Date of Hearing: June 28, 2016

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Rudy Salas, Chair
SB 1193(Hill) – As Amended June 21, 2016

SENATE VOTE: 39-0

SUBJECT: Healing arts

SUMMARY: Extends the operation of the Board of Pharmacy (BOP) and Pharmacy Law until January 1, 2021, and makes various changes to the Pharmacy Law intended to improve BOP oversight of licensees involved in the acquisition, storage, distribution and dispensing of dangerous drugs and dangerous devices, including: oversight by the BOP for outsourcing facilities; registration with the BOP for use of an automated delivery device by a pharmacy; timeline requirements for the BOP to approve clinic licenses; and various other technical changes. This bill also makes various changes that are intended to improve the effectiveness of the Veterinary Medical Board (VMB) and extends the VMB's sunset dates, until January 1, 2021.

EXISTING LAW:

1) Establishes the United States Food and Drug Administration (FDA) to protect the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices through the Food, Drug, and Cosmetic Act (FDCA). (Title 21 United States Code (21 USC) Section 301, *et seq.*)

2) Establishes the Drug Supply Chain Security Act as part of the Drug Quality and Security Act (DQSA), which outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States, which:

    a) Defines an outsourcing facility as a facility at one geographic location or address that:

    b) Is engaged in the compounding of sterile human drugs.

    c) Has elected to register as an outsourcing facility.

    d) Complies with all of the requirements in the newly enacted Section 503B, including:

    e) Reporting biannually to the Secretary of Health and Human Services (HHS) on what drugs are compounding in the facility, the source of ingredients used to compound, and submission of all adverse event reports.

    f) Compliance with the Current Good Manufacturing Practice (CGMP) regulations.

    g) Drugs are compounded under the direct supervision of a licensed pharmacist in a registered facility.

    h) Annual registration with the FDA.

i) Exempts drug products compounded at an outsourcing facilities from FDA approval requirements in Section 505 of the FDCA and from requirements to label products with adequate directions from use if the requirements in Section 503B listed above are met. (21 USC Section 353b)

3) Outlines the types of licensed professionals authorized to establish a professional corporation. (Corporations Code Section 13401.5)

4) Under the Pharmacy Law, provides for the licensure and regulation of pharmacies, pharmacists and wholesalers of dangerous drugs or devices by the BOP within the Department of Consumer Affairs (DCA) until January 1, 2017. (Business and Professions Code (BPC) Section 4000, *et seq.*)

5) Requires the BOP to adopt regulations establishing standards for compounding injectable sterile drug products (sterile injectables) in a pharmacy. Clarifies that a pharmacy cannot compound sterile injectables unless the pharmacy is licensed by the BOP. States that a license to compound sterile injectables cannot be renewed without a BOP inspection. (BPC Sections 4127-4127.1)

6) States that a nonresident pharmacy cannot compound sterile drug products for shipment into California without a sterile compounding pharmacy license issued by the BOP. (BPC Section 4127.2)

7) Authorizes the BOP to issue a cease and desist order to a pharmacy compounding sterile injectables whenever the BOP has reasonable belief, based on information obtained through an investigation or inspection, that there is an immediate threat to public health or safety. (BPC Section 4127.3)

8) Authorizes a pharmacy to provide pharmacy services to a health facility through the use of an automated drug delivery system (ADD) that need not be located at the same location as the pharmacy. Provides that drugs stored in an ADD shall be part of the inventory of the pharmacy providing pharmacy services to that facility, and drugs dispensed from ADD shall be considered to have been dispensed by that pharmacy. (BPC Section 4119.1)

9) Establishes the California Veterinary Medicine Practice Act until January 1, 2017, and requires the VMB within the DCA to, among other things, license and regulate veterinarians, RVTs, RVT schools and programs, and veterinary premises. (BPC Section 4800, *et seq.*)

10) Defines "automated drug delivery system" as a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs; specifies that these systems collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. (Health and Safety Code (HSC) Section 1261.6)

THIS BILL:

1) Extends the operation of the BOP and its Executive Officer (EO) until January 1, 2021.

2) Defines "outsourcing facility" as a facility that is located within the United States at one address that is engaged in the compounding of sterile and nonsterile drugs; has registered

with the FDA pursuant to 21 USC Section 353b; is doing business within or into California; and, is licensed with the BOP pursuant to BPC Section 4129.

