Agenda Item 9A

MEDICAL BOARD OF CALIFORNIA - 2019 TRACKER LIST July 24, 2019

BILL	AUTHOR	TITLE	STATUS	POSITION	AMENDED
AB 149	Cooper	Controlled Substances: Prescriptions	Chaptered, #4	Support	
AB 156	Voepel	Eye Care: Remote Assessment	Asm. B&P	2-Year Bill	
AB 241	Kamlager-Dove	Implicit Bias: Continuing Education: Requirements	Sen. Approps	Support	7/1/19
AB 370	Voepel	Physicians and Surgeons: Forms: Fee Limitations	Asm. Health	2-Year Bill	4/22/19
AB 387	Gabriel	Task Force: Adverse Drug Events: Prescriptions	Sen. Approps	Reco: Oppose	7/2/19
AB 407	Santiago	Fluoroscopy and Radiography Permit or Certification and Continuing Education: Exceptions	Sen. Approps	Neutral	7/1/19
AB 528	Low	Controlled Substances: CURES Database	Sen. Approps	Reco: Support if Amended	7/3/19
AB 544	Brough	Professions and Vocations: Inactive License Fees and Accrued and Unpaid Renewal Fees	Asm. Approps – Suspense – 2-Year	Oppose Unless Amended	3/21/19
AB 613	Low	Professions and Vocations: Regulatory Fees	Sen. B&P – 2-Year	Support	
AB 617	Mullin	Stem Cell and Regenerative Therapy Regulation Advisory Group	Asm. Approps – Suspense	2-Year Bill	5/1/19
AB 714	Wood	Opioid Prescription Drugs: Prescribers	Sen. 3 rd Reading	Support	6/17/19
AB 845	Maienschein	Continuing Education: Physicians: Maternal Mental Health	Sen. 3 rd Reading	Neutral	4/1/19
AB 888	Low	Opioid Prescriptions: Information: Non-Pharmacological Treatments for Pain	Sen. B&P – 2-Year	Support	4/11/19
AB 890	Wood	Nurse Practitioners: Scope of Practice: Unsupervised Practice	Asm. Approps – 2-Year	Oppose	4/22/19
AB 1030	Calderon and Petrie-Norris	Pelvic Examinations: Informational Pamphlet	Sen. Approps	Support	7/3/19

Agenda Item 9A

MEDICAL BOARD OF CALIFORNIA - 2019 TRACKER LIST July 24, 2019

BILL	AUTHOR	TITLE	STATUS	POSITION	AMENDED
AB 1038	Muratsuchi	Health Data: Rates for Health Care Services: Physicians	Asm. Health	2-Year Bill	4/3/19
AB 1264	Petrie-Norris	Medical Practice Act: Dangerous Drugs: Appropriate Prior Examination	Sen. 3 rd Reading	Reco: Neutral	6/25/19
AB 1444	Flora	Physicians and Registered Nurses: Loan Repayment Grants	Asm. Health	2-Year Bill	3/25/19
AB 1467	Salas and Low	Optometrists: Scope of Practice: Delegation of Services Agreement	Sen. B&P – 2-Year	Neutral	
AB 1468	McCarty and Gallagher	Opioid Prevention and Rehabilitation Act	Asm. 3 rd Reading	Support if Amended	5/8/19
AB 1490	Carrillo	Medical Assistants	Asm. B&P	2-Year Bill	
AB 1519	Low	Healing Arts	Sen. Approps	Reco: Support Provisions Relating to the Board	7/2/19
AB 1544	Gipson and Gloria	Community Paramedicine or Triage to Alternate Destination Act	Sen. Approps	Neutral	7/11/19
SB 53	Wilk	Open Meetings	Asm. Approps	Reco: Oppose Unless Amended	3/5/19
SB 159	Wiener	HIV: Preexposure and Postexposure Prophylaxis	Asm. B&P	Support if Amended	7/1/19
SB 201	Wiener	Medical Procedures: Treatment or Intervention: Sex Characteristics of a Minor	Sen. B&P	2-Year Bill	3/25/19
SB 276	Pan	Immunizations: Medical Exemptions	Asm. Approps - Suspense	Support in Concept	7/1/19
SB 377	McGuire	Juveniles: Psychotropic Medications: Medical Information	Asm. Approps	Support	6/27/19
SB 425	Hill	Health Care Practitioners: Licensee's File: Probationary Physician's Certificate: Unprofessional Conduct	Asm. Approps	Support	6/27/19

Agenda Item 9A

MEDICAL BOARD OF CALIFORNIA - 2019 TRACKER LIST July 24, 2019

BILL	AUTHOR	TITLE	STATUS	POSITION	AMENDED
	Archuleta	Radiologist Assistants	Sen. B&P	2-Year Bill	
SB 697	Caballero	Physician Assistants: Practice Agreement: Supervision	Asm. Approps	Support	7/11/19
SB 786	(B&P Comm.)	Healing Arts	Asm. Approps	Support Provisions Relating to the Board	6/25/19

BILL NUMBER: AUTHOR: BILL DATE: SUBJECT: SPONSOR: POSITION: AB 241 Kamlager-Dove July 1, 2019, Amended Implicit Bias: Continuing Education: Requirements Author Support

DESCRIPTION OF CURRENT LEGISLATION:

This bill would require continuing education courses for physicians, nurses, and physician assistants (PAs) to include the understanding of implicit bias.

BACKGROUND:

Existing law requires physicians and surgeons to complete at least 50 hours of approved CME during each two-year license renewal cycle. Currently, physicians and surgeons only have a mandatory one-time CME requirement of 12 hours in the subject of pain management and the treatment of the terminally ill or on the subject of the treatment and management of opiate-dependent patients. There is also a mandate in existing law that requires general internists and family physicians who have a patient population of which over 25 percent are 65 years of age or older to complete at least 20 percent of all mandatory CME in a course in the field of geriatric medicine or the care of older patients.

Existing CME courses approved by the Medical Board of California's (Board) Licensing Program include:

- Programs accredited by the Institute for Medical Quality/California Medical Association (IMQ/CMA), the American Medical Association (AMA), and the Accreditation Council for Continuing Medical Education (ACCME) that qualify for AMA PRA Category 1 Credit(s);
- Programs that qualify for prescribed credit from the American Academy of Family Physicians (AAFP); and
- Other programs offered by other organizations and institutions acceptable to the Board.

ANALYSIS:

This bill would make findings and declarations regarding implicit bias and its contribution to health disparities. This bill would include continuing education requirements for physicians, nurses, and PAs; however, this analysis will only include information on the requirements for physicians.

This bill would require, beginning January 1, 2022, all continuing medical education (CME) courses for physicians to contain curriculum that includes the understanding of implicit bias. This bill would specify that a CME course dedicated solely to research or other issues that does not have a direct patient care component or a course offered by a CME provider that is not located in California is not required to contain curriculum that includes implicit bias in the practice of medicine.

This bill would require associations that accredit CME courses to develop standards before January 1, 2022 for compliance with this bill. This bill would allow associations to update these standards, as needed, in conjunction with an advisory group established by the association that has the expertise in the understanding of implicit bias.

This bill would require CME courses to address at least one of a combination of the following in order to satisfy the requirements of this bill:

- Examples of how implicit bias affects perceptions and treatment decisions of physicians, leading to disparities in health outcomes.
- Strategies to address how unintended bias in decision making may contribute to health care disparities by shaping behavior and producing differences in medical treatment along lines of race, ethnicity, gender identity, sexual orientation, age, socioeconomic status, or other characteristics.

According to the author, California's medical community should be at the forefront to improve treatment and outcomes for patients who have been underserved by their health providers. The author believes this bill would reduce disparities in health care by requiring physicians and other health care practitioners to undergo implicit bias training as part of their already mandated CME.

The Board believes that implicit bias training is important and requires it for all of its employees and other individuals that are involved in the Board's enforcement process. Requiring CME for physicians to include information on implicit bias could help to reduce health disparities, which would further the Board's mission of consumer protection. As such, the Board has taken a support position on this bill.

FISCAL: None

SUPPORT: American Civil Liberties Union of California; American Federation of State, County, and Municipal Employees; Anti-Recidivism Coalition; APLA Health; California Black Health Network; California Black Women's Health Project; California Hawaii State Conference on the National Association for the Advancement of Colored People; California Immigrant Policy Center; California LGBTQ Health and Human Services Network; California Voices for Progress; California Health Executives Association; Courage Campaign; Disability Rights California; Emtrain; Equal Justice Society; Equality California; Fathers and Families of San Joaquin; HathawaySycamores; Legal Aid at Work; Maternal Mental Health NOW; Medical Board of California; National Center for Lesbian Rights; Perinatal Mental Health Care; Planned Parenthood Affiliates of California; San Francisco AIDS Foundation; San Mateo Adult School Federation of Teachers – CFT Local 4681; Santa Cruz County Community Coalition to Overcome Racism; United Domestic Workers/AFSCME Local 3930; Union of American Physicians and Dentists; and United Nurses Association of California/Union of Health Care Professionals

<u>OPPOSITION:</u> Board of Registered Nursing

ATTACHMENT: AB 241, as amended, Kamlager-Dove. Implicit bias: continuing education: requirements Version: 07/01/19 – Amended Senate

BILL NUMBER: AUTHOR: BILL DATE: SUBJECT: SPONSOR: AB 387 Gabriel July 2, 2019, Amended Task Force: Adverse Drug Events: Prescriptions Author

DESCRIPTION OF CURRENT LEGISLATION:

This bill would establish the Prescription Labeling and Adverse Drug Event Prevention Advisory Task Force (Task Force) for the purposes of developing information and making recommendations to the Medical Board of California (Board), the California Board of Pharmacy (BOP), and the Legislature on ways to increase adherence to prescription medication and decrease adverse drug events.

BACKGROUND:

Current law already requires a prescription label to include the condition or purpose for which the drug was prescribed, if requested by the patient, which is an "opt-in" system. This means that if a patient does not request a physician to include the medication's purpose on the prescription, a pharmacist is not required to include it on the prescription label.

According to the author, adverse drug events (ADEs) due to medications with similar names are common and estimated to be responsible for thousands of deaths and millions of dollars in costs every year. One study indicated that up to 25% of medication errors can be attributed to name confusion and 33% to packaging and labeling confusion. In addition to increasing hospital admissions, prolonging hospital stays, requiring additional clinical visits, and increasing risks of disability or death, ADEs are estimated to cost the healthcare system approximately \$50 billion annually.

ANALYSIS:

This bill would establish a Task Force until January 1, 2024, which must be composed of the following members:

- A representative from the Board.
- A representative from BOP.
- A representative with pharmacy or medical expertise appointed by the Governor's office.
- A representative from the California Department of Public Health.
- A representative with pharmacy or medical expertise appointed by the Senate Committee on Rules.

- A representative with pharmacy or medical expertise appointed by the Speaker of the Assembly.
- A representative from community pharmacies.
- A representative from retail pharmacies.
- A representative from a patient advocacy group.
- A representative from a physician organization.
- A representative from a family physician organization.

This bill would specify that the representatives from the Board and the BOP will serve as the chairs of the Task Force. This bill would specify that members of the Task Force shall not receive compensation or any other payment for their service on the Task Force. This bill would specify that all administrative expenses for the Task Force shall be absorbed by the Board and the BOP. This bill would allow the Task Force to receive funding pursuant to an appropriation in the Budget Act.

This bill would require the Task Force to develop information and make recommendations to the Board, the BOP, and the Legislature on ways to increase adherence to prescription medication and decrease ADEs. This bill would specify that the information developed by the Task Force shall include, but not be limited to, information on the following topics:

- The prevalence of patient opt-in.
- Prescriber and pharmacy compliance with existing BOP regulations that require prescription labels to include the condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.
- Barriers to increasing the number of patient opt-ins.
- A cost-benefit analysis of the benefits of increasing patient opt-ins versus the administrative burden caused by increased patient opt-ins.
- Prevalence of ADEs for varying demographics, including, but not limited to, race, age, gender, income, disabilities, and geographic location.
- Recommendations to improve the patient opt-in process, increase the prevalence of patient opt-in, and reduce the prevalence of ADEs.

This bill would require the Task Force to prepare and submit a report on its findings and recommendations to the Board, the BOP and the Legislature by September 1, 2020. This bill would require the Board and the BOP to adopt regulations to implement recommendations in the report that are within the jurisdiction of the relevant board if, in the independent determination of the board, the regulations will achieve the goals of improving the patient opt-in process, increasing the prevalence of patient opt-in, and reducing the prevalence of ADEs.

The Board previously had a support position on this bill when it changed existing law that requires a physician to include the purpose for a drug or device on the prescription label from an opt-in basis to an opt-out basis. However, this bill now requires a Task Force to meet, develop specified information, and make recommendations to the Board, the BOP, and the Legislature. This bill is unnecessary; a task force can be created without statute. Interested stakeholders could look into these issues now, as could the

Board and the BOP. It is also unlikely that recommendations could be implemented via regulations, as regulations only make law more specific, they cannot require something new that existing law does not already require. For these reasons, Board staff is recommending that the Board take an oppose position on this bill.

FISCAL:	This bill will result in increased workload and administrative expenses of the Task Force that must be absorbed by the Board and the BOP.
<u>SUPPORT:</u>	California Medical Association
OPPOSITION:	None on file.
POSITION:	Recommendation: Oppose
<u>ATTACHMENT:</u>	AB 387, as amended, Gabriel. Task force: adverse drug events: prescriptions. Version: 07/02/19 – Amended Senate

BILL NUMBER: AUTHOR: BILL DATE: SUBJECT:

SPONSOR:

POSITION:

AB 407 Santiago July 1, 2019, Amended Fluoroscopy and Radiography Permit or Certification and Continuing Education: Exceptions California Orthopaedic Association California Podiatric Medical Association Neutral

DESCRIPTION OF CURRENT LEGISLATION:

This bill would allow a physician or a doctor of podiatric medicine to provide fluoroscopy and radiography services and supervise radiologic technologists prior to receiving a fluoroscopy permit or certification if the physician or doctor of podiatric medicine has completed the radiation safety training provided by a facility accredited by the Centers for Medicare and Medicaid Services' (CMS) Conditions for Coverage relating to radiation safety.

BACKGROUND:

According to the Food and Drug Administration, fluoroscopy is a type of medical imaging that shows a continuous X-ray image on a monitor, much like an X-ray movie. During a fluoroscopy procedure, an X-ray beam is passed through the body. The image is transmitted to a monitor so that the movement of a body part or of an instrument or contrast agent ("X-ray dye") through the body can be seen in detail. Fluoroscopy is used in a wide variety of examinations and procedures to diagnose or treat patients.

To use fluoroscopy equipment in California, an individual must obtain either a radiologic technologist fluoroscopy permit, a fluoroscopy supervisor and operator permit, or a Physician Assistant's fluoroscopy permit. One of the requirements to obtain a permit is to pass an examination administered by the American Registry of Radiology Technologists (AART). A fluoroscopy supervisor and operator permit is also issued to a licensee of the healing arts defined as a licensed physician and surgeon, licensed podiatrist, or licensed chiropractor. To supervise a radiologic technologist in the operation of fluoroscopy equipment or to operate fluoroscopy equipment, a physician, podiatrist or chiropractor must pass the examination administered by AART. According to the California Department of Public Health, as of June 1, 2018, there are 8,771 physicians and podiatrists with current/valid fluoroscopy permits.

In order to participate in and receive federal payments from Medicare or Medicaid programs, a health care organization must meet the government requirements for program participation, including a certification of compliance with the health and safety

requirements, which are set forth in federal regulations. The certification is achieved based on either a survey conducted by a state agency on behalf of the federal government, such as CMS, or by a national accrediting organization, such as The Joint Commission, that has been recognized by CMS (through a process called "deeming") as having standards and a survey process that meet or exceed Medicare's requirements. As of January 1, 2019, all fluoroscopy operators working in facilities accredited by the Joint Commission are now required to undergo radiation safety training to maintain their privileges. This on-site training will be provided on an annual basis and surveyed by the accrediting agency, and, unless the law is changed, this will be in addition to the required examination.

ANALYSIS:

This bill would require a physician or doctor of podiatric medicine that has completed the radiation safety training provided by a facility accredited by CMS to submit evidence that they have completed the facility's radiation safety training to the California Department of Public Health (CDPH) within 60 days of completing the training. This bill would specify that the training shall serve in lieu of passing the Fluoroscopy X-ray Supervisor and Operator's permitting or certification test required by CDPH. This bill would specify that after receiving evidence that the radiation safety training is complete, CDPH shall issue the physician or doctor of podiatric medicine a Fluoroscopy X-ray Supervisor and Operator's permit or certification without requiring a permitting or certification examination.

This bill would specify that a physician or doctor of podiatric medicine, who works in a setting that is in compliance with CMS' Conditions for Coverage relating to radiation safety, satisfies the requirement for fluoroscopy and radiography continuing education.

According to the author, with the new radiation safety requirement in place, it makes sense that anyone undergoing training and deemed competent in radiation safety should not be withheld a fluoroscopy certification simply because they need to pass an additional test. These physicians should be able to perform fluoroscopy in any CMS accredited facility following compliance with CMS' radiation safety guidelines. The author believes it is time to update this archaic system and adopt new training requirements so that more providers are deployed to safely perform these procedures and treat patients.

Due to the new radiation safety training required in CMS certified facilities, it seems reasonable to no longer require physicians and doctors of podiatric medicine working in these facilities to pass the certification tests that are currently required in order to obtain a Fluoroscopy X-ray Supervisor and Operator's permit or certification. The Board has taken a neutral position on this bill.

