State of California Office of Administrative Law

In re: Department of Health Care Access and Information

Regulatory Action:

Title 22, California Code of Regulations

Adopt sections: 97140, 97145, 97150, 97155, 97160

NOTICE OF APPROVAL OF REGULATORY ACTION

Government Code Section 11349.3

OAL Matter Number: 2022-1006-01

OAL Matter Type: Regular (S)

This action proposes to require hospitals that perform transcatheter aortic valve replacements (TAVR) to submit information to the STS/ACC TVT Registry in order to accurately track clinical data for this procedure.

OAL approves this regulatory action pursuant to section 11349.3 of the Government Code. This regulatory action becomes effective on 1/1/2023.

Date: November 18, 2022

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Ashita Mohandas Attorney

For: Kenneth J. Pogue Director

Original: Elizabeth Landsberg, Director Copy: Nancy Coronado

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22 CCR § 97140-97160 Article 6.5 TAVR Data Acquisition § 97140. Definitions, as Used in this Article.

Definitions:

(a) "Department" means the Department of Health Care Access and Information (HCAI).

(b) "TAVR" means transcatheter aortic valve replacement.

(c) "TAVR hospital" means a California licensed general acute care hospital that performs TAVR.

(d) "Program" means the Department's TAVR outcomes reporting program.

(e) "NCDR®" means National Cardiovascular Data Registry.

(f) "STS/ACC TVT Registry™" means the Society of Thoracic Surgeons/American. College of Cardiology Transcatheter Valve Therapy Registry.

(g) "DRCF" means the Data Release Consent Form and Addendum to the TVT Registry Participation Agreement Between the American College of Cardiology Foundation, the Society of Thoracic Surgeons, and Participant (November 2022) which is hereby incorporated by reference and available on the Department's website.

Note: Authority cited: Section 128810, Health and Safety Code. Reference: Sections 128745 and 128748, Health and Safety Code.

<u>§ 97145. TAVR data.</u>

(a) TAVR hospitals shall:

 (1) Participate in and provide timely submission of TAVR data elements from the STS/ACC TVT Registry[™] TAVR Version 3.0 Data Collection Form (November 22, 2021), hereby incorporated by reference, to the STS/ACC TVT Registry[™].
 (2) Confer rights to transfer the TAVR data submitted pursuant to paragraph (1) to the Department by completing and signing the DRCF and submitting it to the American College of Cardiology NCDR[®] at the email address on the DRCF and sending a copy of the executed form to the Program via email at

TAVR@hcai.ca.gov. The DRCF is available for download from HCAI's website and the Department will make a hardcopy available on request.

(b) For hospitals performing TAVR between January 1, 2022 and December 31, 2022 the DRCF shall be completed, signed and submitted by March 1, 2023.

(c) For hospitals that did not perform TAVR in calendar year 2022 but perform TAVR after December 31, 2022, the DRCF shall be completed, signed and submitted by March 1 of the year following the year TAVRs were performed.

(d) This section shall not apply to a hospital where all TAVRs performed are on patients under 18 years of age on the date of the procedure.

Note: Authority cited: Section 128810, Health and Safety Code. Reference: Sections 128745 and 128748, Health and Safety Code.

§ 97150. Compliance.

TAVR hospitals that do not meet the requirements specified in § 97145 (a), (b), and (c) shall be deemed and reported as non-compliant in the annual outcomes report.

Note: Authority cited: Section 128810, Health and Safety Code. Reference: Sections 128745 and 128748, Health and Safety Code.

§ 97155. Hospital Data Contact.

(a) Each TAVR hospital shall designate a primary data contact person. A hospital shall notify Program of the designation by email at TAVR@hcai.ca.gov within 30 days of the effective date of this regulation or within 30 days of beginning or resuming TAVR procedures. A notification shall include the designated person's name, title, telephone number(s), mailing address, and email address.

(b) A TAVR hospital shall notify Program by email at TAVR@hcai.ca.gov within 30 days after any change in the person designated as the primary TAVR data contact person, or in the title, telephone number(s), mailing address, or email address, of the individual.

Note: Authority cited: Section 128810, Health and Safety Code. Reference: Sections 128745 and 128748, Health and Safety Code.

§ 97160. Audit Procedure.

 (a) The Department may conduct periodic audits of a hospital's patient medical records for its TAVR patients. Audits may be performed remotely or at the hospital's location.
 (b) The Department shall notify a hospital a minimum of two weeks before the date of an audit. Upon notification that an audit is planned, a hospital shall designate a person to serve as the audit contact person. A hospital shall provide to the Department the contact person's name, title, telephone number, and email address.

(c) A hospital shall retrieve and make available the requested patient medical records for an audit, and if requested by the Department, provide a reasonable space in which the Department may conduct an audit.

(d) Data abstracted during an audit may, at the Department's discretion, replace data HCAI acquires from the STS/ACC TVT Registry[™]. Replacement data shall be used in calculating risk-adjusted mortality rates for outcomes reports.

Note: Authority cited: Section 128810, Health and Safety Code. Reference: Sections 128745 and 128748, Health and Safety Code.