

Date of Hearing: April 20, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS

Evan Low, Chair

AB 691 (Chau) – As Amended April 5, 2021

SUBJECT: Optometry: SARS-CoV-2 vaccinations: SARS-CoV-2 clinical laboratory tests or examinations.

SUMMARY: Expands the authority of a qualified optometrist to administer immunizations to include the administration of the COVID-19 vaccine, and authorizes an optometrist to engage in specified COVID-19 testing.

EXISTING LAW:

- 1) Establishes the California State Board of Optometry (Board) for the licensure and regulation of optometrists, registered dispensing opticians, contact lens dispensers, spectacle lens dispensers, and nonresident contact lens dispensers. (Business and Professions Code (BPC) § 3000 *et seq.*)
- 2) Provides that the practice of optometry 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 habilitative or rehabilitative optometric services, and specifically authorizes an optometrist who is certified to use therapeutic pharmaceutical agents to perform various enumerated procedures. (BPC § 3041(a)-(d))
- 3) 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))

- 4) Includes within the meaning of the term “laboratory director” for purposes of the laws relating to clinical laboratories a duly licensed optometrist serving as the director of a laboratory that only performs clinical laboratory tests authorized in the Optometry Practice Act.

THIS BILL:

- 1) Adds SARS-CoV-2 (commonly referred to as COVID-19) to the list of immunizations a qualified optometrist is authorized to administer.
- 2) Codifies the contents of an application form for the certification required for an optometrist to perform immunizations and expands that certificate to include the administration of immunization for COVID-19.
- 3) Expressly provides that performing a clinical laboratory test or examination classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) necessary to detect the presence of COVID-19 is within the scope of practice of an optometrist.
- 4) Provides that 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, it is necessary 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 **California Optometric Association**. According to the author:

“The COVID-19 pandemic has dramatically impacted California residents. As of March 2021, there have been 3,566,464 confirmed cases of COVID-19 in California, resulting in 57,788 deaths. The quickest way to get our state back to normal is to administer vaccines to the population. As of March 2021, 29.4% of Californians have received a COVID-19 vaccine, for a total of 17,649,015 administered doses. The Centers for Medicare and Medicaid Services (CMS) recommends that states consider expanding the type of health care providers allowed to administer immunizations to assist in administering COVID-19 vaccines. 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. Current law, authorizes immunization certified optometrists to administer three vaccines for those 18 or older, which include influenza, herpes zoster virus, and pneumococcus. Clinical Laboratory Improvement Amendments of 1988 (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 and end the pandemic.”

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.

AB 443 (Salas) of 2017 made a number of changes to the Optometry Practice Act including broadening the scope of practice for optometrists by permitting an optometrist to conduct additional procedures on their patients. This includes an optional certification that allows an optometrist to administer immunizations for influenza, herpes zoster virus (commonly referred to as “shingles”), and pneumococcus. Once a certification has been obtained, optometrists may independently administer these immunizations in compliance with ACIP vaccine recommendations published by the CDC for persons 18 years of age or older.

As the COVID-19 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 the virus. 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 optometrists to 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, as well as existing certification requirements under the Optometry Practice Act. The bill would additionally codify the application form for certification that is currently required to be approved by the Board.

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 Optometry Practice 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 COVID-19. This expansion would allow optometrists to utilize their existing authority to perform clinical laboratory tests relating to eye conditions to also engage in CLIA-waived testing for COVID-19. The author contends that this authority is important given that optometrists and their staff are at high risk of infection in the normal course of treatment.

Current Related Legislation. AB 526 (Wood) would authorize both dentists and doctors of podiatric medicine to independently prescribe and administer influenza and COVID-19 vaccines and provide additional authority for dentists to administer rapid point-of-care tests for COVID-19. *This bill is pending in the Assembly Committee on Appropriations.*

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 443 (Salas, Chapter 549, Statutes of 2017) expanded the scope of practice for optometrists to include additional procedures including the administration of specific immunizations for optometrists who meet certain training requirements.

SB 762 (Hernandez, Chapter 330, Statutes of 2018) required the training program to be endorsed by the federal Centers for Disease Control and Prevention or the Accreditation Council for Pharmacy Education

ARGUMENTS IN SUPPORT:

The **California Optometric Association** (COA) is sponsoring this bill. According to the COA, “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 waiver 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.”

ARGUMENTS IN OPPOSITION:

The **California Association for Medical Laboratory Technology** (CAMLT) has an “oppose unless amended” position on this bill. CAMLT argues that “ordering of or testing for COVID-19 is not within the scope of optometry. The scope of optometry should remain restricted to tests necessary for the diagnosis of conditions and diseases of the eye or adnexa.” CAMLT opposes

this bill unless the provisions allowing for optometrists to perform CLIA-waived tests for COVID-19 are removed.

REGISTERED SUPPORT:

California Optometric Association (*Sponsor*)
Vision Service Plan

REGISTERED OPPOSITION:

California Association for Medical Laboratory Technology

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