NOTICE OF PROPOSED RULEMAKING
Title 22, California Code of Regulations

General Acute Care Hospital: Clinical Laboratory, Dietetic and Pharmaceutical Services DPH-07-011
Notice Published July 26, 2024

Notice is hereby given that the California Department of Public Health (Department) is proposing the regulation described below. This notice of proposed rulemaking commences a rulemaking to make the regulations permanent after considering all comments, objections, and recommendations regarding the regulation.

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 (all of which are hereinafter referred to as comments) relevant to the action described in the Informative Digest/Policy Statement Overview section of this notice.

To request copies of the regulatory proposal in an alternate format, please write or call: Anita Shumaker, Office of Regulations, 1415 L Street Suite 500, Sacramento, CA 95814, at 279-217-0867, email to Anita.Shumaker@cdph.ca.gov or use the California Relay Service by dialing 711.

PUBLIC HEARING

A public hearing has not been scheduled for this rulemaking. However, the Department will conduct a public hearing if a written request for a public hearing is received from any interested person, or his or her authorized representative, no later than 15 days prior to the close of the written comment period, pursuant to Government Code Section 11346.8.

Assistive Services:

For individuals with disabilities, the Department will provide assistive services such as conversion of written materials into Braille, large print, audio format, and computer disk. For public hearings, assistive services can include sign-language interpretation, real-time captioning, note takers, reading, or writing assistance. To request these assistive services, please call Anita Shumaker at (279) 217-0867 or (California Relay at 711 or 1-800-735-2929), or email Regulations@cdph.ca.gov or write to the Office of Regulations

at the address noted above. Note: The range of assistive services available may be limited if requests are received less than 10 business days prior to public hearing.

WRITTEN COMMENT PERIOD

Written comments pertaining to this proposal, regardless of the method of transmittal, must be received by Office of Regulations on September 12, 2024, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely.

Written Comments must 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-07-011 GACH Clinical Laboratory, Dietetic and Pharmaceutical Services" in the subject line to facilitate timely identification and review of the comment.

2. By fax transmission to: (916) 636-6220.

3. By postal service or hand delivered to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All comments, including email or fax transmissions, should include the regulation package identifier, DPH-07-011 GACH Clinical Laboratory, Dietetic and Pharmaceutical Services, along with your name and your mailing address or email address in order for the Department to provide copies of any notices for proposed changes to the regulation text on which additional comments may be solicited.

AUTHORITY AND REFERENCE

The Department's authority to adopt, amend, or repeal the hospital regulations is provided in HSC sections 20, 1254, 1275, and 131200. HSC sections 1254 and 1275 provide the Department the authority to inspect, license, and oversee hospitals. The Department of Health Services (DHS) reorganization created two new departments: the Department of Health Care Services and the Department. HSC section 20 allocates the former DHS's function of licensing and oversight of hospitals to the Department and HSC section 131200 establishes the Department has the authority to adopt and enforce regulations for the execution of its duties.

The Department proposes adding as reference citations HSC sections 131000, 131050, 131051, and 131052 that delineate the Department's responsibilities and authority under the bill that reorganized DHS, the California Public Health Act of 2006.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Summary of Proposal

The California Department of Public Health (Department) proposes amendments to Title 22 of the California Code of Regulations (Title 22 CCR) Division 5, Chapter 1 concerning general acute care hospitals (hospitals), specifically the Clinical Laboratory Service (Lab) regulations in sections 70241 through 70249, the Pharmaceutical Service

(Pharmacy) regulations in sections 70261 through 70269, the Dietetic Service (Dietary) regulations in sections 70271 through 70279, and the Governing Body (Administration) regulation section 70701. These regulations, enacted in 1975, contain outdated language and obsolete citations that have the potential to result in confusion among the regulated community and negatively affect public health outcomes. The Department proposes to update existing regulations to adopt current industry standards and establish processes to improve health and safety measures, patient care and safety, and to improve public health.

Background

The Department's Center for Health Care Quality (CHCQ) is responsible for licensing hospitals pursuant to Health and Safety Code (HSC) section 131050 subdivision (a)(2). Currently there are 419 licensed hospitals in the State of California. HSC sections 1275 and 131200 give the Department the authority to adopt, amend, repeal, and enforce regulations and HSC section 1254, authorizes the Department to inspect and license all health facilities, including hospitals. The Laboratory Field Service (LFS) examiners enforce the Lab regulations by surveying and investigating complaints about laboratories that relate to the performance of patient tests and the accuracy, reliability, and reporting of patient test-results. The Public Health Pharmaceutical Consultants (PHPCs) enforce Pharmacy regulations by surveying and investigating complaints about the Pharmacy. The Public Health Nutrition Consultant (PHNC) surveyors enforce the Dietary regulations by surveying and investigating complaints about hospital Dietetic Service. In collaboration with LFS examiners, and PHPC and PHNC surveyors, CHCQ developed the proposed amendments for the Lab, Pharmacy, and Dietary regulations.

