California State Assembly

BUSINESS AND PROFESSIONS

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CHAIR

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AGENDA

Tuesday, April 13, 2021
9 a.m. -- State Capitol, Assembly Chamber

BILLS HEARD IN FILE ORDER

1.	AB 468	Friedman	Emotional support dogs.
2.	AB 293	Kalra	Preneed funeral arrangements: unclaimed property.
3.	AB 384	Kalra	Cannabis and cannabis products: animals: veterinary medicine.
4.	AB 54	Kiley	COVID-19 emergency order violation: license revocation.(Urgency)
5.	AB 484	Medina	Alarm company operators: advertisements.
6.	AB 392	Nazarian	Clinical laboratories: total protein test: authorization.
7.	AB 1278	Nazarian	Physicians and surgeons: payments: disclosure: notice.
8.	AB 847	Quirk	Electrically conductive balloons.
9.	AB 526	Wood	Dentists and podiatrists: clinical laboratories and vaccines.(Urgency)
10.	AB 527	Wood	Controlled substances.
11.	AB 1430	Arambula	Pharmacy: dispensing: controlled substances.
12.	AB 1194	Low	Conservatorship.

COVID FOOTER

SUBJECT:

We encourage the public to provide written testimony before the hearing by visiting the committee website at http://abp.assembly.ca.gov/. Please note that any written testimony submitted to the committee is considered public comment and may be read into the record or reprinted.

Due to ongoing COVID-19 safety considerations, including guidance on physical distancing, seating for this hearing will be very limited for press and for the public. All are encouraged to watch the hearing from its live stream on the Assembly's website at https://www.assembly.ca.gov/todaysevents.

The Capitol will be open for attendance of this hearing, but the public is strongly encouraged to participate via the web portal, Remote Testimony Station, or phone. Any member of the public attending a hearing in the Capitol will need to wear a mask at all times while in the building. We encourage the public to monitor the committee's website for updates.

Date of Hearing: April 13, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
AB 468 (Friedman) – As Amended April 6, 2021

SUBJECT: Emotional support dogs.

SUMMARY: Requires a person or business that sells or provides an emotional support dog to provide an explicit disclosure form stating that the dog does not have the special training required, and is not entitled to the rights and privileges accorded by law to a guide, signal, or service dog. Requires a person or business that sells or provides a certificate, identification, tag, vest, leash, or harness for an emotional support dog to provide an explicit disclosure form stating that such material does not entitle the dog to the rights and privileges of service dog. Requires a health care practitioner to meet certain requirements before issuing documentation related to a person's need for an emotional support dog, as specified.

EXISTING FEDERAL LAW AND REGULATIONS:

1) Establishes the American with Disabilities Act (ADA), which generally prohibits discrimination against individuals with disabilities in areas of employment, transportation, public accommodations and more. (42 United States Code Section 12101 et seq.)

2) Defines a "service animal" under the ADA as any dog that is individually trained to do work or perform tasks for the benefit of an individual with a disability, including a physical, sensory psychiatric intellectual, or other mental disability. States that the work or tasks performed by a service animal must be directly related to the individual's disability. Specifies that other species of animals, whether wild or domestic, trained or untrained, are not considered service animals (Code of Federal Regulations (CFR) Title 28 Section 35.104)

3) States that a public entity, regardless of pet policy, shall accommodate and permit the use of a service animal. Further declares that individuals with disabilities shall be permitted to be accompanied by their service animals in all areas of a public entity's facilities where members of the public are allowed to go. (28 CFR Section 35.136(a) and 35.136(g))

EXISTING STATE LAW AND REGULATIONS:

1) Defines a "guide dog" as a dog that has been trained or is being trained to assist blind or visually impaired individuals. (Business and Professions Code (BPC) Section 7201)

2) Defines a "signal dog" as a dog trained to alert an individual who is deaf or hard of hearing to intruders or sounds (Penal Code Section 365.5(e) and Civil Code Section 54.1(b)(6)(B)(ii))

3) Defines a "service dog" as a dog trained individually trained to do work or perform tasks for the benefit of an individual with a disability, including, but not limited to, minimal protection work, rescue work, pulling a wheelchair, or fetching dropped items (Penal Code section 365.5(f) and Civil Code Section 54.1(b)(6)(B)(ii))

4) Defines a "guide dog instructor" as a person who instructs or trains persons who are blind or visually impared in the use of guide dogs or who engages in the business of training, selling, hiring, or supplying guide dogs for persons who are blind or visually impaired. (BPC Section 7201(a))

5) Prohibits a person from advertising or presenting themselves as a "guide dog instructor," "certified guide dog instructor," or any related terms without having knowledge of the special problems of persons who are blind or visually impaired and being able to teach them, being able to demonstrate the ability to train guide dogs with which persons who are blind or visually impaired would be safe under various traffic conditions, or being employed by a guide dog school certified by the International Guide Dog Federation (BPC Section 7200)

6) States that any person who knowingly and fraudulently represents themselves to be the owner or trainer of a guide, signal, or service dog is guilty of a misdemeanor punishable by imprisonment in county jail not exceeding six months, by a fine not exceeding $1,000, or by both that fine and imprisonment. (Penal Code Section 365.7)

7) Establishes the Polanco-Lockyer Pet Breeder Warranty Act, which regulates the breeding and sale of dogs. (Health and Safety Code, Section 122045 et seq.)

8) Establishes the California fair Employment and Housing Act (FEHA) which, broadly, provides discrimination protections in employment and housing. (Government Code Section 12900 et seq)

9) Interprets "support animals" for the purposes of the FEHA, as animals that provide emotional, cognitive, or other support to an individual with a disability. Clarifies that a support animal does not need to be trained or certified. States that support animals are also known as comfort animals or emotional support animals (2 California Code of Regulations (CCR) Section 12005(d)(2))

THIS BILL:

1) Requires a person or business that sells or provides a dog as an emotional support dog to provide an explicit disclosure form stating that the dog does not have the special training required of a guide, signal, or service dog and is not entitled to the rights and privileges accorded by law to a guide, signal, or service dog.

2) Requires a person or business that offers to sell or provide a certificate, identification, tag, vest, leash, or harness for an emotional support dog to provide an explicit disclosure form to the buyer or potential buyer stating that the material does not entitle an emotional support dog to the rights and privileges accorded by law to a guide, signal or service dog.

3) Prohibits a person or business that sells or provides certification or registration of an emotional support dog from implying that there is government validation or endorsement of such certification or registry.

4) Prohibits a health care practitioner from providing documentation relating to an individual's need for an emotional support dog unless the health care practitioner:

   a) Has a valid, active license and includes the effective date, license number, jurisdiction, and type of professional license in the documentation

   b) Has jurisdiction in which the documentation is provided

   c) Establishes a client-provider relationship with the individual for at least 30 days prior to providing the documentation requested the individual's need for an emotional support dog.

   d) Completes an in-person clinical evaluation of the individual regarding the need for an emotional support dog.

5) States that a person who violates the bill's provisions may be punished by a fine or civil penalty.

6) Clarifies that the bill shall not be construed to restrict or change existing federal and state law related to a person's rights for reasonable accommodation and equal access to housing.

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

COMMENTS:

Purpose. The bill is sponsored by the **Guide Dogs for the Blind** and **Canine Companions for Independence.** According to the author: "It is a privilege to be the owner of an emotional support or service dog although the two classifications do not merit the same levels of access. Unfortunately, individuals have taken advantage of the Americans with Disabilities Act (ADA) for their own privileged access in public spaces that is putting everyone else around them at risk of harm. People with disabilities who use task trained service dogs earn their right to be in public spaces as a result of a rigorous training process and ensuring their service dogs satisfy behavioral standards under the ADA. The fraudulent selling of emotional support dogs and identifying equipment as entitling the same access rights as service dogs not only creates confusion for the owner of the animal but also the general public which has to comply with ADA laws. AB 468 will help curtail the misrepresentation of buying and selling emotional support dogs and their identifying equipment as having equal access rights as trained service dogs, creating a safer public space for all - especially people with disabilities who rely on task trained service dogs for independence."

Background.

The Americans with Disabilities Act and Service Animals. Established in 1990, the Americans with Disabilities Act (ADA) is a landmark civil rights law prohibiting discrimination against individuals with disabilities across broad categories, including employment, education, transportation, and access to public accommodations. The ADA recognizes that many individuals with disabilities use service animals in order to fully participate in everyday life – to that end, the ADA defines a service animal as a dog that has been individually trained to work or perform

tasks for an individual with a disability. It is important to note that in order to be considered a service dog, the tasks performed by the animal must be directly related to the person's disability. For example, the dog must be trained to help a visually impaired individual with navigating their surroundings safely, or be trained to sense the onset of seizures for individuals suffering from epilepsy. Under the ADA, public entities must reasonably accommodate individuals with disabilities, and allow service animals into their facilities regardless of established pet policies. California has several statutory provisions extending the same protections over the use of service animals, notably under the California Fair Employment and Housing Act, the Unruh Civil Rights Act and the Disabled Persons Act.

Training of Service Animals. California and the United States are home to a number of dog schools whose mission and focus is to train service animals. Often accredited by third-party organizations, these schools provide intensive training to ensure service animals can appropriately help their human partner live normal and productive lives. As an example, many guide dog schools will screen young puppies and administer behavioral tests to ensure obedience, calm temperament, attention to surroundings, or ability to learn. If selected for guide dog training, puppies will work with trained guide dog instructors who will help the dog develop key skills, such as stopping at curbs, avoiding obstacles, stopping for traffic, and other safe navigation practices. Guide dog training also includes advanced training such as "intelligent disobedience," which teaches the animal to deliberately disobey a command – such as an order to walk into a hazard or into traffic – in order to protect the life of the human partner. The training of service animals can be resource intensive: according to the Guide Dog Foundation for the Blind, it costs over $50,000 to breed, raise, train, and place a single guide dog. Despite those costs, many guide dog schools partner the animal with an individual at little to no cost, relying on charitable donations and support to fund training operations.

Service Animals vs. Emotional Support Animals. In recent years, a new category of assistance animals has emerged, often referred to as "emotional support animals" (ESAs). ESAs are legally different from service animals. As previously referenced, service animals are defined under federal and California law as a dog that is individually trained to do work or perform tasks for the benefit of an individual with a disability. An ESA is a dog (or other animal) that is not trained to perform specific acts related to a person's disability. Instead, the owner of an ESA derives a sense of well-being, fulfillment, companionship, or lessened anxiety with the presence of the animal. Of note, ESAs do not enjoy the same legal privileges as trained service dogs: for example, while service dogs must be allowed to accompany their human partner in public places, ESAs do not have to be accommodated.

According to the author and sponsors, the emergence of ESAs has led to an increase in the fraudulent selling and subsequent misrepresenting of emotional support dogs as service dogs. Canine Companions for Independence, one of the bill's sponsors, states that in its 2019 poll of graduate teams, 78% reported that an uncontrolled dog has interfered with, distracted, snapped at, bitten, and/or vocalized at their dog in a public establishment where pet dogs are not normally allowed – representing a 12% increase from the previous year's poll. Additionally, 60% feel service dog fraud has negatively impacted their quality of life and independence.

Such instances can lead to consumer protection issues: a person with a disability partnered with a fraudulent service animal could be placed in danger if working with a dog that did not receive

the appropriate training. Additionally, the public may be harmed by an untrained animal that has been allowed in a public setting reserved for service dogs under the ADA. For example, airline company Delta Air reported a nearly 85 percent increase in animal incidents between 2016 and 2021 related to emotional support animals allowed on board – including urination, defecation and biting. In response to these trends, the U.S. Department of Transportation issued a rule in December of 2020 stating that airline carriers no longer had to recognize emotional support animals as service animals, and allowed airline carriers to request documentation attesting to a service dog's health, training, and behavior.

A number of business interests have also formed around emotional support animals. According to the bill's sponsors, individuals and business entities are now selling certificates and accessories – such as vests and identification tags – that provide a misleading sense that such items grant an ESA the same rights and privileges as service animals or provide an endorsement from the government. As an example, a search for "emotional support dog vest" on Amazon's online marketplace yields 413 results for products ranging from vests, tags, patches, holographic identification cards prominently featuring the words "Emotional Support Animal" and in some instances "ESA, Protected Under Federal Law."

This bill aims to address the fraudulent sale and misrepresentation of emotional support animals by requiring a person or business that sells a dog as an emotional support to provide an explicit disclosure form stating that the dog does not have the special training required of a guide, signal, or service dog and is not entitled to the rights and privileges accorded by law to a guide, signal, or service dog. AB 468 also requires a person or business sells a certificate, identification, tag, vest, leash, or harness for an emotional support dog to provide an explicit disclosure form stating that the material does not entitle an emotional support dog to the rights and privileges accorded by law to a guide, signal, or service dog. In addition, the bill prohibits a person or business selling a certificate or registration for an emotional support dog to imply that such certification or registration has government validation or endorsement.

Notable Privileges for ESAs. While ESAs do not have the same rights and privileges as service dogs, there are notable exceptions, particularly in housing statutes. Under federal and California laws, individuals with a disability may request to keep an assistance animal as a reasonable accommodation to a housing provider's pet restrictions. In the context of housing, an assistance animal includes both service dogs and any animals that provides emotional support. Generally, reasonable accommodation requests involve a request to allow the animal to live in a property with a no-pets policy, or a request to waive a pet deposit fee. In specified instances, the housing provider may request disability-related information, such as documentation from a health care provider, if the disability and the disability-related need for the animal were not apparent. In order to respect these existing privileges, this bill clarifies that its provisions shall not be construed to restrict or change existing federal and state law related to a person's rights for reasonable accommodation and equal access to housing.

Documentation issued by health care or mental health providers. Letters from health care and mental health providers are sometimes requested to show that an animal provides a disability-related benefit to an individual. In some instances, ESAs can provide legitimate therapeutic benefits and play an important role in supplementing mental health. However, documentation from a provider may be required to bolster the legitimacy of an ESA, particularly in the context

of housing and travel. As a result, it has become increasingly common for individuals to request a health care or mental health provider to provide such documentation. Providers who may issue such documentation may include physicians, psychiatrists, psychologists, licensed marriage and family therapists, licensed clinical social workers, and licensed professional clinical counselors.

In order to ensure legitimacy and prevent fraudulent issuing of such documentations, the bill proposes to enact specific criteria that must be met before a health care practitioner can issue documentation related to an individual's need for an ESA. Specifically, the provider must (1) have a valid, active license and include the effective date, license number, jurisdiction, and type of professional license in the documentation; (2) have jurisdiction in which the documentation is provided; (3) establish a client-provider relationship with the individual for at least 30 days prior to providing the documentation requested the individual's need for an emotional support dog and (4) completes an in-person clinical evaluation of the individual regarding the need for an emotional support dog.

Current Related Legislation.

None.

Prior Related Legislation.

AB 1705 (Low, Chapter 669, Statutes of 2017): Sunset the State Board of Guide Dogs for the Blind.

ARGUMENTS IN SUPPORT:

Guide Dogs for the Blind writes in support: "AB 468 is designed to address the growing online sale of fraudulent service animal certificates by unscrupulous opportunists. These certificates are often sold online with the promise of providing pets public access equal to that of service dogs as defined by Federal law under the ADA. In addition to misleading people, these unscrupulous business practices have also resulted in putting innocent untrained animals in uncomfortable, scary, and even dangerous situations. These so called 'emotional support animals' are pets with little or no specialized training. Both legitimate service dogs as well as innocent bystanders have unfortunately been also attacked and hurt by these untrained animals. AB468 will [also] require health care practitioners who provide documentation relating to an individual's need for an emotional support animal […].

In recent years, confusion between legitimate service dogs and pets has been fueled by the growing availability of service dog certificates and vests via the internet. The confusion this creates makes it more difficult for our guide teams to travel without being harassed. Doing so will reduce a fundamental threat to the access and independence that legitimate guide dogs and other service dogs enable."

Canine Companions of Independence and the Humane Society of the United States collectively write in support: "AB 468 […] will prevent the sale of emotional support animals as guide, signal, or service dogs, and requires the sale of emotional support animals be accompanied with a disclosure. The impact of the pet and emotional support animal sector on task-trained service dogs has been extreme. Vendors of emotional support animals and

credentials perpetuate misinformation around the access rights of emotional support, pet, and service dogs. The result is a dramatic rise in the number of incidents of untrained pet dogs in public accommodations, the number of altercations and effects of untrained pet dogs on legitimate task-trained service dogs assisting people with disabilities, and an increase in access denials for people with disabilities who rely on legitimate service dogs for independence. Currently, individuals seeking an emotional support dog or credentials including medical documentation can establish a one-time relationship with mental healthcare providers online to receive documentation of need in less than 10 minutes, without a legitimate evaluation of need for an emotional support animal."

The California Council for the Blind writes in support: "Users of service animals have long faced public backlash due to the inappropriate use and conduct of emotional support animals in public places, as well as from the conduct arising out of people who fraudulently call their animals emotional support animals. The provisions of this bill are not only good policy for the general public and for service animal users, but also for those responsible emotional support dog users who benefit in important ways from the use of these animals."

Golden State Guide Dog Handlers, Inc writes in support: "Access for trained guide dogs and their handlers to public places is critical, and business owners find themselves in a quandary when encountering disruptive behavior demonstrated by untrained emotional support dogs. AB 468 will help to stop the sale of phony licenses and gear that falsely implies that a dog is trained as a service or signal dog. It also puts forth guidelines for health care providers to clearly indicate the criteria for establishing a need for an emotional support dog. AB 468 will establish the fines and punishment for businesses who falsely qualify animals as an emotional support animal. It will allow trained guide or signal dog teams to function in all public places without needing to navigate the terrain of untrained and disruptive and sometimes dangerous situations.

The California Apartment Association writes in support: "CAA members understand the importance that guide, signal, and service dogs play in the lives of many disabled individuals. However, our members regularly encounter questionable documentation from businesses that sell service dog certificates without any proof or verification. This practice is unfair to people with disabilities who have a legitimate need for these animals."

The Western Manufactured Housing Communities Association writes in support: "As you may know, WMA is the largest statewide trade association representing the owners of mobilehome parks across California. WMA is vitally concerned about the health, safety, and well-being of mobilehome park residents. As such, recognize the important role that emotional support dogs play and believe [AB 468] takes great care to put additional consumer protections in place.

ARGUMENTS IN OPPOSITION:

None on file.

REGISTERED SUPPORT:

Guide Dogs for the Blind (Sponsor)
Canine Companions for Independence (Sponsor)

California Council for the Blind
Golden State Guide Dog Handlers, Inc.
The California Apartment Association
The Western Manufactured Housing Communities Association

REGISTERED OPPOSITION:

None on File.

Analysis Prepared by: Patrick Le / B. & P. / (916) 319-3301

Date of Hearing: April 13, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
AB 293 (Kalra) – As Introduced January 21, 2021

SUBJECT: Preneed funeral arrangements: unclaimed property.

SUMMARY: Sets the conditions by which abandoned preneed funeral trust funds can escheat to the state. Specifies the procedures and noticing requirements regarding preneed funeral agreements for funeral establishments that cease operations. Requires the Cemetery and Funeral Bureau to create the necessary forms and regulations regarding notices and notice retention, as specified.

EXISTING LAW:

1) Establishes the Cemetery and Funeral Bureau (Bureau) under the Department of Consumer Affairs to license and regulate crematories, cremated remains disposers, cemeteries, cemetery managers, cemetery salespersons, cemetery brokers, funeral establishments, funeral directors and embalmers. (Business and Professions Code (BPC) Section 7600 et seq.))

2) Authorizes a licensed funeral establishment to enter into a preneed contract, in which a party pays the funeral establishment in advance to deliver funeral-related services, but only if the money paid or securities delivered are held in trust until the terms of the preneed contract are met. (BPC Section 7735)

3) Provides for the following definitions:

   a) "Trustee" means any banking institution or trust company legally authorized and empowered by the State of California to act as trustee in the handling of trust funds, or not less than three persons only one of whom may be an employee of the funeral establishment.

   b) "Trustor" means any person who pays the money or deposits the securities used to cover the cost of a preneed contract.

   c) "Beneficiary" means be the person for whom the funeral services are arranged.

   d) "Corpus of the trust" means all monies paid and securities delivered by the trustor. (BPC Section 7736)

4) Allows the income generated from the trust to be used to pay an annual fee determined by the Bureau to cover the costs of administering the trust. (BPC Section 7735)

5) Allows the income from the trust to be used to establish a reserve, not to exceed 10 percent of the value of the trust, which may be used as a revocation fee in the event the preneed contract is canceled. (BPC Section 7735)

6) States that the trust agreement includes a mandate requiring a trustee to deliver the money and securities paid into the trust to the funeral establishment, upon receipt of the following:

a) The signatures of a majority of the trustees.

b) A certified copy of the death certificate or other satisfactory evidence of the beneficiary's death.

c) Satisfactory evidence that the funeral establishment provided the agreed-upon merchandise and services. (BPC Section 7737)

7) States that the trust agreement must include a mandate requiring a trustee, upon written demand, to deliver the money and securities paid into the trust to the trustor, including any accrued income but minus the revocation fee, as long as the funeral establishment has not yet furnished the goods and services agreed upon. (BPC Section 7737)

8) Exempts preneed funeral arrangements from the asset tests for aid to families with dependent children and for state supplemental income benefits; further authorizes such trusts to be made irrevocable if needed to qualify for these exemptions. (BPC Section 7737; Welfare and Institutions Code Section 11158; Welfare and Institutions Code Section 12152.)

