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**Department of Health Care Access and Information
Transcatheter Aortic Valve Replacement Data Acquisition**

NOTICE OF PROPOSED RULEMAKING

CALIFORNIA CODE OF REGULATIONS

TITLE 22, DIVISION 7, CHAPTER 10, ARTICLE 6.5: TAVR Data Acquisition

NOTICE IS HEREBY GIVEN that the Department of Health Care Access and Information (HCAI) proposes to add Sections 97140-97160 of Title 22 of the California Code of Regulations (CCR).

HCAI also proposes to incorporate by reference the American College of Cardiology National Cardiovascular Data Registry (NCDR®) TVT Data Release Consent Form (DRCF) for the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry (STS/ACC TVT Registry™).

I. PUBLIC HEARING

HCAI 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 HCAI'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 HCAI no later than 5:00 p.m., PDT on September 26, 2022.

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:

Nancy Coronado
Research Data Specialist, Quality Indicators Group
Information Services Division – Healthcare Analytics Branch
Department of Health Care Access and Information

2020 W. El Camino, Suite 1100
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Tel: (916) 326-3879, Fax: (916) 445-7534
E-mail: Nancy.Coronado@HCAI.ca.gov

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

Holly Hoegh, Ph.D.
Manager, Quality & Performance Section
Information Services Division - Healthcare Analytics Branch
Department of Health Care Access and Information
2020 W. El Camino, Suite 1100
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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 128745.

Reference: California Health and Safety Code, Sections 128745 and 128748.

IV. INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

1. Summary of Existing Laws and Regulations

Health and Safety Code Section 128745 requires HCAI to publish at least one risk-adjusted outcome report for coronary artery bypass graft surgery, transcatheter aortic valve replacement (TAVR), or any type of interventional cardiovascular procedure for procedures performed in the state annually.

Health and Safety Code Sections 128745 and 128748 provide for the appointment of a Clinical Advisory Panel (CAP) to advise HCAI on aspects of cardiovascular outcomes reporting. Upon recommendation of the CAP, HCAI may add any clinical data elements included in the Society of Thoracic Surgeons' database or other relevant databases to be collected from hospitals. At the November 4, 2021 public meeting, the CAP recommended HCAI move forward with hospital-level TAVR outcomes reporting and at the April 13, 2022 public meeting, recommended collection of TAVR data elements through participation in and transferring data from the STS/ACC TVT Registry™ that is part of the NCDR®.

There are currently no regulations related to TAVR data collection. These new sections will require California TAVR hospitals (current and future) to participate in the STS/ACC TVT Registry™. In addition, this section will require all California TAVR hospitals to complete, sign and submit a DRCF that directs the NCDR® to transfer their data to HCAI.

2. Policy Statement Overview/Specific Benefits of Proposed Regulation

TAVR is an established treatment for severe, symptomatic, aortic stenosis (AS) in patients of all risk categories and now comprises 12.5% of all aortic valve replacements. TAVR is a less invasive alternative to traditional surgical aortic valve replacement (SAVR), with equivalent or superior outcomes. The success and increase in use of TAVR are a result of advances in technology, greater operator experience, and improved outcomes. Indications have recently expanded to include patients considered to be at low risk for SAVR. In California, TAVR has expanded from 86 procedures in 2011 to 7,356 procedures in 2020.

The objective of the proposed new section of regulations is to acquire STS/ACC TVT Registry™ data for California TAVR hospitals in order to produce risk-adjusted outcomes.

The Centers for Medicare and Medicaid Services (CMS) require participation in the STS/ACC TVT Registry™ in order for hospitals to be reimbursed. Currently, more than 95% of California TAVR hospitals participate in this registry (accounting for more than 97% of California TAVR volume). Acquiring this registry data eliminates the burden to hospitals that otherwise would be required to report the same data directly to HCAI. In addition, this would yield clinical data that is more complete for accurately reporting on TAVR outcomes and accounting for underlying risk than the administrative data collected at HCAI.

3. Determination of Inconsistency/Incompatibility with Existing State Regulations

As required by Government Code Section 11346.5, subsection (a)(3)(D), HCAI evaluated the language contained in the proposed section. HCAI has determined that these proposed regulations are not inconsistent with or incompatible with existing state regulations.