FISCAL: None

<u>SUPPORT:</u>	California Orthopaedic Association (Co-Sponsor) California Podiatric Medical Association (Co-Sponsor) California Chapter, American College of Cardiology
<u>OPPOSITION:</u>	California Radiological Society California Society of Radiologic Technologists
<u>ATTACHMENT:</u>	AB 407, as amended, Santiago. Fluoroscopy and radiography permit or certification and continuing education: exceptions. Version: 07/01/19 – Amended Senate

BILL NUMBER: AUTHOR: BILL DATE: SUBJECT: SPONSOR: AB 528 Low July 3, 2019, Amended Controlled Substances: CURES Database Author

DESCRIPTION OF CURRENT LEGISLATION:

This bill would change the timeframe for dispensers to report dispensed prescriptions to the Controlled Substance Utilization Review and Evaluation System (CURES) from seven days to the following working day and would add Schedule V drugs to CURES. This bill would allow delegates to access information in CURES and allow a prescriber to check information obtained from the CURES database to meet existing mandates, instead of requiring the prescriber to check the CURES database, among other changes.

BACKGROUND:

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

Existing law requires prescribers to consult the CURES database to review a patient's controlled substance history before prescribing a Schedule II, III, or IV controlled substance to the patient for the first time and at least every four months thereafter if the controlled substance remains part of the patient's treatment, with specified exceptions. Existing law also allows an entity that operates a health information technology system to integrate with and submit queries to CURES, as specified.

According to the Centers for Disease Control and Prevention, drug overdose deaths continue to increase in the United States. Drug overdose deaths continue to increase in the United States. From 1999 to 2017, more than 700,000 people have died from a drug overdose. Around 68% of the more than 70,200 drug overdose deaths in 2017 involved an opioid. In 2017, the number of overdose deaths involving opioids (including prescription opioids and illegal opioids like heroin and illicitly manufactured fentanyl) was 6 times higher than in 1999. On average, 130 Americans die every day from an opioid overdose.

ANALYSIS:

This bill states that it is the intent of the Legislature that state laws regarding the operation and use of PDMPs continue to empower health care oriented technology solutions to the opioid crisis.

This bill would require dispensers to report prescription information to CURES within one working day after the date a controlled substance is dispensed and this bill would add Schedule V controlled substances to CURES.

This bill would allow delegates of prescribers and pharmacists to access controlled substances prescribing information in CURES. This bill would allow a licensed physician who does not hold a DEA registration to submit an application to register for CURES.

This bill would allow a prescriber to consult information from the patient activity report obtained from CURES in order to meet the requirements in existing law. This bill would change the time period in existing law where a prescriber has to check CURES from every four months after prescribing a Schedule II through IV controlled substance to every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment.

This bill would also add to the existing types of facilities that are exempted from having to check CURES if a prescriber furnishes a controlled substance to be administered to a patient in a facility or during a transfer between the facilities, another medical facility, including but not limited to, an office of a health care practitioner and an imaging center. This bill would also exempt health care practitioners from the requirement to check CURES if they administer, order or furnish a controlled substance to a patient as part of the patient's treatment for a radiotherapeutic or diagnostic procedure and the quantity does not exceed a non-refillable seven-day supply of the controlled substance in specified facilities, including, but not limited to, the office of a health care practitioner. This bill would exempt health care practitioners from the requirement to check CURES that are serving in the absence of the patient's physician if that practitioner orders a renewal request of a medically indicated controlled substance for an amount not exceeding the original prescription strength or amount or for more than one refill. This bill also includes other minor technical changes.

According to the author, PDMPs are recognized by experts as a powerful tool to combat the abuse and diversion of prescription drugs like opioids. Data reported to CURES provides health professionals, regulators, and law enforcement with critical information to promote safe prescribing and identify abuse.

The Board previously took a support position on this bill, however, this bill has been significantly amended. The Board has supported adding Schedule V drugs to CURES in the past and changing the time period that a physician has to check CURES from four months to six months seems reasonable. However, Board staff has concerns with allowing a delegate to access CURES and no longer requiring a prescriber to consult CURES, and instead allowing them to consult information obtained from CURES and documenting it in the patient's medical record. This would make the requirement to check CURES almost impossible to enforce. Board staff recognizes that the law does allow health information technology systems to integrate with CURES, but Board staff believes there should be some type of an auditing trail so the Board can ensure that physicians are checking CURES. In addition, providing an exemption for practitioners that are treating another physician's patient in their absence is not appropriate, as each physician needs to be responsible for patients they prescribe to, regardless of the reason they are seeing that patient, and that physician should still be required to check CURES.

Board staff recommends that the Board take a support if amended position on this bill. The amendments would be to allow the Board to enforce the requirement to check CURES, delegates should not be able to access information in CURES because if a delegate accesses the information, there would be no audit trail to show the physician checked CURES. If a prescriber's health information technology system is integrated with CURES, a read receipt should be required to be used and accepted by DOJ when data is queried on an automated basis by the health information technology system. A prescriber should only be allowed to consult information from the CURES database if their health information technology system is integrated with CURES, otherwise the prescriber should be consulting the CURES database directly. Lastly, all prescribers should be following the mandate to check CURES, even if they are serving in the absence of the patient's physician, so the provision that provides an exemption in this circumstance should be deleted.

- FISCAL: None
- <u>SUPPORT:</u> California Academy of Child and Adolescent Psychiatry; California Academy of Family Physicians; California Chapter of the American College of Emergency Physicians; California Chiropractic Association; California Medical Association; California Narcotic Officers' Association; California Radiological Society; California Pharmacists Association; California State Board of Pharmacy; California Veterinary Medical Association; County Behavioral Health Directors Association; and County of San Diego

OPPOSITION:	None on file
POSITION:	Recommendation: Support if Amended
ATTACHMENT:	AB 528, as amended, Low. Controlled substances: CURES database. Version: 07/03/19 – Amended Senate

BILL NUMBER: AUTHOR: BILL DATE: SUBJECT: SPONSOR: POSITION: AB 714 Wood June 17, 2019, Amended Opioid Prescription Drugs: Prescribers Author Support

DESCRIPTION OF CURRENT LEGISLATION:

This bill clarifies existing law that requires prescribers to offer a prescription for naloxone and provide education to a patient to specify that the requirements only apply when an opioid or benzodiazepine is prescribed and expressly exempts patients in inpatient facilities and hospice care.

BACKGROUND:

According to the Centers for Disease Control and Prevention, drug overdose deaths continue to increase in the United States. From 1999 to 2017, more than 700,000 people have died from a drug overdose. Around 68% of the more than 70,200 drug overdose deaths in 2017 involved an opioid. In 2017, the number of overdose deaths involving opioids (including prescription opioids and illegal opioids like heroin and illicitly manufactured fentanyl) was 6 times higher than in 1999. On average, 130 Americans die every day from an opioid overdose.

According to the author, this bill is a "clarifying" bill for AB 2760 (Wood, Chapter 324, Statutes of 2018). AB 2760 requires a prescriber to offer a prescription for naloxone or another drug approved by the U.S. Food and Drug Administration (FDA) for the complete or partial reversal of opioid depression, when: the prescription dosage for the patient is 90 or more morphine milligram equivalents of an opioid medication per day; or an opioid medication is prescribed concurrently with a prescription for a benzodiazepine; or the patient presents with an increased risk for overdose, including a patient history of overdose, a patient with a history of substance use disorder, or a patient at risk for returning to a high dose of opioid medication to which the patient is no longer tolerant. This bill also requires a prescriber, consistent with the existing standard of care, to provide education to a patient, or the patient's parent or guardian, or designee, on overdose prevention and the use of naloxone or other similar drug approved by the FDA.

Since the passage of AB 2760, the Board has received many calls from stakeholders raising questions regarding when a requirement to offer naloxone is required, specifically around the co-prescribing of a benzodiazepine and the increased risk for overdose, as the bill did not specify if it was related to opioid overdose. Concerns were

also raised regarding inpatient facilities and hospice care, as no exemption was included in AB 2760. The Board put together frequently asked questions and worked with the author's office to alert them of areas of concern in implementing AB 2760.

ANALYSIS:

This bill would define the term "administer" for purposes of this section of law to mean the direct application of a drug or device to the body of a patient by injection, inhalation, ingestion, or other means. This bill would define the term "order" for purposes of this section of law to mean an order entered on the chart or medical record of a patient registered in an inpatient health facility by or on the order of a prescriber. This bill would define "prescriber" for the purposes of this section of law to mean a person licensed, certified, registered, or otherwise subject to regulation or an initiative act, who is authorized to prescribe prescription drugs. This bill would specify that "prescriber" does not include a person licensed under the Veterinary Medicine Practice Act.

This bill would clarify the existing requirement for a prescriber to offer naloxone or other FDA approved drug for the complete or partial reversal of opioid-induced respiratory depression is only required when the prescriber is prescribing an opioid or benzodiazepine medication and one or more of the specified at-risk conditions are present. This bill would clarify that a concurrent prescription of an opioid medication and benzodiazepine means that the benzodiazepine medication was dispensed to the patient within the last year. This bill would clarify that the condition related to increased risk for overdose is related to an opioid overdose, not any kind of substance use overdose. This bill would clarify that the requirement to provide education on opioid prevention and the use of naloxone is required when a prescriber is prescribing an opioid or benzodiazepine medication. This bill would provide that a prescriber need not provide the education if the patient declines the education or has received the education within the past 24 months.

This bill would exempt prescribers from the requirements in AB 2760 when ordering medications to be administered to a patient while the patient is in an inpatient or outpatient setting and when prescribing medications to a terminally ill patient as defined in subdivision (c) of Section 11159.2 of the Health and Safety Code.

This bill includes an urgency clause and would take effect immediately upon signature.

This bill is needed to clarify the law that was enacted pursuant to AB 2760. The Board received many calls from stakeholders with implementation concerns. This bill addresses those concerns and will provide clarity, which will help the Board enforce these requirements. The Board has taken a support position on this bill.

FISCAL: None

<u>SUPPORT:</u> California Association for Health Services at Home; California Chronic Care Association; California Dental Association; California

Hospital Association/California Association of Hospitals and Health Systems; California Pharmacists Association; California Society of Health System Pharmacists; Medical Board of California; and Providence St. Joseph

- <u>OPPOSITION:</u> California Academy of Family Physicians
- ATTACHMENT: AB 714, as amended, Wood. Opioid prescription drugs: prescribers. Version: 06/17/19 – Amended Senate

BILL NUMBER: AUTHOR: BILL DATE: SUBJECT:

SPONSOR: POSITION: AB 845 Maienschein April 1, 2019, Amended Continuing Education: Physicians and Surgeons: Maternal Mental Health Maternal Mental Health NOW and 2020 Mom Neutral

DESCRIPTION OF CURRENT LEGISLATION:

This bill would allow for an optional continuing medical education (CME) course in maternal mental health.

BACKGROUND:

Existing law requires physicians and surgeons to complete at least 50 hours of approved CME during each two-year license renewal cycle. Currently, physicians and surgeons only have a mandatory one-time CME requirement of 12 hours in the subject of pain management and the treatment of the terminally ill or on the subject of the treatment and management of opiate-dependent patients. There is also a mandate in existing law that requires general internists and family physicians who have a patient population of which over 25 percent are 65 years of age or older to complete at least 20 percent of all mandatory CME in a course in the field of geriatric medicine or the care of older patients.

Existing CME courses approved by the Medical Board of California's (Board) Licensing Program include:

- Programs accredited by the Institute for Medical Quality/California Medical Association (IMQ/CMA), the American Medical Association (AMA), and the Accreditation Council for Continuing Medical Education (ACCME) that qualify for AMA PRA Category 1 Credit(s);
- Programs that qualify for prescribed credit from the American Academy of Family Physicians (AAFP); and
- Other programs offered by other organizations and institutions acceptable to the Board.

ANALYSIS:

This bill would require the Board, when determining CME requirements, to consider including a course in maternal mental health, which must address the following:

• Best practices in screening for maternal mental health disorders, including cultural competency and unintended bias as a means to build trust with mothers.

- The range of maternal mental health disorders.
- The range of evidence-based treatment options, including the importance of allowing a mother to be involved in developing the treatment plan.
- When an obstetrician or a primary care doctor should consult with a psychiatrist versus making a referral.
- Applicable requirements under Sections 123640 and 123616.5 of the Health and Safety Code.

Although the Board has historically opposed mandated CME, this bill would not mandate particular CME for physicians. This bill only requires the Board to consider a course on maternal mental health. If the Board decides that it is important to get out information to physicians on this particular type of CME to encourage attendance in these types of CME courses, it could include an article in its Newsletter or put information out on the Board's website. The Board has taken a neutral position on this bill.

FISCAL:	None
<u>SUPPORT:</u>	Maternal Mental Health NOW (Co-Sponsor); 2020 Mom (Co- Sponsor); County Behavioral Health Directors Association of California; and Depression and Bipolar Support Alliance
OPPOSITION:	None on file
ATTACHMENT:	AB 845, as amended, Maienschein. Continuing education: physicians and surgeons: maternal mental health. Version: 04/01/19 – Amended Assembly

BILL NUMBER: AUTHOR: BILL DATE: SUBJECT: SPONSOR: POSITION: AB 1030 Calderon and Petrie-Norris July 3, 2019, Amended Pelvic Examinations: Informational Pamphlet Author Support

DESCRIPTION OF CURRENT LEGISLATION:

This bill would require the Medical Board of California (Board), on or before July 1, 2020, in coordination with the American College of Obstetricians and Gynecologists (ACOG), the California Medical Association (CMA), and the California Academy of Family Physicians (CAFP) to develop an informational pamphlet for patients undergoing pelvic examinations.

BACKGROUND:

Existing law requires a physician primarily responsible for providing a patient an annual gynecological examination to provide, during the annual examination, a standardized summary containing a description of the symptoms and appropriate methods of diagnoses for gynecological cancers. This information is required to be provided in a layperson's language and in a language understood by the patient. Existing law allows these requirements to be met using existing publications or pamphlets developed by nationally recognized cancer organizations or by the State Department of Health Care Services. Existing law authorizes an administrative fine upon the second and subsequent complaints against a physician who fails to provide the pamphlet.

According to the Assembly Health Committee analysis, many organizations, including the Centers for Disease Control, Planned Parenthood, and ACOG, have developed informational brochures or provide information on their website regarding what to expect during a first gynecologic visit. ACOG's teen-specific information answers the following questions:

- When should I have my first gynecologic visit?
- Is it normal to be nervous before the first visit?
- What should I expect at the first gynecologic visit?
- What exams are performed?
- What happens during a general physical exam?
- What happens during an external genital exam?
- What are the pelvic exam and Pap test?
- What are vaccinations?
- What special concerns can be discussed with my ob-gyn? and,

• What can I do to stay healthy?

The ACOG document also provides a glossary of terms, and includes information that the physician should be wearing gloves. The only information required by this bill, that is not already included on the ACOG document, is the information regarding privacy expectations and the telephone number for the Board.

ANALYSIS:

This bill would require the informational pamphlet for patients undergoing pelvic examinations to include, but not be limited to, all of the following:

- What a pelvic exam is and how it is properly performed.
- If applicable, a description of other relevant exams.
- Privacy expectations, including that privacy should be provided for the patient both when undressing and dressing and that a gown or drape should be provided.
- An explanation of what a speculum is and how it should be properly used during an examination.
- That gloves should be worn by the licensee during the examination.
- A telephone number for the Board at which a patient may report any misconduct that the patient feels may have occurred.

This bill would define a "licensee" for purposes of this bill as a person licensed, certified, registered, or otherwise subject to regulation, who, acting within the scope of their practice in accordance with standardized protocols where they exist and in conformity with the standard of care for their profession, is authorized to perform pelvic examinations.

This bill would require the informational pamphlet to be made available for use by licensees performing pelvic examinations. The informational pamphlet must either be posted as a printable file on the Board's website or made available for order as a printed deliverable on the Board's website, or both. This bill would require the pamphlet to be written in layperson's language and be made available in both English and Spanish.

This bill would require a licensee to provide a patient the informational pamphlet before the patient's first pelvic examination. This bill would require the licensee to obtain a signed acknowledgement of receipt from the patient, which must be maintained in the patient's medical record.

This bill would specify that a licensee who violates the requirements in this bill may be cited and assessed an administrative fine by the appropriate licensing board. This bill would specify that a citation shall not be issued and a fine shall not be assessed upon the first complaint. Upon the second and subsequent complaints a citation may be issued and an administrative fine may be assessed. This bill would specify that all fines collected shall be credited to the contingent fund of the Board, to be used by the Office of Women's Health within the California Department of Public Health for outreach

services that provide information to women about gynecological cancers, but shall not be expended until they are appropriated by the Legislature in the Budget Act or another statute.

This bill would specify that it will not become operative until one month after the Board makes the informational pamphlet available on its website.

According to the author, this bill will empower patients by giving them much needed information. The author states this bill will ensure that female patients receive the information they need in order to identify, and hopefully prevent, instances of severe misconduct. The author notes that this bill requires the Board and ACOG to develop an informational pamphlet for patients undergoing a gynecological pelvic examination, with basic information regarding how the procedure should be properly performed, privacy and sanitary expectations, and contact information in order to report any instances of misconduct.

ACOG already has information for teens that addresses most of the requirements in this bill. This bill would require physicians to give information on pelvic examinations to patients, which will help to protect consumers by providing them information on a proper examination. This may help to prevent sexual misconduct and ensure that instances of misconduct are reported to the Board, as such, the Board has taken a support position on this bill.

- FISCAL: Minor and absorbable.
- <u>SUPPORT:</u> California Health Coalition Advocacy Consumer Attorneys of California Medical Board of California
- <u>OPPOSITION:</u> ACOG District IX California Academy of Family Physicians California Medical Association One individual, a former patient of Dr. Tyndall
- ATTACHMENT: AB 1030, as amended, Calderon and Petrie-Norris. Pelvic examinations: informational pamphlet. Version: 07/03/19 – Amended Senate

BILL NUMBER: AUTHOR: BILL DATE: SUBJECT: AB 1264 Petrie-Norris June 25, 2019, Amended Medical Practice Act: Dangerous Drugs: Appropriate Prior Examination Planned Parenthood Affiliates of California

SPONSOR:

DESCRIPTION OF CURRENT LEGISLATION:

This bill would clarify that the requirement to provide an "appropriate prior examination" before prescribing, dispensing, or furnishing dangerous drugs does not require a real time interaction between the patient and the licensee.

