doctor of podiatric medicine licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California may include a statement that he or she is certified or eligible or qualified for certification by a private or public board or parent association, including, but not limited to, a

multidisciplinary board or association, if that board or association meets one of the following requirements: (i) is approved by the Council on Podiatric Medical Education, (ii) is a board or association with equivalent requirements approved by the California Board of Podiatric Medicine, or (iii) is a board or

association with the Council on Podiatric Medical Education approved postgraduate training programs that provide training in podiatric medicine and podiatric surgery. A doctor of podiatric medicine licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California who is certified by a board or association referred to in clause (i), (ii), or (iii) shall not use the term "board certified" unless the full name of the certifying board is also used and given comparable prominence with the term "board certified" in the statement. A doctor of podiatric medicine licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California who is certified by an organization other than a board or association referred to in clause (i), (ii), or (iii) shall not use the term "board certified" in reference to that certification.

For purposes of this subparagraph, a "multidisciplinary board or association" means an educational certifying body that has a psychometrically valid testing process, as determined by the California Board of Podiatric Medicine, for certifying doctors of podiatric medicine that is based on the applicant's education, training, and experience. For purposes of the term "board certified," as used in this subparagraph, the terms "board" and "association" mean an organization that is a Council on Podiatric Medical Education approved board, an organization with equivalent requirements approved by the California Board of Podiatric Medicine, or an organization with a Council on Podiatric Medical Education approved postgraduate training program that provides training in podiatric medicine and podiatric surgery.

The California Board of Podiatric Medicine shall adopt regulations to establish and collect a reasonable fee from each board or association applying for recognition pursuant to this subparagraph, to be deposited in the State Treasury in the Podiatry Fund, pursuant to Section 2499. The fee shall not exceed the cost of administering this subparagraph.

(6) A statement that the practitioner provides services under a specified private or public insurance plan or health care plan.

(7) A statement of names of schools and postgraduate clinical

training programs from which the practitioner has graduated, together with the degrees received.

(8) A statement of publications authored by the practitioner.

(9) A statement of teaching positions currently or formerly held by the practitioner, together with pertinent dates.

(10) A statement of his or her affiliations with hospitals or clinics.

(11) A statement of the charges or fees for services or commodities offered by the practitioner.

(12) A statement that the practitioner regularly accepts installment payments of fees.

(13) Otherwise lawful images of a practitioner, his or her physical facilities, or of a commodity to be advertised.

(14) A statement of the manufacturer, designer, style, make, trade name, brand name, color, size, or type of commodities advertised.

(15) An advertisement of a registered dispensing optician may include statements in addition to those specified in paragraphs (1) to (14), inclusive, provided that any statement shall not violate subdivision (a), (b), (c), or (e) or any other section of this code.

(16) A statement, or statements, providing public health information encouraging preventative or corrective care.

(17) Any other item of factual information that is not false, fraudulent, misleading, or likely to deceive.

(i) Each of the healing arts boards and examining committees within Division 2 shall adopt appropriate regulations to enforce this section in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

Each of the healing arts boards and committees and examining committees within Division 2 shall, by regulation, define those efficacious services to be advertised by businesses or professions under their jurisdiction for the purpose of determining whether advertisements are false or misleading. Until a definition for that service has been issued, no advertisement for that service shall be disseminated. However, if a definition of a service has not been issued by a board or committee within 120 days of receipt of a request from a licensee, all those holding the license may advertise the service. Those boards and committees shall adopt or modify regulations defining what services may be advertised, the manner in which defined services may be advertised, and restricting advertising that would promote the inappropriate or excessive use of health services or commodities. A board or committee shall not,

by regulation, unreasonably prevent truthful, nondeceptive price or otherwise lawful forms of advertising of services or commodities, by either outright prohibition or imposition of onerous disclosure requirements. However, any member of a board or committee acting in good faith in the adoption or enforcement of any regulation shall be deemed to be acting as an agent of the state.

(j) The Attorney General shall commence legal proceedings in the appropriate forum to enjoin advertisements disseminated or about to be disseminated in violation of this section and seek other appropriate relief to enforce this section. Notwithstanding any other provision of law, the costs of enforcing this section to the respective licensing boards or committees may be awarded against any licensee found to be in violation of any provision of this section. This shall not diminish the power of district attorneys, county counsels, or city attorneys pursuant to existing law to seek appropriate relief.

(k) A physician and surgeon or doctor of podiatric medicine licensed pursuant to Chapter 5 (commencing with Section 2000) by the Medical Board of California who knowingly and intentionally violates this section may be cited and assessed an administrative fine not to exceed ten thousand dollars ($10,000) per event. Section 125.9 shall govern the issuance of this citation and fine except that the fine limitations prescribed in paragraph (3) of subdivision (b) of Section 125.9 shall not apply to a fine under this subdivision.

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AB 916

MEDICAL BOARD OF CALIFORNIA
LEGISLATIVE ANALYSIS

Bill Number: AB 1000
Author: Wieckowski
Bill Date: June 18, 2012, amended
Subject: Physical Therapists: Direct Access to Services:
Sponsor: California Physical Therapy Association

STATUS OF BILL:

This bill is in the Assembly Business, Professions and Consumer Protection Committee.

DESCRIPTION OF CURRENT LEGISLATION:

This bill would allow a physical therapist (PT) to make a physical therapy diagnosis. This bill would allow a patient to directly access PT services, without being referred by a physician, provided that the treatment is within the scope of a PT as long as specified conditions are met.

ANALYSIS:

This bill would allow a PT to make a "physical therapy diagnosis", which is defined as a systemic examination process that culminates in assigning a diagnostic label identifying the primary dysfunction toward with physical therapy treatment will be directed, but shall not include a medical diagnosis or a diagnosis of a disease.

This bill would also allow a patient to directly access PT services, without being referred by a physician, provided that the treatment is within the scope of a PT and the following conditions are met:

- If the PT has reason to believe the patient has signs or symptoms of a condition that requires treatment beyond the scope of practice of a PT, the PT shall refer the patient to a physician, an osteopathic physician, or to a dentist, podiatrist or chiropractor.
- The PT shall disclose to the patient any financial interest in treating the patient.
- The PT shall notify the patient's physician, with the patient's written authorization, that the PT is treating the patient.

This bill would specify that it does not expand or modify the scope of practice of a PT, including the prohibition on a PT to diagnose a disease. This bill would also specify that it does not require a health care service plan or insurer to provide coverage for direct access to treatment by a PT.

This bill changes the scope of practice of a PT by allowing a PT to make a "physical therapy diagnosis" and allowing a PT to treat patients without a referral from a physician. The Board has taken oppose positions in the past on bills that allowed for direct patient access to PT services. The Board was opposed to these bills because they expanded the scope of practice for PT's by allowing them to see patients directly, without having the patients first seen by a physician, which puts patients at risk. A patient's condition cannot be accurately determined without first being examined by a physician, as PTs are not trained to make these comprehensive assessments and diagnoses. Because this bill will compromise patient care and consumer protection, staff is suggesting that the Board oppose this bill.

FISCAL: None

SUPPORT: California Physical Therapy Association (Sponsor)

OPPOSITION: None on file

POSITION: Recommendation: Oppose

AMENDED IN ASSEMBLY MARCH 21, 2013

california legislature—2013–14 regular session

ASSEMBLY BILL No. 1000

Introduced by Assembly Member Wieckowski

February 22, 2013

An act to amend ~~Section 2630 of~~ *Sections 2620 and 2660 of, and to add Section 2620.1 to,* the Business and Professions Code, relating to physical therapy.

legislative counsel's digest

AB 1000, as amended, Wieckowski. ~~Physical therapy.~~ *Physical therapists: direct access to services.*

Existing law, the Physical Therapy Practice Act, creates the Physical Therapy Board of California and makes it responsible for the licensure and regulation of physical therapists. The act defines the term "physical therapy" for its purposes as, among other things, including physical therapy evaluation, treatment planning, instruction, and consultative services. The act makes it a crime to violate any of its provisions. The act authorizes the board to suspend, revoke, or impose probationary conditions on a license, certificate, or approval issued under the act for unprofessional conduct, as specified.

This bill would revise the definition of "physical therapy" to instead include examination and evaluation to determine a physical therapy diagnosis, as defined, prognosis, treatment plan, instruction, or consultative service.

This bill would specify that patients may access physical therapy treatment directly and would, in those circumstances, require a physical therapist to refer his or her patient to another specified healing arts practitioner if the physical therapist has reason to believe the patient

has a condition requiring treatment or services beyond that scope of practice, to disclose to the patient any financial interest he or she has in treating the patient, and, with the patient's written authorization, to notify the patient's physician and surgeon, if any, that the physical therapist is treating the patient. The bill would provide that failure to comply with these provisions constitutes unprofessional conduct subject to disciplinary action by the board.

Because the bill would specify additional requirements under the Physical Therapy Practice Act, the violation of which would be a crime, it would impose a state-mandated local program.

