

**DEPARTMENT OF CONSUMER AFFAIRS  
CALIFORNIA STATE BOARD OF OPTOMETRY**

**INITIAL STATEMENT OF REASONS**

**Hearing Date:** The Board has not scheduled a public hearing on this proposed action. However, the Board will hold a hearing if it receives a written request for a public hearing from any interested person, or the interested person's authorized representative, no later than 15 days prior to the close of the written comment period. A hearing may be requested by making such request, in writing, addressed to the individuals listed under "Contact Person" in this Notice.

**Subject Matter of Proposed Regulations:** Fees and Immunization Certificate Applications

**Sections Affected:** Amend Section 1524 and adopt Section 1572 of Division 15 of Title 16 of the California Code of Regulations (CCR).

**Background and Statement of the Problem:**

The California State Board of Optometry (Board) currently regulates approximately 9,200 optometrists and 4,200 dispensing opticians. Business and Professions Code (BPC) section 3010.1 provides that protection of the public is the highest priority for the Board in exercising its licensing, regulatory and disciplinary functions. BPC section 3025 authorizes the Board to make rules and regulations governing procedure of the Board, the admission of applicants for examination for an optometry license, and the practice of optometry.

The purpose of this proposal is to implement changes enacted by Assembly Bill 443 (Salas, Chapter 549, Statutes of 2017) (AB 443). Effective January 1, 2018, AB 443 amended BPC section 3041, which defines the scope of practice for optometrists. Section 3041(g) authorizes an optometrist who is certified to use therapeutic pharmaceutical agents (TPA) to administer immunizations provided the optometrist meets certain requirements. Senate Bill 762 (Hernandez, Chapter 330, Statutes of 2018) (SB 762), effective September 10, 2018, provides that immunization training programs may also be endorsed by the Accreditation Council for Pharmacy Education.

Under BPC section 3041(g)(2), "immunization" means the administration of 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.

The Board first reviewed the issue at its February 1, 2019 meeting, and reviewed proposed text at its April 4, 2019 public meeting. The Board approved the proposed text and accompanying form at the October 25, 2019 public meeting.

**Specific Purpose of Amendment and/or Adoption, Anticipated Benefits, and Rationale:**

**Amend Section 1524 of Division 15 of Title 16 of the CCR (Fees)**

Purpose: The purpose of proposed subdivision (r) is to establish an application fee of \$50 for an immunization certification application.

Anticipated Benefit(s): The proposed amendment allows the Board to recover the costs necessary for review and processing of applications for immunizations. It also provides a means of notifying the public of the cost of an immunization certification application.

Rationale: BPC section 3152(t) provides that the application fee for a certificate to administer immunizations shall not exceed \$50. The Board established the fee for the application at \$50 because the Board projects an Office Technician (OT) will take approximately 45 minutes per application to perform any registration workload with total costs estimated as follows:

AB 443 Registration Workload and Costs												
Registration Type	Fee Costs	Years Ongoing Applications Per Year										
		1	2	3	4	5	6	7	8	9	10	Total
Applications Per Year		500	100	100	100	100	100	100	100	100	100	1,400
Office Technician (45 minutes @ \$1 per minute)	\$45	\$22,500	\$4,500	\$4,500	\$4,500	\$4,500	\$4,500	\$4,500	\$4,500	\$4,500	\$4,500	\$40,500
Certificate	\$5	\$2,500	\$500	\$500	\$500	\$500	\$500	\$500	\$500	\$500	\$500	\$7,000
Postage and materials	\$5	\$2,500	\$500	\$500	\$500	\$500	\$500	\$500	\$500	\$500	\$500	\$7,000
<b>Total Costs:</b>	<b>\$55</b>	<b>\$27,500</b>	<b>\$5,500</b>	<b>\$5,500</b>	<b>\$5,500</b>	<b>\$5,500</b>	<b>\$5,500</b>	<b>\$5,500</b>	<b>\$5,500</b>	<b>\$5,500</b>	<b>\$5,500</b>	<b>\$54,500</b>

Any workload and costs will be minor and absorbable within existing workload. The Board notes projected initial processing costs of \$55 exceed the statutory maximum fee level of \$50 per certificate. As a result, the proposed regulatory fee amount is set at the statutory maximum of \$50.

**Adopt Section 1572 of Division 15 of Title 16 of the CCR (Immunization Certificate Applications)**

Purpose: The purpose of adopting section 1572 is to establish the fee for the application and the components of the application a licensed optometrist must submit to obtain an

immunization certificate pursuant to BPC section 3041(g)(1).

