INITIAL STATEMENT OF REASONS

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 These regulations, enacted in 1975, contain outdated language and obsolete citations that have the potential to result in confusion among the regulated community and negatively affect public health outcomes.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

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

[2] 42 Code of Federal Regulations (CFR) part 493.1.

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.

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

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

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, 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.

Policy Statement Overview
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): The 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 gets integrated into the hospital-wide QAPI program.

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;

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

- 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.

Authority and Reference Citations
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.[5] 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.

Alternatives
All comments submitted to the Department in 2011 regarding updates to the Lab, Pharmacy, and Dietary regulations have been carefully considered along with the survey responses provided on the Lab regulations in 2017. Responses from interviews and surveys conducted in 2018 and 2019 for the economic analysis and written and oral comments made during and after the August 30, 2019 stakeholder engagement meeting. The Department has adopted several of the suggestions in the proposed amendments. Under the broad authority granted to the Department to protect public health, LFS examiners, and PHPC and PHNC surveyors use existing CMS and industry practice standards in their survey activities. Hospitals must comply with the regulations as enforced by the Department. Failing to update these regulations to existing standards would result in confusion to the regulated community and potential negative public health outcomes. Therefore, the Department does not consider non-amendment of the regulations a viable approach given the Legislature's clear instructions.

DETAILED DISCUSSION OF REGULATIONS AFFECTED

The Department proposes amendments to the hospital regulations in Title 22 CCR, Division 5, Chapter 1, Article 3, sections 70241, 70243, 70245, 70247, 70249 (Lab), 70261, 70263, 70265, 70267, 70269 (Pharmacy), 70271, 70273, 70275, 70277, 70279

[5] Senate Bill (SB) 162 (the California Public Health Act of 2006) Ortiz, Chapter 241, Statutes of 2006.

(Dietary), and Division 5, Chapter 1, Article 7 section 70701. Unless otherwise noted, all references to sections refer to sections of Title 22 CCR.

Common Changes in All Sections
The Department proposes amendments incorporating gender-neutral language and adding a serial comma where applicable. These amendments are necessary to foster stylistic uniformity among the Department's regulations and to provide clarity to the regulated community.

Replace "personnel" with "staff": The Department proposes to replace "personnel" with "staff" to maintain consistency with the Department's other Title 22 regulatory revisions. Personnel is an outdated word and is preferable replaced with staff, meaning all people who work in the hospital no matter who pays them. This amendment is needed to comply with the correct use and definition as well as updated terms to current industry language.

Adding developed, documented, implemented, and maintained policies and procedures to general requirements sections. The Department proposes to add "develop" so the hospital must create the policies and procedures. "Documented" needs to be added so the Department can verify that the policies and procedures exist and determine whether the hospital is complying with them. Add "implemented" so the hospital must train the staff on policies and procedures and the staff will know what the policies and procedures are and be able to comply with them. Add "maintained" so the Department can enforce the policies and procedures if they are not being followed, regardless of how much time has passed since the policies and procedures were last documented. These changes are necessary to provide clarification among the regulated community when developing their policies and procedures, to maintain consistency with other proposed Title 22 regulations, and to protect the health and safety of patients.

Add quotation marks to define terms. The Department proposes to add quotation marks around the term being defined. Placing quotation marks around terms being defined avoids situations in which it is not clear which words belong in the defined term. The OAL standard for clarity states that situations in which OAL may presume a regulation is unclear includes a situation in which the regulation has more than one meaning. For this reason and to avoid ambiguity, quotation marks around defined terms are used through these proposed regulations. These amendments define precisely the word being defined and is necessary to align with the rest of the Department's Title 22 regulatory revisions.

Common Changes in Authority and Reference Citations
Amend sections 70241, 70247, 70249, 70261, 70265, 70267, 70269, 70271, 70277 70279 and 70701 to add authority and reference citations: The Department proposes the addition of HSC sections 20, 1254, 1275, and 131200 as authority citations, and HSC sections 1276, 131050, 131051, and 131052 as reference citations to satisfy the requirements of the Administrative Procedures Act.[6] The proposed authority citations are necessary to establish the Department's authority to inspect and license health facilities, clarify the Department's power to adopt, amend, and enforce these regulations, and clarify the Department's roles and responsibilities.

The Department's proposed addition of HSC section 1276 as a reference citation is necessary to provide clarity to the regulated community and to retain consistency with Title 22 CCR sections 70243, 70245, 70263, 70273, and 70275, that list HSC section 1276 as a reference citation. HSC section 1276 addresses hospital building standards and the Department's authority to grant program flexibility requests. The Department proposes to add HSC sections 131050, 131051, and 131052 as reference citations to clarify the Department's responsibility for licensing and certification of hospitals. The Department's proposed amendments to the hospital regulations implement the above-referenced statutes.

The Department proposes adding HSC sections 1602.5 and 1602.6 concerning Blood Bank and Transfusion Services (BB/TS) as reference citations for sections 70247 because the Department's proposed amendments to section 70247 implement those sections of the HSC.

Amend sections 70243, 70245, and 70273 to update authority and reference citations: The Department proposes to delete HSC section 208 subdivision (a) as an authority citation because HSC section 208 was repealed by Senate Bill 1360 (Chapter 241, Statutes of 1995) and is no longer applicable.[7] The Department proposes to add HSC sections 20, 1254, and 131200 as authority citations to the above-referenced sections. The addition of HSC section 20 as an authority citation clarifies the Department's roles and responsibilities after the DHS reorganization. HSC section 1254 clarifies that the Department has the authority to inspect and license health facilities. HSC 131200 clarifies the Department's authority to adopt and enforce regulations. These changes are necessary to provide clarity to the regulated community.

Additionally, the Department proposes to add HSC sections 131050, 131051, and 131052 as reference citations for sections 70243, 70245, and 70273. These additions are necessary because HSC sections 131050, 131051, and 131052, taken together, explain how after the reorganization of DHS, the Department assumed responsibility for licensing and certifying hospitals. The Department's proposed amendments to the Lab regulations implement the above-referenced statutes.

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[6] See Government Code section 11346.2 subdivision (a)(2).

[7] SB 1360 (Chapter 241, Statutes of 1995) section 28.

The Department further proposes to add HSC sections 1602.5 and 1602.6 (concerning BB/TS) as reference citations for section 70243. This addition is necessary because the Department's proposed amendments to section 70243 implement those sections of the HSC.

Amend sections 70263 and 70275 to update authority and reference citations: The Department proposes the addition of HSC sections 20 and 1254 authority citations to the above-named sections. The addition of HSC section 20 as an authority citation is necessary to clarify the Department's roles and responsibilities after the DHS reorganization. HSC section 1254 clarifies that the Department has the authority to inspect and license health facilities.

The Department's proposed addition of HSC section 1265.4 (concerning dietetic service supervisors) to section 70275 is necessary because the Department's proposed amendments to section 70275 implement that section of the HSC.

CLINICAL LABORATORY SERVICE

Amend section 70241: The Department proposes to repeal the word 'appropriate' and to add a requirement that staff, supplies and equipment, and space meet the needs of the patients.

Section 70243: Clinical Laboratory Service General Requirements

Amend subdivision (a): The Department proposes amendments to subdivision (a) to update an incorrect citation to the Business and Professions Code (BPC) and to remove an outdated citation to the California Administrative Code (which was re-named as the California Code of Regulations in 1988[8]). These amendments are necessary to update the regulations to reflect current industry practices and to provide clarity to the regulated community.

The Department further proposes the addition of language to specify that hospital Blood Banks and Transfusion Services must follow the statutory requirements in HSC sections 1602.5 and 1602.6. The inclusion of the statutory requirements under HSC sections 1602.5 and 1602.6 is necessary to provide clarity to the regulated community. Duplicating HSC section 1602.5 provides clarity for the regulated community and is necessary to clearly inform facilities and individuals of the law. Regulations do not ordinarily permit amendments or updates to regulatory standards unless the regulated community has had an opportunity to comment. Including the statutory provision in the regulation ensures that the regulated community will be aware that they are expected to comply with updates to the American Association of Blood Banks' (AABB's), Standards for Blood Banks and Transfusion Services, required by HSC sections 1602.5 and 1602.6, even if they have not had an opportunity to comment on changes.

[8] Rose, Research & Practice Guide: California Regulatory History & Intent (2011). Legislative Research & Intent LLC (as of Feb. 7, 2018).

The Department further proposes language to this subdivision specifying that Blood Banks and Transfusion Services comply with HSC sections 1600 through 1630 (licensing provisions for human whole blood, human whole blood derivatives, and other biologics). This is necessary to update the regulations to current industry standards and to clarify the additional statutory requirements that Blood Banks and Transfusion Services must follow. By updating the proposed regulations with specific citations, the Department will provide clarity to the regulated community and better equip Laboratory Field Services (LFS) examiners to enforce compliance with the cited statutes.

Amend subdivision (b): Additionally, the proposed amendments add chemistry, serology, and microbiology to the list of routine tests a lab must be able to conduct on-site. For many years, LFS examiners have required labs to provide these tests in connection with the transfusion service; however, these tests are not currently specified in the current regulatory language. Adding these specific tests as a requirement is necessary to bring the regulatory language up to date with current standards imposed on labs by LFS examiners and to protect public health and safety by providing clarity to the regulated community.

Amend subdivision (c): The Department proposes non-substantive grammatical changes to update and clarify this subdivision and to provide stylistic consistency with the rest of the Department's regulations.

Amend subdivision (d): The Department proposes amendments to this subdivision to require that the responsibility and accountability of the lab be defined in writing. LFS examiners have found that when hospitals document responsibilities, they provide lab personnel, medical staff, and the administration with a reference. The document also serves as a record for LFS examiners to review. This amendment is necessary to update the regulations to current industry standards.

Amend subdivision (e): The Department proposes amendments clarifying that the clinical laboratory director is responsible for certain written policies and procedures. This specific language is necessary to align the regulations with requirements in the AABB's Standards for Blood Banks and Transfusion Services, requirements that are mandated by statute.[9] The Department further proposes an amendment specifying that all policies must be approved in writing by the governing body. This is also necessary to align the regulations with requirements in the AABB's Standards for Blood Banks and Transfusion Services. The Department additionally proposes an amendment adding that approvals of procedures must be made in writing while making non-substantive changes to clarify existing language about approvals of procedures that is determined appropriate by the lab director. The proposed amendments are necessary to bring the regulations current with industry standards that require written approvals of policies and procedures. LFS examiners observe that hospitals with written policies and procedures have better compliance with regulatory requirements because lab personnel, medical

[9] HSC sections 1602.5 and 1602.6.

staff, and the administration have written materials for reference. Policies and procedures document how the lab intends to meet regulatory and statutory standards given the hospital's size, resources, geographic location, and other unique variables. Written policies and procedures facilitate LFS examiners' oversight function, as the examiners first review the lab's policies and procedures, and then ascertain if the lab is following their own policies and procedures. The proposed amendments are necessary to bring the regulations current with industry standards and protect the health and safety of the patients.

Amend subdivisions (f) through (j): The Department proposes the insertion of new language into subdivision (f) and the subsequent re-numbering of the following subdivisions for the clarity of the regulated community.

Adopt new subdivision (f): The Department proposes the insertion of new language into subdivision (f) specifying that the clinical laboratory service must ensure that services relating to the care and safety of donors and transfusion recipients are directed as specified in the federal Clinical Laboratory Improvement Amendments (CLIA) and the California Business and Professions Code as mandated by California Health and Safety Code sections 1602.5 and 1602.6. This amendment is necessary to update the regulations to reflect current industry standards and to ensure compliance with the mandate in HSC sections 1602.5 and 1602.6 (see the discussion of subdivision (d)).

Amend existing subdivision (f): Renumber to subdivision (g). The Department proposes amendments to this subdivision specifying that the clinical laboratory service must follow the federal CLIA statutes and regulations,[10] applicable BPC statutes, and AABB's standards. These are statutory requirements not yet included in the current version of the regulations.

Amend paragraph (1): The Department proposes to make specific the time requirement by replacing "in a timely fashion" to "within a timeframe that meets the needs of the patients as determined by patient care plans and physicians' orders." Physicians' orders and patient care plans contain specific instructions and stakeholders will know how to comply with the requirement. This amendment is necessary to meet the clarity standard.

Amend paragraph (2): The Department proposes amendments specifying that, for all patients, labs must establish procedures for the collection of specimens and to ensure specimen integrity. The current language is vague, applies only to outpatient specimens, and may be misinterpreted by the regulated community, leading to negative health outcomes. These proposed amendments are necessary to bring these regulations in line with current industry standards and provide clarity to the regulated community.

[10] BPC section 1265(a)(1).

Amend paragraph (3): The Department proposes amendments specifying that identifying information on specimens must include the name (or other identifier) of the patient from whom the specimen was taken, the date and time the test was requested, the time of day that the test results were made available to medical personnel and, as necessary, any other information that may be required by laboratory procedures or requested by a physician for test result interpretation. The Department proposes addition of language clarifying that collected specimens shall be maintained and documented containing the required information. As patient data collection is more robust and encompasses more collection categories than it did 40 years ago, the above-listed requirements are necessary to align the regulations with current laboratory standards. The collection of this additional information will aid the lab's efforts to improve how specimens move through lab processes, help lab programs with ongoing compliance and improvement efforts, and is necessary to effectuate the regulatory intention of providing improved patient care.

Amend paragraphs (4) through (8): The Department proposes the elimination of existing subdivision (f)(4) and the subsequent re-numbering of the existing subdivisions (f)(5) through (f)(8) for the clarity of the regulated community. The proposed amendments are necessary to avoid redundancy as the existing provisions in (f)(4) are now accounted for in subdivision (g)(2).

Amend existing paragraph (5): Renumber to paragraph (4). The Department proposes amendments specifying that the lab's communication system must be able to exchange information with other clinicians, departments, and other lawfully authorized parties. This is necessary to expand and make specific the previous requirement that labs facilitate communication with "related areas." Hospitals now routinely communicate with more departments than are accounted for by the current regulations. When the regulations were originally promulgated in 1975, infectious diseases like Acquired Immune Deficiency Syndrome (AIDS), Ebola virus, and Severe Acute Respiratory Syndrome (SARS) virus were unknown, as were the tests for genetic variations which potentially change different patients' responses to treatment. By requiring clinical laboratory directors to maintain effective communication across hospital departments and with any other lawfully authorized parties, this amendment ensures that labs follow commonly accepted industry standards designed to protect patient health.

Amend existing paragraph (6): Renumber to paragraph (5). Add a provision for a Quality Assessment and Performance Improvement (QAPI) program pursuant to 42 CFR part 482.21 and as defined in Title 22 CCR section 70701. It is necessary to update the term "quality control system" to the term "QAPI program" in this paragraph to reflect current industry practices and terminology. The Department further proposes the addition of language requiring that, as part of a QAPI program, labs establish and maintain regularly scheduled collection and evaluation of quality indicator data. In 2003, the Centers for Medicare & Medicaid (CMS) began requiring hospitals to use QAPI programs, replacing existing "quality control systems." All hospitals that receive CMS funding established QAPI programs approximately 15 years ago, and the success of

QAPI in driving improvements has made it the prevailing standard for quality control in the industry. The proposed amendments are necessary to bring these regulations current with accepted industry standards known to protect patient health and promote worker safety.

Amend existing paragraph (7): Renumber to paragraph (6). The Department proposes amendments specifying that reports of test results be recorded and added to a patient's medical record. Failure to post results of tests and lab exams can result in missed or incorrect diagnosis, incorrect treatments, and negative patient outcomes - including possible fatalities. These amendments uphold the Department's commitment to patient safety by making the clinical laboratory director ultimately responsible to assure the timely recording of lab results.

Amend existing paragraph (8): Renumber to paragraph (7). Former subdivision (f)(8) is renumbered as (g)(7) for reasons discussed in the amendments to sections 70243 subdivisions (f)(4)-(8), above.

Amend existing subdivision (g): Renumber to subdivision (h). The Department proposes language clarifying the eligibility requirements for physicians who examine tissue specimens by removing the phrase, "or its equivalent." Existing language allows that both physicians who are "eligible for certification" in anatomical or clinical pathology, as well as physicians who possess "qualifications which are equivalent to those required for certification" in anatomical or clinical pathology, may examine tissue samples. This language is redundant and confusing as the personnel described by the first requirement already qualify to examine tissue samples under the second. These amendments are necessary to provide clarity to the regulated community. The Department further proposes to amend identical language within this section relating to the qualifications of dentists certified as oral pathologists for the same reasons.