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, until January 1, 2014, establishes the Physical Therapy Board of California, which oversees the licensing and regulation of physical therapists. Existing law prohibits any person or persons from practicing or offering to practice physical therapy in this state for compensation, or to hold himself or herself out as a physical therapist, unless he or she holds a valid license, as specified.~~

~~This bill would make a technical, nonsubstantive change to these 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. The Legislature finds and declares that an individual's access to early intervention to physical therapy treatment may decrease the duration of a disability, reduce pain, and lead to a quicker recovery.

SEC. 2. Section 2620 of the Business and Professions Code is amended to read:

2620. (a) Physical therapy means the art and science of physical or corrective rehabilitation or of physical or corrective treatment of any bodily or mental condition of any person by the use of the physical, chemical, and other properties of heat, light, water, electricity, sound, massage, and active, passive, and resistive

exercise, and shall include *examination and evaluation to determine a* physical therapy ~~evaluation,~~ *diagnosis, prognosis,* treatment ~~planning, instruction and~~ *plan, instruction, or* consultative ~~services.~~ *service.* The practice of physical therapy includes the promotion and maintenance of physical fitness to enhance the bodily movement related health and wellness of individuals through the use of physical therapy interventions. The use of roentgen rays and radioactive materials, for diagnostic and therapeutic purposes, and the use of electricity for surgical purposes, including cauterization, are not authorized under the term "physical therapy" as used in this chapter, and a license issued pursuant to this chapter does not authorize the diagnosis of disease.

(b) For the purposes of this section, "physical therapy diagnosis" means a systematic examination process that culminates in assigning a diagnostic label identifying the primary dysfunction toward which physical therapy treatment will be directed, but shall not include a medical diagnosis or a diagnosis of disease.

~~(b)~~

(c) Nothing in this section shall be construed to restrict or prohibit other healing arts practitioners licensed or registered under this division from practice within the scope of their license or registration.

SEC. 3. Section 2620.1 is added to the Business and Professions Code, to read:

2620.1. (a) In addition to receiving wellness and evaluation services from a physical therapist, a person may initiate physical therapy treatment directly from a licensed physical therapist if the treatment is within the scope of practice of physical therapists, as defined in Section 2620, and all of the following conditions are met:

(1) If, at any time, the physical therapist has reason to believe that the patient has signs or symptoms of a condition that requires treatment beyond the scope of practice of a physical therapist, the physical therapist shall refer the patient to a person holding a physician and surgeon's certificate issued by the Medical Board of California or by the Osteopathic Medical Board of California or to a person licensed to practice dentistry, podiatric medicine, or chiropractic.

(2) The physical therapist shall disclose to the patient any financial interest he or she has in treating the patient.

(3) With the patient's written authorization, the physical therapist shall notify the patient's physician and surgeon, if any, that the physical therapist is treating the patient.

(b) The conditions in paragraphs (1), (2), and (3) of subdivision (a) do not apply to a physical therapist when providing evaluation or wellness physical therapy services to a patient as described in subdivision (a) of Section 2620.

(c) This section does not expand or modify the scope of practice for physical therapists set forth in Section 2620, including the prohibition on a physical therapist diagnosing a disease.

(d) This section does not require a health care service plan or insurer to provide coverage for direct access to treatment by a physical therapist.

SEC. 4. Section 2660 of the Business and Professions Code is amended to read:

2660. The board may, after the conduct of appropriate proceedings under the Administrative Procedure Act, suspend for not more than 12 months, or revoke, or impose probationary conditions upon any license, certificate, or approval issued under this chapter for unprofessional conduct that includes, but is not limited to, one or any combination of the following causes:

(a) Advertising in violation of Section 17500.

(b) Fraud in the procurement of any license under this chapter.

(c) Procuring or aiding or offering to procure or aid in criminal abortion.

(d) Conviction of a crime that substantially relates to the qualifications, functions, or duties of a physical therapist or physical therapist assistant. The record of conviction or a certified copy thereof shall be conclusive evidence of that conviction.

(e) Habitual intemperance.

(f) Addiction to the excessive use of any habit-forming drug.

(g) Gross negligence in his or her practice as a physical therapist or physical therapist assistant.

(h) Conviction of a violation of any of the provisions of this chapter or of the Medical Practice Act, or violating, or attempting to violate, directly or indirectly, or assisting in or abetting the violating of, or conspiring to violate any provision or term of this chapter or of the Medical Practice Act.

(i) The aiding or abetting of any person to violate this chapter or any regulations duly adopted under this chapter.

(j) The aiding or abetting of any person to engage in the unlawful practice of physical therapy.

(k) The commission of any fraudulent, dishonest, or corrupt act that is substantially related to the qualifications, functions, or duties of a physical therapist or physical therapist assistant.

(*l*) Except for good cause, the knowing failure to protect patients by failing to follow infection control guidelines of the board, thereby risking transmission of blood-borne infectious diseases from licensee to patient, from patient to patient, and from patient to licensee. In administering this subdivision, the board shall consider referencing the standards, regulations, and guidelines of the State Department of Public Health developed pursuant to Section 1250.11 of the Health and Safety Code and the standards, regulations, and guidelines pursuant to the California Occupational Safety and Health Act of 1973 (Part 1 (commencing with Section 6300) of Division 5 of the Labor Code) for preventing the transmission of HIV, hepatitis B, and other blood-borne pathogens in health care settings. As necessary, the board shall consult with the Medical Board of California, the California Board of Podiatric Medicine, the Dental Board of California, the Board of Registered Nursing, and the Board of Vocational Nursing and Psychiatric Technicians of the State of California, to encourage appropriate consistency in the implementation of this subdivision.

The board shall seek to ensure that licensees are informed of the responsibility of licensees and others to follow infection control guidelines, and of the most recent scientifically recognized

safeguards for minimizing the risk of transmission of blood-borne infectious diseases.

(m) The commission of verbal abuse or sexual harassment.

(n) Failure to comply with the provisions of Section 2620.1.

SEC. 5. 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 2630 of the Business and Professions Code is amended to read:~~

~~2630. It is unlawful for any person or persons to practice, or offer to practice, physical therapy in this state for compensation received or expected, or to hold himself or herself out as a physical therapist, unless at the time of so doing he or she holds a valid, unexpired, and unrevoked license issued under this chapter.~~

~~Nothing in this section shall restrict the activities authorized by their licenses on the part of any persons licensed under this code or any initiative act, or the activities authorized to be performed pursuant to Article 4.5 (commencing with Section 2655) or Chapter 7.7 (commencing with Section 3500).~~

~~A physical therapist licensed pursuant to this chapter may utilize the services of one aide engaged in patient-related tasks to assist the physical therapist in his or her practice of physical therapy. "Patient-related task" means a physical therapy service rendered directly to the patient by an aide, excluding non-patient-related tasks. "Non-patient-related task" means a task related to observation of the patient, transport of the patient, physical support only during gait or transfer training, housekeeping duties, clerical duties, and similar functions. The aide shall at all times be under the orders, direction, and immediate supervision of the physical therapist. Nothing in this section shall authorize an aide to independently perform physical therapy or any physical therapy procedure. The board shall adopt regulations that set forth the standards and requirements for the orders, direction, and immediate supervision of an aide by a physical therapist. The physical therapist shall provide continuous and immediate supervision of the aide. The physical therapist shall be in the same facility as, and in proximity to, the location where the aide is performing~~

~~patient-related tasks, and shall be readily available at all times to provide advice or instruction to the aide. When patient-related tasks are provided to a patient by an aide, the supervising physical therapist shall, at some point during the treatment day, provide direct service to the patient as treatment for the patient's condition, or to further evaluate and monitor the patient's progress, and shall correspondingly document the patient's record.~~

~~The administration of massage, external baths, or normal exercise not a part of a physical therapy treatment shall not be prohibited by this section.~~

MEDICAL BOARD OF CALIFORNIA
LEGISLATIVE ANALYSIS

Bill Number: AB 1278
Author: Hueso
Bill Date: As proposed to be amended
Subject: Integrative Cancer Treatment
Sponsor: California Citizens for Health Freedom

STATUS OF BILL:

This bill is in the Assembly Health Committee.

DESCRIPTION OF CURRENT LEGISLATION:

This bill would allow a physician to prescribe integrative cancer treatment, under specified circumstances.

ANALYSIS

Current law restricts cancer therapy exclusively to conventional drugs, surgery, and radiation (those approved by the Food and Drug Administration). This bill would allow a physician to prescribe integrative cancer treatment, under specified circumstances.

This bill defines integrative cancer treatment as the use of a combination of evidence-based substances or therapies for the purpose of reducing the size of cancer, slowing the progression of cancer, or improving the quality of life of a patient with cancer. This bill would specify that a treatment meets the evidence-based medical standard if the methods of treatment are recognized by the Physician's Data Query of the National Cancer Institute; or if the methods of treatment have been reported in at least three peer reviewed articles published in complementary and alternative medicine journals to reduce the size of cancer, slow the progression of cancer, or improve the quality of life of a patient with cancer; or if the methods have been published in at least three peer-reviewed scientific medical journals.

This bill would prohibit a physician from recommending or prescribing integrative cancer treatment, unless specified informed consent is given; the treatment meets the evidence –based medical standard; the physician complies with the patient reevaluation requirements; and the physician complies with the standards of care for integrative cancer treatment.