The California Legislature has urged the Department to revise these regulations to bring them up to current industry standards and practices, and to prevent any confusion leading to negative public health outcomes. Since the promulgation of the regulations in 1975, advances in laboratory science, pharmaceutical practices, dietetics, nutrition, and the practice of medicine that are not accounted for in existing regulatory language.

In 1988, the United States Congress passed the Clinical Laboratory Improvement Amendments (CLIA) to enlist state assistance in establishing quality standards for all clinical laboratories performing tests or examinations on humans in the United States. Under federal law, all clinical laboratories must be CLIA certified to legally perform tests or examinations on human specimens or must be covered by a specific exemption in 42 United States Code section 263a, and 42 Code of Federal Regulations (CFR) section 493.513. The Department is amending the Lab regulations to bring them into alignment with the CLIA standards, which are the prevailing standards of laboratory practice.

Senate Bill (SB) 493 (Hernandez, Chapter 469, Statutes of 2013) expanded the scope of practice for interested pharmacists to address the state's projected physician shortage. SB 493 created a new license category, Advanced Practice Pharmacist (APP), with licensed APPs having the authority to conduct some patient assessments, order and interpret tests, and carry out other functions previously reserved for physicians. APPs often work within hospital treatment delivery teams. SB 493 also expanded pharmaceutical practice by authorizing any pharmacist who voluntarily completes education prerequisites to dispense self-administered hormonal

contraception, nicotine replacement products, vaccinations, and prescription drugs that do not require a diagnosis that are recommended for international travelers, without a doctor's prescription when done pursuant to protocols developed by the Medical Board of California and the California State Board of Pharmacy.

SB 311 (Hueso, Chapter 384, Statutes of 2021) expanded the Compassionate Use Act of 1996 (Ryan's Law, an initiative measure) that prohibits certain criminal penalties from being imposed on terminally ill patients and their providers for the use of medical cannabis. SB 311 is intended to allow terminally ill patients to use cannabis in specified health care facilities. It adds HSC Division 2, Chapter 4.9, sections 1649 which require general acute care hospitals (GACH) and certain other health care facilities to allow a terminally ill patient's use of medicinal cannabis when specified requirements are met. Compliance with SB 311 may not be used as a condition of obtaining, retaining, or renewing a license as a health care facility. A health care facility may not prohibit cannabis solely because it is a Schedule I drug pursuant to the federal Uniform Substances Control Act.

Advances in dietetic science and current industry practices have improved the prevention of contraindicated interactions between drugs and patient food. Also, since 1975, there are many advances in dietetic science and medicine not accounted for in existing regulatory language. Research on how the body absorbs nutrients has led to a new type of treatment, medical nutrition therapy. Medical nutrition therapy is prescribed as an adjunct treatment to help assist in the primary treatment of diabetes, cardiovascular disease, kidney disease, surgical recovery, certain cancers, gastro-intestinal disorders, pulmonary disease, and more.

In addition to the advances in medicine since the original promulgation of these regulations, the California Public Health Act of 2006 reorganized the State Department of Health Services (DHS) and divided its responsibilities between the newly established Department of Health Care Services and the Department. This change has yet to be accounted for by existing regulatory text. After the reorganization the Legislature urged the Department to update the hospital regulations to provide clarity to the regulated community.

On December 17, 2010, the Department announced pre-notice hearings in the California Regulatory Notice Register, in All Facilities Letter 10-45, and in an online posting regarding amendments to the Lab, Pharmacy and Dietary regulations, and invited interested parties to provide written comments. The Department received comments until the hearing on April 12, 2011. On September 20, 2017, the Department sent an All Facilities Letter (AFL 17-18) to all hospitals soliciting additional stakeholder input on the Lab regulations via a survey. On August 15, 2019, the Department issued All Facilities Letter 19-27 announcing a stakeholder engagement meeting. Written comments were also accepted. The meeting was held on August 30, 2019, with attendance in-person and through online conferencing. Additionally, in 2018 and 2019, while producing the fiscal economic analysis for this regulatory package, the Department asked industry stakeholders about key parts of the proposed changes and invited hospital officials to complete a survey on current practices and estimated costs of complying with proposed changes to the regulations. The Department has carefully

considered all comments and survey responses when drafting the proposed amendments.

Problem Statement
Governing Body and Clinical Laboratory, Pharmaceutical, and Dietetic Services regulations are outdated, requiring amendments to avoid confusion to the regulated community and to preserve and protect the health and safety of patients.

