Informative Digest

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 These regulations, enacted in 1975, contain outdated language and obsolete citations that have the potential to result in confusion among the regulated community and negatively affect public health outcomes.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.

Authority and Reference

Health and Safety Code sections 20, 1254, 1275, and 131200 authorize the Department to adopt, amend, or repeal these proposed regulations.

The proposed regulations implement, interpret, and make specific the requirements for the standard cannabinoids test method to be used by all licensed laboratories pursuant to Health and Safety Code sections 131000, 131050, 131051, and 131052.

The Department is responsible for licensing hospitals pursuant to Health and Safety Code (HSC) section 131050 subdivision (a)(2). HSC sections 1275 and 131200 give the Department the authority to adopt, amend, repeal, and enforce regulations and HSC 1254 authorizes the Department to inspect and license all health facilities, including hospitals.

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)[1] 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[2] 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.[3] 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.

HSC Division 2, Chapter 4.9, sections 11357 *et. seq.*, (September 2021), sets forth requirements for storage of medicinal cannabis and section 1645.5 states that storage of medicinal cannabis must not be a condition for obtaining, retaining, or renewing a license as a health care facility. These proposed regulations are licensing regulations, therefore medicinal cannabis is not included in rules for storage of medicinal cannabis.

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,

[1] 42 United States Code sections 263a-1 et seq.

[2] 42 Code of Federal Regulations part 493.1.

[3] The statute declares, "pharmacists are health care providers who have the authority to provide health care services." Business & Professions Code Section 4050(c).

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.[4] 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, during the course of 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.

Policy Statement Overview

Problem Statement*:* Governing Body and Clinical Laboratory, Pharmaceutical, and Dietetic Services regulations are outdated, requiring amendments to avoid confusion among the regulated community and to preserve and protect the health and safety of patients.

Objectives (Goal): Broad objectives of this proposed regulatory action are to:

- 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 will be integrated into the hospital-wide QAPI program.

[4] Health and Safety Code sections 20, and 131050 through 131225.

Benefits: Anticipated benefits from amending the Governing Body and Clinical Laboratory, Pharmaceutical, and Dietetic Service 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 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.

Substantial Difference from Federal Regulations or Statute

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

Incorporation 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.

Fiscal Impact Statements

Fiscal Impact on Local Government

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.

Fiscal Impact on State Government/Agencies
The Department does not anticipate an increase in enforcement costs, staff, or budget as a result of the proposed regulations.

Fiscal Impact on Local Agencies
The Department has determined that these regulations would not impose a mandate on any local agencies or school districts.

Fiscal Impact on Federal Funding
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.

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.

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.

Statement of the Results of the Economic Impact Assessment
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.

Alternatives Statement
The Department must determine that no reasonable alternative considered or otherwise identified and brought to its attention would be more effective in carrying out the purpose for which this action is proposed or would be as effective as 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.