3) Requires a pharmacy using an automated drug delivery system (ADD) to register use of the ADD with the BOP within 30 days of installation of the device, and annually thereafter, including the address at which the ADD is being used; and, requires a pharmacy to advise the BOP within 30 days if the pharmacy discontinues the use of an ADD.

4) Allows a pharmacy to use an ADD only if the pharmacy uses the ADD consistent with legal requirements; the pharmacy's policies and procedures related to the ADD include appropriate security and monitoring measures; the pharmacy reports drug losses as required by law; and, the pharmacy license is unexpired and not subject to disciplinary action. Exempts from registration with the BOP an ADD operated by a licensed hospital pharmacy for doses administered in a facility operated under a consolidated license.

5) Authorizes the BOP to prohibit a pharmacy from using an ADD if these conditions are not met; requires the BOP to give the pharmacy written notice explaining the basis for the determination; and allows the pharmacy to appeal the decision within 30 days.

6) Requires a pharmacy that issues a recall notice regarding a nonsterile compounded drug product to contact the recipient pharmacy, prescriber, or patient (as applicable) and the BOP within 12 hours of the recall notice if both the use or exposure to the recalled drug may cause serious adverse health consequence or death, and if the recalled drug was dispensed or intended for use in this state.

7) Requires a pharmacy to report to MedWatch within 72 hours if the pharmacy has been advised that a patient has been harmed by using a nonsterile compounded product potentially attributable to the pharmacy.

8) Requires outsourcing facilities, as defined under federal law, to be licensed by the BOP; prohibits an outsourcing facility to be simultaneously licensed with the BOP as a sterile compounding pharmacy at the same location; prohibits a licensed outsourcing facility from filling patient specific prescriptions; requires an outsourcing facility to notify the BOP of any disciplinary or other action taken by another state or the FDA or of any recall notices or any adverse events potentially attributable to an outsourcing facility's products; requires the BOP to inspect the location of a nonresident outsourcing facility to ensure that the facility is in compliance with all laws and regulations before issuing or renewing a nonresident outsourcing facility's license; authorizes the BOP to issue a cease and desist order to an outsourcing facility if the BOP has reasonable belief that the products produced by the facility poses an immediate threat to the public health or safety and; establishes a $780 fee for an outsourcing facility license.

9) Includes pharmacists in the list of licensed professionals authorized to establish a professional corporation.

10) Extends the sunset date for the VMB and Executive Officer until January 1, 2021.

11) Authorizes a veterinarian and RVT, who is under the director supervision of a veterinarian with a current and active license, to compound a drug for anesthesia, the prevention, cure, or relief of a wound, fracture, bodily injury, or disease of an animal in a premises currently and

actively registered with the VMB, as specified, and would authorize the BOP and the VMB to ensure compliance with these requirements.

12) Requires veterinarians engaged in the practice of veterinary medicine and employed by the University of California or by Western University of Health Sciences, while engaged in the performance of specific duties, to be licensed as a veterinarians in the state or hold a university license issued by the VMB, and that the applicant for a university license to meet certain requirements, including that the applicant passes a specified exam.

13) Provides that a veterinary premise registration may be canceled after five years of delinquency, unless the VMB finds circumstances or conditions that would justify a new premise registration to be issued.

14) Makes technical changes to the BPC regarding the VMB.

FISCAL EFFECT: According to the May 27, 2016, Senate Committee on Appropriations analysis, the provisions of this bill related to the BOP will result in:

1) Ongoing costs of $20 million per year for the continued operation of the Board of Pharmacy. The Board's operations are fully supported by licensing fees.

2) One-time costs of $335,000 and ongoing costs of $320,000 per year for licensing and inspection activities relating to outsourcing facilities.

3) Ongoing costs of about $160,000 per year for the BOP to coordinate inspection and enforcement activities with respect to the regulation of drug compounding on veterinary premises.

4) Ongoing costs of about $160,000 per year for the BOP to coordinate inspection and enforcement activities with respect to the regulation of drug compounding on veterinary premises.

According to the May 27, 2016, Senate Committee on Appropriations analysis for SB 1195, pertaining to the VMB, this bill will result in:

1) Ongoing costs of about $4.8 million per year for the continued operation of the VMB. All costs to operate the VMB are funded with licensing fees.

2) Minor costs are anticipated by the VMB for the changes in the bill to its statutory requirements and procedures.