The Department further proposes language in this subdivision to allow labs to hire physicians certified by the American Osteopathic Board of Pathology. This is allowed under CLIA laws and regulations, and the amendment is necessary to reduce confusion in the regulated community, improve outcomes, and align the regulations with the CLIA regulations, increasing the available pool of eligible physicians. Finally, the Department proposes to update the reference to the American Board of Oral Pathology found in this subdivision to its current organizational name: the American Board of Oral and Maxillofacial Pathology. This is necessary to accurately reflect changes within the industry and provide clarity to the regulated community.

Amend existing subdivision (h): Renumber to subdivision (i). The Department proposes language updating an outdated citation to the California Administrative Code, re-named as the California Code of Regulations (CCR) in 1988.[11] Updating this citation

[11] Rose, Research & Practice Guide: California Regulatory History & Intent (2011). Legislative Research & Intent LLC (as of Feb. 7, 2018).

to the California Radiation Control Regulations (Title 17 CCR section 30100 et seq.) is necessary to conform to current industry standards, provide clarity to the regulated community, and protect worker safety by making specific the regulations labs must follow to use, store, and dispose of radioactive materials.

Amend existing subdivision (i): Renumber to subdivision (j). The Department proposes amendments to ensure suppliers can meet the needs of the Blood Banking and Transfusion Services (BB/TS), which by statute must follow the AABB standards,[12] the Department proposes amendments requiring the BB/TS of any lab that contracts with outside suppliers maintain written policies and procedures on the selection of suppliers. The Department further proposes language requiring BB/TS participation in evaluating and selecting outside suppliers. LFS examiners have observed that the effective delivery of care may be compromised in hospitals where suppliers were unable to meet BB/TS needs. Requiring the BB/TS to develop written policies and procedures and be involved in the evaluation and selection of suppliers where possible, facilitates the proper selection of suppliers that can meet BB/TS needs and promotes patient safety.

The Department further proposes amendments requiring all new contracts to specify the expectations of both the BB/TS and the supplier, and to detail how those expectations will be met. LFS examiners have observed problems when BB/TS needs are not addressed in contracts and amendments with suppliers. Labs can better ensure patient safety by identifying potential problems with suppliers before contracts and amendments are signed. This amendment is necessary to update the regulations to current industry standards and to protect the public health and safety.

Delete existing subdivision (j): The Department proposes deleting former subdivision (j) to eliminate the requirement that lab services be periodically evaluated by a committee of medical staff. This provision is not current industry practice. The proposed amendments in section 70243 subdivision (f)(5) require the clinical laboratory director to establish and implement a QAPI process (the current industry practice), making an additional evaluation of lab services by a committee of medical staff redundant and burdensome.

Section 70245: Clinical Laboratory Service Staff
Amend subdivision (a): The Department proposes amendments clarifying the certification requirements for clinical laboratory directors. These amendments authorize the American Osteopathic Board of Pathology as an additional certifying entity that may be used to qualify pathologists to perform the duties of clinical laboratory directors. These amendments conform to the qualifications specified in CLIA regulations and are necessary to provide clarity to the regulated community and to protect public health and safety. The Department also proposes to make specific the required timing of consultations by changing “suitable intervals” to “intervals that meet the needs of the

[12] HSC sections 1602.5 and 1602.6.

patients." The needs of the patients can be accurately determined by reviewing patient care plans and physicians' orders, which contain specific instructions. The proposed amendments make other non-substantive changes.

Adopt new subdivision (b): The Department proposes to adopt subdivision (b) to make sure the Director of the clinical lab service must obey federal and state laws pursuant to CLIA, Business and professions Code, and Health and Safety Codes. This provides clarity for the regulated community.

Amend existing subdivision (b): Renumber to subdivision (c). The Department proposes to replace the outdated term "technologist" with the more commonly used "scientist" to bring the regulatory language in line with current industry terminology. The Department also proposes to replace the term "at all times" with "24 hours per day, 7 days per week" to make the requirement clearer and to maintain stylistic consistency with other Title 22 regulatory proposals. This is necessary to ensure that the laboratory is available whenever it is needed.

Amend existing subdivision (c): Renumber to subdivision (d). The Department proposes non-substantive grammatical changes to this regulatory section to update and clarify its language and provide stylistic consistency with the rest of the Department's regulations. The Department also proposes to require staffing that meets the needs of the patients rather than the needs of the service. The "needs of the service" are not clear, while the "needs of the patients" can be determined with specificity by examining patient care plans and physicians' orders. The Department proposes to replace "trained and experience staff" with "who are certified or licensed by the Department" to add clarity on who can work in the lab. Those who are licensed and certified by the Department have completed the necessary training and experience and it has been verified by the Department. Adding specific staff who are licensed by the Department gives clarity to the regulation. Staff may include these services but by adding "not limited to" gives room for future positions that have not been created.

Section 70247: Clinical Laboratory Service Equipment and Supplies
Amend subdivision (a): The Department proposes to require equipment and supplies to meet the needs of the patients rather than the needs of the service. The "needs of the service" are not clear, while the "needs of the patients" can be determined with specificity by examining patient care plans and physicians' orders.

Amend subdivision (b): The Department proposes non-substantive grammatical changes to the regulation for stylistic consistency and clarity. Also, the Department proposes to update an out-of-date reference regarding to California Administration Code with current reference regarding California Code of Regulations for clarity. Also, the Department proposes to replace "at appropriately short intervals each day of the week" with "must be inspected every seven days" to add specificity to the requirements. This adds clarity to the regulation as the original text is vague, difficulty to enforce, and allows for misinterpretation.

Section 70249: Clinical Laboratory Service Space

Amend subdivision (a): The Department proposes to replace the requirement for "adequate laboratory space as determined by the Department" with a requirement to comply with Title 24, California Building Code, section 1224.17. 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.[13] This change is necessary to align the regulations with current statutory requirements.

Adopt new subdivision (b): The Department proposes to adopt a requirement for sufficient space in the laboratory for specimen storage, equipment storage, and staff movement. The authority to determine building and design requirements was given to the Department of Health Care Access and Information (HCAI) (formerly known as the Office of Statewide Health Planning and Development).

Amend existing subdivision (b): Renumber to subdivision (c). The Department proposes grammatical changes to subdivision (c) and amend original text from passive to active voice. This aligns with Federal Plain Language Guidelines and is necessary to comply with the Administrative Procedures Act "plain language" requirements.

PHARMACEUTICAL SERVICE

Section 70261: Pharmaceutical Service Definition

Amend section 70261: The Department proposes amendments updating and clarifying the functions of the pharmaceutical service (service). These amendments replace the term "manufacturing" with "repackaging" to reflect current industry terminology and add drug-disposal to the list of the service's functions. The Department further proposes adding the evaluation and monitoring of the appropriate use of drugs and drug-related devices to the list of the service's functions, along with language allowing hospitals to include drug-therapy management by qualified licensed pharmacists as part of the service. Department subject matter experts have determined that the word "appropriate" provides specificity because it is a term of art in the pharmacy profession and has a specific meaning when used in this context. It means monitoring items such as dose, frequency, route of administration, etc. to ensure the safety and efficacy of a drug based on standards such as the U.S. Pharmacopeia and publications by the Food and Drug Administration (FDA). These amendments reflect changes made in the hospital industry since the passage of SB 493 (Hernandez, Chapter 469, Statutes of 2013) and are necessary to reflect the current scope of pharmaceutical practice. The proposed amendments consider that hospital pharmacists work as part of interdisciplinary care teams and update the definition of the service so that it aligns with current industry practices. This update is necessary to protect public health by providing clarity to the regulated community. The Department also proposes repeal of the words "appropriate," "qualified," and "adequate" because they are vague and open to interpretation by the

[13] HSC sections 20, and 131050 through 131225.

regulated community. The new language provides the specificity that is needed to understand the requirements.

Section 70263: Pharmaceutical Service General Requirements
Amend subdivision (a): The Department proposes amendments changing the number of beds that is the dividing point for the type of pharmacy license needed based on licensed bed capacity. The “100 or more beds” dividing point in the existing regulation differed from the pharmacy licensing regulations that make the dividing point “100 beds or fewer.” This amendment is necessary to align the regulation with the pharmacy licensing regulations in the BPC. Additionally, a reference to BPC section 4029 is provided so that hospitals with both more than 100 beds and those with 100 beds or less are referred to the appropriate BPC section for their licensed bed capacity. This amendment is necessary to update the regulation to current industry practices and provide clarity to the regulated community.

Amend subdivision (b): The Department proposes the addition of the phrase “in writing” to this subdivision to clarify and make specific the method by which the responsibility and the accountability of the service to the medical staff and administration shall be recorded. Public Health Pharmaceutical Consultant (PHPC) surveyors have observed that hospitals with written documentation have better compliance with regulatory requirements and are more likely to provide this documentation as guidance materials to their staff, and this improves patient outcomes. This amendment does not impose a new obligation on hospitals as Title 21 CCR section 70019 explains that the term “defined” means “defined in writing.” This amendment reflects current industry practice and is necessary to protect public health.

Amend subdivision (c): The Department proposes to remove “…or its [the P&T Committee’s] equivalent.” The P&T committee is referred to industry-wide as the P&T committee and there is no equivalent. The removal of the word “equivalent” makes specific what committee the regulation refers to and aligns the language with current industry standards. The revised language establishes the P&T Committee and states who is part of the P&T Committee. These amendments reflect current practice in many hospitals and are necessary to provide clarity to the regulated community.

Adopt subdivision (d): The Department proposes to add subdivision (d) to specify what the P&T Committee must do in paragraphs (1-3). This adds clarity to the regulation and to the regulated community.

Amend paragraph (1): To specify the P&T Committee must develop, implement, and maintain documented policies and procedures that are consistent with state and federal laws and regulations and accepted standards of practice that cover listed topics. Adding develop, implement, and maintain is necessary to provide clarification among the regulated community when developing the policies and procedures, to maintain consistency with other proposed Title 22 regulations, and to protect the health and safety of patients. This is to ensure that the hospital must create policies and

procedures, train the staff on the policies and procedures and the Department can enforce the policy and procedures if they are being followed, regardless of how The Department proposes to add drug compounding, repackaging, and drug administration to reflect current industry practice and standards to protect patient health.

Adopt paragraph (2): To specify the P&T Committee must develop, implement and maintain documented policies and procedures consistent with state and federal laws and regulations and accepted standards of practice that cover the topics set forth in subdivisions (A) through (K).

Adopt subdivision (A): To add disposal of all drugs to the list of topics the P&T Committee must address. The P&T Committee must develop and approve documented policies on disposal of all drugs and, if appropriate, procedures that adopt current industry standards to protect patient health.

Adopt subdivision (B): To add selection, use and disposal of chemicals and cleaning agents in areas where sterile compounding is performed to the list of topics the P&T Committee must address. The Board of Pharmacy has adopted new regulations concerning sterile compounding.[14] The P&T Committee must develop and approve documented policies on the issues around chemicals and cleaning agents in areas where sterile compounding is performed and, if appropriate, procedures that adopt current industry standards to protect patient health.

Adopt subdivision (C): To add drug error reporting and prevention to the list of topics the P&T Committee must address. New requirements in this area have been imposed by statute.[15] The P&T Committee must develop and approve documented policies on drug error reporting and prevention and, if appropriate, procedures that adopt current industry standards to protect patient health.

Adopt subdivision (D): To add medical reconciliation for high-risk patients upon admission to the hospital to the list of topics the P&T Committee must address. New requirements in this area have been imposed by statute.[16] The P&T Committee must develop and approve documented policies on medical reconciliation for high-risk patients upon admission to the hospital and, if appropriate, procedures that adopt current industry standards to protect patient health.

Adopt subdivision (E): To add development, implementation, and maintenance of a formulary and a formulary system of drugs to the list of topics the P&T Committee must address. Industry standards on this topic have evolved,[17] and the P&T Committee must

[14] Title 16 CCR section 1751 et. seq.

[15] HSC section 1339.63.

[16] BPC section 4118.5.

[17] American Society of Health-System Pharmacists (ASHP) “Pharmacy and Therapeutics Committee and the Formulary System” (2008)

develop and approve documented policies and, if appropriate, procedures that adopt current industry standards to protect patient health.

Adopt subdivision (F): To add use and procurement of non-formulary drugs as necessary to the list of topics the P&T Committee must address. Again, industry standards on this topic have evolved,[18] and the P&T Committee must develop and approve documented policies and, if appropriate, procedures that adopt current industry standards to protect patient health.

Adopt subdivision (G): To add minimization of drug diversion to the list of topics the P&T Committee must address. The opioid epidemic has increased demand for drugs stored in hospitals, and the P&T Committee must develop and approve documented policies and, if appropriate, procedures that adopt current industry standards to protect patient health.

Adopt subdivision (H): To add management of drug recalls and shortages to the list of topics the P&T Committee must address. PHPC surveyors have found that hospitals with documented policies and procedures experience less disruption to patient care when drug recalls and shortages arise. Such policies and procedures provide clear guidelines for pharmacy staff to follow and help facilitate better interactions with patients and other healthcare professionals in the event of a shortage. This is a common industry practice and is necessary to update the regulations and protect patient health.

Adopt subdivision (I): To add use of drug delivery systems and drug-related devices, including automated drug dispensing systems (ADDS), drug compounding devices, and drug administration devices to the list of topics the P&T Committee must address. Having written policies and, when deemed appropriate by the Committee, procedures for the use of these devices is a common in the industry but not recognized in current regulatory language. Having written policies and procedures on the proper use of drug delivery systems and drug-related devices facilitates the use of industry best practices and helps PHPC surveyors' oversight. These amendments are necessary to bring the regulations in line with current best practices known to protect patient health and to provide clarity to the regulated community.

Adopt subdivision (J): To add use of medicinal cannabis. Under SB 311 (Hueso, Chapter 384, Statutes of 2021), GACHs are required to allow terminally ill patients to possess and use medicinal cannabis unless action is taken against the facility by certain agencies. Health and Safety Code section 1649.2 requires GACHs to develop written guidelines for cannabis. There are statutory requirements and safety concerns that apply to the use and storage of medicinal cannabis that do not apply to other drugs, therefore, it is necessary for the pharmaceutical service to have policies and procedures specific to medicinal cannabis that ensure both compliance with the law and the safety of patients, guests, and hospital staff.

[18] ASHP "Pharmacy and Therapeutics Committee and the Formulary System" (2008).

Adopt subdivision (K): The P&T Committee must address new drugs, devices, and treatments that develop in the future. The P&T Committee must develop, implement, and maintain documented policies to address these new developments and procedures that adopt to current industry standards to provide clarity to service staff and protect patient health.

Adopt paragraph (3): To specify the P&T Committee must participate in procurements decisions, evaluation, and monitoring of drug delivery systems and drug-related devices.[19] PHPC surveyors report that P&T Committee involvement in the procurement decisions and use of such systems and devices facilitates greater efficiencies and improves patient care. Requiring P&T Committee involvement is necessary to bring the regulations in line with current best practices known to protect patient health and provide clarity to the regulated community.

The above-described amendments and adoptions significantly revising subdivision (c) require the P&T Committee to develop policies and, where appropriate, procedures for new developments in pharmaceutical practice created by law or regulation, or due to industry advances. The amendments and adoptions listing these topics reflect current practice in many hospitals known to protect patient health and produce better patient outcomes and are necessary to provide clarity to the regulated community. Written policies and procedures provide clarity to service staff, and facilitate PHPC surveyors' oversight function, allowing them to ensure the hospital follows its own written policies and procedures. The Department also proposes non-substantive grammatical changes to this subdivision to provide clarity to the regulated community.

Adopt new subdivision (e): The Department proposes to adopt subdivision (e) to clarify the regulation. The Director of Pharmaceutical Service with consultation of administration and knowledgeable health care professionals to approve procedures adds consistency and clarity to the regulation.

