

**Office of Statewide Health Planning and Development California Coronary
Artery Bypass Graft Outcomes Reporting Program**

INITIAL STATEMENT OF REASONS

Title 22, California Code of Regulations
Section 97174

BACKGROUND INFORMATION

Health and Safety Code Section 128745 requires the Office of Statewide Health Planning and Development (OSHPD) to prepare and publish annually risk-adjusted outcome reports for Coronary Artery Bypass Graft (CABG) surgeries performed in California hospitals. The California CABG Outcomes Reporting Program (CCORP) collects data from each hospital in which CABG surgeries are performed, on each CABG patient.

Hospitals are required by law to file certain patient-level information with OSHPD every six (6) months. The data collected include demographic and clinical data from the patient records. OSHPD analyzes the data and prepares the risk-adjusted outcome reports that compare outcomes by hospital and, in every other year, by cardiac surgeon.

Hospitals submit their patient-level information for CABG surgeries using the Cardiac Online Reporting for California (CORC) system, an online data reporting tool. Regulations were adopted in 2009 that specify the method of electronic data submission for this system – Title 22, CCR 97177.15.

Health and Safety Code Sections 128745 and 128748 provide for the appointment of a nine (9) member Clinical Advisory Panel (CAP) to advise OSHPD on aspects of the CABG program. OSHPD must seek the recommendations of CAP before making changes to the data elements collected for CCORP. CAP may make recommendations to OSHPD about the addition, deletion, or revision to any of the data elements.

At a February 3, 2015 meeting, CAP approved an additional outcome measure for public reporting of risk-adjusted mortality rates for CABG plus valve procedures. At a September 18, 2015 meeting, CAP recommended OSHPD revise the data element “ISOLATED CABG” to “TYPE of CABG” and modify the definition in the CCORP database. A letter from the Chair of CAP is included in the rulemaking file.

THE PROBLEM TO BE ADDRESSED

Hospitals that perform CABG surgeries are required by statute to report their CABG surgery data elements to OSHPD.

Currently, the data element “ISOLATED CABG” only differentiates between CABGs done without another major procedure and those done with another major procedure. It does not allow hospitals to identify CABG plus valve surgeries. This term refers to CABG surgeries that also include a replacement of an aortic valve and/or a repair or replacement of a mitral valve. As a result, for cases that meet certain exclusion criteria, hospitals must manually review and abstract patient level medical records after data submission. Abstracted information must then be sent to CCORP for clinical review to ensure the accuracy and integrity of the data. Not only is this manual process inefficient it may adversely impact data quality and timelines for producing public reports. The STD 399 and attached Cost Estimate indicates that a minor savings of \$157 per hospital could be realized. In addition, OSHPD can absorb the necessary programming changes to CORC.

Changing “ISOLATED CABG” to “TYPE of CABG” would allow hospitals to identify the CABG plus valve cases when initially abstracting their data. This change will lessen the burden and costs to both hospitals and CCORP.

PURPOSE AND BENEFITS OF THIS REGULATORY ACTION

OSHPD is proposing to amend the regulations to improve efficiency and data quality, and to reduce costs to reporting hospitals by automating what is currently a manual abstraction process. The amended regulation would allow for clear differentiation between the types of CABG surgeries being performed by reporting hospitals.

Purpose: Revising this data element would allow hospitals to prospectively identify their CABG plus valve cases and categorize them in their data submission. It would eliminate manual abstraction after data submission, reduce clinical review, ensure the integrity and quality of the data being collected and publicly reported, and decrease the cost to hospitals and CCORP.

Benefit: The benefit of revising this data element and its definition is to improve data quality and efficiencies to hospitals and OSHPD. In addition, it would result in a minor cost savings to hospitals by lessening the burden of manual abstraction and to CCORP by eliminating clinical review after data submission. Hospitals would be able to code these cases during the initial data abstraction/submission period rather than after the data abstraction/submission period. The revision would also result in improved data quality, risk analysis, and outcomes reporting.