9) Establishes the Unclaimed Property Law (UPL) which specifies the conditions for intangible personal property to escheat to the state from its holder, and provides specific requirements for when banking, financial, insurance, and other businesses or entities that hold another's property must transmit that property to the State Controller. (Code of Civil Procedure (CCP) Sections 1500 et seq.)

10) Requires the holder of escheated property to timely submit a verified report, containing specified information, to the State Controller on an approved form. (CCP Section 1530)

11) Permits a person who claims to be the owner of property delivered to the State Controller under the UPL to file a claim for the property or the net proceeds of any sale of the property. Requires the Controller to consider each claim within 180 days and to either return the property to the claimant, or provide a written explanation to the claimant if it denies the claim. (CCP Section 1540-1541.)

THIS BILL:

1) Requires that funds maintained in a preneed funeral trust to escheat to the state, if, for more than three years after the funds become "payable and distributable", the beneficiary or trustor have not corresponded nor indicated interest in the trust property, as established by the records of the funeral establishment or trustee.

2) Deems preneed funeral trust funds to become "payable and distributable" under any of the following circumstances:

a) The beneficiary of the trust attained, or would have attained if living, 105 years of age.

b) Forty-five years have passed since execution of the agreement establishing the preneed funeral arrangement.

c) The holder has received notification of the death or presumed death of the beneficiary and has not provided the contracted-for funeral goods and services.

d) The preneed funeral trust is an installment trust, in which the amount due has not been paid in the three preceding years, and neither the trustor nor the beneficiary has communicated with the funeral establishment or the trustee about the trust during that time.

3) States that the preneed trust agreement must include a mandate requiring the trustee to deliver the corpus of the trust and any income accrued from the trust, including interest, dividends, and capital gains, as follows:

a) To the funeral establishment upon the filing of a certified copy of the death certificate or other satisfactory evidence of the death of the beneficiary, together with satisfactory evidence that the funeral establishment has furnished the merchandise and services.

b) To the trustor, if the trustor cancels the preneed funeral arrangement and the funeral establishment has not provided the merchandise and services agreed upon in the preneed contract.

c) In accordance with the UPL per the escheatment conditions established by this bill.

d) To the State Controller, if the preneed funeral arrangement is deemed abandoned;

e) To the trustor, beneficiary, or their legal representative if the funeral establishment is dissolved, closed, or has its license revoked; but if these persons cannot be located, then to the state, through escheatment, in accordance with the UPL.

4) Authorizes a funeral establishment that intends to cease engaging in business operations because of dissolution, closure, sale, or license revocation, to transfer a preneed funeral agreement to another funeral establishment if certain conditions are met.

5) Requires a funeral establishment that intends to cease business operations due to dissolution, closure, sale, or license revocation, and that intends to transfer its preneed funeral agreements to a successor establishment, to do the following:

a) Transfer the agreements only to a successor establishment that is licensed under the Bureau.

b) Provide notice, at least 60 days before ceasing operations, to the agreements' beneficiaries or trustors, as well as the trustees holding the trusts associated with these agreements. This notice must give each beneficiary or trustee 60 days to cancel their agreement after receipt.

c) Provide the Bureau with a copy of the notice, a list of all preneed funeral agreements transferred to the successor, and proof that notice was provided to the beneficiaries or trustors.

d) Obtain prior written approval of both the trustee, and the beneficiaries or trustors, for any transfer if the successor establishment is located 60 or more miles away.

6) Requires a licensed successor funeral establishment inheriting preneed agreements to retain a copy of the notice provided by the preceding funeral establishment, and proof that the notice was provided, and provide a copy of both to the Bureau upon request.

7) Requires a funeral establishment that intends to cease business operations due to dissolution, closure, sale, or license revocation, and that does not intend to transfer its preneed funeral agreements to a successor establishment, to do the following:

   a) Provide notice, at least 60 days before ceasing operations, to the agreements' beneficiaries or trustors, the trustees holding the trusts associated with these agreements, and the Bureau. The notice must inform recipients that their agreements will be canceled and the funds (including accrued income) escheated to the state, unless the beneficiary or trustor informs the trustee in writing within six months that they wish the funds returned to them.

   b) Cause funds held in trust (including accrued income) to escheat to the state if the funeral establishment or trustee is unable to locate a beneficiary or trustor, or if the beneficiary or trustor does not inform the trustee within six months that they wish the funds returned to them.

8) Mandates that, if a funeral establishment intends to cease business operations, and a beneficiary or trustor cancels its preneed agreement or requests return of funds under, that the funds must be returned to the beneficiary or trustor within 30 days.

9) Requires the Bureau, by January 1, 2023, to create the necessary forms to be used by funeral establishments when issuing the required notices above, and requires the Bureau to adopt and publish regulations regarding the type of proof of notice regarding the type of proof of notice the funeral establishment ceasing operations and the licensed successor funeral establishment are required to provide or retain.

10) States that the escheatment of funds to the State Controller releases the funeral establishment from any obligation to provide goods or services under the original preneed funeral arrangement.

11) Safeguards the funeral establishment if it provides goods or services to the beneficiary of a preneed funeral arrangement post-escheatment, by permitting the funeral establishment to recover escheated funds through submitting appropriate documentation to the State Controller.

12) Prohibits a trustee or funeral establishment from charging a trust, trustor, or beneficiary any fees or costs associated with searches or verifications required to fulfill the requirements of this bill, but does permit the recoupment of these fees or costs from the annual trust administration fees currently permitted by law.

13) Clarifies that delivery of funds in a preneed funeral trust to the State Controller relieves the trustee and the funeral establishment of any further liability with respect to those funds.

14) Exempts from escheatment under the UPL funds received by a funeral establishment, cemetery, or other person for funeral plots.

15) Declares that the bill's provisions become operative on January 1, 2023.

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

COMMENTS:

Purpose. This bill is sponsored by the **State Controller's Office.** According to the author: "AB 293 protects consumers and their surviving loved ones by providing a convenient way to locate and claim unused preneed trust funds. Specifically, AB 2332 would clarify the party responsible for reporting abandoned trust accounts, outline dormancy triggers to assume the death or presumed death of the beneficiary, and establish requirements for communication with owners of preneed funeral trust accounts."

Background.

Cemetery and Funeral Bureau. The Cemetery and Funeral Bureau, an entity under the Department of Consumer Affairs, licenses and regulates over 13,000 licensees across various categories, including funeral establishments, funeral directors, embalmers, cemeteries, cemetery managers, cemetery brokers, cemetery salesperson, crematories, crematory managers, and cremated remains disposers. Among its many regulatory responsibilities, the Bureau oversees both the fiduciary and operational activities of its licensees, and has authority to enforce the provisions of the laws governing the death care industry.

Unclaimed Property Law. Established in 1959 and administered by the State Controller's Office, the UPL establishes procedures for the escheatment of unclaimed personal property to the state. Broadly, escheating is a legal process transferring ownership of abandoned property to the state of California. Once escheated, the property is in state custody until the rightful owner is found or reclaims the property. Unclaimed Property is generally defined as any financial asset that has been left inactive by the owner for a period of time. Common types of unclaimed property include bank accounts, stocks, mutual funds, certificates of deposits, matured or terminated insurance policies, as well as escrow accounts and trust funds. California's UPL requires financial institutions, insurance companies, corporations and other entities, often referred to as "holders," to annually report and deliver property to the State Controller's Office after there has been no activity on the account or contact with the owner for a period of time. For example, contact can be lost between the property owner and the holder if the owner forgets that the account exists, or does not provide contact information after moving. In some instances, particularly with preneed funeral arrangements, the owner dies and the heirs have no knowledge of the property.

Preneed Funeral Arrangements. Preneed funeral arrangements are contracts between a party and a funeral establishment in which the party pays for funeral products and services in advance. Although preneed contracts can vary, generally a person will decide in advance which services they want (e.g.: burial, entombment, cremation, scattering, inurnment, etc...) and either pay the full sum in advance or make installment payments. Preneed funeral agreements can often lower funeral costs, as individuals are able to lock-in price of services, and avoid paying the cost of inflation down the line.

California law requires monies or securities paid for a preneed funeral agreement to be held in trust. This means that the individual seeking preneed funeral services pays money into a trust account that is managed by a bank or other third-party financial institution. When the the individual passes, the trust funds are disbursed to the funeral establishment, upon the filing of a death certificate or other satisfactory evidence of the death of the beneficiary, as well as evidence that the funeral establishment has provided the services agreed upon in the preneed contract.

Escheatment of Preneed Contracts. Although preneed funeral payments held in trust are already subject to the Unclaimed Property Law, California statutes are silent about the conditions that must be met before abandoned preneed trust funds can escheat to the state. Preneed funeral trusts can be abandoned, for example, when a beneficiary neglects to tell family members about existing preneed arrangement prior to passing, leaving the trust account to lie dormant indefinitely.

This bill aims to address this problem by establishing a set of dormancy rules, which, when triggered, would allow abandoned preneed trust funds to escheat to the state. Under AB 293, funds held in trust under a preneed funeral agreement would be deemed payable and distributable under UPL if one of the following conditions is met: (1) the beneficiary has attained, or would have attained if still living, 105 years of age; (2) forty-five years have passed since execution of the agreement establishing the preneed funeral arrangement; (3) the holder has received notification of the death or presumed death of the beneficiary and has not provided the contracted-for funeral goods and services; or (4) the preneed funeral trust is an installment trust, the amount due has not been paid in the three preceding years, and neither the trustor nor the beneficiary has communicated with the funeral establishment or the trustee about the trust during that time. If three years elapse after any one of these dormancy criteria is triggered, this bill would require that preneed funds held in trust escheat to the state. In the event that the arrangement was found not to be abandoned, but funds were already escheated to the state, this bill provides an option for the funeral establishment to issue the agreed-upon services and receive reimbursement from the State Controller.

Funeral Homes Ceasing Operations. AB 293 also outlines a set of requirements for funeral establishments who cease business operations because of dissolution, closure, sale, or license revocation by the Bureau. In such a situation, a funeral establishment may opt to transfer its preneed funeral agreements to a successor establishment licensed by the Bureau.

If the funeral establishment ceasing business intends to transfer preneed agreements to a successor establishment, it must provide a written notice to the beneficiaries, trustors, as well as the trustees responsible for the trust. The notice must give the recipients a window of 60 days upon receipt to decide whether or not to cancel the preneed agreement. In addition, the funeral establishment must obtain prior written approval if the successor establishment is located 60 or more miles away. To ensure proper oversight of the noticing requirements, the funeral establishment ceasing business must provide the Bureau with a list of all preneed agreements transferred. The closing funeral establishment must also provide both the Bureau and the successor funeral establishment with a copy of the notices and proof that they were issued. Finally, the succeeding funeral establishment shall retain a copy of the notice provided, proof that they were provided, and provide a copy of both to the Bureau upon the Bureau's request.

Should the closing funeral establishment decide not to transfer preneed agreements to a successor, it must provide a written notice, at least 60 days in advance to ceasing operations, to the Bureau, the beneficiaries and the trustees. The notice must inform the recipients that their preneed funeral agreements will be canceled and the funds will be escheated to the state unless the beneficiary or trustor informs the trustee in writing within six months of receiving the notice that they wish those funds to be returned to them.

To facilitate those noticing requirements, this bill directs the Bureau by January 1, 2023, to create and post on its website the necessary notices to be used by funeral establishments who are

ceasing operations. In addition, the Bureau shall issue regulations regarding the type of proof of notice funeral establishments – whether ceasing operations or inheriting preneed agreements – are required to provide and retain.

Current Related Legislation.

AB 466 (Petrie-Norris, 2021): This bill would have authorize the Franchise Tax Board to provide the State Controller with additional information from business entity tax returns regarding unclaimed property.

SB 308 (Min, 2021): This bill would allow holders of unclaimed cash to electronically transfer these funds to the State Controller if they total at least $2,000, down from the current $20,000.

Prior Related Legislation.

AB 2332 (Kalra, 2020): This bill contained similar provisions as AB 293.

AB 1637 (Smith, Chap. 320, Stats. 2019): Authorizes the State Controller to transfer property reported to the state under the Unclaimed Property Law in the name of a local agency or state agency directly to that agency without the agency needing to file a claim, and provided that existing immunity from suit under the UPL also applies to the transfer of this property.

ARGUMENTS IN SUPPORT:

The State Controller's Office writes in support: "Preneed funeral trust accounts have not been specified in the unclaimed property law. These accounts are funds held in trust by funeral establishments for merchandise and services to be provided after death. In some cases, the decedent's survivors contact the funeral establishment in order to fulfil the agreement. For cases in which the survivors do not contact the establishment for funeral services, accounts can remain in trust indefinitely.

Laws regulating preneed funeral trust accounts only ensure the funds for merchandise and services are available at the time of death. Funeral establishments are not required to have consistent contact with the owners of record or adequately address handling of abandoned trust accounts.

AB 293 closes this loophole by bringing unclaimed preneed funeral trust accounts under unclaimed property law. This bill would define unclaimed preneed funeral trust accounts as unclaimed property, clarify the party responsible for reporting abandoned trust accounts, outline dormancy triggering events and establish requirements for contact with owners of trust accounts."

ARGUMENTS IN OPPOSITION:

None on file.

REGISTERED SUPPORT:

State Controller's Office (Sponsor)

REGISTERED OPPOSITION:

None on File.

Analysis Prepared by: Patrick Le / B. & P. / (916) 319-3301

Date of Hearing: April 13, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
AB 384 (Kalra) – As Amended March 30, 2021

SUBJECT: Cannabis and cannabis products: animals: veterinary medicine.

SUMMARY: Authorizes a veterinarian to recommend the use of cannabis for use on an animal for potential therapeutic effect of health supplementation purposes, and requires the Veterinary Medical Board to adopt and publish guidelines by January 1, 2023 for veterinarians to follow when recommending cannabis. This bill amends the definition of a "cannabis product" and "edible cannabis product" under the Medicinal and Adult-Use Cannabis Regulation and Safety Act to include cannabis products intended for use on, or consumption by, an animal.

EXISTING LAW:

1) Establishes the Veterinary Medical Board (Board) under the jurisdiction of the Department of Consumer Affairs and responsible for licensing and regulating veterinarians, registered veterinary technicians, veterinary assistant substance controlled permit holders, and veterinary premises. (Business and Professions Code (BPC) Section 4800 et seq.)

2) Requires a veterinarian, each time they initially prescribe, dispense, or furnish a dangerous drug in an outpatient setting, to offer to provide to the client responsible for the animal patient, a consultation, as specified. (BPC Section 4829.5)

3) Prohibits a licensee from dispensing or administering cannabis or cannabis products to an animal patient. (BPC Section 4884(a))

4) States that, notwithstanding any other law and absent negligence or incompetence, a licensed veterinarian shall not be disciplined by the Board solely for discussing the use of cannabis on an animal for medical purposes. (BPC Section 4884(b))

5) Required the Board on or before January 1, 2020 to adopt guidelines for veterinarians to follow when discussing cannabis within the veterinarian-client-patient relationship and post the guidelines on the Board's website. (BPC Section 4884(c))

6) Authorizes the VMB to deny, revoke, or suspend a license or registration or asses a fine for:

   a) Accepting, soliciting, or offering any form of remuneration from or to a cannabis licensee if the veterinarian or his or her immediate family have a financial interest with the cannabis licensee;

   b) Discussing cannabis with a client while the veterinarian is employed by, or has an agreement with, a cannabis license;

   c) Distributing any form of advertising for cannabis in California. (BPC Section 4883(p), 4883(q), and 4883(r))

7) Establishes the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA) to regulate the cultivation, distribution, transport, storage, manufacturing, processing, and sale of both medicinal and adult-use cannabis. (BPC Section 26000 et seq.)

8) Defines "cannabis product" as cannabis that has undergone a process whereby the plant material has been transformed into a concentrate, including, but not limited to, concentrated cannabis, or an edible or topical product containing cannabis or concentrated cannabis and other ingredients (BPC Section 26001(i) and Health and Safety Code (HSC) Section 11018.1)

9) Defines "edible cannabis product" as a cannabis product that is intended to be used, in whole or in part, for human consumption, excluding food products, as specified. Further clarifies that an edible cannabis product is not considered food. (BPC Section 26001(t))

10) Defines "cannabis concentrate" as cannabis that has undergone a process to concentrate one or more active cannabinoids, thereby increasing the product's potency. (BPC Section 26001(h))

11) States that the State Department of Public Health (CDPH) must promulgate regulations governing the licensing of cannabis manufacturers and standards for the manufacturing, packaging, and labeling of all manufactured cannabis products.

THIS BILL:

1) Prohibits the Board from disciplining a veterinarian solely for recommending the use of cannabis on an animal for potential therapeutic effects or health supplementation purposes.

2) Requires the Board, on or before January 1, 2023, to adopt and publish on its website guidelines for veterinarians to follow when recommending cannabis within the veterinarian-client-patient relationship.

3) Specifies that the Board may deny, revoke, or suspend a license if a veterinarian is recommending cannabis use with a client while the veterinarian is employed by, or has an agreement with, a cannabis licensee.

4) Amends the definition of a "cannabis product" to include cannabis products intended for use on an animal.

5) Amends the definition of "edible cannabis product" to include cannabis products intended for consumption by an animal.

6) Clarifies that a cannabis concentrate or edible cannabis product is not considered a processed pet food.

7) States that if a cannabis product is intended for use on an animal, the product shall confirm with any additional relevant standards established by the State Department of Public Health.

8) Defines an animal, for the purpose of MAUCRSA, to include any member of the animal kingdom except for food animals and livestock.

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

COMMENTS:

Purpose. This bill is author-sponsored. According to the author: "Californians have greater access to cannabis more than ever before and many pet owners are already looking at the use of cannabis-derived CBD to provide therapeutic benefits to their pets. Preliminary research has identified derivatives in cannabis to be similarly useful in addressing pain, anxiety, inflammation, nausea, loss of appetite and seizures in animals, and pet owners should be able to seek recommendations from veterinary medical professionals who can better inform a pet owner's decision on how best to use cannabis products in a safe, responsible way. AB 384 also ensures these products are accessible to consumers in a regulated market."

Background.

The Medicinal and Adult-Use Cannabis Regulation and Safety Act. In 1996, California voters approved Proposition 215, known as the Compassionate Use Act, which legalized the use of medicinal cannabis in the state. In October 2015, Governor Jerry Brown signed a legislative package made of AB 243 (Wood, Chapter 688, Statutes of 2015), AB 266 (Bonta, Cooley, Jones-Sawyer, Lackey, and Wood, Chapter 689, Statutes of 2015), and SB 643 (McGuire, Chapter 719, Statutes of 2015) – collectively referred to as the Medical Cannabis Regulation and Safety Act (MCRSA) – which established California's first comprehensive regulatory framework for medicinal cannabis. In 2016, California voters subsequently approved Proposition 64, the Adult Use of Marijuana Act (AUMA), which aimed to legalize the recreational use of cannabis in the state by 2018. In June 2017, AUMA and MCRSA were combined to form one system for the regulation of cannabis, known as MAUCRSA.

Currently, MAUCRSA is applicable to both recreational and medicinal products – however, it does not specifically address cannabis products intended for use on animal patients. This bill amends the definitions of "cannabis products" and "edible cannabis products" under MAUCRSA to include products that are intended for use on, or consumption by, animals. Additionally, the bill mandates that cannabis products intended for animals must conform to any additional regulatory standards established by the California Department of Public Health. According to the author, these changes aim to ensure that animal cannabis products can be accessed in licensed dispensaries if they adhere to relevant manufacturing, packaging, and labeling standards, and encourage safe cannabis animal products to come to the regulated market.

Veterinary Medicine. Licensed veterinarians provide health care to several types of animals, from domestic companions such as dogs, cats, rabbits, birds, hamsters and snakes, to agricultural livestock such as cattle, poultry, fish, goats, pigs, and horses. Similar to human medicine, there are recognized specialties within the veterinary profession, including surgery, internal medicine, microbiology, pathology and more. In California, the practice of veterinary medicine is regulated under the Veterinary Practice Act (Act), a set of laws outlining the licensure requirements, scope of practice, and responsibilities of licensed veterinary professionals. The Act is enforced by the Veterinary Medical Board, a state regulatory agency under the umbrella of the Department of Consumer Affairs which is responsible for the licensing, examination, and enforcement of professional standards of the veterinary profession. In order to obtain a license as a veterinarian, a candidate must generally graduate from an accredited postsecondary institution recognized by

the Board, as well as pass a national examination, a state examination, and an examination testing the knowledge of the laws and regulations related to the practice of veterinary medicine in California.