BACKGROUND:

Existing law authorizes a physician, registered nurse, certified nurse-midwife, nurse practitioner, physician assistant, or pharmacist to, within their respective scope of practice, use a self-screening tool to identify patient risk factors for the use of self-administered hormonal contraceptives by a patient. Existing law allows the self-administered hormonal contraceptives to be prescribed, furnished, or dispensed to the patient after an appropriate prior examination.

Existing law defines "synchronous interaction" as a real-time interaction between a patient and a health care provider located at a distant site.

Telehealth is seen as a tool in medical practice, not a separate form of medicine. There are no legal prohibitions to using technology in the practice of medicine, as long as the practice is done by a California licensed physician. The standard of care is the same whether the patient is seen in-person, through telehealth or other methods of electronically enabled health care. Physicians need not reside in California, as long as they have a valid, current California license.

ANALYSIS:

This bill would expressly clarify that the requirement to provide an "appropriate prior examination" before prescribing, dispensing, or furnishing dangerous drugs does not require a synchronous interaction between a patient and the licensee and can be achieved through the use of telehealth, including, but not limited to, a self-screening tool or a questionnaire, provided that the licensee complies with the appropriate standard of care. This bill would include an urgency clause and would become effective immediately upon signature.

According to the author, this bill provides needed clarification around certain types of asynchronous care. Today, in order to access birth control on Planned Parenthood Direct, a patient must answer a health questionnaire, self-report their blood pressure, and schedule a video chat before submitting their request for contraceptives. This is because of an interpretation that using telehealth to meet the requirement for an "appropriate prior examination" to occur after the use of the self-screening tool, it must involve a synchronous interaction between the patient and the heath care practitioner. According to the author, clarifying the ability for birth control to be prescribed via teleconference without a video chat will expand access and address the unmet needs for birth control in California.

The Board does not interpret an appropriate prior examination to require a real-time interaction between a physician and a patient. It depends on the circumstances of each specific patient and their medical history for a physician to determine what is an appropriate prior examination, pursuant to the standard of care. This bill does specifically require the licensee to comply with the appropriate standard of care. As such, this bill is clarifying in nature and Board staff recommends that the Board again take a neutral position on this bill.

- FISCAL: None
- <u>SUPPORT:</u> Planned Parenthood Affiliates of California (Sponsor) California Society of Health-System Pharmacists NARAL Pro-Choice California
- OPPOSITION: None on File
- POSITION: Recommendation: Neutral

ATTACHMENT: AB 1264, as amended, Petrie-Norris. Medical Practice Act: dangerous drugs: appropriate prior examination. Version: 06/25/19 – Amended Senate

BILL NUMBER: AUTHOR: BILL DATE: SUBJECT: SPONSOR: POSITION: AB 1468 McCarty and Gallagher May 8, 2019, Amended Opioid Prevention and Rehabilitation Act Author Support if Amended

DESCRIPTION OF CURRENT LEGISLATION:

This bill would establish the Opioid Prevention and Rehabilitation Act (OPRA), which would be funded by manufacturers and wholesalers of opioid drugs and would become inoperative on July 1, 2027 and be repealed as of January 1, 2028.

BACKGROUND:

According to the Centers for Disease Control and Prevention, drug overdose deaths continue to increase in the United States. From 1999 to 2017, more than 700,000 people have died from a drug overdose. Around 68% of the more than 70,200 drug overdose deaths in 2017 involved an opioid. In 2017, the number of overdose deaths involving opioids (including prescription opioids and illegal opioids like heroin and illicitly manufactured fentanyl) was 6 times higher than in 1999. On average, 130 Americans die every day from an opioid overdose.

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

ANALYSIS:

This bill would define several terms for the purpose of OPRA. This bill would define "department" as the California Department of Public Health (CDPH). This bill would define "opioid stewardship payment" as the total amount to be paid into the Opioid Prevention and Rehabilitation Program Fund (Fund) for each fiscal year. This bill would define "ratable share" as the individual portion of the opioid stewardship payment to be paid by each manufacturer or wholesaler that is subject to this bill. This bill would define "opioid" as an opiate or any synthetic or semisynthetic narcotic that has opiate-like activities but is not derived from opium and has effects similar to natural opium alkaloids, and any derivatives thereof. This bill would define "opiate" as the dried, condensed juice of a poppy, Papaver somniferum that has a narcotic, soporific, analgesic, and astringent effect. This bill would define "distribute" or "distribution" as the delivery for sale of an opioid drug other than by administering or dispensing to the ultimate user, including intracompany transfers between any division, affiliate, subsidiary, parent, or other entity under complete common ownership and control.

This bill would require, beginning with the 2021-22 fiscal year and for each fiscal year thereafter, a manufacturer or wholesaler that sells or distributes opioid drugs in California to submit to CDPH a report that details all opioid drugs sold or distributed in California during the preceding fiscal year. This bill would require the report to include the following:

- The name, address, telephone number, federal Drug Enforcement Agency (DEA) registration number, and license number of the manufacturer or wholesaler, as applicable.
- The name, address, and DEA registration number of the entity to which the opioid drug was sold or distributed.
- The date of the sale or distribution of the opioid drug.
- The gross receipt total, in dollars, of all opioid drugs sold or distributed.
- The name and National Drug Code (NDC) of the opioid drug sold or distributed.
- The number of containers and the strength and metric quality of controlled substances in each container of the opioid drug sold or distributed.
- The total number of morphine milligram equivalents (MMEs) attributed to the opioid drugs sold or distributed. MMEs shall be determined pursuant to a formulation that is issued by CDPH and updated as CDPH deems necessary to determine the ratable share.
- Any other elements relating to the sale or distribution of the opioid drug, as CDPH deems necessary to determine the ratable share.

Beginning with the 2021–22 fiscal year, and for each fiscal year thereafter, this bill would require CDPH, in consultation with the California State Board of Pharmacy, to calculate the ratable share of a manufacturer or wholesaler, according to all of the following steps:

• The total number of MMEs attributed to opioid drugs sold or distributed in this state by the manufacturer or wholesaler for the preceding fiscal year, divided by the total number of MMEs attributed to opioid drugs sold or distributed in

California by all manufacturers and wholesalers for the preceding fiscal year, in order to determine the payment percentage for the manufacturer or wholesaler.

- The payment percentage shall be multiplied by the opioid stewardship payment.
- The product of the above-described calculation would be the manufacturer's or wholesaler's ratable share.

For purposes of the calculation of the ratable share, the total number of MMEs attributed to opioid drugs sold or distributed by a manufacturer or wholesaler shall not include the number of MMEs attributed to opioid drugs that are manufactured in this state but the final point of delivery or sale is outside this state or the number of MMEs attributed to buprenorphine, methadone, or morphine.

For purposes of the calculation of the ratable share, opioid drugs sold or distributed in California shall not be double-counted. The total number of MMEs attributed to opioid drugs sold or distributed by a wholesaler shall not include the number of MMEs attributed to opioid drugs that a manufacturer has sold or distributed in California. Those opioid drugs shall be counted only for the calculation of the manufacturer's ratable share.

This bill would require CDPH to notify the manufacturer or wholesaler, in writing, of the value of the ratable share for that manufacturer or wholesaler. In any fiscal year that CDPH determines that a manufacturer or wholesaler failed to report information required by this bill, CDPH shall estimate, based on available data, the number of MMEs attributed to opioid drugs sold or distributed by that manufacturer or wholesaler. The other manufacturers and wholesalers complying with the requirements in this bill would receive a decreased assessment of their corresponding ratable share in the following fiscal year, with the decrease equaling the amount that was overpaid by that compliant manufacturer or wholesaler in the current fiscal year.

This bill would allow the manufacturer or wholesaler to have the opportunity to appeal the ratable share determination by submitting information to CDPH explaining why the ratable share determined pursuant to this section is erroneous or otherwise not warranted.

Beginning with the 2021–22 fiscal year, and for each fiscal year thereafter, a manufacturer or a wholesaler subject to the requirements in this bill would be required to make quarterly payments to CDPH, of the manufacturer's or wholesaler's corresponding ratable share of the opioid stewardship payment.

This bill would specify that all ratable share payments, minus refunds and the CDPH's administrative costs, would be deposited quarterly into the Fund. This bill would specify that the opioid stewardship payment shall be equal to fifty million dollars (\$50,000,000) for each fiscal year, which shall be the amount used to calculate the ratable share for a manufacturer or wholesaler. This bill would specify that if the total number of MMEs attributed to opioid drugs sold or distributed in California by all manufacturers and wholesalers subject to this bill during the 2021-22 fiscal year, or any fiscal year

thereafter, is smaller than the total number of MMEs attributed to opioid drugs sold or distributed in California by all manufacturers and wholesalers subject to this bill during the 2020-21 fiscal year, the opioid stewardship payment shall be reduced from fifty million dollars (\$50,000,000) by a percentage equal to the percentage of that reduction in the total number of MMEs. This bill would specify that the combined sum of ratable share payments by manufacturers and wholesalers may be less than the amount of the opioid stewardship payment in a fiscal year, if CDPH makes adjustments to the ratable share of a manufacturer or wholesaler.

This bill would specify that a manufacturer or wholesaler that fails to comply with the reporting requirements in this bill would be subject to a civil penalty not exceeding five hundred dollars (\$500) per calendar day. This bill would specify that a manufacturer or wholesaler that fails to make a ratable share quarterly payment pursuant to this bill would be subject to a civil penalty of not less than 10 percent of, and not greater than 300 percent of, the ratable share quarterly payment that is due. This bill would specify that any penalties collected pursuant to this bill shall be deposited in the Fund.

This bill would create the Fund in the State Treasury. This bill would specify that all moneys in the fund are continuously appropriated to CDPH to carry out the requirements in this bill. This bill would require CDPH to distribute moneys in the Fund to counties or local non-profit community-based organizations, including, but not limited to, community clinics, on an annual basis for purposes of opioid prevention and rehabilitation programs, based on applications submitted by those counties or organizations that elect to participate. This bill would specify that distribution of moneys in the Fund to counties or local non-profit community-based organizations would be based on county needs, using the most recent data of the following information, as provided by CDPH:

- The ratio of opioid overdose deaths per county population.
- The ratio of opioid overdose emergency department visits per county population.
- The ratio of opioid overdose hospitalizations per county population.

According to the author, the opioid epidemic is an ongoing and growing problem that desperately needs assistance for both prevention and treatment. The Fund will generate an important, on-going source of funding for prevention and treatment centers in order to save lives. The money collected will be distributed based on need and population. Dealing with the opioid epidemic requires a holistic approach and participation from all involved parties, including the drug manufacturers and wholesalers.

The growing opioid abuse epidemic remains a matter of concern for the Board and it is a priority for the Board to help prevent inappropriate prescribing and misuse and abuse of opioids. This bill will impose fees on manufacturers and wholesalers of opioid drugs, based on the amount of opioid drugs they sold and distributed, which seems to be a reasonable funding source to contribute to the growing opioid abuse epidemic. This bill will help collect funding for opioid prevention and rehabilitation programs, which is much needed in California. The Board took a support if amended position on this bill and requested an amendment to ensure that the fees are not passed on to consumers. However, Board staff was informed by the author's office that the reason they cannot include language to ensure that fees are not passed on to consumers is because New York had a similar bill that included that language and it was found unconstitutional, as it would have protected consumers in one state from the tax, but not citizens in other states. With this information, Board staff recommends that the Board change its position to support.

FISCAL:	None
<u>SUPPORT:</u>	County Behavioral Health Directors Association California Health+ Advocates County Health Executives Association of California
<u>OPPOSITION:</u>	Association for Accessible Medicines.; Biocom; California Chronic Care Coalition; California Dental Association; California Hospice & Palliative Care Association; California Society of Health-System Pharmacists; and Healthcare Distribution Alliance
POSITION:	Recommendation: Support
ATTACHMENT:	AB 1468, as amended, McCarty and Gallagher. Opioid Prevention and Rehabilitation Act.
	Version: 05/08/19 – Amended Assembly

BILL NUMBER: AUTHOR: BILL DATE: SUBJECT: SPONSOR: AB 1519 Low July 2, 2019, Amended Healing Arts Author

DESCRIPTION OF CURRENT LEGISLATION:

This bill would clarify that oral and maxillofacial surgery residency programs accredited by the Commission on Dental Accreditation (CODA) count toward the 36 months of required Board-approved postgraduate training. This bill would also specify that all laws and regulations that apply to a health care provider also apply while providing telehealth services.

BACKGROUND:

SB 798 (Hill, Chapter 775, Statutes of 2017), the Medical Board of California's (Board) sunset bill, made revisions to the postgraduate training/licensing requirements effective January 1, 2020. Among other changes, the law modified the minimum requirements for postgraduate training to require successful completion of thirty-six months of board-approved postgraduate training for all applicants, regardless of whether the medical school attended was domestic or international.

SB 798 did include language to specify that an applicant who has completed at least 36 months of board-approved postgraduate training, not less than 24 months of which was completed as a resident after receiving a medical degree from a combined dental and medical degree program accredited by CODA)or approved by the board, is eligible for licensure.

ANALYSIS:

This bill is the sunset bill for the Dental Board of California. This analysis will only cover the provisions in the bill that impact the Board.

This bill would specify that oral and maxillofacial surgery residency programs accredited by CODA shall be approved as postgraduate training required for licensure if the applicant attended the program as part of the combined dental and medical degree program accredited by CODA. This bill would specify that these programs do not have to comply with the requirement that the postgraduate training must include four months of general medicine.

This bill would also specify in the telehealth section of law that all laws and regulations governing professional responsibility, unprofessional conduct, and standards of practice

that apply to a health care provider under the health care provider's license shall apply to that health care provider while providing telehealth services.

After SB 798 (Hill, Chapter 775, Statutes of 2017) was signed into law, the Board received concerns from oral and maxillofacial surgery residency programs that they could not meet the general medicine requirement and that the language in the bill wasn't clear enough to ensure that individuals in these residency programs would be eligible for licensure. This bill will make it clear that oral and maxillofacial residency programs accredited by CODA count toward the 36 months of Board-approved postgraduate training, which will address the concerns raised. Board staff recommends that the Board support the provisions in this bill relating to the Board.

- FISCAL: None
- SUPPORT: California Dental Association Center for Public Interest Law Dental Hygiene Board of California
- OPPOSITION: None on file

<u>POSITION:</u> Recommendation: Support Provisions Relating to the Board

ATTACHMENT: AB 1519, as amended, Low. Healing arts. Version: 07/02/19 – Amended Senate

BILL NUMBER: AUTHOR: BILL DATE: SUBJECT:

SPONSOR:

POSITION:

AB 1544 Gipson and Gloria July 11, 2019, Amended Community Paramedicine or Triage to Alternate Destination Act California Chapter of American College of Emergency Physicians and California Professional Firefighters Neutral

DESCRIPTION OF CURRENT LEGISLATION:

This bill would establish the Community Paramedicine or Triage to Alternate Destination Act of 2020 to establish state guidelines to govern the implementation of community paramedicine programs (CPPs) or triage to alternate destination programs (TADPs) by local emergency medical service agencies (LEMSAs) in California. The provisions in this bill would sunset on January 1, 2030.

BACKGROUND:

Under existing law, a paramedic is limited to providing care in emergency situations, during ambulance transports, and while working in a hospital. Beginning in late 2014, thirteen CPP pilot projects began in California, testing six concepts as part of the Health Workforce Pilot Project (HWPP) #173. These HWPP pilot projects were coordinated through the Office of Statewide Health Planning and Development (OSHPD).

ANALYSIS:

This bill would authorize a LEMSA within a county to elect to develop a CPP or TADP. A LEMSA that elects to develop a CPP or TADP is required to do the following:

- Integrate the proposed CPP or TADP into the LEMSA's emergency medical services plan.
- Develop a process to select community paramedicine providers or triage to alternate destination providers, to provide the services authorized by this bill.
- Facilitate any necessary agreements with one or more community paramedicine or triage to alternate destination providers for the delivery of community paramedicine or triage to alternate destination services within the LEMSA's jurisdiction that are consistent with the proposed CPP or TADP. The LEMSA must provide medical control and oversight of the program.
- The LEMSA shall not include the provision of CPP specialties or TADP specialties as part of an existing or proposed contract for the delivery of emergency medical transport services.

- Coordinate, review, and approve any agreements necessary for the provision of community paramedicine specialties or triage to alternate destination services consistent with all of the following:
 - Provide a first right of refusal to the public agency or agencies within the jurisdiction of the proposed program area to provide the proposed program specialties. If the public agency or agencies agree to provide the proposed program specialties, the LEMSA shall review and approve any written agreements necessary to implement the program with those public agencies.
 - Review and approve agreements with community paramedicine triage to alternate destination providers that partner with a private provider to deliver those program specialties.
 - If a public agency declines to provide the proposed program specialties, the LEMSA shall develop a process to select community paramedicine or triage to alternate destination providers to deliver the program specialties.
- Facilitate necessary agreements between the TADP provider and the existing emergency medical transport provider to ensure transport to the appropriate facility.
- At the discretion of the local medical director, develop additional triage and assessment protocols commensurate with the need of the local programs authorized under this act.
- Prohibit triage and assessment protocols or a triage paramedic's decision to authorize transport to an alternate destination facility from being based on, or affected by, a patient's ethnicity, citizenship, age, preexisting medical condition, insurance status, economic status, ability to pay for medical services, or any other characteristic listed in existing law, except to the extent that a circumstance such as age, sex, preexisting medical condition, or physical or mental disability is medically significant to the provision of appropriate medical care to the patient.
- Certify and provide documentation and periodic updates to the Emergency Medical Services Authority (EMSA) showing that the alternate destination facility authorized to receive patients maintains adequate licensed medical and professional staff, facilities, and equipment that comply with the requirements of the EMSA's regulations and the provisions of this chapter.
- Secure an agreement with the alternate destination facility that requires the facility to notify the LEMSA within 24 hours if there are changes in the status of the facility with respect to protocols and the facility's ability to care for patients.
- Secure an agreement with the alternate destination that requires the facility to operate in accordance with existing law regarding emergency services and care. The agreement shall provide that failure to operate in accordance with this existing law will result in the immediate termination of use of the facility as part of the triage to alternate destination facility.
- In implementing a TADP, the LEMSA shall continue to use, and coordinate with, any emergency medical transport providers operating within the jurisdiction of the LEMSA. The LEMSA must not in any manner eliminate or reduce the services of the emergency medical transport providers.

