Date of Hearing: May 21, 2020

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
AB 2199 (Nazarian) – As Amended May 18, 2020

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. (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 who 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 my only perform the test, if the 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 the 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 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 the 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) Specifies following device criteria:

a) Is used within 30 feet of the donor for whom the test is being conducted. (BPC § 1246.7(b)(1))

b) Is used in accordance with the donor test management system, the quality control program, and the comprehensive quality assurance program established and maintained by the laboratory, as specified. (BPC § 1246.7(b)(2))

c) Performs total protein tests classified as waived or of moderate complexity under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. Sec. 263a). (BPC § 1246.7(b)(3))

d) Performs total protein tests using a digital refractometer on biological specimens that require manual blood collection, centrifugation to separate the blood cells from the plasma, pipetting the plasma from the cells, and application of the plasma into the refractometer. (BPC § 1246.7(b)(4))

e) Provides total protein test results without calculation or discretionary intervention by the testing personnel. (BPC § 1246.7(b)(5))

f) Performs total protein tests without the necessity for testing personnel to perform calibration or maintenance, except basic cleaning, resetting, and daily standardization pursuant to the manufacturer's instructions. (BPC § 1246.7(b)(6))

7) 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 the CDPH, as specified. (BPC § 1246.7(c))

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

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

FISCAL EFFECT: Unknown. This bill is keyed fiscal by the Legislative Counsel.

COMMENTS:

Purpose. This bill is sponsored by the *Plasma Protein Therapeutics Association*. According to the author, "By allowing trained and qualified plasma donation centers employees to perform the total protein test with a digital refractometer, [this bill] 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.

Background. This bill would extend an exemption under California clinical laboratory testing requirements 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. The sponsor of this bill represents private sector manufacturers of plasma protein therapies and collectors of source plasma. According to the sponsor, plasma protein therapies are used to treat medical conditions resulting from insufficient levels of plasma protein, including immune deficiencies and bleeding disorders.

The manufacturers and collectors require plasma donations in order to produce the therapies. In the U.S., plasma donors are paid, and the amount of payment varies by plasma center. These processes are regulated under federal and state biological product and clinical laboratory laws.

Plasma Derived Biologics. Plasma is a component of whole blood and contains blood proteins, which support ordinary bodily functions. Plasma that is separated from blood for the purposes of manufacturing medical products is known as source plasma. Among other things, source plasma can be used to produce therapeutic proteins. Facilities that produce products derived from blood are regulated and licensed under federal and state biologics laws (42 U.S. Code § 262; BPC §§ 1600-1630).

The process for separating source plasma from whole blood is called plasmapheresis. Like dialysis, plasmapheresis is a process during which blood is removed from a donor, the plasma separated from the formed elements, and the remaining blood is returned to the donor. Due to the risks involved, both federal and state biologics laws impose safety precautions for source plasma donations, including various testing, timing, and fatality reporting requirements.

CLIA. In addition to regulation under the biologics laws, plasma collectors and plasma derivative manufacturers must comply with the clinical laboratory testing requirements under CLIA. Federal and state law require that a plasma collection center test a donor's total protein level, among other things, prior to undergoing plasmapheresis (42 CFR §640.65(b)(1)(i); CCR, tit. 17, § 1025(b)). According to the sponsor, the total protein test helps detect underlying conditions that may cause complications.

At both the federal and state level, a facility that performs laboratory tests on human specimens for diagnostic or assessment purposes must be certified under CLIA. While CLIA establishes the minimum standards under federal law, it allows states to establish more stringent requirements under state law.

In all cases, the requirements for CLIA certification 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 laboratory tests under CLIA. 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.

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 the sponsors, the centers typically use a digital refractometer to perform the total protein test, which the FDA has categorized as a moderate complexity test. A refractometer is a device that shines a beam of light through a sample of liquid. The device measures the amount of light that is refracted (bent) due to the solids in the sample. In blood, protein causes light to bend. The greater the amount of protein, the more light is bent from the light path.

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. Because the test is categorized as moderate complexity at the federal level, state law requires that the test is performed by various licensed personnel under the BPC, such as a registered nurse or clinical laboratory scientist. The sponsor argues that the amount of training and education needed for these personnel is in excess of the amount needed for a total protein test using a digital refractometer in a plasma collection facility.

