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- 35 Request for Stakeholder Input in Amending General Acute Care Hospital Records and Reporting 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As CDPH is aware, the majority of Title 22 regulations are outdated and no longer relevant to current hospital delivery of care.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. 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.

Attached is a chart with CHA’s suggested amendments and rationale for Sections 70733-70746.

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,

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

Attachments: Draft Regulatory Language for Sections 70733-70746
### Rationale

- This regulation should be revised to clarify that the documents may be maintained electronically, and they don’t need to be “filed” in the “administrative offices of the hospital.”
- A record retention period should be specified, so hospitals know how long they must keep patient admission rosters, policy and procedure manuals, etc.

### 22 CCR § 70733

**§ 70733. Records and Reports.**

(a) Each hospital shall maintain copies of the following applicable documents on file in the administrative offices of the hospital:

1. Articles of incorporation or partnership agreement.
2. Bylaws or rules and regulations of the governing body.
3. Bylaws and rules and regulations of the medical staff.
4. Minutes of the meetings of the governing body and the medical staff.
5. Reports of inspections by local, state and federal agents.
6. All contracts, leases and other agreements required by these regulations.
7. Patient admission roster.
8. Reports of unusual occurrences for the preceding two years.
12. Minutes and reports of the hospital Infection Control Committee.
13. Any other records deemed necessary for the direct enforcement of these regulations by the Department.

(b) The records and reports mentioned or referred to above shall be made available for inspection by any duly authorized officer, employee or agent of the Department.

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### 22 CCR § 70735

**§ 70735. Annual Reports.**

All hospitals shall submit annual reports to the Department on forms supplied by the Department and by the date specified on the form.

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<tr>
<td>- This regulation should be repealed or clarified – what “form” is being reference here?</td>
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### 22 CCR § 70736

**§ 70736. Sterilization Reporting Requirements.**

(a) All hospitals performing tubal ligations, vasectomies, and hysterectomies shall submit to the Department a quarterly report containing the following information:

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<td>- This section should be repealed. Hospitals report this information to the Office of Statewide Health Planning and Development.</td>
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(1) The total number of such sterilizations performed, including diagnoses and types of procedures employed.
(2) The number and type of such sterilizations performed by each physician on the medical staff preserving the anonymity of the physicians and patient.
(3) Demographic and medical data as required by the Department.

Note: Authority cited: Sections 208, 1275, 1276, HSC. Reference: Sections 1250 et seq. HSC.

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<th>22 CCR § 70737</th>
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<tr>
<td>§ 70737. Reporting.</td>
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<tr>
<td>(a) Reportable Disease or Unusual Occurrences. All cases of reportable diseases shall be reported to the local health officer in accordance with Section 2500, Article 1, Subchapter 4, Chapter 4, Title 17, California Administrative Code. Any occurrence such as epidemic outbreak, poisoning, fire, major accident, disaster, other catastrophe or unusual occurrence which threatens the welfare, safety or health of patients, personnel or visitors shall be reported as soon as reasonably practical, either by telephone or by telegraph, to the local health officer and to the Department. The hospital shall furnish such other pertinent information related to such occurrences as the local health officer or the Department may require.</td>
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<td>(b) Testing for Phenylketonuria. Hospitals to which maternity patients or infants 30 days of age or under may be admitted shall comply with the requirements governing testing for phenylketonuria (PKU) contained in Section 6500 of Title 17, California Administrative Code.</td>
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<td>(c) Rhesus (Rh) Hemolytic Disease of the Newborn. Hospitals to which maternity patients may be admitted shall comply with the requirements for the determination and reporting of the rhesus (Rh) blood type of maternity patients and the reporting of rhesus (Rh) hemolytic disease of the newborn contained in Section 6510 of Title 17, California Administrative Code.</td>
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<tr>
<td>(d) Child Placement. Hospitals shall report to the Department on forms supplied by them, within 48 hours, the name and address of any person other than a parent or relative by blood or marriage, or the name and address of the organization or institution into whose custody a child is given on discharge from</td>
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- Delete redundant reporting requirements; there is no need to reiterate reporting requirements that are already set forth in other laws (reportable communicable diseases, PKU, Rh disease, and discharge of a minor).
- The terms “catastrophe” or “unusual occurrence” are vague and unclear. They should be deleted or defined, so that this regulation is very clear about the types of events that must be reported. Today, there is a lot of variation in interpretation among surveyors about what must be reported. The reporting requirement seems to be limited to large-scale events, yet some surveyors have stated that even events that affect a single patient may be reportable.
- This section was promulgated prior to the enactment of the adverse event and privacy breach reporting laws. It is unclear how this section relates to those requirements, if at all.
The release of children for adoption shall be in conformity with the state law regulating adoption procedure.