- Establish a process to verify training and accreditation of community paramedics in each of the proposed CPP specialties.
- Establish a process for training and accreditation of triage paramedics in each of the proposed TADP specialties.
- Facilitate funding discussions between a CPP, TADP, or incumbent emergency medical transport provider and public or private health system participants to support the implementation of the LEMSA's CPP or TADP.

If a LEMSA elects to develop a CPP or TADP program, the county board of supervisors would be required to establish an emergency medical care committee (EMCC) that would be required to include the following members:

- One emergency medicine physician who is board certified or board eligible and practicing at an emergency department within the LEMSA's jurisdiction
- One registered nurse practicing within the LEMSA's jurisdiction.
- One licensed paramedic practicing in the LEMSA's jurisdiction. Whenever possible, the paramedic should be employed by a public agency.
- One acute care hospital representative with an emergency department operating within the LEMSA's jurisdiction.
- If the LEMSA elects to implement a TADP to a sobering center, one individual with expertise in substance use disorder detoxification and recovery.
- Additional advisory members in the fields of public health, social work, hospice, or mental health practicing within the jurisdiction of the LEMSA with expertise commensurate with the program specialty or specialties that the LEMSA proposes to adopt.

The EMCC would advise the LEMSA on the development of the program and other matters relating to emergency medical services. Where a committee is already established, the county board of supervisors or the mayor, as appropriate, must ensure that the membership meets the requirements in this bill.

This bill would state the intent of the Legislature to establish state guidelines to govern the implementation of CPPs or TADPs by LEMSAs in California and would state the intent and purpose of CPPs and TADPs.

This bill would require EMSA to review a LEMSA's proposed CPP or TADP and review the LEMSA's program protocols to ensure compliance with the statewide minimum protocols. This bill would allow EMSA to impose conditions as part of the approval of the CPP or TADP. This bill would require EMSA to approve, approve with conditions, or deny the proposed CPP or TADP no later than six months after it is submitted by the LEMSA.

This bill would define a community paramedic as a paramedic who is in good standing and who has completed the curriculum for community paramedic training, has received certification in one or more of the CPP specialties, and is certified and accredited to provide community paramedic services by a LEMSA as part of an approved CPP. This bill would define a CPP as a program developed by a LEMSA and approved by EMSA to provide community paramedicine services consisting of: providing directly observed therapy to persons with tuberculosis in collaboration with a public health agency to ensure effective treatment of the tuberculosis and to prevent spread of the disease; and providing case management services to frequent emergency medical services users in collaboration with, and by providing referral to, existing appropriate community resources.

This bill would define a TADP as a program developed by a LEMSA and approved by EMSA to provide triage paramedic assessments operating under triage and assessment protocols developed by the LEMSA that are consistent with the minimum triage and assessment protocols established by EMSA. Triage paramedic assessments may consist of: providing care and comfort services to hospice patient in their homes in response to 911 calls by providing for the patient's and the family's immediate care needs, including grief support in collaboration with the patient's hospice agency until the hospice nurse arrives to treat the patient; and providing patients with advanced life support triage and assessment by a triage paramedic and transportation to an alternate destination facility.

This bill would require EMSA to develop regulations that establish minimum standards for the development of a CPP or TADP. This bill would require the Commission on Emergency Medical Services (Commission) to review and approve the regulations. This bill would add the following members to the existing Commission: one physician specializing in the comprehensive care of individuals with co-occurring mental health or psychosocial and substance use disorders appointed by the Governor in consultation with the California Psychiatric Association and the California Society of Addiction Medicine; and one licensed clinical social worker appointed by the Governor in consultation with the California State Council of the Service Employees International Union and the California Chapter of the National Association of Social Workers.

This bill would require the regulations for CPPs and TADPs to be based upon, and informed by, the Community Paramedicine Pilot Program under HWPP #173 and the protocols and operation of the pilot projects approved. This bill would require the regulations that establish the minimum standards for CPPs and TADPs to consist of all of the following:

- Minimum standards and curriculum for each program specialty for CPPs.
- Minimum standards and curriculum for each program specialty for TADPs.
- A process for verifying on a paramedic's license the successful completion of the required training.
- Minimum standards for approval, review, withdrawal, and revocation of a CPP or TADP. Those standards shall include, but not be limited to, both of the following:
 - A requirement that facilities participating in the program accommodate privately or commercially insured, Medi-Cal, Medicare, and uninsured patients.

- Immediate termination of participation in the program by the alternate destination facility or CPP or TADP if it fails to operate in accordance with existing law regarding emergency services and care.
- Minimum standards for collecting and submitting data to EMSA to ensure patient safety that include consideration of both quality assurance and quality improvement. These standards shall include, but not be limited to, all of the following:
 - Intervals for CPPs or TADPs, participating health facilities, and LEMSAs to submit community paramedicine services data.
 - Relevant program use data and the online posting of program analyses.
 - Exchange of electronic patient health information between CPP or TADP providers and facilities. EMSA may grant a one-time temporary waiver, not to exceed five years, of this requirement for alternate destination facilities that are unable to immediately comply with the electronic patient health information requirement.
 - Emergency medical response system feedback, including feedback from the EMCC.
 - If the TADP utilizes an alternate destination facility, consideration of ambulance patient offload times for the alternate destination facility, the number of patients that are turned away, diverted, or required to be subsequently transferred to an emergency department, and identification of the reasons for turning away, diverting, or transferring the patient.
 - A process to assess of each CPP or TADP's medical protocols or other processes.
 - A process to assess the impact that implementation of a CPP or TADP has on the delivery of emergency medical services, including the impact on response times in the local EMS agency's jurisdiction.

This bill would specify that a community paramedicine pilot program approved under OSHPD's HWPP # 173 before January 1, 2020, is authorized to operate until one year after the above-described regulations become effective. This bill would specify that a community paramedicine short-term, post-discharge follow-up pilot program that was approved on or before January 1, 2019, under OSHPD's HWPP #173, and was continuing to enroll patients as of January 1, 2019, may continue operation until January 1, 2023. EMSA must seek federal funding or funding from private sources to support the continued operation of the post-discharge programs. As part of any annual reports submitted in 2022 and 2023, EMSA shall include an analysis of the post-discharge follow-up pilot programs.

This bill would specify that regulations adopted by EMSA relating to a TADP must include all of the following:

• LEMSAs participating in providing patients with advanced life support triage and assessment by a triage paramedic and transportation to an alternate destination facility shall ensure that any patient who meets the triage criteria for transport to an alternate destination facility, but who requests to be transported to an

emergency department of a general acute care hospital, shall be transported to the emergency department of a general acute care hospital.

- LEMSAs participating in providing patients with advanced life support triage and assessment by a triage paramedic and transportation to an alternate destination facility shall require that a patient who is transported to an alternate destination facility and, upon assessment, is found to no longer meet the criteria for admission to an alternate destination facility, be immediately transported to the emergency department of a general acute care hospital.
- The LEMSA shall ensure that the alternate destination facilities send each patient at the time of transfer, or, in the case of an emergency, as promptly as possible, copies of all medical records related to the patient's transfer. To the extent practicable and applicable to the transfer, the medical records shall include current medical findings, diagnosis, laboratory results, medications provided prior to transfer, a brief summary of the course of treatment provided prior to transfer, ambulation status, nursing and dietary information, name and contact information for the treating provider at the alternate destination facility, and, as appropriate, pertinent administrative and demographic information related to the patient, including name and date of birth. The requirements in this paragraph do not apply if the alternate destination facility has entered into a written transfer agreement with a local hospital that provides for the transfer of medical records.
- For authorizing transport to an alternate destination facility, training and accreditation for the triage paramedic shall include topics relevant to the needs of the patient population, including, but not limited to, a requirement that a participating triage paramedic complete instruction on all of the following:
 - Mental health crisis intervention, to be provided by a licensed physician and surgeon with experience in the emergency department of a general acute care hospital.
 - Assessment and treatment of intoxicated patients.
 - LEMSA policies for the triage, treatment, transport, and transfer of care, of patients to an alternate destination facility.
 - A requirement that the LEMSA verify that the participating triage paramedic has completed training in all of the following topics meeting the standards of the United States Department of Transportation National Highway Traffic Safety Administration National Emergency Medical Services Education Standards: psychiatric disorders; neuropharmacology; alcohol and substance abuse; patient consent; patient documentation; and medical quality improvement.
- For authorizing transport to a sobering center, a training component that requires a participating triage paramedic to complete instruction on all of the following:
 - The impact of alcohol intoxication on the local public health and emergency medical services system.
 - Alcohol and substance use disorders.
 - Triage and transport parameters.
 - Health risks and interventions in stabilizing acutely intoxicated patients.
 - Common conditions with presentations similar to intoxication.

- Disease process, behavioral emergencies, and injury patterns common to those with chronic alcohol use disorders.
- A process for LEMSAs to certify and provide periodic updates to EMSA to demonstrate that the alternate destination facility authorized to receive patients maintains adequate licensed medical and professional staff, facilities, and equipment pursuant to the authority's regulations and the provisions of this chapter, which shall include all of the following:
 - Identification of qualified staff to care for the degree of a patient's injuries and needs.
 - Certification of standardized medical and nursing procedures for nursing staff.
 - Certification that the necessary equipment and services are available at the alternate destination facility to care for patients, including, but not limited to, an automatic external defibrillator and at least one bed or mat per individual patient.

This bill would require EMSA to develop and periodically review and update the minimum medical protocols applicable to each CPP and TADP. This bill would require EMSA to establish and consult with an advisory committee comprised of the following members:

- Individuals in the fields of public health, social work, hospice, substance-use or mental health with expertise commensurate with the program specialty or specialties described in the definition of CPPs and TADPs.
- Physicians whose primary practice is emergency medicine.
- Two local EMS medical directors selected by the EMS Medical Directors Association of California.
- Two local EMS directors selected by the California Chapter of the American College of Emergency Physicians.

This bill would require EMSA to submit an annual report on the CPPs and TADPs operating in California to the relevant policy committees of the Legislature and post the report on its website. This bill would require EMSA to submit and post its first report six months after EMSA adopts the CPP and TADP regulations, and every January 1 thereafter for the next five years. This bill would allow the annual report to include recommendations for changes to, or elimination of, CP program specialties that do not achieve the goals expressed in this bill. This bill would require the report to include all of the following:

- An assessment of each program specialty, including an assessment of patient outcomes in the aggregate and an assessment of any adverse patient events resulting from services provided under plans approved pursuant to this chapter.
- An assessment of the impact that the program specialties have had on the emergency medical system.
- An update on the implementation of program specialties operating in local EMS agency jurisdictions.
- Policy recommendations for improving the administration of local plans and patient outcomes.

This bill would require EMSA, on or before June 1, 2028, to submit a final report on the results of the CPPs and TADPs operating in California to the relevant policy committees of the Legislature and post the report on its website. This bill would require EMSA to contract with an independent third-party evaluation to develop the final report. This bill would require the final report to include the following:

- A detailed assessment of each CPP and TADP operating in LEMSA jurisdictions.
- An assessment of patient outcomes in the aggregate resulting from services provided under approved plans under the program.
- An assessment of workforce impact due to implementation of the program.
- An assessment of the impact of the program on the emergency medical services system.
- An assessment of how the currently operating program specialties achieve the legislative intent.
- An assessment of community paramedic and triage training.

This bill would allow the final report to include recommendations for changes to, or elimination of, CPP or TADP program specialties that do not achieve the community health and patient goals.

This bill would specify that a person or organization shall not provide community paramedicine or triage to alternate destination services or represent, advertise, or otherwise imply that it is authorized to provide community paramedicine or triage to alternate destination services unless it is expressly authorized by a LEMSA to provide those services as part of a CPP or TADP approved by EMSA.

This bill would specify that a community paramedic shall provide community paramedicine services only if the community paramedic has been certified and accredited to perform those services by a LEMSA and is working as an employee of an authorized community paramedicine provider. This bill would specify that a triage paramedic shall provide triage to alternate destination services only if the triage paramedic has been accredited to perform those services by a LEMSA and is working as an employee of an authorized triage to alternate destination provider.

This bill would specify that entering into an agreement to be a community paramedicine or triage to alternate destination provider pursuant to this bill shall not alter or otherwise invalidate an agency's authority to provide or administer emergency medical services.

According to the author, today's existing model of directing all transports to emergency departments has created gridlock. Patients requiring services such as mental health intervention or a sobering facility, for example, are too often subjected to numerous providers who deny them the expeditious care they need. The author states that community paramedicine can play an important role in improving California's health care delivery system. CPP is an innovative model of care that seeks to improve the effectiveness and efficiency of health care delivery by using specially trained paramedics in partnership with other health care providers to address the needs of local health care systems.

Board staff, working with a Board Member who is a physician, provided input to OSHPD on HWPP #173 and raised patient safety concerns. One of these concerns being that persons recently discharged from the hospital should be seen by their primary care physician for follow up care. The additional training that would be required would not be sufficient enough to teach paramedics the basics of disease management or how to diagnose and treat medical conditions. The other concern raised was that the pilot project did not specifically delineate what services will be allowed to be performed by community paramedics.

However, this bill is very similar to a bill that the Board took a neutral position on, SB 944 (Hertzberg, 2018). The Board took a neutral position because it recognized the important role that emergency responders play in emergency care in California and because SB 944 was amended to increase the oversight of CPPs, to add a sunset date, and add requirements for additional protocols and enhanced reporting. Because this bill includes all of these elements, the Board has taken a neutral position on this bill.

- FISCAL: None
- <u>SUPPORT:</u> California Chapter of the American College of Emergency Physicians (Co-Sponsor); California Professional Firefighters (Co-Sponsor); California Fire Chiefs Association; California State Firefighters' Association; City of Alameda; City of Murieta; City of San Diego; City of Santa Monica; League of California Cities; and the Steinberg Institute
- <u>OPPOSITION:</u> Advocates for Health Economics and Development; Association of Regional Center Agencies; California Ambulance Association; California Association for Health Services at Home; California Coalition for Children's Safety and Health; California Emergency Nurses Association; California Nurses Association/National Nurses United; California Paramedic Foundation; California State Association of Counties (unless amended); County Health Executives Association of California (unless amended); Emergency Medical Services Administrators' Association of California (unless amended); Emergency Medical Services Medical Directors Association of California (unless amended); Rural County Representatives of California (unless amended); San Joaquin County Board of Supervisors (unless amended); and Urban Counties of California (unless amended)

ATTACHMENT: AB 1544, as amended, Gipson and Gloria. Community Paramedicine or Triage to Alternate Destination Act. Version: 07/11/19 – Amended Senate

MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

BILL NUMBER: AUTHOR: BILL DATE: SUBJECT: SPONSOR: SB 53 Wilk March 5, 2019, Amended Open Meetings Author

DESCRIPTION OF CURRENT LEGISLATION:

This bill would amend the definition of "state body" in the Bagley-Keene Open Meeting Act (Open Meeting Act) to specify that standing committees, even those composed of less than three members, are a "state body" and subject to the requirements in the Open Meeting Act.

BACKGROUND:

The Bagley-Keene Act of 1967, officially known as the Bagley-Keene Open Meeting Act, implements a provision of the California Constitution which declares that "the meetings of public bodies and the writings of public officials and agencies shall be open to public scrutiny," and explicitly requires open meetings for California State agencies, boards, and commissions. The purpose of the Open Meeting Act is to facilitate accountability and transparency of government activities and protects the rights of citizens to participate in state government deliberations.

Former Governor Brown vetoed similar bills authored by Senator Wilk in 2014 and in 2015. In the veto message of AB 2058, former Governor Brown wrote, "Any meeting involving formal action by a state body should be open to the public. An advisory committee, however, does not have authority to act on its own and must present any findings and recommendations to a larger body in a public setting for formal action. That should be sufficient."

ANALYSIS:

This bill would specifically require two-member advisory bodies of a "state body" comply with the Open Meeting Act if at least one member of the advisory body is a member of the larger state body and the advisory body is supported by state funds.

This bill includes an urgency clause and will become effective immediately upon signature.

According to the author, "The bill provides much-needed transparency to state government. The Bagley-Keene Act, which sets open meeting requirements for state government, is ambiguous in its definition of which state bodies must comply with the Bagley-Keene Act. The ambiguity of the Bagley-Keene Act has for years provided a loophole for state agencies that create two-member committees and claim they are exempt from open meeting requirements so long as they do not take action on anything." The author adds, "This bill clarifies the Bagley-Keene Act to state in definite terms that any multimember body that is funded by another state body and served by one of its officials falls under the scope of the Act. By clarifying this nebulous language, SB 53 ensures maximum transparency for state government."

After reviewing the language in this bill, staff has determined that it will impact outreach done by Board Members, including the Medical Board of California's (Board) annual Legislative Day. If this bill gets signed into law, Board Members could no longer participate in this type of outreach, as every outreach event where Board Members participate in would now be subject to the Open Meetings Act. Board staff recommends that the Board oppose this bill unless it is amended to allow an exception for public outreach provided by Board Members.

