SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT

Senator Steven Glazer, Chair
2019 - 2020 Regular

Bill No:	AB 2199	**Hearing Date:**	August 8, 2020
Author:	Nazarian		
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Urgency:	No	**Fiscal:**	Yes
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Subject: Healing arts: clinical laboratories

SUMMARY: 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 person.

Existing law:

1) Provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the California Department of Public Health (CDPH), with specified exceptions. (Business and Professions Code (BPC) § 1200-1327)

2) Defines, for purposes of state regulation of clinical laboratories, the following:

   a) "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a; P.L. 100-578) and the regulations adopted thereunder by the federal Health Care Financing Administration and effective on January 1, 1994, or any later date, when adopted in California pursuant to subdivision (b) of Section 1208. (BPC § 1202.5(a))

   b) "Clinical laboratory" meant any place used, or any establishment or institution organized or operated, for the performance of clinical laboratory tests or examinations or the practical application of the clinical laboratory sciences. That application may include any means that applies the clinical laboratory sciences. (BPC § 1206(a)(8))

3) Authorizes a person to perform a total protein test using a digital refractometer in a licensed plasma collection center in this state, as specified. (BPC § 1246.7(a))

4) Specifies that the person may only perform the test, if CDPH, as part of its routine, fee-supported inspection of the licensed plasma collection center, including its review of personnel reports for licensed and unlicensed personnel and job descriptions of all center positions for a licensed plasma collection center, determines that the following conditions are met:

   a) The person has earned a high school diploma or equivalent, as determined by the federal Centers for Medicare and Medicaid Services (CMS) pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA). (42 U.S.C. Sec. 263a) (BPC § 1246.7(a)(1)(A))

b) The person has training sufficient to demonstrate that the individual has the skills and abilities required of unlicensed laboratory personnel performing CLIA testing, as specified. (BPC § 1246.7(a)(1)(B))

c) In addition to the education and training requirements specified above, the person has received five hours of training in the proper procedures to be employed when performing a total protein test using a digital refractometer and the procedures for recording the test results, as specified. (BPC § 1246.7(a)(2)(A))

d) The person's training in the proper procedure to be employed when performing a total protein test using a digital refractometer has been certified by a moderate complexity laboratory technical consultant as specified, by a physician and surgeon licensed in this state, or by a licensed clinical laboratory director who is in charge of the licensed plasma collection center. (BPC § 1246.7(a)(2)(B))

e) The instructor documents, and the plasma collection center maintains the documentation of, the individual's successful completion of training in the performance of the total protein test using a digital refractometer. This documentation must be made available to CDPH upon request. (BPC § 1246.7(a)(2)(C))

f) The person performs the total protein test using a digital refractometer under the supervision of one of the authorized individuals who is physically onsite in the licensed plasma collection center and is available for consultation and direction while the person is processing specimens and performing the test. (BPC § 1246.7(a)(3))

g) Authorizes the following individuals to supervise the person:

    i) A moderate complexity laboratory technical consultant, as specified. (BPC § 1246.7(a)(3)(A))

    ii) A licensed registered nurse. (BPC § 1246.7(a)(3)(B))

    iii) A licensed physician or surgeon. (BPC § 1246.7(a)(3)(C))

    iv) A clinical laboratory director licensed pursuant to this chapter. (BPC § 1246.7(a)(3)(D))

h) The person performs the total protein test using a digital refractometer in accordance with (1) standardized operating procedures required by the licensed plasma collection center's license and (2) standardized procedures developed and approved by the licensed plasma collection center's supervising physician and surgeon or licensed clinical laboratory director for administration of the total protein test by the persons authorized to perform the total protein test pursuant to this section. These standardized procedures must be made available to the CDPH upon request. (BPC § 1246.7(a)(4))

i) The person does not draw the blood sample required for the test using a procedure that requires a registration, certification, or license under state law

unless the person is properly registered, certified, or licensed to perform the procedure. (BPC § 1246.7(a)(5))

j) The person's competency in performing total protein tests using a digital refractometer is evaluated before testing on donors, and again every six months, by the CLIA lab director or technical consultant by direct observation. A licensed plasma collection center must maintain documentation of the competency evaluation, which must be made available to CDPH upon request. (BPC § 1246.7((a)(6))