22 CCR § 70738
Written policies and procedures shall be adopted and implemented to accurately identify infants and to protect infants from removal from the facility by unauthorized persons. The policies and procedures shall be reviewed and updated by the facility every two years, as needed.
Note: Authority cited: Sections 208(a) and 1275, HSC. Reference: Section 1276, HSC.

22 CCR § 70741
§ 70741. Disaster and Mass Casualty Program. Emergency Management Program
(a) A written emergency operations plan (EOP) that includes a mass casualty incident plan, disaster and mass casualty program shall be developed and maintained in consultation with representatives of the medical staff, nursing staff, administration and fire, and safety and emergency management experts. The program shall be in alignment with local emergency planning, conformity with the California Emergency Plan of October 10, 1972 developed by the State Office of Emergency Services and the California Emergency Medical Mutual Aid Plan of March 1974 developed by the Office of Emergency Services, Department of Health. The program-EOP shall be approved by the medical staff and administration. A copy of the program-EOP shall be available on the premises for review by the Department.

(b) The program-EOP shall cover disasters occurring in the community and widespread disasters. It shall provide for at least the following:

1. Availability of adequate basic utilities and supplies, including gas, water, food and essential medical and supportive materials.
2. An efficient system of notifying and assigning personnel.
4. Conversion of all usable space into clearly defined areas for efficient triage, for patient observation and for immediate care.

Updated to reflect current nomenclature and practices
Harmonizes with additional existing requirements
Edited for clarity
(5) **Prompt, Appropriate** transfer of casualties, when necessary and after preliminary medical or surgical services have been rendered, to the facility most appropriate for administering definite care.

(6) A **tracking mechanism for patients** and a **special disaster medical record** that is accessible throughout the continuum of care shall be established, such as an appropriately designed tag, that accompanies the casualty as he is moved.

(7) Procedures for the **prompt evaluation and discharge or transfer** of patients already in the hospital at the time of the disaster who can be moved without jeopardy.

(8) Maintaining _security_ in order to keep relatives and curious persons out of the triage area. Of patients, personnel and visitors and the facility as needed.

(9) Establishment of a public information center and assignment of public relations liaison information officer duties to a qualified individual. Advance arrangements with communications media will be made to provide organized dissemination of information.

(c) The program EOP shall be **reviewed and revised, as needed, at least annually, brought up-to-date, at least annually, and All personnel shall be instructed in its requirements on their expected roles and responsibilities as outlined in the EOP.** There shall be evidence in the personnel files, e.g., orientation checklist or elsewhere, indicating that all new employees have been oriented to the program and procedures within a reasonable time after commencement of their employment.

(d) The disaster plan EOP shall be **rehearsed exercised** at least twice a year. An actual event may count as one of the required exercises. There shall be a written report and evaluation of all drills. The actual evacuation of patients to safe areas during the drill is optional. There shall be a written after action report and incident action plan for all exercises and actual events.

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22 CCR § 70743

§ 70743. Fire Safety Plan and Drills, and Internal Disasters. (a) A written fire and internal disaster program plan, incorporating evacuation procedures, shall be developed with the assistance of fire, safety and other appropriate experts. This plan may be a part of the organization’s emergency.
<table>
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<th><strong>22 CCR § 70745</strong></th>
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<td><strong>§ 70745. Fire Safety.</strong></td>
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<td>All hospitals shall be maintained in conformity with the regulations adopted by the Office of the State Fire Marshal for the prevention of fire and for the protection of life and property against fire and panic. All hospitals shall secure and maintain a clearance relative to fire safety from the State or local Fire Marshal with jurisdiction over the hospital.</td>
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<td><strong>§ 70746. Disruption of Services.</strong></td>
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<td>(a) Each hospital shall develop a written plan to be used when a discontinuance or disruption of services occurs.</td>
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<td>(b) The administrator shall be responsible for informing the Department, via telephone, immediately upon being notified of the intent of the discontinuance or disruption of services or upon the threat of a</td>
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<td><strong>walkout of a substantial number of employees, or earthquake, fire, power outage or other calamity that causes damage to the facility or threatens the safety or welfare of patients or clients</strong> shall be immediately reported, via telephone, to the department under the unusual occurrence reporting required in section 70746.</td>
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