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**SENATE COMMITTEE ON  
BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT**  
Senator Richard Roth, Chair  
2021 - 2022 Regular

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**Bill No:** AB 691  
**Author:** Chau  
**Version:** April 5, 2021  
**Urgency:** Yes  
**Consultant:** Elissa Silva

**Hearing Date:** June 30, 2021

**Fiscal:** Yes

**Subject:** Optometry: SARS-CoV-2 vaccinations: SARS-CoV-2 clinical laboratory tests or examinations

**SUMMARY:** Authorizes a licensed optometrist to utilize a CLIA-waived test to detect the presence of SARS-CoV-2, authorizes a licensed optometrist certified to use Therapeutic Pharmaceutical Agents to provide the SARS CoV-2 immunization, and establishes the required form necessary to obtain certification from the Board of Optometry (Board) necessary for optometrists seeking to administer immunizations, as specified, and makes this bill an urgency.

**Existing law:**

- 1) Establishes the Board to regulate the practice of optometry through the Optometry Practice Act (act). (Business and Professions Code (BPC) § 3010.5 et seq.)
- 2) Authorizes the Board to adopt rules and regulations that are, in its judgement, reasonable and necessary to ensure that optometrists have the knowledge to adequately protect the public health and safety by establishing educational requirements for admission to the examination for licensure. (BPC § 3025.1)
- 3) Authorizes the Board to adopt rules and regulations that are, in its judgement, reasonable and necessary to ensure that optometrists have the knowledge to adequately protect the public health and safety by governing its accreditation of schools, colleges, and universities that provide optometric education. (BPC § 3025.2)
- 4) Authorizes the Board to adopt regulations clarifying the level of training and the level of supervision of assistants. (BPC § 3025.6)
- 5) Defines the acts which constitute optometry, as specified. (BPC § 3041)
- 6) Requires an applicant, in order to be eligible to practice optometry, to have graduated from an accredited school of optometry, passed the required examinations for licensure, and not meet any of the grounds for denial, as specified. (BPC § 3046)
- 7) Authorizes an optometrist who is certified to use therapeutic pharmaceutical agents to administer immunizations for influenza, herpes zoster virus, and pneumococcus, in compliance with individual Advisory Committee on Immunization Practices (ACIP)

vaccine recommendations published by the CDC for persons 18 years of age or older, if they meet all the following requirements:

- a) Completes an immunization-training program endorsed by the federal Centers for Disease Control and Prevention (CDC) or the Accreditation Council for Pharmacy Education that, at a minimum, includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and maintains that training.
- b) Is certified in basic life support.
- c) Complies with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health.
- d) Applies for an immunization certificate on a board-approved form. (BPC § 3041(g))

**Existing Federal Law:**

- 1) Establishes CLIA under federal law, which regulates clinical laboratories that perform tests on human specimens and sets standards for facility administration, personnel qualifications and quality control. These standards apply to all settings, including commercial, hospital or physician office laboratories. (Code of Federal Regulations (CFR) Title 42 § 493)
- 2) Defines CLIA waived tests as simple laboratory examinations and procedures approved by the Food and Drug Administration (FDA) for home use, employ methodologies that are simple and accurate as to render the likelihood of erroneous results negligible or pose no reasonable risk of harm to the patient if performed incorrectly. (CFR Title 42 § 493)

**This bill:**

- 1) Authorizes a licensed optometrist to administer a clinical laboratory test or examination classified as waived, under the federal CLIA law, necessary to detect the presence of SARS-CoV2.
- 2) Adds the SARS-CoV2 immunization to the list of immunizations an optometrist is authorized to perform.
- 3) Requires a person requesting to be certified to use therapeutic pharmaceutical agents to apply for a certificate from the Board, pursuant to an application that must be in substantially the form prescribed in this bill.
- 4) Declares this bill an urgency in order to protect public health and preserve the future health care workforce by ensuring that qualified optometrists can assist to prevent the spread of COVID-19 by administering vaccinations and testing for COVID-19.