k) The person accurately records the results of the total protein test in a federal FDA 510k-approved blood establishment computer system (BECS), which must be verified. (BPC § 1246.7(a)(7))

l) The person's results are verified in one of the following ways:

i) Using a digital refractometer that creates an electronic record of the test results. (BPC § 1246.7(a)(7)(A))

ii) Having each record entered by the individual verified for accuracy at the time the test result is recorded and while the result remains visible on the digital refractometer by a registered nurse or by the individual who is supervising the individual performing the test. The individual certifying the accuracy shall affix their name to the record verifying the accuracy of the entries. (BPC § 1246.7(a)(7)(B))

iii) Affixing a date- and time-stamped photograph of the digital refractometer test results to the spreadsheet. (BPC § 1246.7(a)(7)(C))

iv) The plasma collection center utilizing a double blind computer entry system that requires the test results to be accurately entered into the record twice before the results are recorded as final. (BPC § 1246.7(a)(7)(D))

5) Requires the digital refractometer used to perform a total protein test pursuant under this exemption to meet specified criteria. (BPC § 1246.7(b))

6) Requires a licensed plasma collection center to assess the competency and performance of persons authorized to perform the total protein test pursuant to this authorization and to make any required information or test results available to CDPH, as specified. (BPC § 1246.7(c))

7) Requires records of digital refractometer test results collected to be maintained for three years and made available to CDPH upon request. (BPC § 1246.7(d))

8) Specifies that this authorization remains in effect only until January 1, 2021.

This bill:

1) Extends the operation of the above provisions until January 1, 2023, thereby extending the application of a crime and the provisions that make the records described above confidential.

2) Authorizes a total protein test to be performed under the supervision of a clinical laboratory scientist.

3) Makes a technical change to the standardized procedures that may apply to the performance of a total protein test under these provisions, as specified.

4) Makes other technical and clarifying changes.

FISCAL EFFECT: According to Assembly Committee on Appropriations, this bill will result in minor and absorbable costs to CDPH to continue oversight of this exemption.

COMMENTS:

1. **Purpose.** The Plasma Protein Therapeutics Association is the Sponsor of this bill. According to the author, "By allowing trained and qualified plasma donation centers employees to perform the total protein test with a digital refractometer, AB 2199 will make sure four things: 1) licensed individuals are utilized to the highest level of their job skills resulting in more efficient source plasma donor screening; 2) it will ensure appropriate controls are in place for the digital refractometer to maintain continued donor safety when a Total Protein Test is administered; 3) bring California in line with the majority of other states that allow a Total Protein Test to be administered this way and; 4) will ensure Californians with rare disease have appropriate access to the "lifesaving drug" that plasma proteins therapies provide."

2. **Background.**

   Federal and State Regulation of Plasma for Donor Safety. Source plasma is a biologic and product derived from blood so the process of collecting source plasma is regulated and licensed under federal and state biologics laws to ensure donor safety. (42 U.S. Code § 262; BPC §§ 1600-1630). When donors give plasma, they undergo plasmapheresis: a process where a donor gives blood, plasma is separated from the formed elements, and then that blood is returned to the donor. Given this process, federal and state biologics laws provide safety precautions for source plasma donations, including various testing, timing, and fatality reporting requirements. They also require that a plasma collection center test a donor's total protein level, among other things, before undergoing plasmapheresis. (42 CFR §640.65(b)(1)(i); CCR, tit. 17, § 1025(b))

   Federal and State Regulation for Clinical Laboratory Testing. A facility that performs laboratory tests on human specimens for diagnosis or assessment must be certified under CLIA. CLIA certification requirements vary depending on the complexity of the laboratory tests performed.

   Clinical laboratories or other testing sites need to know whether each test system used is waived, moderate, or high complexity. In general, the more complicated the test, the more stringent the requirements, including increased training and licensing of laboratory personnel. At a minimum, all laboratories must have a licensed clinical laboratory director…The FDA determines the complexity of CLIA laboratory tests.

