

**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



**Ashita Mohandas
Attorney**

**For: Kenneth J. Pogue
Director**

**Original: Elizabeth Landsberg, Director
Copy: Nancy Coronado**

REGULAR

(See instructions on reverse)

For use by Secretary of State only

OAL FILE NUMBERS	NOTICE FILE NUMBER Z-2022-0719-03	REGULATORY ACTION NUMBER 2022-1006-01S	EMERGENCY NUMBER
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For use by Office of Administrative Law (OAL) only

ENDORSED - FILED
 In the Office of the Secretary of State
 of the State of California

NOV 18 2022

1:46pm

NOTICE	REGULATIONS
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OFFICE OF ADMIN. LAW
 2022 OCT 6 PM 1:52

AGENCY WITH RULEMAKING AUTHORITY
 Department of Health Care Access and Information

AGENCY FILE NUMBER (If any)

A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE		TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE	
3. NOTICE TYPE <input type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other		4. AGENCY CONTACT PERSON		TELEPHONE NUMBER	FAX NUMBER (Optional)
OAL USE ONLY <input type="checkbox"/> Approved as Submitted <input type="checkbox"/> Approved as Modified <input type="checkbox"/> Disapproved/Withdrawn		NOTICE REGISTER NUMBER 2022, 30-2		PUBLICATION DATE 7/29/2022	

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S) Transcatheter Aortic Valve Replacement Data Acquisition	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S)
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2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)	
SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)	ADOPT 97140, 97145, 97150, 97155, 97160
TITLE(S) 22	REPEAL

3. TYPE OF FILING			
<input checked="" type="checkbox"/> Regular Rulemaking (Gov. Code §11346)	<input type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.	<input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h))	<input type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
<input type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)	<input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)	<input type="checkbox"/> File & Print	<input type="checkbox"/> Print Only
<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))	<input type="checkbox"/> Other (Specify)		

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)
July 29, 2022 to September 26, 2022 *Am 11/17/22 per agency request*

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)			
<input checked="" type="checkbox"/> Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))	<input type="checkbox"/> Effective on filing with Secretary of State	<input type="checkbox"/> §100 Changes Without Regulatory Effect	<input type="checkbox"/> Effective other (Specify)

6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY		
<input checked="" type="checkbox"/> Department of Finance (Form STD. 399) (SAM §6660)	<input type="checkbox"/> Fair Political Practices Commission	<input type="checkbox"/> State Fire Marshal
<input type="checkbox"/> Other (Specify)		

7. CONTACT PERSON Nancy Coronado	TELEPHONE NUMBER 916-326-3879	FAX NUMBER (Optional)	E-MAIL ADDRESS (Optional) nancy.coronado@hcai.ca.gov
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8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE Elizabeth A Landsberg <small>Digitally signed by Elizabeth A Landsberg Date: 2022.10.05 20:34:23 -0700</small>	DATE 10/5/2022
TYPED NAME AND TITLE OF SIGNATORY Elizabeth Landsberg, Director	

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 Office of Administrative Law

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.

§ 97145. TAVR data.

(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.