

Date of Hearing: June 2, 2020

# ASSEMBLY COMMITTEE ON APPROPRIATIONS

Lorena Gonzalez, Chair

AB 2199 (Nazarian) – As Amended May 18, 2020

Policy Committee: Business and Professions Vote: 18 - 0

Urgency: No State Mandated Local Program: Yes Reimbursable: No

## SUMMARY:

This bill extends the authorization for laboratory personnel who meet specified requirements to perform a total protein test using a digital refractometer in a licensed plasma collection center in this state until January 1, 2023, and adds a clinical laboratory scientist as one of the personnel who can supervise the laboratory personnel.

## FISCAL EFFECT:

Minor and absorbable costs to California Department of Public Health (CDPH) to continue oversight of this exemption (Licensing and Certification Fund).

## COMMENTS:

- 1) **Purpose.** The author states this bill is necessary to continue a narrow exemption in the law to allow time for CDPH to assess safety data related to the exemption.
- 2) **Background.** Federal and state law jointly govern the provision of laboratory services, and the CDPH regulates laboratories on behalf of the state and federal government. The Clinical Laboratory Improvement Amendments (CLIA), is the federal framework for laboratory oversight. Under CLIA, tests are classified as either waived, moderate-complexity or high-complexity. Waived tests are simple and low-risk, while moderate- and high-complexity tests are subject to more stringent regulation. Existing law authorizes certain exceptions from normal rules governing which professionals can conduct certain tests.

AB 613 (Nazarian), Chapter 799, Statutes of 2018, established the exemption this bill would extend for an additional two years. It allows unlicensed persons to perform a total protein test using a digital refractometer in a licensed plasma collection center. The test measures blood protein and is important for determining a donor's eligibility. According to the sponsor, Plasma Protein Therapeutics Association, 48 other states allow this exemption. AB 613 had a sunset in order to allow CDPH to review safety data to inform whether the exemption should continue. According to CDPH, that data is still under review.

- 3) **Support and Opposition.** The plasma industry and related advocacy organizations support this bill. Supporters indicate it will improve efficiency and even assert ending the exemption would result in more plasma centers being built, creating jobs and offering greater access to Californians to donate plasma. The California Nurses Association opposes this bill, citing concerns about safety and about "de-skilling" the nursing profession, as well as questioning the bill's necessity.

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