- FISCAL: None
- <u>SUPPORT:</u> California News Publishers Association; California Association of Licensed Investigators; Californians Aware; and League of Women Voters California
- <u>OPPOSITION:</u> California Acupuncture Board; California Board for Professional Engineers, Land Surveyors, and Geologists; California Board of Accountancy; California Board of Chiropractic Examiners; California Board of Psychology; Contractors State License Board; and the Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board
- POSITION: Recommendation: Oppose Unless Amended

ATTACHMENT: <u>SB 53, as amended, Wilk. Open meetings.</u> Version: 03/05/19 – Amended Senate

MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

BILL NUMBER: AUTHOR: BILL DATE: SUBJECT: SPONSOR: SB 159 Wiener July 1, 2019, Amended HIV: Preexposure and Postexposure Prophylaxis California Pharmacists Association; California Society of Health-System Pharmacists; Equality California; and San Francisco AIDS Foundation Support if Amended

POSITION:

DESCRIPTION OF CURRENT LEGISLATION:

This bill would allow a pharmacist, exercising appropriate professional judgement, to furnish a 60-day supply of preexposure prophylaxis (PrEP) or postexposure prophylaxis (PEP), if specified conditions are met. This bill would prohibit a health plan or insurer from subjecting combination antiretroviral drug treatments that are medically necessary for the prevention of AIDS/HIV, including PrEP and PEP, to prior authorization or step therapy. This bill would prohibit plans and insurers from prohibiting, or allowing a pharmacy benefit manager to prohibit, a pharmacy provider from providing PrEP or PEP. This bill would prohibit a health plan or insurer from covering PrEP, as authorized, in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber. This bill would require Medi-Cal to reimburse pharmacies for initiating and furnishing PrEP and PEP.

BACKGROUND:

According to the committee analysis:

In 2012, the U.S. Food and Drug Administration (FDA) approved Truvada, a name brand daily-use drug for PrEP that can reduce the risk of sexually acquired HIV-infection in adults at high risk. According to the CDC, PrEP is "highly effective for preventing HIV if used as prescribed, but it is much less effective when not taken consistently. Daily PrEP reduces the risk of getting HIV from sex by more than 90%. Among people who inject drugs, it reduces the risk by more than 70%." For over 20 years, CDC has recommended PEP to protect healthcare workers who have been accidentally exposed to HIV in the workplace.

PEP involves taking certain HIV medicines within 72 hours after a possible exposure to HIV to prevent infection. PEP involves taking HIV medications every day for 28 days, and the CDC indicates that it should be used only in emergency situations, and is not intended to replace regular use of other HIV prevention methods, such as PrEP.

In 2017, the CDC published Preexposure Prophylaxis for HIV Prevention in the United States – 2017 Update: A Clinical Practice Guideline, which provided comprehensive information for the use of daily oral antiretroviral PrEP to reduce the risk of acquiring HIV infection in adults. The CDC Guidelines indicate that "Daily oral PrEP … has been shown to be safe and effective in reducing the risk of sexual HIV acquisition in adults; therefore, PrEP is recommended as one prevention option for sexually-active adult men who have sex with men, …adult heterosexually active men and women, …and injection drugs users at substantial risk of HIV acquisition."

In assessing an individual's clinical eligibility prior to prescribing PrEP, CDC recommends the person have a documented negative HIV test, no signs or symptoms of acute HIV infection, normal renal function, no use of contraindicated medications, no documented hepatitis B virus infection, and a hepatitis B vaccination.

The CDC further recommends that HIV infection should be assessed at least every 3 months while patients are taking PrEP, renal function should be assessed at baseline and monitored at least every 6 months, and follow-up visits at least every 3 months should provide the following: HIV testing, medication adherence counseling, behavioral risk reduction support, side effect assessment, and STI symptom assessment.

The most recent CDC guidelines for PEP, Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Non-occupational Exposure to HIV— United States, 2016, encourage health care providers to evaluate individuals for PEP when care is sought within 72 hours after a potential non-occupational exposure that presents a substantial risk for HIV acquisition.

CDC recommends individuals considering PEP take an HIV test, but if one is unavailable and PEP is otherwise indicated, PEP "should be initiated without delay and can be discontinued if the patient is later determined to have HIV infection already or the source is determined not to have HIV infection." A complete course of PEP is 28 days of a 3-drug antiretroviral regimen. The guidelines further indicate, "All persons evaluated for possible PEP should be provided any indicated prevention, treatment, or supportive care for other exposure-associated health risks and conditions (e.g., bacterial sexually transmitted infections, traumatic injuries, hepatitis B virus and hepatitis C virus infection, or pregnancy). All persons who report behaviors or situations that place them at risk for frequently recurring HIV exposures (e.g., injection drug use, or sex without condoms) or who report receipt of [more than one] course of PEP in the past year should be provided risk-reduction counseling and intervention services, including consideration of PrEP."

ANALYSIS:

This bill would allow a pharmacist to initiate and furnish HIV PrEP and PEP in accordance with this bill.

This bill would define PrEP to mean a fixed-dose combination of tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), or another drug or drug combination that meets the same clinical eligibility recommendations provided in CDC guidelines. This bill would define the CDC Guidelines for PrEP as the "2017 Preexposure Prophylaxis for the Prevention of HIV Infection in the United States–2017 Update: A Clinical Practice Guideline," published by the CDC.

This bill would require, before furnishing PrEP to a patient, a pharmacist to complete a training program approved by the Board of Pharmacy (BOP), in consultation with the Medical Board of California (Board), on the use of PrEP and PEP. This bill would require the training to include information about financial assistance programs for PrEP and PEP, including the HIV prevention program described in existing law. This bill would require BOP to consult with the Board, as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the California Department of Public Health (CDPH), on training programs that are appropriate to meet the requirements of this bill.

This bill would allow a pharmacist exercising appropriate professional judgment, to furnish a 60-day supply of PrEP if all of the following conditions are met:

- The patient is HIV negative, as documented by a negative HIV test result obtained within the previous seven days from an HIV antigen/antibody test or antibody-only test or from a rapid, point-of-care finger stick blood test approved by the federal FDA. If the patient does not provide evidence of a negative HIV test in accordance with this paragraph, the pharmacist would be required to order an HIV test. If the test results are not transmitted directly to the pharmacist, this bill would require the pharmacist to verify the test results to the pharmacist's satisfaction. If the patient tests positive for HIV infection, the pharmacist or person administering the test would be required to direct the patient to a primary care provider and provide a list of providers and clinics in the region.
- The patient does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms.
- The patient does not report taking any contraindicated medications.
- The pharmacist provides counseling to the patient on the ongoing use of PrEP, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of child-bearing capacity. The pharmacist would be required to notify the patient that the patient must be seen by a primary care provider to receive subsequent prescriptions for PrEP and that a pharmacist may not furnish a 60-day supply of PrEP to a single patient more than once every two years.
- The patient reports having normal kidney function, and the pharmacist orders a test to measure kidney function. This bill would require the patient to provide contact information and sign an agreement to stop taking PrEP if laboratory results indicate that the patient should not take PrEP. This bill would require the pharmacist to contact the patient if laboratory results indicate that the patient if laboratory results indicate that the patient should not take PrEP.

- The pharmacist documents, to the extent possible, the services provided by the pharmacist in the patient's health record. This bill would require the pharmacist to maintain records of PrEP furnished to each patient.
- The pharmacist does not furnish a 60-day supply of PrEP to a single patient more than once every two years, unless directed otherwise by a prescriber.
- The pharmacist notifies the patient's primary care provider that the pharmacist completed the requirements specified in this subdivision. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, this bill would require the pharmacist to provide the patient a list of physicians, clinics, or other health care service providers to contact regarding ongoing care for PrEP.

This bill would define PEP as any of the following: "

- Tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), taken once daily, in combination with either raltegravir (400 mg), taken twice daily, or dolutegravir (50 mg), taken once daily.
- Tenofovir disoproxil fumarate (TDF) (300 mg) and emtricitabine (FTC) (200 mg), taken once daily, in combination with darunavir (800 mg) and ritonavir (100 mg), taken once daily.
- Another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.

This bill would define "CDC guidelines" for PEP as the "Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV–United States, 2016," published by CDC.

This bill would allow a pharmacist exercising appropriate professional judgment, to furnish a complete course of PEP if all of the following conditions are met:

- The pharmacist screens the patient and determines the exposure occurred within the previous 72 hours and the patient otherwise meets the clinical criteria for PEP consistent with CDC guidelines.
- The pharmacist provides HIV testing or determines the patient is willing to undergo HIV testing consistent with CDC guidelines. If the patient refuses to undergo HIV testing but is otherwise eligible for PEP under this section, the pharmacist may furnish PEP.
- The pharmacist provides counseling to the patient on the use of PEP consistent with CDC guidelines, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV and sexually transmitted diseases. The pharmacist shall also inform the patient of the availability of PrEP for persons who are at substantial risk of acquiring HIV.
- The pharmacist notifies the patient's primary care provider of the PEP treatment. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist would be required to provide the patient a list of physicians, clinics, or other health care service providers to contact regarding follow-up care for PEP.

This bill would specify that a pharmacist initiating or furnishing PrEP or PEP shall not allow the person to whom the drug is furnished to waive the consultation required by BOP.

This bill would require BOP, by July 1, 2020, to adopt emergency regulations to implement this bill in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. This bill would require BOP to consult with the Board in developing these regulations.

This bill would specify that a health care service plan or health insurer must not subject combination antiretroviral drug treatments that are medically necessary for the prevention of AIDS/HIV, PrEP or PEP, to prior authorization or step therapy. This bill would specify that a health care service plan or health insurer shall not prohibit, or permit a delegated pharmacy benefit manager to prohibit, a pharmacy provider from dispensing PrEP or PEP. This bill would specify that a health care service plan or health insurer shall not cover PrEP that has been furnished by a pharmacist in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber.

This bill would specify that it does not require a health care service plan or health insurer to cover PrEP or PEP by a pharmacist at an out-of-network pharmacy, unless the health care service plan has an out-of-network pharmacy benefit. This bill would require Medi-Cal to reimburse pharmacies for initiating and furnishing PrEP and PEP.

According to the author's office, "Currently, PrEP and PEP both require a physician's prescription, which delays or prevents some people from accessing it. Some people are not comfortable going to see a doctor. Others struggle to access a doctor or are confronted with long delays to obtain an appointment. And, sadly, although many doctors understand the need for PrEP, too many doctors don't know much about it, judge people for requesting it, try to persuade them not to request it, and, generally, don't know enough about sexual health, particularly LGBTQ sexual health. To be clear, many doctors 'get it' and do a great job in this area. Significant work remains to educate the profession. Another barrier to PrEP and PEP uptake is the requirement by some insurance companies for prior authorization. Notably, Medi-Cal does not require a prior authorization. Prior authorizations can lead to delays of weeks or months in accessing PrEP and can lead to someone becoming HIV positive."

The Board previously took a support if amended position on this bill. The Board supported the use of PrEP and PEP and believed they are both important medications to use to help prevent HIV infections. The Board supports pharmacists being able to dispense a complete course of PEP, as it will increase access to PEP, which is important as it must be initiated 72 hours after exposure and PEP only requires a 28-day course. However, the Board believed that because PrEP requires regular monitoring, testing, and adherence, that it is not appropriate for pharmacists to initiate PrEP, as they do not have the ability to provide the monitoring and testing on an on-

going basis. In addition, the Board believed it is important that PEP only be allowed to be dispensed pursuant to protocols adopted and approved by the BOP and the Board, as was required when pharmacists were given the authority to dispense naloxone, hormonal contraceptives, immunizations, and nicotine replacement therapy products, without a prescription.

This bill was amended to require a pharmacist to complete a training program approved by the BOP, in consultation with the Board, on the use of PrEP and PEP. This would address the Board's concern about protocols. In addition, this bill would limit PrEP to 60-day supply to a single patient once every two years and would not allow health care service plans or insurers to provide coverage over this limit. The Board should determine if the additional training, limits on PrEP, and conditions imposed address the Board's concerns regarding pharmacists initiating PrEP.

FISCAL: None

- SUPPORT: California Pharmacists Association (co-sponsor); California Society of Health System Pharmacists (co-sponsor); Equality California (cosponsor); San Francisco AIDS Foundation (co-sponsor); Alameda County; American Civil Liberties Union of California; APLA Health; California Health+ Advocates California LGBTQ Health and Human Services Network; California Life Sciences Association; California Retailers Association; City of West Hollywood; City and County of San Francisco; County Health Executives Association of California; County of Los Angeles; County of Santa Clara; Health Officers Association of California; Human Rights Campaign; Los Angeles LGBT Center; Lutheran Social Services of Northern California; NARAL Pro-Choice California; National Association of Chain Drug Stores; National Association of Social Workers, California Chapter; San Francisco Department of Public Health; San Francisco Hepatitis C Task Force; San Francisco Lesbian Gay Bisexual Transgender Community Center; Shanti; St. Anthony's Medical Clinic; St. James Infirmary; and United Nurses Associations of California/Union of Health Care Professionals
- <u>OPPOSITION:</u> AIDS Healthcare Foundation (unless amended); American College of Obstetricians and Gynecology District IX; California Academy of Preventive Medicine; California Chapter of the American College of Cardiology; California Medical Association (unless amended); California Urological Association; and Infectious Diseases Association of California
- ATTACHMENT: SB 159, as amended, Wiener. HIV: preexposure and postexposure prophylaxis. Version: 07/01/19 – Amended Assembly

MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

BILL NUMBER: AUTHOR: BILL DATE: SUBJECT:

SPONSOR: POSITION: SB 377 McGuire June 27, 2019, Amended Juveniles: Psychotropic Medications: Medical Information Author Support

DESCRIPTION OF CURRENT LEGISLATION:

This bill would require judicial council forms to be revised, by July 1, 2020, to create a process to enable foster youth to authorize the Medical Board of California (Board) to obtain their medical records, in order to determine whether there is excessive prescribing of psychotropic medications.

BACKGROUND:

In August 2014, the Board received a letter from Senator Lieu, who was at the time the Chair of the Senate Business, Professions and Economic Development Committee. The letter asked the Board to look into the issue of inappropriate prescribing of psychotropic medication to foster children. The Board receives very few complaints regarding foster children being prescribed psychotropic medications, so the Board researched other avenues to identify physicians who may be inappropriately prescribing. The Board met with the Department of Health Care Services (DHCS) and the Department of Social Services (DSS) regarding what data was available, what could be provided to the Board, and what data would assist in the identification of inappropriately prescribing physicians. After many meetings, a Data Use Agreement (DUA) was finalized in April 2015 requesting a listing of all physicians who had prescribed three or more psychotropic medications for 90 days or more. For each child that fit into this category, the Board requested a list of the medications prescribed, the start and stop date for each medication, the prescriber's name and contact information, the child's birth date, and any other information that DHCS and DSS thought might be relevant to assist in this process.

Upon receipt of the information requested in the DUA in 2015, the Board secured an expert pediatric psychiatrist to review the information and determine any physician who may be potentially prescribing inappropriately. It is important to note that once a physician is identified, the Board's normal complaint process was followed, including obtaining medical records, conducting a physician interview and having an expert physician review the case. The complaint and investigation process is confidential, and nothing is public until an accusation is filed. Upon review by the Board's expert, it was

determined that 86 children were identified as potentially being prescribed to inappropriately. The Board then requested assistance from DSS, since the data provided to the Board did not include the names of the foster children receiving the prescriptions. Per the data use agreement, DSS will facilitate contact with county child welfare agencies, the juvenile courts, county counsel, children's attorneys and other relevant entities, to assist the Board in obtaining child-specific information, including relevant medical records. The Board and DSS worked with the relevant entities to create an authorization letter to send to current and former foster children and their guardians, as appropriate, to receive authorization to obtain the medical records of the foster children. DSS staff sent out 33 letters to last known addresses of foster children who had transitioned out of foster care. Unfortunately, some of those letters came back as undeliverable/returned. DSS staff also reached out to the counties on 14 children to see if there was a medical rights holder who could authorize the release of information. Of those children, two had a legal guardian with medical rights who was sent the letter and authorization form. The remaining 12 children in those counties require court orders to obtain the release and the medical records. DSS has stated that at least one county counsel is willing to assist with obtaining the court orders and the Board will work with DSS on the process to move forward on seeking court orders. DSS staff are also preparing the letters and authorization forms for the children in the remaining counties to be sent out. The Board only received releases from 4 individuals. It is important to note, that without the authorization for the medical records, the Board cannot move forward with investigating these matters. Although the Board continues to work with DSS, the Board is not receiving the authorizations necessary in order for the Board to obtain the patient records to it can investigate these cases.

SB 1174 (McGuire, Chapter 840, Statutes of 2016) added to the Board's priorities, repeated acts of clearly excessive prescribing, furnishing, or administering psychotropic medications to children without a good faith prior exam and a medical reason. SB 1174 codified the Board's DUA with DHCS and DSS and required the Board to confidentially collect and analyze data submitted by DHCS and DSS, related to physicians prescribing psychotropic medications to children.

ANALYSIS:

This bill would require the Judicial Council, by July 1, 2020, to revise its forms to include a request for authorization by the foster youth or the youth's attorney to release the youth's medical information to the Board in order to ascertain whether there is excessive prescribing of psychotropic medication that is inconsistent with the standard of care. This bill would specify that the authorization is limited to medical information relevant to the prescription of the psychotropic medication and the information may only be used for the purposes set forth in existing law.

In order to address confidentiality concerns, this bill was amended to require the Board or its representative to request the medical information obtained to be sealed if that information is admitted as an exhibit in an administrative hearing. Amendments were also taken at the request of the Assembly Judiciary Committee to require the Judicial Council, when updating the forms, to consult with the California Department of Social Services (CDSS), the Board, the County Welfare Directors Association of California, the Chief Probation Officers of California, and groups representing foster children, dependency counsel, and children's advocates to help ensure that the foster youth and the youth's attorney are provided with sufficient information to understand the request for authorization to obtain the child's medical information and the reasons for the request. This bill would allow the Judicial Council to include in the form a requirement that the person completing the form affirm that the child or child's attorney has been asked about the authorization.

