State of California—Health and Human Services Agency
California Department of Public Health

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NOTICE OF PROPOSED RULEMAKING
Title 17. PUBLIC HEALTH
2003 Clinical Lab Improvement Amendment (CLIA) Crosswalk Part 2
Publication Date: February 21, 2020

NOTICE IS HEREBY GIVEN that the California Department of Public Health (Department) proposes to adopt the proposed regulations described below after considering all comments, objections, and recommendations regarding the proposed action.

PUBLIC PROCEEDINGS

The Department is conducting a 45-day written public proceeding during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions (referred to as comments) relevant to the action described in the Informative Digest/Policy Statement Overview section of this notice.

PUBLIC HEARING

A hearing is not scheduled. Pursuant to Government Code section 11346.8, a written request for a hearing may be submitted no later than 15 days prior to the close of the written comment period.

WRITTEN COMMENT PERIOD

Written comments pertaining to this proposal, regardless of the method of transmittal, must be received by Office of Regulations **on April 6, 2020**, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely.

Written comments may be submitted as follows:

1. By email to: Regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "DPH-16-002, 2003 CLIA Crosswalk Part 2" in the subject line identification and review of the comment;
2. By fax transmission to 1(916) 636-6220;
3. By completing the online comment form on the rulemaking's Web page at DPH-16-002, 2003 CLIA Crosswalk Part 2;
4. By postal service or hand delivered to California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, MS 0507, Sacramento, CA 95814.

ASSISTIVE SERVICES

The Department can provide assistive services such as the conversion of written materials into Braille, large print, audiocassette, and computer disk. For public hearings, assistive services can include sign-language interpretation, real-time captioning, note taking, reading, or writing assistance. To request these services, please call (916) 558-1710 or California Relay at 711, 1-800-735-2929 (at no cost) or 1-800-735-2922, if you do not have a TDD. Note: The range of assistive services available may be limited if requests are made less than 10 business days prior to a public hearing.

AUTHORITY AND REFERENCE

The Department proposes to adopt the proposed action under the authority granted by the California Business and Professions Code sections 1208 and 1224, and Health and Safety Code section 131200. The proposed regulations implement, interpret, and make specific sections 1220, 1225 and 1265 of the Business and Professions Code, and sections 131050, 131051, and 131052 of the Health and Safety Code.

COMPARABLE FEDERAL REGULATIONS OR STATUTES

The Department has conducted a review of federal regulations and statutes and determined there are no comparable federal regulations or statutes.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Business and Professions Code section 1208, subdivision (b), (hereafter section 1208, subd. (b)) requires the Department, in consultation with the California Laboratory Technology Advisory Committee (CLTAC) to review any Clinical Laboratory Improvement Amendments (CLIA) regulation adopted by the Health Care Finance Administration[1] (HCFA) as a final rule after January 1, 1994, and make a stringency determination for each subpart of the regulation. Section 1208, subd. (b) provides the means to adopt via operation of law those subparts found to be equivalent to or more stringent than California law. The subparts of 2003 CLIA determined to be equivalent to or more stringent than California law became effective by operation of law 60 days after the October 7, 2016, publication date in the California Regulatory Notice Register. (California Regulatory Notice Register 2016, No. 41-Z, pages 1825-1826; see Bus. & Prof. Code, § 1208, subd. (b).)

Section 1208, subd. (b) requires the Department to notice any federal regulation found to be less stringent than California law "as a comparable state regulation for a rulemaking proceeding in accordance with Chapter 3.5 (commencing with section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, which shall result in the adoption, amendment, or rejection of that noticed state regulation." (Bus. & Prof. Code, § 1208, subd. (b).)

State law requires clinical laboratories to retain the records listed in Business and Professions Code section 1265, subdivision (j)(2), for three years. The records listed include test requisition and authorization records, test procedure records, quality control and patient test records, test system performance specifications, quality systems

[1] The HCFA is now known as the Centers for Medicare and Medicaid Services (CMS).

assessment records, and test reports. (Bus. & Prof. Code, § 1265, subd. (j)(2).) The federal requirement under the CLIA of 1988 (42 C.F.R. § 493 et seq.), effective January 24, 2003, is to retain these types of records for two years. (42 C.F.R. § 493.1105(a)(1), (2), (3), (3)(i), (5), & (6).) The effect of the proposed rulemaking action is to reject the six subparts of federal regulations pertaining to clinical laboratory record retention requirements that are less stringent than California law.

Anticipated Benefits of the Proposed Regulation:

Once the proposed action becomes effective, California law will uniformly incorporate updates to CLIA after the adoption of the CLIA regulations in 1994 and make clear which provisions of 2003 CLIA are less stringent than California law.

The broad objectives of this proposed regulatory action are to:

- Comply with the statutory mandate to adopt or reject the 2003 updates to CLIA.
- Adhere to federal laboratory guidelines while preserving California authority when state law is more stringent than federal law.