COMMENTS:

Purpose. This bill extends the operation of the BOP and Pharmacy Law until 2021 and makes various changes to the Pharmacy Law intended to improve BOP oversight of licensees involved in the acquisition, storage, distribution and dispensing of dangerous drugs and dangerous devices, including: oversight by the BOP for outsourcing facilities; registration with the BOP for use of an automated delivery device by a pharmacy; timeline requirements for the BOP to approve clinic licenses; and technical changes. The bill also makes various changes that are intended to improve the effectiveness of the VMB and extends the VMB's sunset dates.

This bill is sponsored by the author, and is one of five "sunset bills" the author is sponsoring this year. According to the author, "this bill is necessary to make changes to the Pharmacy Law and Veterinary Practice Act in order to strengthen the laws to improve [BOP] and VMB oversight of licensees."

Background. *Joint Oversight Hearings and Sunset Review of DCA Licensing Boards.* In March of 2016, the Assembly Committee on Business and Professions and the Senate Committee on Business, Professions and Economic Development (Committees) conducted multiple joint oversight hearings to review 11 regulatory boards within the DCA and one regulatory entity outside of the DCA. The sunset bills are intended to implement legislative changes recommended in the respective background reports drafted by the Committee staff for the agencies reviewed this year.

The Sunset Review Process. The sunset review process provides a formal mechanism for the DCA; the Legislature; the regulatory boards, bureaus and committees; interested parties; and stakeholders to make recommendations for improvements to the authority of consumer protection boards and bureaus. This is performed on a standard four-year cycle and was mandated by SB 2036 (McCorquodale), Chapter 908, Statutes of 1994. Each eligible agency is required to submit to the Committees a report covering the entire period since last reviewed that includes, among other things, the purpose and necessity of the agency and any recommendations of the agency for changes or reorganization in order to better fulfill its purpose. During the sunset review hearings, the Committees take public testimony and evaluate the eligible agency prior to the date the agency is scheduled to be repealed. An eligible agency is allowed to sunset unless the Legislature enacts a law to extend, consolidate, or reorganize the eligible agency.

The legislation pertaining to this bill is based on specific issues raised and addressed in the reports on the BOP and VMB released by the Senate Committee on Business, Professions and Economic Development along with the Sunset Review Hearing on March 14, 2016.

Background on the BOP. The BOP is responsible for enforcing federal and state laws pertaining to the acquisition, storage, distribution and dispensing of dangerous drugs (including controlled substances) and dangerous devices. The BOP has over 140,000 licensees in 23 license categories that include both personal and business licenses. As an agency that regulates the individuals and businesses that dispense, compound, provide, store and distribute prescription drugs and devices and pharmaceutical services to the public, or to other health care practitioners in compliance with state and federal law, the licensing of pharmacists, pharmacies, and pharmacy technicians is the primary focus of BOP activity, with consumer protection at the core of the BOP's operations. The BOP's regulatory authority, as described in the Pharmacy Law, extends over individuals and firms located both within and outside California, if they provide services in California. The BOP notes that it also ensures the safety of drug products dispensed to patients and regulates those who handle, store, and ship products from the manufacturer through the supply chain to the pharmacy and ultimately to the patient.

The BOP is a special fund agency whose activities are funded through regulatory fees and license fees. Pharmacists also convey information related to drug therapy management and are the health care provider most educated on pharmaceutical care and management. The BOP has a highly diverse and detailed licensing program for the individuals and facilities the BOP regulates, reflecting the careful and deliberative manner in which the U.S. regulates the manufacturing, distributing, and dispensing of prescription drugs and devices.

The BOP's enforcement activities are the core of its program, with the majority of its staff and resources dedicated to enforcement functions. The BOP aims to prevent events that could result in patient harm and ensure that there are consequences to deter events from occurring in other pharmacies. The BOP employs investigators who work from home offices throughout the state and perform random, unannounced inspections to detect violations, investigate complaints, monitor licensees on probation, educate licensees about Pharmacy Law requirements, serve as expert witnesses in disciplinary hearings and identify violations and issues that non-pharmacists may not be able to identify.

The following are some of the major issues pertaining to the BOP that this bill addresses.