In order to comply with the informed consent requirements, the physician must have the patient sign a form that either includes the contact information for the physician who is providing the patient conventional care, or that the patient has declined to be under the care of an oncologist or other physician providing conventional cancer care. The form must also include a statement that says the type of care the patient is receiving or that is being recommended is not the standard of care for treating cancer in California; that the standard of care for treating cancer in California consists of radiation, chemotherapy, and surgery; that the

treatment the physician will be prescribing or recommending is not approved by the federal Food and Drug Administration for the treatment of cancer; that the care that the patient will be receiving or is being recommended is not mutually exclusive of the patient receiving conventional cancer treatment. The form must also include the following written statements:

> THE STATE DEPARTMENT OF PUBLIC HEALTH AND THE PHYSICIAN PRESCRIBING YOUR INTEGRATIVE CANCER CARE RECOGNIZE THE IMPORTANCE OF USING CONVENTIONAL CANCER TREATMENTS, INCLUDING RADIATION, CHEMOTHERAPY, AND SURGERY. IT IS HIGHLY RECOMMENDED THAT YOU SEE AN ONCOLOGIST OR ANOTHER PHYSICIAN TO PROVDE YOU WITH CONVENTIONAL CANCER CARE.
>
> ANY AND ALL MEDICAL TREATMENTS INVOLVE SOME DEGREE OF RISK OF INJURY UP TO AND INCLUDING DEATH.

This bill would require a physician prescribing integrative cancer treatment to comply with patient reevaluation requirements, as follows:

- The patient must be informed of the measurable results achieved within an established timeframe and at regular and appropriate intervals during the treatment plan.
- The physician must reevaluate the treatment when progress stalls or reverses in the opinion of the physician or the patient, or as evidenced by objective evaluations.
- The patient must be informed about and agree to any proposed changes in treatment, including but not limited to, the risks and benefits of the proposed changes, the costs associated, and the timeframe in which the proposed changes will be reevaluated.

This bill would also set forth the standards of care in prescribing integrative cancer treatment that the physician must comply with, as follows:

- The physician must provide the patient information regarding the treatment prescribed, including its usefulness in treating cancer; a timeframe and plan for reevaluation the treatment using standard and conventional means in order to assess treatment efficacy; and a cost estimate for the prescribed treatment.
- The physician must make a good faith effort to obtain all relevant charts, records and laboratory results relating to the patient's conventional cancer care, prior to prescribing or changing treatment.
- At the request of the patient, the physician must make a good faith effort to coordinate the patient's care with the physician providing conventional cancer care to the patient.
- At the request of the patient, the physician must provide a synopsis of any treatment rendered to the physician providing conventional cancer care to the patient, including subjective and objective assessment of the patient's state of health and response to the treatment.

This bill would specify that failure to comply with this bill's provisions would constitute unprofessional conduct and cause for discipline by that individual's licensing entity.

According to the author, integrative cancer treatment gives consumers options for care and helps patients cope with the common side effects of chemotherapy and radiation. Integrative treatment incorporates uses of unconventional medicines that have proven results. The author believes this bill will provide cancer patients with more options to complement conventional therapy. This bill requires integrative cancer treatment to meet an evidence-based medical standard, and includes language that encourages communication with a patient's oncologist, as well as treatment with conventional therapies.

FISCAL: None

SUPPORT: California Citizens for Health Freedom (sponsor)
Cancer Victors
Cancer Control Society
Bobbiey's Foundation
Several Individuals

OPPOSITION: Association of Northern California Oncologists
Medical Oncology Association of Southern California, Inc.

POSITION: Recommendation: Neutral

Amendments Mock-up for 2013-2014 AB-1278 (Hueso (A))

**********Amendments are in BOLD**********

Mock-up based on Version Number 99 - Introduced 2/22/13

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 2234.1 of the Business and Professions Code is amended to read:

2234.1. (a) A physician and surgeon shall not be subject to discipline pursuant to subdivision (b), (c), or (d) of Section 2234 solely on the basis that the treatment or advice he or she rendered to a patient is alternative or complementary medicine, including the treatment of persistent Lyme Disease, if that treatment or advice meets ~~all~~ *one* of the following requirements*, as applicable*:

(1) The treatment or advice is for a condition other than cancer and meets all of the following requirements:

~~(1)~~

(A) It is provided after informed consent and a good-faith prior examination of the patient, and medical indication exists for the treatment or advice, or it is provided for health or well-being.

~~(2)~~

(B) It is provided after the physician and surgeon has given the patient information concerning conventional treatment and describing the education, experience, and credentials of the physician and surgeon related to the alternative or complementary medicine that he or she practices.

~~(3)~~

(C) In the case of alternative or complementary medicine, it does not cause a delay in, or discourage traditional diagnosis of, a condition of the patient.

~~(4)~~

(D) It does not cause death or serious bodily injury to the patient.

(2) The treatment or advice is for cancer and is given in compliance with Article 2.5 (commencing with Section 109400) of Chapter 4 of Part 4 of Division 104 of the Health and Safety Code.

(b) For purposes of this section, "alternative or complementary medicine," means those health care methods of diagnosis, treatment, or healing that are not generally used but that provide a reasonable potential for therapeutic gain in a patient's medical condition that is not outweighed by the risk of the health care method.

(c) Since the National Institute of Medicine has reported that it can take up to 17 years for a new best practice to reach the average physician and surgeon, it is prudent to give attention to new developments not only in general medical care but in the actual treatment of specific diseases, particularly those that are not yet broadly recognized in California.

SEC. 2. Section 2257 of the Business and Professions Code is repealed.

~~2257.~~

~~The violation of Section 109275 of the Health and Safety Code, relating to informed consent for the treatment of breast cancer, constitutes unprofessional conduct.~~

SEC. 3. Section 109270 of the Health and Safety Code is amended to read:

109270. The department shall:

(a) Prescribe reasonable regulations with respect to the administration of this article and Article 2 (commencing with Section 109300).

(b) Investigate violations of this article ~~and~~, Article 2 (commencing with Section 109300), *and Article 2.5 (commencing with Section 109400),* and report the violations to the appropriate enforcement authority.

(c) Secure the investigation and testing of the content, method of preparation, efficacy, or use of drugs, medicines, compounds, or devices proposed to be used, or used, by any individual, person, firm, association, or other entity in the state for the diagnosis, treatment, or cure of cancer, prescribe reasonable regulations with respect to the investigation and testing, and make findings of fact and recommendations upon completion of any such investigation and testing.

(d) Adopt a regulation prohibiting the prescription, administration, sale or other distribution of any drug, substance, or device found to be harmful or of no value in the diagnosis, prevention, or treatment of cancer*, except as authorized under Article 2.5 (commencing with Section 109400).*

(e) Hold hearings ~~in~~ *with* respect ~~of~~ *to* those matters involving compliance with this article ~~and~~, Article 2 (commencing with Section 109300)*, and Article 2.5 (commencing with Section 109400),* and subpoena witnesses and documents. Any or all hearings may be held before the Cancer Advisory Council. Any administrative action to be taken by the department as a result of

the hearings shall be taken only after receipt of the recommendations of the council. Prior to issuance of a cease and desist order under Section 109345, a hearing shall be held. The person furnishing a sample *or manufacturer contact information* under Section 109295 shall be given due notice of the hearing and an opportunity to be heard.

(f) Contract with independent scientific consultants for specialized services and advice.

In the exercise of the powers granted by this section, the department shall consult with the Cancer Advisory Council.

SEC. 4. Section 109285 of the Health and Safety Code is amended to read:

109285. For the purposes of this article ~~and~~, Article 2 (commencing with Section 109300), *and Article 2.5 (commencing with Section 109400),* "cancer" means all malignant neoplasms regardless of the tissue of origin, including malignant lymphoma, Hodgkins disease, and leukemia.

SEC. 5. Section 109295 of the Health and Safety Code is amended to read:

109295. *(a)* On written request by the department, delivered personally or by mail, any individual, person, firm, association, or other entity engaged, or representing himself, *herself,* or itself, as engaged, in the diagnosis, treatment, alleviation, or cure of cancer shall ~~furnish~~ *do all of the following:*

(1) Furnish the department with the sample as the department may deem necessary for adequate testing of any drug, medicine, compound, or device used or prescribed by the individual, person, firm, association, or other entity in the diagnosis, treatment, alleviation, or cure of ~~cancer, and shall specify~~ *cancer. The individual, person, firm, association, or other entity may alternatively furnish the department with the contact information of the manufacturer of the drug, medicine, compound, or device.*

(2) Specify the formula of any drug or compound and name all ingredients by their common or usual ~~names, and shall, upon like~~ *names.*

(3) Upon request ~~by~~ *of* the department, furnish further necessary information as ~~it~~ *the department* may request as to the composition and method of preparation of and the use that any drug, compound, or device is being put by the individual, person, firm, association, or other entity. ~~This~~

(b) This section shall apply to any individual, person, firm, association, or other entity that renders health care or services to individuals who have or believe they have cancer. This section also applies to any individual, person, firm, association, or other entity that by implication causes individuals to believe they have cancer.