Except under certain circumstances, state law requires a licensed veterinarian to establish a veterinarian-client-patient relationship (VCPR) prior to providing treatment of therapy for an animal. Generally, VCPR is established when the animal owner has authorized the veterinarian to assume responsibility for making medical judgements regarding the health of the animal; when the veterinarian has sufficient knowledge of the animal to initiate at minimum a preliminary diagnosis of potential medical conditions; and when the veterinarian has assumed responsibility for making medical judgements and has communicated with the client a course of treatment appropriate for the animal.

Under the Act, veterinarians can prescribe and administer drugs or medications, but are explicitly prohibited under state law from dispensing or administering cannabis or cannabis products to an animal patient. In addition, the Federal Drug Enforcement Administration (DEA), which has enforcement authority over federal controlled substance regulations, continue to classify cannabis, tetrahydrocannabinol, and other cannabinoids as a Schedule I controlled substances. As such, the DEA does not give health care practitioners, including veterinarians, the authority to possess administer, dispense, recommend, or prescribe cannabis products. In human health care, this issue has led to policy discussions distinguishing between prescribing and recommending cannabis products. For example, the Medical Board of California published in 2017 guidelines for the recommendation of cannabis for medicinal purposes on human patients.

Veterinary Guidelines for Discussing Cannabis Use on Animals. In 2018, the legislature enacted AB 2215 (Kalra, Chapter 819, Statutes of 2018), which authorized veterinarians to "discuss" the use of cannabis on an animal patients for medicinal purposes. The bill also required the Board to adopt and publish guidelines for veterinarians to follow when discussing cannabis within the veterinarian-client-patient-relationship (VCPR) on or before January 1, 2020. In 2019, the Board approved and made available on its website "Guidelines for Veterinarian Discussion of Cannabis within the Veterinarian-Client-Patient Relationship." Among other items, the guidelines state that:

- A veterinarian should document that an appropriate VCPR is established prior to discussing cannabis with the animal-owner client.

- A documented physical examination and collection of relevant clinical history is required, and should include both subjective and objective data and must obtained prior to discussing cannabis for medical purpose.

- The discussions should be evaluated in accordance with accepted standards of practice as they evolve over time. This documentation may include advice about potential risks of the medical use of cannabis, including the variability of quality, source, safety, and testing of cannabis products; the side effects and signs of overdose of toxicity; and the lack of clinical research regarding dose, toxicity, and efficacy.

AB 2215 also enacted a number of conflict of interest provisions, and authorized the Board to take disciplinary actions against veterinarians accepting, soliciting, or offering any form of

remuneration from or to a cannabis licensee if the veterinarian or his or her immediate family have a financial interest with the cannabis licensee. AB 2215 also prohibited a veterinarian from discussing cannabis with a client while the veterinarian is employed by, or has an agreement with, a cannabis licensee, and prohibited a veterinarian from distributing any form of advertising for cannabis in California.

Recommendation of Cannabis Products by a Veterinarian. AB 384 expands upon those statutory provisions authorizing a veterinarian to "discuss" cannabis products, and would allow a veterinarian to "recommend" the use of cannabis on an animal for potential therapeutic effect or health supplementation purposes. Mirroring the legislative requirement in AB 2215 to develop cannabis discussion guidelines for veterinarians, AB 384 requires the Board to adopt and publish on its website guidelines for veterinarians to follow when recommending cannabis within the veterinarian-client-patient relationship by January 1, 2023. AB 384 also aligns conflict of interest provisions by prohibiting a veterinarian from recommending cannabis products for medicinal use with a client while the veterinarian is employed by, or has an agreement with, a cannabis licensee. Existing statutory provisions would continue to prohibit a veterinarian from dispensing or administering cannabis or cannabis products to an animal patient.

Recent amendments to the bill changed references for "medicinal" cannabis to cannabis that would have potential therapeutic effect or health supplementation purposes. According to the author, the change is primarily intended to address potential conflicts with federal law and to avoid confusion or additional restrictions on a veterinarian being able to administer or prescribe drugs that may be derived from cannabis. It remains federally unlawful to market any CBD-containing product with health claims, such as claims that a cannabis product can cure, prevent, or mitigate a medical condition. The amendments aim to avoid limitations on the type of products that could be available for recommendation by veterinarians.

Animal Cannabis Products and Available Research. Cannabis products designed for animals have seen an increase in popularity and availability in recent years. According to a 2020 report by Grand View Research, the global CBD pet market size was valued at USD 27.7 million in 2019 and is expected to grow at a compound annual growth rate of 40.3% from 2020 to 2027 – a surge driven by the perceived benefits of cannabis, high awareness among pet owners, and increased preference for natural pet supplements. Available products range from CBD chews, gels, creams, capsules, to shampoos and conditioners. Depending on how these products are sourced and labeled, their legality can be uncertain given the constantly shifting landscape of cannabis regulations at the state and federal level. However, animal cannabis products often cite that they are derived from hemp, a legal agricultural product with very low THC content and not regulated under MAUCRSA.

While anecdotal evidence suggests that there are therapeutic or medicinal benefits using cannabis products on animals, little clinical research is available on the topic. Classified as a Schedule I substance, cannabis is subject to the highest level of restrictions, and researchers conducting clinical studies on cannabis must often apply for multiple state and federal permits, including the DEA. For example, in California, all clinical research involving Schedule I or II substances must be registered with and approved by the Research Advisory Panel of California in the Attorney General's Office.

Despite those barriers, more evidence is beginning to emerge regarding the use and potential benefits of cannabis – particularly CBD products – on animals. In 2018, research from Cornell University's College of Veterinary Medicine and published in Frontiers in Veterinary Science found that CBD based oils was efficacious for pain in dogs with osteoarthritis, chronic joint pain and geriatric pain and soreness, with veterinary assessment showing decreased pain during CBD treatment. Additional research from Colorado State University in 2019 and published in the Journal of the American Veterinary Medical Association also indicated that use of CBD on dogs suffering from epilepsy showed a significant reduction in seizure frequency with no adverse behavioral effects reported by owners.

Of note, in 2018, the U.S. Food and Drug Administration (FDA) approved Epidiolex, the first of its kind FDA-approved drug containing a highly purified form of CBD to treat seizures associated with rare forms of epilepsy. The drug was subsequently placed as a Schedule V by the DEA, the least restrictive schedule for controlled substances. Although Epidioloex is labeled for use in human patients, the Animal Medicinal Drug Use Clarification Act (AMDUCA) of 1994 authorizes extralabel use of human drugs in veterinary medicine. Under AMDUCA, the FDA can decide to restrict extralabel use of specific drugs on animals. However, the FDA has not restricted extralabel use of Epidiolex at this time.

AMENDMENTS:

The committee recommends the following technical amendment to align the bill's provision regarding conflict of interest:

AMENDMENT:

On page 5, in line 23, strike out "medicinal"

Section 4883(q) of the bill would read:

"(q) Discussing or recommending cannabis for ~~medicinal~~ use with a client while the veterinarian is employed by, or has an agreement with, a cannabis licensee. For purposes of this subdivision, "cannabis licensee" shall have the same meaning as "licensee" in Section 26001

Current Related Legislation.

None.

Prior Related Legislation.

AB 2215 (Kalra, Chapter 819, Statutes of 2018): Prohibits the Veterinary Medical Board from disciplining, or denying, revoking, or suspending the license of, a licensed veterinarian solely for discussing the use of cannabis on an animal for medicinal purposes, absent negligence or incompetence. Required the board to adopt guidelines for these discussions on or before January 1, 2020, and would require the board to post the guidelines on its Internet Web site. Authorized the board to revoke or suspend a veterinarian license, or to assess a fine, for accepting, soliciting, or offering any form of remuneration from or to a Medicinal and Adult-Use Cannabis Regulation

and Safety Act (MAUCRSA) licensee if the veterinarian or his or her immediate family has a financial interest, as defined.

SB 627 (Galgiani, 2019): Would have required the Veterinary Medical Board to adopt guidelines for veterinarians to follow when recommending cannabis within the veterinarian-client-patient relationship. Would have authorized a licensed veterinarian to discuss the use of medicinal cannabis or cannabis products on an animal patient and, after guidelines are adopted, allows a veterinarian to recommend the use of medicinal cannabis or cannabis products under certain conditions. Would have adjusted other cannabis-related statutes to accommodate medicinal use on an animal patient by adults who are 21 years of age and older.

ARGUMENTS IN SUPPORT:

The California Veterinary Medical Association writes in support: "What we have learned since the passage of AB 2215-Kalra (2018) is that more and more pet owners are purchasing cannabis products for their pets and are then bringing them in to the veterinary hospital, seeking help from their veterinarian regarding dosing questions. This is a very common scenario in veterinary practices and veterinarians would like to have the ability to look at the product, discuss the potential impact of the product on the animal, and then suggest a safe dose, if applicable. Without the guidance of a veterinary medical professional, the animal-owning client is left to make his or her own "guesstimate" regarding dosing; or more troubling, they might seek dosing information from a cannabis dispensary clerk. The veterinary medicine community is very active in its exploration of the impact of cannabis in pets through its work with our national association, continuing education opportunities with leading experts, and medical reports. As we continue to monitor the issue, AB 384 becomes an important next step in bringing clinical discussions between veterinarians and their animal-owning pets together in a safe setting, to contemplate reasonable recommendations for usage."

The California Cannabis Industry Association, Americans for Safe Access Bay Area Chapter, Hanaeleh Horse Rescue & Advocacy, the Parelli Foundation, Love Grass, DMV 360, Women United for Animal Welfare, Urbn Leaf, Vital Equine Holistic Veterinary Medicine, and Se7en Leaf collectively write in support: "AB 384 will allow veterinarians to recommend cannabis as a therapy for pets, whereas current law only allows veterinarians to discuss cannabis without offering clear recommendations about specific products or dosage. This bill will also bring all cannabis products intended for animal consumption under the MAUCRSA regulatory framework. This will allow therapeutic products intended for pet consumption to be sold with clear labeling and instructions for use, and ensure such products are tested to the rigorous safety standards required under California law. It is in the best interest of families and their pets, as well hundreds of thousands of pets in California shelters, to ensure access to therapeutic cannabis for pets."

California NORML writes in support: "California NORML frequently hears from pet owners who have used or wished to use cannabis to treat their pets. Those who have done so report generally favorable results. Cannabis has a documented history of safe use in animals dating back over a century. As in humans, there are no known reports of fatal overdoses in pets, although non-fatal poisonings have been reported in pets that have accidentally eaten high-dosage edibles meant for human consumption. Numerous veterinary cannabis products are now

on the market. Pets and their owners would benefit by the professional guidance of a veterinarian's recommendation in choosing them. Recent animal studies have found cannabis products to be useful in relieving epilepsy, dermatitis, arthritis and osteoarthritis. As has proven the case with human patients under Prop. 215, AB 384 would help expand our knowledge about medicinal cannabis by enabling professional veterinarians to more closely and systematically monitor its efficacy in treating other conditions in animals."

CMG / Caliva writes in support: "CMG / Caliva's retail operation historically has found that many customers value cannabis products as therapeutic treatment for their pets. Many topical products provide relief from pain, anxiety, nausea and inflammation for pets as they do for humans. The cannabidiol (CBD) extract that is the primary therapeutic ingredient in products like creams and tinctures is not psychoactive but has been shown to improve the quality of life for pets with treatable conditions or need for pain management. We allow physicians to make recommendations for medicinal cannabis; it is incongruous with current state law to not give veterinarians the same authority."

ARGUMENTS IN OPPOSITION:

Lovingly and Legally writes in opposition: "This bill recklessly opens the floodgates for an untapped market in the cannabis industry. Many greedy operators will take advantage of this and the Animals, their Owners, and the Veterinary Profession will suffer. Veterinarians desperately need the authority to recommend, but let's get it right. Put safety rails on the bill and remove them as required. […] The ability to recommend needs to be authorized per MAUCRSA not just the prohibition of disciplinary action per Veterinary Practices Act. A pet owner that does not have a recommendation could not get a medical cannabis product. Some people will likely try to "self-medicate", in the name of their pets, with adult use products, but let's give the option of a trusted source by requiring a veterinarian's recommendation for veterinary medical cannabis. […] For Animals, cannabis is medicine and should require a veterinarian's recommendation; not a manufacturer's advertising or a retail salesperson's advice. Cannabis is NOT a panacea and a Veterinarian is the only person that should be able to diagnose and recommend treatment of any kind. […] There is no mention of designating animals as patients and, consequently, eligible for a portion of the, much needed, medical research monies that are statutorily allowed for in Proposition 64. […] The Regulatory Authority's legal team bend to the legislative modifications to the statute. They do NOT assume authority to make regulations that overstep their direction nor do they interpret the legislation in a way that could (even remotely) lead to a lawsuit. Any assumption that these issues will be corrected on a regulatory level is folly.

The Veterinary Cannabis Society writes as opposed unless amended: "The most recent amendments made to AB 384 further bring into question the true spirit of this bill. The amendments strip the term "medicinal" and replace it with "therapeutic effect or health supplementation." The only explanation for this change is to sidestep the question of why medical products for animals would be sold in recreational use dispensaries. The bill, as it is now written, no longer describes cannabis as medicine for animals. Now it is a non-medicinal supplement which somehow qualifies it to be sold alongside pre-rolls and ultra-high THC cannabis resin. Furthermore, the verbiage change opens the floodgates for all manner of products for animals containing cannabis to be sold in recreational dispensaries including treats, food, and

anything else a producer might want to put a picture of a dog on. To add insult to injury, the bill states that cannabis products for animals are "not to exceed 10 milligrams THC per serving." Ten milligrams of THC would likely cause toxicity in even the largest dogs and is potentially lifethreatening for small dogs and cats. Making products like these available to the general public with no veterinary guidance is unconscionable. It endangers animals and completely contradicts what AB 384 is purported to do."

REGISTERED SUPPORT:

California Veterinary Medical Association
California Cannabis Industry Association
Americans for Safe Access, Bay Area Chapter
Hanaeleh Horse Rescue & Advocacy
Parelli Foundation
Love Grass
DMV 360
Women United for Animal Welfare
Urbn Leaf
Vital Equine Holistic Veterinary Medicine
Se7en Leaf
California NORML
CMG / Caliva
293 individuals

REGISTERED OPPOSITION:

Lovingly and Legally
Cannabis Veterinary Society
1 individual

Analysis Prepared by: Patrick Le / B. & P. / (916) 319-3301

Date of Hearing: April 13, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
AB 54 (Kiley) – As Amended April 5, 2021

SUBJECT: COVID-19 emergency order violation: license revocation.

SUMMARY: Prohibits the Department of Consumer Affairs (DCA), any non-healing arts board under the DCA, and the Department of Alcoholic Beverage Control (ABC) from revoking a license for failure to comply with any COVID-19 emergency orders unless the board or department can prove that lack of compliance resulted in transmission of COVID-19.

EXISTING LAW:

1) Establishes the DCA within the Business, Consumer Services, and Housing Agency. (Business and Professions Code (BPC) § 100)

2) Enumerates various regulatory boards, bureaus, committees, and commissions under the DCA's jurisdiction. (BPC § 101)

3) Defines "board" as also inclusive of "bureau," "commission," "committee," "department," "division," "examining committee," "program," and "agency." (BPC § 22)

4) Provides that all boards, bureaus, and commissions within the DCA are established for the purpose of ensuring that those private businesses and professions deemed to engage in activities which have potential impact upon the public health, safety, and welfare are adequately regulated in order to protect the people of California. (BPC § 101.6)

5) States in myriad practice acts enforced by boards and bureaus under the DCA that protection of the public shall be the highest priority. (BPC § 7301.1; § 2001.1; § 1601.2; § 2450.1; § 2460.1; § 2531.02; § 2570.25; § 2602.1; § 2708.1; § 2841.1; § 2920.1; § 3010.1; § 3320.1; § 3504.1; § 3710.1; § 4001.1; § 4501.1; § 4800.1; § 4928.1; § 4990.125; § 5000.1; § 5510.15; § 5620.1; § 6710.1; § 7000.6; § 7303.1; § 7501.05; § 7601.1; § 7810.1; § 8005.1; § 8520.1; § 9810.1; § 9880.3; § 18602.1; 19004.1; § 94770.1; *etc.*)

6) Requires each board under the DCA to develop criteria to aid it, when considering the denial, suspension, or revocation of a license, to determine whether a crime is substantially related to the qualifications, functions, or duties of the business or profession it regulates. (BPC § 481)

7) Authorizes a board to revoke or suspend a current license on the ground that the licensee has been convicted of a crime, if the crime is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued. (BPC § 490)

8) Establishes the ABC within the Business, Consumer Services, and Housing Agency. (BPC § 23050)

9) Prohibits any person from exercising any privilege or performing any act regulated under the Alcoholic Beverage Control Act without a license from the ABC. (BPC § 23300)

10) Establishes the California Emergency Services Act to confer upon the Governor and upon the chief executives and governing bodies of political subdivisions of the state certain emergency powers. (Government Code (GOV) §§ 8550 *et seq.*)

11) Authorizes the Governor to make, amend, and rescind orders and regulations necessary to carry out the provisions of the California Emergency Services Act, which have the force and effect of law. (GOV § 8567)

THIS BILL:

1) Prohibits the DCA and any board from revoking revoke a license for failure to comply with any COVID-19 emergency orders, unless the DCA or board can prove that lack of compliance resulted in the transmission of COVID-19.

2) Exempts healing arts boards from the above prohibition.

3) Prohibits the ABC from revoking revoke a license for failure to comply with any COVID-19 emergency orders, unless the ABC can prove that lack of compliance resulted in the transmission of COVID-19.

4) States that in order to protect businesses, including small businesses, which continue to make significant contributions to economic security, which helps ensure public safety, during these unprecedented times caused by the COVID-19 pandemic, as soon as possible, it is necessary for the bill to take effect immediately

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

COMMENTS:

Purpose. This bill is sponsored by the author. According to the author:

> "Businesses should not be forced to choose between obeying the Governor's mandates and providing for their families and employees. The state should focus on educating and supporting small businesses during this time, rather than penalization. AB 54 will prohibit the Department of Consumer Affairs and the Board of Barbering and Cosmetology from revoking licenses due to noncompliance with COVID-19 mandates. It's time to end this untenable choice forced upon businesses."

Background.

COVID-19 Pandemic. On March 4, 2020, Governor Gavin Newsom proclaimed a State of Emergency as a result of the impacts of the COVID-19 public health crisis. On March 12, 2020, the Governor issued an executive order that directed residents to follow public health directives and guidance, including to cancel large non-essential gatherings that do not meet certain state criteria. On March 19, 2020, the Governor formally issued a statewide "stay at home order," directing Californians to only leave the house to provide or obtain specified essential services. Subsequent guidance from the State Public Health Officer expressly exempted from that order the following professionals regulated by the DCA:

- Physicians and Surgeons;
- Dentists;
- Psychologists;
- Mid-level practitioners (generally interpreted to include optometrists, physician assistants, nurse practitioners, certified nurse midwives, nurse anesthetists, and naturopathic doctors);
- Nurses and assistants;
- Pharmacists and necessary pharmacy employees;
- Physical Therapists and assistants;
- Occupational Therapists and assistants;
- Social Workers and behavioral health workers;
- Speech-Language Pathologists;
- Workers in other medical facilities;
- Funeral homes, crematoriums, and cemetery workers;
- Veterinarians;
- Private security, including Private Patrol Operators;
- Construction workers, engineers, and contractors, including plumbers and electricians;
- Cannabis retailers and workers;
- Automotive Repair Dealers and workers;
- Structural Pest Control operators and exterminators;
- Court Reporters, subject to guidance from the Chief Justice for essential operation of the courts;
- Professional service providers, including accountants, when necessary for compliance with legally mandated activities and critical sector services.

The Governor's original stay at home order was subsequently replaced with a tiered system which allowed for services to be provided or obtained within a given county based on that county's positivity rate, adjusted case rate, and health equity metric. County risk levels are assessed on a color scale of "minimal" (or yellow) to "widespread" (or purple). Certain business are then allowed to be operated and patronized once a county has been placed in a certain tier for at least two weeks, based on the Governor's *Blueprint for a Safer Economy*.

While many services offered by individuals licensed under the DCA have remained open as essential services or have been allowed in tiers under the *Blueprint for a Safer Economy*, some services have persistently remained restricted. For example, barbering and cosmetology establishments have either been closed or forced to operate under highly restricted parameters throughout the pandemic. In response, on February 23, 2021, the Governor signed an economic relief package for businesses that were impacted by the COVID-19 pandemic which specifically waived renewal fees for licensees of the Board of Barbering and Cosmetology.

Throughout the pandemic, there have been reports that certain businesses have chosen to openly defy the Governor's orders in regards to restricted activities. In August of 2020, hundreds of salons were reported to have chosen to openly defy the state's restrictions on barbering and cosmetology businesses, declaring that they were instead following an "Open Safe California" movement. There have subsequently been reports of officers with the DCA entering salons and ordering that activities cease, with some salons receiving misdemeanor citations.

