August 31, 2018

Scott Vivona, Acting Deputy Director
California Department of Public Health
Center for Health Care Quality
Attn: Regulations Unit, MS 3201
P.O. Box 99737
Sacramento, CA 95899-3201

Subject: AFL 18-34, Medical Services Regulations

Dear Mr. Vivona:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) respectfully offers the following comments on revising certain Title 22 regulations. CHA provided detailed recommendations for each section of Title 22 in 2011; the following recommendations update the sections for which the California Department of Public Health (CDPH) has solicited comments. CHA commends the CDPH Center for Healthcare Quality for beginning the significant and complex process of revising the cardiovascular surgery, cardiac catheterization laboratory, anesthesia services and surgical services sections of Title 22. To assist in that effort, CHA offers the following general recommendations that we believe must be considered to achieve a successful outcome.

As CDPH is aware, the majority of Title 22 regulations are outdated and no longer relevant to current hospital delivery of care. Consequently, Title 22 precludes CDPH’s ability to provide effective oversight. Equally problematic, the current regulations are among the many obstacles California hospitals face in providing high-quality health care under tight financial restrictions, while utilizing the most current technological advancements. CHA applauds CDPH for undertaking the monumental task of rewriting Title 22, and underscores the need to ensure a proper foundation and infrastructure are created to support this endeavor.

It is important that updated regulations: 1) are consistent with existing laws and regulations, as well as national standards; 2) can be readily implemented at the facility and unit levels; 3) allow for innovation in a constantly changing environment, to ensure their requirements remain relevant for decades; and 4) are organized in a manner that facilitates clear understanding of the requirements and compliance. We also encourage CDPH to review existing program flexibility to identify current practice standards.

CHA recommends that CDPH:

Require Hospitals to Adopt and Follow National Standards
CHA strongly urges CDPH to consider aligning Title 22 requirements with the Centers for Medicare & Medicaid Services’ (CMS) Conditions of Participation (CoPs). If the department were to codify the existing CoPs in Title 22, those regulations would become outdated when CMS next updates the COPs. Instead, CDPH could adopt the standards by reference, to allow Title 22 regulations to remain relevant as CoPs change in the future. In addition, CHA believes that, to keep pace with existing standards of care, hospitals should be required to choose relevant national standards to use as a foundation for their policies and procedures. Facilities would base this decision on their patient population and the services they provide in each clinical service line. This will ensure that, as practice changes, Title 22 requirements remain relevant and hospitals continue to be held to the current community standard. Conformity with the CMS CoPs and the adoption of national standards in hospitals’ policies and procedures will eliminate inconsistencies, inefficiencies and confusion.

Streamline Common Requirements for Basic and Supplemental Services
For each basic and supplemental service, hospitals must establish written policies and procedures, have specified equipment and meet other common requirements. CHA recommends that regulations pertaining to administrative policies and procedures be streamlined for basic and supplemental service areas. For example, one section of Title 22 should require each clinical service line to develop and implement policies and procedures, based on national standards identified by the hospital; provide sufficient trained and qualified staff; and provide sufficient equipment to serve the needs of the patient population. If there are special requirements for a specific basic or supplemental service those requirements should be placed in a section devoted to that clinical area (e.g. medical services, intensive care unit, etc.). This will reduce redundancy and improve consistency on the key provisions that are unique to a particular service.

Eliminate Title 24 Building Standards from Title 22
CHA wishes to emphasize that Title 22 should be rewritten to allow California hospitals to provide care and design buildings that meet the needs of modern health care delivery. The Office of Statewide Health Planning and Development has jurisdiction over hospital building standards, including square footage, electrical and ventilation, and other non-operational standards. CHA strongly encourages CDPH to immediately remove those requirements from Title 22, unless the department has identified an operational concern.

Streamline Medical Services Regulations
CHA suggests that CDPH revise the medical service section to include only those requirements not addressed in the requirements common to all clinical units. CHA suggests eliminating sections § 70203, § 70205, 22 CCR § 70207,CCR § 70209, as they would be codified in the common requirements for basic and supplemental services. CHA suggests keeping the following language:

- § 70201. Medical Service Definition. Medical service means those preventive, diagnostic and therapeutic measures performed by or at the request of members of the organized medical staff. The hospital shall identify national or professional standards appropriate to the care of patients on the medical service to base its base its policies and procedures.
• § 70203. Medical Service Monitoring. Patients with a written order for admission or observation on the medical service, who do not meet the criteria for admission or observation on the critical care unit (section 70217 (a) (1)), step-down unit (section 70217 (a) (9), or telemetry unit (secton 70217 (a) (10), may be monitored using telemetry or other methods of non-invasive monitoring.

CHA's recommendations are not an exhaustive list, but an initial submission during this pre-notice period. Moving forward, CHA is ready to assist CDPH in updating the Title 22 regulations to provide a structure for hospitals that supports the safe provision of patient care.

Thank you for the opportunity to comment as the department begins its work on these important regulations. We look forward to working with you. If you have any questions, please do not hesitate to contact me at drogers@calhospital.org or (916) 552-7575.