Waived tests are simple tests with a low risk for an incorrect result. They include tests listed in the CLIA regulations, tests cleared by the FDA for home use, and tests approved for waiver by the FDA using the CLIA criteria. Tests not classified as waived are assigned a moderate or high complexity category based on seven criteria given in the CLIA regulations, including ease of use, knowledge required, and types of materials tested. For commercially available FDA-cleared or approved tests, the test complexity is determined by the FDA during the pre-market approval process.

While CLIA establishes minimum federal standards, it allows states to enact more stringent state law requirements. At the federal level and in California, anyone may perform a waived test in a licensed laboratory. For moderate complexity tests, federal law requires that, at a minimum, personnel have 1) a high school diploma or equivalent and 2) documentation of training appropriate for the testing performed prior to analyzing patient specimens. However, in California, only specified licensed, certified, or otherwise authorized individuals may perform moderate complexity tests. There are two exceptions allowing unlicensed individuals to perform a moderate complexity test in California. One is for anyone performing a blood gas analysis under BPC § 1245 and anyone in a physician's office laboratory with a physician readily available."

Total Protein Digital Refractometer Test. According to information provided by the author, donor centers typically use a digital refractometer to perform the total protein test. FDA considers the refractometer as a moderate complexity test. There are multiple types of protein refractometer devices, ranging from manual to automatic and handheld to benchtop. Depending on the device, the rest requires varying, small samples of blood from the donor, which is then placed into the device. Generally, a manual device requires the user to analyze the sample and calculate the result. An automatic device performs the analysis without input from the user and displays the result, which the user then compares to a set of standard guidelines for total protein levels. The FDA's medical device database shows that the FDA has classified all total protein refractometer devices as of moderate complexity under CLIA…the total protein test helps to detect underlying conditions that may cause complications.

CDPH and Extending the Existing Pilot Program. Until 2018, state law required that the refractometer test be performed by various licensed personnel, such as a registered nurse or a clinical laboratory scientist, because the test is classified as a moderate complexity test under federal law. In 2015, AB 757 (Gomez of 2015) was introduced to authorize a person who met certain criteria to perform a total protein refractometer test using an automatic, button-operated refractometer with a digital readout in a licensed plasma collection facility in this state. Governor Brown vetoed the bill, stating that "f]ailure to perform and report this test accurately could lead to serious health consequences for the donor. The California Department of Public Health does not believe that the standards outlined in the bill for persons to perform this test ensure the health and safety of plasma donors."

In response, AB 613 (Nazarian, Chapter 799, Statutes of 2018) established a pilot program in order to demonstrate that an unlicensed individual could safely conduct a refractometer test. The pilot program, now codified into law, allows anyone with a

high school diploma to carry out the test, as long as that person has completed certain training requirements. The program sunsets at the beginning of 2021.

This bill would extend this pilot program by two years, allowing an unlicensed individual to perform a total protein test using a digital refractometer during the donor screening process at plasma donation centers until January 1, 2023. As they did for AB 613 in 2018, the sponsors of this bill argue that individuals conducting a digital refractometer test only need the current level of education and training outlined in the existing pilot program, rather than the previously-imposed standard.

Current Licensing Requirements for Operating a Refractometer. Under current state law, a person performing a total protein test must be supervised by a licensed individual who is available for consultation while the individual is processing specimens. These licensed individuals can be a moderate complexity laboratory technical consultant, a licensed registered nurse, a licensed physician or surgeon, or a clinical laboratory director. This bill would add a clinical laboratory scientists to the list of licensed professionals who can supervise an individual running the test.

Of the professionals listed, moderate complexity laboratory technical consultants have the most comparable training and experience to clinical laboratory scientists. However, there are important differences in training and experience between the two. Moderate clinical laboratory technical consultants must have an active license in California to perform high complexity testing or to practice medicine, osteopathy or podiatry. They also must have a minimum of two years of experience in moderate or high complexity testing in the specialty or specialties in which they are consulting. They are also generally responsible for the technical and scientific oversight of the laboratory.

In contrast, a clinical laboratory scientist is licensed to engage in clinical laboratory practice under the supervision of a clinical laboratory director. A person licensed as a clinical laboratory scientist and qualified under CLIA may perform clinical laboratory tests or examinations classified as of high or moderate complexity under CLIA. This means that clinical laboratory scientists: 1) are not licensed medical professionals whereas moderate complexity laboratory technical consultants may be, 2) are not required to have two years of experience in the field, and 3) do not have the training for a good understanding of the technical and scientific oversight of a laboratory.