The intent of this bill is essentially to provide a safe harbor for businesses that have chosen to defy COVID-19 emergency order by prohibiting the DCA or any non-healing arts board within it from revoking a license unless it can prove the violation resulted in the transmission of COVID-19. The author contends that the emergency orders issued by the Governor were draconian and unnecessary. In addition to the DCA and its boards, the bill would institute a similar prohibition for alcohol license revocations by the ABC.

ARGUMENTS IN SUPPORT:

The **California Chamber of Commerce** (CalChamber) supports this bill. CalChamber argues that "businesses throughout the state have spent scarce financial resources trying to comply with state guidelines for remaining open or reopening. Shifting health and safety requirements have made compliance difficult and expensive especially for small businesses. For instances, nail salons purchased protective shields and ventilation equipment while restaurant invested in outdoor dining furniture only to be forced to shut down again. Proving the virus was not transmitted at their establishments is well beyond their available financial means leaving the only option to close down."

ARGUMENTS IN OPPOSITION:

County Health Executives Association of California (CHEAC) opposes this bill. According to CHEAC, "during an emergency, quick action can save lives and state and local health orders are critical to protecting public health and preventing the spread of disease. Enforcement of these orders support greater compliance and begin with education, only escalating to fines, penalties, and closures after repeated incidences of non-compliance. Non-compliance comes in many different forms and can range from exceeding the capacity limits, neglecting masking requirements, or failure to report cases, among others. Requiring agencies to prove a direct correlation for every instance and scenario of non-compliance and transmission is not feasible and risks further the spread of the virus."

POLICY ISSUE(S) FOR CONSIDERATION:

Consumer Safety. As codified in numerous practice acts and authorizing statutes, the highest priority for boards under the DCA is protection of the public. During a health pandemic, this mission is all the more important as each entity within the government is tasked with ensuring the safety of Californians. By placing such a strict prohibition against enforcement actions for violation of laws intended to protect the health, safety, and welfare of residents during a public health crisis, this bill would necessarily contradict and undermine each board's public protection mandate.

Fairness. Despite the significant economic loss resulting from the Governor's emergency orders, many businesses responsibly acted to comply and prioritized the state's efforts to "flatten the curve" and save lives over their own economic interest. This sacrifice should be commended as history recalls the actions of the public during the pandemic. Subsequently allowing businesses that chose to openly defy emergency orders and deprioritize the interests of public health is arguably rewarding bad behavior. Those businesses that did comply with the orders may therefore view this bill as fundamentally inequitable and unjust.

Practicality. This bill would still allow for the DCA, a board, or the ABC to revoke a license when they can prove that the violation resulted in a transmission of COVID-19. Presenting this type of evidence would be incredibly challenging, if not altogether impossible, for a department or board engaged in disciplinary action. The result would essentially be a ban on license revocations altogether. Considering the extensive number of emergency orders that this bill would be implicitly allowing licensees to violate with impunity and the potential for risk to the public, the appropriateness of the bill's prohibition should be carefully considered.

REGISTERED SUPPORT:

California Chamber of Commerce
California Landscape Contractor's Association

REGISTERED OPPOSITION:

County Health Executives Association of California

Analysis Prepared by: Robert Sumner / B. & P. / (916) 319-3301

Date of Hearing: April 13, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
AB 484 (Medina) – As Introduced February 8, 2021

SUBJECT: Alarm company operators: advertisements.

SUMMARY: Changes how security alarm companies advertise to potential customers.

EXISTING LAW:

1) Establishes the Bureau of Security and Investigative Services (BSIS) within the Department of Consumer Affairs (DCA). (BPC §§ 101(r), 6980.1, 7501, 7591)

2) Provides that protection of the public shall be the highest priority for the BSIS in exercising its licensing, regulatory, and disciplinary functions and that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. (BPC § 7501.05)

3) Provides for the licensure and regulation of alarm company operators and alarm agents under the Alarm Company Act and requires the BSIS to administer and enforce the act. (BPC §§ 7590-7599.80) Provides that the BSIS director may assess fines for any violation as enumerated in this article and issue citations. (BPC §§ 7591.9 and 7599.30)

4) Defines an "alarm company operator" as a person who engages in business or accepts employment to install, maintain, alter, sell on premises, monitor, or service alarm systems or who responds to alarm systems. (BPC § 7590.2) Further provides that an "alarm company operator" includes any entity that is retained by a licensed alarm company operator, a customer, or any other person or entity, to monitor one or more alarm systems, whether or not the entity performs any other duties within the definition of an alarm company operator. (BPC § 7590.2)

5) Defines an "alarm system" to mean an assembly of equipment and devices arranged to signal the presence of a hazard requiring urgent attention and to which police may respond. (BPC § 7590.1(c))

6) Provides that for the purposes of the Alarm Company Act (Chapter 11.6 of Division 3 of the BPC) an "advertisement" means any written or printed communication for the purpose of soliciting, describing, or promoting the licensed business of the licensee, including a brochure, letter, pamphlet, newspaper, periodical, publication, or other writing, including a directory listing caused or permitted by the licensee which indicates his or her licensed activity, as well as a radio, television, or similar airwave transmission that solicits or promotes the licensed business of the licensee. (BPC § 7590.1(a))

7) Provides that every advertisement by a licensee soliciting or advertising business shall contain his or her name and license number as they appear in the records of the bureau. Provides that a violation of that provision may result in a fine of five hundred dollars ($500) for the first violation and one thousand dollars ($1,000) for each subsequent violation.(BPC 7599.44)

THIS BILL:

1) Provides that in the case of a radio, television, or billboard advertisement, if a licensed alarm company operator maintains an internet website, the licensee may direct potential customers to the licensee's website for the licensee's name and license number, in lieu of providing that information in the advertisement.

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

COMMENTS:

Purpose. This bill is sponsored by *California Cable & Telecommunications Association (CCTA)*. According to the Author, "[This bill] seeks to update, modernize, and clarify the current code section by separating different forms of advertisement. This will clarify and update alarm company advertising regulations. Thus allowing them to be more flexible when directing customers to their license name and license number."

Background. Alarm company operators are regulated by the Bureau of Security and Investigative Services (BSIS) within the Department of Consumer Affairs (DCA). Existing law requires licensed alarm companies, on every advertisement, to disclose their company name and license number. This list includes radio ads, TV ads, print ads, website ads, and billboards. The statute has a monetary penalty of $500 for the first violation and $1000 for each subsequent violation. Also, the law imposes a criminal penalty for violating these provisions.

This statute, created before the internet, was an effort to capture all possible ways that an alarm company can advertise by mandating "every advertisement." However, according to the sponsor, the average person does stop and pause the radio or TV to write down an alarm companies license number. This makes it unnecessary and unhelpful to display/voice the license number in radio and TV ads. In keeping with modern times, alarm companies, typically have some form of website where the license number can be displayed and written down if needed.

Prior Related Legislation. AB 2783 (Medina, 2020). This bill did not move forward due to the truncated hearings at the end of the session affected by restrictions caused COVID-19 pandemic.

SB 673 (Sieroty) (Statutes of 1982, Chapter 1210). Enacted the Alarm Company Act.

ARGUMENTS IN SUPPORT:

According to *California Cable & Telecommunications Association, "*This bill would provide consumers with a better process for vetting security alarm services before signing choosing a particular vendor. More specifically, [this bill] would require security alarm companies to identify its licensee's name and license number on all print and online advertisements as they appear in the records of the Bureau of Security and Investigative Services at the California Department of Consumer Affairs. For any security alarm company that maintains a website, this bill would require any radio or television advertisements to direct potential customers to an easy-to-find "license information" page on the company website. However, if a security alarm company does not have a website, then any radio or television advertisements to direct potential

customers would have to identify its licensee's name and license number within the radio or television commercial.

The current law requiring ALL security alarm company advertisements to contain the licensee's name and license number as they appear in the records of the bureau was first established in 1982 (Chapter 1210, Section 12), just as the Internet was starting to become available to the public. Rather than announcing a rapid-fire business license number during a radio or television commercial, this bill would refer potential customers to a company website that would not only provide the consumer with the business license number but also thorough information about the service.

In this age of the digital world, this proposal is an improvement to California's consumer protections for security alarm services."

AMENDMENTS:

This bill was amended on April 5, 2021 to remove a reference to the Contractors State License Law (CSLL) (Chapter 9 (commencing with Section 7000) of Division 3 of the Business and Professions Code).

The bill sponsors note that many alarm company operators licensed by BSIS may also hold a contractor's license issued by the Contractors State License Board (CSLB). However, prior to the amendment, the bill could have been interpreted as an attempt to extend its provisions to advertising activities by contractors subject to licensure by CSLB, when this bill is intended to modify advertising requirements for those selling alarm company operator services.

The Alarm Company Act (Chapter 11.6 of Division 3 of the BPC) does not apply to licensed contractors. In addition, the CSLL provides that a contractor's license is not required for any person who performs work regulated by the Alarm Company Act. (BPC § 7054). Therefore, under existing law, the activities of a business regulated by BSIS as an alarm company operator are not subject to review by CSLB if those activities are confined to installing, maintaining, monitoring, selling, altering, or servicing alarm systems.

Furthermore, licensed contractors have their own advertising requirements. For example, a licensed contractor must include a license number in all construction contracts, subcontracts, bids, and advertising. (BPC § 7030.5). And CSLB's broad definition of "advertising" includes electronic transmissions and airwaves (Section 861 of Article 7, Title 16 of the California Code of Regulations). Therefore, under existing law, any person who advertises for construction work regulated by the CSLL must comply with the advertising provisions for contractors.

As such, a company licensed by BSIS will need to comply with the CSLL if the content of their advertising extends to work that requires a contractor's license to perform. The reference to the CSLL in this bill prior to the April 5 amendment would not have overturned this statutory scheme and may have caused confusion as a result. It is for this reason the Committee understands that the reference to the CSLL was removed.

REGISTERED SUPPORT:

California Cable & Telecommunications Association (CCTA), (Sponsor)

REGISTERED OPPOSITION:

None on file.

Analysis Prepared by: Danielle Sires / B. & P. / (916) 319-3301

Date of Hearing: April 13, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
AB 392 Nazarian – As Amended April 6, 2021

SUBJECT: Clinical laboratories: total protein test: authorization.

SUMMARY: Authorizes licensed plasma collection centers that utilize personnel, including unlicensed personnel, to perform a total protein test using a digital refractometer under a temporary authorization that is set to repeal on January 1, 2023, to do so under standardized procedures that are approved by the facility, rather than standardized procedures that are both approved and developed by the facility.

EXISTING LAW:

1) Provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the California Department of Public Health (CDPH), with specified exceptions. (BPC § 1200-1327)

2) Defines "CLIA" as the federal Clinical Laboratory Improvement Amendments of 1988 (United States Code, title 42, § 263a; Public Law 100-578) and the regulations adopted by the federal Health Care Financing Administration (HFCA) that are effective on January 1, 1994, or later when adopted by the CDPH after being deemed equivalent to or more stringent than California laws or regulations, as specified. (BPC § 1202.5(a); BPC § 1208(b))

3) Defines "Clinical laboratory" as any place used, or any establishment or institution organized or operated, for the performance of clinical laboratory tests or examinations or the practical application of the clinical laboratory sciences. That application may include any means that applies clinical laboratory sciences. (BPC § 1206(a)(8))

4) Authorizes a person who meets specified requirements to perform a total protein test using a digital refractometer classified as waived or moderate complexity in a licensed plasma collection center, as specified. (BPC § 1246.7)

5) Specifies that the person may only perform the test if the CDPH, as part of its routine, fee-supported inspection of the licensed plasma collection center, including its review of personnel reports for licensed and unlicensed personnel and job descriptions of all center positions for a licensed plasma collection center, determines that the following conditions are met:

    a) The person has earned a high school diploma or equivalent, as determined by the federal Centers for Medicare and Medicaid Services (CMS) pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. Sec. 263a). (BPC § 1246.7(a)(1)(A))

b) The person has training sufficient to demonstrate that the individual has the skills and abilities required of unlicensed laboratory personnel performing CLIA testing, as specified. (BPC § 1246.7(a)(1)(B))

c) In addition to the education and training requirements specified above, the person has received five hours of training in the proper procedures to be employed when performing a total protein test using a digital refractometer and the procedures for recording the test results, as specified. (BPC § 1246.7(a)(2)(A))

d) The person's training in the proper procedure to be employed when performing a total protein test using a digital refractometer has been certified by a moderate complexity laboratory technical consultant as specified, by a physician and surgeon licensed in this state, or by a licensed clinical laboratory director who is in charge of the licensed plasma collection center. (BPC § 1246.7(a)(2)(B))

e) The instructor documents the individual's successful completion of training in the performance of the total protein test using a digital refractometer and the plasma collection center maintains the documentation. The documentation must be made available to the CDPH upon request. (BPC § 1246.7(a)(2)(C))

f) The person performs the total protein test using a digital refractometer under the supervision of one of the authorized individuals who are physically onsite in the licensed plasma collection center and is available for consultation and direction while the person is processing specimens and performing the test. (BPC § 1246.7(a)(3))

g) Authorizes the following individuals to supervise the person performing the test:

   i) A moderate complexity laboratory technical consultant, as specified. (BPC § 1246.7(a)(3)(A))

   ii) A licensed registered nurse. (BPC § 1246.7(a)(3)(B))

   iii) A licensed physician or surgeon. (BPC § 1246.7(a)(3)(C))

   iv) A licensed clinical laboratory director. (BPC § 1246.7(a)(3)(D))

   v) A licensed clinical laboratory scientist. (BPC § 1246.7(a)(3)(E))

h) The person performs the total protein test using a digital refractometer under 1) standardized operating procedures required by the licensed plasma collection center's license and 2) standardized procedures developed and approved by the licensed plasma collection center's supervising physician and surgeon or licensed clinical laboratory director for administration of the total protein test by the persons authorized to perform the total protein test under this section. These standardized procedures must be made available to the CDPH upon request. (BPC § 1246.7(a)(4))

i) The person does not draw the blood sample required for the test using a procedure that requires a registration, certification, or license under state law unless the person is properly registered, certified, or licensed to perform the procedure. (BPC § 1246.7(a)(5))

j) The person's in performing total protein tests using a digital refractometer is evaluated before testing on donors, and again every six months, by the CLIA lab director or technical consultant by direct observation. A licensed plasma collection center must maintain documentation of the competency evaluation, which must be made available to the CDPH upon request. (BPC § 1246.7((a)(6))

k) The person accurately records the results of the total protein test in a federal Food and Drug Administration (FDA) 510k-approved blood establishment computer system (BECS), which must be verified. (BPC § 1246.7(a)(7))

l) The person must verify the input of their results in one of the following ways:

i) Using a digital refractometer that creates an electronic record of the test results. (BPC § 1246.7(a)(7)(A))

ii) Having each record entered by the individual verified for accuracy at the time the test result is recorded and while the result remains visible on the digital refractometer by a registered nurse or by the individual who is supervising the individual performing the test. The individual certifying the accuracy shall affix their name to the record verifying the accuracy of the entries. (BPC § 1246.7(a)(7)(B))

iii) Affixing a date- and time-stamped photograph of the digital refractometer test results to the spreadsheet. (BPC § 1246.7(a)(7)(C))

iv) The plasma collection center utilizing a double-blind computer entry system that requires the test results to be accurately entered into the record twice before the results are recorded as final. (BPC § 1246.7(a)(7)(D))

6) Requires the person performing a total protein test under this exemption to use a digital refractometer used that meets specified criteria. (BPC § 1246.7(b))

7) Specifies that the digital refractometer used by the person performing a total protein test meets the following:

a) Is used within 30 feet of the donor for whom the test is being conducted. (BPC § 1246.7(b)(1))

b) Is used in accordance with the donor test management system, the quality control program, and the comprehensive quality assurance program established and maintained by the laboratory, as specified. (BPC § 1246.7(b)(2))

c) Performs total protein tests classified as waived or of moderate complexity under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. Sec. 263a). (BPC § 1246.7(b)(3))

d) Performs total protein tests using a digital refractometer on biological specimens that require manual blood collection, centrifugation to separate the blood cells from the plasma, pipetting the plasma from the cells, and application of the plasma into the refractometer. (BPC § 1246.7(b)(4))

e) Provides total protein test results without calculation or discretionary intervention by the testing personnel. (BPC § 1246.7(b)(5))

f) Performs total protein tests without the necessity for testing personnel to perform calibration or maintenance, except basic cleaning, resetting, and daily standardization according to the manufacturer's instructions. (BPC § 1246.7(b)(6))

8) Requires a licensed plasma collection center to assess the competency and performance of persons authorized to perform the total protein test according to this authorization and to make any required information or test results available to the CDPH, as specified. (BPC § 1246.7(c))

9) Requires records of digital refractometer test results collected to be maintained for three years and made available to the CDPH upon request. (BPC § 1246.7(d))

10) Specifies that this authorization remains in effect only until January 1, 2023.

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

COMMENTS:

Purpose. This bill is sponsored by the *Plasma Protein Therapeutics Association*. According to the author, "By allowing trained and qualified plasma donation centers employees to perform the total protein test with a digital refractometer, [this bill] will make sure four things: 1) licensed individuals are utilized to the highest level of their job skills resulting in more efficient source plasma donor screening; 2) it will ensure appropriate controls are in place for the digital refractometer to maintain continued donor safety when a Total Protein Test is administered; 3) bring California in line with the majority of other states that allow a Total Protein Test to be administered this way and; 4) will ensure Californians with a rare disease have appropriate access to the 'lifesaving drug' that plasma proteins therapies provide."

Background. This bill makes a minor change to the California clinical laboratory testing requirements that allow any unlicensed individual to perform a total protein test using a digital refractometer during the donor screening process at plasma donation centers until January 1, 2023. The change authorizes the use of standardized procedures under that program to be developed by a person or entity that are approved by the facility, rather than standardized procedures that are both approved and developed by the facility.

The sponsor of this bill represents private-sector manufacturers of plasma protein therapies and collectors of source plasma. According to the sponsor, plasma protein therapies are used to treat medical conditions resulting from insufficient levels of plasma protein, including immune deficiencies and bleeding disorders.

The manufacturers and collectors require plasma donations to produce the therapies. In the U.S., plasma donors are paid, and the amount of payment varies by plasma center. These processes are regulated under federal and state biological product and clinical laboratory laws.

Plasma Derived Biologics. Plasma is a component of whole blood and contains blood proteins, which support ordinary bodily functions. The donated plasma that is separated from blood to manufacture medical products is known as source plasma. Among other things, source plasma can be used to produce therapeutic proteins. Facilities that produce products derived from blood are regulated and licensed under federal and state biologics laws (United States Code, tit. 42, § 262; BPC §§ 1600-1630).

The process for separating source plasma from whole blood is called plasmapheresis. Similar to dialysis, plasmapheresis is a process during which blood is removed from a donor, plasma is separated, and the remaining blood is returned to the donor. Due to the risks involved, both federal and state biologics laws impose safety precautions for source plasma donations, including testing, timing, and fatality reporting requirements.

Clinical Laboratory Testing and Screening. In addition to regulation under the biologics laws, plasma collectors and plasma derivative manufacturers must comply with the clinical laboratory testing requirements under CLIA. Federal and state law require that a plasma collection center test a donor's total protein level, among other things, before undergoing plasmapheresis (Code of Federal Regulations (CFR), tit. 46, § 640.65(b)(1)(i); CCR, tit. 17, § 1025(b)). According to the sponsor, the total protein test helps detect underlying conditions that may cause complications.

At both the federal and state level, a facility that performs laboratory tests on human specimens for diagnostic or assessment purposes must be certified under CLIA. While CLIA establishes the minimum standards under federal law, it allows states to establish more stringent requirements.

In all cases, the requirements for CLIA certification vary depending on the complexity of the laboratory tests performed. Clinical laboratories or other testing sites need to know whether each test system used is waived, moderate, or high complexity. In general, the more complicated the test, the more stringent the requirements, including increased training and licensing of laboratory personnel. At a minimum, all laboratories must have a licensed clinical laboratory director.

The FDA determines the complexity of laboratory tests under CLIA. Waived tests are simple tests with a low risk for an incorrect result. They include tests listed in the CLIA regulations, tests cleared by the FDA for home use, and tests approved for a waiver by the FDA using the CLIA criteria. Tests not classified as waived are assigned a moderate or high complexity category based on seven criteria given in the CLIA regulations, including ease of use, knowledge required, and types of materials tested. For commercially available FDA-cleared or approved tests, the test complexity is determined by the FDA during the pre-market approval process.

Under federal and California law, anyone providing care may perform a waived test in a licensed laboratory or as part of a nondiagnostic health assessment program. For moderate complexity tests, federal law requires that, at a minimum, personnel have 1) a high school diploma or equivalent and 2) documentation of training appropriate for the testing performed before analyzing patient specimens.

However, in California, only specified licensed, certified, or otherwise authorized individuals may perform moderate complexity tests. Two exceptions are allowing unlicensed individuals to perform a moderate complexity test in California. One is for anyone performing a blood gas

analysis under BPC § 1245 and anyone in a physician's office laboratory with a physician readily available.

