

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

NOTICE OF PROPOSED RULEMAKING

CALIFORNIA CODE OF REGULATIONS

TITLE 22, DIVISION 7, CHAPTER 10, ARTICLE 7: CABG DATA REPORTING
REQUIREMENTS

The Office of Statewide Health Planning and Development (OSHPD) proposes to amend Section 97174 of Title 22 of the California Code of Regulations (CCR).

OSHPD proposes to revise one data element reported in the California CABG Outcomes Reporting Program (CCORP) to more precisely differentiate between the types of Coronary Artery Bypass Graft (CABG) surgery being performed.

I. PUBLIC HEARING

OSHPD has not scheduled a public hearing. Any interested person, or his or her duly authorized representative, may submit a written request for a public hearing, pursuant to Section 11346.8(a) of the Government Code. The written request for a hearing must be received by OSHPD's contact person, designated below, no later than 15 days prior to the close of the written comment period.

II. WRITTEN COMMENT PERIOD AND CONTACT PERSON

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action. All comments must be received by OSHPD no later than 5:00 p.m., PDT on August 15, 2016.

Inquiries and comments concerning the proposed regulations should be addressed to the primary contact person named below. Comments delivered by e-mail are preferred. Comments may also be faxed, hand delivered, or mailed to:

Lisa A. Christensen (Cook)
Contract Manager, Clinical Data Programs
Healthcare Outcomes Center
Office of Statewide Health Planning and Development
400 R Street, Room 250
Sacramento, CA 95811-6213
Tel: (916) 326-3867, Fax: (916) 322-9718
E-mail: lisa.cook@oshpd.ca.gov

Inquiries and comments may also be addressed to the backup contact person:

Holly Hoegh, Ph.D.
Manager, Clinical Data Programs
Healthcare Outcomes Center
Office of Statewide Health Planning and Development
400 R Street, Room 250
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Each comment may include the author's name, U.S. Postal Service address, and e-mail address, if applicable, so that the addressee may be included in future communications if the text of the currently proposed regulations changes.

III. AUTHORITY AND REFERENCE

Authority: California Health and Safety Code, Section 128810.

Reference: California Health and Safety Code, Section 128745.

IV. INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

1. Summary of Existing Laws and Regulations

Health and Safety Code Section 128745 requires that on an annual basis OSHPD prepare and publish risk-adjusted outcome reports for CABG surgeries performed in California hospitals. To produce these reports, OSHPD is mandated to collect certain data from these hospitals.

Section 97172 of Title 22, CCR mandates that every six (6) months, hospitals performing CABG surgeries file a report with OSHPD that contains certain patient level information. Known as CCORP, this program collects data from each hospital for each CABG patient.

Currently, CABG surgeries are performed in 127 hospitals. The reported data includes demographic and clinical data elements from the patient medical record. OSHPD analyzes the data, along with data collected from other sources, and prepares the risk-adjusted outcome reports that compare outcomes by hospital and, in every other year, by hospital and cardiac surgeon.

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 recommend that OSHPD add, delete, or revise data elements. At a meeting on February 3, 2015, CAP approved an additional outcome measure for public reporting of risk-adjusted mortality rates for CABG plus valve procedures. At a meeting on September 18, 2015, CAP recommended OSHPD revise one data element and modify the definition in the CCORP database.

CCORP data elements are defined in Section 97174 of Title 22, CCR. The revision will be implemented for any patients discharged on or after January 1, 2016.

2. Policy Statement Overview/Specific Benefits of Proposed Regulation

The data element “ISOLATED CABG” currently only differentiates between CABG surgeries done without another major procedure and those done with another major procedure. For CABG surgery cases that meet certain exclusion criteria, hospitals must manually abstract patient level medical records after data submission. Hospitals must then send that information to CCORP for clinical review to ensure the accuracy and integrity of the data. This manual process is inefficient, and may adversely impact data quality and timelines for producing public reports.

OSHPD is proposing to amend the regulation by changing “ISOLATED CABG” to “TYPE of CABG” and modifying the definition. Amending this regulation will lessen the burden to reporting hospitals by eliminating retrospective manual abstraction of CABG plus valve cases and lessen the burden to CCORP by eliminating clinical review of these cases, resulting in administrative efficiencies and minor cost savings to hospitals and CCORP.

This would also result in higher quality data and improve risk-adjusted outcomes for all types of CABG surgery.