Plasma Donation and COVID-19. The sponsors of this bill report that they are developing potential treatments for COVID-19 patients using plasma donated by individuals who have recovered from COVID-19. The goal is to use the antibodies found in the collected manufacture of hyperimmune globulins to treat COVID-19 patients. The convalescent plasma is being collected at licensed plasma donation centers in the United States, including California.

3. **Prior Related Legislation.** AB 613 (Nazarian, Chapter 799, Statutes of 2018) authorized an unlicensed individual who meets specified education and training requirements to perform a total protein test using a digital refractometer in a licensed plasma collection facility until January 1, 2021.

AB 757 (Gomez of 2015) would have authorized a person, who met specified criteria, to perform a total protein refractometer test using an automatic, button-operated refractometer with a digital readout in a licensed plasma collection facility in this state. This bill was vetoed by Governor Brown, who stated that "[f]ailure to perform and report this test accurately could lead to serious health consequences for the donor. The California Department of Public Health does not believe that the standards outlined in the bill for persons to perform this test ensure the health and safety of plasma donors."

4. **Arguments in Support.** Biocom writes in support: "Plasma therapy is an important element in many treatments, including hemophilia and several immunological diseases. It has also been widely discussed as a promising candidate for use as a treatment in the fight against COVID-19 in multiple ways. AB 2199 will facilitate significantly more plasma collection to occur in California, which is already home to significant research in this field."

   Cigna writes in support noting that its "specialty pharmacy, Accredo, provides specialty services to patients that need Immunoglobulin Therapy (IG) delivered in their home by its team of nurses. IG is obtained from a part of human blood called plasma. During production, the plasma is tested to make sure it is free from agents that may cause infection. Therefore, it's important that we continue to have plasma donation centers collecting and testing blood for protein levels so our patients have access to medicines and therapies that may save their lives. We are not aware of any quality of care concerns issues arising out of the existing pilot program that has been operating for a number of years in California. Moreover, the current practice of training personal and maintaining clinical oversight ensures that these donation centers are operating in a safe, efficient and effective manner."

   Immune Deficiency Foundation states that "California is home to only a handful of plasma donation centers, largely due to burdensome regulations. These regulations prevent licensed professionals from being utilized to the highest level of their job skills, resulting in less efficient source plasma donor screening. The lack of efficiency and minimal presence of plasma donation centers in California creates a reliance on plasma collection elsewhere and contributes to the strain on the global plasma supply. The need for plasma and plasma-derived products grows each year, for the PI community as well as globally, and updating the governance around plasma donation in California can help address that need. IDF believes that extending the pilot program in question is a step in this direction, and that it will demonstrate more efficient plasma collection in California, without compromised safety for plasma donors or users."

   According to Grifols, Inc. "In 2018, the California Legislature passed legislation to create a pilot to determine if a properly trained individual may satisfactorily perform a total protein test using a digital refractometer in a licensed plasma collection center. This is the federal standard followed in most of the 44 states where plasma is collected. Grifols was fortunate to have 5 plasma collection centers participate in the pilot and the results have shown that the properly trained, but unlicensed individual is able to satisfactorily perform the total protein test with no harm to the potential donor. These results are not surprising since properly trained, but unlicensed individuals perform the total protein test using a digital refractometer in

more than 800 source plasma donation centers in the United States. This test is performed to ensure an individual is suitable to donate source plasma on a given day."

Takeda Pharmaceuticals America states that "The outbreak of COVID-19 provides one example of the critical need for plasma-derived therapies and for robust plasma collection. Takeda has announced the company's participation in the CoVIg-19 Plasma Alliance which is an unprecedented partnership of world-leading plasma companies formed to meet the unprecedented challenge of COVID-19. The Alliance was established to accelerate the development of a potential plasma-derived hyperimmune globulin therapy for COVID-19. We will refer to the potential therapy as CoVIg-19. Alliance membership has expanded to include 10 plasma companies and now also includes global organizations from outside the plasma industry who are providing vital support to encourage more people to donate convalescent plasma (Microsoft, Google & Uber Health)."

