SENATE RULES COMMITTEE AB 2199
Office of Senate Floor Analyses
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THIRD READING

Bill No: AB 2199
Author: Nazarian (D)
Amended: 8/25/20 in Senate
Vote: 21

SENATE BUS., PROF. & ECON. DEV. COMMITTEE: 9-0, 8/8/20
AYES: Glazer, Chang, Archuleta, Dodd, Galgiani, Hill, Leyva, Pan, Wilk

SENATE APPROPRIATIONS COMMITTEE: Senate Rule 28.8

ASSEMBLY FLOOR: 72-0, 6/8/20 - See last page for vote

SUBJECT: Healing arts: clinical laboratories

SOURCE: Plasma Protein Therapeutics Association

DIGEST: 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 person.

Senate Floor Amendments of 8/25/20 add technical and clarifying language.

ANALYSIS:

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 certain conditions have been met, including training for the individual performing testing and supervision and practice protocols.

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.

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. 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 Section 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. 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.

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 adds 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.

FISCAL EFFECT: Appropriation: No Fiscal Com.: Yes Local: Yes

SUPPORT: (Verified 8/25/20)

Plasma Protein Therapeutics Association (source)
Biocom
Cigna
Grifols, Inc.
Immune Deficiency Foundation
Takeda Pharmaceuticals America
The American Plasma Users Coalition

OPPOSITION: (Verified 8/25/20)

California Nurses Association

ARGUMENTS IN SUPPORT: Generally, supporters argue that the pilot program has provided data showing that properly trained, but unlicensed individuals are able to satisfactorily perform the total protein test with no harm to the potential donor. They argue extending the pilot program during COVID-19 makes sense so that the program can continue and so that plasma centers can be ready in the event that scientists develop a plasma therapy treatment for COVID-19.

ARGUMENTS IN OPPOSITION: The California Nurses Association argues that AB 2199 deskills the workforce and creates potential health risks, noting that "supporters have not demonstrated that there is a shortage of licensed and experienced personnel requiring this change in law. AB 2199 is simply unnecessary."

ASSEMBLY FLOOR: 72-0, 6/8/20
AYES: Aguiar-Curry, Arambula, Bauer-Kahan, Berman, Bigelow, Bloom, Boerner Horvath, Bonta, Brough, Burke, Calderon, Carrillo, Cervantes, Chau, Chen, Choi, Chu, Cooley, Cooper, Cunningham, Megan Dahle, Daly, Diep, Eggman, Flora, Fong, Frazier, Gabriel, Gallagher, Cristina Garcia, Eduardo Garcia, Gipson, Gloria, Gray, Grayson, Holden, Irwin, Jones-Sawyer, Kamlager, Kiley, Lackey, Levine, Limón, Low, Maienschein, Mathis, Mayes, McCarty, Medina, Mullin, Nazarian, Obernolte, O'Donnell, Patterson, Petrie-Norris, Quirk-Silva, Ramos, Reyes, Luz Rivas, Robert Rivas, Rodriguez, Blanca Rubio, Salas, Santiago, Smith, Mark Stone, Ting, Voepel, Waldron, Weber, Wood, Rendon
NO VOTE RECORDED: Chiu, Friedman, Gonzalez, Kalra, Muratsuchi, Quirk, Wicks

Prepared by: Dana Shaker / B., P. & E.D. /
8/26/20 15:01:00

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