~~The~~

(c) Upon the failure to ~~either~~ provide the sample *or the manufacturer's contact information*, disclose the formula, or name the ingredients as required by this section, *it* shall be conclusively presumed that the drug, medicine, compound or device that is the subject of the department's request has no value in the diagnosis, treatment, alleviation, or cure of cancer.

SEC. 6. Section 109300 of the Health and Safety Code is amended to read:

109300. The sale, offering for sale, holding for sale, delivering, giving away, prescribing, or administering of any drug, medicine, compound, or device to be used in the diagnosis, treatment, alleviation, or cure of cancer is unlawful and prohibited unless ~~(1) an~~ *one of the following applies:*

(a) An application with respect thereto has been approved under Section 505 of the federal Food, Drug, and Cosmetic Act~~, or (2) there~~.

(b) The use is consistent with Article 2.5 (commencing with Section 109400).

(c) There has been approved an application filed with the board setting forth *all of the following*:

~~(a)~~

(1) Full reports of investigations that have been made to show whether or not the drug, medicine, compound, or device is safe for the use, and whether the drug, medicine, compound, or device is effective in the use;

~~(b)~~

(2) A full list of the articles used as components of the drug, medicine, compound, or device;

~~(c)~~

(3) A full statement of the composition of the drug, medicine, compound, or device;

~~(d)~~

(4) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug, medicine, or compound or in the case of a device, a full statement of its composition, properties, and construction and the principle or principles of its operation;

~~(e)~~

(5) Such samples of the drug, medicine, compound, or device and of the articles used as components of the drug, medicine, compound, or device as the board may require; and

~~(f)~~

(6) Specimens of the labeling and advertising proposed to be used for the drug, medicine, compound, or device.

SEC. 7. Section 109350 of the Health and Safety Code is amended to read:

109350. The department may direct that ~~any~~ *an* individual, person, firm, association, or other entity shall cease and desist any further prescribing, recommending, or use of any drug, medicine, compound, or device for which no application has been approved under this article and Article 1 (commencing with Section 109250) unless its use is exempt under Section 109325 or 109330 *or authorized under Article 2.5 (commencing with Section 109400).*

SEC. 8. Section 109375 of the Health and Safety Code is amended to read:

109375. The director shall investigate possible violations of this article ~~and~~, Article 1 (commencing with Section 109250), *and Article 2.5 (commencing with Section 109400),* and report violations to the appropriate enforcement authority.

SEC. 9. Article 2.5 (commencing with Section 109400) is added to Chapter 4 of Part 4 of Division 104 of the Health and Safety Code, to read:

Article 2.5. Integrative Cancer Treatment

109400. For purposes of this article:

(a) "Integrative cancer treatment" means the use of ***a combination of*** evidence-based substances or therapies **~~that are not the standard of care for cancer treatment~~**, for the purpose of reducing the size of a cancer, slowing the progression of a cancer, or improving the quality of life of a patient with cancer, by a physician and surgeon practicing within his or her scope of practice.

(b) "Physician and surgeon" means a physician and surgeon licensed pursuant to Section 2050 of the Business and Professions Code or an osteopathic physician and surgeon licensed pursuant to the Osteopathic Act.

~~(c) An individual "prescribes" a treatment when he or she orders the treatment or a course of treatment.~~

~~**(d) An individual "provides" a treatment when he or she actually renders, administers, furnishes, or dispenses the treatment to the patient.**~~

109401. (a) Notwithstanding any other provision of law, a physician and surgeon shall not recommend or prescribe integrative cancer treatment for cancer patients unless the following requirements are met, as applicable:

(1) The treatment is recommended or prescribed after informed consent is given, as provided in Section 109402.

(2) The treatment recommended or prescribed meets the evidence-based medical standard provided in Section 109403.

(3) The physician and surgeon prescribing the treatment complies with the patient reevaluation requirements set forth in Section 109404 after the treatment begins.

(4) The physician and surgeon prescribing the treatment complies with all of the standards of care set forth in Section 109405.

(b) A physician and surgeon shall not provide integrative cancer treatment for cancer patients unless the treatment is prescribed by a physician and surgeon in compliance with subdivision (a).

109402. (a) For purposes of paragraph (1) of subdivision (a) of Section 109401, informed consent has been given if the patient signs a form stating either of the following:

(1) The name and telephone number of the physician and surgeon from whom the patient is receiving conventional cancer care and whether the patient has been informed of the type of cancer from which the patient suffers and his or her prognosis using conventional treatment options.

(2) That the patient has declined to be under the care of an oncologist or other physician and surgeon providing conventional cancer care.

(b) The form described in subdivision (a) shall include all of the following information:

(1) The type of care the patient will be receiving or that is being recommended is not the standard of care for treating cancer in California.

(2) The standard of care for treating cancer in California consists of radiation, chemotherapy, and surgery.

(3) The treatment that the physician and surgeon will be prescribing or recommending is not approved by the federal Food and Drug Administration for the treatment of cancer.

(4) The care that the patient will be receiving or that is being recommended is not mutually exclusive of the patient receiving conventional cancer treatment.

(5) The following written statements:

THE STATE DEPARTMENT OF PUBLIC HEALTH AND THE PHYSICIAN PRESCRIBING YOUR INTEGRATIVE CANCER CARE RECOGNIZE THE IMPORTANCE OF USING CONVENTIONAL CANCER TREATMENTS, INCLUDING RADIATION, CHEMOTHERAPY, AND SURGERY. IT IS HIGHLY RECOMMENDED THAT YOU SEE AN ONCOLOGIST OR ANOTHER PHYSICIAN TO PROVIDE YOU WITH CONVENTIONAL CANCER CARE.

ANY AND ALL MEDICAL TREATMENTS INVOLVE SOME DEGREE OF RISK OF INJURY UP TO AND INCLUDING DEATH.

109403. For purposes of paragraph (2) of subdivision (a) of Section 109401, a treatment meets the evidence-based medical standard for integrative cancer treatment if ~~**all**~~ **one** of the following requirements are met:
The methods of treatment are recognized by the Physician's Data Query of the National Cancer Institute; or
(b) The methods have been published in at least three peer-reviewed scientific medical journals.
(c) The methods of treatment have been reported in at least three peer-reviewed articles published in complementary and alternative medicine journals to have the potential of reducing the size of a cancer, slowing the progression of a cancer, or improving the quality of life of a patient with cancer.

(a) The methods of treatment are recognized by the Physician's Data Query of the National Cancer Institute; or

~~**(a) In the opinion of the physician and surgeon recommending or prescribing the treatment, the**~~ **(b) The methods of** treatment **have been reported in at least three peer-reviewed articles published in complementary and alternative medicine journals** ~~**has the potential**~~ to reduce the size of a cancer, slow the progression of a cancer, or improve the quality of life of a patient with cancer~~**, based on reasonable evidence from peer-reviewed scientific medical journals**~~**; or**
(c) The methods have been published in at least three peer-reviewed scientific medical journals.

~~**(b) In the opinion of the physician and surgeon recommending or prescribing the treatment, the expected benefits of the treatment substantially outweigh the expected harm from the treatment, as derived from peer-reviewed scientific or medical journals.**~~

~~**(c) The treatment, when properly provided, does not cause death or bodily injury to the patient.**~~

109404. For purposes of paragraph (3) of subdivision (a) of Section 109401, a physician and surgeon prescribing integrative cancer treatment complies with the patient reevaluation requirements if all of the following conditions are satisfied:

(a) The patient is informed regarding the measurable results achieved within the timeframe established pursuant to paragraph (2) of subdivision (a) of Section 109405 and at regular and appropriate intervals during the treatment plan.

(b) The physician and surgeon reevaluates treatment when progress stalls or reverses in the opinion of the physician and surgeon or the patient, or as evidenced by objective evaluations.

(c) The patient is informed about and agrees to any proposed change or changes in treatment, including, but not limited to, the risks and benefits of the proposed change or changes, the costs associated with the proposed change or changes, and the timeframe within which the proposed change or changes will be reevaluated.

109405. For purposes of paragraph (4) of subdivision (a) of Section 109401, a physician and surgeon complies with all of the standards of care in prescribing integrative cancer treatment under this article if all of the following requirements are met:

(a) The physician and surgeon provides the patient with all of the following when prescribing the treatment:

(1) Information regarding the treatment prescribed, including its usefulness in treating cancer.

(2) A timeframe and plan for reevaluating the treatment using standard and conventional means in order to assess treatment efficacy.

(3) A cost estimate for the prescribed treatment.

(b) The physician and surgeon ensures that relevant, generally accepted tests are administered to confirm the effectiveness and progress of the treatment.

(c) The physician and surgeon, prior to prescribing or changing the treatment, makes a good faith effort to obtain from the patient all relevant charts, records, and laboratory results relating to the patient's conventional cancer care.

(d) At the request of the patient, the physician and surgeon makes a good faith effort to coordinate the care of the patient with the physician and surgeon providing conventional cancer care to the patient.