Adopt new subdivision (f): The Department proposes to move "Policies shall be approved by governing body" from (c)(1) to (f) for clarity of the regulation. The Department also changes the regulation from passive voice to active voice to align with Administrative Procedures Act standards.

Amend existing subdivision (d): Renumber to subdivision (g). The Department proposes non-substantive grammatical changes to this subdivision to provide clarity to the regulated community.

Amend existing subdivision (e): Renumber to subdivision (h). The Department proposes minor grammatical changes to this subdivision, substituting the phrase

[19] ASHP "Minimum Standards for Hospitals" see "Standard VI, Drug delivery systems, administration devices, and automated dispensing machines" at pages 605-606.

"establish and maintain" for "must be … maintained," and specifying this is the pharmaceutical service's responsibility. The proposed amendments are reasonably necessary to provide clarity to the regulated community.

Adopt new subdivision (i): The Department proposes a new requirement that the pharmacy ensure the availability of the most current information on drugs 24 hours a day. Current industry standards require physicians and other health care providers to have the ability to obtain drug information at all hours, even when the pharmacy is closed. Drug information is needed 24 hours a day in hospitals, particularly in hospitals with clinical programs requiring intensive drug therapy such as transplant or open-heart surgery programs, neonatal intensive care units, and trauma centers. The proposed amendments bring the regulations up to date with current industry practices and are necessary to protect patient health and provide clarity to the regulated community.

Amend existing subdivision (f): Renumber to subdivision (j).

Amend paragraph (1): To clarify that the P&T Committee is responsible for the written policies and procedures pertaining to the emergency drug supply. Existing regulations call for such policies and procedures but do not designate who is responsible for creating and maintaining them. This provision is necessary to prevent any confusion leading to negative health outcomes.

Amend paragraph (2): To clarify who may stock the emergency drug supply, and how the emergency drug supply cart or container is labelled. This aligns the regulations with changes made by SB 1039 (Hernandez, Chapter 319, Statutes of 2014), enacted in BPC section 4115, subdivision (j)(1-3) and section 4119.6. SB 1039 provided pharmacy interns and technicians with authority to restock the emergency drug supply under the supervision of a pharmacist. Hospital pharmacists and the Department's PHPC surveyors check the expiration dates of the emergency drug supply to determine whether the drugs are still potent and safe to use. Requiring a list of the contents of the emergency drug supply on the outside of any secondary cart or container in which the emergency drug supply is kept aligns this provision with the current industry practice of keeping the emergency drug supply in a sealed tray in a drawer in an emergency crash cart. By aligning the regulation with statute and current industry practice, these amendments promote patient health, and provide clarity to the regulated community.

Adopt paragraph (3): To require the service have a monitoring system that ensures the emergency drug supply is properly stocked when it is not being stocked by a pharmacist. This is a common industry practice that improves outcomes and ensures ongoing scrutiny and improvement of the stocking and sealing of the emergency drug supply. This amendment is necessary to align the regulations with accepted industry standards and to provide clarity to the regulated community.

Amend existing paragraph (3): Renumber to paragraph (4). Allow pharmacy interns and, under the supervision of a pharmacist, pharmacy technicians to inspect the

emergency drug supply. SB 1039 (see discussion under (j)(2) above) authorized pharmacy interns and technicians to conduct these inspections under the supervision of a pharmacist. The proposed amendments are necessary to align the regulation with statute and provide clarity to the regulated community. The Department also proposes non-substantive grammatical changes to this paragraph for the clarity of the regulated community.

Amend existing subdivision (g): Renumber to subdivision (k). Move the text with requirements for drug orders into paragraphs (1) through (3). Move the text in current paragraphs (k)(1) and (k)(2) into subdivisions (k)(3)(A) and (k)(3)(C). The Department proposes amendments allowing practitioners acting within the scope of their practice to order drugs if allowed by hospital policy. For example, in some hospitals Physician Assistants (PAs) and Advanced Practice Registered Nurses (APRNs)[20] already order drugs under restricted circumstances, while some hospitals do not want PAs and APRNs prescribing drugs at all. Hospitals can individually determine who may act as an authorized prescriber and pharmacists will only fill orders from practitioners acting within their scope of practice and allowed by hospital policies. The amendments are necessary to update the regulations to meet current industry practices, allow hospitals to manage the risks associated with various prescribers, and provide clarity to the regulated community. These amendments also make non-substantive grammatical changes.

Amend paragraph (1): To update existing language relating to drug orders. These amendments add language requiring that indications for use be included on the order and allow the prescriber or authorized practitioner to provide an electronic signature. This is necessary to bring the regulations up to date with existing standards of practice and to provide clarity to the regulated community. Additionally, the Department proposes language that allows individuals acting within their scope of practice to sign drug orders if allowed by hospital policy. This amendment aligns the regulations with existing standards of practice, allows hospitals to manage risks associated with various prescribers, and provides clarity to the regulated community.

Amend paragraph (2): To specify that drug orders can be electronically transcribed, and to add “practitioners acting in accordance with scope-of-practice laws and hospital policies,” to the list of persons from which drug orders may be received. These amendments are necessary to align the regulations with existing standards of practice, allow hospitals to manage risks associated with various prescribers, and to provide clarity to the regulated community.

Amend paragraph (3): To specify that, to the extent possible, verbal and telephone drug orders must be avoided. The American Society of Health-System Pharmacists

[20] PAs may already be delegated the authority to issue a drug order by a supervising surgeon or physician (see BPC §3502.1). Following standardized procedures jointly promulgated by the Division of Licensing of the Medical Board of California and the Board of Registered Nursing, APRNs may order drugs (see BPC §2725).

(ASHP) in “ASHP Guidelines: Minimum Standards for Pharmacies in Hospitals” (2013) in Standard VI, section A, paragraph “Medication Orders,” at page 605, states: “Oral orders should be avoided to the extent possible.” There are drugs commonly confused because of similarities in name, and this has a negative impact on patient health. The “ASHP Guidelines on Preventing Medication Errors in Hospitals” (November 2017) in the section “Ordering, Transcribing, and Receiving,” paragraph 5, at page 274, states: “Verbal or telephonic medication orders should be reserved only for situations in which it is impossible or impracticable for the prescriber to write the order or enter it into the computer (e.g., during an emergency situation or if prescriber is involved in a sterile procedure).” The Department adds clarifying language so that when physicians or other prescribers have their staff call in orders, the name of the person calling in the order as the physician’s or prescriber’s agent must be entered in the patient’s medical record. Persons employed by a physician in their private practice who are not employees of the hospital are not lawfully authorized to call in drug orders. These amendments are necessary to align the regulations with existing standards of practice and clarify those standards. The Department further proposes amendments allowing verbal orders to be countersigned in writing or electronically by prescribers or persons acting as an authorized prescriber in accordance with scope of practice laws and hospital policy. These amendments implement existing standards of practice while still allowing hospitals to manage their prescriber-associated risk and are necessary to protect public health by providing clarity to the regulated community.

Amend existing paragraph (1): Renumber to subdivision (A). To specify that telephone orders, like verbal orders, may be recorded only by individuals working within the scope of their license. This is necessary to ensure that verbal and telephone orders are handled consistently, and ensure the regulations track with changing scope of practice laws. Additionally, the Department proposes adding new language to this subdivision to specify all verbal and telephone orders must be read back to the person making the order. The “ASHP Guidelines: Minimum Standards for Pharmacies in Hospitals,” (September 2013) in Standard VI, section A, paragraph “Medication Orders,” at page 605, recommends that “[o]rder transmittal safeguards should be used to ensure the security of the prescriber’s order.” The “ASHP Guidelines on Preventing Medication Errors in Hospitals,” (November 2017) section “Ordering, Transcribing, and Receiving,” paragraph 5, at page 274, states: “The recipient must read back the order to the prescriber slowly, clearly and articulately to avoid confusion.” These amendments are necessary to protect patient health by ensuring that verbal and telephone drug orders are as accurate as possible and to provide clarity to the regulated community by bringing the regulations in line with existing industry practices.

Adopt subdivision (B): To forbid verbal or telephone orders for chemotherapeutic drugs unless it is to discontinue usage. This is a common industry practice recommended in the “ASHP Guidelines: Preventing Medication Errors with Chemotherapy and Biotherapy” (April 2015) section “Recommendations for Healthcare Organizations,” paragraph “Verbal Orders for Chemotherapy Medications” on page 296, that states: “Except for discontinuing treatment, medication-use systems should not

permit healthcare providers to use or accept verbal orders to commence or modify chemotherapy medications." These amendments are necessary to protect patient health by ensuring orders for chemotherapy drugs are as error-free as possible and provide clarity to the regulated community by bringing the regulations in line with common industry practices.

Amend existing subdivision (2): Renumber to subdivision (C). A non-substantive change is proposed to update and clarify existing language and provide stylistic consistency with the rest of the Department's regulations.

Amend existing subdivision (h): Renumber to subdivision (I). The Department proposes language allowing printed and electronic pre-approved order sets and drug therapy protocols to be used when signed by a person lawfully authorized to prescribe. The Department proposes applying, with minor amendments, the existing requirements for standing orders (existing subdivision (h), paragraphs (1) through (4)), to pre-approved order sets and drug therapy protocols, while removing the reference to standing orders. Pre-approved order sets and drug therapy protocols are patient-specific orders issued by physicians and other authorized prescribers for a specific patient. Once a pre-approved order set and drug therapy protocol is signed ordering drugs for a specific patient, the drug is administered. The proposed language of this subdivision would also:

No changes to paragraph (1).

Amend paragraph (2): The Department proposes to replace "standing orders" with "order set or drug therapy protocol" to add clarity to the regulation.

Amend paragraph (3): To remove "or its [the P&T Committee's] equivalent." The P&T committee is referred to industry-wide as the P&T committee and there is no equivalent. The removal of the word "equivalent" makes specific what committee the regulation refers to and aligns the language with current industry standards.

Amend paragraph (4): To specify that pre-approved order sets and drug therapy protocols must specify the indication for the drug to be prescribed.

Adopt paragraph (5): To require pre-approved order sets and protocols be signed by the lawfully authorized prescriber at the time the order is given for a specific patient and be included in the patient's medical record. The above-described amendment to paragraph (4) and adoption of paragraph (5) are necessary to protect patient health, bring the regulations up to date with existing standards of practice, and provide clarity to the regulated community.

Adopt subdivision (m): The Department proposes language handling standing orders differently than pre-approved order sets and drug therapy protocols, by allowing hospitals to have standing orders that allow authorized personnel to administer drugs to

a patient without first obtaining a patient-specific order from a physician or authorized prescriber. To administer drugs pursuant to a standing order, authorized personnel must determine the patient meets the pre-defined criteria in the standing order or associated protocol. The Department proposes to retain, with minor amendments, the existing requirements for standing orders (existing subdivision (h) paragraphs (1) through (4)). The proposed language of this subdivision would also:

Amend paragraph (3): Add the requirement that the P&T Committee must approve a standing order and review the standing order at least annually.

Amend paragraph (4): Specify that standing orders must specify the indication for the drug being administered.

Adopt paragraph (5): Require the standing order be documented in the patient's medical record at the time of initiation, or as soon as possible thereafter, and require the attending physician or another authorized practitioner retrospectively review the order and document if the order was medically necessary or not in the patient's medical record. The amendments to paragraphs (3) and (4) and the adoption of paragraph (5) are necessary to bring the regulations up to date with existing standards of practice and provide clarity to the regulated community.

Amend existing subdivision (i): Renumber to subdivision (n). The Department proposes requiring that standing orders of an individual physician must be approved by the P&T Committee and that approval documented before the relevant drugs may be administered. The P&T Committee must review the standing orders of individual physicians at least annually. The Department also proposes to remove "or its [the P&T Committee's] equivalent." The P&T committee is referred to industry-wide as the P&T Committee and there is no equivalent. The removal of the word "equivalent" makes specific what committee the regulation refers to and aligns the language with current industry standards. These amendments reflect current industry best practices and are necessary to protect patient health by providing clarity to the regulated community.

Amend existing subdivision (j): Renumber to subdivision (o). The Department proposes minor grammatical changes, substituting the word "documented" for the word "recommended" for emphasis. The Department also proposes to remove "or its equivalent" when referring to the P&T committee and when referring to the executive committee of the medical staff. The P&T committee is referred to industry-wide as the P&T committee and there is no other recognized name for the committee. All hospitals have an executive committee of the medical staff and there is no other recognized name for the executive committee. The removal of the word "equivalent" makes specific what committees the regulation refers to and aligns the language with current industry standards. The proposed amendments are necessary to provide clarification to the regulated community.

Amend existing subdivision (k): Renumber to subdivision (p): The Department proposes to delete existing subdivision (k) and adopt new language requiring recording all drug orders in the patient's health record, with the pharmacist receiving a copy of the order. The Department proposes additional language requiring all drug orders be reviewed by the pharmacist for appropriateness before administration or automatic dispensing, except in the case of an emergency. Department subject matter experts have determined that the word "appropriateness" provides specificity because it is a term of art in the pharmacy profession and has a specific meaning when used in this context. It means reviewing for variables such as dose, frequency, route of administration, etc. to ensure the safety and efficacy of a drug based on industry standards such as the U.S. Pharmacopeia and the Food and Drug Administration (FDA) publications. The Department further proposes that drugs administered or dispensed in emergencies must be reviewed retrospectively following the hospital's policies and procedures.[21] These amendments are necessary to protect patient health by ensuring a pharmacist's review of all drug orders before the first dose is administered to the patient, and ensuring a retrospective review for drugs administered or dispensed in emergencies, and to provide clarity to the regulated community by aligning the regulations with existing industry practices.

Amend existing subdivision (l): Renumber to subdivision (q). The Department proposes amendments requiring, with the exception of drugs administered parenterally, that any drugs left at the bedside must be secured to prevent unauthorized access. New technologies can secure drugs without the use of locks. There is an exception for medical cannabis because Health and Safety Code section 1649.2 requires it to be stored in a locked container. The Department further proposes adding Schedule V drugs to the list of drugs that cannot be left at a patient's bedside. With the opioid crisis, Schedule V drugs containing codeine have become targets for abuse. Additionally, there is now a Schedule V drug containing cannabinoids (a Schedule I substance), and more drugs containing cannabinoids may be approved as Schedule V drugs in the future. The Department proposes amendments adding that the service should also have documented policies and procedures for administering and documenting the use of bedside drugs. The proposed amendments are necessary to protect patient health, bring the regulations current with existing technologies, medical developments, and standards of practice, provide flexibility to hospitals, and provide clarity to the regulated community. These amendments include non-substantive grammatical changes to provide clarity to the regulated community.

Amend existing subdivision (m): Renumber to subdivision (r). The Department proposes amendments specifying the conditions that must be met for the administration of drugs brought in by or with a patient. The proposed language of this subdivision would also:

[21] ASHP "Minimum Standards for Hospitals" see Standard VI. section A, paragraph "Review of Medication Orders," page 605.

Amend paragraph (1): Specify that drugs brought in by or with a patient will only be administered if they were ordered by authorized practitioners. This change aligns this paragraph with the list of who may order drugs provided in subdivision (h) and provides clarity to the regulated community. This amendment also makes a non-substantive grammatical change to provide clarity to the regulated community.

No changes to paragraph (2).

Amend paragraph (3): Make a non-substantive change to provide clarity to the regulated community.

Adopt paragraph (4): Specify that the verification must be recorded in the patient's medical record, as foreign drugs need to be identified to ensure patient safety. Requiring the verification be recorded in the patient medical record is recommended in "ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals," (September 2013) in Standard IV, section A, paragraph "Patient's Own Medications," at page 604: "Drug products and related devices brought into the hospital by patients shall be identified by pharmacy and documented to the patient's medical record… which should ensure the pharmacist's identification and validation of medication integrity." Verifying the identity and validity of patient drugs brought into the hospital ensures both that the drugs are as described on the drug label and that the drugs were properly prescribed for the patient. This directly protects patient health. Providing this information in the patient medical record also protects patient health by assisting physicians in addressing of the risks of polypharmacy. Patients who concurrently take multiple drugs sometimes get too little benefit for the risks involved and end up being harmed more than helped. These amendments reflect current industry standards and are necessary to protect patient health and provide clarity to the regulated community.

