

FINAL STATEMENT OF REASONS

The information contained in the Initial Statement of Reasons (ISOR) at the time of the Public Notice and the Supplemental Statement of Reasons (SSOR) at the time of the Notice of Notice Availability remains unchanged.

Addendum I **45-Day Public Notice** **Summary of Comments and Responses to Comments**

The Department received only one comment letter during the 45-Day public notice period beginning on June 14, 2013 and ending on July 29, 2013. The six comments below are summarized from a letter sent by the California Nurses Association/National Nurses United, signed by Kelly Green.

Comment: Given the acuity of the cath lab inpatients, it is vital that the state ensures that any transfer of an inpatient to the outpatient cath lab setting is done so only when safe and only in the best interest of that patient. The decision to serve an inpatient in the outpatient setting should be made only after full consideration of the condition of the patient; the type of the procedure needed by the patient; and, only when the inpatient cath lab has reached capacity *with inpatients*.

Department Response: In response to the commenter's suggestion, the Department has modified the proposed regulation text. The revised language is added to reflect the need for inpatient care policies and procedures to focus on the best interest of the patient. The Department chose not to use the exact wording that the commenter suggested as it felt the term "safe" was ambiguous in this context. Instead, the Department chose to amend the proposed regulation text by including the phrase "medically appropriate," which the Department believes captures the spirit of the commenter's suggestion that the policies and procedures should explicitly consider the best interest of the patient. As noted in the Supplemental Statement of Reasons (SSOR), adding the "medically appropriate" provision addresses this concern and defers to the medical staff in determining the appropriate care for the patient.

Comment: We believe it is 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 language 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. Our proposed amendment aims to remove all ambiguity as to whether or not a hospital may fill

its cath lab schedule with a combination of inpatients and outpatients before transferring an inpatient to the expanded cath lab space. This would make it 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.

Department Response: In response to the commenter's suggestion, the Department has modified the proposed regulation text. The Department carefully considered the commenter's suggested language which adds the phrase "with inpatients" to the end of section 70483.2(b)(3) and generally agrees with the commenter's concern, conceptually. However, as noted in the SSOR, the Department is concerned that this specific language could have unintended consequences in which an inpatient in an emergent situation couple potentially be excluded from needed care. Instead, the Department has amended this section to clarify the priority for inpatients in the hospital's cardiac catheterization laboratory space. In the revised proposed regulation text, the emphasis on scheduling has been removed, and instead placed on whether the space is actively being used. The Department believes doing so establishes priority for inpatients in a workable manner.

Comment: Additionally, we seek clarity with regard to the proposed Section 70438.2(c). This proposed section aims to implement provisions of AB 491 which requires that no more than 25 percent of the GACH's inpatients in need cardiac catheterization laboratory services may have such procedures performed in the expanded cath lab space. However, there is no temporal reference in AB 491 or the proposed regulations upon which a hospital should rely. For example, a hospital could interpret the law to mean that, over the course of a year, it cannot transfer more than 25 percent of its inpatients to the expanded cath lab space. This would allow the hospital to transfer more than 25 percent of its inpatients to the expanded cath lab space during any given period of time, as long as it does not exceed more than 25 percent of its total inpatient population for the year. We believe that it is the intent of AB 491 to apply this provision to the shortest duration of time possible to ensure that no more than 25 percent of inpatients are treated in the expanded cath lab setting at any given time.

Department Response: In response to the commenter's suggestion, the Department has modified the proposed regulation text. The revised language, which includes the phrase "per calendar year", is added to reflect the need for a temporal component to the inpatient ratio provision. The Department considered carefully the commenter's suggestion of basing the inpatient ratio on a per shift basis. However, as noted in the SSOR, the Department believes that in the interest of reporting and enforcement efficiency, a per calendar year standard is the most reasonable approach.

Comment: The Department was unable to identify recommendations regarding safe transport times in relevant scientific literature. In light of that, the Department proposed its emergency transport regulations on simulation information provided by Cedars-Sinai.

Regulations pertaining to emergency transport of patients should be based on what is in the best interest of the patient, not on what the hospital reports is possible for it to do based on its own simulations. We do not believe this is the way to craft strong public policy that will protect patients. The proposed emergency transport regulations should be rooted in clinical analysis and based on science-based evidence of the best patient outcomes. It is not clear that CDPH conducted any analysis, and based on what is included in the ISOR, it appears that CDPH simply relied upon information provided by Cedars-Sinai. Cedars-Sinai's simulation does not provide any analysis as to whether or not the 8.5 minute transport time is optimal or safe for patients. Rather, it simply outlines what the shortest possible transport time could be based on the distance between the extended cath lab and the OR, taking into consideration various routes, team response to simulated distance, and travel time to simulated distance including bridge transit and elevator. Nowhere does this simulation outline the potential impact of the simulated transport time on patients with emergent needs. During the drafting of these comments, we discussed emergency transport times with cath lab RNs. Based on their experiences, emergency transport times from the hospital cath lab to the OR were generally between 3 to 5 minutes. However, it appears that the current general transport time standard stands at half that being proposed by CDPH. CDPH should demonstrate that it exercised its due diligence in determining that the transport times proposed in the regulations are safe for patients, and will not result in an increased risk of life-threatening complications or patient mortality.