The specific benefits of the proposed action are:

- Protection of public health and safety by rejecting federal laboratory standards that are less stringent than current California law.
- Elimination of confusion among the regulated public by completing the statutorily mandated process of adopting CLIA updates.
- Creation of uniformity in the California regulatory scheme by consistent reference to 2003 CLIA rather than 1994 CLIA.
- Clarification in regulation of the adoption of 2003 CLIA, via operation of law, when the Department published its decision in the California Regulatory Notice Register in 2016.

Adopt California Code of Regulations, Title 17, section 1053 as follows:

Adopt subdivision (a): The Department proposes to adopt subdivision (a) in order to make clear in regulation the adoption of 2003 CLIA, via operation of law, when the Department published its decision in the California Regulatory Notice Register in 2016. The reference to the 2003 CLIA Crosswalk package (published in the California Regulatory Notice Register 2016, Number 41-Z, pp. 1825-26) is necessary to notify the regulated public of the change in the law and to provide clarity on how subdivision (b) fits into the regulatory scheme after 2003 CLIA Crosswalk became effective via operation of law.

Adopt subdivision (b): The Department proposes to adopt subdivision (b) in order to interpret and make specific the mandate in section 1208(b) to identify the subparts of 2003 CLIA that are less stringent than California law. This regulation identifies and rejects the six subparts that are less stringent. The Department made the stringency determinations for each subpart listed in subdivision (b) in consultation with the Department's multidisciplinary committee, CLTAC. (Document Relied Upon No. 2, pp. 19-27.) The Department published the stringency determinations in the 2003 CLIA Crosswalk Report, and the subparts are discussed on the following pages of the report:

- 42 C.F.R. § 493.1105(a)(1) on pages 19-20
- 42 C.F.R. § 493.1105(a)(2) on pages 20-21
- 42 C.F.R. § 493.1105(a)(3) on pages 21-22
- 42 C.F.R. § 493.1105(a)(3)(i) on pages 22-23
- 42 C.F.R. § 493.1105(a)(5) on pages 24-25
- 42 C.F.R. § 493.1105(a)(6) on pages 25-26

This regulation is necessary to clarify for the regulated public which subparts of 2003 CLIA should not be followed and that they should instead follow the more stringent provisions in California law. This regulation is also necessary because there are currently no regulations in the California Code of Regulations concerning record retention requirements for clinical laboratories. Current record retention standards are found in Business and Professions Code section 1265, subdivision (j) and in section 1220, subdivision (d)(2), which is a reference to two subparts of 2003 CLIA. Section 1053 subdivision (b) of Title 17 provides a convenient cross-reference for laboratories to locate the federal and state standards for record retention in one regulation. The reference to applicable state law ensures that this regulation is consistent with current state statutes requiring retention of records by clinical laboratories. (See Bus. & Prof. Code, §§ 1220, subd. (d)(2), 1265, subd. (j).)

The requirement in subdivision (b) to comply with applicable state law is a necessary duplication of an existing state statute in Business and Professions Code section 1265, subdivision (j) (hereinafter section 1265(j)) because it notifies the regulated public of the correct standard to follow for record retention. The rejection of the federal standards in 2003 CLIA that are listed in subdivision (b) necessitates a reference to the correct standard in section 1265(j) for clarity.

Adopt subdivision (b), Table 1: The Department proposes to adopt Table 1 in subdivision (b) in order to show the parts of California law that have changed and those that have not changed. The table is necessary to present in an organized fashion the history of adoption of 2003 CLIA in California and the current state of the law upon adoption of this regulation. Because this regulation rejects updated federal standards in favor of existing state standards, the regulated public will have to look to multiple sources of law to determine the correct standard to follow for each type of record listed in the table. Table 1 consolidates all applicable law into one location and provides a clear directive to clinical laboratories for which standard to follow.

The notation of the state statute section that clinical laboratories should comply with in the table is a necessary duplication of an existing state statute in section 1265(j) because it notifies the regulated public of the correct standard to follow for record retention. The rejection of the federal standards in 2003 CLIA that are listed in subdivision (b) and in the table necessitates a reference to the correct standard in section 1265(j) for clarity.

Evaluation of Inconsistency/Incompatibility with Existing State Regulations:

The Department has decided that these regulations are neither inconsistent nor incompatible with other state regulations. These regulations require that all clinical

laboratories licensed or registered by the Department comply with applicable state law regarding retention of records.

INCORPORATION BY REFERENCE

There are no documents or forms incorporated by reference in the proposed regulation.