Amendments were also taken in Assembly Judiciary Committee to require CDSS, by January 1, 2020, to convene a working group consisting of the Judicial Council, the Board, the County Welfare Directors Association of California, the Chief Probation Officers of California, and groups representing foster children, dependency counsel, and children's advocates to consider various options for seeking authorization from a dependent child, a ward, or their attorney, for release of the dependent child's or ward's medical information regarding psychotropic medication prescribed between January 1, 2017, and July 1, 2020, and CDSS must report to the Legislature by April 15, 2020, on those options and on any recommendations to best reach those children and their attorneys to seek authorization.

According to the author, this bill will give the Board "the information they need in order to carry out their requirements pursuant to investigating potential overprescribing patterns of psychotropic drugs to foster youth. Following the passage of SB 1174 (McGuire, Chapter 840, Statutes of 2016), the Board is required to contract with an expert consultant who reviews prescribing data from DHCS and DSS for foster youth who have been on three or more psychotropic medications for 90 days or more. The Board has been unable to conduct internal confidential investigations into potential overprescribing because they do not have access to the related medical records for the foster youth who fit the requirements under SB 1174. Currently, the Board must work with DSS to get letters out to the identified youth to request authorization for the Board to contact the individuals. If the Board receives authorization to contact the individual, they must next then obtain an authorization for release of medical records." The author further states that "SB 377 will cut through this red tape and allow the Board to carry out their oversight authority. When the juvenile court judicial officer authorizes the administration of a psychotropic medication through the JV 220 form, the judicial officer shall also authorize the Board to review limited patient medical record information of the child authorized to receive psychotropic medication."

The Board needs authorization to receive medical records for foster youths that the Board expert has identified as victims of potential inappropriate prescribing in order to look into these cases. The Board's position changed from support if amended to support because the bill was amended to allow the Board to have access to all of the information in the foster youth's medical records. However, amendments were taken at the request of the Assembly Judiciary Committee to specify that the authorization is limited to medical information relevant to the prescription of the psychotropic medication. Board staff requested that the author change this language to specify that the authorization is limited to medical information that is relevant to <u>the investigation of</u> the prescription of psychotropic medication, as the Board would be the one to determine what is relevant to the investigation. The author's office has committed to taking these amendments; as such, Board staff recommends that the Board continue to support this important bill.

FISCAL:	None
SUPPORT:	Medical Board of California
OPPOSITION:	None on File
ATTACHMENT:	<u>SB 377, as amended, McGuire. Juveniles: psychotropic</u> <u>medications: medical information.</u> Version: 06/27/19 – Amended Assembly

MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

BILL NUMBER: AUTHOR: BILL DATE: SUBJECT: SB 425 Hill June 27, 2019, Amended Health Care Practitioners: Licensee's File: Probationary Physician's and Surgeon's Certificate: Unprofessional Conduct Author Support

SPONSOR: POSITION:

DESCRIPTION OF CURRENT LEGISLATION:

This bill would require health facilities and entities that allow a licensed health care professional to provide care for patients, to report allegations of sexual abuse and sexual misconduct made by a patient against a licensed health care practitioner to that practitioner's licensing board within 15 days, and would impose a fine for failure to report. This bill would make other changes related to the Medical Board of California's (Board) disciplinary action and enforcement process.

BACKGROUND:

In 2018, an investigation by the LA Times reported on multiple unresolved complaints of alleged sexual misconduct by a doctor who worked at the University of Southern California's (USC) student health center. Although many individuals complained to various employees of USC, none of these complaints were reported to the Board.

The other changes in this bill related to the Board were approved as legislative proposals at the Board's October 2018 Board Meeting.

ANALYSIS:

This bill would require a health facility or other entity that makes any arrangement under which a healing arts licensee is allowed to practice or provide care for patients to file a report of any allegation of sexual abuse or sexual misconduct made against a healing arts licensee by a patient, if the patient or the patient's representative makes the allegation in writing, to the appropriate licensing board within 15 days of receiving the written allegation of sexual abuse or sexual misconduct. This bill would define an arrangement under which a licensee is allowed to practice or provide care for patients to include, but not be limited to, full staff privileges, active staff privileges, limited staff privileges, courtesy staff privileges, locum tenens arrangements, and contractual

arrangements to provide professional services, including, but not limited to, arrangements to provide outpatient services.

This bill would specify that the report must be kept confidential and is not subject to discover, except that information may be disclosed in any subsequent disciplinary hearing conducted pursuant to the Administrative Procedure Act.

This bill would specify that a willful failure to file the required report is punishable by a fine not to exceed one hundred thousand dollars (\$100,000) per violation. The fine may be imposed in any civil or administrative action or proceeding brought by or on behalf of any agency having regulatory jurisdiction over the licensee regarding whom the report was or should have been filed. If the person who is designated or otherwise required to file the report under this section is a licensed physician and surgeon, the action or proceeding shall be brought by the Board. If the person who is designated or otherwise required to file the report required under this section is a licensed doctor of podiatric medicine, the action or proceeding shall be brought by the Board. If the Podiatric Medical Board of California. The fine shall be paid to that agency, but not expended until appropriated by the Legislature. A violation of this subdivision may constitute unprofessional conduct by the licensee. A person who is alleged to have violated this subdivision may assert any defense available at law. As used in this subdivision, "willful" means a voluntary and intentional violation of a known legal duty.

This bill would specify that any failure to file the report is punishable by a fine not to exceed fifty thousand dollars (\$50,000) per violation. The fine may be imposed in any civil or administrative action or proceeding brought by or on behalf of any agency having regulatory jurisdiction over the person regarding whom the report was or should have been filed. If the person who is designated or otherwise required to file the report required under this section is a licensed physician and surgeon, the action or proceeding shall be brought by the Board. If the person who is designated or otherwise required to file the report required under this section is a licensed doctor of podiatric medicine, the action or proceeding shall be brought by the Podiatric Medical Board of California. The fine shall be paid to that agency, but not expended until appropriated by the Legislature. The amount of the fine imposed, not exceeding fifty thousand dollars (\$50,000) per violation, shall be proportional to the severity of the failure to report and shall differ based upon written findings, including whether the failure to file caused harm to a patient or created a risk to patient safety; whether any person who is designated or otherwise required by law to file the report required under this section exercised due diligence despite the failure to file or whether the person knew or should have known that a report required under this section would not be filed; and whether there has been a prior failure to file a report required under this section. The amount of the fine imposed may also differ based on whether a health care facility or clinic is a small or rural hospital as defined in Section 124840 of the Health and Safety Code.

This bill would specify that a person, including an employee or individual contracted or subcontracted to provide health care services, a health facility or clinic or other entity

shall not incur any civil or criminal liability as a result of making a report required by this section if made in good faith.

This bill would require the licensing board to investigate the circumstances underlying a report received pursuant to this bill.

The Board supports three of the provisions in this bill already, as they were previously approved as legislative proposals. The Board supports the provision that amends Business and Professions Code (BPC) Section 800(c)(1) to strike the word "comprehensive" in front of summary; the Board supports the provision that amends BPC Section 2221 to require probationary license information to stay on the Board's website for a period of 10 years; and the Board supports the provision that amends BPC Section 2234(h) regarding physician interviews to include in the definition of unprofessional conduct the failure of a licensee, in the absence of good cause, to attend and participate in an interview by the Board, current law requires the failure to be repeated. The Board believes these provisions will help to prevent delays in the Board's enforcement process, which negatively impact the Board's enforcement timelines, and increase transparency to consumers by providing access to information that is public, but not available on the Board's website after the probationary period is completed.

According to the author, "SB 425 closes legal loopholes that can allow a subject of repeated sexual abuse and misconduct complaints to work at a health facility for years because the relevant regulatory board is not notified by the facility of the allegations against a licensee. Allegations of sexual abuse or misconduct by doctors and other medical professionals must be reported swiftly to the appropriate licensing board for review so that regulators can determine whether to conduct an independent, confidential investigation. State regulatory boards cannot fulfill their responsibilities to protect patients and other consumers, if they are not notified of these serious allegations involving their licensees. The failure to do so shields bad actors while exposing patients to greater risks."

The requirements for health care facilities and entities to report allegations of sexual abuse and sexual misconduct made by a patient against a licensed health care practitioner to that practitioner's licensing board would further the Board's mission of consumer protection and ensure that the Board is aware of these allegations so the Board can look into these incidences of potential sexual abuse and misconduct. The Board has taken a support position on this bill.

FISCAL:

SB 425 will result in a significant increase in complaints, which will impact the Board's enforcement workload. The Board is estimating that the increase will be at least three times the current complaints received via BPC Section 805 reports, since these reports are also for incidents that happened in a facility, although BPC Section 805 reports must go through a formal peer review process and action must be taken by the peer review

body before anything is reported to the Board. In fiscal year 2017/18, the Board received 141 BPC Section 805 reports. Three times that amount would be 423 new complaints per year. The Board is estimating that it will need a .5 PY at an MST level and 1 PY at the AGPA level in the Board's Central Complaint Unit to process and review these 423 new complaints. These ongoing costs per year are \$37,000 for the MST and \$114,000 for the AGPA.

The Board is estimating that 20% of the 423 complaints will be consolidated into one investigation, which would be 339 new cases. The Board is estimating that each case will take 60 hours to investigate, as they will be more complex. 339 cases times 60 hours equals 20,340 hours. An investigator PY is 1,776 hours per year. This equates to the Board needing to pay for 11 new investigators in HQIU. One investigator costs \$132,000 per year and on-going, so this would result in \$1,452,000 in fiscal impact to the Board.

The Board is estimating that 1/3 of the cases investigated will go the AG's Office for prosecution, so that results in about 100 cases going to the AG's office. For the AG's Office, each case takes about \$20,000 in billing to prosecute. This equals \$2,000,000 in AG costs.

The Board is estimating that 20% of the 100 cases will go to the Office of Administrative Hearings (OAH) for a hearing. The costs of each case to go to OAH is \$12,500 times 20 is \$250,000 in costs for OAH.

The total costs for this bill are \$151,000 for Board position costs; \$1,452,000 for HQIU Investigator PY costs; \$2,000,000 for AG costs and \$250,000 for OAH costs. This results in \$3,853,000 in total costs to the Board.

<u>SUPPORT:</u> California Acupuncture Board; California Chiropractic Examiners Board; California Psychology Board; California Hospital Association; Consumer Attorneys of California; Consumer Watchdog; Medical Board of California; and University of California

OPPOSITION: None on file

ATTACHMENT: SB 425, as amended, Hill. Health care practitioners: licensee's file: probationary physician's and surgeon's certificate: unprofessional conduct.

Version: 06/27/19 – Amended Assembly

MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

BILL NUMBER: AUTHOR: BILL DATE: SUBJECT:

SPONSOR: POSITION: SB 697 Caballero July 11, 2019, Amended Physician Assistants: Practice Agreement: Supervision California Academy of Physician Assistants (CAPA) Support

DESCRIPTION OF CURRENT LEGISLATION:

This bill would revise the Physician Assistant Practice Act (Act) to allow multiple physicians and surgeons to supervise a physician assistant (PA), would replace the delegation of services agreement (DSA) with a practice agreement, would eliminate the existing medical records review requirement, and would make other substantive and technical changes.

BACKGROUND:

The first Physician Assistant training program began in 1965 at Duke University with the admission of four ex-military corpsmen into a two-year program. California began regulating the profession in 1970 "to redress the growing shortage and geographic misdistribution of health care services in California." The PA practice act permitted the supervised delegation of certain medical services to PAs, thus freeing physicians to focus their skills on other procedures.

To become licensed in California, a PA must attend and graduate from an accredited PA program associated with a medical school that includes classroom studies and clinical experience. The professional curriculum for PA education includes basic medical, behavioral, and social sciences; introduction to clinical medicine and patient assessment; supervised clinical practice; and health policy and professional practice issues. A PA performs many of the same diagnostic, preventative, and health maintenance services as a physician. These services include, but are not limited to, the following: taking health histories; performing physical examinations; ordering X-rays and laboratory tests; ordering respiratory, occupational, or physical therapy treatments; performing routine diagnostic tests; establishing diagnoses; treating and managing patient health problems; administering immunizations and injections; instructing and counseling patients; providing referrals within the health care system; performing minor surgery; providing preventative health care services; acting as first or second assistants during surgery; and responding to life-threatening emergencies.

Existing law authorizes a PA to perform medical services under the supervision of a physician and surgeon who must be physically available to the PA. Existing law defines a DSA as the writing that delegates to a PA, from a supervising physician, the medical services the PA is authorized to perform. Existing law states that a PA acts as an agent of the supervising physician when performing any activity authorized by the Act. Existing law requires the PA and the PA's supervising physician and surgeon to establish written guidelines for adequate supervision and adhere to specific medical records review processes. Existing law authorizes a supervising physician and surgeon to delegate the authority to issue a drug order to a PA, and may limit this authority by specifying the manner in which the PA may issue delegated prescriptions by adopting a formulary and protocols that specify all criteria for the use of a particular drug or device. The drugs listed in the protocols shall constitute the formulary and shall include only drugs that are appropriate for use in the type of practice engaged in by the supervising physician and surgeon.

Both PAs and Nurse Practitioners (NPs) are mid-level healthcare professionals with overlapping scopes of practice. Each have distinct training and philosophies: nurses follow a patient-centered model in which they focus on disease prevention and health education, while PAs follow a disease-centered model in which they focus on the biologic and pathologic components of health. In California, a substantial differentiating factor between the two professions is the comparatively higher level of administrative duties related to supervision required by the PA's Practice Act.

Existing law limits a physician and surgeon to supervising up to four PAs at one time and up to four NPs.

NPs operate under supervision of a physician under standardized procedures and protocols. Existing law specifies that physician supervision shall not be construed to require the physical presence of the physician, but does include collaboration on the development of the standardized procedure, approval of the standardized procedure, and availability by telephonic contact at the time of patient examination by the NP. Existing law authorizes a NP to furnish or order drugs or devices when operating in accordance with standardized protocols developed by the NP and supervising physician and authorizes the physician to determine the extent of supervision necessary for an NP to furnish and order drugs.

ANALYSIS:

This bill would revise the Act's legislative intent to emphasize coordinated care between PAs and other health care professionals.

This bill would update the existing definition of a supervising physician by taking out the reference of improper use and replacing it with, prohibiting employment or supervision of a PA. This bill would prohibit physician supervision from requiring the physical presence of the physician, but it would require the following:

- Adherence to adequate supervision, as agreed to in the practice agreement.
- The physician being available by telephone or other electronic communication method at the time the PA examines the patient.

This bill would specify that it does not prohibit the Physician Assistant Board (PAB) from requiring the physical presence of a physician as a term or condition of a PA's reinstatement or probation.

This bill would define an organized health care system to include a licensed clinic, an outpatient setting, a health facility, a county medical facility, an accountable care organization, a home health agency, a physician's office, a professional medical corporation, a medical partnership, a medical foundation, and any other organized entity that lawfully provides medical services and is in compliance with existing law that bans the corporate practice of medicine.

This bill would strike all reference to a DSA in the Act and replaces these references with a "practice agreement". This bill would define a practice agreement as a writing, developed through collaboration among one or more physicians, one or more PAs, and, if applicable, administrators of an organized health care system, that defines the medical services the PA is authorized to perform and that grants approval for physicians on the staff of an organized health care system to supervise one or more PAs in the organized health care system. This bill would specify that any reference to a DSA relating to PAs in any other law shall have the same meaning as a practice agreement.

This bill would delete the medical records review definition and requirement from existing law. This bill would delete existing law that states a PA acts as an agent of a supervising physician when performing any activity under the Act.

This bill would authorize a PA to perform the medical services set forth in the Act if the following requirements are met:

- The PA renders the services under the supervision of a physician who is not subject to a disciplinary condition imposed by the Medical Board of California (Board) or the Osteopathic Medical Board prohibiting that supervision or prohibiting the employment of a PA.
- The PA renders the services pursuant to a practice agreement.
- The PA is competent to perform the services.
- The PA's education, training, and experience have prepared the PA to render the services.

This bill would prohibit the Act from requiring a supervising physician to review or countersign a patient's medical record who was treated by a PA, unless required by the practice agreement. This bill would allow the PAB, as a condition of probation or reinstatement of a licensee, to require the review or countersignature of records of patients treated by a PA for a specified duration.

This bill would specify that a PA rendering services in a hospital must be supervised by a physician with privileges to practice in that hospital

This bill would redraft the provisions of law relating to PAs ordering drugs and devices in relation to the practice agreement changes. This bill would allow a PA to furnish or order a drug or device in accordance with the practice agreement and consistent with the PA's educational preparation or for which clinical competency has been established and maintained. This bill would require the practice agreement to specify which PAs may furnish or order a drug or device, which drugs or devices may be furnished or ordered, under what circumstances, the extent of physician supervision, the method of periodic review of the PA's competence, including peer review, and review of the practice agreement. This bill would specify that if the practice agreement authorizes the PA to furnish a Schedule II controlled substance, the practice agreement must address the diagnosis of the illness, injury, or condition for which the PA may furnish the Schedule II controlled substance This bill would require the PA to furnish or order drugs or devices under physician supervision, but this supervision shall not be construed to require the physical presence of the physician, but does require adherence to adequate supervision agreed to in the practice agreement and that the supervising physician be available by telephone or other electronic communication method at the time the PA examines the patient.