Plasma Donation Statistics. According to the sponsors, In 2019, there 53.5 million donations in the United States. 1.6 million of those donations were made in California plasma donation centers. 226,000 donations were made in New York, the other state that requires a license for the moderate complexity test performance. More than 51.5 million of those donations were performed using the same type of personnel as allowed in the pilot. The sponsors also report that, as of February 28, 2020, there are 849 plasma donation centers in the United States. 27 are in California. 12 are in New York. 810 centers utilize unlicensed personnel.

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.

Prior Related Legislation. AB 613 (Nazarian), Chapter 799, Statutes of 2018, established the exemption this bill would extend.

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 "Failure 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."

ARGUMENTS IN SUPPORT:

The *Plasma Protein Therapeutics Association* writes in support, "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 donated.

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. 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. The test is done to make sure an individual is suitable to donate source plasma on a given day.

[This bill] 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. It takes more than 130 source plasma donations to manufacture the Ig needed annually to treat an individual with primary immune deficiency….

This is where California may make a difference. California currently has 26 source plasma donation centers. This is a result of laws that are not conducive to source plasma donation. For comparison, there are more than 100 source plasma donation centers in Texas, more than 60 in Florida, and more than 40 in Ohio…. Plasma donation centers benefit the communities they are in by providing good jobs to more than 50 employees per center and an economic impact of more than $4 million annually."

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, [this bill] 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 result…. Moreover, supporters have not demonstrated that there is a shortage of licensed and experienced personnel requiring this change in law. [This bill] 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."

POLICY ISSUE(S) FOR CONSIDERATION:

Sunset Extension. This bill would extend the sunset date on a pilot program put into place in 2018. The goal of the program was to explore the safety of the use of unlicensed personnel or other individuals who are otherwise untrained to generally perform CLIA tests of moderate complexity using an automated digital refractometer to screen potential and repeat plasma donors. The prior bill that established the pilot put numerous patient safety provisions in place, including limiting the device to a class of point of care devices normally used by unlicensed personnel.

The initial version of this bill would have extended the program indefinitely. However, the prior bill provided several mechanisms allowing for the reporting of safety and accuracy data to the CDPH. According to the CDPH, that data is still under review. To allow the CDPH additional time, the author recently accepted amendments that further extended the sunset date.

However, plasma donation centers may not be willing to invest if the program is always at risk of sunsetting, the author may wish to continue to work with the CDPH and stakeholders to determine whether the sunset date should be eliminated upon the CDPH's review of the data.

IMPLEMENTATION ISSUES:

Training. According to the sponsors, the 5-hour training requirement put in place by the prior bill is arbitrary and redundant, as existing law already requires the plasma donation center and supervisors to appropriately train all personnel. The author recently accepted amendments to

reinsert this requirement to allow CDPH additional time to review data. Once the CDPH is able to review the data, the author may wish to continue to work with the CDPH and stakeholders to determine whether the training requirement should be removed or replaced.

Verification. The prior bill required that the unlicensed person accurately record the results of the total protein test in a federal FDA 510k-approved blood establishment computer system. It also required that the unlicensed person verify the results in one of four ways:

1) Using a digital refractometer that creates an electronic record of the test results.

2) 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 must affix their name to the record verifying the accuracy of the entries.

3) Affixing a date- and time-stamped photograph of the digital refractometer test results to the spreadsheet.

4) Using 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.

According to the sponsors, the verification requirement is onerous and conflicts with federal Good Manufacturing Practices for pharmaceuticals.

The author recently accepted amendments to reinsert this requirement to allow CDPH additional time to review data. Once the CDPH is able to review the data, the author may wish to continue to work with the CDPH and stakeholders to determine whether the verification requirement should be removed or replaced.

Clinical Laboratory Scientist Supervisor. The author recently accepted amendments to add clinical laboratory scientists as a supervisor under this bill at the request of the opposition. That request has been withdrawn. If this bill passes this committee, the author may wish to delete that provision.

REGISTERED SUPPORT:

Plasma Protein Therapeutics Association (sponsor)
American Plasma Users Coalition
Biocom
CSL Behring
Grifols, Inc.
Immune Deficiency Foundation
Takeda Pharmaceuticals America
Over 70 Individuals with Primary Immunodeficiencies

REGISTERED OPPOSITION:

California Nurses Association

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