INITIAL STATEMENT OF REASONS

Summary of the Proposed Regulatory Action

The California Department of Public Health (Department) proposes to adopt section 1053 in Title 17 of the California Code of Regulations to complete the process of adopting the 2003 updates to federal regulations concerning clinical laboratories in California law. This regulation package is a follow-up to DPH-Exempt-15-013, titled 2003 CLIA Crosswalk. The purpose of that package was to adopt as California law the January 24, 2003, updates to the federal Clinical Laboratory Improvement Amendments (CLIA). (Document Relied Upon No. 3.) 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. (Document Relied Upon No. 1; see Bus. & Prof. Code, § 1208, subd. (b).)

Business and Professions Code section 1208 (hereafter section 1208) requires the Department, in consultation with the California Laboratory Technology Advisory Committee (CLTAC), to review any CLIA regulation adopted by the Health Care Financing Administration[1] (HCFA) as a final rule after January 1, 1994, and make a stringency determination for each subpart of the regulation. Section 1208 subdivision (b) provides the means to adopt via operation of law those subparts found to be equivalent to or more stringent than California law, and requires regulations to be noticed that result in adoption, amendment, or rejection of those subparts found to be less stringent than California law.

This regulation package is needed to complete the process, mandated in section 1208, of adopting the 2003 CLIA updates by making stringency determinations for six subparts of 2003 CLIA found to be less stringent than California law. Without this package, California has adopted the subparts of 2003 CLIA that are equivalent to or more stringent than California law, but leaves unclarified those subparts that are less stringent. Once the proposed rulemaking action becomes effective, California law will uniformly incorporate updates to CLIA after the adoption of the CLIA regulations in 1994.

Background and Summary of Existing Laws and Regulations

The following is taken from the California Regulatory Notice Register 2016, October 7, No. 41-Z, pages 1825-1826. (Document Relied Upon No. 1.)

> California's clinical laboratory licensing scheme incorporates the federal CLIA regulations for proficiency testing, patient test management, and quality control. When California first adopted subparts of the federal Clinical Laboratory Improvement Amendments (CLIA) regulations under Senate Bill (SB) 113 (Maddy, Chapter 510, Statutes of 1995), the State expressly incorporated the version of the CLIA regulations in effect on January 1, 1994. Without any action by the California Department of Public Health (Department) (under the mechanism described below) or an

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

act of the Legislature (through legislation), the January 1, 1994, version of the CLIA regulations remains effective in California despite federal updates to the underlying CLIA regulations.

The Legislature provided the Department with a mechanism to update the incorporated CLIA regulations to ensure that California remains consistent with the changes to the federal CLIA regulations that occur over time. Section 1208, subsection (b), of the California Business and Professions Code states that any CLIA regulation adopted by the Health Care Financing Administration of the federal Department of Health and Human Services (HCFA) as a final rule must be evaluated by the Department in consultation with the Department's multidisciplinary committee called the Clinical Laboratory Technical Advisory Committee (CLTAC). (A final rule is a document that is published in the Federal Register which adds to, amends, or repeals a provision of the Code of Federal Regulations after a specified effective date.) In evaluating the final rule, the Department must determine whether the revised federal CLIA regulation is less stringent, equivalent to, or more stringent than an existing California law or regulation.

Any new federal CLIA requirement that the Department deems equivalent to or more stringent than an existing California requirement becomes effective in California by operation of law 60 days after the Department notices its determination in the California Regulatory Notice Register. Any new federal CLIA regulation that the Department determines is less stringent than California law must be noticed for a rulemaking proceeding pursuant to the Administrative Procedure Act (APA) as a "comparable state regulation," to result in the adoption, amendment, or rejection of the less stringent provision.

On January 24, 2003, the Centers for Medicare and Medicaid Services published a final rule entitled "Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications," which, among other things, significantly revised the federal CLIA regulations by amending and consolidating portions of Subparts H, J, K, and P.

The 2003 CLIA Crosswalk project (undertaken by the Department and CLTAC) involved comparing changes in Subpart K of CLIA, relating to laboratory quality systems, between the 1994 version and the 2003 revisions. This portion of the 2003 CLIA Crosswalk was preempted by the legislature in 2015 when SB 75 (Ch. 18, Stats. 2015) amended Business and Professions Code, section 1220, subdivision (d)(2), effectively updating the incorporated version of the CLIA regulations for Subpart K to the version in effect on January 1, 2015. As a result, all the stringency determinations for Subpart K were removed from the 2003 CLIA Crosswalk, as they are now superseded by statute. The remainder of the

2003 CLIA Crosswalk compares revisions to the federal CLIA regulations under the final rule stated above in Subparts H and J. The latest version is intended to be comprehensive of the revisions in the final rule.

In the consultation process with CLTAC, the Department has prepared a justification document which includes the new CLIA regulation, an inventory of existing California law, and the legal rationale behind each proposed stringency determination. To the extent available, the comparison sheet also includes the federal Health and Human Services' supporting reasoning for changes to the CLIA regulations. For the purposes of the crosswalk, "more stringent" and "equivalent" have the same legal effect- i.e., when noticed, the provision is adopted as a California regulation by operation of law.