This bill would only allow a PA to furnish or order controlled substances that have been agreed upon in the practice agreement or a patient-specific order approved by the treating or supervising physician. The PA must satisfactorily complete a course in pharmacology covering the drugs or devices to be furnished or ordered, or completed a program for instruction of PAs that meet the requirements in regulations, as those provisions read on June 7, 2019. This bill would allow a physician, through a practice agreement, to determine the extent of supervision necessary in the furnishing or ordering of drugs and devices. This bill would specify that PAs who hold an active license and who are authorized through a practice agreement to furnish Schedule II controlled substance, and who have not successfully completed a one-time course that met the requirements in regulations as they read on June 7, 2019, must complete, as part of their continuing education requirements, a course that covers Schedule II controlled substances and the risks of addiction associated with their use, based on the standards developed by PAB. PAB would be required to establish the requirement for satisfactory completion of this requirement. This bill would specify that evidence of completion of a course meeting the standards, including pharmacological content established in regulations as those provisions read on June 7, 2019, shall be deemed to meet the requirements of this bill.

This bill would specify that furnishing or ordering shall include the following:

- Ordering a drug or device in accordance with the practice agreement.
- Transmitting an order of a supervising physician.
- Dispensing a medication.

This bill would define a drug order or order as an order for medication that is dispensed to or for an ultimate user, issued by a PA as an individual practitioner, within the meaning of federal regulations.

This bill would require drug orders issued pursuant to the Act to be treated in the same manner as a prescription of a supervising physician. This bill would specify that all references to a prescription in the Business and Professions Code (BPC) and the Health and Safety Code shall include drug orders issued by PAs. This bill would specify that the signature of a PA on a drug order issued pursuant to the Act is deemed to be the signature of a prescriber for purposes of the BPC and the Health and Safety Code.

This bill would require the practice agreement to include provisions that address the following:

- The types of medical services a PA is authorized to perform.
- Policies and procedures to ensure adequate supervision of the PA, including, but not limited to, appropriate communication, availability, consultations, and referrals between a physician and the PA in the provision of medical services.
- The methods for the continuing evaluation of the competency and qualifications of the PA.
- The furnishing or ordering of drugs or devices by a PA.
- Any additional provisions agreed to by the PA and physician or organized health care system.

This bill would require the practice agreement to be signed by the PA and one or more physicians or a physician who is authorized to approve the practice agreement on behalf of the staff of the physicians on the staff of an organized health care system. This bill would specify that a DSA in effect prior to January 1, 2020, shall be deemed to meet the requirements of this bill. This bill would allow a practice agreement to designate a PA as an agent of a supervising physician. This bill would specify that it shall not be construed to require approval of a practice agreement by the PAB.

This bill would delete existing provisions of law that conflict with the principle of multiple physician and surgeon supervision of a PA. This bill would delete outdated sections of existing law relating to the requirement that a supervising physician apply to the PAB and pay a fee and Board oversight that is outdated. This bill would also make technical changes.

This bill would specify that its provisions are severable, and if any provision of this bill or its application is held invalid, the invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

According to the author's office, "There are several disparities between PAs and other medical professionals in the same arena when it comes to the relationship between PAs and physicians. In practice, this means PAs are subject to burdensome regulations such as chart review, co-signatures, DSA requirements, and outdated ratios for prescribing

purposes. These regulations incur a burden upon the physician as well, who may not be incentivized to hire a PA if a less regulated NP is available.

It is very possible that this disincentive to hire PAs may be contributing to the lack of healthcare services across our state, but especially in rural areas. If regulations were lessened on PAs to better match a NP's status, there would be little or no disparity and PAs could be better utilized by physicians in areas where health care services are lacking. This bill seeks to reduce the burdens on the physician – PA relationship, so practices can thrive and potentially expand."

The purpose of this bill is to align the PA supervision requirements to those of an NP. This bill originally would have deleted all references to physician supervision and would have made PAs independent practitioners. This current version of the bill is a result of negotiations with the author's office, sponsors and various stakeholders who were previously opposed. The Board has taken a support position on this bill. The recent amendments attempt to address concerns raised by the PAB, but do not impact the reasons the Board supported this bill.

- FISCAL: None
- <u>SUPPORT:</u> CAPA (Sponsor); America's Physician Groups; Association of California Healthcare Districts, and Affiliated Entity Alpha Fund; California Academy of Family Physicians; California Association for Health Services at Home; California Hospital Association; California Medical Association; California Psychiatric Association; California Health+ Advocates; and Medical Board of California
- <u>OPPOSITION:</u> California Chapter of the American College of Emergency Physicians (unless amended), California Rheumatology Alliance (unless amended); California Society of Plastic Surgeons; Physician Assistant Board (unless amended); and One Individual (unless amended)

<u>ATTACHMENT:</u> <u>SB 697, as amended, Caballero. Physician assistants: practice agreement: supervision.</u> Version: 07/11/19 – Amended Assembly

MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

BILL NUMBER: AUTHOR:

BILL DATE: SUBJECT: SPONSOR: POSITION: SB 786 Comm. on Business, Professions and Economic Development June 25, 2019, Amended Healing Arts: Various Healing Arts Boards Support Provisions Related to the Medical Board of California

DESCRIPTION OF CURRENT LEGISLATION:

This bill is the committee bill that includes technical and clarifying changes for healing arts boards under the Department of Consumer Affairs. This analysis will only include the provisions that impact the Medical Board of California (Board). This bill would make technical and clarifying changes and delete outdated sections of the Business and Professions Code (BPC) that are related to the Board.

BACKGROUND:

The technical and clarifying changes in this bill that impact the Board were approved by the Board at the October 2018 Board Meeting.

ANALYSIS:

This bill would clean up inconsistent language in BPC Section 803.1, including changing "physicians and surgeons" to "licensees".

This bill would delete BPC Section 2234(g), which becomes operative upon implementation of the proposed registration program described in BPC Section 2052.5, as this subdivision is no longer needed because BPC 2052.5 has been repealed.

This bill would delete BPC Sections 2155-2167 (Loans to Medical Students) and 2200-2213 (Physician and Surgeon Incentive Pilot Program), as these programs are not active.

These changes will clean up the code section and delete language regarding programs that are not active; the Board is supportive of these provisions in SB 786.

FISCAL: None

SUPPORT: Dental Hygiene Board of California and Medical Board of California

OPPOSITION: None on file

ATTACHMENT: SB 786, as amended, Committee on Business, Professions and Economic Development. Healing arts. Version: 06/25/19 – Amended Assembly

MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

BILL NUMBER: AUTHOR: BILL DATE: SUBJECT: SPONSOR: SB 276 Pan July 1, 2019, Amended Immunizations: medical exemptions American Academy of Pediatrics, California; California Medical Association; and Vaccinate California Support in Concept

POSITION:

DESCRIPTION OF CURRENT LEGISLATION:

This bill would require the California Department of Public Health (CDPH), by January 1, 2021, to develop and make available for use by physicians an electronic, standardized, and statewide medical exemption certification form. This bill would require CDPH to annually review immunization reports from all schools and institutions. Beginning January 1, 2021, this bill would require clinically trained staff members at CDPH to review exemptions from schools or institutions with immunization rates of less than 95% and exemptions from physicians who submit five or more medical exemptions in a calendar year. This bill would permit CDPH to deny or revoke a medical exemption determined to be inappropriate or invalid, as specified. This bill would establish an appeals process for medical exemptions that are denied or revoked and would create an independent review panel made up of three physicians for appeal purposes.

BACKGROUND:

SB 277 (Pan and Allen, Chapter 35, Statutes of 2015) eliminated the personal belief exemption from the requirement that children receive specified vaccines for certain infectious diseases prior to being admitted to any private or public elementary or secondary school, or day care center, as specified.

Existing law waives the existing immunization requirements if the parent or guardian files with the governing authority a medical exemption, which is a written statement by a licensed physician to the effect that the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe, indicating the specific nature and probable duration of the medical condition or circumstances including, but not limited to, family medical history, for which the physician does not recommend immunization.

Since the passage of SB 277 in 2015, the Medical Board of California (Board) has faced obstacles in investigating complaints related to medical exemptions. For all quality of care cases, the Board must obtain authorization from the patient or their parent or

guardian (if the patient is a minor) to release the medical records. For medical exemption cases, many times the parent or guardian does not want the Board to investigate the physician who issued their medical exemption, so the parent will not sign an authorization. This has created barriers to the Board investigating these cases because for most of these medical exemption cases, the Board does not have enough evidence to subpoen the medical records. Without the medical records, the Board's physician expert cannot review the case to determine if the physician acted within the standard of care.

According to the federal Centers for Disease Control and Prevention (CDC), from January 1 to April 19, 2019, 626 individual cases of measles have been confirmed in 19 states. This is the second-greatest number of cases reported in the U.S. since measles was eliminated in 2000. The states that have reported cases to CDC are Arizona, California, Colorado, Connecticut, Florida, Georgia, Illinois, Indiana, Kentucky, Massachusetts, Michigan, Missouri, Nevada, New Hampshire, New Jersey, New York, Oregon, Texas, and Washington. Two outbreaks have been highly publicized in the news: Washington and New York. In Clark County, Washington, there have been 73 confirmed cases since January 1. Of these cases, 53 were age one to ten years, 15 cases were 11 to 18 years, one case was 19 to 29 years, and four cases were 30 to 39 years. Sixty-three infected individuals were unimmunized. In New York City, as of April 18, 2019, there have been 359 confirmed cases of measles in Brooklyn and Queens since October.

SB 277 (Pan and Allen, Chapter 35, Statutes of 2015) eliminated all non-medical exemptions for immunizations required for school entry. While SB 277 was successful in raising immunization rates, the number of medical exemptions issued more than tripled since the law went into effect. Many of the exemptions are clustered in the same schools, creating concentrated pockets of unvaccinated individuals. At almost 60 schools in the state, more than 10% of kindergarteners had medical exemptions.

ANALYSIS:

This bill would require CDPH, by January 1, 2021, to develop and make available for use by physicians an electronic, standardized, statewide medical exemption certification form (exemption form) that would be required to be transmitted directly to CDPH's existing California Immunization Registry (CAIR). This bill would require the exemption form to be printed, signed, and submitted directly to the school or institution at which the child will attend, submitted directly to the governing authority of the school or institution, or submitted to that governing authority through the CAIR where applicable.

This bill would specify that beginning January 1, 2021, the exemption form is the only documentation of a medical exemption that the governing authority may accept. This bill would require the exemption form to require all of the following information, at a minimum:

• The name, California medical license number, business address, and telephone number of the physician who issued the medical exemption, and of the primary

care physician of the child, if different from the physician who issued the medical exemption.

- The name of the child for whom the exemption is sought, the name and address of the child's parent or guardian, and the name and address of the child's school or other institution.
- A statement certifying that the physician has conducted a physical examination and evaluation of the child consistent with the relevant standard of care and complied with all applicable requirements of this section.
- Whether the physician who issued the medical exemption is the child's primary care physician. If the issuing physician is not the child's primary care physician, the issuing physician shall also provide an explanation as to why the issuing physician, and not the primary care physician, is filling out the exemption form.
- How long the physician has been treating the child.
- A description of the medical basis for which the exemption for each individual immunization is sought. Each specific immunization shall be listed separately and space on the form shall be provided to allow for the inclusion of descriptive information for each immunization for which the exemption is sought.
- Whether the medical exemption is permanent or temporary, including the date upon which a temporary medical exemption will expire. A temporary exemption shall not exceed one year.
- An authorization for CDPH to contact the issuing physician for purposes of this section and for the release of records related to the medical exemption CDPH, the Board, and the Osteopathic Medical Board of California.
- A certification by the issuing physician, under penalty of perjury, that the statements and information contained in the form are true, accurate, and complete.

This bill would prohibit an issuing physician from charging for filling out an exemption form and for a physical examination related to the renewal of a temporary medical exemption.

This bill would require, beginning January 1, 2021, if a parent or guardian requests a licensed physician to submit a medical exemption, the physician must inform the parent or guardian of the requirements of this bill. If the parent or guardian consents, the physician must examine the child and submit a completed exemption form to CDPH. An exemption form may be submitted to the department at any time.

This bill would require CDPH, by January 1, 2021, to create a standardized system to monitor immunization levels in schools and institutions, and to monitor patterns of unusually high medical exemption form submissions by a particular physician.

This bill would specify that if a medical exemption has been authorized prior to the passage of this bill, a parent or guardian would be required to submit, by January 1, 2021, a copy of the medical exemption to CDPH for inclusion in a state database in order for the medical exemption to remain valid.

This bill would require CDPH, at a minimum, to annually review immunization reports from all schools and institutions. This bill would require a clinically trained immunization CDPH staff member, who is either a physician or a registered nurse (RN), to review all medical exemptions from any of the following:

- Schools or institutions with an overall immunization rate of less than 95 percent.
- Physicians who have submitted five or more medical exemptions in a calendar year.
- Schools or institutions that do not provide reports of vaccination rates to CDPH.

This bill would require CDPH to identify those medical exemptions that do not meet applicable CDC, federal Advisory Committee on Immunization Practices (ACIP), or American Academy of Pediatrics (AAP) criteria for appropriate medical exemptions. CDPH may contact the primary care physician or the issuing physician to request additional information to support the medical exemption.

This bill would allow CDPH, based on the medical discretion of the clinically trained immunization staff member, to accept a medical exemption that is based on other contraindications or precautions, including consideration of family medical history, if the issuing physician provides written documentation to support the medical exemption that is consistent with the relevant standard of care.

This bill would specify that a medical exemption that the reviewing CDPH immunization staff member determines to be inappropriate or otherwise invalid would also be required to be reviewed by the State Public Health Officer, who is a physician, or another physician from CDPH's immunization program designated by the State Public Health Officer. Pursuant to this review, the State Public Health Officer or designee may revoke the medical exemption.

This bill would require CDPH to notify the parent or guardian, issuing physician, the school or institution, and the local public health officer with jurisdiction over the school or institution of a denial or revocation. This bill would specify that if a medical exemption is revoked, the child shall continue in attendance at his or her school. However, within 30 calendar days of the revocation, the child shall begin the immunization schedule required for conditional admittance, unless an appeal is filed within that 30-day time period. If an appeal is filed, the child shall continue in attendance at his or her school and shall not be required to comply with immunization requirements unless and until the revocation is upheld on appeal.

This bill would specify that if CDPH determines that a physician's practice is contributing to a public health risk in one or more communities, CDPH shall report the physician to the Board or the Osteopathic Medical Board of California, as appropriate. This bill would prohibit CDPH form accepting a medical exemption from the physician until the physician demonstrates to CDPH that the public health risk no longer exists, but in no event shall the physician be barred from submitting these forms for less than two years.

This bill would specify that if there is a pending accusation against a physician with the Board or the Osteopathic Medical Board of California relating to immunization standards of care, CDPH shall not accept a medical exemption from the physician unless and until the accusation is resolved in favor of the physician.

This bill would require CDPH to notify the Board or the Osteopathic Medical Board of California, as appropriate, of any physician who has five or more medical exemption forms in a calendar year that are revoked.

This bill would allow a clinically trained CDPH immunization program staff member who is a physician or an RN to review any exemption in the CAIR or other state database as necessary to protect public health.

This bill would allow a medical exemption that is revoked to be appealed by a parent or guardian to the Secretary of California Health and Human Services (CHHS). This bill would specify that parents or guardians may provide necessary information for purposes of the appeal. This bill would require the Secretary of CHHS to establish an independent expert review panel, consisting of three licensed physicians who have relevant knowledge, training, and experience relating to primary care or immunization to review appeals. This bill would require CHHS to establish the process and guidelines for the appeals process. This bill would require CHHS to post this information on CHHS' website. This bill would require CHHS to establish requirements, including conflict-of-interest standards that a physician must meet in order to qualify to serve on the panel.

This bill would require the independent expert review panel to evaluate appeals consistent with CDC, ACIP, or AAP guidelines or the relevant standard of care, as applicable. This bill would require the independent expert review panel to submit its determination to the Secretary of CHHS. This bill would require the Secretary of CHHS to adopt the determination of the independent expert review panel and promptly issue a written decision to the child's parent or guardian. This bill would specify that the decision shall not be subject to further administrative review.

This bill would specify that a child whose medical exemption revocation is appealed shall continue in attendance and shall not be required to begin the immunization required for conditional admittance, provided that the appeal is filed within 30 calendar days of revocation of the medical exemption. This bill would specify that CDPH and CHHS appeals process is exempt from the rulemaking and administrative adjudication provisions in the Administrative Procedure

This bill would require CDPH, the Board, and the Osteopathic Medical Board of California to enter into a memorandum of understanding or similar agreement to ensure compliance with the requirements of this section.

This bill would require CDPH and the independent expert review panel to comply with all applicable state and federal privacy and confidentiality laws. This bill would require CDPH to establish the process and guidelines for review of medical exemptions. This bill would require CDPH to communicate the process to providers and post this information on CDPH's website.

This bill would specify if CDPH or CHHS determines that contracts are required to implement this bill, CDPH may award these contracts on a single-source or sole-source basis. This bill would allow CDPH to implement and administer the requirements in this bill through provider bulletins, or similar instructions, without taking regulatory action.

This bill will still require the exemption form to include an authorization to release medical records to the Board. This will remove the obstacles the Board is currently facing in medical exemption cases and allow the Board to receive the medical records so the Board's experts can review these cases and opine on whether the physician followed the standard of care. The Board has taken a support in concept position on this bill. The Board supports the concepts that allow the Board to receive the medical records related to medical exemptions and require review of medical exemptions.