Adopt paragraph (5): Specify that in addition to the requirements in paragraphs (1) – (4), medical cannabis brought to the hospital by a terminal patient must meet the requirements of Health and Safety Code sections 1649 – 1649.6. These requirements, such as the use of locked storage and the prohibition of smoking and vaping, are specific to medical cannabis and are needed to ensure the safety of other patients, guests, and employees of the hospital, and the safe operations of the hospital.

Amend existing subdivision (n): Renumber to subdivision (s). The Department proposes language requiring a pharmacist to review all drug orders before drugs are removed from the after-hours drug supply. This provision would not apply to emergencies. This CMS requirement is the industry standard (CMS Interpretive Guidelines, section 482.25(b)(4) Revision 37 issued October 2008).[22] These amendments would also add language that allows designated and trained registered nurses access to the after-hours drug supply, and allows them to use an electronic

[22] See also, "ASHP Guidelines: Minimum Standards for Hospitals" standard I, paragraph "After-Hours Pharmacy Access," at pages 599 and 600.

signature when recording the removal of drugs.[23] These amendments protect public health by ensuring pharmacist review of all drug orders, and by allowing hospitals to improve nurse access to the after-hours drug supply. The proposed amendments are necessary to bring the regulations current with existing standards of practice and provide clarity to the regulated community.

Amend existing subdivision (o): Renumber to subdivision (t). Move the text for the conditions for a patient to continue taking an investigational drug into paragraph (1). Move the text that sets forth the responsibilities of the pharmacist in regard to investigational drugs into paragraph 2. The Department proposes the addition of the phrase “at all times” to existing requirements to specify when information on investigational drugs must be made available at the nursing station. These amendments are necessary to protect patient health by ensuring the service keeps informed of professional practice standards regarding investigational drug use and provide clarity to the regulated community by aligning the regulations with existing industry practices. Non-substantive changes are also proposed to update and clarifying existing language and provide stylistic consistency with the rest of the Department’s regulations.

Amend existing subdivision (p): Renumber to subdivision (u). The Department proposes non-substantive changes to these requirements, updating outdated terminology and providing stylistic consistency with the rest of the Department’s regulations.

Amend existing subdivision (q): Renumber to subdivision (v). The Department proposes amendments specifying how drugs are labeled and stored. The proposed language of this subdivision would also:

Amend paragraph (1) and (2): Delete existing paragraph (1) of this subdivision because the regulation is out of date and move up, unchanged, existing paragraph (2) to become paragraph (1)**.** The proposed amendment would also move up, unchanged, existing paragraph (3) to become paragraph (2).

Add paragraph (3): Add new language as paragraph (3) clarifying that drugs brought into the hospital by or with the patient that are not being continued will be sent to the pharmacy for storage or sent home with the patient’s designated representative. The proposed amendments are necessary to protect patient health by removing all drugs the patient will not continue taking while in the hospital from the patient’s bedside. This ensures patients do not take these drugs, reduces the risks of polypharmacy, and provides clarity to the regulated community by aligning the regulations with existing industry practices.

No changes to Paragraphs (4) through (5).

[23] Consistent with CMS State Operations Manual (SOM) Appendix A tag A-506, Interpretive Guidelines.

Amend paragraph (6): Require that drugs be stored at appropriate temperatures that follow the manufacturer's guidelines, or if the manufacturer doesn't specify storage temperatures, the guidelines in federal regulations. Subdivision (c) of section 205.50 of Part 205 of Title 21 of the CFR requires drugs be stored as required on the label or following the requirements set forth in the official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

Amend subdivision (A): Change the range of temperatures encompassed in the term "controlled cold temperature (refrigerated)." The "ASHP Guidelines on Compounding Sterile Preparations," on page 118 in Table 5, adopts the 34th revision of the USP/NF standard,[24] that defines controlled cold temperature (refrigerated) as falling within the range between 2 degrees and 8 degrees Celsius (36- and 46-degrees Fahrenheit). Amending subparagraph (A) is necessary so that the Department is consistent with federal mandates.

Amend subdivision (B): To specify the range of temperatures encompassed in the term "controlled freezer temperature." The "ASHP Guidelines on Compounding Sterile Preparations," on page 118 in Table 5, adopts the 34th revision of the USP/NF standard, that defines controlled freezer temperature as falling within the range between -10 degrees and -35 degrees Celsius (-13 degrees and 14 degrees Fahrenheit). Amending subparagraph B is necessary so that the Department is consistent with federal mandates.

Amend subdivision (C): To specify the range of temperatures encompassed by the term "controlled room temperature." The Department's proposed controlled room temperature range is consistent with the 34th revision of the USP/NF standards cited in "ASHP Guidelines on Compounding Sterile Preparations," (2013), on page 118 in Table 5. The Department also proposes language specifying the outer temperature limits allowed when stored drugs encounter temperatures outside the range for controlled room temperature range. The outer temperature limits for fluctuations in temperature outside controlled room temperature are in the USP/NF standard USP <659> "Packaging and Storage Requirements," which is the industry standard.[25] The amendments to subdivision C are necessary to align the Department's regulations with federal regulations and existing standards of practice and provide clarity to the regulated community.

Amend subdivision (D): To require the pharmacy keep temperature records of all locations where drugs and vaccines are stored, and to keep such records readily available for three years. The CDC recommends that refrigerator and freezer

[24] General notices and requirements. In: The United States Pharmacopeia, 34th rev., and The National Formulary, 29th ed. Rockville, MD: The United States Pharmacopeial Convention; 2011:11–12.

[25] ECA Academy "What are the Regulatory Definitions for "Ambient", "Room Temperature" and "Cold Chain"?" (March 2, 2017).

temperature logs for vaccines be kept for at least 3 years,[26] so a hospital can look back and see if any freezer or refrigeration unit is developing a problem. The proposed amendments are necessary to protect patient health, bring the regulations current with existing standards of practice, and provide clarity to the regulated community.

Amend paragraph (7): To specify that drugs must be stored in a clean and orderly manner in locations large enough to prevent overcrowding. PHPC surveyors report that in hospitals that do this, pharmaceutical staff can fill drug orders more efficiently and accurately. Include that the storage of drugs must be free from foreign and organic material is necessary to add clarity for the regulated community. The proposed amendments are necessary to protect patient health, align the regulations with existing industry practices, and provide clarity to the regulated community.

Amend paragraph (8): The Department proposes to repeal "responsible" because it is unclear and open to interpretation. The Department also proposes to correct a reference from 70263(l) to 70263(q) in this paragraph so the regulated community can find the correct information.

Amend paragraph (9): To add "mislabeled" drugs and "drugs otherwise unusable for use" to the list of drugs that must not be available for patient use. This is necessary to provide clarity to the regulated community by updating the regulations to reflect existing industry practices.

Amend paragraph (10): To allow a pharmacy intern or technician to inventory drugs located outside of the hospital's pharmacy, and to require irregularities in the inventory, no matter who performed the inventory, be reported within 24 hours to the director of the pharmacy service, the Director or Chief Executive Officer of the hospital, and to the director of nursing. The proposed amendments implement statute and are necessary to bring the regulations current with existing standards of practice and provide clarity to the regulated community.

Amend paragraph (11): To specify how to destroy discontinued individual patients' drugs not supplied by the hospital left behind by a discharged patient (regardless of lot number). The exemption from being destroyed for discontinued individual patient drugs identified by lot number is removed, as the existing standard of practice is to destroy all discontinued individual patient drugs left after discharge, regardless of lot number. The proposed amendment is necessary to align the regulation with the existing practice. The Department also proposes applying the existing protocol for destroying Scheduled drugs listed in Schedules II-IV in 21 U.S.C. section 812, to drugs listed in Schedule V. The opioid crisis has raised concerns about the theft of leftover Schedule V drugs, despite their relatively low potential for abuse compared to Schedule IV drugs. Requiring Schedule V drugs be destroyed following the existing protocol for the destruction of leftover Schedule II-IV drugs will reduce these concerns. The proposed

[26] U.S. Centers for Disease Control. Vaccine Storage & Handling Toolkit (2018).

amendments are necessary to bring the regulations current with existing standards of practice and provide clarity to the regulated community.

Amend subdivision (A) & (B): The Department proposes applying the existing protocol for destroying drugs listed in Schedules II-IV in 21 U.S.C. section 812, to also include drugs listed in Schedule V. The opioid crisis has raised concerns about the theft of leftover Schedule V drugs, despite their relatively low potential for abuse compared to Schedule IV drugs. Requiring Schedule V drugs be destroyed following the existing protocol for the destruction of leftover Schedule II-IV drugs will reduce these concerns. Subdivision B is amended to maintain continuity with subdivision A, so drugs listed in Schedule V are excluded from the list of drugs that may be destroyed in the presence of only one pharmacist. The proposed amendments are necessary to bring the regulations current with existing standards of practice and provide clarity to the regulated community. These amendments also update the references to Scheduled drugs so that the citation refers to the federal regulations instead of the federal statute and make minor grammatical changes.

Delete existing subdivisions (r) and (s): The Department proposes to delete existing subdivisions (r) and (s), as they are outdated. These deletions are necessary to bring the regulations up to current industry standards and provide clarity to the regulated community.

Adopt new subdivision (w): The Department proposes to adopt new language requiring the pharmacy to have a controlled substance record system for tracking all Scheduled drugs. This new language is necessary to bring the regulations up to date with existing practice standards known to protect public health, and to provide clarity to the regulated community.

Adopt paragraph (1): To require the controlled substance record system be immediately retrievable by hospital staff when requested by a surveyor. Rapid access to either an online or a hard copy of the Scheduled drugs record system is critical to the effectiveness of PHPC surveyors' review. The proposed addition is necessary to bring the regulations current with existing standards of practice, protect the public health, and provide clarity to the regulated community.

Adopt paragraph (2): To require the controlled substance record system to be able to facilitate the identification and extent of loss or diversion of controlled substances. Controlled substance record systems that track loss and diversion information provide better tools for detecting and correcting related problems. These amendments are necessary to protect public health by enhancing hospital efforts to prevent the diversion of controlled substances into the general population, align the regulations with existing industry practice and provide clarity to the regulated community.

Adopt new subdivision (x): The Department proposes to require the service to develop, implement, and maintain a Quality Assessment and Performance Improvement (QAPI) program in accordance with hospital-wide QAPI processes as defined in 42 CFR

482.21 for the pharmacy and for the drug-use processes throughout the hospital. The proposed amendment is necessary to bring the regulations current with accepted industry standards known to protect patient health and promote worker safety.

Adopt paragraph (1): To require documented monitoring systems for repackaging and compounding drugs that meet industry standards and applicable laws and regulations. PHPC surveyors report that hospitals with documented monitoring systems for drug repackaging and compounding have fewer problems compared to hospitals that have none. The Department further proposes language requiring a licensed pharmacist by the Pharmacy Board of California must develop and conduct in-service training programs to educate the professional staff on compliance with quality control procedures for drug repackaging and compounding. Hospitals that train both service staff and nursing staff that do bedside compounding on quality control procedures for repackaging and compounding drugs increase likelihood that staff will follow those procedures, and this better protects patients. These amendments are necessary to improve drug repackaging and compounding within hospitals, protect the public health, and provide clarity to the regulated community,

Adopt paragraph (2): To require that the service develop and assess performance indicators for all contracted pharmaceutical services. Under Title 22 CCR section 70713, all contracted services must follow the Department's hospital regulations. PHPC surveyors have observed services that develop and regularly assess performance indicators more effectively monitor work done by outside contractors. This requirement that the service measure and assess contractor performance increases the service's scrutiny of outside contractors, and that increases the likelihood that outside contractors comply with the Department's regulations. This proposed addition is necessary to protect public health, align the regulations with existing industry practice, and provide clarity to the regulated community.

Adopt paragraph (3): To require the contracted pharmaceutical service conduct periodic audits assessing drug therapy protocols for high-risk/high alert drugs. "High-risk/high-alert drugs" is the industry terminology for drugs that have a greater chance of causing significant harm to patients if used in error. The American Society of Health-System Pharmacists (ASHP) publication "ASHP Guidelines on Preventing Medication Errors in Hospitals" (2018) mentions three ways hospitals can improve their handling of such drugs.[27] Each hospital should examine their error rate around high-risk/high-alert drugs and adapt their drug therapy protocols accordingly. PHPC surveyors have observed that practice standards to reduce the risk of errors in dispensing high-

[27] ASHP's Guidelines on Preventing Medication Errors in Hospitals (2018). Require high-risk drugs be reviewed and reconciled within 24 hours of inpatient admission (paragraph "Patient Admission" at page 19); require work on high-risk drug products (for chemotherapy, pediatric drugs, total parenteral drugs) be independently checked by a second individual, preferably a pharmacist (paragraph "Dispensing" at page 32); and use a Medication-Use Evaluation to evaluate and audit a specific high-alert or high-risk drug (at paragraph "Medical Use Evaluation" at page 46). ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System (2008) at page 214.

risk/high-alert drugs are still evolving. Requiring the service conduct periodic audits ensures hospitals pay attention to and adopt industry standards as they are developed. The proposed amendments are necessary to protect patient health, encourage implementation of evolving industry practice standards, and provide clarity to the regulated community.

Amend existing subdivision (t): Renumber to subdivision (y). The Department proposes to delete the requirement that the P&T Committee make recommendations to the administration after conducting a periodic evaluation of the contracted pharmaceutical service. The Department proposes instead that the P&T Committee's evaluation and recommendations be provided to the medical staff on an ongoing basis, which exercises oversight over the service and will make recommendations to the service and elevate recommendations to the administration. The proposed amendment is necessary to bring the regulations current with existing standards of practice, and to provide clarity to the regulated community.

Section 70265: Pharmaceutical Service Staff
Amend subdivision (a): The Department proposes amendments clarifying the responsibilities and qualifications of the director of the contracted pharmaceutical service and requiring these responsibilities and qualifications to be included in the job description or agreement between the director and the hospital. Additionally, the Department proposes to eliminate the service director's responsibilities of "procurement, storage and distribution of all drugs" so that hospitals may have a service director who is not the pharmacist-in-charge (PIC) as defined in Title 16 CCR section 1709.1. Hospitals either may have the PIC direct the contracted pharmaceutical service, or may have a qualified pharmacist direct the service, with the PIC working on as a senior member of the service staff. PHPC surveyors observed no problems in hospitals with non-PIC service directors. The Department proposes this change to give hospitals greater flexibility to meet their contracted pharmaceutical service staffing needs, to reflect current practices, and to eliminate program flexibility requests related to having a non-PIC service director. The proposed amendments are necessary to bring the regulations current with existing standards of practice, promote better patient health, and provide clarity to the regulated community.

Adopt paragraph (1): To require that the pharmacist director of the contracted pharmaceutical service have experience in hospital pharmacy practice. This requirement is necessary to provide greater patient protection and to update the regulations to reflect current practices. Current hospital pharmacy practice involves handling many more types of drugs for different medical specialties than existed when these regulations were adopted in 1975. PHPC surveyors find hospitals have fewer violations and areas of concern when the director of the contracted pharmaceutical service has training and expertise in hospital pharmacy practice.

Amend paragraph (2): To clarify that hospitals with 100 beds or fewer must have a director who works either part-time or as a consultant but must work enough hours to

meet the hospitals' patients' drug use needs. This is required whether the director works out of a hospital pharmacy or a drug closet. Existing regulation (section 70263(a)) allowed only hospitals with fewer than 100 beds (i.e., 99 beds or less) to operate on a limited license and purchase drugs wholesale. BPC section 4056 allows hospitals with 100 beds or fewer (i.e., 100 beds or less) to purchase drugs wholesale. This mismatch between statutory and regulatory language created unnecessary confusion for smaller hospitals with exactly 100 beds. The proposed amendments are necessary to eliminate confusion due to conflict with the statute and provide clarity to the regulated community.

Amend paragraph (3): To add to the job description or agreement of the service director the qualifications of the position, to add the terms "report directly" to the requirement the service director report to the administrator, and to remove the term "written" from the description of the reports the director provides to the administrator. Service directors presently give both verbal and written reports and recommendations to the administrator. If an administrator prefers a report or recommendation to be in writing, the administrator can request the service director provide a written version. This change aligns the regulations with existing industry practices and makes the service director's reporting requirements more specific. Further non-substantive changes to this paragraph replace gender-specific language with gender-neutral language in accordance with the Department's other regulations and make grammatical changes for the clarity of the regulated population.