Objectives (Goals) of the Regulation
- Update citations to state and federal statutes and regulations to protect public health and safety;
- Incorporate Centers for Medicare and Medicaid Services (CMS) guidelines and current industry standards; and
- Require each service to implement and maintain a Quality Assessment and Performance Improvement (QAPI) program as defined in federal regulations that gets integrated into the hospital wide QAPI program.

Anticipated Benefits
Anticipated benefits from amending the Governing Body and Clinical Laboratory, Pharmaceutical, and Dietetic Services regulations as a part of this proposed regulatory action are:
- Elimination of confusion among the regulated community;
- Alignment of state regulations with CMS guidelines and current industry standards;
- Adoption of a definition of a QAPI program;
- Adopt service-specific QAPI programs integrated into the hospital-wide QAPI program; and
- Improvements in patient care and health outcomes for the people of California.

Evaluation as to Whether the Proposed Regulations Are Inconsistent or Incompatible with Existing State and Federal Regulations
The Department has determined that this proposed regulatory action is not inconsistent or incompatible with existing regulations. After conducting a review for any regulations that would relate to or affect general acute care hospitals, the Department has concluded that no known statute or regulation conflicts with this proposed regulatory action.

FORMS INCORPORATED BY REFERENCE
The following documents are incorporated by reference into the proposed amendments to the regulations:
- Institute of Medicine, Dietary Reference Intakes: The Essential Guide to Nutrient Requirements (2006). This is a statutory requirement under 42 Code of Federal Regulations part 482.28(b)(1).
- Caroline Steele and Emily Collins, *Infant and Pediatric Feedings*: *Guidelines for Preparation of Human Milk and Formula in Health Care Facilities*, 3rd Ed. (2018). Pediatric Nutrition Practice Group.
- National Sanitation Foundation International (March 2017). NSF 3-2017, *Commercial Warewashing Equipment*. P.O. Box 130140, 789 N Dixboro Road, Ann Arbor, MI 48105.

MANDATED BY FEDERAL LAW OR REGULATIONS

This proposed regulation does not substantially differ or conflict with existing federal regulations or statutes.

OTHER STATUTORY REQUIREMENTS

There are no other statutory requirements.

LOCAL MANDATE

The Department has determined that this regulation action would not impose a mandate on local agencies or school districts.

FISCAL IMPACT ESTIMATES

Cost to any local agencies or school districts that must be reimbursed pursuant to Section 17561 of Government Code:

The Department has determined that there will be no such costs to any local agency or school district.

The cost or savings to any state agency

The Department does not anticipate an increase in enforcement costs, staff, or budget as a result of the proposed regulations.

Other Nondiscretionary Cost or Savings Imposed on Local Agencies:

The direct, local government impact of the proposed regulations is the cost and cost savings to local hospitals. Twenty-four hospitals are city or county hospitals. The average net patient revenue (NPR) for all city and county hospitals is over $283 million. In aggregate, local hospital experience $705 thousand in one-time costs and $112 thousand in ongoing gross costs. Local hospitals also experience $167 thousand in ongoing gross savings.

Cost or Savings in Federal Funding to the State:

The Department has determined that the regulations will not affect federal funding.

HOUSING COSTS

The Department has determined that the regulations will not affect housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

The Department has made an initial determination that these regulations would not have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

The Department estimates that the economic impact of this regulation (which includes the fiscal impact) is between $11.3 million and $28.3 million dollars. 419 general acute care hospitals will be impacted. 9.4% of the hospitals are small businesses. No businesses will be created or eliminated. Regulatory costs will be extremely small compared to net patient revenue.

STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ASSESSMENT (EIA)

The Department has made an initial determination that these regulations would not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The proposed regulations would not significantly affect:

1. **The creation or elimination of jobs within the State of California**. The proposed amendments clarify and specify existing standards of clinical laboratory, pharmacy, and nutrition and dietetics practice, and require the implementation and maintenance of a QAPI process. Hospitals that receive Medicare and Medicaid (Medi-Cal, in California) funds are already required to follow CMS and existing standards of practice and to implement and maintain a hospital-wide QAPI process. The proposal may create up to five jobs and does not eliminate any jobs within the State of California. "The proposed regulatory changes will have minimal impact on statewide employment. We used IMPLAN to estimate the impact of a recurring $900 thousand increase in California household income, due to reduced health insurance premiums, on employment in the state. When household spending increases, demand for goods and services increases, compelling employers to hire more workers. Overall, annual employment rises by about 5 workers. The sectors most likely to hire additional workers are full and limited-service restaurants, real estate, hospitals, and individual and family services, as defined by IMPLAN. The annual increase in labor income is estimated to be $346 thousand. However, these estimates are likely an upper bound of the net effects of proposed regulations due to an offsetting reduction in hospital payroll and reduction in worker take-home pay."
2. **Creation of new businesses or the elimination of existing businesses within the State of California.** For the reasons stated above, the proposal is not anticipated to have any impact upon the creation or elimination of new businesses within the State of California.
3. **The expansion of businesses currently doing business within the State of California.** This proposal does not create the need for expansion of businesses currently doing business within the State of California.
4. **The benefits of the regulation to the health and welfare of California residents, worker safety, and the state's environment.** By updating and clarifying the existing hospital Lab, Pharmacy, and Dietary regulations, the proposed amendments are anticipated to resolve issues observed by LFS examiners and PHPC and PHNC surveyors that have the potential to compromise patient safety. By bringing the current regulations up to CMS and existing industry standards that encompass the latest advances in laboratory science, pharmacy practice and nutrition and dietetics, the Department anticipates that this regulatory proposal will improve patient care, worker safety, and reporting and accountability activities in California's hospitals. The proposed amendments are not anticipated to contribute negatively to the state's environment as they do not relate to environmental or natural resource issues.