Sincerely,

[Signature]

Debby Rogers, RN, MS, FAEN
Vice President, Clinical Performance and Transformation

Attachments: Draft Regulatory Language - AFL 18-34 Medical Service
### Article 3 Basic Services

<table>
<thead>
<tr>
<th>§ 70200</th>
<th>Rationale</th>
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<td>(a) Hospital basic services include medical, nursing, surgical, anesthesia, laboratory, radiology, pharmacy, and dietary services.</td>
<td>For each basic and supplemental service, hospitals must establish written policies and procedures, have specified equipment and meet other common requirements. CHA recommends that regulations pertaining to administrative policies and procedures be streamlined for basic and supplemental service areas. For example, one section of Title 22 should require each clinical service line to develop and implement policies and procedures, based on national standards identified by the hospital; provide sufficient trained and qualified staff; and provide sufficient equipment to serve the needs of the patient population. If there are special requirements for a specific basic or supplemental service, those requirements should be placed in a section devoted to that clinical area (e.g., medical services, intensive care unit, etc.). This will reduce redundancy and improve consistency on the key provisions that are unique to a particular service.</td>
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<td>(b) In establishing standards for each inpatient clinical service line or inpatient unit, the hospital shall:</td>
<td>Each clinical unit should be added to Article 3 and Article 4 with only those requirements specific to that unit. All overarching requirements should be listed in this section.</td>
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<td>(1) Appoint a physician with appropriate training and education to have responsibility of the clinical service.</td>
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<td>(2) Develop, maintain and implement written policies and procedures.</td>
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<td>(3) Ensure the nursing staff on each service is trained and knowledgeable on that clinical service and has an annual competency evaluation. Each clinical service shall be managed by a nurse manager.</td>
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<td>(4) Ensure sufficient nursing personnel to ensure safe patient care and compliance with section 20217.</td>
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<td>(5) Establish cardiopulmonary resuscitation education and infection control education for clinical staff.</td>
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<td>(6) Ensure continuing staff education on relevant topics.</td>
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<td>(7) Ensure adequate equipment and supplies, including emergency equipment to care for the needs of patients cared for on that unit.</td>
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### § 70201. Medical Service Definition.
Medical service means those preventive, diagnostic and therapeutic measures performed by or at the request of members of the organized medical staff.

### § 70203. Medical Service General Requirements-
(a) A committee of the medical staff shall be assigned responsibility for:
(1) Recommending to the governing body the delineation of medical privileges.

Any requirement that applies to all inpatient units should be listed in the newly created section 70200 above.
(2) Developing, maintaining and implementing written policies and procedures in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate.

(3) Developing and instituting, in conjunction with members of the medical staff and other hospital services, a continuing cardiopulmonary resuscitation training program.

(4) Determining what emergency equipment and supplies should be available in all areas of the hospital.

(b) The responsibility and accountability of the medical service to the medical staff and administration shall be defined.

(c) The following shall be available to all patients in the hospital:

1. Electrocardiographic testing.
2. Pulmonary function testing.
3. Intermittent positive pressure breathing apparatus.
4. Cardiac monitoring capability.
5. Suction.

(d) Periodically, an appropriate committee of the medical staff shall evaluate the services provided and make appropriate recommendations to the executive committee of the medical staff and administration.

Patients with a written order for admission or observation on the medical service, who do not meet the criteria for admission or observation on the critical care unit (section 70217 (a) (1)), step-down unit (section 70217 (a) (9)), or telemetry unit (section 70217 (a) (10)) may be monitored using telemetry or other methods of non-invasive monitoring. In circumstances where a patient needing admission to a critical care unit, step-down unit or telemetry unit at a time when that a bed in that unit is not available may be cared for on a medical or surgical unit with telemetry or other method of non-invasive monitoring.

§ 70205. Medical Service Staff.

A physician shall have overall responsibility for the medical service. This physician shall be certified or eligible for certification in internal medicine by the American Board of Internal Medicine. If such an internist is not available, a physician, with training and experience in internal medicine, shall be responsible for the service.

§ 70207. Medical Service Equipment and Supplies.

There shall be adequate equipment and supplies maintained related to the nature of the needs and the services offered.

Section 70203 would allow any patient on admitted or on observation status to be monitored with telemetry or other non-invasive monitoring. This will increase patient safety.

This type of requirement, which applies to all inpatient units, should be listed in the newly created section 70200 above.
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<th>§ 70209. Medical Service Space.</th>
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<tr>
<td>There shall be adequate space maintained to meet the needs of the service.</td>
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**Eliminate Title 24 Building Standards from Title 22**

CHA wishes to emphasize that Title 22 should be rewritten to allow California hospitals to provide care and design buildings that meet the needs of modern health care delivery. The Office of Statewide Health Planning and Development has jurisdiction over hospital building standards, including square footage, electrical and ventilation, and other non-operational standards. CHA strongly encourages CDPH to immediately remove those requirements from Title 22, unless the department has identified an operational concern.