The American Plasma Users Coalition (APLUS) believes that "the provisions found in AB 2199 will ensure that licensed professionals are utilized to the highest level of their job skills resulting in more efficient source plasma donor screening. It will free up specialized staff to perform other essential functions in these source plasma donation centers, such as conducting new donor physical examinations. This is critical because the growing clinical need for plasma medicines means we need more source plasma donations."

The Plasma Protein Therapeutics Association writes in support: "Plasma donation center personnel perform the total protein test as part of the pre-donation screening of potential donors. The purpose of the test is to monitor the protein levels of frequent donors. Infrequent donors are allowed to donate without a total protein test. The protein test is not a donor safety issue. Pilot-operators have successfully performed more than 360,000 pilot tests. There were more than 50,000,000 tests performed last year in the states that follow CLIA standards which are the California pilot standards. The pilot has shown that the properly trained, but unlicensed individual is able to satisfactorily perform the total protein test with no harm to the potential donor."

5. **Arguments in Opposition.** The California Nurses Association writes in opposition: "By shifting work that should be done by licensed and experienced personnel to unlicensed health care workers, AB 2199 deskills this workforce and creates potential health risks. The total protein refractometer test is used prior to a donor undergoing plasmapheresis. Because of the risks involved in this procedure, both federal and state laws require that a donor's total protein level be tested in order to ensure the donor's safety and well-being. The total protein refractometer test helps detect underlying conditions that may cause complications. If the test is performed incorrectly, significant harm to donor patients could results….Moreover, **supporters have not demonstrated that there is a shortage of licensed and experienced personnel requiring this change in law. AB 2199 is simply unnecessary.** In addition, it is clear that manufacturers of digital refractometers and other businesses stand to gain financially by this bill. Donor patients, on the other hand, will lose."

6. **Policy Considerations.**

COVID-19. COVID-19 has dramatically shifted policy priorities at the local, state, federal, and global levels, particularly in the healthcare industry. With scientists in a race for a cure, there is a desire to increase laboratories and centers that could potentially house and distribute a medical remedy. The sponsors of the bill have argued that increasing plasma centers could be crucial in distributing a plasma-based COVID-19 cure, and they report they have been developing a potential COVID-19 treatment. However, there is no evidence to suggest that a plasma therapeutic will appear on the market at this time. Additionally, those wishing to build and operate plasma centers in California are currently able to do so under existing law, and the COVID-19 crisis has taken a toll on the employees and resources of CDPH in particular. Therefore, while the intention to lay the groundwork for distribution of a COVID-19 cure is a good one, there are questions as to whether this legislation is necessary at this particular moment.

Qualified Personnel and Shortage of Personnel? With the data at CDPH still under review, it is currently unclear whether the pilot program has definitely proven what it set out to accomplish. The sponsors claim it has, stating that "[p]ilot-operators have successfully performed more than 360,000 pilot tests. There were more than 50,000,000 tests performed last year in the states that follow CLIA standards which are the California pilot standards." Opposition states there are still risks involved in the procedure, which is the reason why federal and state law required higher educational and experiential standards, and that "supporters have not demonstrated that there is a shortage of licensed and experienced personnel requiring this change in law." While changing existing law at this time by not extending the sunset date could create more confusion, it is also compelling that there is currently no demonstrated shortage of licensed and experienced personnel. The data from CDPH will provide important information to lay the groundwork for the path forward.

Are Experienced Supervisors Necessary? The fact that there are required experiential differences between a moderate complexity laboratory technical consultant—let alone a registered nurse, physician, or surgeon—and a clinical laboratory scientist as a supervisor should be noted when considering this bill. While supporters argue that none of these elements are necessary for the refractometer test supervised individuals are conducting, requiring years of experience supervising a particular test seems to be an important asset in ensuring donor safety and preventative measures/caution, especially in these COVID-19 times when the normal procedure protocols are changing.

SUPPORT AND OPPOSITION:

Support:

The Plasma Protein Therapeutics Association (sponsor)
Biocom
Cigna
Grifols, Inc.
Immune Deficiency Foundation
Takeda Pharmaceuticals America

The American Plasma Users Coalition

Opposition:

California Nurses Association

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