Adopt subdivision (b): The Department proposes new language requiring hospitals to have staff sufficient to meet the needs of the hospital's patient population. Different geographical locations have populations with differing drug and drug-related equipment needs. When the medical conditions of a hospital's patient population are more complex and require more service time to properly provide for those patients, staffing should be adjusted so patient needs are met. Current hospital pharmacy practice standards require staffing sufficient to meet patient needs. The proposed amendments are necessary to protect patient health, bring the regulations up to present industry practice standards, and to provide clarity to the regulated community.

Section 70267: Pharmaceutical Service Equipment and Supplies
Amend subdivision (a): The Department proposes non-substantive grammatical changes to avoid using passive voice in accordance with the Department's other regulations and for the clarity of the regulated population. The Department also proposes to remove the word "adequate" because it is vague, and it is not needed to convey the intent of the regulation.

Amend subdivision (b): The Department proposes amendments requiring reference materials on drugs be available in patient care areas where drugs are distributed to patients. Current Board of Pharmacy regulations (see Title 16 CCR section 1707.5 Patient-Centered Labels for Prescription Drug Containers; Requirements, and Title 16 CCR section 1707.6 Notice to Consumers) and industry standards emphasize improving communication with patients and educating patients about their medications.

When patients understand how to take their medications and the condition for which they are taking the drug, drugs are taken correctly, this produces better results, and improves public health. The proposed amendments are necessary to protect patient health and provide clarity to the regulated community.

Section 70269: Pharmaceutical Service Space
Adopt subdivision (a): The Department proposes to adopt a requirement for the pharmaceutical service to comply with Title 24, California Building Code section 1224.19. The Public Health Act of 2006 gave jurisdiction of building and design specifications to the Department of Healthcare Access and Information (HCAI), formerly known as the Office of Statewide Health Planning and Development (OSHPD). Under the Act, the Department may require what kinds of space are needed and HCAI must write the building and design specifications needed to make the space suitable for the intended purpose. The reference makes clear that the hospital must comply with the combined requirements from Title 22 and Title 24, California Building Code.

Amend existing subdivision (a): Renumber to subdivision (b). The Department proposes amendments revising this regulation to avoid passive voice in accordance with the Department's other regulations and make necessary grammatical changes for the clarity of the regulated population. The Department proposes to remove the word "adequate" because it is vague and open to interpretation by the regulated community. The Department proposes to add additional language to make sure the space available and maintained for drug storage and preparation is pursuant to Title 24 standards. This adds clarity for the regulated community.

Amend existing subdivision (b): Renumber to subdivision (c). The Department proposes amendments replacing the word "lockable" with the word "securable," and adding language specifying that spaces and areas for drug storage should only be accessible to licensed staff granted access by the P&T Committee. This amendment grants hospitals greater flexibility to secure stored drugs with devices other than locks. Restricting access to stored drugs to "licensed" rather than simply "authorized" personnel refers to the professional licenses granted by various state boards, including the Medical Board (which licenses physicians and physician assistants), the Board of Pharmacy (which licenses pharmacists, pharmacy interns, and pharmacy technicians), the Board of Registered Nursing (which licenses nurses) and others. Restricting access to stored drugs to licensed staff authorized by the P&T Committee allows the pharmaceutical service to revise access polices as needed. In recent years, statutory changes have expanded the types of licensed health care staff that may prescribe or furnish drugs. This amendment provides hospitals with flexibility to decide, through their P&T Committee, who among the licensed staff should have access to the stored drug supply. The proposed amendments are necessary to bring the regulations in line with to industry standards of practice, promote patient health, and provide clarity to the regulated community.

Adopt subdivision (d): The Department proposes new language to specify the functions for which the pharmaceutical service requires adequate space for: storing, packaging, labeling, and dispensing of drugs; sterile and non-sterile compounding; office space for the service director and service managers; and for the service staff to perform clinical functions. The practice of pharmacy has changed dramatically since these regulations were adopted, the breadth of hospital pharmacy's drug supply has grown, and sterile and non-sterile compounding has changed with advances in drug and infection control. When the pharmaceutical service has the space required to perform these essential tasks, patients benefit, and public health is improved. Current industry standards require the hospital pharmaceutical service to have adequate space to perform these critical tasks. PHPC surveyors have investigated complaints against hospitals arising out of attempts to perform these critical service tasks in inadequate space and have noted deficiencies and pointed out unsafe practices that occur because essential tasks are being performed in an inadequate space. The proposed amendments are necessary to protect patient health, bring the regulations current with existing standards of practice, and provide clarity to the regulated community.

DIETETIC SERVICE

Amend section 70271: Dietetic Service Definition

The Department proposes amendments to specify that the dietetic service must be an organized department following an operational plan to provide meals to all patients, make medical nutrition therapy assessments, and provide medical nutrition therapy when prescribed. This necessary so that:

1) Hospitals may accommodate and implement future advances in dietetics and nutritional science by updating their plan of operation, and
2) To specify that the service provides medical nutrition therapy assessments, and medical nutrition therapy.

Advances in dietetic science and medicine have led to a greater understanding of how medical nutrition therapy facilitates the treatment of conditions such as renal disease and diabetes, thus promoting better health and healing. Updating this provision with a more current definition of dietetic services may help the Department effectuate its regulatory intent to provide better health outcomes for the people of California.

Section 70273: Dietetic Service General Requirements

Amend subdivision (a): The Department proposes to move the text in paragraphs (a)(1) through (a)(4) to subdivision (b) and to renumber the existing subdivision (b) to subdivision (e). The Department proposes to move the text in the first sentence in paragraph (a)(5) to subdivision (c) and renumber the existing subdivision (c) to subdivision (f). The Department proposes to move the text in the second sentence in paragraph (a)(5) to subdivision (d) and renumber the existing subdivision (d) to subdivision (g). The Department proposes an amendment to replace the phrase "physicians' orders" with the phrase "the practitioner's orders." Other medical professionals, such as Physician Assistants (PAs) and Advanced Practice Registered

Nurses (APRNs) can order therapeutic diets.[28] The proposed amendment is necessary to bring the regulations up to date with current industry standards and provide clarity to the regulated community. The Department proposes amendments to remove a citation to an outdated reference guide and to specify instead that the dietetic service must follow the "Dietary Reference Intakes: The Essential Guide to Nutrient Requirements" (2006) by the Institute of Medicine (incorporated by reference). Hospitals are required to follow this guide by 42 CFR part 482.28(b)(1).[29] The proposed amendments are necessary to provide clarity to the regulated community.

Adopt new subdivision (b): Renumber from paragraphs (a)(1) through (a)(4). Move existing subdivision (b) to subdivision (e).

Amend paragraph (b)(1): Renumber from paragraph (a)(1). The Department proposes amendments to allow patients to decline meal service by replacing the term "served" with "provide." The existing language was overly prescriptive and was interpreted in different ways by different hospitals. In the worst case, the literal reading of the regulation required serving a meal to a nauseated patient before throwing it away.

Amend paragraph (b)(2): Renumber from paragraph (a)(2).

Amend paragraph (b)(3): Renumber from paragraph (a)(3).

Amend paragraph (b)(4): Renumber from paragraph (a)4). The Department proposes further amendments to paragraph (b)(4) to make minor changes to existing language. The proposed amendments provide greater flexibility, so the regulated community does not have to serve meals to patients who decline meals due to nausea or other conditions. The proposed amendments are necessary to provide flexibility and clarity to the regulated community.

Amend existing paragraph (a)(5) first sentence; renumber to subdivision (c). The Department proposes to add language requiring that any outside food service company that provides food to the dietetic service designate a liaison with the medical staff and administration for recommendations on dietetic policies affecting patient treatment. This is necessary to ensure optimal patient care and is an existing requirement in the State Operations Manual, Appendix A, section 482.28 (October 2008), pg. 364. These amendments align the California regulations with CMS requirements and provide clarity to the regulated community.

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[28] PAs may, under the appropriate circumstances, "make an assessment" and "order …. therapeutic diets" (see 16 CCR 1399.541). APRNs may take health histories, provide complete physical exams, diagnose, and treat acute and chronic illnesses, and implement standardized procedures that may include ordering a therapeutic diet. (BPC section 2725).

[29] CMS SOM, Appendix A, Regulations and Interpretive Guidelines for Hospitals, tag number A-0629, covering section 482.28(b)(1).

Amend existing paragraph (a)(5) second sentence; renumber to subdivision (d). The Department proposes to add a reference to space requirements found in Title 24, California Building Code, section 1224.20. The Public Health Act of 2006 gave jurisdiction of building and design specifications to the Department of Healthcare Access and Information (HCAI), formerly known as the Office of Statewide Health Planning and Development (OSHPD). Under the Act, the Department may require what kinds of space are needed and HCAI must write the building and design specifications needed to make the space suitable for the intended purpose.

Amend existing subdivision (b): Renumber to subdivision (e). The Department proposes language specifying the methods by which a dietetic service's policies and procedures shall be implemented, developed, and maintained. PHNC surveyors have observed that hospitals with written policies and procedures have better compliance with regulatory requirements and provide better guidance for the medical staff, nursing staff, and administration. Written policies and procedures facilitate PHNC surveyors' oversight function because surveyors first review the service's policies and procedures and then ascertain if the service is following their own directives. The proposed amendments are necessary to improve regulatory compliance and provide clarity to the regulated community.

Adopt paragraph (1): The Department proposes new language to specify that the dietetic service's written policies and procedures must cover the topics of food storage, preparation, and service. PHNC surveyors review the policies and procedures of the service at every hospital and find better compliance with regulations if the service's policies and procedures cover these topics. The proposed amendments are necessary to improve regulatory compliance and provide clarity to the regulated community.

Adopt paragraph (2): The Department proposes new language to specify how often written policies and procedures must be reviewed, revised, and dated. Written policies and procedures that are regularly reviewed and revised improve implementation of commonly accepted industry standards designed to protect patient health and produce better patient outcomes. The proposed regulations are necessary to facilitate the timely adoption of industry standards and provide clarity to the regulated community.

Amend existing subdivision (c): Renumber to subdivision (f). The Department proposes to add the phrase "in writing and documented" to specify the method by which the responsibility and the accountability of the dietetic service to the medical staff and administration shall be defined. PHNC surveyors have observed that hospitals with a written definition have better compliance with regulatory requirements and provide better guidance materials for their medical staff and administration. These amendments are necessary to ensure all hospitals have a written definition of their responsibility to staff and to provide clarity to the regulated community.

Amend existing subdivision (d): Renumber to subdivision (g). The Department proposes amendments specifying that diet manuals must be approved by a registered

dietician and used as the basis for ordering and serving food. The approved manuals must also be used as a guide to identify routinely ordered regular and therapeutic diets within the hospital. The Department further proposes to add the word “registered” to the outdated term “dietitian” as “registered dietitian” (RD) is the term currently used in the industry. Diet manuals that conform to current industry standards provide more information to assist medical professionals in deciding the proper diet order for a patient and assist staff in requesting substitutions while serving patient meals. These amendments are necessary to update the regulations to meet current industry standards and terminology, protect patient health, and provide clarity to the regulated community.

Adopt paragraph (1): The Department proposes new requirements to be included in the diet manual. Current industry practice is for the diet manual to provide information on the purpose and principles of each diet, the meal pattern, foods allowed and not allowed, and the nutritional adequacy for each type of diet provided.[30] Providing physicians, nurses and other appropriate personnel with this information better informs all personnel of the role nutrition plays in optimizing patient health. This proposal is necessary to bring the regulations up to current industry standards and provide clarity to the regulated community.

Amend paragraph (2): The Department proposes language specifying that hospitals must make copies of the diet plan available to physicians, nurses, and other appropriate staff in either a hard copy or electronic format. This amendment would also replace the term “nursing stations” with the updated term “patient care unit.” This is necessary to allow hospitals procedural flexibility, update the regulations to reflect current industry standards and terminology, and provide clarity to the regulated community.

Amend paragraph (3): The Department proposes new language specifying that diet manuals must be reviewed and updated at least every five years and dated to reflect when last reviewed. This is necessary to bring the regulations up to CMS standards under 42 CFR part 482.28(b)(3). Allowing for frequent updates as necessary also recognizes the ongoing advances in dietetics and nutrition science that improve patient health. These amendments are necessary to promote continuous improvement of patient health and to provide clarity to the regulated community.

Adopt subdivision (h): The Department proposes language specifying that the preparation of infant feeding solutions must follow the standards set forth by the Pediatric Nutrition Practice Group of the American Dietetic Association (now the Academy of Nutrition and Dietetics) in “Infant and Pediatric Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities,” 3rd Edition (2018) by the Pediatric Nutrition Practice Group of the Academy of Nutrition and Dietetics, Steele, C. and Collins, E. Editors. These amendments would further require the service to

[30] Department of Developmental Services, California Health and Human Services Agency. Diet Manual. (2010).

follow the compounding practices of the USP recommended by the American Society for Parenteral and Enteral Nutrition, and safe food handling practices.[31] Advances in medicine have facilitated more live births earlier in the gestation period and, as a result, more premature and medically fragile infants survive birth and require specialized feeding. PHNC surveyors find that the feeding practices detailed in the three previously named publications are the commonly accepted guidance documents for feeding premature and medically fragile infants. The proposed amendments are necessary to protect the health of premature and medically fragile infants and to provide clarity to the regulated community.

Adopt subdivision (i): The Department proposes a new provision to specify that if a hospital has a separate room or dedicated area in which to prepare infant feedings, the dietetic service must adopt written policies and procedures to minimize the risk of food-borne illness.

The Department further proposes language specifying that policies and procedures must address safe and sanitary handling practices for infant feedings because newborns are vulnerable to food-borne illnesses. When a service maintains written policies and procedures for safe and sanitary handling practices, PHNCs observe that infant patients have better health outcomes. These amendments are necessary to provide clarity to the regulated community, and to ensure that hospitals take steps to protect infants from food-borne illness.

Amend existing subdivision (e): Renumber to subdivision (j). The Department proposes adding modified diets to the types of diets that must be provided and planned, prepared, and provided under the supervision or consultation of an RD. Changing the reference to “registered dietitian” updates the regulation to the current industry title. Modified diets are diets regular diets that are modified for texture and/or to include or exclude certain components like vitamins, minerals, fats, and calories. These amendments are necessary for consistency with the existing industry practice that the RD supervises or consults on and the planning, preparation, and provision of modified diets. These amendments bring the regulation up to industry standards while providing clarity to the regulated community.

Amend existing subdivision (f): Renumber to subdivision (k). The Department proposes amendments requiring that a record be kept of patient food preferences, allergies, and current diet orders to better meet each patient’s unique dietary needs and that this record be used as a guide for providing meals. Patients are given a variety of modified diets as a part of medical nutrition therapy for medical conditions impacted by diet, such as diabetes, high blood pressure, etc. Patients can have specific dietary needs as a result of their disease symptoms, such as lack of appetite in people with the human immunodeficiency virus (H.I.V.), chewing difficulties for patients with mouth and

[31] U.S. Food & Drug Administration, Safe Food Handling Fact Sheet (March, 2017) and CA Dept. of Public Health, Safe Food Handling Practices (June, 2017).

throat cancers, etc. Patients can need dietary modifications due to treatment side effects such as mouth sores from radiation, lack of appetite due to chemotherapy drugs, tenderness from surgeries that impact chewing or digestion. Good nutrition is critical to healing. It is common industry practice to keep such a guide so patients are offered meals they can eat despite their medical conditions, disease symptoms, and treatment side effects. It is reasonably necessary to record this information so the service can work with patients' dietary needs. PHNC surveyors have observed that including the proposed additional information makes the patients' food preference records more useful to the staff and provides the RD more information on individual patient dietary preferences and needs. The Department further proposes updating an outdated reference to "dietitian" and replacing it with "registered dietitian," the current industry title. The proposed amendments are necessary to update the regulations to reflect current industry practices and to provide clarity to the regulated community.