(e) At the request of the patient, the physician and surgeon provides a synopsis of any treatment rendered pursuant to this article to the physician and surgeon providing conventional cancer care to the patient, including subjective and objective assessments of the patient's state of health and response to that treatment.

109406. The failure of a physician and surgeon to comply with this article constitutes unprofessional conduct and cause for discipline by that individual's licensing entity. That person shall not be subject to Section 109335 or 109370.

MEDICAL BOARD OF CALIFORNIA
LEGISLATIVE ANALYSIS

Bill Number: AB 1308
Author: Bonilla
Bill Date: March 21, 2013, Amended
Subject: Midwifery
Sponsor: American Congress of Obstetricians and Gynecologists, District IX

STATUS OF BILL:

This bill is in the Assembly Business, Professions, and Consumer Protection Committee.

DESCRIPTION OF CURRENT LEGISLATION:

This bill would allow a licensed midwife (LM) to directly obtain supplies, order testing, and receive reports that are necessary to the LM's practice of midwifery and consistent with the scope for practice for a LM. This bill would also require the Medical Board of California (Board) to adopt regulations by July 1, 2015 defining the appropriate standard of care and level of supervisions required for the practice of midwifery and identifying complications necessitating referral to a physician. This bill would require a LM to disclose in oral and written form to a prospective client the specific arrangement for the referral of complications to a physician and surgeon.

ANALYSIS

Current law requires the Board to adopt regulations defining the appropriate standard of care and level of supervisions required for the practice of midwifery. Due to the inability to reach consensus on the supervision issue, the Board bifurcated this requirement and in 2006 adopted Standards of Care for Midwifery. Three previous attempts to resolve the physician supervision issue via legislation and/or regulation have been unsuccessful due to the widely divergent opinions of interested parties and their inability to reach consensus.

This bill would allow a LM to directly obtain supplies, order testing, and receive reports that are necessary to his or her practice of midwifery and consistent with the scope for practice for a LM. This bill would also require the Board to adopt regulations by July 1, 2015 defining the appropriate standard of care and level of supervision required for the practice of midwifery and identifying complications necessitating referral to a physician and surgeon. This bill would require a LM to disclose in oral and written form to a prospective client the specific arrangement for the referral of complications to a physician.

Although required by law, physician supervision is essentially unavailable to LMs

performing home births, as California physicians are generally prohibited by their malpractice insurance companies from providing supervision of LMs who perform home births. According to these companies, if a physician supervises or participates in a home birth the physician will lose their insurance coverage resulting in loss of hospital privileges. The physician supervision requirement creates numerous barriers to care, in that if the LM needs to transfer a patient/baby to the hospital, many hospitals will not accept a patient transfer from a LM as the primary provider who does not have a supervising physician. California is currently the only state that requires physician supervision of LMs. Among states that regulate midwives, most require some sort of collaboration between the midwife and a physician.

LMs have difficulty securing diagnostic lab accounts, even though they are legally allowed to have lab accounts. Many labs require proof of physician supervision. In addition, LMs are not able to obtain the medical supplies they have been trained and are expected to use; oxygen and medical supplies that are included in approved licensed midwifery school curriculum (CCR section 1379.30). The inability for a licensed midwife to order lab tests often means the patient will not obtain the necessary tests to help the midwife monitor the patient during pregnancy. In addition, not being able to obtain the necessary medical supplies for the practice of midwifery adds additional risk to the LMs patient and child.

The Board, through the Midwifery Advisory Council (MAC) has held many meetings regarding physician supervision of licensed midwives and has attempted to create regulations to address this issue. The concepts of collaboration, such as required consultation, referral, transfer of care, and physician liability have been discussed among the interested parties with little success. There is disagreement over the appropriate level of physician supervision, with licensed midwives expressing concern with any limits being placed on their ability to practice independently. The physician and liability insurance communities have concerns over the safety of midwife-assisted homebirths, specifically delays and/or the perceived reluctance of midwives to refer patients when the situation warrants referral or transfer of care.

The Board, through MAC has also held meetings regarding the lab order and medical supplies/medication issues and has attempted to create regulatory language to address this issue. However, based upon discussions with interested parties, it appears the lab order and medical supplies/medication issues will need to be addressed through the legislative process.

This bill would address one of the barriers of care by allowing a LM to directly obtain supplies, order testing and receive reports necessary to the LM's practice of midwifery, which would help to ensure consumer protection. This bill would also require the Board to adopt regulations to address physician supervision and to identify complications necessitating referral to a physician; however, the Board has been unsuccessful in endeavors to adopt regulations regarding physician supervision in the past. Board staff will continue to work with the author's office and sponsors on language that will help to solve the issue of physician supervision and remove barriers to care, while at the same time help to ensure consumer protection. Board staff is suggesting that the Board support this bill if it is amended to better clarify what the supervision requirements should be in statute, versus in regulation.

FISCAL: None, as the Board is already required to adopt regulations, but has been unsuccessful as of yet.

SUPPORT: ACOG (sponsor)

OPPOSITION: None on file

POSITION: Recommendation: Support if amended to better clarify what the supervision requirements should be in statute, versus in regulation.

AMENDED IN ASSEMBLY MARCH 21, 2013

california legislature—2013–14 regular session

ASSEMBLY BILL No. 1308

Introduced by Assembly Member Bonilla

February 22, 2013

An act *to amend Sections 2507 and 2508 of the Business and Professions Code,* relating to professions and vocations.

legislative counsel's digest

AB 1308, as amended, Bonilla. Midwifery.

Existing law, the Licensed Midwifery Practice Act of 1993, provides for the licensing and regulation of midwives by the Board of Licensing of the Medical Board of California. The license to practice midwifery authorizes the holder, under the supervision of a licensed physician and surgeon, as specified, 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. *Under the act, a licensed midwife is required to make certain oral and written disclosures to prospective clients.* A violation of the act is a crime.

This bill would additionally authorize a licensed midwife to directly obtain supplies, order testing, and receive reports that are necessary to his or her practice of midwifery and consistent with his or her scope of practice and would require a licensed midwife to disclose to prospective clients the specific arrangements for referral of complications to a physician and surgeon.

~~This bill would state the intent of the Legislature to enact legislation to remove barriers to care in order to provide a more efficient and safer delivery method for mother and infant by allowing licensed midwives to practice in a manner originally intended in prior legislation.~~

Existing law requires the board, by July 1, 2003, to adopt regulations defining the appropriate standard of care and level of supervision required for the practice of midwifery.

This bill would require the board, by July 1, 2015, to revise and adopt regulations defining the appropriate standard of care and level of supervision required for the practice of midwifery and identifying complications necessitating referral to a physician and surgeon.

By expanding the disclosures a licensed midwife is required to make to prospective clients, this bill would expand the scope of a crime thereby imposing a state-mandated local program.

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: ~~no~~ *yes*. State-mandated local program: ~~no~~ *yes*.

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

SECTION 1. ~~(a)~~ The Legislature finds and declares the following:

~~(1)~~

(a) Licensed midwives have been authorized to practice since 1993 under Senate Bill 350 (Chapter 1280 of the Statutes of 1993), which was authored by Senator Killea. Additional legislation, Senate Bill 1950 (Chapter 1085 of the Statutes of 2002), which was authored by Senator Figueroa, was needed in 2002 to clarify certain practice issues. While the midwifery license does not specify or limit the practice setting in which licensed midwives may provide care, the reality is that the majority of births delivered by licensed midwives are planned as home births.

~~(2)~~

(b) Planned home births are safer when care is provided as part of an integrated delivery model. For a variety of reasons, this integration rarely occurs, and creates a barrier to the best and safest care possible. This is due, in part, to the attempt to fit a midwifery model of care into a medical model of care.

~~(b) It is the intent of the Legislature to enact legislation that would systematically remove unnecessary barriers to care in order to provide a more efficient and safer delivery for mother and infant by allowing licensed midwives to practice in a manner originally intended in the authorizing legislation.~~

SEC. 2. Section 2507 of the Business and Professions Code is amended to read:

2507. (a) The license to practice midwifery authorizes the holder, 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.

(b) As used in this article, the practice of midwifery constitutes the furthering or undertaking by any licensed midwife, 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. All complications shall be referred to a physician and surgeon immediately. The practice of 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 and surgeon.

(d) The ratio of licensed midwives to supervising physicians and surgeons shall not be greater than four individual licensed midwives to one individual supervising physician and surgeon.

(e) A midwife is not authorized to practice medicine and surgery by this article.

(f) A midwife is authorized to directly obtain supplies, 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)~~

(g) The board shall, not later than July 1, ~~2003,~~ *2015, revise and* adopt in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code), regulations defining the appropriate standard of care and level of supervision required for the practice of ~~midwifery.~~ *midwifery and identifying complications necessitating referral to a physician and surgeon.*

SEC. 3. Section 2508 of the Business and Professions Code is amended to read:

2508. (a) A licensed midwife shall disclose in oral and written form to a prospective client all of the following:

(1) All of the provisions of Section 2507.

(2) If the licensed midwife does not have liability coverage for the practice of midwifery, he or she shall disclose that fact.