Department Response: In response to the commenter's suggestion, the Department has modified the proposed regulation text to clarify the Department's belief that the actual transport time from the expanded cardiac catheterization laboratory space to the definitive care option should not exceed five minutes. As provided in the original regulation text, a patient in the expanded cardiac catheterization laboratory space was required to arrive in a definitive care option within 10 minutes of a physician deeming the patient in need of such care. This 10 minute period was intended to include two discrete functions, the pre-transport patient preparation (such as intubating the patient, additional interventions to stabilize the patient, preparing for transport and moving the patient to a gurney), as well as the actual transporting of the patient from the expanded cardiac catheterization space to the definitive care option. As provided in the SSOR, the Department has added language to the regulation text explicitly limiting the actual transport time of the patient to five minutes or less. As the commenter indicates, anecdotal evidence from clinicians suggests that transport times in this type of environment generally range from three to five minutes. This is consistent with the Department's own discussions with clinicians, and forms the basis of the change. Adding this five minute standard, the Department believes, clarifies the intent of the regulation, is consistent with industry practice, and ultimately serves the best interest of the patient. As the Department noted in the ISOR, the Department's review of relevant scientific literature found no recommended transportation time from a cardiac

catheterization laboratory in an attached setting to a cardiovascular surgical space, or other such definitive care option. Thus, like the commenter, who did not provide any scientific data in opposition to the proposed timeframes, the Department has had to rely upon anecdotal evidence of clinicians.

Comment: [I]t is unclear upon what rationale that CDPH proposes to increase the 8.5 minutes demonstrated by Cedars-Sinai's simulation to 10 minutes. In the ISOR, CDPH asserts that, "...given the nature of such medical emergencies, transporting a patient to the suggested treatment as quickly as possible should reduce negative health outcomes, including, but not limited to, death of patient." Given this assertion, for what purpose does CDPH believe that an additional 1.5 minutes should be allowed in order to get a patient from the expanded cath lab to the surgery suite, or other definitive care option, in an emergency? This is not explained in the ISOR, nor in any of the "Documents Relied Upon", published along with the proposed regulations.

Department Response: No change is made to accommodate the recommendation for the reason that the Department did not rely exclusively on the time studies provided by Cedars-Sinai. As noted in the response to the previous comment, the Department also conferred with clinicians to understand cardiac catheterization laboratory practices and clinical norms, which was not expressly indicated in the ISOR. The 10 minute total timeframe and five minute transport time that the Department determined would be reasonable is based in part on input from licensed clinicians within the Department. Therefore, the Department believes transport times not to exceed five minutes and no more than 10 minutes from the physician determining that the patient is in need of definite care is appropriate.

Comment: We recommend CDPH limit the type of cardiac cath lab procedures offered to inpatients in the expanded cath lab setting to only those allowed under 22 CCR §70438.1(b). The set of procedures listed under §70438.1(b) are allowed for hospitals which do not provide cardiac surgery. Although the two hospitals affected by these proposed regulations do offer cardiac surgery, we believe it would be prudent to limit the range of expanded cath lab procedures performed on inpatients until regulations pertaining to safe and appropriate emergency transport times are vetted.

Department Response: No change is made to accommodate the recommendation for the reason that the provisions of the referenced California Code of Regulations are expressly directed at hospitals that do not have cardiac surgery available. In this case, however, the two hospitals affected have cardiac surgery space in their main buildings, which will be accessible through the all-weather enclosed passageway. The Department believes that this proximity is sufficient for patient safety and should not limit the types of procedures performed in the expanded cardiac catheterization laboratory space, except for those already expressly provided for in law.

Addendum II – List of 15-day Commenters

The following people commented on the changes to the proposed regulations during the 15-day public comment period beginning on September 27, 2013 and ending on October 11, 2013.

Commenter No.	Comment letter representing:	Signature or submitted by:
1	Scripps Health	Michael D. Bardin
2	California Nurses Association/NNU	Kelly Green

Addendum III 15-Day Notice of Public Availability Summary of Comments and Responses to Comments

Comment: The addition of the 5 minute transport language arbitrarily bifurcates a dynamic process of patient stabilization, preparation and transport into discreet episodes, thereby placing emphasis on meeting timeframes rather than the unique needs of an individual patient who may need definitive care for diverse reasons.