1) *Outsourcing Facilities.* The BOP currently licenses entities that would be considered outsourcing facilities as sterile compounding pharmacies. They are referred to as "resident" facilities if they are located in California and "non-resident" facilities if located out of state and ships into California. There is no distinction between large scale and small scale facilities. This bill requires outsourcing facilities to be licensed by the BOP; prohibits an outsourcing facility to be simultaneously licensed with the BOP as a sterile compounding pharmacy at the same location; prohibits a licensed outsourcing facility from filling patient specific prescriptions; requires an outsourcing facility to notify the BOP of any disciplinary or other action taken by another state or the FDA or of any recall notices or any adverse events potentially attributable to an outsourcing facility's products; requires the BOP to inspect the location of a nonresident outsourcing facility to ensure that the facility is in compliance with all laws and regulations before issuing or renewing a nonresident outsourcing facility's license; authorizes the BOP to issue a cease and desist order to an outsourcing facility if the BOP has reasonable belief that the products produced by the facility poses an immediate threat to the public health or safety and; establishes a $780 fee for an outsourcing facility license.

2) *Automated Drug Delivery Systems (ADDS).* The BOP reports that it is not currently able to track how many of these delivery devices are in use, where they are in use, or which pharmacy is responsible for specific delivery devices. A registration would enable the BOP to identify which pharmacies operate these delivery devices and where each is located. This bill requires a pharmacy using an automated drug delivery system (ADD) to register use of the ADD with the BOP, including the address at which the ADD is being used.

3) *Backlogs.* The BOP aims to issue a permit as quickly as possible once the applicant has been determined to be qualified for licensure. The BOP notes that it works with applications from new businesses that must be licensed by the BOP, and strives to ensure that they can open on the date they desire, even when they turn applications in very close to the desired opening date. This bill requires the BOP to issue a license to, or incorporate changes reported by, a clinic, within 30 days of receiving a completed application and payment of any prescribed fees.

4) *Cease and Desist for Unlicensed Activity.* The BOP does not currently have the authority to issue a cease and desist order to businesses involved in unlicensed activity. Simply citing and fining an unlicensed business is often an insufficient consequence to stop unlicensed activity because the Board reports that frequently the business will continue to do the very action which violates the law. This bill authorizes the BOP to issue a cease and desist to an

entity practicing activities without a license if those activities would require licensure by the BOP.

5) *Professional Corporations.* Pharmacy corporations were authorized in 1996 in the Pharmacy Practice Act, rather than the Corporations Code. Current law allows a pharmacy corporation's officers, directors, and shareholders to be anyone who is a "licensed person" as defined in Section 13401 of the Corporations Code. The "same professional services" rendered by the corporation is an expansive concept, it can be argued that a physician can be an officer, director, or shareholder of a pharmacy corporation. It follows, then, that it would be equitable for a pharmacist to be an officer, director, or shareholder of a medical corporation. This bill includes pharmacists in the list of licensed professionals authorized to establish a professional corporation.

6) *Continued Regulation by the BOP.* The BOP has shown over the years a strong commitment to improve its overall efficiency and effectiveness and has worked cooperatively with the Legislature and this Committee to bring about necessary changes. This bill extends the operation of the BOP and its executive officer until January 1, 2021.

Background on the VMB. The mission of the VMB is to protect consumers and animals through development and maintenance of professional standards, licensing of veterinarians, RVTs, and premises, and diligent enforcement of the California Veterinary Medicine Practice Act. The VMB is composed of eight members: four veterinarians, one RVT, and three public members. The VMB licenses 12,086 Veterinarians and 6,424 RVTs. The licensee population has increased steadily over the past five years. The VMB also requires registration of all premises where veterinary medicine, veterinary dentistry, veterinary surgery, and the various branches thereof, is being practiced. The VMB currently registers 3,636 veterinary premises.

The VMB seeks to assure the public that veterinarians and RVTs possess the level of competence required to perform services by developing and enforcing standards for examinations, licensing, and hospital and school inspection. The VMB also conducts regular practice analyses to validate the licensing examinations for both veterinarians and RVTs. Additional eligibility pathways have also been approved for licensure of internationally trained veterinary graduates and certification of RVTs to allow qualified applicants from other states in the U.S. and countries around the world to come to California and to improve the provision of veterinary health care for consumers and their animals. The VMB's goals, as stated in its Strategic Plan, include decreased enforcement cycle times, enhanced quality and training of hospital inspectors, inspecting existing hospitals within one year of registration, and working with DCA to reduce the amount of unlicensed activity occurring in the marketplace.

The following are some of the major issues pertaining to the VMB that this bill addresses.