4. Documents Incorporated by Reference

TAVR Data Release Consent Form revised 6/21/2022

V. DISCLOSURES REGARDING THE PROPOSED ACTION

HCAI 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 costs to HCAI for acquiring the data and producing the report are absorbable.
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 private persons or businesses: The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

7. Significant effect on housing costs: None
8. Significant statewide adverse economic impact directly affecting business: HCAI 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 other businesses in other states.
9. Effect on Small Business: HCAI has determined that the proposed section 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)

Outreach to California TAVR hospitals determined that this regulatory action will have a negligible economic impact to their programs. Over 95% of these hospitals currently participate in the STS/ACC TVT Registry™, so minimal additional data abstraction or submission will be required.

Therefore, HCAI 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 using this data for outcomes reports will provide health care consumers and purchasers with a tool to assess the relative quality of health care delivered to TAVR patients. The proposed regulations are not expected to affect worker safety or the state's environment.

VII. REASONABLE ALTERNATIVES STATEMENT

In accordance with Government Code Section 11346.5, subsection (a)(13), HCAI 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

HCAI 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 regulations, the initial statement of reasons, economic impact assessment contained in the initial statement of reasons, a letter from the CAP Chair and all documents incorporated by reference.

In developing these regulations, HCAI conducted webinars with affected hospitals where discussions determined that the fiscal impact to TAVR hospitals will be negligible.

IX. AVAILABILITY OF SUBSTANTIAL CHANGES TO ORIGINAL PROPOSAL

After considering all timely and relevant comments received, HCAI may adopt the proposed regulations substantially as described in this notice. If HCAI 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 HCAI 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 HCAI's website at:

<https://HCAI.ca.gov/about/laws-regulations/>

HCAI 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 and Rulemaking File including a summary of all comments and responses will be available, after its completion, through HCAI's website at:

<https://HCAI.ca.gov/about/laws-regulations/>

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 the Notice of Proposed Action, the Initial Statement of Reasons, and text of the proposed regulations in underline and strikeout can be accessed through our website at:

<https://HCAI.ca.gov/about/laws-regulations/>



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Department of Health Care Access and Information Transcatheter Aortic Valve Replacement

INITIAL STATEMENT OF REASONS

Title 22, California Code of Regulations
Sections 97140-97160

BACKGROUND INFORMATION

Health and Safety Code Section (HSC) 128745 requires the Department of Health Care Access and Information (HCAI) to publish at least one risk-adjusted outcome report for coronary artery bypass graft (CABG) surgery, transcatheter aortic valve replacement (TAVR), or any type of interventional cardiovascular procedure for procedures performed in the state annually.

Health and Safety Code Sections 128745 and 128748 provide for the appointment of a Clinical Advisory Panel (CAP). The CAP has been in place since 2002, advising HCAI on risk-adjusted outcomes reports for CABG surgery. Recent additions to the HSC expand the purview of the CAP to include advising HCAI on aspects of all cardiovascular outcomes reporting, not just CABG.

Upon recommendation of the CAP, HCAI may add any clinical data elements included in the Society of Thoracic Surgeons' (STS) database or other relevant databases to be collected from hospitals. At the November 4, 2021 public meeting, the CAP recommended HCAI move forward with hospital-level TAVR outcomes reporting. They also recommended expanding the CAP membership to include two experts on TAVR, nominated by the California chapter of the American College of Cardiology (ACC). At the April 13, 2022 public meeting, these experts were sworn in and the CAP recommended collection of TAVR data elements through participation in and transferring data from the STS/ACC TVT Registry™ (TVT Registry). A letter from the CAP Chair is attached.

As a requirement of Centers for Medicare & Medicaid Services (CMS) reimbursement, hospitals that perform TAVR must participate in a prospective, national, audited registry. The decision memo is available here ([CMS TAVR Decision Memo](#)) and attached. The TVT Registry serves this required CMS reporting purpose.

The TVT Registry is part of the American College of Cardiology National Cardiovascular Data Registry (NCDR®) and was created by a collaboration between the STS and the ACC. The TVT Registry monitors patient safety and real-world outcomes related to transcatheter valve replacement and repair procedures – emerging treatments for valve disease patients. Employing state-of-the-art heart valve technology, transcatheter heart valve procedures provide new treatment options for patients who are not eligible for conventional heart valve replacement or repair surgery.

