AB-2107 Clinical laboratory technology: remote review. (2023-2024)

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Assembly Bill No. 2107

CHAPTER 699

An act to amend Section 1265 of, to add Section 1265.2 to, and to add and repeal Section 1265.3 of, the Business and Professions Code, relating to healing arts.

[Approved by Governor September 27, 2024. Filed with Secretary of State September 27, 2024.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2107, Chen. Clinical laboratory technology: remote review.

Existing law requires the State Department of Public Health to license, inspect, and regulate clinical laboratories and specified clinical laboratory personnel. Existing law requires a clinical laboratory, as defined, performing clinical laboratory tests or examinations classified as of moderate or of high complexity under the federal Clinical Laboratory Improvement Amendments (CLIA) to obtain a clinical laboratory license, as specified. Existing law requires a separate license or registration to be obtained for each laboratory location, except for, among other things, laboratories that are not at a fixed location, as specified.

This bill would authorize, upon determination by the department that the authorization conforms to federal law, practice by a pathologist who is performing pathology services at a primary laboratory site licensed by the state to review digital materials, as defined, at a remote location under a primary site's CLIA certificate. The bill would require the department, on or before June 30, 2025, to consult with the federal Centers for Medicare and Medicaid Services and would require the department to make a determination on or before January 1, 2026, for those purposes. This bill would require the department, if it determines that the authorization conforms to federal law, to communicate its determination to the Legislature and the Legislative Counsel Bureau. The bill would classify a location where digital materials are accessed by pathologists through virtual private networks, or other secure method, to be an extension of a primary site's CLIA certificate and would prohibit that remote location from requiring a separate license or registration, consistent with the interpretation of CLIA regulations by the federal Centers for Medicare and Medicaid Services guidelines, as specified.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. The Legislature finds and declares all of the following:

(a) The Legislature recognizes that the federal Centers for Medicare and Medicaid Services has taken steps to allow for remote review of pathology digital slides and other digital images or data in order to respond to recent public health emergencies.

(b) The Legislature is committed to ensuring that California's clinical laboratories can respond to the threat of a growing number of respiratory illness and other illnesses to ensure patient health and safety.

(c) In order to expand laboratory capacity and improve health care delivery, the Legislature finds it necessary to allow for remote review of pathology digital data, results, and images in accordance with guidelines established by the federal Centers for Medicare and Medicaid Services.

SEC. 2. Section 1265 of the Business and Professions Code is amended to read:

1265. (a) (1) A clinical laboratory performing clinical laboratory tests or examinations classified as of moderate or of high complexity under CLIA shall obtain a clinical laboratory license pursuant to this chapter. The department shall issue a clinical laboratory license to any person who has applied for the license on forms provided by the department and who is found to be in compliance with this chapter and the regulations pertaining thereto. No clinical laboratory license shall be issued by the department unless the clinical laboratory and its personnel meet the CLIA requirements for laboratories performing tests or examinations classified as of moderate or high complexity, or both.

(2) A clinical laboratory performing clinical laboratory tests or examinations subject to a certificate of waiver or a certificate of provider-performed microscopy under CLIA, shall register with the department. The department shall issue a clinical laboratory registration to any person who has applied for the registration on forms provided by the department and is found to be in compliance with this chapter, the regulations pertaining thereto, and the CLIA requirements for either a certificate of waiver or a certificate of provider-performed microscopy.

(b) An application for a clinical laboratory license or registration shall include the name or names of the owner or the owners, the name or names of the laboratory director or directors, the name and location of the laboratory, a list of the clinical laboratory tests or examinations performed by the laboratory by name and total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assurance, or proficiency testing purposes). The application shall also include a list of the tests and the test kits, methodologies, and laboratory equipment used, and the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures, and any other relevant information as may be required by the department. If the laboratory is performing tests subject to a provider-performed microscopy certificate, the name of the provider or providers performing those tests shall be included on the application. Application shall be made by the owners of the laboratory and the laboratory directors prior to its opening. A license or registration to conduct a clinical laboratory if the owners are not the laboratory directors shall be issued jointly to the owners and the laboratory directors and the license or registration shall include any information as may be required by the department. The owners and laboratory directors shall be severally and jointly responsible to the department for the maintenance and conduct thereof or for any violations of this chapter and regulations pertaining thereto.

(c) The department shall not issue a license or registration until it is satisfied that the clinical laboratory will be operated within the spirit and intent of this chapter, that the owners and laboratory directors are each of good moral character, and that the granting of the license will not be in conflict with the interests of public health.

(d) A separate license or registration shall be obtained for each laboratory location, with the following exceptions:

(1) Laboratories that are not at a fixed location, that is, laboratories that move from one testing site to another, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations, may apply for and obtain one license or registration for the designated primary site or home base, using the address of that primary site.

(2) Not-for-profit, or federal, state, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests, as defined under CLIA, per license) public health testing may apply for and obtain a single license or registration.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction, may file a single application or multiple applications for a license or registration of laboratory locations within the same campus or street address.

(4) Locations within a single street and city address that are under common ownership may apply for and obtain a single license or registration or multiple licenses or registrations, at the discretion of the owner or owners.

(e) (1) A license or registration shall be valid for one year unless revoked or suspended. A clinical laboratory license or registration shall be automatically revoked 30 days from a major change of laboratory directorship or ownership. The clinical laboratory shall be required to submit a completed application for a new clinical laboratory license or registration within those 30 days or cease engaging in clinical laboratory practice.