Anticipated Benefit(s): This proposal will promote public safety by allowing optometrists certified to use TPAs to be registered with the Board in order to provide immunizations. Certification of optometrists for this purpose will provide patients with additional opportunities to get vaccinated and make it more convenient for them to do so, particularly in the rural areas where primary care doctors are scarce.

Rationale: BPC section 3041(g) authorizes an optometrist who is certified to use TPAs to administer immunizations if the optometrist meets certain specified requirements. Specifically, when certified, optometrists may administer immunizations for influenza, herpes zoster virus, and pneumococcus.

These immunizations may only be performed if the licensee meets the requirements set forth in subdivision (g)(1)(A) through (D). These requirements are:

- (A) Completion of 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) Certification in basic life support.
- (C) Compliance 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) Completion of an application for an immunization certificate on a Board-approved form.

To enable licensees to obtain this certification, the Board proposes to use an application form which solicits the following information from a licensee:

- (1) First, Middle and Last Name;
- (2) Email address;
- (3) License number;

The Board asks for these items of information to verify the license status of the applicant, and to communicate with applicants about the status of their applications.

(4) A declaration by the applicant that the information provided, including all accompanying documents or other requested proof of completion, is true and accurate, and that the applicant understands and agrees that any misstatements of material facts may be cause for denial of the application and discipline by the board, under the penalty of perjury; and

The Board requests that the applicant certify the information provided is true and accurate. This helps to ensure that representations made by the applicant contain truthful factual representations and are made in good faith.

(5) A declaration by the applicant under the penalty of perjury that the applicant will comply 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 California State Department of Public Health.

The Board requests this certification from the applicant to ensure that the applicant understands and will comply with the requirement contained in BPC section 3041(g)(1)(C).

These application requirements are reflected in proposed section 1572(a)(1) through (5).

Licensees must also submit the following fee and information to the Board with their application:

- (1) The \$50.00 application fee set forth in proposed section 1524(r);
- (2) A certificate or other documents certifying completion of an immunization training program endorsed by the federal Centers for Disease Control (CDC) and Prevention or the Accreditation Council for Pharmacy Education, which was completed after September 10, 2018; and
- (3) A certificate or other documents showing certification in basic life support.

The Board seeks the latter two items of information to verify that the applicant qualifies for certification in accordance with BPC section 3041(g)(1)(A) and (B). These application requirements are reflected in proposed section 1572(b)(1) through (3).

Proposed subdivision (c) requires an optometrist to meet and maintain all requirements

set forth in Section 3041(g) to be eligible for and maintain an immunization certificate.

**Underlying Data:**

- Approved Board meeting minutes and relevant materials from the February 1, 2019 meeting.
- Approved Board meeting minutes and relevant materials from the April 5, 2019 meeting.
- Draft Board meeting minutes and relevant materials from the October 25, 2019 meeting.
- Assembly Bill 443 (Salas, Chapter 549, Statutes of 2017).
- Senate Bill 762 (Hernandez, Chapter 330, Statutes of 2018).

**Business Impact:**

The Board has determined that the proposed amendment to section 1524 and adoption of section 1572 will not have a statewide adverse economic impact on businesses, including the ability of California businesses to compete with businesses in other states. The proposed regulations affect optometrist licensees only, not a business. Licensees who want to obtain an authorization for immunization certificate with the Board would be required to complete an immunization training course which meets the requirements of BPC section 3041. The pricing for such courses varies between \$600.00 - \$800.00, in addition to the fee of \$50.00 for registering with the Board. Therefore, the Board estimates that a licensee applying for training to obtain immunization authorization would incur a cost of up to approximately \$850.00. This fiscal impact would only be applicable to those licensees who choose to obtain the authorization and would be entirely voluntary.

The Board estimates 500 licensees will initially apply for registration in year one of implementation and 100 per year annually thereafter. Registration costs are estimated to range from \$425,000 in year one to \$85,000 per year ongoing and up to \$1.19 million over a ten-year period as follows:

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AB 443 Registration Costs														
Registration and License Type	Applicants Per Year	Fee Costs Per Year	Years Ongoing										Total	
			1	2	3	4	5	6	7	8	9	10		
Initial Registration (Year 1)	500	\$50	\$ 25,000	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$25,000
Immunization Training	500	\$800	\$400,000	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$400,000
Initial Registration (Ongoing)	100	\$50	\$ -	\$5,000	\$5,000	\$5,000	\$5,000	\$5,000	\$5,000	\$5,000	\$5,000	\$5,000	\$5,000	\$45,000
Immunization Training	100	\$800	\$ -	\$80,000	\$80,000	\$80,000	\$80,000	\$80,000	\$80,000	\$80,000	\$80,000	\$80,000	\$80,000	\$720,000
<b>Total Costs:</b>			<b>\$425,000</b>	<b>\$85,000</b>	<b>\$85,000</b>	<b>\$85,000</b>	<b>\$85,000</b>	<b>\$85,000</b>	<b>\$85,000</b>	<b>\$85,000</b>	<b>\$85,000</b>	<b>\$85,000</b>	<b>\$85,000</b>	<b>\$1,190,000</b>

## **Economic Impact Assessment:**

This regulatory proposal will have the following effects:

- It will not create or eliminate jobs within the State of California because the proposed regulations establish a fee and a process for licensees to obtain a certification in administering immunizations. The Board does not anticipate that this certification will create or eliminate jobs.
- It will not create new business or eliminate existing businesses within the State of California because the proposed regulations establish a fee and a process for licensees to obtain a certification in administering immunizations. The Board does not anticipate that this certification will create new businesses or eliminate existing businesses.
- It will not affect the expansion of businesses currently doing business within the State of California because the proposed regulations establish a fee and a process for licensees to obtain a certification in administering immunizations. The Board does not anticipate that this certification will expand businesses.
- It benefits the health and welfare of California residents because it will require optometry licensees who wish to administer immunizations to obtain the proper training and subsequent certification with the Board, which increases access to care and immunizations while protecting the public.
- It does not affect worker safety because the proposed regulations are not related to worker safety.
- It does not affect the state's environment because the proposed regulations are not relevant to the state's environment.

## **Specific Technologies or Equipment:**

This regulation does not mandate the use of specific technologies or equipment.

## **Consideration of Alternatives:**

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

Set forth below are the alternatives which were considered and the reasons each alternative was rejected:

- Do not promulgate these regulations. This alternative was rejected. The Board is directed by BPC section 3041 to develop the appropriate regulation and application form.

**Fiscal Impact Assessment:**

The Board estimates 500 certificates will be issued in year one of implementation and 100 certificates per year annually thereafter. An Office Technician (OT) will take approximately 45 minutes per application to perform any registration workload with total costs estimated as follows:

AB 443 Registration Workload and Costs													
Registration Type	Fee Costs	Years Ongoing Applications Per Year											
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Applications Per Year		500	100	100	100	100	100	100	100	100	100	100	1,400
Office Technician (45 minutes @ \$1 per minute)	\$45	\$22,500	\$4,500	\$4,500	\$4,500	\$4,500	\$4,500	\$4,500	\$4,500	\$4,500	\$4,500	\$4,500	\$40,500
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Postage and materials	\$5	\$2,500	\$500	\$500	\$500	\$500	\$500	\$500	\$500	\$500	\$500	\$500	\$7,000
<b>Total Costs:</b>	<b>\$55</b>	<b>\$27,500</b>	<b>\$5,500</b>	<b>\$5,500</b>	<b>\$5,500</b>	<b>\$5,500</b>	<b>\$5,500</b>	<b>\$5,500</b>	<b>\$5,500</b>	<b>\$5,500</b>	<b>\$5,500</b>	<b>\$5,500</b>	<b>\$54,500</b>

Any workload and costs will be minor and absorbable within existing workload. The Board notes projected initial processing costs of \$55 exceed the statutory maximum fee level of \$50 per certificate. As a result, the proposed regulatory fee amount is set at the statutory maximum of \$50.

Applicants will be required to pay a one-time registration fee of \$50 to the Board, which will generate revenues ranging from \$25,000 in year one to \$5,000 per year ongoing and up to \$70,000 over a ten-year period as follows:

AB 443 Registration Revenues													
Registration and License Type	Applicants Per Year	Fee Costs Per Year	Years Ongoing										
			1	2	3	4	5	6	7	8	9	10	Total
Initial Registration (Year 1)	500	\$50	\$ 25,000	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$25,000
Initial Registration (Ongoing)	100	\$50	\$ -	\$ 5,000	\$5,000	\$5,000	\$5,000	\$5,000	\$5,000	\$5,000	\$5,000	\$5,000	\$45,000
<b>Total Revenues:</b>			<b>\$25,000</b>	<b>\$5,000</b>	<b>\$5,000</b>	<b>\$5,000</b>	<b>\$5,000</b>	<b>\$5,000</b>	<b>\$5,000</b>	<b>\$5,000</b>	<b>\$5,000</b>	<b>\$5,000</b>	<b>\$70,000</b>