The TVT Registry has been approved by CMS to meet their registry requirements. The STS is a national organization dedicated to ensuring the best possible outcomes for surgeries of the heart and other surgical procedures within the chest and the ACC's mission is to transform cardiovascular care and improve heart health. Together, STS and ACC have more than 35 years of registry experience, more than 100 years leading the cardiovascular medicine profession and more than 56,000 members worldwide. The TVT Registry was developed in collaboration with the Federal Drug Administration (FDA), CMS and with input from the Society for Cardiovascular Angiography and Intervention and the American Association for Thoracic Surgery.

Hospitals performing TAVR should already be participating in the TVT Registry as a requirement for CMS reimbursement. There is currently more than 95% participation in the TVT Registry by California-licensed acute care hospitals that perform adult TAVRs.

Even though most California TAVR hospitals currently participate in the TVT Registry, this proposal adds language that will require all TAVR hospitals (current and future) to participate in the registry and to complete, sign, and submit the TVT Data Release Consent Form (DRCF) to the American College of Cardiology National Cardiovascular Data Registry (NCDR®). The DRCF permits NCDR® to transfer the hospital data to HCAI. For hospitals performing TAVR between January 1, 2022 and December 31, 2022 the DRCF shall be completed, signed and submitted by March 1, 2023. For hospitals that did not perform TAVR in calendar year 2022 but perform TAVR after December 31, 2022, the DRCF form shall be completed, signed and submitted by March 1 of the year following the year TAVR was performed. The DRCF will remain in effect for the duration of HCAI's public reporting of risk-adjusted TAVR outcomes.

The TAVR data transfer from NCDR® to HCAI will include all data elements in the TAVR component of the TVT Registry. This allows HCAI to fully evaluate all risk factors and assess other components related to quality of healthcare such as social determinants of health.

THE PROBLEM TO BE ADDRESSED

TAVR is the fastest growing cardiovascular intervention/procedure in California and the most common valve intervention/procedure. In California, TAVR has expanded

from 86 procedures in 2011 to 7,356 procedures in 2020. The CAP recommended HCAI produce risk-adjusted outcomes reports for TAVR to provide useful information to hospitals, consumers and providers.

PURPOSE AND BENEFITS OF THIS REGULATORY ACTION

Purpose: HCAI proposes to add regulations to require California-licensed general acute care hospitals that perform TAVR to participate in the TVT Registry and allow the registry to transfer their data to HCAI.

Benefits: Risk-adjusted outcomes reports using clinical data can be used to flag potential quality problems and highlight successes for hospitals and interventionalists, provide health care consumers and purchasers with a tool to assess the relative quality of health care delivered to patients and encourage hospitals to promote quality improvements within their practice. It also supports the state's efforts to use data-driven information to improve the health care delivery system by holding hospitals accountable to consumers, payers, and employers and increasing the transparency of procedure/intervention outcomes.

The benefit of acquiring clinical data previously submitted to a national registry is two-fold. It provides data that is more complete for accurately reporting on TAVR outcomes and accounting for underlying risk than administrative data collected at HCAI and lessens the burden to hospitals that would have to report data directly to HCAI. Currently, most California TAVR hospitals participate in the TVT Registry.

HCAI can absorb the costs of purchasing the TVT Registry data and creating the public reports.

NECESSITY

Health and Safety Code Section 128745 allows for HCAI to publish a risk-adjusted outcomes report for TAVR and allows for clinical data elements included in the TVT Registry to be collected from hospitals but does not specify this process.

These regulations are necessary to provide instructions for TAVR hospitals to ensure HCAI can acquire their TVT Registry data. They will also ensure that HCAI has complete California TAVR data to use when preparing the risk-adjusted outcome reports outlined in statute.

THE SPECIFIC PURPOSE OF EACH AMENDMENT

22 CCR 97140 Definitions, as Used in this Article

The definitions define the terms.

22 CCR 97145 TAVR Data

This section will require all California-licensed TAVR hospitals (current and future) to participate in the TVT Registry and complete, sign and submit a DRCF that directs NCDR® to transfer their data to HCAI. For hospitals performing TAVR between January 1, 2022 and December 31, 2022 the DRCF shall be completed, signed and submitted by March 1, 2023. 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.