Necessity: CCORP’s on-line CABG surgery data collection for the first half of 2016 opens September 2016. It is necessary to amend Section 97174 prior to data collection to improve efficiencies, eliminate retrospective manual abstraction and clinical review of data, and to lessen the likelihood of data errors. The existing manual processes impact

the workload of hospital and OSHPD staff and may negatively impact the quality of data being reported.

The order of the data elements and definitions listed in Section 97174 is the order by which hospitals and CORC program their systems for CABG surgery data submission and collection. The text, listed in its entirety, in Subsection (a) is in underline format and therefore appears that all of the text is being amended. Note that only Subsection (a)(2) is being amended.

The data elements and definitions in the amended regulations would apply for any CABG surgery patients discharged on or after January 1, 2016.

The data elements and definitions in the current regulations would apply for any CABG surgery patients discharged before January 1, 2016.

ECONOMIC IMPACT ASSESSMENT (Government Code 11346.3(b))

Purpose:

OSHPD proposes to amend California Code of Regulations (CCR) section 97174 by changing one data element "ISOLATED CABG" to "TYPE of CABG". This change would allow hospitals to prospectively identify their CABG + valve surgery cases and categorize them in their data submission. It would eliminate manual abstraction after data submission, reduce clinical review, ensure the integrity and quality of the data being collected and publicly reported, and decrease the cost to hospitals and CCORP.

The Creation or Elimination of Jobs Within the State of California

The regulation is designed to ensure the quality and integrity of the data OSHPD collects from hospitals that perform CABG surgery to publicly report risk-adjusted outcomes reports on an annual basis. The regulation would automate what is currently a manual abstraction process for both the hospital and OSHPD. The regulation will only affect hospital and OSHPD staff. Therefore, OSHPD has determined that this regulatory proposal will not have an impact on the creation or elimination of jobs in the State of California.

The Creation of New Businesses or the Elimination of Existing Businesses Within the State of California

The regulation is designed to ensure the quality and integrity of the data OSHPD collects from hospitals that perform CABG surgery to publicly report risk-adjusted outcomes reports on an annual basis. The regulation would automate what is currently a manual abstraction process for both the hospital and OSHPD. The regulation will only affect hospitals and OSHPD is not relevant to the creation or elimination of businesses in California. Therefore, OSHPD has determined that this regulatory proposal will not have a significant impact on the creation of new businesses or the elimination of existing

businesses in the State of California.

The Expansion of Businesses Currently Doing Business Within the State of California

The regulation is designed to ensure the quality and integrity of the data OSHPD collects from hospitals that perform CABG surgery to publicly report risk-adjusted outcomes reports on an annual basis. The regulation would automate what is currently a manual abstraction process for both the hospital and OSHPD. The regulation will only affect hospitals and OSHPD is not relevant to the expansion of businesses in California.

Therefore, OSHPD has determined that this regulatory proposal will not have a significant impact on the expansion of businesses in the State of California.

Benefits of the Regulations to the Health and Welfare of California Residents, Worker Safety, and the State's Environment

The benefit of changing this data element is to more accurately report on risk-adjusted CABG surgeries and could indirectly benefit the health and welfare of California residents who may use such data to understand California's healthcare environment. These regulations do not benefit worker safety and the State's environment.

TECHNICAL, THEORETICAL, AND EMPIRICAL STUDY, REPORTS OR SIMILAR DOCUMENTS RELIED UPON

OSHPD did not rely upon any technical, theoretical, and empirical studies, reports, or similar documents in proposing the amendment to this regulation.

REASONABLE ALTERNATIVES

OSHPD has not identified any alternatives to the proposed regulation that would be less burdensome and equally effective in achieving the purposes of the regulation, and no alternatives have otherwise been identified and brought to the attention of OSHPD.

OSHPD has not identified any reasonable alternatives to the proposed regulatory action, including alternatives that would lessen any adverse impact on small business. The regulation as proposed would have no impact on small business.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON BUSINESS

OSHPD has made an initial determination that permanent adoption of this regulation would result in minor cost savings to hospitals that report their CABG surgery using the CORC system, and would ensure that CCORP data elements will continue to provide the highest quality data possible.

CCORP conducted a survey of hospital data managers to determine the estimated cost savings. These managers abstract patient medical records and submit the

required data to CCORP.