

Assembly Bill No. 1175

CHAPTER 61

An act to amend Section 1209.5 of the Business and Professions Code, relating to clinical laboratories, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor July 12, 2007. Filed with
Secretary of State July 12, 2007.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1175, Niello. Clinical laboratories: personnel.

Existing law provides for the regulation and licensure of clinical laboratories and clinical laboratory personnel by the State Department of Health Services until June 30, 2007, and thereafter by the State Department of Public Health.

Existing law requires a laboratory director or a licensed authorized designee, who is required to be appointed by the laboratory director, to establish, validate, and document explicit criteria by which clinical laboratory test or examination results are autoverified, as defined.

This bill would instead specify that an authorized designee may be appointed by the laboratory director.

This bill would declare that it is to take effect immediately as an urgency statute.

The people of the State of California do enact as follows:

SECTION 1. Section 1209.5 of the Business and Professions Code is amended to read:

1209.5. (a) "Autoverification" means the use of a computer algorithm in conjunction with automated clinical laboratory instrumentation to review and verify the results of a clinical laboratory test or examination for accuracy and reliability.

(b) The laboratory director or authorized designee shall establish, validate, and document explicit criteria by which the clinical laboratory test or examination results are autoverified.

(c) The laboratory director or authorized designee shall annually revalidate the explicit criteria by which the clinical laboratory test or examination results are autoverified. The laboratory director shall approve and annually reapprove the computer algorithm.

(d) An authorized designee may be appointed by the laboratory director for the purposes of this section. The authorized designee shall be licensed to engage in clinical laboratory practice pursuant to this chapter and shall

be qualified as a clinical consultant, technical supervisor, general supervisor, or technical consultant pursuant to regulations adopted by the department.

(e) A person licensed to perform the applicable type and complexity of testing pursuant to Section 1206.5 shall be physically present onsite in the clinical laboratory and shall have documented competency pursuant to Section 1209 in all tests being autoverified, and shall be responsible for the accuracy and reliability of the results of the clinical laboratory test or examination when the results are autoverified and reported.

SEC. 2. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to protect the public's health and safety as soon as possible by clarifying the duties and responsibilities of clinical laboratory personnel, it is necessary that this act take effect immediately.