Total Protein Digital Refractometer Test. According to the sponsors, the centers typically use a digital refractometer to perform the total protein test, which the FDA has categorized as a moderate complexity test. A refractometer is a device that shines a beam of light through a sample of liquid. The device measures the amount of light that is refracted (bent) by the solids in the sample. In blood, protein causes light to bend. The greater the amount of protein, the more light is bent from the light path.

There are multiple types of protein refractometer devices, ranging from manual to automatic and handheld to benchtop. Depending on the device, the test requires varying amounts of small samples of blood from the donor, which is then placed into or onto the device. Generally, a manual device requires the user to analyze the sample and calculate the result. An automatic device performs the analysis without input from the user and displays the result, which the user then compares to a set of standard guidelines for total protein levels.

The FDA's medical device database shows that the FDA has classified all total protein refractometer devices as of moderate complexity under CLIA. Because the test is categorized as moderate complexity at the federal level, state law requires that the test is performed by various licensed personnel under the BPC, such as a registered nurse or clinical laboratory scientist. The sponsor argues that the amount of training and education needed for those professionals is not needed to safely perform a total protein test using a digital refractometer as described under the temporary exemption in a plasma collection facility.

Plasma Donation and COVID-19. The sponsors of this bill report that they are developing potential treatments for COVID-19 patients using plasma donated by individuals who have recovered from COVID-19. The goal is to use the antibodies found in the collected plasma to manufacture hyperimmune globulins to treat COVID-19 patients. The plasma, called convalescent plasma because it is collected post-recovery, is being collected at licensed plasma donation centers in the United States, including California.

Prior Related Legislation. AB 2199 (Nazarian), Chapter 127, Statutes of 2020 extended the pilot program discussed under this bill until January 1, 2023.

AB 613 (Nazarian), Chapter 799, Statutes of 2018 established the pilot program discussed under this bill until January 1, 2021.

AB 757 (Gomez) of 2015 would have established a similar program as discussed under this bill, authorizing a person who meets specified criteria to perform a total protein refractometer test using an automatic, button-operated refractometer with a digital readout in a licensed plasma collection facility in this state. AB 757 was vetoed by Governor Brown who stated, "Failure to perform and report this test accurately could lead to serious health consequences for the donor. The California Department of Public Health does not believe that the standards outlined in the bill for persons to perform this test ensure the health and safety of plasma donors."

ARGUMENTS IN SUPPORT:

The *Plasma Protein Therapeutics Association* (sponsor) writes in support:

> In 2018… the California Legislature passed legislation to create a pilot to determine if a properly trained individual may satisfactorily perform a total protein test using a digital refractometer in a licensed plasma collection center. This is the federal standard followed in most of the 45 states where plasma is donated. The pilot was continued by the legislature in 2020.
>
> The pilot has shown that the properly trained, but unlicensed individual, is able to satisfactorily perform the total protein test with no harm to the potential donor. These results are not surprising since properly trained but unlicensed individuals perform the total protein test using a digital refractometer in more than 900 source plasma donation centers in the United States.
>
> It is critical to increase plasma donation in California because there is an urgent need for source plasma donations. Reports vary, but plasma collectors experienced significant declines in collections due, in part, to the impacts of social distancing measures and other mobility restrictions caused by the COVID-19 pandemic. Considering the complex manufacturing of plasma-derived therapies can take 7-12 months, any decline in plasma donations could impact patients' ability to access their lifesaving therapies. This sharp decline in plasma collections could cause more significant challenges in the months to come.
>
> This is where California may make a difference. California currently has 28 plasma donation centers collecting source plasma. This number is relatively low when compared to other states. For comparison, there are more than 100 source plasma donation centers in Texas, more than 60 in Florida, and more than 40 in Ohio. Passage of [this bill] will make permanent laws that harmonize California's laws with those in the rest of the country. This permanent change should result in more centers opening in the state.
>
> Passage of [this bill] will ensure that licensed professionals are utilized to the highest level of their job skills resulting in more efficient source plasma donor screening. It will free up specialized staff to perform other essential functions in these source plasma donation centers, such as conducting new donor physical examinations. Before the pilot our members were struggling to find licensed personnel to work at plasma donation centers because of the shortage of nurses in California. The pandemic has only exacerbated this problem. The nurses who perform the total protein test question the utility of their skills in performing such an easy test that outside of California is routinely done by any trained employee.
>
> Passage of [this bill] should also improve the lives of people where source plasma donation centers will be located. Passage of this legislation will increase the number of source plasma donation centers in the state. Plasma donation centers benefit the communities they are in by providing good jobs to more than 50 employees per center and an economic impact of more than $4 million annually.

Grifols, Inc. writes in support:

> Grifols was fortunate to have 5 plasma collection centers participate in the pilot and the results have shown that the properly trained, unlicensed individual is able to satisfactorily perform the total protein test with no harm to the potential donor. These results are not surprising since properly trained, unlicensed individuals perform the total protein test using a digital refractometer in more than 900 source plasma donation centers in the United States. Almost all other states allow this test to be performed by properly trained unlicensed individuals. This test is performed to ensure an individual is suitable to donate source plasma on a given day….
>
> [This bill] would bring California's laws in line with the majority of other states that allow a total protein refractometer test to be administered by trained and qualified plasma donation employees. Considering the recent COVID-19 pandemic, it would further address the limited nursing staff available in the State. It would allow for a more streamlined collection of plasma from donors, which would improve the donor experience as well as meet the growing demand for plasma medicines.

The *Immune Deficiency Foundation (IDF)* writes in support:

> In California alone, there are an estimated 30,000 people diagnosed with [primary immunodeficiencies (PI)] and many more undiagnosed. Fortunately, most people with PI can live healthy, productive lives if they receive lifelong immunoglobulin (Ig) replacement therapy that replaces the antibodies the body is unable to produce sufficiently. However, because Ig derives from human plasma, it cannot be produced without a continuous supply of source plasma from donors. It takes approximately 130 human plasma donations to produce enough immunoglobulin to treat an adult with PI for a year. As a result, the PI community relies upon an adequate number of plasma donors and donation centers across the country.
>
> Despite the state's large population, California is home to only a handful of these plasma donation centers, largely due to regulatory practices that hinder plasma production. These regulations prevent licensed professionals from being utilized to the highest level of their job skills, resulting in less efficient source plasma donor screening. The lack of efficiency and minimal presence of plasma donation centers in California creates a reliance on plasma collection elsewhere and contributes to the strain on the global plasma supply. The need for plasma and plasma-derived products grows each year – both for the PI community and the larger global population. Updating the governance around plasma donation in California (by removing the sunset in question) can help address that need.
>
> On behalf of individuals with PI, IDF encourages lawmakers in California to move forward thoroughly and quickly on this vital legislation to synchronize California's laws with those in much of the rest of the country and facilitate the establishment of an adequate number of plasma donor centers in the state. The expansion of donation centers in the State of California will help to alleviate the strain on the global plasma supply, which, if gone unaddressed, will continue the

> trend of an increasing number of Californians unable to receive this lifesaving therapy.
>
> Some of the most medically vulnerable citizens in the state are suffering because California and a handful of other states have inadvertently created barriers for plasma collection. [This bill] will help solve this issue and provide plasma to those who need it so vitally.

ARGUMENTS IN OPPOSITION:

The *California Association of Medical Laboratory Technicians* writes in opposition, [waiting on confirmation that they are removing their opposition]

POLICY ISSUES FOR CONSIDERATION:

Sunset Date. While this bill only makes a technical change, the goal of the author and sponsor is to delete the sunset date and indefinitely extend the pilot program, which was put into place in 2018. The goal of the program was to explore the safety of the use of unlicensed personnel or other individuals who are otherwise untrained to generally perform CLIA tests of moderate complexity using an automated digital refractometer to screen potential and repeat plasma donors. The prior bill that established the pilot put numerous patient safety provisions in place, including limiting the device to a class of point-of-care devices normally used by unlicensed personnel.

Because there have been no recorded instances of hard, the introduced version of this bill would have extended the program indefinitely. However, the bill that first enacted the pilot program provided several mechanisms allowing for the reporting of safety and accuracy data to the CDPH. According to the CDPH, that data is still under review. To allow the CDPH additional time, the author recently amended the bill to leave in the sunset date.

However, the author and sponsors note that plasma donation centers may not be willing to invest the time and resources to set up in California if the pilot program is always at risk of being repealed. If this bill passes this Committee, the author and sponsors have stated they will continue to work with the CDPH and stakeholders to determine whether the bill should be amended again to repeal the sunset date upon the CDPH's review of the data.

IMPLEMENTATION ISSUES:

Verification. The introduced version of this bill deleted the requirement that the unlicensed person verifies their own recording of the results of the total protein test in a federal FDA 510k-approved blood establishment computer system. The current requirement specifies that the unlicensed person verifies the results in one of four ways:

1) Using a digital refractometer that creates an electronic record of the test results.

2) Having each record entered by the individual verified for accuracy at the time the test result is recorded and while the result remains visible on the digital refractometer by a registered nurse or other authorized personnel who is supervising the individual performing the test.

The personnel certifying the accuracy must affix their name to the record verifying the accuracy of the entries.

3) Affixing a date- and time-stamped photograph of the digital refractometer test results to the spreadsheet.

4) Using a double-blind computer entry system that requires the test results to be accurately entered into the record twice before the results are recorded as final.

According to the sponsors, the verification requirement is onerous and conflicts with federal Good Manufacturing Practices for pharmaceuticals. The recently accepted amendments reinserted this requirement to allow CDPH additional time to review data. Once the CDPH reviews the data, the author and sponsors have stated they will continue to work with the CDPH and stakeholders to determine whether the verification requirement should be removed or updated.

REGISTERED SUPPORT:

Plasma Protein Therapeutics Association (sponsor)
Grifols, Inc.
Immune Deficiency Foundation
Takeda Pharmaceuticals America

REGISTERED OPPOSITION:

California Association of Medical Laboratory Technologists [TBD]

Analysis Prepared by: Vincent Chee / B. & P. / (916) 319-3301

Date of Hearing: April 13, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
AB 1278 (Nazarian) – As Amended March 17, 2021

SUBJECT: Physicians and surgeons: payments: disclosure: notice.

SUMMARY: Requires a physician and surgeon who receives remuneration from a drug or device company to disclose it both orally and in writing to their patient prior to the intended use or prescription of that drug or device, and requires all physicians and surgeons to post a notice informing patients of a federal database containing information regarding such remunerations.

EXISTING LAW:

1) Establishes the Medical Board of California (MBC), a regulatory board within the Department of Consumer Affairs (DCA) comprised of 15 appointed members, including 7 public members. (Business and Professions Code (BPC) § 2001)

2) Requires the MBC to post on its Internet Web site the current status of its licensees; any revocations, suspensions, probations, or limitations on practice, including those made part of a probationary order or stipulated agreement; historical information regarding probation orders by the board, or the board of another state or jurisdiction, completed or terminated, including the operative accusation resulting in the discipline by the board; and other information about a licensee's status and history. (BPC § 2027)

3) Establishes the Osteopathic Medical Board of California (OMBC), which regulates osteopathic physicians and surgeons that possess effectively the same practice privileges as those regulated by the MBC but with a training emphasis on diagnosis and treatment of patients through an integrated, whole-person approach. (BPC § 2450)

4) Requires every board under the Department of Consumer Affairs to adopt regulations to require its licensees to provide notice to their clients or customers that the practitioner is licensed by this state. (BPC § 138)

5) Requires the MBC to adopt regulations to require its licentiates and registrants to provide notice to their clients or patients that the practitioner is licensed or registered in California by the board, that the practitioner's license can be checked, and that complaints against the practitioner can be made through the board's Internet Web site or by contacting the board. (BPC § 2026)

6) Requires healing arts boards to each create and maintain a central file of the names of all persons who hold a license or similar authority from the board confidentially containing an individual historical record for each licensee containing, among other things, disciplinary information. (BPC § 800)

7) Requires the MBC, the OMBC, the Podiatric Medical Board of California, and the Physician Assistant Board to disclose to an inquiring member of the public information regarding any enforcement actions taken against a licensee, including probationary status and limitations on practice. (BPC § 803.1)

8) Enacts the Patient's Right to Know Act of 2018 to require certain healing arts licensees, including physicians and surgeons, who are on probation for certain offenses to provide their patients with information about their probation status prior to the patient's first visit. (BPC § 2228.1)

9) Requires drug companies to adopt a Comprehensive Compliance Program and include limits on gifts or incentives provided to medical or health professionals. (Health and Safety Code § 119402)

THIS BILL:

1) Defines "drug or device company" as a manufacturer, developer, or distributor of pharmaceutical drugs or any device used in the context of the physician and surgeon's or osteopathic physician and surgeon's practice.

2) Defines "health care employer" as an employer that provides health care services and that employs a physician and surgeon or an osteopathic physician and surgeon.

3) Defines "open payments database" as the database created to allow the public to search for data provided pursuant to federal law and that is maintained by the federal Centers for Medicare and Medicaid Services (CMS).

4) Defines "physician and surgeon" as a physician and surgeon licensed under either the MBC or the OMBC.

5) Requires a physician and surgeon to post in each location where the physician and surgeon practices, in an area that is likely to be seen by all persons who enter the office, an open payments database notice containing the following text:

> "For informational purposes only, a link to the federal Centers for Medicare and Medicaid Services (CMS) Open Payments web page is provided here. The federal Physician Payments Sunshine Act requires that detailed information about payment and other payments of value worth over ten dollars ($10) from manufacturers of drugs, medical devices, and biologics to physicians and teaching hospitals be made available to the public."

6) Requires a physician and surgeon who receives remuneration from a drug or device company to disclose the source of the remuneration orally and in writing to each patient or patient representative prior to the intended use or prescription of a device or drug manufactured or distributed by the company.

7) Requires the disclosure to cover any remuneration received on or after January 1, 2014.

8) Requires that the written disclosure shall include a signature from the patient or patient representative and the date of signature.

9) Requires the written disclosure to include the following text: "If you would like further details on the information provided above you may discuss with Dr. ____ and/or visit openpaymentsdata.cms.gov, a federal tool used to search payments made by drug and device companies to physicians and teaching hospitals."

10) Requires a physician and surgeon to include in the written or electronic records for the patient a record of the disclosure and to give to the patient or patient representative a copy of the signed and dated disclosure.

11) If a physician and surgeon is employed by a health care employer, provides that the health care employer shall be responsible for meeting the posting requirements.

12) Requires a physician and surgeon to conspicuously post the open payments database notice on the internet website used for the physician and surgeon's practice.

13) Provides that violations of the bill constitute unprofessional conduct.

14) Exempts a physician and surgeon working in a hospital emergency room from the bill.

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

COMMENTS:

Purpose. This bill is sponsored by the **Center for Public Interest Law**. According to the author:

> "AB 1278 would empower patients with important information about their recommended medical treatment so that they can make informed choices about any treatment prescribed. When it comes down to it- patients deserve transparency and accountability when it comes to treatment. By requiring physicians and surgeons to engage patients as trusted partners in decision making, we are creating local accountability what will both serve the doctor and patients alike."

Background.

The Physician Payments Sunshine Act (Act) is a federal law that was passed in 2010 as part of the Patient Protection and Affordable Care Act. The Act requires medical product manufacturers to disclose to the Centers for Medicare and Medicaid Services (CMS) any payments or other transfers of value made to physicians or teaching hospitals. The intention of the Act is to increase transparency regarding financial relationships between health care providers and pharmaceutical manufacturers.

Manufacturers are required to submit annual data on all payments and transfers of value made to physicians, who have 45 days to review the data and dispute errors before public release. CMS then publishes the data through its Open Payment Program website, which allows members of the public to search for physicians, teaching hospitals, or companies making payments by name, city, state, and specialty. The Open Payments database enables patients to see if their providers have received some form of payment from the manufacturer of a drug or device that has been recommended as part of their treatment plan, which may ultimately inform their health care decisions.

In addition to allowing the public to search for specific payments and transfers of value, CMS makes its Open Payments data generally available to researchers. In 2016, four key research studies explored the association between industry payments and physician-prescribing patterns by cross-linking federal Open Payments data with national Medicare Part D prescribing information.

When examining general brand-name prescribing rates, one study found that physicians who received any industry payments had, on average, a brand-name prescribing rate two percentage points higher than physicians who did not receive any payments. A dose-response relationship was examined, meaning that as the payment amount increased, the difference in the brand-name prescribing rates of non-payment recipients and payment recipients increased. Another study analyzing 2013 Open Payments data found that even after adjusting for potential influencing factors, industry payments were associated with greater prescription costs per beneficiary. This was again a dose-response relationship, with greater payments associated with greater prescribing costs per patient. One study published in *JAMA Internal Medicine* in August 2016 found that receipt of meals costing as little as $20 were associated with higher relative prescribing rates.

This bill is intended to ensure that patients are informed of when their physician and surgeon has received some form of payment from the manufacturer of a drug or device intended to be prescribed or used in their treatment by requiring all physicians to disclose directly to their patients when they have received remunerations that would be reportable under the Act. Further, the bill would increase consumer awareness of the Open Payments database by requiring all physician and surgeon offices to post a notice advertising the website. The author believes that doing so will greatly increase the impact of the federal law in California and result in a better informed patient population.

Prior Related Legislation. SB 790 (McGuire, Chapter 558, Statutes of 2018) would have prohibited or limited the offering or giving of gifts to a health care provider by a drug manufacturer. *The contents of this bill were subsequently struck and replaced with provisions relating to dreissenid mussel infestation prevention plans.*

SB 1448 (Hill, Chapter 570, Statutes of 2018) requires physicians and surgeons, osteopathic physicians and surgeons, podiatrists, acupuncturists, chiropractors and naturopathic doctors to notify patients of their probationary status beginning July 1, 2019.

SB 798 (Hill, Chapter 775, Statutes of 2017) originally contained language that would have required physicians and surgeons to notify patients of their probationary status. *This bill was chaptered with the provisions regarding probation status disclosure removed.*

SB 1033 (Hill) of 2016 would have required physicians and surgeons, podiatrists, acupuncturists, chiropractors, and naturopathic doctors to notify patients of their probationary status before visits take place. *This bill failed passage on the Senate Floor.*

SB 763 (Hill) of 2015 would have required the MBC, the OMBC, and the BPM to disclose to an inquiring member of the public and to post on their websites specified information concerning each licensee including revocations, suspensions, probations, or limitations on practice. *This bill died in Assembly Rules following substantial amendments.*

ARGUMENTS IN SUPPORT:

The **Center for Public Interest Law** (CPIL) is sponsoring this bill. According to CPIL, "disclosure of financial conflicts of interest by doctors is a moral obligation not enforced by law. AB 1278 would remedy this problem by mandating physician disclosure of any financial conflicts of interest to their patients, and empowering patients to make better and more informed choices about their treatment. Preceding any treatment, physicians would be required to explain their healthcare recommendation, the clinical evidence supporting it, as well as disclosing any financial ties they have to the drug or device manufacturer. The result would be strengthened

trust between patients and doctors, as well as patients being fully apprised of information relevant to their care to aid them as they evaluate health care decisions."

Health Access California also supports this bill. According to Health Access, "in a world where prescription drug prices are consistently rising, despite major innovations and more choices among medications, consumers should be aware if their doctor is receiving financial compensation from these companies. If there is a cheaper or different drug that a consumer can be taking, but the doctor is incentivized to prescribe a costlier pharmaceutical – that not only does the patient a disservice at the pharmacy counter, but it increases prescription drug costs for the system as a whole. There is also a risk of patients being harmed by getting a prescription or medical device that may not be right for them."

ARGUMENTS IN OPPOSITION:

The **California Rheumatology Alliance** (CRA) opposes this measure. The CRA argues that existing law is sufficient to provide full transparency to patients regarding physicians and surgeons who have received payments from drug and device companies. The CRA states that "we believe this process is the best way to allow patients to understand a physician's relationship with a pharmaceutical or device company."

The **California Academy of Family Physicians** (CAFP) opposes this bill unless amended to remove the written, spoken, and signatory requirements from the bill, "and instead allow the requested information to be put on the same publicly posted notice regarding Medical Board of California reporting and the Sunshine Act." CAFP states that "while we appreciate the author's intent, and share support for transparency, this bill would result in the diversion of crucial patient time when easily accessible information on this issue is readily available."

POLICY ISSUE(S) FOR CONSIDERATION:

Terminology. As drafted, the bill references physicians and surgeons who receive "remuneration" from a drug or device company. While the term "remunerate" does generally mean to provide compensation, it more typically refers to payment for labor or services provided as part of an employment relationship. The CMS Open Payments website refers instead to "the payment or transfer of value," which may be more appropriately tailored to the intent of the bill.

Duplicative Disclosure. The bill currently requires a physician and surgeon to disclose remunerations from a drug or device company both orally and in writing to patients. However, the bill only requires the patient to sign an acknowledgment that they received the written disclosure. It may be more practical to simply require the written disclosure, which is likely both more effective and more enforceable.