Amend existing subdivision (g): Renumber to subdivision (l). The Department proposes new language specifying that the RD must follow the recommended dietary intake allowances from "Dietary Reference Intakes: The Essential Guide to Nutrient Requirements" (2006) by the Institute of Medicine (incorporated by reference) when planning and approving menus. These guidelines contain the current versions of tables and data the RD must consult to plan menus that comply with government standards. The proposed amendments are necessary to uphold the Department's commitment to patient safety by requiring all menus follow current industry guidelines and to provide clarity to the regulated public.

Amend paragraph (1): Non-substantive changes.

Amend paragraph (2): The Department proposes amendments to specify that the RD must approve changes where a meal varies from the planned menu. Hospital food service managers (referred to in statute as "dietetic service supervisors") do not have the knowledge of dietetics and nutrition that an RD does. PHNC surveyors have observed dietary service supervisors making changes to the planned menu that were not in the best interests of the patients. The RD approves the facility diet manual, which lists the foods allowed, potential substitutions, and food not recommended for various types of diets (Vegetarian, No Added Salt, Carbohydrate Controlled, Renal, Lactose Reduced, etc.). Requiring the RD to approve all changes when the meal varies from the planned menu helps ensure the food provided meets patient nutritional needs. The proposed amendments are necessary to uphold the Department's commitment to patient safety and to provide clarity to the regulated public.

No changes to Paragraphs (3) through (6).

Amend paragraph 7: The Department proposes to replace "appropriate yield" with "the amount needed for patient census" to add clarity to the regulation.

Amend existing subdivision (H): Renumber to subdivision (m). The Department proposes to delete the word "attractively" because it is vague and to make non-substantive grammatical changes to update and clarify this subdivision and provide stylistic consistency with the rest of the Department's regulations. The Department also proposes to keep appropriate temperatures and add a description to define appropriate set forth by the Health and Safety Code section 114002. This adds clarity to the regulation and protects patient safety. The Department proposes to change "nutritive" with "nutritional" because the term is more commonly used. Subject matter experts state that they both describe the nutrient value in foods.

Amend existing subdivision (i): Renumber to subdivision (n). The department proposes no language to specify that dietary orders must be ordered by the physician or someone lawfully able to do so, Also, to add the dietary service must have policies and procedures for dietary consultations by the registered dietician. This amendment is necessary to reflect current industry practice and to provide clarity to the regulated community.

Add paragraph (1): The Department proposes new language specifying that a nutritional assessment that includes the patient's height, weight, chewing ability and results of pertinent laboratory tests must be completed by an RD, physician, or other medical professional practicing within the scope their license within 24 hours of a patient being screened for nutritional risk. PHNC surveyors recommend that a nutritional assessment, at a minimum, should specify the patient's height, weight, chewing ability and pertinent laboratory tests, and be completed within 24 hours of a patient being identified as being at nutritional risk based on the Academy of Nutrition and Dietetics (AND) standards. "Another medical professional practicing within the scope of their license" refers to Physician Assistants (PAs) and Advanced Practice Registered Nurses (APRNs).[32] With the passage of SB 993 (Mitchell, Chapter 622, Statutes of 2013), providing nutritional assessments is within the scope of an RD's license.[33] The proposed amendments are necessary bring the regulations up to date with current industry standards and to provide clarity to the regulated community.

Amend paragraph (2): The Department proposes language clarifying the specific information that must be documented by a lawfully authorized person[34] as part of a patient's nutritional treatment (including observations, assessments, diagnoses,

[32] PAs may already, under the appropriate circumstances, "make an assessment" and "order …. therapeutic diets" (see 16 CCR 1399.541). Under the appropriate circumstances, APRNs may take health histories, provide complete physical exams, and diagnose and treat acute and chronic illnesses, and those actions may include conducting a comprehensive nutritional assessment (BPC section 2725).

[33] BPC section 2586.

[34] In light of the increased professionalization of different types of health care personnel, and workplace shortages, the legislature may authorize additional categories of hospital staff to be allowed to make entries into the medical record. The phrase "lawfully authorized person" encompasses those persons presently authorized, and should the law change, any new categories of people who are given this authority.

interventions, monitoring, goals for the patient, and ongoing evaluation of the patient's response to nutrition therapy). PHNC surveyors report that the inclusion of this information in the patient's record improves patient care. The proposed amendments are necessary to bring the regulations current with industry standards and terminology, and to provide clarity to the regulated community.

Amend Paragraph (3): The Department proposes amendments specifying that the nutritional care plan must be included in the patient transfer discharge record. This is necessary to ensure continuity of care. PHNC surveyors have observed that when discharge records do not include the nutritional care plan, there is a higher rate of failure to provide proper nutritional care, which can result in patients needing to be readmitted. These proposed amendments are necessary to provide clarity to the regulated community and to improve and protect patient health and safety.

Adopt Paragraph (4): The Department proposes new language to clarify that each hospital must have written policies and procedures for medical nutrition therapy. Clinical nutritional care is an adjunct therapy used together with the primary treatment of the patient to improve the effectiveness of the primary treatment. While clinical nutritional care had not been developed when these regulations were initially adopted, having written policies and procedures is a common industry practice known to facilitate better oversight of clinical nutrition care, improve patient outcomes, and better protect patient health. The proposed adoption is necessary to bring the regulations up to date with current industry standards, and to provide clarity to the regulated community.

Adopt Paragraph (5): New requirements to propose, at least annually, a review of the nutritional manual to determine if changes are needed. The date of the review must be documented on the nutritional manual because it is necessary to ensure dietetic service staff is following the most current manual when providing medical nutrition therapy. Reviewing written policies and procedures, at least once a year, is a common industry practice known to facilitate better oversight of medical nutrition therapy, improve patient outcomes, and better protect patient health. This proposed adoption will also provide clarity to the regulated community and to improve and protect patient health and safety.

Adopt paragraph (6): New language is proposed to require the revision of the nutritional manual when determined during the review required in paragraph (5). Additionally, the date of the revisions to the written policies and procedures for medical nutrition therapy is necessary to ensure the dietetic service staff is following the most current manual when providing clinical nutrition care. This proposed adoption will provide clarity to the regulated community and to improve and protect patient health and safety.

Amend existing subdivision (j): Renumber to subdivision (o). Renumbered from subdivision (j). The Department proposes updates to existing language to include commonly accepted in-service education programs, and to clarify that the dietetic service must keep records of competency assessments. Training programs called for in

existing regulations help staff develop specific skills, while education programs teach theoretical knowledge, increasing staff understanding of the big picture and how and why things work together. PHNC surveyors have observed that staff in hospitals that provide education programs along with training programs seem to have a better understanding of how the service should work. PHNC surveyors have also observed that when dietetic services keep a record of competency assessments, the material covered is taken more seriously by staff. These amendments are reasonably necessary because staff can gain both specific skills and a broader understanding of topics relevant to the service, and to ensure that assessments are used to reinforce staff learning.

The Department further proposes new language clarifying that the RD must be involved in planning and conducting in-service training programs and competency assessments. As a part of maintaining their professional registration, RDs stay abreast of current trends in dietetics, sanitation, and infection control, and should pass this information on to staff through education and training programs to improve health outcomes. These amendments are necessary to ensure the RD's involvement in staff education and training, protect patient health and safety, and provide clarity to the regulated community.

Finally, the Department proposes the following amendments to specify the topics that must be covered in education and training programs. PHNC surveyors have observed numerous training programs that fail to cover the information staff needs to know to comply with procedures. Staff who understand the reasons for the many procedures they must follow have better compliance, which positively affects patient health. The following provisions are necessary to broaden and improve staff education and training, protect patient health, and provide clarity to the regulated community.

Adopt paragraph (1) and subdivisions (A) through (E) respectively: The Department proposes requiring that the education and training programs must include instruction in personal hygiene, the proper inspection, handling, preparation, and serving of food, the proper cleaning and the safe operation of equipment, therapeutic diets, and sanitation and dishwashing.

Adopt paragraph (2): The Department proposes new language clarifying that the service may conduct informal, or as needed, training sessions when the following information is kept in a written record: subject areas covered, the date and duration of each session, any competency assessments, and a list of attendees. PHNC surveyors have observed informal training programs can improve staff knowledge just as well as formal programs. Allowing a documented informal training program encourages such training while ensuring PHNC surveyors review any informal training conducted. These amendments are necessary to increase options for staff training and is intended to facilitate positive patient health outcomes and to provide clarity to the regulated community.

Adopt existing subdivision (k): Renumber to subdivision (p). The Department proposes new language to specify kitchen and food storage areas must be well-ventilated, not subject to sewage or wastewater backflow, and protected from contamination by condensation, leakage, or vermin. To reduce the risk of contamination and prevent the spread of disease, the hospital regulations require clean conditions throughout the hospital. The conditions specifically described in the added language are conditions observed in hospital kitchen and food storage areas by PHNC surveyors that hospitals acknowledged but argued that those areas were clean. Adding this language clarifies the standards of cleanliness required in hospital kitchen and food storage areas.

Repeal Paragraph (1) and amend and renumber Paragraph (2): The Department proposes to delete existing Paragraph (1) because cleanliness is covered in other requirements and proposes amendments to Paragraph (2) specifying that dry and staple items must be stored in a well-ventilated room, at least 6 inches up off the floor, within the temperature range of 10 degrees Celsius (50 degrees Fahrenheit) and 21 degrees Celsius (70 degrees Fahrenheit). The specified temperature range is an industry standard.[35] The term “well-ventilated” replaces the lower standard of merely “ventilated.” When food is fried, grease evaporates, becomes airborne, and is deposited on walls and ceiling. This creates unhygienic conditions, which happens more slowly when a kitchen is well-ventilated. Cleaning agents employed in cleaning kitchen and food storage areas (like ammonia and chlorine bleach) give off fumes and should only be used in well-ventilated areas. When food storage areas are well-ventilated, there is less contamination of food items stored nearby when an individual food item spoils. These amendments are necessary to protect patient health and provide clarity to the regulated community.

Dry food is protected from contamination when stored at least six (6) inches up off the floor. The proposed amendments are a reduction of the previous clearance requirement of 12 inches and align the regulations with statute (California Retail Food Code, HSC section 114047(b)), and reduce the burden on the regulated community. These amendments are necessary to protect patient health and provide clarity to the regulated community.

Amend existing paragraph (3) renumber to Paragraph (2): The Department proposes amendments requiring that upper and lower temperature ranges for perishable food and beverages be between 5 degrees C (41 degrees F) and 57 degrees C (135 degrees F). These amendments are necessary to clarify the temperature range at which food must be maintained to reduce the growth of pathogenic bacteria causing food infections and/or food intoxication, as explained by the U.S. Department of Agriculture.[36] The industry standard for the required temperature for refrigerated items is now 5 degrees F colder than previously required. The Department proposes further

[35] United States Department of Agriculture: Food Safety Facts. *How Temperatures Affect Food*. (2013).
[36] United States Department of Agriculture: Food Safety Facts. How Temperatures Affect Food. (2013).

amendments to specify that frozen food must remain frozen. This is necessary to clarify that hospitals are not to serve food that has been defrosted and refrozen. PHNC surveyors have cited facilities for a disproportionate number of violations of refrigerator and freezer temperature requirements. These amendments uphold the Department's commitment to patient safety by bringing the regulations current with accepted industry standards known to protect patient health and provide clarity to the regulated community.

Add Paragraph (3): To require that food, whether refrigerated or not, must be covered, labeled, and dated to indicate when it was stored. Stored food that is not covered, labeled, and dated can become cross-contaminated or spoil, so this provision is necessary to protect patient health by eliminating unnecessary exposures that increase the risk of food-borne illness. PHNC surveyors indicate that these requirements are a less restrictive approach than barring all storage of leftover food. These amendments are reasonably necessary to uphold the Department's commitment to patient safety by bringing the regulations up to date with accepted industry standards known to protect patient health and to provide clarity to the regulated community.

Amend Paragraph (4): To require all refrigerators and freezers have ‑ thermometers, and that daily temperature logs for all refrigerators and freezers be kept for ninety (90) days. This is necessary to ensure all hospitals follow existing industry practices. In addition, Department subject matter experts recommend 90 days for enforcement purposes. Requiring hospitals to have working thermometers for checking refrigerators and freezers ensures accurate freezer and refrigerator temperature logs. Temperature logs help dietary personnel identify earlier when a freezer or refrigerator is no longer working properly. This reduces food spoilage and protects patient health.

Amend Paragraph (5): The Department proposes to replace utensils, dishware, and glassware with tableware to add conciseness and clarity to the regulation. According to the Oxford Dictionary, tableware means utensils, dishware, and glassware.
Amend Paragraph (6): To require soaps and other cleaning compounds stored in food storage areas be kept in a manner that prevents cross-contamination. Previously, the storage of these items in food storage areas was banned; however, recent discussions with PHNC surveyors indicate a complete ban on storing chemicals, in particular surface cleaners and sanitizers, is necessary to promote food safety. The proposed amendments are necessary to uphold the Department's commitment to patient safety while protecting public health in a less restrictive manner.

Amend existing subdivision (l) and renumber to subdivision (q).

Repeal Paragraphs (1): The Department proposes to repeal paragraph (1) because it is repetitive with new subdivision (p). By repealing paragraph (1), renumbering (2 through 5) will now be (1 through 4).

Amend existing paragraph (2) renumber to paragraph (1).

Amend existing paragraph (3) renumber to paragraph (2).

Amend existing paragraph (4): Renumber to Paragraph (3). Specify that ice machines on hospital premises shall be used and maintained per the manufacturer's recommendations and the hospital's infection control guidelines. PHNC surveyors have seen ice contaminated with mold and other biological contaminants due to improper ice machine maintenance. This amendment is therefore necessary to protect public health. Additionally, while current regulations specify that ice must be generated and handled in a sanitary manner, this further specification is necessary to better protect patient health and provide clarity to the regulated community.

Renumber existing paragraph (5) to Paragraph (4): No changes.

Amend existing subdivision (m): Renumber to subdivision (r). The Department proposes amendments to add the term "tableware" and to specify that single-use tableware cannot be reused. The existing language requires all utensils[37] to be cleaned and disinfected or discarded after each use. This proposed clarification is necessary even though the practice of reusing single-use items is banned by statute.[38] Single-use items are defined in the California Retail Food Code (CRFC) in HSC section 113914 and are forbidden to be reused under HSC section 114081 subdivision (d). PHNC surveyors have observed hospitals reusing single-use items, such as cottage cheese containers, to store leftovers. Those items are not made to go through repeated cleaning in hospital dishwashers, or even multiple hand washings, without leaching chemicals. The proposed amendments are necessary to protect public health and provide clarity to the regulated community.

Amend Paragraph (1): The Department proposes to delete existing Paragraph (1) and replace it with new language specifying that food must be scraped off at the start of both manual and mechanical ware washing, and if needed, pre-soaked, scrubbed, or pre-cleaned. The existing language states: "Gross food particles shall be removed by scraping and prerinsing in running water." Failure to remove or completely loosen debris during cleaning violates statute (HSC sections 114097 and 114099.1(b)). PHNC surveyors have observed hospitals that fail to remove all food particles from utensils and, as a result, soiled items come in contact with patient food. These amendments are reasonably necessary to ensure the updated regulations accurately convey current industry standards and terminology, for the protection of patient health, and to provide clarity to the regulated community.

Amend Paragraph (2): To require that hospitals use three (3)-compartment sinks for manual washing, as has been required in retail food kitchens by statute since the

[37] "Utensil" is defined in Merriam Webster Dictionary as "an implement, instrument, or vessel used in a household and especially a kitchen."

[38] HSC sections 113700 to 114427.

CRFC's adoption in 2007.[39] The sink's three compartments are used for washing, rinsing, and sanitizing equipment and tableware. This requirement is necessary because food can become contaminated when prepared on unsanitary equipment or served on or with unsanitary tableware. The proposed language does not require immediate remodeling of two compartment sinks in use on December 31, 2007. Only when a hospital is replacing a two-compartment sink on or after January 1, 2008 must a three-compartment sink be installed. This proposed language is necessary to ensure hospitals maintain currently accepted best practices known to protect patient health by preventing the spread of contamination.

The department proposes to renumber this provision to account for the insertion of paragraph (2) above and to update the minimum required temperature for manual ware washing in hot water from 43 degrees Celsius (110 degrees Fahrenheit) to 37.77 degrees Celsius (100 degrees Fahrenheit). This is necessary to align regulatory language with statute.[40] The Department further proposes to replace the term "hot" with the term "clear," as this is the term used in statute for addressing rinsing utensils (HSC section 114099.2(c)). These amendments are necessary to conform to statute, protect patient health, and provide clarity to the regulated community.