(3) The specific arrangements for the referral of complications to a physician and surgeon.

~~(3)~~

(4) 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.

~~(4)~~

(5) The procedure for reporting complaints to the Medical Board of California.

(b) The disclosure shall be signed by both the licensed midwife and the client and a copy of the disclosure shall be placed in the client's medical record.

(c) The Medical Board of California may prescribe the form for the written disclosure statement required to be used by a licensed midwife under this section.

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.

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MEDICAL BOARD OF CALIFORNIA
LEGISLATIVE ANALYSIS

Bill Number: **S**B 352
Author: Pavley
Bill Date: February 20, 2013, Introduced
Subject: Medical Assistants: Supervision
Sponsor: California Academy of Physician Assistants (CAPA)

STATUS OF BILL:

This bill is in the Senate Business, Professions, and Economic Development Committee.

DESCRIPTION OF CURRENT LEGISLATION:

This bill would allow a physician assistants (PAs), nurse practitioner (NPs) and nurse-midwives (NMs) to supervise medical assistants (MAs)

ANALYSIS

MAs are unlicensed personnel trained to perform basic administrative, clerical, and technical support services in a medical office or clinical setting. These services include, but are not limited to, taking blood pressure, charting height and weight, administering medication, performing skin tests, and withdrawing blood by venipuncture. The Bureau of Labor and Statistics (2011) reports nearly 82,000 MAs are employed in California.

Currently, a physician must be present in the practice site to supervise an MA in most settings. PAs and NPs can currently supervise MAs in licensed community and free clinics. If a physician is not present, MAs are limited to performing administrative and clerical duties and cannot perform or assist with simple technical supportive services if the physician is not on the premises, except in community and free clinics. This means that in many settings, MAs cannot perform many of the tasks that they are qualified for and are needed to perform. This bill would allow PAs, NPs, and NMs to supervise MAs in all settings.

According to the sponsors, physicians have been delegating the task of supervising MAs when the physician is not in the office for over a decade in community clinics and the Physician Assistant Board and the Department of Consumer Affairs have not reported any patient safety issues or disciplinary action related to PA supervision of MAs. The sponsors believe that this bill will eliminate legal restrictions and barriers to efficient coordinated care. The sponsors believe this change is necessary if California hopes to accommodate the dramatic increase in patients expected to result from health care reform.

With the health care reform being implemented in 2014, this bill may help to

accommodate the expected increase in patients, as well as help to ensure that MAs are being supervised while a physician is not physically present in the office. Given that PAs, NPs, and NMs are currently allowed to supervise MAs in some settings now, and that this authority would have to be delegated by the physician, it makes sense for this to be allowed in all settings. However, existing law (BPC 2264) prohibits physicians from aiding and abetting unlicensed individuals from engaging in the practice of medicine. Board staff suggests that the Board take a Neutral position on this bill if it is amended to include language to ensure that if a PA, NP, or NM were to allow the MA to perform tasks that are not in the approved scope of responsibility, that the PA, NP, or NM would be held responsible and subject to discipline by their licensing board.

FISCAL: None

SUPPORT: CAPA (sponsor)

OPPOSITION: None on file

POSITION: Recommendation: Neutral if Amended

SENATE BILL No. 352

Introduced by Senator Pavley
(Principal coauthor: Senator Hernandez)

February 20, 2013

An act to amend Section 2069 of the Business and Professions Code, relating to healing arts.

legislative counsel's digest

SB 352, as introduced, Pavley. Medical assistants: supervision.

Existing law authorizes a medical assistant to perform specified services relating to the administration of medication and performance of skin tests and simple routine medical tasks and procedures upon specific authorization from and under the supervision of a licensed physician and surgeon or podiatrist, or in a specified clinic upon specific authorization of a physician assistant, nurse practitioner, or nurse-midwife.

This bill would delete the requirement that the services performed by the medical assistant be in a specified clinic when under the specific authorization of a physician assistant, nurse practitioner, or nurse-midwife. The bill would also delete several obsolete references and make other technical, nonsubstantive changes.

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 2069 of the Business and Professions Code is amended to read:

2069. (a) (1) Notwithstanding any other ~~provision of~~ law, a medical assistant may administer medication only by intradermal,

subcutaneous, or intramuscular injections and perform skin tests and additional technical supportive services upon the specific authorization and supervision of a licensed physician and surgeon or a licensed podiatrist. A medical assistant may also perform all these tasks and services ~~in a clinic licensed pursuant to subdivision (a) of Section 1204 of the Health and Safety Code~~ upon the specific authorization of a physician assistant, a nurse practitioner, or a nurse-midwife.

(2) The supervising physician and surgeon ~~at a clinic described in paragraph (1)~~ may, at his or her discretion, in consultation with the nurse practitioner, nurse-midwife, or physician assistant,

provide written instructions to be followed by a medical assistant in the performance of tasks or supportive services. These written instructions may provide that the supervisory function for the medical assistant for these tasks or supportive services may be delegated to the nurse practitioner, nurse-midwife, or physician assistant within the standardized procedures or protocol, and that tasks may be performed when the supervising physician and surgeon is not onsite, ~~so long as~~ *if either of* the following apply:

(A) The nurse practitioner or nurse-midwife is functioning pursuant to standardized procedures, as defined by Section 2725, or protocol. The standardized procedures or protocol shall be developed and approved by the supervising physician and surgeon, the nurse practitioner or nurse-midwife, and the facility administrator or his or her designee.

(B) The physician assistant is functioning pursuant to regulated services defined in Section 3502 and is approved to do so by the supervising physician ~~or~~ *and* surgeon.

(b) As used in this section and Sections 2070 and 2071, the following definitions ~~shall~~ apply:

(1) "Medical assistant" means a person who may be unlicensed, who performs basic administrative, clerical, and technical supportive services in compliance with this section and Section 2070 for a licensed physician and surgeon or a licensed podiatrist, or group thereof, for a medical or podiatry corporation, for a physician assistant, a nurse practitioner, or a nurse-midwife as provided in subdivision (a), or for a health care service plan, who is at least 18 years of age, and who has had at least the minimum amount of hours of appropriate training pursuant to standards established by the ~~Division of Licensing~~ *board*. The medical

assistant shall be issued a certificate by the training institution or instructor indicating satisfactory completion of the required training. A copy of the certificate shall be retained as a record by each employer of the medical assistant.

(2) "Specific authorization" means a specific written order prepared by the supervising physician and surgeon or the supervising podiatrist, or the physician assistant, the nurse practitioner, or the nurse-midwife as provided in subdivision (a), authorizing the procedures to be performed on a patient, which shall be placed in the patient's medical record, or a standing order prepared by the supervising physician and surgeon or the supervising podiatrist, or the physician assistant, the nurse practitioner, or the nurse-midwife as provided in subdivision (a),

authorizing the procedures to be performed, the duration of which shall be consistent with accepted medical practice. A notation of the standing order shall be placed on the patient's medical record.

(3) "Supervision" means the supervision of procedures authorized by this section by the following practitioners, within the scope of their respective practices, who shall be physically present in the treatment facility during the performance of those procedures:

(A) A licensed physician and surgeon.

(B) A licensed podiatrist.

(C) A physician assistant, nurse practitioner, or nurse-midwife as provided in subdivision (a).

(4) "Technical supportive services" means simple routine medical tasks and procedures that may be safely performed by a medical assistant who has limited training and who functions under the supervision of a licensed physician and surgeon or a licensed podiatrist, or a physician assistant, a nurse practitioner, or a nurse-midwife as provided in subdivision (a).

(c) Nothing in this section shall be construed as authorizing ~~the~~ *any of the following:*

(1) The licensure of medical assistants. ~~Nothing in this section shall be construed as authorizing the~~

(2) The administration of local anesthetic agents by a medical assistant. ~~Nothing in this section shall be construed as authorizing the division to~~

(3) The board to adopt any regulations that violate the prohibitions on diagnosis or treatment in Section 2052.

(e) Nothing in this section shall be construed as authorizing a medical assistant to perform any clinical laboratory test or examination for which he or she is not authorized by Chapter 3 (commencing with Section 1206.5). Nothing in this section shall be construed as authorizing a nurse practitioner, nurse-midwife, or physician assistant to be a laboratory director of a clinical laboratory, as those terms are defined in paragraph (8) of subdivision (a) of Section 1206 and subdivision (a) of Section 1209.

(d) Notwithstanding any other ~~provision of~~ law, a medical assistant ~~may~~ *shall* not be employed for inpatient care in a licensed general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

(4) A medical assistant to perform any clinical laboratory test or examination for which he or she is not authorized by Chapter 3 (commencing with Section 1200).

(5) A nurse practitioner, nurse-midwife, or physician assistant to be a laboratory director of a clinical laboratory, as those terms are defined in paragraph (8) of subdivision (a) of Section 1206 and subdivision (a) of Section 1209.

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MEDICAL BOARD OF CALIFORNIA
LEGISLATIVE ANALYSIS

Bill Number: SB 809
Author: DeSaulnier and Steinberg
Bill Date: February 22, 2013, introduced
Subject: Controlled Substances: Reporting
Sponsor: Department of Justice

STATUS OF BILL:

This bill is in the Senate Business, Professions and Economic Development Committee.

