

SUPPLEMENTAL STATEMENT OF REASONS

The California Department of Public Health (the “Department”) has instituted additional changes to these proposed regulations which are discussed below. These changes are either initiated by the Department or in response to comments that were received during the 45-day public comment period which ended on July 29, 2013.

Section 70438.2:

Subparagraph (a)(1)

A proposed non-substantive amendment to subparagraph (a)(1), in which the word “below” is deleted at the end of the sentence. This is amended as the word “below” is unnecessary.

Subparagraph (b)(1)(A)

Due to public comments, the Department proposes amendments to subparagraph (b)(1)(A) to provide a maximum transport time for patients being moved from the expanded cardiac catheterization laboratory space to the definitive care option within the general acute care hospital (GACH). Under the amended regulation text, the proposed transport of the patient to the definitive care option shall not exceed five minutes. This change is in response to a comment suggesting that based on the experience of clinicians, emergency transport times generally range from three to five minutes. Under the original proposed regulation text, a patient was required to be transported to a definitive care option in 10 minutes or less, from the time a physician deems that the patient is in need of transport. The proposed regulation text change is consistent with the Department’s original intent, but provides additional clarity, in that the proposed 10 minute threshold is intended to include pre-transport patient preparation, which can take several minutes. The Department, however, believes that it is important to require a specific transport time of no more than five minutes, as this is consistent with the industry norms of which both the commenter and the Department are aware. Adding this standard clarifies the intent of this subparagraph and the Department believes it to be in the best interest of patient safety.

Subparagraph (b)(2)(A)

Due to public comments, the Department proposes amendments to subparagraph (b)(2)(A) to provide additional clarity as to the purpose of the subparagraph’s requirement that inpatient care policies and procedures for the expanded cardiac catheterization laboratory space include consideration of the acuity of the patient and

the type of procedure needed by the patient. As part of the revised proposed regulation text, the Department adds the language "...for the purpose of determining whether the placement of an inpatient in the expanded cardiac catheterization laboratory space is medically appropriate." The Department believes this change addresses a comment that expresses the opinion that any transfer of an inpatient to the expanded cardiac catheterization laboratory space is done so only when safe and only in the best interest of that patient. The addition of this "medically appropriate" provision provides clarity that the policies and procedures are to factor in the best interest of the patient. The commenter suggested the Department add the word "safe" instead of "medically appropriate," however the Department was concerned that the word "safe" was too imprecise and lacked the clarity needed. By including "medically appropriate" the Department is acknowledging the need to address the purpose of the policies and procedures, while deferring to the medical staff to determine what is medically appropriate care for the patient.

Paragraph (b)(3)

Due to public comments, the Department proposes amendments to paragraph (b)(3) to clarify the proposed regulations as they relate to use of the GACH's cardiac catheterization laboratory space for inpatients. A commenter suggested that the Department add the phrase "with inpatients" to the end of paragraph (b)(3). The commenter suggested this language because they believed it was important to make it "crystal clear that inpatients should only be placed in the expanded cath lab setting when the schedule of the lab within the hospital has reached its capacity with inpatients." The commenter further noted that the proposed regulation text "does not expressly prohibit a hospital from transferring an inpatient to the expanded cath lab setting after filling its inpatient cath lab schedule with a combination of inpatients and out patients" and that adding "with inpatients" to the regulation text would make clear that "hospitals may only transfer an inpatient to the expanded cath lab setting when the cath lab within the hospital has reached its capacity with inpatients only."

However, the Department does not believe this approach is in the best interest of the inpatients. Should the Department adopt the commenter's suggestion, in the event an inpatient needs an immediate, unscheduled cardiac catheterization procedure and all of the GACH cardiac catheterization laboratory space is actively being used, and the space includes at least one outpatient, the inpatient would not be able to undergo a procedure in the expanded cardiac catheterization laboratory space. Such a result would run counter to the inpatient's best interest, as the inpatient would not be able to receive treatment in the GACH and would be prohibited by regulation from having the

procedure performed in the expanded cardiac catheterization laboratory space, even if that space was not at capacity.

Instead, the Department has amended paragraph (b)(3) to further clarify the proposed regulatory intent of providing priority for inpatients in the GACH's cardiac catheterization laboratory space. Under the original proposed text, the prohibition on inpatients being served in the expanded cardiac catheterization laboratory space was based on the GACH's cardiac catheterization laboratory space schedule reaching capacity. In the revised proposed regulation text, the emphasis on scheduling has been removed, and instead placed on whether the space is actively being used. In doing so, the Department keeps in place the priority inpatients have for the GACH cardiac catheterization laboratory space and prohibition on those inpatients having access to the expanded cardiac catheterization laboratory space, but amends the condition on which the expanded catheterization laboratory space can be used by inpatients. By limiting inpatient use of the expanded cardiac catheterization laboratory space to only those instances when all of the GACH's cardiac catheterization laboratory space is in use, the Department believes it provides additional protection to inpatients, who, as the Department noted in the Initial Statement of Reasons, typically are the most at-risk.

Subdivision (c)

Due to public comments, the Department proposes amendments to subdivision (c) to provide clarity on the reporting requirements for the statutorily-required 25 percent inpatient limit. The Department proposes adding "per calendar year" to the end of the first sentence in subdivision (c). As a commenter noted, there was no temporal reference included in either the statute or the original regulation text and further clarification is needed. The commenter suggested adding "per shift," though the Department believes such a requirement would prove cumbersome to monitor and enforce. Furthermore, it is the Department's understanding that the 25 percent requirement contemplated in the statute is based on the Legislature's desire to mirror the existing 25 percent requirement of Health & Safety Code section 129725(b)(1). This statute deals with seismic safety and is not directly related to patient care. Under the provisions of section 129725(b)(1), inpatient percentage data are to be reported annually. In keeping with this precedent, and in the interest of reporting and enforcement efficiency, the Department believes a temporal component of reporting such information per calendar year makes the most sense.