January 6, 2023

Cassie Dunham, 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

SENT VIA E-MAIL: chcqregulations@cdph.ca.gov

Subject: AFL 22-22; Stakeholder Input on GACH Observation Services Regulations, Health and Safety Code Section 1253.7

Dear Ms. Dunham:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) respectfully offers the following comments in response to the department's request for stakeholder input on the development of general acute care hospital (GACH) observation service regulations. CHA appreciates the opportunity to provide input to support the development of policies and practices that meet the needs of hospital patients and communities.

Observation Services vs. Observation Units

CHA is concerned that the current request from the California Department of Public Health (CDPH) does not distinguish between observation *services* and observation *units.* While the subject of All Facilities Letter (AFL) 22-22 is "GACH Observation Services," the questions advanced for stakeholder feedback appear to focus on requirements for observation units. **CHA respectfully requests that CDPH clarify its goal in collecting feedback from stakeholders.**

Observation Services

Health and Safety Code 1253.7 defines observation services as *"outpatient services provided by a general acute care hospital and that have been ordered by a provider, to those patients who have unstable or uncertain conditions potentially serious enough to warrant close observation, but not so serious as to warrant inpatient admission to the hospital."*

Individuals with serious medical problems that require highly technical skilled care and who will likely need to be in the hospital for more than one day are admitted to the hospital as inpatients. Persons with conditions that require monitoring but who have an unclear need for longer care are generally placed on

observation status. As monitoring continues, observation patients may be admitted to inpatient care or remain on observation status until discharge.

Patient status and admission decisions are the responsibility of the attending physician. These inherently complex clinical judgments are formulated after consideration of numerous factors, including the severity of the condition, anticipated treatment needs, and the patient's medical history.

It is important to note, however, that a patient's status as observation does not determine, and is not determined by, their location in the hospital. For example, observation patients may remain in the hospital emergency department (ED) for the duration of their care or may be moved to a bed in an inpatient unit in the hospital, based on the assessments by qualified clinical staff. In addition, CDPH has established that hospitals **may** establish one or more observation units.

Observation Units
CDPH defines an observation unit as an area in which observation services are provided in a setting outside of an inpatient unit and not part of an ED of a general acute care hospital. In the circumstance where a hospital chooses to set up an observation unit, CDPH requires that the unit complies with the same licensed nurse-to-patient ratios as those applicable to supplemental emergency services. Additionally, the unit must be marked with signage that identifies the observation unit area as an outpatient area.

In order to receive meaningful input, CDPH must clarify its intent of updated regulations. Specifically, does CDPH plan to update existing regulations for observation ***units?*** Or is CDPH contemplating the development of regulations for observation ***services*** provided by general acute care hospitals in settings other than in an observation unit?

Response to Questions for Stakeholder Engagement
As previously noted, the questions accompanying the AFL appear to focus on the requirements for a designated observation unit and are not relevant for hospitals that provide observation services in their ED and/or an inpatient unit.

Based on existing licensing requirements, the ED of a general acute care hospital will meet or exceed the conditions considered in the questions, including (Question 1) direction by qualified clinical staff; (Question 2) access to necessary equipment; and (Question 5) availability of case management, therapy services, and consultants. Similarly, these services are routinely available in inpatient acute care units, where observation patients may be housed. **CHA urges CDPH to clarify that these requirements are applicable to designated observation *units.*** Hospitals that provide observation services in their ED and/or inpatient unit should continue to be subject to licensing requirements for those specific areas, and not these proposed requirements.

For hospitals that operate designated observation units, Questions 3 and 4 relate to the status and mix of patients cared for, including observation patients who are not waiting for a determination about admission, as well as patients who have orders to admit but are waiting for an inpatient bed. CHA is concerned that these requirements are unrealistic and inconsistent with the sound and efficient delivery of patient care.

As previously discussed, the determination of a patient's admission status (observation vs. inpatient) is a clinical decision, made by the attending physician and driven by the individual patient's medical status and anticipated care needs. In this context, it is unrealistic to mandate specific requirements for the "mix" of patient status in the observation unit. Patients — including those who are admitted to inpatient care as well as those who remain on observation status — should be housed in the setting most appropriate to their specific care needs.

Stakeholder Question 4 alludes to a finding that "problems are created when the observation unit has too many patients who have orders to admit but are waiting for an inpatient bed." CHA agrees that it is undesirable to delay the transition to an inpatient bed, and hospitals and clinicians should strive to proceed with admission on as timely a basis as possible. Their ability to do so, however, is often limited by capacity issues such as those seen during recent surges related to respiratory illnesses. Hospitals cannot be expected to move patients when beds are full and secondary to other factors.

Recommendations

In summary, the determination of observation vs. inpatient status and the provision of observation services is a necessary and routine clinical function of all EDs in general acute care hospitals, regardless of whether the hospitals have chosen to establish a designated observation unit.

As CDPH proceeds with its work on this issue, CHA strongly recommends that CDPH:

- Focus additional guidance on licensing standards for observation units, clearly distinguished and separate from the provision of observation services
- To the extent appropriate, identify characteristics of designated observation units
- Communicate that services provided by licensed general acute care hospitals and the EDs they operate are inclusive of observation services

Thank you for this opportunity to provide input on this important initiative. Should you have additional questions or if we can be of further assistance, please feel free to contact Trina Gonzalez at tgonzalez@calhospital.org or Pat Blaisdell at pblaisdell@calhospital.org.

Sincerely,

Trina A. Gonzalez
Vice President, Policy