



ISSUE MEMORANDUM

DATE	January 7, 2022
TO	Members, California State Board of Optometry (CSBO)
FROM	Shara Murphy, Executive Officer
SUBJECT	Agenda Item #3 - Legislation: AB 407 and AB 691 – Discussion and Possible Action Regarding Optometrist Authority to Direct Clinical Laboratory Operations

Background / Summary:

As of January 1, 2022, AB 407 and AB 691 are effective and in law. These bills made changes to Business and Professions Code Section 3041 and DCA has raised a concern with changes made by these bills. It appears AB 407 and AB 691 removed the authority of a licensed optometrist to direct a laboratory that performs clinical laboratory tests as authorized by BPC Section 1209:

(a) As used in this chapter, "laboratory director" means any person who is any of the following:

- (1) A duly licensed physician and surgeon.*
- (2) Only for purposes of a clinical laboratory test or examination classified as waived, is any of the following:*
 - (A) A duly licensed clinical laboratory scientist.*
 - (B) A duly licensed limited clinical laboratory scientist.*
 - (C) A duly licensed naturopathic doctor.*
 - (D) A duly licensed optometrist serving as the director of a laboratory that only performs clinical laboratory tests authorized in paragraph (10) of subdivision (d) of Section 3041.*

The reference to BPC Section 3041(d), which is no longer in law:

(d) An optometrist who is certified to use therapeutic pharmaceutical agents pursuant to Section 3041.3 may also perform all of the following procedures:

(1)-(9) ...

(10) A clinical laboratory test or examination classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. Sec. 263a; Public Law 100-578) and designated in paragraph (9) necessary for the diagnosis of conditions and diseases of the eye or adnexa, or if otherwise specifically authorized by this chapter.

Instead, as of January 1, 2022, [BPC 3041 \(a\)\(5\)\(E\)](#) now sets out the following for a TPA certified optometrist:

(E) Utilizing the following techniques and instrumentation necessary for the diagnosis of conditions and diseases of the eye and adnexa:

(i) Laboratory tests or examinations ordered from an outside facility.

(ii) Laboratory tests or examinations performed in an office classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. Sec. 263a; Public Law 100-578), which shall also be allowed for:

(I) Detecting indicators of possible systemic disease that manifests in the eye for the purpose of facilitating appropriate referral to or consultation with a physician and surgeon.

(II) Detecting the presence of SARS-CoV-2 virus.

(iii) Skin testing performed in an office to diagnose ocular allergies, limited to the superficial layer of the skin.

As stated above, BPC Section 3041 (d)(10) no longer exists, and BPC 1209 will have no basis for allowing ODs to direct waived tests for purposes of optometry. DCA believes the new language in (a)(5)(E) may be intended to replace the authority within the old BPC Section 3041(d)(10) that allows ODs to direct waived testing used for purposes of optometry, but the bills don't amend BPC 1209 to include a reference to the new section. This may create a problem for labs that list ODs as directors, because their authority to direct a waived lab will no longer exist, and it is unclear that they will be able to direct the lab doing the testing.

Staff requests Board discussion and direction on the following:

1. Is this authority even needed? How often do ODs direct clinical labs?
2. If so, how far-reaching should this authority go?
3. Should staff investigate the issue further in conjunction with DCA and the California Optometric Association, and recommend changes to the Board at a future meeting?
4. The Board may wish to direct and delegate authority to the Executive Officer to work with DCA and the Legislature on amending BPC 1209 and 3041 to ensure this authority is reinstated via a bill.