**FISCAL EFFECT:** This bill is keyed fiscal by Legislative Counsel. According to the Assembly Committee on Appropriations, this bill will result in “Costs to the Board of Optometry in the Department of Consumer Affairs are expected to be minor and absorbable (Optometry Fund). The board notes if 500 additional optometrists apply for the certificate that allows them to administer immunizations in the first year, and if an 100 additional optometrists apply per year thereafter, it would generate revenues ranging of \$25,000 in year one to \$5,000 per year ongoing.”

## **COMMENTS:**

1. **Purpose.** The California Optometric Association is the sponsor of this bill. According to the author, “In an effort to quickly administer COVID-19 vaccines to 40 million Californians, the California Department of Consumer Affairs (DCA) recently authorized a waiver that allows certified optometrists to administer COVID-19 vaccines to persons 16 years of age or older, including epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction. The waiver is expected to stand during the declared state of emergency, resulting from the COVID-19 pandemic. Legislation is needed to make this authorization permanent...The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulate all laboratory testing on human specimens for health assessment or the diagnosis, prevention or treatment of disease. It waives test systems for home-use that are cleared by the Food and Drug Administration. CLIA recently waived point-of-care tests for COVID-19. While optometrists are authorized to administer CLIA waived tests, they are restricted to conditions of the eye. AB 691 would ensure that optometrists are authorized to administer CLIA waived COVID-19 tests and COVID-19 vaccines in an effort to help identify and stop the spread of this virus.”
2. **Background.**

*Board of Optometry and the Practice of Optometry.* The Board regulates the largest population of optometrists and dispensers in the United States with over 20,000 licenses, registrations, certificates and permits. The Board is also responsible for issuing optometry certifications for Diagnostic Pharmaceutical Agents, Therapeutic Pharmaceutical Agents, Lacrimal Irrigation and Dilation, and Glaucoma.

An optometrist (Doctor of Optometry or O.D.) is an independent primary health care professional for the eye. Optometrists examine, diagnose, treat, and manage diseases, injuries, and disorders of the visual system, the eye, and associated structures, as well as identify related systemic conditions affecting the eye. Optometrists prescribe medications, low vision rehabilitation, vision therapy, spectacle lenses, contact lenses, and perform certain surgical procedures. In order to obtain a license to practice by the Board, an individual must obtain an O.D. degree; pass the three-part National Board of Examiners in Optometry examination and the California Optometric State Law examination.

The practice of optometry is specified in BPC § 3041, and includes the prevention and diagnosis of disorders and dysfunctions of the visual system and the treatment and management of certain disorders and dysfunctions of the visual system, as well as the provision of rehabilitative optometric services, and any or all of the acts

further specified in BPC § 3041. As a result of AB 443 (Salas, Chapter 549, Statutes of 2017), beginning in January 1, 2018, an optometrist who is certified to use Therapeutic Pharmaceutical Agents is authorized to administer immunizations provided the optometrist meets certain requirements. That bill authorized optometrists to provide the following immunizations: influenza, herpes zoster virus, and pneumococcus. SB 762 (Hernandez, Chapter 330, Statutes of 2018) established an additional pathway for optometrists to obtain the required immunization training by authorizing the use of immunization training programs might also be endorsed by the Accreditation Council for Pharmacy Education. This bill would add an additional vaccination that can be performed by an optometrist to include the SARS CoV-2 (may be referred to as the COVID vaccine) which they are currently permitted to do through an Executive Waiver issued by the Director of the DCA.

*Current COVID-19 Waivers.* In February 2021, the Director of DCA issued a waiver of BPC § 3041 to the extent it prohibited licensed optometrists from independently ordering and administering COVID-19 vaccines approved or authorized by the federal Food and Drug Administration to persons 16 years of age or older. This waiver essentially expanded the scope of practice for optometrists to allow them to administer the COVID-19 vaccine. In order for licensed optometrists to be eligible to provide the vaccination, optometrists had to complete either an immunization training program endorsed by the federal Centers for Disease Control and Prevention or the Accreditation Council for Pharmacy Education and completes the COVID-19 training programs prescribed by the California Department of Public Health. This bill would simply include the SARS CoV-2 vaccination with the other currently permitted vaccinations for optometrists under existing law.