COMPARABLE FEDERAL REGULATIONS OR STATUTES

The requirements of proposed section 1053 in subdivision (b), including paragraphs (1) through (6), differ from comparable federal regulations containing record retention requirements for clinical laboratories. The federal requirement for the types of records specified in 42 Code of Federal Regulations part 493.1105(a), subparts (1), (2), (3), (3)(i), (5), and (6) is to retain records for two years. The state law requirement for the same types of records, located in Business and Professions Code section 1265, subdivision (j)(2), is to retain records for three years. The Department has opted to reject the standard in federal regulations because it is less stringent than state law, under its authority pursuant to section 1208, subd. (b).

MANDATED BY FEDERAL LAW OR REGULATIONS

Federal regulations at 42 CFR § 493.1105(a)(1), (2), (3), (3)(i), (5), and (6) require clinical laboratories to retain records for two years. The proposed regulations require clinical laboratories to follow the more stringent requirements of California law at Business and Professions Code section 1220, subdivision (d)(2), and section 1265, subsection (j), which require laboratories to retain records for three years. This preserves California authority where state law is more stringent than federal law.

OTHER STATUTORY REQUIREMENTS

There are no other requirements identified in the Notice that are specific to the agency or to any specific regulation or class of regulation.

LOCAL MANDATE

The proposed regulations do not impose a mandate on local agencies or school districts.

FISCAL IMPACT ESTIMATE

Cost to any local agency or school district requiring reimbursement pursuant to Government Code sections 17500 through 17630:
The proposed regulations do not impose any cost to any local agencies or school district requiring reimbursement pursuant to Government Code sections 17500 et seq.

Cost or saving to any state agency:
The proposed regulations do not impose any cost or result in any saving to any state agency.

Other non-discretionary cost or saving imposed on local agencies:
The proposed regulations do not impose any non-discretionary cost or result in any nondiscretionary saving upon local agencies.

Cost or saving in federal funding to the state:
The proposed regulations do not impose any cost or result in any saving in federal funding to the state.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING THE ABILITY TO COMPETE WITH BUSINESSES IN OTHER STATES

The proposed regulations will not have any statewide adverse economic impact directly affecting business or the ability of California businesses to compete with businesses in other states.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS

The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The Department has made an initial determination and conclude that the proposed regulation will not significantly affect:

(A) The creation or elimination of jobs within the state.
(B) The creation of new businesses or the elimination of existing businesses within the state.
(C) The expansion of businesses currently doing business with the state.
(D)The benefits of the regulation to the health and welfare of California residents, worker safety, and the state's environment are maintained by the State's rejection of the federal laboratory standards for record retention that are less stringent than the requirements of current California clinical laboratory laws. The proposed regulations will also eliminate confusion among the regulated public by completing the statutorily mandated process of adopting federal CLIA updates in California law.

BUSINESS REPORTING REQUIREMENT

The proposed regulations do not require businesses to make any reports.

HOUSING COSTS

The proposed regulations will not have a significant effect on housing costs.

EFFECT ON SMALL BUSINESS

The proposed regulations will not affect small businesses because they do not require any businesses to make changes to current practices. They clarify that businesses, including small businesses, must continue to follow the record retention requirements in current California law.

SPECIFIC TECHNOLOGIES OR EQUIPMENT

This regulation does not mandate the use of specific technologies or equipment.

ALTERNATIVES CONSIDERED

In accordance with Government Code section 11346.5, subdivision (a)(13), the Department must determine that no reasonable alternative it considered or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Department did not identify any alternatives to the regulation. Current state law requires a record retention period that is more stringent than the record retention period for the six subparts of 2003 CLIA listed in this regulation. Therefore, the Department has no discretion to create a regulation that conflicts with the statutory retention requirement and must reject the six subparts of 2003 CLIA. Performance standards were not considered as an alternative because this regulation is not prescriptive.

The Department invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations at the scheduled hearing or during the written comment period.

CONTACT PERSONS

Inquiries regarding the subject proposed regulations should be directed to Mary Wogec, from the Department's Laboratory Field Services branch at (510) 620-3793. Other questions concerning the notice may be directed to the Office of Regulations at (916) 440-7673, or to Michael Boutros, Chief of Regulations at (916) 440-7822.

AVAILABILITY STATEMENTS

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, at the address noted above, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

To request a copy of the public notice, regulation text, and the initial statement of reasons or an alternate format, please call (916) 558-1710 (or California Relay at 711/1-800-735-2929), or email regulations@cdph.ca.gov, or write to the Office of Regulations at the address noted above (**Enter DPH-16-002 in the subject line**.) Upon specific request, these documents will be made available in Braille, large print, and audiocassette or computer disk.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

FINAL STATEMENT OF REASONS

Upon its completion, copies of the final statement of reasons may be obtained by checking the website at the link provided below.

Materials regarding the action described in this notice (the regulation text and the initial statement of reasons) may be accessed via the Internet at www.cdph.ca.gov . From CDPH.ca.gov, Click “Programs,” “Office of Regulations”, then the link “Proposed Regulations.”