Consolidating Posting Requirements. Existing law already required the MBC to promulgate regulations mandating that every physician and surgeon provide notice to each patient stating that medical doctors are licensed and regulated by the Board and providing the Board's contact information. This notice can be provided by "Prominently posting the notice in an area visible to patients on the premises where the licensee provides the licensed services, in which case the notice shall be in at least 48-point type in Arial font." It may be reasonable to allow for a physician and surgeon to post the notice required by this bill within a notice they have already posted to comply with existing disclosure requirements.

AMENDMENTS:

1) To update terminology used in the bill to refer more specifically to the types of payments intended to be covered, the word "remuneration" should be struck and replaced with "payment or transfer of value" throughout.

2) To clarify and simplify the bill's disclosure requirements, strike "orally and" from the proposed subdivision (a) of Section 661 to only require that the disclosure be provided in writing.

3) To allow for the consolidation of required public postings, subdivision (d) should be added to the bill's proposed Section 662 to read:

   (d) The posting required by this section may be placed within the same notice posted by the physician and surgeon pursuant to Sections 138 or 2026.

REGISTERED SUPPORT:

Center for Public Interest Law *(Sponsor)*
Association for Medical Ethics
Breast Implant Safety Alliance
Consumer Attorneys of California
Consumer Watchdog
Health Access California
Heartland Health Research Institute
Informed Patient Institute
Mending Kids

REGISTERED OPPOSITION:

California Academy of Family Physicians
California Chapter, American College of Cardiology
California Rheumatology Alliance
California Society of Plastic Surgeons

Analysis Prepared by: Robert Sumner / B. & P. / (916) 319-3301

Date of Hearing: April 13, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
AB 847 (Quirk) – As Amended March 25, 2021

SUBJECT: Electrically conductive balloons.

SUMMARY: Regulates the sale of celebratory foil balloons in the State of California and allows the manufacture and sale of celebratory foil balloons if those balloons do not cause faults when they contact overhead electric power lines.

EXISTING LAW:

1) Prohibits the sale or distribution of any balloon that is constructed of electrically conductive material, and filled with a gas lighter than air without:

   a) Affixing an object of sufficient weight to the balloon or its appurtenance to counter the lift capability of the balloon;

   b) Affixing a statement on the balloon, or ensuring that a statement is affixed, that warns the consumer about the risk if the balloon comes in contact with electrical power lines; and

   c) A printed identification of the manufacturer of the balloon. (Penal Code § 653.1(a)).

2) Prohibits the sale or distribution of any balloon filled with a gas lighter than air that is attached to an electrically conductive string, tether, streamer, or other electrically conductive appurtenance. (Penal Code § 653.1(b)).

3) Prohibits the sale or distribution of any balloon that is constructed of electrically conductive material and filled with a gas lighter than air and that is attached to another balloon constructed of electrically conductive material and filled with a gas lighter than air. (Penal Code § 653.1(c)).

4) Prohibits any person or group from releasing balloons made of electrically conductive material and filled with a gas lighter than air, outdoors as part of a public or civic event, promotional activity, or product advertisement. (Pen. Code, § 653.1(d)).

5) Punishes a violation of the above prohibited conduct as an infraction with a fine of not more than $100, unless the person has twice been convicted of any of the above. A third or subsequent conviction is a misdemeanor. (Pen. Code, § 653.1(e)).

6) States that this prohibition does not apply to manned hot air balloons, or to balloons used in governmental or scientific research projects. (Pen. Code, § 653.1(f)).

THIS BILL:

1) Requires the Office of Energy Infrastructure Safety, on or before September 1, 2024, in consultation with the Office of Emergency Services, to adopt regulations governing the sale or manufacture in the state of celebratory balloons constructed of electrically conductive material and filled with lighter than air gas. Require the regulations to do certain things, including requiring that the balloons pass a standard test performed by a reputable electric testing center without causing a fault at high-voltage electric distribution levels, as provided.

2) Requires a business that sells or manufactures a celebratory balloon that is constructed of electrically conductive material to permanently mark the balloon with specified information, including the dangers of releasing balloons which may contact overhead power lines and the identity of the manufacturer.

3) Requires a business that sells or manufactures a celebratory balloon that is constructed of electrically conductive material that is filled with lighter than air gas to affix an object of sufficient weight to the balloon or its appurtenance, as provided, and prohibits the business from attaching an electrically conductive string, or other object, to the balloon.

4) On and after September 1, 2025, would prohibit a business from selling or offering for sale, and a manufacturer from manufacturing for sale, a celebratory balloon made of electrically conductive material unless the balloon complies with these provisions of the bill.

5) The bill would make a business or person violating these provisions subject to a civil penalty of $50 for each violation.

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

COMMENTS:

Purpose. This bill is sponsored by *San Diego Gas & Electric*. According to the Author, "Foil balloons (a.k.a Mylar™ balloons) cause thousands of power outages and spark fires across California every year. These foil balloons are made with metallic films that conduct electricity so, when they drift into to power lines, they can cause an electrical fault. These electrical faults damage power infrastructure, cause power outages, and start fires that require costly repairs, inconvenience utility customers, and threaten the safety of utility workers and the public. Recent developments in the balloon manufacturing process can minimize the safety and fire risks of foil balloons. AB 847 would ensure that balloons manufactured or sold in California are manufactured using best practices to minimize the risks to energy infrastructure and public safety. AB 847 requires the Office of Energy Infrastructure Safety to regulate the materials used to manufacture celebratory foil balloons, so that only balloons which pass a standard test set by the Institute of Electrical and Electronics Engineers may be manufactured or sold in California. By ensuring that the materials used in these balloons do not conduct electricity, AB 847 will mitigate the risks of balloon-caused fires and power outages while also allowing manufacturers and retailers to sell popular celebratory foil balloons."

Background. *Balloons and Power Outages*. Two main types of balloons are in use today throughout California – latex and mylar. While latex balloons are biodegradable because they are made of natural rubber, mylar balloons are not biodegradable because they are made with mylar nylon and are typically coated with a metallic finish. Since the metallic finish on mylar

balloons conducts electricity, if they are not weighted and are released into the air, they have the potential to travel several miles and end up tangling in power lines. When these electrically conductive metallic balloons come into contact with power lines, power outages are often the result. It was recently reported that 456 power outages were caused by these metallic mylar balloons in 2017 across PG&E's service area of northern and central California, disrupting service to more than 371,000 homes and businesses.

(https://www.sonomacountygazette.com/sonoma-county-news/mylar-balloons-create-power-outage-hazards [as of February, 2018]).

Mylar Balloons. There are two common types of balloons currently in use, Mylar and latex balloons. Mylar balloons are made with Mylar nylon, a material not classified as biodegradable, and are typically coated with a metallic finish. Latex balloons are biodegradable and do not typically conduct electricity. If Mylar balloons are not sufficiently weighted and are released into the air, they have the potential to travel several miles and end up tangling in power lines. The metallic finish on Mylar balloons conduct electricity, so if these balloons come in contact with electrical lines, they can cause a bridge resulting in power outages. Mylar balloons are often released for celebrations, such as birthdays or memorials, or as part of a mass balloon release b non-profit organizations and charity groups to raise funds. PG&E reports that they typically see a spike in the number of power outages caused by metallic balloons during the graduation season.

Southern California Edison has reported that metallic balloon-related outages are on the rise causing Edison to handle a record 1,094 Mylar balloon-related power outages in 2017 which caused 1.4 million customers to experience outages caused by balloons. PG&E reported that 456 power outages were caused by these metallic mylar balloons in 2017, across PG&E's service area of norther and central California, disrupting service to more than 371,000 homes and businesses. Recently on June 3, 2018, 4,500 customers in Palo Alto lost power when a Mylar balloon got caught in the powerlines, which the Palo Alto Utilities reported was the number one cause to power outages in the area. Balloons stuck in power lines can harm energy company workers tasked with removing the balloons from the powerlines and lead to fires.

Other States. Bans on metallic foil balloons have started to gain traction at the local level and in other states. In 2019, the Massachusetts legislature introduced a bill that would ban all balloons, including metallic foil balloons. In California, the cities of Glendale and Hermosa Beach enacted bans on the sale of metallic foil balloons, though the sale of metallic balloons that will not float and that are attached to a pole or other structure will still be allowed in Glendale. A violation is punishable by either a fine of up to $1,000, up to 180 days of jail time or both. In Hermosa Beach, the sale and the use or distribution of metallic balloons on public property was banned.

Prior Related Legislation. AB 2450 (Quirk) Chapter 262, Statutes of 2018, requires manufacturers of balloons constructed of electrically conductive material in California to permanently mark each balloon with a warning about the dangerous risk of fires if a balloon comes in contact with an electrical power line. This bill also makes violating specified requirements related to the selling or distribution of balloons constructed of electrically conductive material subject to civil, rather than criminal, penalties.

AB 1091 (Quirk) of 2017 would have amended Penal Code Section 653.1 to require that a balloon made of electrically conductive material be released willfully for it to be a crime, and would have further prohibited the release of these balloons even during a public or civic event, promotional activity, or product advertisement. *NOTE: AB 1091 was vetoed by Governor*

Brown, stating, "I do not believe that expanded criminal liability is the best solution to the problem of electrically conductive balloons interfering with power lines . . . our Penal Code is already far too complex and unnecessarily proscriptive."

AB 2709 (Quirk), of the 2015-2016 Legislative Session, would have made it a crime to sell or distribute any balloon constructed of electrically conductive material or any balloon that is attached to an electrically conductive material. AB 2709 would have also made it a crime to release, outdoors, balloons made of electrically conductive material, regardless of whether the outdoor release is part of a public or civic event, promotional activity, or product advertisement. AB 2709 would have exempted specified balloons from these provisions, including balloons that are not designed to be buoyant in ambient air when filled with any gas. *NOTE: AB 2709 was held in the Assembly Committee on Appropriations.*

SB 1499 (Scott), of the 2007-2008 Legislative Session, would have increased the fine for a violation of those provisions punished as an infraction. SB 1499 would have further specified the type of weight that must be attached to the balloon and the specifications for the required warning, and would have required that the consumer be provided a separate warning notice, as specified. SB 1499 would also have prohibited a manufacturer or distributor from sending or shipping these types of balloons to retailers without the shipment containing a notice describing the retailer's responsibilities. *NOTE: SB 1499 was vetoed by Governor Schwarzenegger*.

SB 1990 (Ayala) Chapter 1559, Statutes of 1990, prohibited the sale or distribution of a balloon which is either constructed of electrically conductive material or is attached to electrically conductive string, tether, streamer, or other electrically conductive appurtenance, unless a specified weight and consumer warning regarding powerlines are affixed to the balloon and the manufacturers identification printed on it.

ARGUMENTS IN SUPPORT:

According to *San Diego Gas and Electric (SDGE),* "In SDG&E's service territory, existing celebratory foil balloons cause around 100 power outages each year and have sparked an average of 3 to 4 reportable fires every year from 2015 to 2019. This happens because the metallic exterior of the celebratory foil balloon conducts electricity, so when a celebratory foil balloon floats into an overhead power line it can cause an electrical fault, blackouts, and sparks that can start fires. Seeking to solve the conductivity issue while allowing celebratory foil balloons to remain a consumer product, SDG&E worked with a leading U.S. balloon manufacturer to develop and test a balloon that was electrically non-conductive. This balloon was successfully tested in conditions common to SDG&E's, Southern California Edison's (SCE), and Pacific Gas & Electric's (PG&E) electrical distribution configurations."

REGISTERED SUPPORT:

San Diego Gas & Electric, a Sempra Utility (Sponsor)
California State Association of Electrical Workers
Coalition of California Utility Employees
Pacific Gas and Electric Company
Sempra Energy Utilities

REGISTERED OPPOSITION:

None on file.

Analysis Prepared by: Danielle Sires / B. & P. / (916) 319-3301

Date of Hearing: April 13, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
AB 526 (Wood) – As Amended April 6, 2021

SUBJECT: Dentists and podiatrists: clinical laboratories and vaccines.

SUMMARY: Authorizes both dentists and doctors of podiatric medicine to independently prescribe and administer influenza and COVID-19 vaccines and provides additional authority for dentists to administer rapid point-of-care tests for COVID-19.

EXISTING LAW:

1) Establishes the Dental Board of California (DBC) within the Department of Consumer Affairs (DCA) to regulate the practice of dentistry. (Business and Professions Code (BPC) §§ 1600 *et seq.*)

2) Defines "dentistry" as the diagnosis or treatment, by surgery or other method, of diseases and lesions and the correction of malpositions of the human teeth, alveolar process, gums, jaws, or associated structures; and such diagnosis or treatment may include all necessary related procedures as well as the use of drugs, anesthetic agents, and physical evaluation. (BPC § 1625)

3) Establishes the Podiatric Medical Board of California (PMBC) within the jurisdiction of the Medical Board of California (MBC) and vests the BPM with regulation of podiatric medicine. (BPC §§ 2460 *et seq.*)

4) Defines "podiatric medicine" as the diagnosis, medical, surgical, mechanical, manipulative, and electrical treatment of the human foot, including the ankle and tendons that insert into the foot and the nonsurgical treatment of the muscles and tendons of the leg governing the functions of the foot. (BPC § 2472)

5) Provides that a licensed dentist may perform a clinical laboratory test or examination classified as waived under the federal Clinical Laboratory Improvement Amendments (CLIA) Program, provided that the laboratory test or examination is performed under the overall operation and administration of a qualified laboratory director. (BPC § 1206.5)

THIS BILL:

1) Authorizes a dentist to independently prescribe and administer influenza and COVID-19 vaccines approved or authorized by the United States Food and Drug Administration (FDA) in compliance with the individual federal Advisory Committee on Immunization Practices (ACIP) influenza and COVID-19 vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC) to persons 3 years of age or older.

2) Authorizes a doctor of podiatric medicine to independently prescribe and administer influenza and COVID-19 vaccines under those same conditions.

3) Adds "a duly licensed dentist" to the list of persons qualified to be a laboratory director for purposes of the federal CLIA Program, to the extent that any clinical laboratory tests are authorized within the scope of practice of dentistry.

4) Requires that dentists and doctors of podiatric medicine meet immunization training program and recordkeeping requirements prior to prescribing and administering a vaccine pursuant to the bill.

5) Authorizes the DBC and the PMBC respectively to adopt regulations to implement the bill.

6) Provides that any vaccine training program provided through the federal CDC, including courses that were completed by a licensed dentist, registered dental hygienist, or licensed doctor of podiatric medicine on or after January 4, 2021 pursuant to emergency order or waiver, shall count toward the fulfillment of required continuing education requirements.

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

COMMENTS:

Purpose. This bill is sponsored by the **California Dental Association**. According to the author:

> "Despite extensive training and expertise, existing law does not authorize the administration of flu and/or COVID-19 vaccines within the scope of practice for dentists or podiatrists. Yet in the early months of 2021, the California Department of Consumer Affairs issued public health emergency waivers permitting dentists and podiatrists to administer the COVID-19 vaccine if specified trainings provided by the CDC were completed. Issuing this waiver acknowledges that dentists and podiatrists with appropriate training can help in not just the existing pandemic but in future public health emergencies. By adding the administration of flu and COVID-19 immunizations to the scopes of practice, dentists and podiatrists are well positioned to assist immediately should future needs arise. Additionally, dentists are not on the list of providers who may register as a laboratory director for purposes of CLIA Certificate of Waiver tests. Since there are no federal qualifications for lab directors to perform tests that have Certificates of Waivers, dentists should be able to be lab directors for purposes of these simple tests in order to have the ability to conduct waived tests that are within their scope of practice."

Background.

COVID-19 Pandemic. On March 4, 2020, Governor Gavin Newsom proclaimed a State of Emergency as a result of the impacts of the COVID-19 public health crisis. On March 30, 2020, the Governor signed an executive order that created a new process for boards and the public to request waivers of requirements related to healing arts professional licensing through the DCA.

Through this waiver process, the DCA has issued multiple waivers of law to authorize various healing arts licensees to order and administer the COVID-19 vaccine. These waivers have extended to pharmacists, pharmacy technicians, dentists, dental hygienists, optometrists, doctors of podiatric medicine, licensed midwives, physician assistants, respiratory care practitioners, veterinarians, medical assistants, healthcare students, and naturopathic doctors.

Vaccinations. Vaccines are regulated and overseen by multiple federal entities responsible for ensuring their safety and efficacy. The FDA is initially responsible for approving new drugs, determining both that they are safe to administer and that their recommended use is clinically supported. During states of emergency, the FDA may expedite their review through the Emergency Use Authorization (EUA) process to hasten the availability of new immunizations or treatments.

Once approved, the federal Advisory Committee on Immunization Practices (ACIP) within the Centers for Disease Control and Prevention (CDC) creates an immunization schedule containing the recommended timing and dosage of the vaccine. These schedules are then published by the CDC as allowable for patients three years of age or older. There are currently fifteen vaccines on the immunization schedule for children and thirteen vaccines for adults. These vaccines include immunizations against chickenpox, polio, mumps, tetanus, and the flu shot.

As the global health pandemic persisted, there was a "race" to develop and bring to market a vaccine. Currently, three vaccines have been approved through the EUA process for COVID-19. California is now pursuing a considerable public health policy objective to make COVID-19 vaccines as widely available to the general population as possible. These efforts have included using the DCA waiver process to expand the scope of practice authority for numerous health professions to include the COVID-19 vaccine, in alignment with similar authority granted federally under the Public Readiness and Emergency Preparedness (PREP) Act for Medical Countermeasures Against COVID–19.

This bill would codify the current authorization for dentists and doctors of podiatric medicine to initiate and administer vaccines approved by the FDA for COVID-19. The authority would be conditioned on the same training and recordkeeping requirements included in the DCA waivers. Additionally, the bill would include the flu shot, which the author contends is another vaccine for which expanded access is of significant public health benefit.

COVID-19 testing by dentists. Rapid point-of-care tests for COVID-19 are classified as "waived tests," which require federal CLIA Certificate of Waivers. Currently, dentists can obtain the federal CLIA certificate, but are not eligible under state law to obtain the needed lab registration. This is because dentists do not have sufficient credentials to list themselves as their own lab director under California law.

Although COVID-19 testing is within the scope of dentistry, dentists aren't able to maintain state regulatory compliance in order to perform them onsite. While earlier nasal swab COVID tests are considered "high complexity" tests, newer rapid point-of-care tests are reliable and efficient. This is particularly important given that dentists and their staff are at very high risk of infection, due to many dental procedures producing aerosols in the normal course of treatment. This bill will ensure that dentists are able to swiftly apply for certificates of waiver by amending the law to list dentists as eligible providers in order to serve as their own lab directors for LFS lab registration applications.

Current Related Legislation. AB 691 (Chau) would codify authorization for optometrists to administer the COVID-19 vaccine and perform waived tests for COVID-19. *This bill is pending in the Assembly Committee on Business and Professions.*

AB 1064 (Fong) would authorize a pharmacist to independently initiate and administer any vaccine approved or authorized by the FDA for persons three years of age and older. *This bill is pending in the Assembly Committee on Business and Professions.*

Prior Related Legislation. AB 1710 (Wood, Chapter 123, Statutes of 2020) authorizes a pharmacist to independently initiate and administer any COVID-19 vaccines approved or authorized by the FDA.

ARGUMENTS IN SUPPORT:

The **California Dental Association** (CDA) is sponsoring this bill. As stated by the CDA, "dentists are well equipped to administer vaccines because they routinely provide injections to particularly sensitive areas of the mouth that are in a dark, wet environment, navigate around major blood vessels, nerves and other complex and important structures like bone, ligaments, joints, a moving tongue and often a gag reflex. Dentists also have extensive training in microbiology, autoimmune response and general anatomy, pharmacology and starting IVs."

The **California Podiatric Medical Association** (CPMA) supports this bill. CPMA states that "authorizing doctors of podiatric medicine to prescribe and administer the COVID-19 vaccine, as well as the influenza vaccine, would ensure that more patients they treat are properly immunized as they receive medically necessary foot care. Doctors of podiatric medicine are ready to join their dental colleagues to safely vaccinate their patients and the community."

ARGUMENTS IN OPPOSITION:

None on file.

REGISTERED SUPPORT:

California Dental Association *(Sponsor)*
Association of Dental Support Organizations
California Podiatric Medical Association

REGISTERED OPPOSITION:

None on file.

Analysis Prepared by: Robert Sumner / B. & P. / (916) 319-3301

Date of Hearing: April 13, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
AB 527 (Wood) – As Amended March 15, 2021

SUBJECT: Controlled substances.

SUMMARY: Provides that if any cannabinoids are federally rescheduled or otherwise made a legally prescribable controlled substance, they shall also be legal to prescribe under state law, and reconciles conflicts between state and federal controlled substance schedules.