Each of the six CLIA revisions deemed "less stringent" related to California's three-year minimum retention period for laboratory and medical records under Business and Professions Code, section 1265, subdivision (j)(2), which is longer than CLIA's two- year retention period for a subset of those records. As indicated above, any new federal CLIA regulations that the Department determines is less stringent must be addressed in a regulation adopted pursuant to the APA.

Policy Statement Overview

Section 1208, subdivision (b), requires the Department to propose regulations that adopt, amend, or reject the subparts of updated federal CLIA regulations found to be less stringent than California law. This regulation package is necessary to complete the process of adopting into state law the 2003 CLIA updates by making stringency determinations for and rejecting the six subparts of 2003 CLIA found to be less stringent than California law. Without this proposed regulation, California has adopted the subparts of 2003 CLIA that are equivalent to or more stringent than California law, but leaves unclarified those subparts that are less stringent. This inconsistency in state law governing clinical laboratories is burdensome for the regulated community because it creates confusion as to which federal and state standards must be followed.

Objectives:

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.

Benefits:

The anticipated benefits of this proposed regulatory 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.

Detailed Discussion of Each Regulatory Provision Proposed to be Amended

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 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.

Documents Relied Upon

1. Notice Concerning “Federal Clinical Laboratory Improvement Amendments” Regulations Adopted as Final Rule by the Federal Health Care Financing Administration and the California Department of Public Health’s Determination of Equivalency in California per Business and Professions Code section 1208, California Regulatory Notice Register Oct. 7, 2016, No. 41-Z 1825-1826.

2. Cal. Dept. of Public Health, Office of Legal Services, 2003 CLIA Crosswalk – DPH-Exempt-15-013 Revisions and Justifications Report (PDF), Oct. 7, 2016 (referenced in the Cal. Reg. Notice Register 2016, 41-Z, on page 1826.)

3. Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; Final Rule, Centers for Medicare and Medicaid Services & Centers for Disease Control and Prevention (68 Fed.Reg. pp. 3640-3642, 3651-3653, 3674-3675, and 3703-3704 (Jan. 24, 2003).

Reasonable Alternatives to the Regulation and the Department's Reasons for Rejecting Those Alternatives

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.

Economic Impact Assessment

The Department has determined that the proposed regulatory action would have no significant direct economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

The proposed regulation rejects federal laboratory standards for test record retention that are less stringent than the requirements of current California clinical laboratory laws. The proposed changes to current regulations do not have any associated costs because they clarify that existing state statutes supersede existing federal regulations, but do not impose new requirements.

Federal law requires clinical laboratory businesses to retain medical and laboratory records for two years; California law at Business and Professions Code section 1265(j)(2) requires clinical laboratories to retain medical and laboratory records for three years. California businesses are required to follow the more stringent of two laws if there are conflicts in compliance requirements.

The proposed regulation does not change federal or state requirements, but only clarifies that businesses must continue to follow the record retention requirements in current California law and maintain their current three-year storage timeframe for records.

Therefore, the proposed regulation will not impose new costs or have any other economic impact on regulated businesses. The regulation does not require businesses to make any changes to current practices, therefore it will not require changes that would create or eliminate jobs, affect housing costs, create new businesses, or eliminate existing businesses. California businesses continuing to operate under current requirements will not gain a new competitive advantage over similar businesses in other states or be put at a new disadvantage. The proposed regulations will not have any distinct impact on small business, as it requires all businesses to continue to follow existing California laws regarding record retention.

It is difficult to calculate the costs for record storage due to the wide range of laboratory configurations. Smaller laboratories with fewer records may pay less overall for their storage systems but use those systems for a variety of applications from administration to testing and record keeping (of all sorts). Other laboratories may only use a small portion of their overall computational or data storage capacity for clinical testing matters and/or clinical testing records storage. The largest laboratories may have centralized

systems to serve multiple sites and functions. Current costs for three years of record storage for a laboratory are estimated to be $16,171.00-$32,342.00 for on-site paper storage, $6,444.00-$12,882.00 for off-site paper storage, and $30.00-$76.50 for electronic storage, but costs may vary depending on the number of records being stored. These costs will not change due to the proposed regulations, as the regulation will clarify that laboratories must continue their current practice of retaining records for three years.

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.

Evidence Supporting Finding of No Significant Statewide Adverse Economic Impact Directly Affecting Business

The proposed regulation will not have any statewide adverse economic impact directly affecting business or the ability of California businesses to complete with businesses in other states because the regulation does not require businesses to make changes to current practices. The proposed regulation does not change state or federal requirements, which require California businesses to follow the more stringent record retention requirements in current California law. The proposed regulation clarifies this requirement for California businesses. Therefore, the proposed regulation will not impose new costs or have any other economic impact on these businesses.

The proposed regulation clarifies that California businesses must continue to follow California record retention requirements, rather than following less stringent federal requirements. There are no economic costs associated with clarifying which law to follow. The regulation does not require businesses to make changes to current practices, therefore it will not create or eliminate jobs, affect housing costs, create new businesses, or eliminate existing businesses. California businesses operating under current requirements will not gain a new competitive advantage over similar businesses in other states or be put at a new disadvantage.