During the discussion on SB 276 at the Board's interim meeting, numerous members raised issues regarding the CDC guidelines being too narrow and the appropriate entity to have oversight of the review of medical exemptions. This bill will now require CDPH to review exemptions using applicable CDC, ACIP, or AAP criteria for appropriate medical exemptions. This bill now also allows CDPH, based on the medical discretion of the clinically trained immunization staff member, to accept a medical exemption that is based on other contraindications or precautions, including consideration of family medical history, if the issuing physician provides written documentation to support the medical exemption that is consistent with the relevant standard of care. This bill now requires CDPH to notify the Board of any physician who has five or more medical exemption forms in a calendar year that are revoked. This bill now narrows the medical exemptions that require CDPH review and ensures that clinically trained personnel, a physician or RN, at CDPH are reviewing the exemption, and requires a final review by a physician before an exemption can be revoked. In addition, an appeals process has been added to allow a parent or guardian to appeal a revocation, and the appeal process is housed in a different agency with a panel of physicians reviewing the appeal and making the final decision. The Board should determine if these changes address the Board's previous concerns and change the Board's position on this bill.

FISCAL: Minimal and absorbable

<u>SUPPORT:</u> American Academy of Pediatrics, California (co-sponsor); California Medical Association (co-sponsor); Vaccinate California (cosponsor); AIDS Healthcare foundation; American College of Physicians, California Chapter; California Academy of Eye Physicians and Surgeons; California Academy of Family Physicians; California Academy of Pain Medicine; California Academy of Preventive Medicine; California Association of Hospitals and Health Systems; California Chapter American College of Cardiology; California Children's Hospital Association; California Hospital Association; California Immunization Coalition; California Life Sciences Association; California Optometric Association; California Orthopedic Association; California School Nurses Organization; California Society for Allergy, Asthma and Immunology; California Society of Health System Pharmacists; California Society of Physical Medicine and Rehabilitation; California State Association of Counties; California State PTA; Children Now; Children's Defense Fund; Children's Specialty Care Coalition; County Health Executives Association of California; County of Los Angeles Board of Supervisors; County of Marin; County of Santa Clara; Donate Life California; Health Officers Association of California: Infectious Disease Association of California; Infectious Disease Association of California; Kaiser Permanente; LA Care Health Plan; March of Dimes; Parent's For Choice; Sonoma County Health Action Committee for Healthcare Improvement; and Sutter Health

A Voice for Choice Advocacy; Advocates for Physicians' Rights; **OPPOSITION:** Alliance for Natural Health USA; Amy's Chocolate; Animal Wellness & Veterinary Pain Management, Inc.; Association of American Physicians and Surgeons; Autism International Association, Inc.; Breath Bodyworks Holistic Healing Network; California Health Coalition Advocacy; California Right to Life Committee, Inc.; Californians for Trusted Healthcare; Children's Health Coalition; Concerned Physicians Opposed to SB 276; Drjockers Com; Eagle Forum of California; Educate.Advocate.; Families for Early Autism Treatment; Matrix Mothers; Moms Across America; National Health Freedom Action; National Vaccine Information Center; Orange County Health Choice; Parentalrights.Org; Parents United 4 Kids; Physicians Association for Anthroposophical Medicine; Physicians for Informed Consent; Progressives for Choice; Raphael Medicine and Therapies Pc; SCV for Parental Rights; U Turn for Christ; Vaccine-Injury Awareness League; West Coast Elite Dance; West Virginians for Health Freedom; and Numerous Individuals.

<u>ATTACHMENT:</u> <u>SB 276, as amended, Pan. Immunizations: medical exemptions.</u> Version: 07/01/19 – Amended Assembly

BILL	AUTHOR	TITLE	STATUS	AMENDED
AB 4	Arambula	Medi-Cal: Eligibility	2-Year	05/17/19
AB 5	Gonzalez	Worker Status: Employees and Independent Contractors	Sen. Approps	07/11/19
AB 8	Chu	Pupil Health: Mental Health Professionals	Sen. Health	05/16/19
AB 62	Fong	State Government: FI\$Cal: Transparency	2-Year	03/28/19
AB 63	Fong	State Government	2-Year	04/03/19
AB 64	Fong	State Project Audits	2-Year	04/04/19
AB 71	Melendez	Employment Standards: Independent Contractors	2-Year	02/25/19
AB 171	Gonzalez	Employment: Sexual Harassment	Sen. Approps	07/03/19
AB 174	Wood	Health Care Coverage: Financial Assistance	Sen. Approps	06/26/19
AB 193	Patterson	Professions and Vocations	2-Year	03/20/19
AB 196	Gonzalez	Paid Family Leave	2-Year	03/26/19
AB 204	Wood	Hospitals: Community Benefit Plan Reporting	Sen. Approps	06/28/19
AB 214	Mullin	The Spinal Cord Injury Research Program	2-Year	
AB 243	Kamlager-Dove	Implicit Bias Training: Peace Officers	Sen. Approps	04/22/19
AB 262	Gloria	Local Health Officers: Communicable Diseases	Sen. 3rd Reading	06/11/19
AB 283	Chu	CalWORKS: School Attendance: Immunizations	Sen. Approps	06/20/19
AB 289	Fong	California Public Records Act Ombudsperson	2-Year	04/24/19
AB 312	Cooley	State Government: Administrative Review: Regulations	2-Year	
AB 319	Rubio, Blanca	Narcotic Treatment: Medication Assisted Treatment: Medi-Cal	2-Year	03/25/19
AB 362	Eggman	Controlled Substances: Overdose Prevention Program	2-Year	04/25/19
AB 365	Garcia, C.	State Civil Service: Examination and Hiring Process	Sen. Approps	06/19/19

BILL	AUTHOR	TITLE	STATUS	AMENDED
AB 372	Voepel	State Employees: Infant at Work Programs	Sen. Approps	04/22/19
AB 379	Maienschein	Youth Athletics: Concussion and Sudden Cardiac Arrest Prevention Protocols	Senate	04/01/19
AB 388	Limon	Alzheimer's Disease	Sen. Approps	06/24/19
AB 389	Santiago	Substance Use Disorder Treatment: Peer Navigators	2-Year	
AB 414	Bonta	Healthcare Coverage: Minimum Essential Coverage	Sen. Approps	07/11/19
AB 420	Lackey	The California Cannabis Research Program	Sen. Approps	07/08/19
AB 451	Santiago	Health Care Facilities: Treatment of Psychiatric Emergency Cond.	Sen. Approps	07/02/19
AB 476	Rubio, B.	Department of Consumer Affairs: Task Force: Foreign- Trained Prof.	Sen. Approps	
AB 496	Low	Business and Professions	Sen. 3rd Reading	05/06/19
AB 499	Mayes	Personal Information: SSNs: State Agencies	2-Year	04/11/19
AB 512	Ting	Medi-Cal: Specialty Mental Health Services	Sen. Approps	07/03/19
AB 521	Berman	Physicians: Firearms: Training	Sen. Approps	05/30/19
AB 537	Wood	Medi-Cal Managed Care: Quality Improvement and Value Based Financial Incentive Prog.	2-Year	
AB 538	Berman	Sexual Assault: Forensic Examinations and Reporting	Sen. Approps	06/13/19
AB 555	Gonzalez	Paid Sick Leave	2-Year	04/29/19
AB 565	Maienschein	Public Health Workforce Planning: Loan Forgiveness & Repayment	Sen. Approps	06/10/19
AB 577	Eggman	Medi-Cal: Maternal Mental Health	Sen. Approps	07/11/19
AB 598	Bloom	Hearing Aids: Minors	Sen. Approps	07/02/19
AB 648	Nazarian	Wellness Programs	2-Year	03/28/19
AB 656	Garcia, E.	Office of Healthy and Safe Communities	Sen. Approps	06/27/19

BILL	AUTHOR	TITLE	STATUS	AMENDED
AB 678	Flora	Medi-Cal: Podiatric Services	Sen. Approps	07/08/19
AB 739	McCarty	Flavored Tobacco Products	2-Year	
AB 741	Kalra	Early and Periodic Screening Program: Trauma Screening	2-Year	03/28/19
AB 743	Garcia, E.	Pupil Health: Self-Admin. Of Prescribed Asthma Medication	Chaptered, #101	04/22/19
AB 744	Aguiar-Curry	Health Care Coverage: Telehealth	Sen. Approps	07/09/19
AB 767	Wicks	Health Care Coverage: Infertility	2-Year	06/06/19
AB 770	Garcia, E.	Medi-Cal: FQHCs: Rural Health Clinics	2-Year	05/02/19
AB 798	Cervantes	Maternal Mental Health	Sen. Approps	06/13/19
AB 802	Stone, M.	Reports to the Legislature	Sen. Approps	06/04/19
AB 805	Obernolte	Reports Submitted to Legislative Committees	Senate	04/02/19
AB 810	Gipson	Organ and Tissue Transplantation: Uninsured or Undocumented Indiv.	2-Year	
AB 822	Irwin	Phlebotomy	2-Year	04/30/19
AB 824	Wood	Business: Preserving Access to Affordable Drugs	Sen. Approps	07/11/19
AB 848	Gray	Medi-Cal: Covered Benefits: Continuous Glucose Monitors	Sen. Approps	
AB 871	Gray	Graduate Medical Education: Funding	Asm. Health	
AB 873	Irwin	California Consumer Privacy Act of 2018	2-Year	05/02/19
AB 874	Irwin	California Consumer Privacy Act of 2018	Sen. Approps	03/25/19
AB 875	Wicks	Pupil Health: In-School Support Services	2-Year	04/11/19
AB 876	Flora	Health Care Coverage	2-Year	

BILL	AUTHOR	TITLE	STATUS	AMENDED
AB 882	McCarty	Termination of Employment: Drug Testing: Med. Assist. Trtmt.	2-Year	
AB 887	Kalra	Office of Health Equity: Surgeon General	2-Year	03/28/19
AB 898	Wicks	Early and Periodic Screening Program: Behavioral Health	Sen. Approps	06/13/19
AB 922	Burke	Reproductive Health and Research: Oocyte Procurement	Sen. 3rd Reading	04/11/19
AB 939	Frazier	Administrative Procedure Act: Major Regulations	2-Year	04/22/19
AB 952	Voepel	Criminal History Information: Conviction Records: DSS	2-Year	
AB 973	Irwin	Pharmacies: Compounding	Asm. Concurrence	05/13/19
AB 977	Stone, M.	Medi-Cal: Early and Periodic Screening, Diagnosis and Treatment	2-Year	03/28/19
AB 990	Gallagher	Medi-Cal Managed Care Plans: Financial Incentives	2-Year	03/28/19
AB 993	Nazarian	Health Care Coverage: HIV Specialists	Sen. 3rd Reading	04/11/19
AB 1033	Cooper	State Employment: New Employees: Information	Sen. Approps	05/16/19
AB 1055	Levine	Publicly Funded Technology Projects	2-Year	04/03/19
AB 1058	Salas	Medi-Cal: Specialty Mental Health Svcs. And Substance Use Disorder	Sen. Approps	06/25/19
AB 1076	Ting	Criminal Records: Automatic Relief	Sen. Approps	07/11/19
AB 1098	O'Donnell	Substance Use Disorders: Youth Programs	Sen. Approps	07/01/19
AB 1105	Gipson	Sickle Cell Disease	2-Year	04/11/19
AB 1107	Chu	Worker's Compensation	2-Year	04/22/19
AB 1131	Gloria	Medi-Cal: Comprehensive Medication Management	Sen. Approps	06/24/19
AB 1174	Wood	Health Care: Anesthesia Services	2-Year	03/25/19

BILL	AUTHOR	TITLE	STATUS	AMENDED
AB 1184	Gloria	Public Records: Writing Transmitted by Email: Retention	Sen. Approps	05/16/19
AB 1189	Wicks	Abortion	2-Year	03/28/19
AB 1209	Nazarian	Long-Term Care Benefits	Sen. Approps	06/25/19
AB 1223	Aguiar-Curry	Living Organ Donation	Sen. 3rd Reading	05/06/19
AB 1224	Gray	Disability Insurance: Paid Family Leave Program	2-Year	04/22/19
AB 1246	Limon	Healthcare Coverage: Basic Health Care Services	Sen. 3rd Reading	07/11/09
AB 1327	Petrie-Norris	Narcotic Treatment Programs: Safe Storage Devices	2-Year	04/04/19
AB 1365	Comm. on Vet. Affairs	Disabled Veteran Business Enterprise Program	Sen. Approps	03/19/19
AB 1372	Grayson	Employers: Prohibited Disclosure of Arrest Information	2-Year	03/27/19
AB 1494	Aguiar-Curry	Medi-Cal: Telehealth: State of Emergency	Sen. Approps	07/11/19
AB 1524	Chiu	Medi-Cal: Provider Enrollment	2-Year	04/02/19
AB 1531	Salas	State Agencies: Bilingual Services	2-Year	
AB 1550	Bonta	Crisis Stabilization Units: Psychiatric Patients	Sen. Approps	06/27/19
AB 1592	Bonta	Athletic Trainers	2-Year	03/28/19
AB 1600	Kalra	Discovery: Personnel Records: Peace Officers & Custodial Officers	Sen. 3rd Reading	06/28/19
AB 1606	Gray	UC: School of Medicine: San Joaquin Valley Reg. Campus Med. Ed. Fund	Asm. 3rd Reading	
AB 1611	Chiu	Emergency Hospital Services: Costs	2-Year	06/27/19
AB 1622	Carrillo	Family Physicians	Sen. Approps	05/13/19
AB 1630	Irwin	Medical Billing Task Force	2-Year	
AB 1676	Maienschein	Health Care: Mental Health	2-Year	04/22/19

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BILL	AUTHOR	TITLE	STATUS	AMENDED
AB 1759	Salas	Health Care Workers: Rural and Underserved Areas	2-Year	05/17/19
AB 1803	Comm. on Health	Pharmacy: HealthCare Coverage: Claims for Prescriptions	Chaptered, #114	
AB 1804	Comm. on Lab. And Emp.	Occupational Injuries and Illnesses: Reporting	Asm. Concurrence	06/13/19
AB 1805	Comm. on Lab. And Emp.	Occupational Safety and Health	Sen. 3rd Reading	04/29/19
AB 1819	Comm. on Jud.	Inspection of Public Records: Use of Requestors Rep. Equip.	Sen. Approps	04/11/19
ACR 28	Gipson	Sickle Cell Disease: Education and Treatment	Asm. Approps	06/25/19
ACR 50	Chiu	Workforce Development	Sen. Approps	
HR 6	Limon	Relative to Women's Reproductive Health	Adopted	
SB 24	Leyva	Public Health: Public Univ. Stud. Health Ctrs: Abortion by Med.	Asm. Approps	06/13/19
SB 34	Wiener	Cannabis: Donations	Asm. Approps	07/03/19
SB 56	Roth	UC, Riverside School of Medicine: Expansion	2-Year	05/17/19
SB 156	Nielsen	Health Facilities: Emergency Medical Services	Asm. Approps	07/05/19
SB 163	Portantino	Healthcare Coverage: Pervasive Dev. Disorder or Autism	Asm. Approps	06/27/19
SB 165	Atkins	Medical Interpretation Services	Asm. Approps	
SB 175	Pan	Health Care Coverage: Minimum Essential Coverage	2-Year	04/03/19
SB 179	Nielsen	Excluded Employees: Arbitration	Asm. Approps	
SB 181	Chang	Healing Arts Boards	Sen. Rules	
SB 207	Hurtado	Medi-Cal: Asthma Preventive Services	Asm. Approps	07/02/19

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BILL	AUTHOR	TITLE	STATUS	AMENDED
SB 223	Hill	Pupil Health: Administration of Medicinal Cannabis: Schoolsites	Asm. 3rd Reading	06/26/19
SB 260	Hurtado	Automatic Health Care Coverage Enrollment	Asm. Approps	06/18/19
SB 275	Pan	Psychologists: Prohibition Against Sexual Behavior	2-Year	
SB 305	Hueso	Compassionate Access to Medical Cannabis Act or Ryan's Law	Asm. Health	05/08/19
SB 382	Nielsen	Medi-Cal: Managed Health Care Plan	Asm. Approps	07/11/19
SB 441	Galgiani	Electronic Health Records: Vendors	2-Year	03/25/19
SB 446	Stone	Medi-Cal: Hypertension Medication Management Services	2-Year	04/11/19
SB 452	Jones	Ken Maddy California Cancer Registry	Asm. Approps	04/11/19
SB 464	Mitchell	California Dignity in Pregnancy and Childbirth Act	Asm. Approps	06/27/19
SB 537	Hill	Worker's Compensation: Treatment and Disability	Asm. Approps	07/02/19
SB 546	Hueso	Unlicensed Activity	Sen. Rules	
SB 569	Stone	Controlled Substances: Prescriptions: Declared Emergency	Asm. Approps	07/02/19
SB 583	Jackson	Clinical Trials	Asm. Approps	06/19/19
SB 590	Stone	Mental Health Evals: Gravely Disabled Due to Impairment by Chronic Alcoholism	Asm. Approps	03/27/19
SB 600	Portantino	Health Care Coverage: Fertility Preservation	Asm. Approps	04/30/19
SB 601	Morrell	State Agencies: Licenses: Fee Waiver	Asm. Approps	06/27/19
SB 612	Pan	Health Care: Data Reporting	2-Year	
SB 615	Hueso	Public Records: Disclosure	2-Year	
SB 627	Galgiani	Medicinal Cannabis & Products: Veterinary Medicine	Asm. Approps	04/30/19

Agenda Item 9A

BILL	AUTHOR	TITLE	STATUS	AMENDED
SB 639	Mitchell	Medical Services: Credit or Loan	Asm. Approps	07/01/19
SB 650	Rubio	Cancer Medication Advisory Committee	Asm. Approps	07/08/19
SB 700	Roth	Business and Professions: Non-Comp. with Support Orders & Tax Delinq.	Sen. Rules	
SB 706	Galgiani	Public Health: Pulmonary Hypertension Task Force	Asm. Approps	07/01/19
SB 746	Bates	Health Care Coverage: Anti-Cancer Medical Devices	Asm. Approps	05/30/19
SB 749	Durazo	California Public Records Act: Trade Secrets	Asm. Approps	06/19/19
SJR 4	Leyva	Title X	Chaptered, #115	
SR 7	Leyva	Relative to Women's Reproductive Health	Adopted	01/07/19