EXISTING LAW:

1) Establishes the Uniform Controlled Substances Act, which divides controlled substances into five schedules ranging with the most serious and heavily controlled substances, classified as Schedule I, and the least serious and most lightly controlled substances, classified as Schedule V. (Health & Safety Code (HSC) §§ 11054 - 11058)

2) Allows only a physician, dentist, podiatrist, veterinarian, naturopathic doctor, registered nurse, certified nurse-midwife, optometrist, or out-of-state prescriber to write or issue a prescription. (HSC) § 11150)

3) States that a prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice, and that the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. (HSC § 11153)

4) Prohibits medical professionals from prescribing, administering, or dispensing a controlled substance to an addict, as defined. (HSC § 11156)

5) Establishes the Controlled Substance Utilization Review and Evaluation System (CURES), for the purposes of collecting records of dispensed Schedule II, III, IV, and V controlled substances. (HSC § 11165)

6) Requires health care practitioners in receipt of a federal Drug Enforcement Administration (DEA) registration providing authorization to prescribe controlled substances, as well as pharmacists, to register for access to the CURES database. (HSC § 11165.1)

7) Prohibits any person from obtaining or attempting to obtain a prescription for controlled substances, by fraud, deceit, misrepresentation, subterfuge, or the concealment of a material fact. (HSC § 11173)

8) Provides that if cannabidiol is federally rescheduled or otherwise made a legally prescribable controlled substance, it shall also be legal to prescribe under state law. (HSC § 11150.2)

9) Enacts the Medicinal and Adult-Use Cannabis Regulation and Safety Act to provide for a comprehensive regulatory framework for the cultivation, distribution, transport, storage, manufacturing, processing, and sale of medicinal and adult-use cannabis. (Business and Professions Code (BPC) §§ 26000 et al.)

10) Exempts products containing cannabidiol that has been approved by the federal Food and Drug Administration (FDA) from regulation under MAUCRSA. (BPC § 26002)

THIS BILL:

1) Expands existing provisions of law providing that federally rescheduled or otherwise legally prescribable products containing cannabidiol may be lawfully prescribed under state law to apply to products containing any cannabinoids.

2) Realigns the state and federal controlled substance schedules by exempting from the state schedules certain combination drugs for which the ratio of the controlled drug component in proportion to the non-controlled ingredients qualifies the drug product for that exemption under the federal schedule.

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

COMMENTS:

Purpose. This bill is sponsored by the author. According to the author:

> "It is important that individuals have access to new drug treatments that have been through the rigorous FDA approval process immediately as they become available rather than having to change California law each time a new drug is approved by the FDA. AB 527 would afford patients the same access to other FDA-approved cannabinoid medicines that the Legislature has already provided to patients under AB 710 of 2018. Further, California should seek to have uniformity and consistency with Federal law related to the scheduling of commonly used drugs that have been through the FDA approval process. AB 527 accomplishes both of these things."

Background.

Regulation of Cannabis in California. In the spring of 2017, SB 94 reconciled the distinct systems for the regulation, licensing, and enforcement of cannabis established under the Legislature's Medical Cannabis Regulation and Safety Act (MCRSA) and Proposition 64, the Adult Use of Marijuana Act. The single consolidated system established by the bill—known as the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA)—created a unified series of cannabis laws and deleted redundant code sections no longer necessary due to the combination of the two systems. MAUCRSA also clarified a number of components, including but not limited to licensing, local control, taxation, testing, and edibles.

Federal Ban on Cannabis. The federal Controlled Substances Act classifies a number of drugs and chemicals into one of five schedules. Drugs falling within Schedules II through V may be prescribed only by health practitioners in possession of a DEA registration and are ranked according to the drug's potential for abuse, with lower numbered schedules representing drugs with a higher risk of abuse or dependence. Schedule I drugs have been determined to have no currently accepted medical use and a high potential for abuse. Schedule I drugs may not be prescribed by any health practitioner in the United States. Examples of Schedule I drugs are heroin, ecstasy, and cannabis.

Cannabis's continued Schedule I status under the federal Controlled Substances Act has created a constant threat of action by the federal government, leading to apprehension among California's cannabis community. A document issued by the United States Attorney General in 2013 known as the "Cole memorandum" indicated that the existence of a strong and effective state regulatory system, and a cannabis operation's compliance with such a system, could allay the threat of federal enforcement interests. Federal prosecutors were urged under the memo to review cannabis cases on a case-by-case basis and consider whether a cannabis operation was in compliance with a strong and effective state regulatory system prior to prosecution. However, on January 4, 2018, U.S. Attorney General Jeff Sessions formally rescinded the Cole memo.

Cannabinoids. The term "cannabinoid" is used to categorically describe one of over a hundred different compounds or substances found in the cannabis plant. One of the most well-known cannabinoid is tetrahydrocannabinol, or THC—this is the cannabinoid responsible for the psychoactive effect produced by smoking or ingesting certain strains of cannabis recreationally. Another cannabinoid is cannabidiol, or CBD, which does not produce a psychoactive effect but has been associated with a number of potential health benefits. According to the National Institute of Health, CBD has pain relieving, anti-inflammatory, anti-psychotic, and tumor-inhibiting properties. There are currently over 100 clinical trials of CBD listed on the National Library of Medicine's website. These trials are testing CBD's utility in treating epilepsy, substance use disorders, pain, psychosis, and anxiety, among other disorders and conditions.

Because cannabis remains a Schedule I drug federally, there is a relative lack of scientific research regarding the risks and benefits of cannabis and products derived from cannabis. The federal government has historically restricted what institutions in receipt of federal funding may study in regards to Schedule I controlled substances. However, SB 847 of 2000 established the University of California San Diego Center for Medicinal Cannabis Research, which has produced multiple of studies regarding the medical benefits of cannabis. Proposition 64 appropriates $2 million in funding from cannabis excise tax revenue to the center to further its objectives, including studies into the efficacy and adverse effects of cannabis as a pharmacological agent.

The federal FDA, meanwhile, has stated that it "supports researchers [in states that have removed restrictions on medical cannabis] who conduct adequate and well-controlled clinical trials which may lead to the development of safe and effective marijuana products to treat medical conditions." The FDA has not yet approved any product containing or derived from botanical marijuana for any indication," meaning that the FDA "has not found any such product to be safe or effective for the treatment of any disease or condition." However, the FDA has approved drugs containing a synthetic tetrahydrocannabinol (THC) for therapeutic uses, including for the treatment of anorexia associated with weight loss in AIDS patients.

In 2018, the FDA approved a drug called Epidiolex, an epilepsy medication containing highly-purified CBD from the cannabis plant. The drug is approved to treat two rare forms of epilepsy: Lennox-Gastaut syndrome and Dravet syndrome. These syndromes are considered to be among the most difficult types of epilepsy to treat and cause frequent seizures in patients. Advocates for the epileptic community actively championed the FDA's approval of Epidiolex, leading to it becoming the first federally approved drug containing cannabinoids. Prior legislation specifically ensured that this drug would also be legal in California.

Subsequently, the FDA also approved Marinol and Syndros, which are drugs containing dronabinol (synthetic THC), and Cesamet, which contains nabilone (a synthetic substance similar to THC). Dronabinol and nabilone are used to treat nausea and vomiting caused by cancer chemotherapy. Dronabinol is also used to treat loss of appetite and weight loss in people with HIV/AIDS.

Another drug, Nabiximols (known as Sativex outside the United States), has been approved for use in the United Kingdom to treat spasticity in adult patients suffering from multiple sclerosis. Nabiximols contains both THC and CBD. Nabiximols was approved by the FDA to undergo trials and it is believed that the drug may ultimately be fully approved in the United States.

While existing law provides for federally legalized drugs containing CBD to be immediately lawful under California law, that provision does not include other cannabinoids. This would mean that health practitioners would not expressly be authorized to prescribe or dispense drugs containing THC, or any of the other more than 100 cannabinoids besides CBD, even if approved by the FDA. This bill seeks to resolve that issue by expanding existing law to include all cannabinoids.

State vs. Federal Scheduling Alignment. While the federal Controlled Substances Act and the state's Uniform Controlled Substances Act are typically aligned in regards to how medications are classified, there are currently some conflicts between the federal and state schedules. Specifically, federal law exempts certain dangerous drugs that from scheduling that remain scheduled in California. Currently, federal law exempts combination drugs where the non-controlled ingredients make up a substantially larger proportion of the drug than the controlled component. Examples of federally exempted combination products include Floricet (butalbital product with barbituric acid); Donnatal (combination product containing phenobarbital); and Librax (combination product containing chloradiazepoxide).

This bill would enact the same exemptions from scheduling under the Uniform Controlled Substances Act in California that currently exist under federal law. This realignment will resolve confusion among pharmacies and reconcile current state and federal conflicts. The author has received technical assistance from the California State Board of Pharmacy in identifying and rectifying these conflicts.

Current Related Legislation. AB 1305 (Lackey) would exempt activity performed pursuant to a registration with the federal DEA from licensure and regulation under MAUCRSA. *This bill is pending in the Assembly Committee on Appropriations*.

Prior Related Legislation. AB 710 (Wood, Chapter 72, Statutes of 2018) rovides that if cannabidiol is federally rescheduled or otherwise made a legally prescribable controlled substance, it shall also be legal to prescribe under state law.

AB 2783 (O'Donnell, Chapter 589, Statutes of 2018) aligned state and federal law regarding the scheduling of hydrocodone combination products.

SB 94 (Committee on Budget and Fiscal Review, Chapter 27, Statutes of 2017) combined AUMA and MCRSA into one system for the regulation of cannabis, resulting in MAUCRSA.

ARGUMENTS IN SUPPORT:

The **California State Board of Pharmacy** (Board) supports this bill. The Board states: "As a consumer protection agency charged with regulating the practice of pharmacy, the Board is seeking changes to the California controlled substances schedule to align with the federal schedule after consideration of comments received from stakeholders that the current discrepancy creates confusion and impacts the Board's licensees. Currently, federal law exempts from scheduling some combination drugs where the ratio of the components meets specified criteria. California does not have similar provisions. This measure will allow for the alignment for the specified combination products."

Greenwich Biosciences supports this bill. According to Greenwich Biosciences, "the narrow amendment proposed in AB 527 simply provides patients the same access to FDA-approved cannabinoid medicines other than those limited to cannabidiol as the active ingredient." Greenwich Biosciences goes on to state that "this change in law is necessary to ensure that patients can access cannabinoid medications that have gone through the rigorous FDA review and approval process and have been rescheduled under the federal Controlled Substances Act."

ARGUMENTS IN OPPOSITION:

None on file.

REGISTERED SUPPORT:

California State Board of Pharmacy
Greenwich Biosciences

REGISTERED OPPOSITION:

None on file.

Analysis Prepared by: Robert Sumner / B. & P. / (916) 319-3301

Date of Hearing: April 13, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
AB 1430 (Arambula) – As Introduced February 19, 2021

SUBJECT: Pharmacy: dispensing: controlled substances.

SUMMARY: Requires a pharmacist who dispenses Schedule II or Schedule IIN controlled substances to dispense the drug in a lockable vial paid for by the drug's manufacturer, include the code for the lockable vial in any patient notes, and provide the patient with an educational pamphlet on the potential for abuse and diversion of controlled substances.

EXISTING LAW:

1) Allows only a physician, dentist, podiatrist, veterinarian, naturopathic doctor, registered nurse, certified nurse-midwife, optometrist, or out-of-state prescriber to write or issue a prescription. (Health and Safety Code (HSC) § 11150)

2) States that a prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice, and that the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. (HSC § 11153)

3) Prohibits medical professionals from prescribing, administering, or dispensing a controlled substance to an addict, as defined. (HSC § 11156)

4) Lists a number of required features that must be included for all prescription forms for controlled substances, including fraud-prevention identifiers, printing information, and information relating to the prescribing practitioner. (HSC § 11162.1)

5) Requires all prescriptions and dispensations of controlled substances to meet a series of requirements including use of a controlled substance prescription form, presence of a signature and date in ink, and the address of the patient. (HSC § 11164)

6) Requires a prescriber to discuss with a minor, or the minor's representative, prior to dispensing or issuing a prescription of opioids for the first time, the risks of addiction and overdose associated with the use of opioids and the increased risk of opioid addiction to an individual suffering from mental and substance abuse disorders. (HSC § 11158.1)

7) Establishes the Controlled Substance Utilization Review and Evaluation System (CURES), a database maintained by the California Department of Justice for the purposes of collecting records of dispensed controlled substances for review by licensed prescribers and dispensers, regulatory investigators, law enforcement, and statistical researchers. (HSC § 11165)

8) Requires schools and youth sports organizations to annually provide athletes of all ages, as well as the parents or guardians of athletes 17 years of age or younger, with a copy of the Opioid Factsheet for Patients published by the Centers for Disease Control and Prevention,

and requires that a signed document acknowledging receipt of the factsheet be returned prior to the athlete's participation in the sport. (HSC § 124236)

9) Requires a prescriber to provide information regarding, and offer a prescription for, naloxone hydrochloride or another drug approved by the United States Food and Drug Administration for the complete or partial reversal of opioid depression to a patient certain conditions are present. (BPC § 471)

10) Establishes the California State Board of Pharmacy (Board) to administer and regulate the Pharmacy Law. (Business and Professions Code (BPC) § 4001)

11) Requires labeling of all containers of prescription drugs stating information about the drug, directions for use, the names of the patient and the prescriber, and other information. (BPC § 4076)

12) Requires a pharmacy or practitioner to prominently display on the label or container for any opioid that is dispensed to a patient for outpatient use a notice that states "Caution: Opioid. Risk of overdose and addiction." (BPC § 4076.7)

13) Requires most pharmacies that dispense Schedule II, III, or IV controlled substances to display safe storage products, as defined, in a place on the building premises that is located close to the pharmacy. (BPC 4106.5)

THIS BILL:

1) Establishes the California Safe Dispensing Act, to become operative on June 30, 2022.

2) Defines "lockable vial" as a disposable container that is special packaging, as defined in federal law, and that has a locking cap that can be unlocked using one of the following:

   a) An alphanumeric passcode or other code;

   b) A unique physical key; or

   c) A locking mechanism that is accessible only by the patient with a code, alphanumeric passcode, or key, or by another secure mechanism.

3) Requires a pharmacist who dispenses in solid oral dosage form a controlled substance in Schedule II or Schedule IIN of the federal Controlled Substances Act to dispense the controlled substance in a lockable vial and provide an educational pamphlet that includes information on the potential for the abuse and diversion of controlled substances.

4) If the lockable vial uses an alphanumeric passcode or other code, requires the pharmacist to include the code in any patient notes in the database or other system used by the pharmacy in the dispensing of prescription drugs.

5) Requires that the patient, or the patient's parent or legal guardian if the patient is a minor or otherwise unable to authorize medical care, choose the code.

6) Requires the Board to develop the required educational pamphlet and provide them to pharmacists in printed form.

7) Exempts from the requirement that a pharmacist dispense a Schedule II or Schedule IIN drug in a lockable vial if one or more of the following applies:

   a) The patient, because of a physical or mental condition, would have difficulty opening the lockable vial.

   b) The prescription, dispensation, and administration of the controlled substance occurs in a hospital or other inpatient care facility.

8) Requires the manufacturer of a controlled substance to reimburse the pharmacy each month for the cost of lockable vials used by the pharmacy to dispense controlled substances in that month.

9) Provides that the manufacturer of a controlled substance shall reimburse the pharmacy within 30 days of receiving the claim and shall pay a reasonable rate for the net acquisition cost of the lockable vials, dispensing costs, and services rendered, including any patient consultation and instruction, and that failure to reimburse a pharmacy within a timely manner shall result in a civil penalty brought by the Board of $1,000 per day of delinquency.

10) Requires that any vendor that contracts with a pharmacy to provide a lockable vial shall make available at all times assistance online or through a toll-free number for patient use.

11) Provides that a practitioner who prescribes a controlled substance dispensed in a lockable vial shall not be liable for any adverse consequences that result from either the failure of any lockable vial to prevent unauthorized access or a patient not being able to access medication in a lockable vial.

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

COMMENTS:

Purpose. According to the author:

> "We should all welcome common-sense solutions when it comes safeguarding our prescribed medications, especially since some people don't suspect that their friends and family may be accessing dangerous pharmaceuticals in their own medicine cabinets. By requiring that these highly addictive medications be dispensed in tamper-proof containers, AB 1430 will help reduce unauthorized access to potentially harmful medications and educate consumers on what to do when pilfering has been discovered in their household."

Background.

Overview of the Opioid Crisis. In October of 2017, the White House declared the opioid crisis a public health emergency, formally recognizing what had long been understood to be a growing epidemic responsible for devastation in communities across the country. According to the Centers for Disease Control and Prevention, as many as 50,000 Americans died of an opioid overdose in 2016, representing a 28 percent increase over the previous year. Additionally, the number of Americans who died of an overdose of fentanyl and other opioids more than doubled during that time with nearly 20,000 deaths. These death rates compare to, and potentially exceed, those at the height of the AIDS epidemic.

Opioids are a class of drugs prescribed and administered by health professionals to manage pain. Modern use of the term "opioid" typically describes both naturally occurring opiates derived from the opium poppy as well as their manufactured synthetics. Common examples of prescription opioids include oxycodone (OxyContin, Percocet); hydrocodone (Vicodin, Norco, Lorcet); codeine; morphine; and fentanyl. Heroin is also an opioid.

In addition to providing pain relief, opioids can be used as a cough suppressant, an antidiarrheal, a method of sedation, and a treatment for shortness of breath. The majority of pharmaceutical opioids are Schedule II drugs under the federal Controlled Substances Act, considered by the federal Drug Enforcement Agency (DEA) to have a high potential for abuse that may lead to severe psychological or physical dependence. However, combination drugs containing lower doses of opioids combined with other active ingredients are typically less restricted; for example, cough syrups containing low doses of codeine are frequently classified Schedule V medications.

The abuse of prescription drugs was historically viewed as a criminal concern analogous to street narcotics cases regularly investigated by law enforcement. In recent years, however, an expert consensus has evolved around the opinion that the opioid crisis must be addressed through the lens of public health policy. This belief is supported by research demonstrating how health professionals may have inadvertently contributed to the origins of the crisis. It is widely accepted that health professionals will play a necessarily critical role in any meaningful solutions.

In the opioid crisis's broader national context, there has been a persistent perception that California represents a relatively minor segment of an epidemic more typically identified with states like New Hampshire and West Virginia. However, there is substantial evidence that communities in California have been much harder hit than may be generally believed. For example, in 2015, several rural counties in California saw as many or more drug overdose deaths per 100,000 residents than some Midwestern states. It has been reported than some small counties had more opioid prescriptions than residents. In total, the California Department of Public Health estimates that nearly 2,000 Californians died of an opioid overdose in 2016.

Safe Storage Products. Among the many solutions to preventing prescription drug abuse and overdose, patient safety advocates have championed the use of safe storage products designed to ensure that children and adolescents, as well as adults with diminished cognitive function, cannot access dangerous medications kept within the home. Reports of accidental poisonings resulting from child access to their parents' medicine cabinets are common anecdotes used to support policies to promote better storage practices.

According to the National Center on Addiction and Substance Abuse, 90 percent of individuals with substance use disorder began using substances before the age of 18, while 70 percent of prescription drugs obtained for non-medical use (12 years and older) came from a household. A study by the Partnership for Drug-Free Kids found that more than three in five teens said pain relievers were easy to obtain from their parents' medicine cabinets.

In response to both public policy imperative and financial incentive as awareness of the opioid crisis grows, a number of manufacturers have begun to market products aimed at providing safe storage options within the home. Current law requires that these products be carried and displayed at the majority of larger pharmacy chains. This bill would go a step further and require that every Schedule II or Schedule IIN drug be dispensed with one of these products, which would then be subsequently paid for by the manufacturer of the drug.

Prior Related Legislation. SB 1109 (Bates, Chapter 693, Statutes of 2018) requires a prescriber to discuss the following with a minor, or the minor's parent, guardian, or other adult authorized to consent to the minor's medical treatment, information relating to the risks associated with opioids prior to dispensing or issuing a prescription of opioids to a minor for the first time.

AB 2859 (Caballero, Chapter 240, Statutes of 2018) Requires certain pharmacies that dispense Schedule II, III, or IV controlled substances to display safe storage products, as defined, for sale in a place on the building premises that is located close to the pharmacy.

AB 2592 (Cooper) from 2016 would have required all pharmacies in receipt of opioid abuse prevention grant dollars to offer all patients who are prescribed an opioid a medicine locking closure package. *This bill died on the Assembly Appropriations suspense file.*

ARGUMENTS IN SUPPORT:

The **California Consortium of Addiction Programs and Professionals** (CCAPP) supports this bill. According to CCAPP, "this bill is important because it will serve as an early warning system for families. While a parent may notice an entire bottle of medication missing, they may not notice one-half or one-third of these extremely strong medications missing. A locking cap that would have to be shattered to gain access would alert parents that it had been opened and bring attention to a need to discuss drug use with young people in the family."

ARGUMENTS IN OPPOSITION:

The **California Pharmacists Association** (CPhA) opposes the bill. CPhA points out in its letter that "in 2018, the Governor signed AB 2859, which requires pharmacies that dispense Schedule II, III, or IV controlled substances to display safe storage products for sale in a place on the building premises that is located close to the pharmacy. AB 1430 adds an unnecessary requirement that only benefits the manufacturer of the lockable vials, and does not advance patient safety."