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.

BUSINESS REPORTING REQUIREMENTS

There are no business reporting requirements.

EFFECT ON SMALL BUSINESS

The Department has determined that these proposed regulations will affect 39 small hospitals. None of these hospitals will be eliminated. The Department estimates that the weighted average initial cost per small hospital is $940. As a percentage of NPR total average one-time costs per hospital represent 0.10 percent for the Type 1 hospital and 0.05 percent for the Type 2 hospital.

SPECIFIC TECHNOLOGIES OR EQUIPMENT

The proposed amendments to the Lab regulations do not mandate the use of any specific technologies or equipment. Any specific technologies or equipment required in the AABB Standards are pre-existing statutory mandates, effective since 1993 for HSC section 1602.6, and since 1999 for HSC sections 1602.5.

The proposed amendments to the Dietary regulations do not mandate the immediate use of a three-compartment sink for manual cleaning and sanitizing, for sinks in use before December 31, 2007, as service areas are remodeled, or a new hospital is built. Use of a three-compartment sink is the existing industry standard, required by statute for retail food establishments since 2007 (CRFC – HSC section 114099(a)), and necessary to protect patient health.

The proposed amendments do not mandate the immediate use of hot water sanitizing sinks that are designed to have an integral heating device capable of maintaining water at a temperature of not less than 77 degrees C (171 degrees F) and are provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water. Instead, this requirement is imposed as sinks used for hot water sanitizing are replaced after December 31, 2007. Requiring sinks used for hot water sanitization to have an integral heating device and a rack or basket to allow complete immersion is an industry standard, placed in statute for retail food establishments in 2018 (CRFC – HSC section 114099.4), and necessary to protect patient health.

The proposed amendments do not mandate the use of any one of the four acceptable methods of chemical sanitizing for manual washing that may be used as an alternative to the hot water immersion method. The existing regulations allow for “immersion in water containing bactericidal chemical as approved by the department,” and the four methods in the proposed amendments are the existing Department-approved methods of chemical sanitizing for manual washing and sanitizing.

The proposed amendments do not impose a new mandate to use of any one of four acceptable methods of chemical sanitizing for mechanical sanitization. The existing regulations mandated the mechanical washing and sanitization produce results “equal to those obtained by the methods outlined” for manual washing and sanitizing. The four methods in the proposed amendments are existing industry standards the Department presently enforces in surveys.

CONSIDERATION OF ALTERNATIVES

The Department must determine that no reasonable alternative considered by the Department, or otherwise identified and brought to the attention of the Department, would be more effective in carrying out the purpose for which the action is proposed, or as effective and less burdensome to affected private persons than the proposed regulatory action (amendments), or more cost-effective to affected private persons and equally effective to protect patients' and workers' safety and health.

CONTACT PERSON

Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Sultana Blair of the Center for Health Care Quality, at sultana.blair@cdph.ca.gov

All other inquiries concerning the action described in this notice may be directed to Anita Shumaker, Anita.Shumaker@cdph.ca.gov, Office of Regulations, at (279) 217-0867, or to the designated backup contact person, Linda Cortez, Linda.Cortez@cdph.ca.gov at (279) 217-0681.

In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-07-011.

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, 1415 L Street, Suite 500, Sacramento, CA 95814, will be the custodian of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please call Anita Shumaker 279-217-0867, (or the California Relay Service at 711), send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audio format, or computer disk.

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 at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

Final Statement of Reasons

A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

INTERNET ACCESS

Materials regarding the action described in this notice (including this public notice, the text of the proposed regulations, and the initial statement of reasons) that are available

via the Internet may be accessed at www.cdph.ca.gov by clicking on these links, in the following order: I am Looking For: Administrative, Proposed Regulations, Current Regulatory Proposals.