DESCRIPTION OF CURRENT LEGISLATION:

This bill would establish the Controlled Substance Utilization Review and Evaluation System (CURES) Fund that would be administered by the Department of Justice (DOJ), and would consist of funds collected from boards that license prescribers and dispensers, manufacturers, and health insurers, for purposes of funding the CURES program and upgrading the CURES system. Once the CURES program is funded and the system is upgraded, all prescribers and pharmacists would be required to consult CURES before prescribing or dispensing Schedule II, III, or IV controlled substances.

ANALYSIS:

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, including the Medical Board of California (Board), to access patient controlled substance history information through a secure Web site.

According to a DOJ, there is currently no permanent funding to support the CURES/ PDMP program. The California Budget Act of 2011 eliminated all General Fund support of CURES/PDMP, which included funding for system support, staff support and related operating expenses. To perform the minimum critical functions and to avoid shutting down the program, DOJ opted to assign five staff to perform temporary dual job assignments on a part-time basis. Although some tasks are being performed, the program is faced with a constant backlog (e.g., four-week backlog on processing new user applications, six-week response time on emails, twelve week backlog on voicemails, etc.).

The only funding currently available to DOJ for CURES is through renewable contracts with five separate regulatory boards (including the Medical Board of California (Board)) and one grant. While DOJ has been able to successfully renew contracts with the boards and receive grant funding this year, these sources of funding are not permanent and may not be available in future years and cannot be used to fund staff positions. In addition, these funding sources are insufficient to operate and maintain the PDMP system, make necessary enhancements or fully fund a PDMP modernization effort.

This bill would make findings and declarations related to the importance of CURES. This bill would establish the CURES Fund that would be funded by an annual 1.16% licensing, certification and renewal fee increase for licensees of the following boards that are authorized to prescribe or dispense Schedule II, III, or IV controlled substances: Medical Board of California; Dental Board of California; Board of Pharmacy (including wholesalers non-resident wholesalers, and veterinary food-animal drug retailers); Veterinary Medical Board; Board of Registered Nursing; Physician Assistant Board; Osteopathic Medical Board of California; State Board of Optometry; and the California Board of Podiatric Medicine. This bill would make the money in the CURES Fund available for allocation to DOJ, upon appropriation by the Legislature, for the purposes of funding the CURES Program. This bill would specify that the fee increase shall not exceed the reasonable costs associated with maintaining CURES.

> The 1.16% annual fee would result in an increase of $18 for physician renewal fees ($9 each year of the two-year renewal cycle), and a $9 initial licensing fee increase. Staff suggests that the word "annual" be taken out, which would instead result in a $9 renewal fee increase and a $9 initial licensing fee increase.

This bill would impose an unspecified one-time tax on health insurers for the purposes of upgrading the CURES system. This bill would impose an unspecified on-going tax on manufacturers of controlled substances for the purposes of creating and maintaining a new enforcement team in DOJ, which would focus on prescription diversion and abuse and criminal activity associated with bringing large quantities of illegal prescription drugs into California. The team would coordinate with state, federal and local law enforcement entities, and work with the various health care boards and departments to conduct investigations based on CURES data and intelligence.

Once CURES is funded, upgraded, and able to handle inquiries from all eligible prescribers and dispensers in California, this bill would require DOJ to notify all prescribers and dispensers who have submitted applications to CURES that they are capable of accommodating this workload. DOJ would also be required to notify the Legislature and post the notification on DOJ's Web site. Once DOJ issues this notification, all prescribers and dispensers eligible to prescribe and dispense Schedule II, III, and IV controlled substances would be required to access and consult the electronic history of controlled substances dispensed to a patient under his or her care, prior to prescribing or dispensing a Schedule II, III, or IV controlled substance.

This bill contains an urgency clause, which means it would take effect immediately once signed into law by the Governor.

This is a concern in relation to the collection of the renewal fee. There needs to be an implementation schedule included, as the Board sends out renewal notices 90 days in advance and would need to give licensees appropriate notice of the renewal fee increase.

Board staff is suggesting the fee increase not be an annual fee increase, but be a 1.16% increase on licensing and renewals. Although this bill requires physicians to utilize CURES prior to prescribing Schedule II, III, and IV controlled substances once DOJ has provided notice that the system is capable, there is no penalty associated if a physician does not comply. In addition, requiring a physician to utilize CURES each time they prescribe a Schedule II, III, or IV controlled substance and also requiring the pharmacist to utilize CURES before they dispense that same prescription, may be overly excessive. In addition, placing a tax on manufacturers to support a new enforcement team in DOJ may be premature, as CURES will not be upgraded for some time.

The Board believes CURES is a very important enforcement tool and an effective aid for physicians to use to prevent "doctor shopping". Although the Board currently helps to fund CURES at a cost of $150,000 this year, these funds cannot be used for staffing. The Board is aware of the issues DOJ is facing related to insufficient staffing and funding for CURES/PDMP, and due to the importance of this program, is suggesting that the Board support any effort to get CURES more fully funded in order for the PDMP to be at optimum operating capacity.

Board staff suggests that the Board take a Support in Concept position, as this bill is still a work in progress. Board staff will continue to participate in work group meetings and will work with the authors' offices on any amendments needed.

FISCAL: This bill would result in an annual 1.16% licensing fee increase for physicians, which equates to a $18 increase for renewals and a $9 increase for initial licensing fees.

SUPPORT: DOJ (sponsor)

OPPOSITION: None on file

POSITION: Recommendation: Support in Concept with noted concerns:

- Fee increase should be biennial versus annual.
- An implementation schedule for the fee increase should be addressed, as it is impossible to implement on the day the bill is signed.
- The requirement for use of CURES should include a minimum penalty if it is not used (cite/fine).
- DOJ enforcement team should not be funded until CURES system is fully operational and upgraded.

SENATE BILL No. 809

Introduced by Senators DeSaulnier and Steinberg
(Coauthors: Senators Hancock, Lieu, Pavley, and Price)
(Coauthor: Assembly Member Blumenfield)

February 22, 2013

An act to add Section 805.8 to the Business and Professions Code, to amend Sections 11165 and 11165.1 of the Health and Safety Code, and to add Part 21 (commencing with Section 42001) to Division 2 of the Revenue and Taxation Code, relating to controlled substances, and declaring the urgency thereof, to take effect immediately.

legislative counsel's digest

SB 809, as introduced, DeSaulnier. Controlled substances: reporting.

(1) 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 all practitioners authorized to prescribe or dispense these controlled substances.

Existing law requires dispensing pharmacies and clinics to report, on a weekly basis, specified information for each prescription of Schedule II, Schedule III, or Schedule IV controlled substances, to the department, as specified.

This bill would establish the CURES Fund within the State Treasury to receive funds to be allocated, upon appropriation by the Legislature, to the Department of Justice for the purposes of funding CURES, and would make related findings and declarations.

This bill would require the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the

Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, and the California Board of Podiatric Medicine to increase the licensure, certification, and renewal fees charged to practitioners under their supervision who are authorized to prescribe or dispense controlled substances, by up to 1.16%, the proceeds of which would be deposited into the CURES Fund for support of CURES, as specified. This bill would also require the California State Board of Pharmacy to increase

the licensure, certification, and renewal fees charged to wholesalers, nonresident wholesalers, and veterinary food-animal drug retailers under their supervision by up to 1.16%, the proceeds of which would be deposited into the CURES Fund for support of CURES, as specified.

(2) Existing law permits a licensed health care practitioner, as specified, or a pharmacist to apply to the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient under his or her care. Existing law also authorizes the Department of Justice to provide the history of controlled substances dispensed to an individual to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

This bill would require licensed health care practitioners, as specified, and pharmacists to apply to the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient under his or her care, and, upon the happening of specified events, to access and consult that information prior to prescribing or dispensing Schedule II, Schedule III, or Schedule IV controlled substances.

(3) Existing law imposes various 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.

This bill would impose a tax upon qualified manufacturers, as defined, for the privilege of doing business in this state, as specified. This bill would also impose a tax upon specified insurers, as defined, for the privilege of doing business in this state, as specified. 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. The bill would require the board to deposit all taxes, penalties, and interest collected pursuant to these provisions in the CURES Fund,

as provided. Because this bill would expand application of the Fee Collection Procedures Law, the violation of which is a crime, it would impose 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.

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

Vote: ⅔. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

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

SECTION 1. The Legislature finds and declares all of the following:

(a) The Controlled Substance Utilization Review and Evaluation System (CURES) is a valuable investigative, preventive, and educational tool for law enforcement, regulatory boards, educational researchers, and the health care community. Recent budget cuts to the Attorney General's Division of Law Enforcement have resulted in insufficient funding to support the CURES Prescription Drug Monitoring Program (PDMP). The PDMP is necessary to ensure health care professionals have the necessary data to make informed treatment decisions and to allow law enforcement to investigate diversion of prescription drugs. Without a dedicated funding source, the CURES PDMP is not sustainable.

