

## ASSEMBLY THIRD READING

AB 2199 (Nazarian)

As Amended May 18, 2020

Majority vote

**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.

**Major Provisions****COMMENTS:**

*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.

*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.

**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."

**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."

#### **FISCAL COMMENTS:**

According to the Assembly Appropriations Committee, minor and absorbable costs to California Department of Public Health (CDPH) to continue oversight of this exemption (Licensing and Certification Fund).

#### **VOTES:**

##### **ASM BUSINESS AND PROFESSIONS: 18-0-1**

**YES:** Low, Brough, Arambula, Bloom, Chen, Cunningham, Eggman, Fong, Gipson, Gloria, Grayson, Holden, Irwin, McCarty, Medina, Mullin, Obernolte, Ting

**ABS, ABST OR NV:** Chiu

##### **ASM APPROPRIATIONS: 18-0-0**

**YES:** Gonzalez, Bigelow, Bauer-Kahan, Bloom, Bonta, Calderon, Carrillo, Chau, Megan Dahle, Diep, Eggman, Fong, Gabriel, Eduardo Garcia, Petrie-Norris, McCarty, Robert Rivas, Voepel

**UPDATED:**

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