1) *University Licensure.* Because veterinarians working at universities are exempt from licensure, the VMB states that it has no authority to pursue disciplinary action and must advise consumers to seek recourse through the university's complaint mediation process. The exemption presents consumer protection issue, and the VMB believes that all veterinarians providing treatment to the public's animals should be licensed and regulated. This bill requires the VMB to provide a separate licensure category for veterinarians practicing solely within the university setting.

2) *Delinquent Registration Status.* Currently, there is no provision for the premises registration to cancel after five years, as would be consistent with other license types regulated by the VMB. Instead hospital premises registrations are left in a delinquent status indefinitely and remain on the VMB's records, which can be confusing for consumers who try to find registered veterinary premises and retrieve data on hospitals that have been in a delinquent status for hospitals that no longer operate veterinary premises. This bill allows for a premise registration to be canceled after five years of delinquency.

3) *Drug Compounding.* There are no specific provisions in the Practice Act to provide oversight of a veterinarian compounding drugs for use in day-to-day veterinary practices and for dispensing to clients. Instead, the VMB has looked to laws and regulations governing pharmacies because veterinarians are authorized prescribers under BPC Section 4170. Pharmacy regulations not only include specific requirements for pharmacies that compound and dispense medications, but also define the "reasonable quantity" of a compounded medication that may be furnished to the pharmacy to administer to the prescriber's patients within their facility, or to dispense to their patient/client. It should be noted that the BOP is currently pursuing a regulatory amendment to its *Compounding Drug Preparation* regulations that includes amendments to the "reasonable quantity" definition of compounded drugs that may be supplied to veterinarians for the purposes of dispensing. This bill establishes authority for drug compounding in the practice of veterinary medicine.

Current Related Legislation. SB 1039 (Hill) of the current Legislative Session, contains several provision relevant to the boards and bureaus in the sunset review process. Among other things, the bill makes an exception for veterinarians holding a current, valid license in good standing in another state or country who provide assistance to a California licensed veterinarian and attend on a specific case, subject to specified conditions; and, modifies specified fees to be paid by licensees and applicants for licensure from the BOP. *STATUS*: *This bill will also be heard before the Assembly Committee on Business and Professions during today's hearing.*

Prior Related Legislation. SB 1243 (Lieu), Chapter 395, Statutes of 2014, extended until January 1, 2017, the provisions establishing the VMB and the term of the executive officer of the Board.

SB 304 (Lieu), Chapter 515, Statutes of 2013, extended until January 1, 2016, the provisions establishing the VMB, subjects the VMB to a review by the appropriate policy committees of the Legislature, and clarifies that the review of the VMB shall be limited to those issues identified by the appropriate policy committees.

SB 1236 (Price), Chapter 332, Statutes of 2012, extended the operation BOP and its authority to appoint an executive officer until January 1, 2017, among other provisions.

ARGUMENTS IN SUPPORT:

The California Veterinary Medical Association (CVMA), writes in support, "CVMA supports the continued existence of a [VMB], under the [DCA], to regulate the practice of veterinary medicine and to provide necessary protection for California consumers."

Community Action Fund of Planned Parenthood of Orange and San Bernardino Counties, Planned Parenthood Affiliates of California, Planned Parenthood Action Fund of the Pacific Southwest, Planned Parenthood Action Fund of Santa Barbara, Planned Parenthood Advocacy

Project Los Angeles County, Planned Parenthood Mar Monte, Planned Parenthood Northern California Action Fund, and Planned Parenthood Advocates Pasadena and San Gabriel Valley similarly write in support, "This bill creates a streamlined process for affiliates to report changes in corporate officers, consulting pharmacists, or medical directors for BOP clinic permits similarly to when they report these changes for DPH clinic licenses. Instead of reporting such changes for each affiliate owned clinic on a "change of permit" application costing $100 per application, this bill allows affiliates to report these changes on a single application for all their clinics."

REGISTERED SUPPORT:

California Veterinary Medical Association
Community Action Fund of Planned Parenthood of Orange and San Bernardino Counties
Planned Parenthood Affiliates of California
Planned Parenthood Action Fund of the Pacific Southwest
Planned Parenthood Action Fund of Santa Barbara
Planned Parenthood Advocacy Project Los Angeles County
Planned Parenthood Mar Monte
Planned Parenthood Northern California Action Fund
Planned Parenthood Advocates Pasadena and San Gabriel Valley

REGISTERED OPPOSITION:

None on file.

Analysis Prepared by: Gabby Nepomuceno / B. & P. / (916) 319-3301