(2) If a clinical laboratory intends to continue to engage in clinical laboratory practice during the 30 days after a major change in directorship occurs and before the laboratory license or registration is automatically revoked, the laboratory owner may appoint an interim director who meets the requirements of this chapter and CLIA. The interim director shall be appointed within five

business days of the major change of the directorship. Written notice shall be provided to the department of the appointment of the laboratory director pursuant to this paragraph within five business days of the appointment.

(f) If the department does not within 60 days after the date of receipt of the application issue a license or registration, it shall state the grounds and reasons for its refusal in writing, serving a copy upon the applicant by certified mail addressed to the applicant at their last known address.

(g) The department shall be notified in writing by the laboratory owners or delegated representatives of the owners and the laboratory directors of any change in ownership, directorship, name, or location, including the addition or deletion of laboratory owners or laboratory directors within 30 days. However, notice of change in ownership shall be the responsibility of both the current and new owners. Laboratory owners and directors to whom the current license or registration is issued shall remain jointly and severally responsible to the department for the operation, maintenance, and conduct of the clinical laboratory and for any violations of this chapter or the regulations adopted thereunder, including any failure to provide the notifications required by this subdivision, until proper notice is received by the department. In addition, failure of the laboratory owners and directors to notify the department within 30 days of any change in laboratory directors, including any additions or deletions, shall result in the automatic revocation of the clinical laboratory's license or registration.

(h) The withdrawal of an application for a license or registration or for a renewal of a license, or registration, issuable under this chapter, shall not, after the application has been filed with the department, deprive the department of its authority to institute or continue a proceeding against the applicant for denial of the license, registration, or renewal upon any ground provided by law or to enter an order denying the license, registration, or renewal upon any such ground, unless the department consents in writing to the withdrawal.

(i) The suspension, expiration, or forfeiture by operation of law of a license or registration issued under this chapter, or its suspension, forfeiture, or cancellation by order of the department or by order of a court of law, or its surrender without the written consent of the department, shall not deprive the department of its authority to institute or continue an action against a license or registration issued under this chapter or against the laboratory owner or laboratory director upon any ground provided by law or to enter an order suspending or revoking the license or registration issued under this chapter.

(j) (1) Whenever a clinical laboratory ceases operations, the laboratory owners, or delegated representatives of the owners, and the laboratory directors shall notify the department of this fact, in writing, within 30 calendar days from the date a clinical laboratory ceases operation. For purposes of this subdivision, a laboratory ceases operations when it suspends the performance of all clinical laboratory tests or examinations for 30 calendar days at the location for which the clinical laboratory is licensed or registered.

(2) (A) Notwithstanding any other provision of law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve medical records and laboratory records, as defined in this section, for three years from the date of testing, examination, or purchase, unless a longer retention period is required pursuant to any other provision of law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department.

(B) For purposes of this subdivision, "medical records" means the test requisition or test authorization, or the patient's chart or medical record, if used as the test requisition, the final and preliminary test or examination result, and the name of the person contacted if the laboratory test or examination result indicated an imminent life-threatening result or was of panic value.

(C) For purposes of this subdivision, "laboratory records" means records showing compliance with CLIA and this chapter during a laboratory's operation that are actual or true copies, either photocopies or electronically reproducible copies, of records for patient test management, quality control, quality assurance, and all invoices documenting the purchase or lease of laboratory equipment and test kits, reagents, or media.

(D) Information contained in medical records and laboratory records shall be confidential, and shall be disclosed only to authorized persons in accordance with federal, state, and local laws.

(3) The department or any person injured as a result of a laboratory's abandonment or failure to retain records pursuant to this section may bring an action in a court of proper jurisdiction for any reasonable amount of damages suffered as a result thereof.

(k) For purposes of this section, in the case of a pharmacy that applies for a registration pursuant to Section 1206.6, "laboratory director" means the pharmacist-in-charge identified pursuant to subdivision (a) of Section 1206.6.

(l) For the purposes of this section, a location where digital materials, as defined in Section 1265.2, are accessed by pathologists through virtual private networks, or other secure method, and for which no additional laboratory equipment is required, shall be interpreted as an extension of a primary site's CLIA certificate and that remote location shall not require a separate license or

registration, consistent with the interpretation of CLIA regulations by the federal Centers for Medicare and Medicaid Services guidelines, and as may be amended or updated from time to time.

SEC. 3. Section 1265.2 is added to the Business and Professions Code, to read:

1265.2. (a) For purposes of this section, “digital materials” means digital laboratory data, digital results, and digital images that do not require a microscope or other equipment essential to a separate laboratory.

(b) A pathologist who is performing pathology services at a primary laboratory site licensed by the state may review digital materials at a remote location under a primary site’s CLIA certificate pursuant to subdivision (l) of Section 1265.

(c) This section shall become operative if the department determines, pursuant to Section 1265.3, that this section conforms to the federal Clinical Laboratory Improvement Amendments of 1988 as amended by Section 353 of the federal Public Health Service Act.

SEC. 4. Section 1265.3 is added to the Business and Professions Code, to read:

1265.3. (a) On or before June 30, 2025, the department shall consult with the federal Centers for Medicare and Medicaid Services for the purpose described in subdivision (b).

(b) (1) On or before January 1, 2026, the department, in consultation with the federal Centers for Medicare and Medicaid Services, shall make a determination whether Section 1265.2 conforms to the federal Clinical Laboratory Improvement Amendments of 1988 as amended by Section 353 of the federal Public Health Service Act.

(2) If the department determines Section 1265.2 conforms to the federal Clinical Laboratory Improvement Amendments of 1988 as amended by Section 353 of the federal Public Health Service Act, it shall communicate this finding in a letter to the Legislature and to the Legislative Counsel Bureau.

(c) This section shall remain in effect only until January 1, 2027, and as of that date is repealed.