*COVID-19 testing by optometrists.* Rapid point-of-care tests for COVID-19 are classified as “waived tests,” which require federal CLIA Certificate of Waivers. Optometrists are currently eligible to obtain the lab registration needed to perform CLIA-waived tests. However, that authority limits their ability to perform clinical laboratory tests to those authorized within their scope of practice within the Act.

This bill would specifically expand the statutory scope of practice for optometrists to include performing a clinical laboratory test or examination classified as CLIA-waived that is necessary to detect the presence of SARS CoV-2. This expansion would allow optometrists to utilize their existing authority to also engage in CLIA-waived testing for COVID-19. The sponsor notes that this authority would also provide optometrists with a mechanism to provide testing for staff.

*Forms.* As specified in BPC § 3041, an optometrists that seeks to administer immunizations must also be certified to use Therapeutic Pharmaceutical Agents as specified in BPC §3041.3. Current law 3041(g) requires an optometrist to apply for a certificate from the Board, on a form prescribed by the Board, in order to provide vaccinations. The bill would additionally codify the application form for certification that is currently required to be approved by the Board.

3. **Related Legislation.** AB 1710 (Wood, Chapter 123, Statutes of 2020) authorized a pharmacist to independently initiate and administer vaccines approved by the federal Food and Drug Administration (FDA) under certain circumstances.

SB 762 (Hernandez, Chapter 330, Statutes of 2018), allowed an optometrist to take an immunization training program endorsed by the Accreditation Council for Pharmacy Education towards certification to administer immunizations.

AB 443 (Salas, Chapter 549, Statutes of 2017) expanded the optometry scope of practice to include further independence from physicians and surgeons, the administration of specified vaccines, and the treatment of additional conditions, as specified.

SB 622 (Hernandez of 2016) would have expanded the scope of practice for optometrists to include the use noninvasive, nonsurgical technology to treat conditions authorized by the Act, perform laser and minor procedures, and administer certain vaccines. (Status: *This bill was held in the Assembly Business and Professions Committee.*)

SB 492 (Hernandez) of 2014 would have authorized an optometrist to administer influenza and herpes zoster virus (shingles) immunizations for persons 18 years of age and older after completing.

SB 493 (Hernández, Chapter 469, Statutes of 2013) allowed pharmacists to furnish self-administered hormonal contraceptives, nicotine replacement products, and prescription medications not requiring a diagnosis that are recommended for international travelers; order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies; order and administer routine vaccinations; and provide consultation on drug therapy, disease management, and prevention.

4. **Arguments in Support.** The California Optometric Association writes in support, “The Department of Consumer Affairs recently granted a waiver to allow optometrists to administer COVID-19 vaccines. AB 691 is necessary to make that new authority permanent. It makes no sense to require optometrists to undergo 21 hours of vaccine training required by the wavier and then not allow them to administer vaccines when the state of emergency is over. Most experts expect the need for ongoing booster shots. This bill also allows optometrists to perform point-of-care (CLIA Waived) COVID-19 (SARS-CoV-2 antigen) tests. Point-of-care tests provide results within minutes of the test being administered. The federal government has announced it will speed up the production of these tests so that more tests will be available soon. More testing by all health care providers will help slow and stop the spread of the virus.”

VSP Vision Care writes in support and notes, “Recently, the California Department of Consumer Affairs authorized a waiver which allows optometrists to administer COVID-19 vaccines. This waiver will only last for the duration of the declared state of emergency. This legislation is needed to permanently allow optometrists to administer COVID-19 vaccines and testing.”

5. **Arguments in Opposition.** California Association for Medical Laboratory Technology is opposed unless amended and notes, “COVID-19 is a disease of the respiratory system. Optometrists are not authorized to order tests for, screen for,

diagnose or treat diseases of the respiratory system. Furthermore, rapid, point-of-care testing for SARS-CoV-2 should only be performed on nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider. Are the optometrists planning to open their offices to the public and offer tests to anyone suspected of COVID-19? If not, are optometrists planning to screen their asymptomatic patients prior to their appointments?"

**SUPPORT AND OPPOSITION:**Support:

California Optometric Association (Sponsor)  
Vision Service Plan

Opposition:

California Association for Medical Laboratory Technology

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