(b) Each year CURES responds to more than 60,000 requests from practitioners and pharmacists regarding all of the following:

(1) Helping identify and deter drug abuse and diversion of prescription drugs through accurate and rapid tracking of Schedule II, Schedule III, and Schedule IV controlled substances.

(2) Helping practitioners make better prescribing decisions.

(3) Helping reduce misuse, abuse, and trafficking of those drugs.

(c) Schedule II, Schedule III, and Schedule IV controlled substances have had deleterious effects on private and public interests, including the misuse, abuse, and trafficking in dangerous prescription medications resulting in injury and death. It is the intent of the Legislature to work with stakeholders to fully fund

the operation of CURES which seeks to mitigate those deleterious effects, and which has proven to be a cost-effective tool to help reduce the misuse, abuse, and trafficking of those drugs.

SEC. 2. Section 805.8 is added to the Business and Professions Code, to read:

805.8. (a) (1) The Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, and the California Board of Podiatric Medicine shall increase the licensure, certification, and renewal fees charged to practitioners under their supervision who are authorized pursuant to Section 11150 of the Health and Safety Code to prescribe or

dispense Schedule II, Schedule III, or Schedule IV controlled substances by up to 1.16 percent annually, but in no case shall the fee increase exceed the reasonable costs associated with maintaining CURES for the purpose of regulating prescribers and dispensers of controlled substances licensed or certificated by these boards.

(2) The California State Board of Pharmacy shall increase the licensure, certification, and renewal fees charged to wholesalers and nonresident wholesalers of dangerous drugs, licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9, by up to 1.16 percent annually, but in no case shall the fee increase exceed the reasonable costs associated with maintaining CURES for the purpose of regulating wholesalers and nonresident wholesalers of dangerous drugs licensed or certificated by that board.

(3) The California State Board of Pharmacy shall increase the licensure, certification, and renewal fees charged to veterinary food-animal drug retailers, licensed pursuant to Article 15 (commencing with Section 4196) of Chapter 9, by up to 1.16 percent annually, but in no case shall the fee increase exceed the reasonable costs associated with maintaining CURES for the purpose of regulating veterinary food-animal drug retailers licensed or certificated by that board.

(b) The funds collected pursuant to subdivision (a) shall be deposited in the CURES accounts, which are hereby created, within the Contingent Fund of the Medical Board of California, the State

Dentistry Fund, the Pharmacy Board Contingent Fund, the Veterinary Medical Board Contingent Fund, the Board of Registered Nursing Fund, the Osteopathic Medical Board of California Contingent Fund, the Optometry Fund, and the Board of Podiatric Medicine Fund. Moneys in the CURES accounts of each of those funds shall, upon appropriation by the Legislature, be available to the Department of Justice solely for maintaining CURES for the purposes of regulating prescribers and dispensers of controlled substances. All moneys received by the Department of Justice pursuant to this section shall be deposited in the CURES Fund described in Section 11165 of the Health and Safety Code.

SEC. 3. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist 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 ~~from~~ *in the CURES accounts within* the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, ~~and~~ the Osteopathic Medical Board of California Contingent Fund, *the Veterinary Medical Board Contingent Fund, the Optometry Fund, the Board of Podiatric Medicine Fund, and 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 or dispense these controlled substances.

(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds ~~from~~ *for* the Department of Justice *for the purpose of finding CURES*. The department may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. ~~Funds~~ *The department shall make information about the amount and the source of all private grant funds it receives for support of CURES available to the public. Grant funds* shall not be appropriated from the Contingent Fund of the Medical Board of California, the

Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.

(c) 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 persons or 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~~ *agency,* as described in this ~~subdivision~~ *subdivision,* shall not be disclosed, sold, or transferred to any third party.

(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 or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

(1) Full name, address, and ~~the~~ 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 and license ~~number;~~ *number, the* federal controlled substance registration ~~number;~~ *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, and federal controlled substance registration number.

(4) ~~NDC (National Drug Code)~~ *National Drug Code (NDC)* number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ~~ICD-9 (diagnosis code),~~ *International Statistical Classification of Diseases, 9th revision (ICD-9) 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) ~~This section shall become operative on January 1, 2005.~~ *The CURES Fund is hereby established within the State Treasury. The CURES Fund shall consist of all funds made available to the Department of Justice for the purpose of funding CURES. Money in the CURES Fund shall, upon appropriation by the Legislature, be available for allocation to the Department of Justice for the purpose of funding CURES.*

SEC. 4. Section 11165.1 of the Health and Safety Code is amended to read:

11165.1. (a) (1) A licensed health care practitioner eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances or a pharmacist ~~may~~ *shall* provide a notarized application developed by the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient maintained within the

Department of Justice, ~~and~~ *and, upon approval,* the department ~~may~~ *shall* release to that practitioner or pharmacist, 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).

(A) 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 for a subscriber.

(ii) Failure to maintain effective controls for access to the patient activity report.

(iii) Suspended or revoked federal Drug Enforcement Administration (DEA) registration.

(iv) Any subscriber who is arrested for a violation of law governing controlled substances or any other law for which the

possession or use of a controlled substance is an element of the crime.

(v) Any subscriber accessing information for any other reason than caring for his or her patients.

(B) Any authorized subscriber shall notify the Department of Justice within 10 days of any changes to the subscriber account.

(2) To allow sufficient time for licensed health care practitioners eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances and a pharmacist to apply and receive access to PDMP, a written request may be made, until July 1, 2012, and the Department of Justice may release to that practitioner or pharmacist the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.

(b) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(c) ~~In~~ *(1) Until the Department of Justice has issued the notification described in paragraph (3), in* order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice 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.

(2) Upon the Department of Justice issuing the notification described in paragraph (3) and approval of the application

required pursuant to subdivision (a), licensed health care practitioners eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances and pharmacists shall access and consult the electronic history of controlled substances dispensed to an individual under his or her care prior to prescribing or dispensing a Schedule II, Schedule III, or Schedule IV controlled substance.

(3) The Department of Justice shall notify licensed health care practitioners and pharmacists who have submitted the application required pursuant to subdivision (a) when the department determines that CURES is capable of accommodating the mandate contained in paragraph (2). The department shall provide a copy of the notification to the Secretary of the State, the Secretary of the Senate, the Chief Clerk of the Assembly, and the Legislative

Counsel, and shall post the notification on the department's Internet Web site.

(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 of Justice pursuant to this section shall be considered 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 prescriber or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

SEC. 5. Part 21 (commencing with Section 42001) is added to Division 2 of the Revenue and Taxation Code, to read:

PART 21. CONTROLLED SUBSTANCE UTILIZATION REVIEW AND EVALUATION SYSTEM (CURES) TAX LAW

42001. For purposes of this part, the following definitions apply:

(a) "Controlled substance " means a drug, substance, or immediate precursor listed in any schedule in Section 11055, 11056, or 11057 of the Health and Safety Code.

(b) "Insurer" means a health insurer licensed pursuant to Part 2 (commencing with Section 10110) of Division 2 of the Insurance Code, a health care service plan licensed pursuant to the

Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code), and a workers' compensation insurer licensed pursuant to Part 3 (commencing with Section 11550) of Division 2 of the Insurance Code.

(c) "Qualified manufacturer" means a manufacturer of a controlled substance doing business in this state, as defined in Section 23101, but does not mean a wholesaler or nonresident wholesaler of dangerous drugs, regulated pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code, a veterinary food-animal drug retailer, regulated pursuant to Article 15 (commencing with Section

4196) of Chapter 9 of Division 2 of the Business and Professions Code, or an individual regulated by the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, or the California Board of Podiatric Medicine.

42003. (a) For the privilege of doing business in this state, an annual tax is hereby imposed on all qualified manufacturers in an

amount of dollars ($), for the purpose of establishing

and maintaining enforcement of the Controlled Substance Utilization Review and Evaluation System (CURES), established pursuant to Section 11165 of the Health and Safety Code.

(b) For the privilege of doing business in this state, a tax is hereby imposed on a one time basis on all insurers in an amount

of dollars ($), for the purpose of upgrading CURES.

42005. Each qualified manufacturer and insurer shall prepare and file with the board a return, in the form prescribed by the board, containing information as the board deems necessary or appropriate for the proper administration of this part. The return shall be filed on or before the last day of the calendar month following the calendar quarter to which it relates, together with a remittance payable to the board for the amount of tax due for that period.

42007. The board shall administer and collect the tax imposed by this part pursuant to the Fee Collection Procedures Law (Part 30 (commencing with Section 55001)). For purposes of this part, the references in the Fee Collection Procedures Law (Part 30

(commencing with Section 55001)) to "fee" shall include the tax imposed by this part and references to "feepayer" shall include a person required to pay the tax imposed by this part.

42009. All taxes, interest, penalties, and other amounts collected pursuant to this part, less refunds and costs of administration, shall be deposited into the CURES Fund.

42011. The board shall prescribe, adopt, and enforce rules and regulations relating to the administration and enforcement of this part.

SEC. 6. 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.

SEC. 7. 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 Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to protect the public from the continuing threat of prescription drug abuse at the earliest possible time, it is necessary this act take effect immediately.

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