Amend subdivision (A): To change the requirement from two minutes immersion time to 30 seconds in the hot water sanitizing rinse, and to update the temperature for immersion from 180 degrees Fahrenheit to 171 degrees Fahrenheit. These changes are mandated by HSC section114099.6(a) and necessary to bring these regulations in line with currently accepted industry standards. The Department further proposes to require the sanitizing compartment of a sink used for hot water sanitization be designed to have an integral heating device that can maintain water at a temperature not less than 77 degrees Celsius (171 degrees Fahrenheit) and be provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water. The proposed language does not require immediate replacement of sinks in use on December 31, 2007, that do not have an integral heating device and a rack or basket. Only when a hospital is replacing a sink used for hot water sanitation on or after January 1, 2008, must a sink with a sanitizing compartment that has an integral heating device and a rack or basket for complete immersion of equipment and utensils be installed. These changes are mandated by HSC section 114099.4 and are necessary to ensure hospitals maintain currently accepted best practices known to improve sanitizing equipment and protect patient health by preventing the spread of contamination.

Amend subdivision (B): Delete language about immersion in clean water at 82 degrees Celsius (180 degrees Fahrenheit) and add new language specifying the methods of chemical sanitation for manual ware washing. The language in proposed

[39] CRFC - HSC section 114099(a). Three-compartment sinks have been required since 2007 under CRFC, and before that, since 1996, when three-compartment sinks were required under the California Uniform Retail Food Facilities Law, the code that preceded the CRFC.

[40] CRFC - HSC section 114099.2(b).

subparagraphs (1) through (4) incorporates the sanitation methods mandated by the CRFC, HSC section 114099.6(b)(1)-(3), and (5) and is reasonably necessary to update the regulations, protect public health, and provide clarity to the regulated community.

Repeal existing subparagraph (C): This subdivision had allowed sanitizing by immersion in unspecified bactericidal chemicals as approved by the Department.

Amend Paragraph (3): No substantive changes.

Amend Paragraph (4): To update the citation to the national standard in NSF 3-2017, "Commercial Warewashing Equipment," published by The National Sanitation Foundation International (2017). The Department further proposes amendments to clarify that while dishwashers that do not meet the above-referenced standards by December 31, 2023, do not need to be immediately replaced to be in compliance, any replacement dishwasher installed on or after January 1, 2024 must comply with the requirement. The proposed amendments are necessary to update the regulations, reflect current industry standards, and provide clarity to the regulated community.

Adopt Paragraph (5): To establish the criteria for mechanical ware sanitization in the final rinse as follows:

Adopt subdivision (A): To require cycling through equipment in accordance with manufacturer's specifications that achieves a tableware surface temperature of 71 degrees Celsius (160 degrees Fahrenheit) as measured by an irreversible registering temperature indicator.

Adopt subdivision (B): To require the mechanical application by pressure spraying methods solutions of either 50 ppm of available chlorine for at least 30 seconds, or 25 ppm available iodine for a least one minute.

Adopt subdivision (C): To require contact with any chemical sanitizer used in accordance with the sanitizer manufacturer's use directions and the machine manufacturer's specifications that meets the requirements of 40 CFR part 180.940 (2004). The language in proposed subdivisions (A) through (C) incorporates the sanitation methods mandated by the CRFC, HSC section 114099.7(a)-(b)(3), that allow for any chemical sanitizer that meets 40 CFR part 180.940 requirements. Adding proposed subdivisions (A) through (C) is reasonably necessary to update the regulations to integrate industry requirements and best practices, protect public health, and provide clarity to the regulated community.

Section 70275: Dietetic Service Staff
Repeal existing subdivisions (a) and (b): The Department proposes the deletion of existing subdivisions (a) and (b) and the subsequent restructuring of this regulatory section to accommodate new language.

Repeal existing subdivision (a) and adopt new subdivision (a): The Department proposes a new subdivision (a) to require that an RD administer and direct the dietetic service. Also, the Department proposes to add that the registered dietitian must be registered through the Commission on Dietetic Registration. The Commission on Dietetic Registration is the credentialing branch of the Academy of Nutrition and Dietetics, formerly known as American Dietetic Association. This is necessary because hospitals have misread HSC section 1265.4 and, as a result, placed a dietetic service supervisor (DSS), who has the authority to overrule the RD's professional judgment, in charge. HSC section 1265.4 was implemented in Assembly Bill (AB) 2128 (Emmerson, Chapter 225, Statutes of 2008) "to expand and update the ways in which individuals can qualify as a DSS to address a shortage of DSSs available to the nursing home industry and rural hospitals."[41] Committee reports on the bill stated unequivocally that the DSS must work with "oversight and responsibility of the operation maintained by the dietitian,"[42] and stressed that the bill merely "codifies current regulations" while improving the pool of available staff.[43] Therefore, HSC section 1265.4 does not change the Department's requirement that a dietitian must oversee and direct the dietetic service.[44] Rather, HSC 1265.4 states that: "The DSS shall receive frequently scheduled consultation from a qualified dietitian." The legislature requires regularly scheduled consultations with the RD to ensure the DSS does not make uninformed decisions that undermine the goal of providing high-quality, healthy, and nutritious food to patients. To avoid further misinterpretation by hospitals, it is necessary to clarify that hospital dietetic services must be administered and directed by an RD. The proposed amendment takes into account that RDs must have a bachelor's degree in nutrition and organizational management, complete an accredited supervised practice program at a health-care facility, community agency, or foodservice corporation, and pass a national exam. RDs also must complete continuing professional education requirements to maintain their credentials. This provision also specifies the RD's responsibilities and brings them in line with current industry practices as follows:

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[41] Assembly Floor Bill Analysis, July 11, 2008 under Comments, see also Assembly Health Bill Analysis, March 21, 2008 under Comments: Purpose of this Bill.

[42] Assembly Health Bill Analysis, March 21, 2008 under Existing Law; Assembly Business and Professions Bill Analysis, April 14, 2008 under Existing Law; Assembly Floor Bill Analysis, July 11, 2008 under Existing Law.

[43] The bill does this because a candidate may become a DSS in various ways, including one method that involves no college coursework, just a state-approved program of 90 hours of classroom instruction and interactive Web-based instruction in dietetic service supervision. HSC section 1265.4(b)(6). See also Assembly Appropriations Bill Analysis, April 29, 2008 under Summary; Assembly Floor Bill Analysis, July 11, 2008 under Summary.

[44] The Department has required the Dietetic Service director be an RD since 1975. The federal conditions of participation for Medicare in the SOM, Appendix A, section 483.28(a)(1) issued 10-17-08 do not require the service director be a RD. However, the interpretive guidelines do require a Dietetic Service director to demonstrate "through education, experience, and/or training the qualifications needed to manage the service, appropriate to the scope and complexity of the food service operations."

Adopt Paragraph (1): The Department proposes to require that the RD provide nutrition care services upon referral from a physician and make nutrition care recommendations to the medical staff. Once a patient is prescribed medical nutrition therapy, the RD creates an individualized diet plan following the dietetic service's written policies and procedures (see section 70273(e)). Medical nutrition therapy helps patients who have compromised nutritional status, a medical condition that is adversely affected by what they eat, or whose medical condition, surgical intervention, or physical condition interferes with their ability to eat, digest, or absorb nutrients. The proposed amendment is necessary to bring the regulations up to current industry practices and provide clarity to the regulated community.

Adopt Paragraph (2): The Department proposes to require that the RD provide medical nutritional therapy to patients and patients' families. Patients whose medical condition is adversely affected by what they eat can benefit from family help in changing the patient's diet to better support their health and healing. The proposed amendments are necessary to update the regulations to reflect current industry practices and provide clarity to the regulated community.

Adopt Paragraph (3): The Department proposes to require that the RD serve as a liaison to, and resource for, the medical and nursing staff. The RD acts as a resource for the medical and nursing staffs in making medical nutritional decisions. The proposed amendment is necessary to update the regulations to reflect current industry practices and provide clarity to the regulated community.

Adopt Paragraph (4): The Department proposes to require that the RD approve all patient menus and the facility diet manual. The facility diet manual provides detailed information on the various types of diets (Vegetarian, No Added Salt, Carbohydrate Controlled, Renal, Lactose Reduced, etc.). Menu selections and food substitutions must follow the information provided in the facility diet manual, making it a critical resource for the service staff and the food service manager. The proposed amendment is necessary to update the regulations to reflect current industry practices and provide clarity to the regulated community.

Adopt Paragraph (5): The Department proposes to require that the RD participate in the development and revision of dietetic service policies and procedures. Developing and revising the policies and procedures is a critical function of the administration of, and overseeing of, the dietetic service. The proposed amendment is necessary to update the regulations to reflect current industry practices and provide clarity to the regulated community.

Adopt Paragraph (6): The Department proposes to require the RD to develop, implement, and maintain a Quality Assessment and Performance Improvement (QAPI) program in accordance with hospital-wide QAPI processes as defined in section 70701 for dietetic service processes throughout the hospital. The proposed amendment is

necessary to bring the regulations current with accepted industry standards known to protect patient health and promote worker safety.

Adopt Paragraph (7): The Department proposes to require the RD to provide direction to the food service manager and dietetic service staff. The proposed amendment is necessary provide clarity to the regulated community.

Adopt Paragraph (8): The Department proposes to require that the RD plan and conduct in-service education and training programs for the dietetic service staff. The proposed amendment is necessary to update the regulations to reflect current industry practices and provide clarity to the regulated community.

Adopt Paragraph (9): The Department proposes to require that the RD advise the hospital administration on dietetic issues. The proposed amendment is necessary provide clarity to the regulated community.

Adopt Paragraph (10): The Department proposes to require the RD to participate with administration and department heads in conferences that are relevant to dietetic service operations. This is a common industry standard and is necessary to update the regulations and provide clarity to the regulated community.

Adopt Paragraph (11): The Department proposes to require the RD participate on hospital committees relevant to dietetic service operations. The RD's involvement on hospital committees ensures hospital policies and planning reflects current knowledge of dietetics and nutrition and keeps the dietetic service informed of activities and proposed changes in the hospital. The proposed amendments are necessary to update the regulations to reflect current industry practices and provide clarity to the regulated community.

Adopt subdivision (b): The Department proposes language requiring, when a hospital does not employ a full-time RD, that there must be a part-time or consultant RD scheduled to work the days and hours needed to meet the needs of patients and administer the service. This is necessary to align these regulations with the federal conditions of participation for Medicare provided in the State Operations Manual, Appendix A, section 482.28(a)(2) (2008) p.367, to update the regulations to reflect current industry practices, and provide clarity to the regulated community.

Adopt paragraph (1): To require that hospitals that hire a consultant RD must specify the responsibilities of the position, including the required frequency and duration of the RD's visits, in the consulting contract. PHNC surveyors have observed that misunderstandings between hospitals and consultant RDs lead to lapses in proper patient care that can be avoided by clarifying these issues before the contract is signed. These amendments are necessary to update the regulations to reflect current industry practices, facilitate PHNC surveyor review of RD visits in relation to the volume of the

hospital patient demands to ensure the protection of patient health, and provide clarity to the regulated community.

Adopt paragraph (2): To require consultant RD's to create reports of all services they perform. This is a currently accepted industry practice that facilitates examination by hospital administration and PHNC surveyors of how a consultant RD fulfills their administrative role to oversee the dietetic service. This amendment is necessary to align the regulations with widely accepted practices known to protect patient health and safety and provide clarity to the regulated community.

Adopt paragraph (3): To require that a consultant RD's contract, regular reports, and résumé be kept in the dietetic service's personnel files. This enables hospital administration and PHNC surveyors to evaluate hospital operations with respect to the food service manager and the consultant RD who administers and provides oversight to the service. The proposed amendments reflect current industry practice and are necessary to protect patient health and safety and provide clarity to the regulated community.

Adopt new subdivision(c): The Department proposes new language clarifying the responsibilities of a food service manager when the hospital does not employ a full-time RD. These amendments clarify that a food service manager can be a person who is DSS qualified under HSC section 1265.4, or another RD. These amendments specify that the food service manager must have scheduled consultations from a qualified dietitian." HSC section 1265.4 applies to all heath facilities, not just hospitals. An RD's educational background and the RD's certification requirement to stay informed of the latest advances in dietetics and nutrition provides critical expertise on how to best feed patients. The frequent consultation with the RD requirement seeks to ensure that all hospitals serve healthy, nutritious food, and that hospitals rapidly implement the latest advances in dietetics and nutritional science. This is a part of the Department's effort to ensure that all health facilities provide patients with appropriate nutrition to support their health and healing. These amendments are necessary to clarify in the hospital setting who may be a food service manager, how the food service manager fits into the management of the dietetic service, and details the responsibilities of the food service manager as follows:

Adopt paragraph (1): To require the food service manager implement the dietetic service's policies and procedures. When a service has only a part-time or consultant RD, it falls to the food service manager to implement the service's policies and procedures. This is necessary to update the regulations to current industry standards and provide clarity to the regulated community.

Adopt paragraph (2): To require the food service manager implement the diet manual and planned menus. While the RD approves the diet manual and planned menus, it is common industry practice that when running the food service operations, the food service manager implements the menus and diet manual which explains the nutritional

requirements met by the various planned menus. This amendment is necessary to update the regulations to meet current industry standards and to provide clarity to the regulated community.

Adopt paragraph (3): To require the food service manager implement the QAPI process developed by the RD. QAPI is the prevailing standard for quality control in the industry. This amendment is necessary to update the regulations to meet current industry standards and provide clarity to the regulated community.

Adopt paragraph (4): To require the food service manager participate in hospital-wide emergency planning. The dietetic service plays a crucial role in feeding patients, staff, and volunteers in a hospital-wide emergency or disaster. In hospitals with a part-time or consultant RD, the food service manager must represent the service in the hospital-wide emergency preparedness planning. This amendment is necessary to reflect changes in the industry and to provide clarity to the regulated community.

Adopt paragraph (5): To require the food service manager participate in conferences for dietetic issues with administration and department heads. This is a common industry standard and is necessary to update the regulations and provide clarity to the regulated community.

Adopt paragraph (6): To require the food service manager participate on hospital committees relevant to the service's operations. This is a common industry standard and is necessary to update the regulations and provide clarity to the regulated community.

Amend existing subdivision (c): Renumber to subdivision (d). The Department proposes additional language to clarify that working hours for service personnel must be enough to meet patient needs. PHNC surveyors requested this be clarified, as the previous wording of this subdivision[45] still resulted in a high number of citations and deficiencies. The Department previously required enough staff be employed and given working hours to provide for the needs of the patients and to maintain the service areas. The proposed amendment uses the phrase "enough working hours" to emphasize and clarify the existing requirement that the service must have enough staff to provide for patient nutritional needs. The Department also proposes adding the term "service" to provide stylistic consistency with the rest of the Department's regulations.

Amend existing subdivision (d): Renumber to subdivision (e). The Department proposes amendments replacing the phrase "be posted" to "made available" to clarify that the service may share work schedules in whatever means (electronic posting, email, etc.) best fits their operations. This is a common industry practice that gives

[45] 45Title 22 CCR 70275(d): "Sufficient dietetic service personnel shall be employed, oriented, trained, and their working hours scheduled to provide for the nutritional needs of the patients and to maintain the dietetic service area."

hospitals greater flexibility in communicating with staff and is necessary to update the regulations and provide clarity to the regulated community.

Amend existing subdivision (e): Renumber to subdivision (f). The Department proposes non-substantive grammatical changes for the clarity of the regulated community.

Amend existing subdivision (f): Renumber to subdivision (g). No change to text,

Amend paragraph (1): The Department proposes to eliminate the requirement that beards and mustaches must be closely cropped and neatly trimmed, and instead require that all facial hair be covered. The elimination of restrictions on facial hair for employees is a widely accepted industry practice, allowing the service greater flexibility in hiring employees. The proposed amendments are further necessary to bring the regulations in line with current statute,[46] which calls for food employees to wear hair restraints, but does not ban facial hair, and does not impose restrictions regarding beards and mustaches being closely cropped and neatly trimmed. The Department further proposes new language prohibiting rings except plain rings pursuant to HSC section 113973. HSC section 113973(a) requires employees contacting food or food-contact surfaces to wear single-use gloves if wearing a ring, except for a plain ring, such as a wedding band. These amendments are necessary to maintain widely accepted sanitation practices for dietetic services and to better align the regulations with governing statutes.