3. Evaluation of Inconsistency/Incompatibility with Existing State Regulations

As required by Government Code Section 11346.5, subsection (a)(3)(D), OSHPD evaluated the language contained in the proposed amendment. OSHPD has determined that these proposed regulations are not inconsistent with or incompatible with existing state regulations. These regulations make a minor modification to an existing program.

V. DISCLOSURES REGARDING THE PROPOSED ACTION

OSHPD has made the following initial determinations:

1. Mandate on local agencies and school districts: None
2. Cost or savings to any state agency: The estimated cost to OSHPD for programming the online reporting system for the revised data element is absorbable. Administrative efficiencies and long term savings are expected because OSHPD will no longer have to manually review supporting clinical documentation from hospitals.

3. Costs to any local agency or school district that are required to be reimbursed by the state in accordance with Government Code Sections 17500 through 17630: None.
4. Other non-discretionary cost or savings imposed on local agencies: None
5. Cost or savings in federal funding to the state: None
6. Cost impact on representative persons or businesses: None. OSHPD estimates that the proposed regulatory change will result in an average savings to each hospital of \$157 annually.
7. Significant effect on housing costs: None
8. Significant statewide adverse economic impact directly affecting business: OSHPD has made an initial determination that the action would not have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.
9. Effect on Small Business: OSHPD has determined that the proposed amendment does not affect small business. The health care facilities affected by the action either have more than 150 beds or more than \$1,500,000 in annual gross receipts. In accordance with Government Code Section 11342.610, these health care facilities are not defined as small businesses.

VI. STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ASSESSMENT (EIA)

Modifying one data element and its definition is anticipated to be beneficial to the reporting hospitals by reducing retrospective manual abstraction, data processing, and clinical review, thereby reducing manual workload and administrative costs. It would also result in improved data quality, risk analysis, and outcomes reporting.

Therefore, OSHPD has concluded that this regulatory action would not affect the following:

- (1) The creation of jobs within the state.
- (2) The elimination of jobs within the State of California.
- (3) The creation of new businesses within California.
- (4) The elimination of existing businesses within California.
- (5) The expansion of businesses currently doing business in the state.
- (6) The benefit to the public is that more accurate and useful data would be available. Such data are used for understanding California's healthcare environment, which may benefit the health and welfare of California residents.

VII. REASONABLE ALTERNATIVES STATEMENT

In accordance with Government Code Section 11346.5, subsection (a)(13), OSHPD must determine that no reasonable alternative it considered or that has otherwise been identified and brought to the attention of the agency would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

VIII. AVAILABILITY OF EXPRESS TERMS, INITIAL STATEMENT OF REASONS, AND INFORMATION UPON WHICH PROPOSED RULEMAKING IS BASED

OSHPD will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its office at the address given for the contact persons. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the text of the proposed regulation, the initial statement of reasons, and an economic impact assessment contained in the initial statement of reasons.

In developing these regulations, OSHPD conducted a survey of affected hospitals. These hospitals were asked to estimate the fiscal impact to their hospitals. Copies of the survey and survey results will be made available upon request.

IX. AVAILABILITY OF SUBSTANTIAL CHANGES TO ORIGINAL PROPOSAL

After considering all timely and relevant comments received, OSHPD may adopt the proposed regulations substantially as described in this notice. If OSHPD makes modifications which are sufficiently related to the originally proposed text, it will make the modified text (with changes clearly indicated) available to the public for at least 15 days prior to the date OSHPD adopts the regulations as revised.

Please send requests for copies of the modified text to the listed contact person. The modified text will also be available on OSHPD's website at:

<http://www.oshpd.ca.gov/LawsRegs/NewRegulations.html>

OSHPD will accept written comments on the modified regulations for 15 days after the date on which they are made available.

X. AVAILABILITY OF FINAL STATEMENT OF REASONS AND RULEMAKING FILE

The Final Statement of Reasons including a summary of all comments and responses will be available, after its completion, through OSHPD's website at:

<http://www.oshpd.ca.gov/LawsRegs/NewRegulations.html>.

The Final Statement of Reasons will also be available for review from the designated contact person.

XI. AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of materials published or distributed through OSHDP's website can be accessed at <http://www.oshpd.ca.gov>. Materials related to this rulemaking can be accessed at:

<http://www.oshpd.ca.gov/LawsRegs/NewRegulations.html>.