SENATE RULES COMMITTEE

Office of Senate Floor Analyses

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THIRD READING

Bill No: AB 691 Author: Chau (D)

Amended: 9/3/21 in Senate Vote: 27 - Urgency

SENATE BUS., PROF. & ECON. DEV. COMMITTEE: 13-0, 6/30/21

AYES: Roth, Archuleta, Bates, Becker, Dodd, Eggman, Hurtado, Jones, Leyva,

Min, Newman, Ochoa Bogh, Pan NO VOTE RECORDED: Melendez

SENATE APPROPRIATIONS COMMITTEE: Senate Rule 28.8

ASSEMBLY FLOOR: 75-0, 5/13/21 (Consent) - See last page for vote

SUBJECT: Optometry: SARS-CoV-2 vaccinations: SARS-CoV-2 clinical

laboratory tests or examinations

SOURCE: California Optometric Association

DIGEST: This bill 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, establishes the required form to obtain certification from the Board of Optometry (Board) for optometrists seeking to administer immunizations, as specified, and makes this bill an urgency.

Senate Floor Amendments of 9/3/21 add language to address a chaptering issue with AB 407 (Salas).

Senate Floor Amendments of 8/18/21 make technical and clarifying changes necessary for implementation.

ANALYSIS:

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)

Existing state law:

- 1) Establishes the Board to regulate the practice of optometry through the Optometry Practice Act (act), and defines the practice of optometry, as specified. (Business and Professions Code (BPC) §§ 3010.5, 3041)
- 2) 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)
- 3) Authorizes an optometrist who is certified to use therapeutic pharmaceutical agents, to administer immunizations for influenza, herpes zoster virus, and pneumococcus, as specified, 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 provided 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))

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) Adds chaptering language.
- 5) 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.

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.

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.

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. This bill authorizes an additional vaccination to include the SARS CoV-2 (may be referred to as the COVID vaccine) which optometrists 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 simply includes the SARS CoV-2 vaccination to the list of permitted vaccinations optometrists are authorized to provide under existing law.

COVID-19 testing by optometrists. The rapid point-of-care test for COVID-19 is classified as a "waived test," 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 specifically expands 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. The sponsor notes that this authority would also provide optometrists with a mechanism to provide testing for staff.

Forms. Current law, BPC § 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 additionally codifies the application form for certification currently required to be approved by the Board.

FISCAL EFFECT: Appropriation: No Fiscal Com.: Yes Local: Yes

SUPPORT: (Verified 9/3/21)

California Optometric Association (source) California Society of Health-System Pharmacists Vision Service Plan

OPPOSITION: (Verified 9/3/21)

None received

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."

The California Society of Health-System Pharmacists writes in support and notes, "As an association that represents providers and experts in medication management, CSHP recognizes the value of providing proper medications to individuals with medical need. As such, CSHP applauds your efforts to address the need for qualified health care professionals to participate in the state's mass immunization and testing programs required to quickly combat the pandemic."

Vision Service Plan 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."

ASSEMBLY FLOOR: 75-0, 5/13/21

AYES: Aguiar-Curry, Arambula, Bauer-Kahan, Bennett, Berman, Bigelow, Bloom, Boerner Horvath, Burke, Calderon, Carrillo, Chau, Chen, Chiu, Choi, Cooley, Cooper, Cunningham, Megan Dahle, Daly, Davies, Flora, Fong, Frazier, Friedman, Gabriel, Cristina Garcia, Eduardo Garcia, Gipson, Lorena Gonzalez, Gray, Grayson, Holden, Irwin, Jones-Sawyer, Kalra, Kiley, Lackey, Lee, Levine, Low, Maienschein, Mathis, Mayes, McCarty, Mullin, Muratsuchi, Nazarian, Nguyen, O'Donnell, Patterson, Petrie-Norris, Quirk, Quirk-Silva, Ramos, Reyes, Luz Rivas, Robert Rivas, Rodriguez, Blanca Rubio, Salas, Santiago, Seyarto, Smith, Stone, Ting, Valladares, Villapudua, Voepel, Waldron, Ward, Akilah Weber, Wicks, Wood, Rendon

Prepared by: Elissa Silva / B., P. & E.D. / 916-651-4104 9/7/21 16:48:39

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