Commenter: 1

Department Response: No change is made to accommodate the recommendation for the reason that the transport language was included to clarify the Department's belief that the actual transport time of the patient should not exceed five minutes, which is consistent with industry norms. Though the Department appreciates that the process of patient stabilization, preparation and transport can be dynamic, it believes that patients benefit from specific standards for transit from the expanded cardiac catheterization laboratory space to the definitive care option.

Comment: We support the other amendment changes proposed.

Commenter: 1

Department Response: The Department appreciates the indication of support for the amended proposal.

Comment: Despite the effort to reduce the actual transport time to 5 minutes, the language would still provide hospitals with a 10-minute timeframe by which to get a patient from the expanded cath lab space to the definitive care option. Thus, our concerns over patient safety and inadequate access to life-saving emergency care remain. We also think that the amendments make subparagraph (b)(1)(A) less clear, and maintain our concerns

over the process by which CDPH devised the 10-minute timeframe. Under the modified text, CDPH would allow hospitals to take up to 5 minutes simply to prepare the patient for transport. But, upon what standards or practices is the 5 minutes based? Did CDPH consider any policies or practices, such as those in the preceding paragraph, that the two hospitals governed by these regulations should be required to implement so that less time is needed to prepare a patient for transport? Further, the amendments to subparagraph (b)(1)(A) make the subparagraph less clear as the language does not distinguish between preparation time and transport time. Finally, it remains unclear upon what the 10-minute timeframe is based. We recognize that the Cedars-Sinai simulation served as the basis for the timeframe, but the proposed 10 minutes appears to be arbitrary as it is not clear that CDPH has done its own analysis on what is an appropriate timeframe.

Commenter: 2

Department Response: No change is made to accommodate the recommendation for the reason that the revised regulation text does, in fact, specify that the actual transport time for the patient has been limited to five minutes or less. The revised regulation text provides that a patient must arrive at a definitive care option within 10 minutes of the physician deeming the patient in need of transport, but limits the actual transport time to no more than five minutes. As the commenter notes, this is consistent with the time studies provided by Cedars-Sinai, but is also based on internal discussions with clinicians as to an acceptable amount of time for pre-transport preparation, as well as the actual transport of the patient. The Department has not provided specific policies and procedure requirements that hospitals must implement related to pre-transport preparation, as the proposed regulations expressly require that the hospital develop, implement and maintain policies and procedures for the expanded cardiac catheterization laboratory space. The Department believes each specific hospital is in the best position to develop, implement and maintain policies and procedures, based on the experience and expertise of both the hospital nurses and the medical staff, for the care of their patients.

Comment: We must oppose the amendments to subdivision (c) which add “per calendar year” to the end of the first sentence. This would allow hospital to transfer more than 25 percent of its inpatients to the expanded cath lab space during any given period of time, as long as it does not exceed more than 25 percent of its total inpatient population for the year. Further, AB 491 does not set forth any requirements for reporting to CDPH, so we do not see how this argument is relevant. We would argue that without specific language in the statute specifying that the 25 percent limit is applied on per calendar year basis, the statute is more logically interpreted to mean that the 25 percent limit is applicable at any given time. Otherwise, based on a straight reading of the statute, how would one know that it would allow a hospital to exceed the 25 percent limit on certain days, weeks, or months, so long as the limit was not exceeded on a calendar year basis? Is there some information in the legislative history of the Health and Safety Code Section 129725(b)(1)

that would confirm this interpretation? Is there some regulatory precedent? If so, that information should be provided to the public.

Commenter: 2

Department Response: No change is made to accommodate the recommendation for the reason the Department believes limiting the expanded cardiac catheterization laboratory space inpatients to no more than 25 percent per calendar year provides the needed temporal component lacking in the original regulation text, without being cumbersome to monitor or enforce. Furthermore, as indicated in the SSOR, it is the Department's understanding that this statutory requirement is based on the Legislature's desire to mirror the existing 25 percent requirement of Health & Safety Code section 129725(b)(1), which deals with seismic safety. Under the provisions of section 129725(b)(1), inpatient percentage data are to be reported annually.

STATEMENTS OF DETERMINATIONS

ALTERNATIVES CONSIDERED

The California Department of Public Health (the Department) has determined that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

LOCAL MANDATE DETERMINATION

The Department has determined that the proposed regulation amendments will not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with section 17500) of Division 4 of the Government Code.

IMPACT ON BUSINESS

The Department has determined that the proposed regulations would not have any significant statewide adverse economic impact directly affecting business, including the ability of California business to compete with businesses in other states.