Amend paragraph (2): To require that, in kitchen areas, employee's must store their personal items and street clothing in an enclosed locker area and add a reference to the Title 24, California Building Code regulation that has requirements for the enclosed area. Change "contained" to "enclosed" so that the language in Title 22 will be the same as the language in Title 24 language, ensuring that stakeholders will know that the rules refer to the same thing. Storing employees' personal items in an enclosed area is a widely accepted industry practice and is proposed to reduce clutter, improve sanitation in service facilities, and provide clarity to the regulated community.

Amend paragraph (3): To clarify that hand sanitizer is not a substitute for hand washing with soap and water. This proposed amendment is based on research cited by the Centers for Disease Control and Prevention (CDC)[47] establishing that hand washing with soap and water is the best way to reduce the number of microbes in most situations, and that hand sanitizers are not as effective when hands are visibly dirty or greasy. Additionally, this language takes into account the CDC's observation that sanitizers may not remove harmful chemicals, such as pesticides or heavy metals. These amendments are necessary to protect patient health by bringing the regulations

[46] CRFC, HSC section 113969(a).

[47] U.S. Centers for Disease Control. Show Me the Science – When & How to Use Hand Sanitizer in Community Settings. (September 2020).

up to date with widely accepted industry practices, and to provide clarity to the regulated community.

Amend paragraph (4): To provide non-substantive grammatical changes for the ease and clarity of the regulated community.

Section 70277: Dietetic Service Equipment and Supplies
Amend subdivision (a): The Department proposes a non-substantive grammatical change and adds a requirement that equipment necessary for sanitation must be provided and maintained. The grammatical change is made to update and clarify this subdivision, to provide stylistic consistency with the rest of the Department's regulations and provide clarity to the regulated community. Effective hot water sanitizing in manual warewashing sinks has improved, and now internal thermometers and racks or baskets that allow for complete immersion are the industry standard and are required in statute. Clarifying that the service must have and maintain equipment needed for sanitation aligns these regulations with statute and provides clarity to the regulated community.

Amend paragraph (1): Repeal the words "objectionable" and "excessive" because they are vague and may confuse the regulated community. Add a reference to Title 22 hospital heating, air conditioning and ventilating systems requirements and add a reference to hospital dietetic area ventilation requirements in Title 24, California Mechanical Code, sections 311 and 313. The regulations referenced make specific the requirements for ventilation.

Amend paragraphs (2) through (3): Non-substantive grammatical changes only (adding serial commas).

Amend subdivision (b): The Department proposes amendments to clarify what the subdivision covers, required food supplies, and the conditions food supplies must meet. This amendment is necessary for the clarity of the regulated community.

Subdivision (1): Change "shall" to "must."

Amend and re-number paragraphs (2) through (8): The Department proposes re-numbering existing subdivisions (b)(2) through (b)(8) to accommodate adoption of new subdivisions (b)(2), (b)(3), and (b)(4), and elimination of existing subdivisions (b)(4) and (b)(6). The proposed adoption of three new paragraphs is necessary to bring the regulations up to current emergency and disaster preparedness standards. The proposed deletions are necessary to remove outdated restrictions about milk no longer required for patient protection, and to remove language about covering and dating leftovers that is covered earlier in these regulations (section 70273(n)). This renumbering is to provide clarity to the regulated community.

Adopt paragraph (2): To require hospitals provide patients with hot and nutritional meals when, absent an official proclamation or declaration of a disaster, the hospital is

rendered unable to prepare meals, or when the outside food service is unable to provide meals. If a hospital kitchen is rendered unusable for any reason other than a disaster, patients are still entitled to hot and appetizing meals that mirror the nutritional adequacy of menus routinely served. Hospitals must have a back-up plan for when their customary outside food service provider encounters an unexpected event, rendering the outside food service unable to provide food as contracted. Hospitals dependent on an outside food service must have on hand the supplies, equipment, and personnel sufficient to prepare hot, nutritious meals. Reheated canned chili and other improvised solutions are not acceptable fare for hospital patients.

Adopt paragraph (3): To require emergency and disaster meals to mirror the macronutrient content of meals routinely served, while adapting to conditions such as having gas, electricity, and potable water in limited supply. In the aftermath of both Hurricane Katrina in 2005 and Hurricane Sandy in 2012, hospitals struggled to prepare meals from the emergency supply without the essentials of gas, electricity, and potable water. The proposed language is necessary to bring the service's emergency and disaster preparedness in line with industry standards and provide clarity to the regulated community.

Adopt paragraph (4): To require each hospital to follow that hospital's all-hazards emergency management plan to determine the amount of food supplies needed for disaster purposes. Rural hospitals, located close to where food is grown, may be able to receive community support allowing them to feed patients and staff in ways urban hospitals cannot if damaged infrastructure limits access to fresh food. Each hospital's all-hazards emergency plan must be individually tailored to assess local resources and estimate that hospital's unique emergency and disaster preparedness needs. All-hazards emergency management plans are a part of CMS requirements, the proposed language to be adopted is necessary to bring the service's emergency and disaster preparedness in line with industry standards, better align with federal regulations, and provide clarity to the regulated community.

Amend existing paragraph (2): Renumber to paragraph (5). To require all frozen food showing evidence of thawing to be rejected and never served to patients. HSC section 114037(e) requires that only frozen food with no visible signs of thawing can be received and accepted by a retail food business. PHNC surveyors requested this additional language to make very clear that cooking and serving food that has been frozen, partially thawed, and then re-refrozen is not allowed in a hospital. While thawed and refrozen food is generally not harmful to eat, the loss of moisture that occurs in thawing and re-freezing significantly and unacceptably degrades the taste and texture of food. The proposed amendment is necessary to better align the regulations with statute and provide clarity to the regulated community.

Amend existing paragraph (3): Renumber to paragraph (6). Add a reference to the definition of "products resembling milk products" to make the regulation specific and to prevent confusion in the regulated community.

Repeal existing paragraph (4): Repeal to avoid duplication and simplify the provisions related to milk storage. Proposed paragraph (6) of this subdivision provides guidance for the handling and storage of milk, making the requirements in existing paragraph (4) unnecessary and burdensome. This is reasonably necessary to provide clarity to the regulated community.

Amend existing paragraph (5): Renumber to Paragraph (7). The Department proposes to delete "as determined by the Department" because requirements are outlined in federal, state, and local codes. "As determined by the Department" does not meet clarity standards.

Repeal existing paragraph (6): The Department proposes to repeal existing subdivision (b) because it duplicates text now in section 70273(o)(3) and it is eliminated here to avoid duplication. The proposed changes are necessary to provide clarity to the regulated community.

Amend existing paragraph (7): Renumber to Paragraph (8). Renumbered from paragraph 7. There are no substantive changes to the text.

Section 70279: Dietetic Service Space
Amend subdivision (a): The Department proposes to require the dietetic service to comply with the dietetic service space requirements in Title 24, California Building Code, section 1224.20. The Public Health Act of 2006 gave jurisdiction of building and design specifications to the Department of Healthcare Access and Information (HCAI), formerly known as the Office of Statewide Health Planning and Development (OSHPD). Under the Act, the Department may require what kinds of space are needed and HCAI must write the building and design specifications needed to make the space suitable for the intended purpose. The Department proposes an amendment to clarify that the space requirements specified in this subdivision must be maintained. Continuing to meet the requirements over time ensures that dietetic personnel remain safe from obstructions during their work.

Amend subdivision (b): The Department proposes amendments to this subdivision to clarify that the food storage areas must meet the needs of the dietetic service operations and be maintained. The food storage area ventilation requirement is now in section 70273, subdivisions (m) and (m)(1), so it is eliminated here to avoid duplication. The proposed amendments are necessary to protect public health and provide clarity to the regulated community.

Amend subdivision (c): The Department proposes to repeal prescriptive requirements for the square footage of floor space per bed for storage of frozen and chilled foods. Add a reference to Title 24, California Building Code, section 1224.20.2.3 requirements for square footage. The Department does not have authority to write hospital building and design standards in Title 22 regulations as that authority has been given to HCAI in

Title 24 regulations. Functional requirements allow Department surveyors to enforce requirements when the space meets Title 24, California Building Code requirements but is not sufficient to meet Title 22 requirements.

Subdivision (d): No substantive changes to the text.

Amend subdivision (e): The Department proposes to repeal prescriptive requirements for the square footage of floor space per person in the employee dining space to functional requirements. Add a reference to Title 24, California Building Code, section 1224.20.2.8.1 requirements for square footage. The Department does not have authority to write hospital building and design standards in Title 22 regulations as that authority has been given to HCAI in Title 24 regulations. Functional requirements allow Department surveyors to enforce requirements when the space meets Title 24, California Building Code requirements but is not sufficient to meet Title 22 requirements.

Amend subdivision (f): The Department proposes amendments that restate the previous requirements and specify functions the administrative staff must be able to accomplish within the office or other suitable space. The Dietary administrative staff must handle employee and staff matters, make calls, store documents, and the administrative office is where the RD director will conduct the many administrative tasks in section 70275, subdivision (a) (1) through (11). Planning appetizing and nutritionally balanced menus that follow the Dietary Reference Intakes and meet the needs of patients while staying within budget requires a space separated from the noise and intensity of food preparations. The Dietary administrative offices are where menus, reports and other records must be stored, and where confidential personnel matters such as interviewing prospective hires, conducting performance reviews, and discussing promotions, reprimands, and leave requests must be handled. The amendment sets a performance standard of what the administrative staff must be able to accomplish and grants hospitals the freedom to set up a suitable space that works best for the dietetic service. The proposed amendments are necessary to specify the space needed for the dietetic service’s administrative offices and provide clarity to the regulated community.

Amend paragraph (1): The Department proposes adding new language to specify the administrative staff offices must have an unobstructed view of the food preparation area. PHNC surveyors report hospitals that meet this building standard have improved compliance with regulations. This subdivision does not require immediate remodeling to comply if the administrative staff offices in use on January 1, 2023, and do not have an unobstructed view of the food preparation area. Having this requirement phased in by requiring compliance only when new construction or when remodeling occurs is a balanced way to implement this requirement. The proposed amendments are necessary to conform the regulations to current industry standards, protect public health, and to provide clarity to the regulated community.

Section 70701: Governing Body

Adopt subdivision (a)(10) to align with 42 CFR 482.21, which specifies requirements for the QAPI program's scope, data-collection, performance improvement projects, and the responsibilities of the hospital's governing body, medical staff, and administrative officials for implementing and maintaining the QAPI program. Furthermore, 42 CFR 482.21 is a CMS condition of participation that became effective March 25, 2003. This condition requires every hospital that accepts CMS funds to have a hospital-wide, data-driven QAPI program that involves all hospital departments and services. As basic services, the Clinical Laboratory, Pharmaceutical, and Dietetic Services, are required to have a QAPI program, the results of which are integrated into the governing body's hospital-wide QAPI program. This amendment is being adopted to clarify reference made to QAPI in the proposed amendments to the Clinical Laboratory, Pharmaceutical, and Dietetic Service regulations. Adopting the reference to QAPI in the federal regulations is necessary to bring the regulatory language up to current standards and provide clarity to the regulated community. The proposed amendments are needed to clarify that all the hospitals' supplemental services, basic services, and contract services must have their own QAPI programs that align with the hospital-wide program, and to protect the health and safety of patients by making the regulations consistent with current industry standards of practice.

Documents Relied Upon

1. AABB, *Who We Are* (2017).
2. Garratty, *Advances in Red Blood Cell Immunology-1960 to 2009* (March 2010), pp. 526 – 535.
3. AABB, *Highlights of Transfusion Medicine History* (2017).
4. Centers for Disease Control and Prevention, *Blood Safety Basics* (Updated Jan. 21, 2013)
5. World Health Organization, *Blood Donor Counselling Implementation Guidelines* (2014).
6. Centers for Medicare and Medicaid, *State Operations Manual*, Appendix C.
7. Rose, Research & Practice Guide: California Regulatory History & Intent (2011). Legislative Research & Intent LLC (2018).
8. California Senate Bill 493 (Regular Session 2013-2014).
9. American Society of Health-System Pharmacists, Inc. *ASHP Guidelines on Pharmacy and Therapeutics Committee and the Formulary System* (2015).
10. American Society of Health-System Pharmacists, Inc. *ASHP Guidelines on Minimum Standards for Pharmacies in Hospitals* (2013).
11. American Society of Health-System Pharmacists, Inc. *ASHP Guidelines on Preventing Medication Errors in Hospitals* (2018).

12. American Society of Health-System Pharmacists, Inc. *ASHP Guidelines on Preventing Medication Errors with Chemotherapy and Biotherapy* (2015).

13. Centers for Medicare and Medicaid, *State Operations Manual*, Appendix A, Regulations and Interpretive Guidelines for Hospitals, tag number A-0506, covering section 482.25(b)(4): "When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law."

14. American Society of Health-System Pharmacists, Inc. *ASHP Guidelines on Compounding Sterile Preparations* (2013).

15. United States Pharmacopeia/National Formulary. *USP 40-NF-35, Packaging and Storage Requirements* (2017).

16. U.S. Centers for Disease Control. *Vaccine Storage & Handling Toolkit* (2018).

17. American Society of Health-System Pharmacists, Inc. *ASHP Guidelines on Medication-Use Evaluation* (1996).

18. American Society of Health-System Pharmacists, Inc. *ASHP Technical Assistance Bulletin on Hospital Drug Distribution and Control (*1980).

19. Centers for Medicare and Medicaid, *State Operations Manual*, Appendix A, *Regulations and Interpretive Guidelines for Hospitals,* tag number A-0629, covering section 482.28(b)(1).

20. Department of Developmental Services, California Health and Human Services Agency. *Diet Manual.* (2010)

21. ECA Academy. *What are the regulatory Definitions for "Ambient", "Room Temperature" and "Cold Chain"?* (2017).

22. United States Department of Agriculture: Food Safety Facts. *How Temperatures Affect Food*. (2013)

23. Journal of the American Dietetic Association. *Centralized infant formula preparation room in the neonatal intensive care unit reduces incidence of microbial contamination.* (October 2008). 108(10):1700-3.

24. U.S. Centers for Disease Control. *Show Me the Science – When & How to Use Hand Sanitizer in Community Settings*. (September 2020).

25. American Academy of Pediatrics. *Frequently Asked Questions*. (2021).

26. Documents within the Legislative history of HSC section 1265.4, which was passed in 2008 as Assembly Bill (AB) 2128. Report of Assembly Committee on Health, March 21, 2008, Report of Assembly Committee on Business and Professions, April 14, 2017, Report of Assembly Committee on Appropriations, April 29, 2008, Concurrence in Senate Amendments, July 11, 2008.

ECONOMIC IMPACT ASSESSMENT

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.

Reasonable Alternatives Considered
The Department has determined 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.

Mandated Use of Specific Technologies
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,[48] and since 1999 for HSC sections 1602.5.[49]

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

[48] HSC 1602.6 concerns importing human whole blood and human whole blood derivatives into the state.
[49] HSC 1602.5 concerns producing human whole blood and human whole blood derivatives within the state.

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.

Impact on Small Business

The Department considers Type 1 (under 26 beds and not part of a network) and Type 2 (under 26 beds and part of a network) hospitals to be "small businesses." There are 30 Type 1 hospitals and 9 Type 2 hospitals for a total of 39, or 9.4%, of the 415 hospitals in the state.

Type 1 hospitals average $36.8 million and Type 2 hospitals average $71.9 million in net patient revenue (NPR) per year. Table 8 of the Cost Estimating Methodology (CEM) shows the total recurring annual gross costs as a percent of total NPR by hospital type. Small hospitals face an almost non-existent burden as a percent of NPR. Because the impact on small businesses will be offset by the increase in NPR due to the regulations, the Department determined no reasonable alternative to the regulations would lessen any adverse impact on small business.