The **California Dental Association** (CDA) also opposes this bill. According to the CDA, "lockable prescription bottles don't prevent people from cutting through, forcing open or shattering the bottle to get the medication. Patients who don't want to deal with the fuss of unlocking the bottle each day will likely leave the multi-digit lock in the unlocked position for ease of use. Patients with complex medical regimens, memory problems or multiple caretakers will likely resort to swapping pill bottles to make medication management less complicated."

The **California Chamber of Commerce** (CalChamber) additionally opposes this bill. CalChamber argues that "the pharmacy would be forced to seek reimbursement for the vial's cost from the drug manufacturer who would have to remit payment within 30 days of receiving a monthly claim. The process will force pharmacies to frontload the vial cost and then depend on timely invoicing and payment practices to avoid financial pitfalls. This process will prove cumbersome and expensive. Specifically, independent pharmacies will likely experience cashflow difficulties since they will need to frontload the vial costs, establish invoicing practices, then rely on timely execution and payment to receive a reimbursement."

POLICY ISSUE(S) FOR CONSIDERATION:

Multiple Statutory Definitions of Similar Products. Existing law already requires pharmacies to carry and display "safe storage products," defined in BPC § 4106.5(a) as "a device or product made with the purpose of storing prescription medications that includes a locking mechanism that is accessible only by the designated patient with a passcode, alphanumeric code, key, or by another secure mechanism. A safe storage product includes, but is not limited to, medicine lock boxes, locking medicine cabinets, locking medication bags, and prescription locking vials." The definition of "lockable vial" is very similar to that definition, but slightly narrower. The author may wish to consider replacing references to "lockable vials" to instead reference the already defined term for "safe storage products." This amendment may be considered reasonable in that pharmacies would be able to meet both their retail stocking and drug dispensing requirements using the same classification of products.

Opt-Outs. Currently, this bill would only allow a pharmacist to dispense a Schedule II or Schedule IIN controlled substance in a container other than a locked vial if the patient's condition would make opening the vial difficult, or if the dispensation occurs within a hospital or other inpatient care facility. The first potential issue is that the pharmacist my not be best equipped to determine whether a patient's condition would make it inappropriate for their medication to be dispensed in a lockable vial; rather, the prescriber should have the ability to make that determination and recommendation. Additionally, patients should arguably have the authority to make their own decision about whether a lockable vial is needed, and in some cases there may be substantial privacy concerns informing that choice. The author therefore may wish to consider allowing either the prescriber of the controlled substance or the patient themselves opt-out of having the medication dispensed using a lockable vial.

Educational Pamphlet. The bill requires the Board to "develop an educational pamphlet that includes information on the potential for the abuse and diversion of controlled substances." This mandate on the Board would arguably result in the duplication of efforts already undertaken and reflected in statue. Existing law requires that the Opioid Factsheet for Patients published by the Centers for Disease Control and Prevention be provided to every athlete participating in a schools and youth sports organization. This factsheet may be viewed as an appropriate substitution for a document that would have to be developed by the Board.

Penalties Against Pharmacies. Statute states that any violation of the Pharmacy Law constitutes a misdemeanor crime. While this bill has separate penalties identified for violations of its provisions by drug manufacturers, it is silent in regards to the penalties for violations by pharmacies. The author may wish to include language clarifying that a pharmacy or pharmacist is not guilty of a misdemeanor for violation of the bill, but that instead the Board may take administrative action.

Financial Hardship. Opposition has pointed out that to effectively comply with the law, pharmacies would have to prepurchase and stock sufficient lockable vials to meet the need for as many Schedule II or Schedule IIN controlled substances they subsequently dispense within the next month. Smaller independent pharmacies may have difficulty purchasing enough lockable vials to meet demand, and in some cases a pharmacy may have reasonably underestimated the number of lockable vials needed. In these instances, the author should consider giving the Board a certain amount of discretion in its disciplinary actions to allow for appropriate leniency.

AMENDMENTS:

1) To align statutory references to products intended to safely store prescription medications, the definition for "lockable vial" should be struck and the term should be struck and replaced throughout the bill with "safe storage product" as defined in Section 4106.5.

2) To expressly provide patients with the ability to opt-out of receiving their medication in a safe storage product, regardless of age, paragraph (3) should be added to subdivision (d) in the proposed Section 4178.1 to read:

   (3) The patient or the patient's representative requests that the patient's medication not be dispensed in a safe storage product.

3) To remove provisions in the bill requiring the Board to develop an educational pamphlet that is arguably duplicative of existing materials already provided to minor patients under current law, the contents of subdivision (c) should be struck and references to an educational pamphlet should instead refer to the Opioid Factsheet for Patients published by the Centers for Disease Control and Prevention.

4) To ensure that pharmacists are not criminally liable for failure to comply with the provisions of the law, a new subdivision (i) should be added stating:

   (i) (1) Section 4321 shall not apply to a violation of this section.

   (2) The board shall assess a fine in an amount to be determined by the board for a violation of this section by a pharmacist.

5) To address concerns that pharmacies may be unable to purchase adequate stock to accommodate all potential dispensations of Schedule II or Schedule IIN controlled substances in advance of future reimbursement by a drug manufacturer, an additional paragraph (3) should be added to the subdivision (i) proposed in Amendment #5 reading:

   (3) The board may choose not to take administrative action against a pharmacy if it determines that compliance with this section would create a financial hardship on the pharmacy or that the pharmacy was temporarily out of stock of safe storage products after taking reasonable steps to ensure an adequate supply for all dispensations of Schedule II or Schedule IIN controlled substances.

REGISTERED SUPPORT:

California Consortium of Addiction Programs and Professionals

REGISTERED OPPOSITION:

American College of Obstetricians and Gynecologists District IX
California Chamber of Commerce
California Dental Association
California Pharmacists Association
California Retailers Association

Analysis Prepared by: Robert Sumner / B. & P. / (916) 319-3301

Date of Hearing: April 13, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
AB 1194 (Low) – As Amended April 6, 2021

SUBJECT: Conservatorship.

SUMMARY: Requires the Professional Fiduciaries Bureau and California Courts to properly oversee and regulate the professional fiduciaries, court appointed conservators and relationship based conservatorships by way of this bill and in accordance with the Conservatorship and Guardianship Reform Act of 2006.

EXISTING LAW:

1) Establishes the Bureau within the Department of Consumer Affairs (DCA), to licenses and regulate professional fiduciaries under the Professional Fiduciaries Act (Act). (Business and Professions Code (BPC) § 6510)

2) Defines "professional fiduciary" as a person who acts as a conservator of the person, the estate, or person and estate, or guardian of the estate, or person and estate, for two or more individuals at the same time who are not related to the professional fiduciary or to each other, as specified. (BPC § 6501)

3) Requires an applicant for licensure to be at least 21 years of age, and have not committed any acts that are grounds for denial, as specified; submit fingerprints; complete the prelicensing requirements, and pass the licensing examination; and, 4) have a bachelor's degree, an associate of arts degree and three years of work experience either as a professional fiduciary or providing professional fiduciary duties, or have not less than five years of work experience, prior to July 1, 2012, as specified. (BPC § 6533)

4) Requires the Bureau to maintain specified information in each of its licensees' file and make it available to a court for specified purposes. (BPC § 6534)

5) Permits a court to appoint a conservator of the person for a person who is unable to provide properly for his or her personal needs for physical health, food, clothing, or shelter, as provided. Permits a court to appoint a conservator of the estate for a person who is substantially unable to manage his or her own financial resources or resist fraud or undue influence, except as provided. (Probate Code (PROB) § 1801. Unless otherwise stated, all further statutory references are to that code.)

6) Provides that a conservatorship continues until terminated by the death of the conservatee or by order of the court. (PROB § 1860)

7) Requires that a guardian or conservator has the duty of custody and conservation of the estate after the death of the ward or conservatee pending the delivery of the estate to the personal representative of the ward's or conservatee's estate or other disposition according to law, and

the guardian or conservator has such powers, as provided, as are necessary for the performance of that duty. (PROB § 2467)

8) Upon the death of a ward or conservatee, allows the guardian or conservator to contract for and pay a reasonable sum for the expenses of the last illness and the disposition of the remains of the deceased ward or conservatee, and for unpaid court-approved attorney's fees, and may pay the unpaid expenses of the guardianship or conservatorship accruing before or after the death of the ward or conservatee, in full or in part, to the extent reasonable, from any personal property of the deceased ward or conservatee which is under the control of the guardian or conservator. If after making those payments, the remaining estate does not exceed the amount of a small estate (currently $150,000 or less), allows the guardian or conservator to petition the court for an order permitting the guardian or conservator to liquidate the estate. Allows the guardian or conservator to make such a petition even if there is a will, if the will does not appoint an executor or if the named executor refuses to act. (PROB § 2631)

9) Allows the court to appoint a guardian of the person, estate or both, taking into consideration the best interest of the proposed ward. (PROB § 1500)

10) Allows the court to appoint a conservator to act on behalf of a person who is unable to adequately provide for his or her personal needs (a conservator of the person) or incapable of managing his or her property or other financial assets (a conservator of the estate). (PROB § 1800)

11) Requires a guardian or conservator, at the expiration of one year from the time of appointment and thereafter not less frequently than biennially, unless otherwise ordered by the court to be more frequent, to present the accounting of the assets of the estate of the ward or conservatee to the court for settlement and allowance as provided, including supporting documents. Requires that all accountings must be submitted on a specific Judicial Council form. (PROB § 2620.)

12) Defines what is required for any matter to be supported, evidenced, established, or proved by a sworn statement, declaration, verification, certificate, oath, or affidavit, in writing of the person making the same, allowing such matter to with like force and effect be supported, evidenced, established or proved by the unsworn statement, declaration, verification, or certificate, in writing of such person which recites that it is certified or declared by them to be true under penalty of perjury, is subscribed by them, and (1), if executed within this state, states the date and place of execution, or (2), if executed at any place, within or without this state, states the date of execution and that it is so certified or declared under the laws of the State of California. Provides a certification or declaration form. (Code of Civil Procedure § 2015.5.)

13) Allows for the establishment, administration, and termination of an LPS conservatorship when an individual is gravely disabled as a result of mental disorder or impairment by chronic alcoholism, and specifies that the appointment of a conservator shall be based on the protection of the public and the treatment of the conservatee. (Welfare and Institutions Code (WIC) § 5350)

THIS BILL:

1) Requires a professional fiduciary with an internet website to post a schedule of fees on their internet website.

2) Requires the bureau to revoke a professional fiduciary's license if a court finds by a clear and convincing standard that they have not acted in the best interests of their client or have committed abuse of an elder or a dependent adult.

3) If the court finds that a conservator has not acted in the best interests of a conservatee, we would make the conservator liable for a civil penalty of up to $25,000 payable to the estate of the conservatee.

4) The bill would require the court to select a professional fiduciary as the conservator of an estate if the estate is valued at $1,000,000 or more.

5) Requires a court investigator to gather *and review* relevant medical reports *and supplemental information* regarding a proposed conservatee, including at least one report from their primary care physician.

6) Requires a court investigator to report to the bureau if they undertake an investigation of a fiduciary.

7) Authorizes any person to petition the court to investigate an allegation of physical abuse or financial abuse of a conservatee, and would require the court to investigate those allegations.

8) Eliminates the court's discretion to authorize a guardian or trustee who is not a trust company to hire or refer business to an entity in which they have a financial interest.

9) Eliminates the court's discretion to compensate a guardian or conservator from the estate for the costs or fees they incurred in unsuccessfully opposing a petition or other action made by or on behalf of a ward or conservatee, and would instead prohibit a guardian or conservator from being compensated from the estate for the costs or fees they incurred in unsuccessfully defending a reduction or denial of their compensation.

10) Requires the court to award the costs of the petition and other expenses and costs of litigation to a successful petitioner if a guardian or conservatee is removed for cause.

11) Requires the Judicial Council to report to the Legislature, on or before January 1, 2023, regarding specified findings and recommendations on court effectiveness in conservatorship cases.

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

COMMENTS:

Purpose. This bill *is Author sponsored*. According to the Author, "While the history of legislation makes it appear that the world of conservatorships is highly regulated with proper

oversight, it is appears to be to the contrary. The Professional Fiduciary Bureau who only oversees licensed fiduciaries is focused primarily on licensing and regulation. The majority of conservators appointed by the Courts are not licensed or registered with very little oversight. The cases that involve complaints and are deemed to be worthy of an investigation are often over looked by law enforcement and ultimately the court system. There is a disconnection between the rights of those conserved and the law. This bill is being introduced to protect those that are forbidden to protect themselves."

Background. *Professional Fiduciaries*. Professional fiduciaries provide critical services to seniors, persons with disabilities, and children. They manage matters for clients including daily care, housing and medical needs, and also offer financial management services ranging from basic bill paying to estate and investment management. Professional fiduciaries are licensed under the Bureau. A person seeking licensure must have a four-year degree from an accredited university, an associate's degree with work as professional fiduciary, or a minimum of five years of experience working as professional fiduciary prior to July 1, 2012. In addition, an applicant must complete 30 hours of prelicensure education, pass and examination, and submit to a fingerprint background check through the Department of Justice (DOJ).

Professional Fiduciary Reporting Requirements. Existing law, BPC Section 6534 requires the Bureau to maintain and make certain information on each licensee available to a court for any purpose including the determination of the appropriateness of that licensee continuing or being removed as a conservator, guardian, trustee or personal representative. Additionally, BPC Section 6561 requires a licensee to report annually to the Bureau specified information including whether or not he or she has been removed as a conservator, guardian, trustee or personal representative amongst other information. In addition, these two sections of law specify what information is made public, kept in the licensee's file or what should be included in an annual report to the Bureau.

Professional Fiduciaries Current Practices. Licensed professional fiduciaries often bill clients for time spent, or time spent by attorneys for responding to complaints against the licensee to the Bureau. It is not common practice amongst other licensees under the DCA who charge clients for responding to complaints or other inquiries from their regulatory authority (board, bureau or committee). Current law was clarified in the last Sunset Review of 2019 that a professional fiduciary may not bill a client for the licensee's time spent responding to the Bureau regarding a consumer complaint made against them. Because the consumer of a fiduciary could potentially be financially harmed for making a complaint to the Bureau, without this clarification in law, it could have had an impact an individual's decision to do so, as they could be financially penalized for doing so.

A brief history of conservatorships and guardianships in California. California adopted its first conservatorship statute in 1957. Prior to that time, the court appointed a "guardian" for any person, child or adult, who was deemed "incompetent" to manage his or her daily affairs. After 1957, the law distinguished between a "guardianship," created for a minor, and a "conservatorship," created for an adult. There are also specific types of conservatorships for persons who are considered "gravely disabled" by reason of mental illness or chronic alcoholism and subject to confinement in a locked psychiatric facility under the Lanterman-Petris-Short Act (Welf. & Inst. Code sections 5330 et seq.) and for "developmentally disabled adults" (Sections

1801(d), 1828.5, and 1830). In addition, California law provides for the appointment of a Public Guardian for any person "who requires a guardian or conservator and there is no one else who is qualified and willing to act." (Section 2920.)

In California, if an adult is unable to manage his or her financial matters, a conservator of the estate may be appointed by a court to manage the adult's or conservatee's financial matters. If the adult is unable to manage his or her medical and personal decisions, a conservator of the person may be appointed. The appointment process requires an in-depth investigation by a court investigator and approval by the court. The conservatorship continues until terminated by the court or the death of the conservatee.

Omnibus Conservatorship and Guardianship Reform Act of 2006. Court oversight includes review of detailed accountings provided by conservators and guardians. The Omnibus Act of 2006 was designed to overhaul California's troubled conservatorship system, remedy alarming deficiencies in California's conservatorship system, and help protect the financial, physical and emotional well-being of vulnerable and dependent adults. In particular, AB 1363 (Jones), Chap. 493, Stats. 2006, was designed to overhaul and increase court oversight of conservators and guardians. That bill required that court investigators increase investigations, limited the waiving of notice before appointment of a temporary conservator or guardian and limited the duties of a temporary conservator, required the probate court to review conservatorships at a noticed hearing six months after appointment of the conservator and annually thereafter, and required the Judicial Council to develop qualifications and continuing education requirements for probate court judges, attorneys and court investigators. In addition, and of particular relevance to this bill, AB 1363 required accountings to include specified supporting documentation and to be subject to random audit.

It is important to note that many of these court oversight requirements, critically important to protect vulnerable seniors from abuse, may not be enforced in many courts. In 2011, the Judicial Council sought and received relief from the mandates during the height of budget cuts caused by the 2008 financial crisis. (SB 78 (Committee on Budget and Fiscal Review), Chap. 10, Stats. 2011.) Unfortunately, while recent court budget increases have more than made up for the prior budget reductions, court conservatorships oversight requirements have not yet been mandated again, putting fail and vulnerable seniors and dependent adults at risk of abuse.

Required accountings must include detailed supporting documentation. As part of court oversight, guardians and conservators, at the expiration of one year from the time of their appointment and not less frequently than biennially thereafter, unless otherwise ordered by the court to be more frequent, must present to the court an accounting of the assets of the ward's or conservatee's estate for settlement and allowance. The accounting must be submitted on a Judicial Council form and must include all supporting documents. The supporting documents include all account statements showing the account balance as of the closing date of the accounting period. If the guardian or conservator is a licensed professional, the guardian or conservator must also file all original account statements showing the balance as of all periods covered by the accounting. Account statements include any original account statement from any financial or other institution, including banks, insurance companies and financial advisors.
5150 detentions and Lanterman-Petris-Short (LPS) conservatorships. When an individual is gravely disabled or presents a threat to themselves or to others, a 72-hour detention period may

be implemented. This three-day detention period is often referred to as a "5150 hold" – a reference to the Welfare and Institutions Code section which outlines the parameters under which such a hold can take place. Following a 5150 hold, an extension of 14 days may be granted to provide intensive treatment, and in certain counties, this period may be extended for an additional 30 days.

Current Related Legislation. SB 602 (2021, Laird). Makes changes to the procedure that conservators must follow after establishing a conservatorship.

SB 724 (2021, Allen). Allows conservatees to put in their preference for legal counsel. Referred to Senate Judiciary Committee.

Prior Related Legislation. AB 1971 (Santiago, Friedman, and Chen) of 2018, would have expanded the definition of "gravely disabled" in the county of Los Angeles until January 1, 2024, to include a person's inability to provide for their basic personal needs for medical treatment, as specified, and contained specified reporting requirements. *Died on the Senate inactive file*.

AB 1539 (2017, Chen) would have expanded the definition of "gravely disabled" to include an individual who is unable to provide for his or her basic need for medical care as a result of a mental health disorder or chronic alcoholism. *Not not heard in the Assembly Health Committee*.

SB 156 (2013, Beall) Prohibits the guardian or conservator from being compensated from the estate for any costs or fees, including attorney's fees, incurred in defending the compensation in the petition, if the court reduces or denies the compensation requested in the petition. *Vetoed by Governor Brown.*

AB 1194 (Eggman), Chapter 570, Statutes of 2015, requires, for purposes of determining whether a person is a danger to self or others, an individual making that determination to consider available relevant information about the historical course of the person's mental disorder if the individual concludes that the information has a reasonable bearing on the determination, and that the individual shall not be limited to consideration of the danger of imminent harm.

AB 193 (2011, Maienschein) would have required court to appoint legal counsel to a conservatees if they cannot afford their own. *Vetoed by Governor Brown*.

AB 1363 (Jones) Chapter 493, Statutes of 2006, The Omnibus Conservatorship and Guardianship Reform Act of 2006 requires the Judicial Council, among other things, to adopt specified rules of court relating to conservatorships and guardianships and to develop educational programs for nonlicensed conservators and guardians and provide proper oversight of the conservator process.

REGISTERED SUPPORT:

None on file.

REGISTERED OPPOSITION:

None on file.

Analysis Prepared by: Danielle Sires / B. & P. / (916) 319-3301

AB 1194 (Low): Conservatorships

- ✓ Requires a professional fiduciary with an internet website to post a schedule of fees on their internet website.
- ✓ Requires the bureau to revoke a professional fiduciary's license if a court finds by a clear and convincing standard that they have not acted in the best interests of their client or have committed abuse of an elder or a dependent adult.
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- ✓ Eliminates the court's discretion to compensate a guardian or conservator from the estate for the costs or fees they incurred in unsuccessfully opposing a petition or other action made by or on behalf of a ward or conservatee, and would instead prohibit a guardian or conservator from being compensated from the estate for the costs or fees they incurred in unsuccessfully defending a reduction or denial of their compensation.
- ✓ Requires the court to award the costs of the petition and other expenses and costs of litigation to a successful petitioner if a guardian or conservatee is removed for cause.
- ✓ Requires the Judicial Council to report to the Legislature, on or before January 1, 2023, regarding specified findings and recommendations on court effectiveness in conservatorship cases.

AB 1194 (Low): Conservatorships