22 CCR 97150 Compliance

This section labels TAVR hospitals that do not meet the requirements of section 97145 as non-compliant and will be reported as such in the annual outcomes report.

22 CCR 97155 Hospital Data Contact

This section requires TAVR hospitals to provide and keep current one designated data contact.

22 CCR 97160 Audit Procedure

This section allows for HCAI to conduct audits of the TAVR patients' medical charts. Data abstracted during an audit may replace data acquired from the TVT Registry for each hospital.

ECONOMIC IMPACT ASSESSMENT (Government Code Section 11346.3(b))

Purpose:

HCAI proposes to add to the California Code of Regulations (CCR) Sections 97140-97160. These additions should result in minimal burden to California TAVR hospitals. As a requirement of CMS reimbursement, hospitals that perform TAVR must participate in the TVT Registry. Currently, more than 95% of the California TAVR hospitals participate in the TVT Registry (accounting for more than 97% of California TAVR volume).

The Creation or Elimination of Jobs Within the State of California

These regulations will provide HCAI with the data necessary to produce risk-adjusted outcomes reports for TAVR. The new regulations will only affect current and new hospitals that perform TAVR and HCAI staff. HCAI 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

These regulations allow for HCAI to obtain quality data on TAVR to produce risk-adjusted outcomes reports on an annual basis. These regulations provide the mechanism for TAVR data to be transferred from NCDR® to HCAI. The new regulations will only affect hospitals currently performing TAVR and those performing TAVR in the future. HCAI has determined that this regulatory proposal will not have a significant adverse 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

These regulations allow for HCAI to obtain quality data on TAVR to produce risk-adjusted outcomes reports on an annual basis. These regulations provide the mechanism for TAVR data to be transferred from NCDR® to HCAI. The new regulations will only affect hospitals currently performing TAVR and those performing TAVR in the future. HCAI has determined that this regulatory proposal will not have a significant adverse 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 new regulations is to provide risk-adjusted outcomes for TAVR hospitals in California and could indirectly benefit the health and welfare of California residents who may use such data to understand California's healthcare environment. HCAI has determined that these regulations do not benefit worker safety and the state's environment.

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

HCAI relied upon the NCDR® for details related to TAVR data. These are publicly available at: <https://www.ncdr.com/WebNCDR/tvt/publicpage/home>.

REASONABLE ALTERNATIVES

HCAI 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 HCAI.

Administrative data from California's hospital discharge data does not provide the detailed data or the clinical data necessary to create these risk-adjusted outcomes reports. Clinical data gathered in the cardiovascular setting of hospitals is necessary to produce these reports.

HCAI currently has an in-house data collection program that requires California-licensed hospitals that perform CABG surgery to submit their data directly to HCAI. Attempting to add TAVR data to this program would be time consuming, expensive and an extreme burden to hospitals and require additional resources at HCAI.

HCAI 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

HCAI held multiple webinars with TAVR hospitals to determine questions and concerns with this regulation, including any estimated economic impacts. Discussions determined that time spent would primarily be on communications with HCAI and that adoption of this regulation would result in negligible costs to TAVR hospitals.

22 CCR § 97140-97160
§ 97140. Definitions, as Used in this Article.

Definitions:

- (1) "Department" means the Department of Health Care Access and Information.
- (2) "TAVR" means transcatheter aortic valve replacement.
- (3) "TAVR hospital" means a California licensed general acute care hospital that performs TAVR.
- (4) "Program" means the Department's TAVR outcomes reporting program.
- (5) "NCDR®" means National Cardiovascular Data Registry
- (5) "STS/ACC TVT Registry™" means the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry.
- (6) "DRCF" means the TVT data release consent form from the STS/ACC TVT Registry™ available on the Department's website and hereby incorporated by reference.

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

§ 97145. TAVR data.

- (1) TAVR hospitals shall:
 - (a) Participate in, and provide timely submission of TAVR data to, the STS/ACC TVT Registry™.
 - (b) Confer rights to transfer the TAVR data submitted pursuant to paragraph (a) 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 hereby incorporated by reference and is available for download from the HCAI website. The Department will make a hardcopy available on request.
- (2) For hospitals performing TAVR between January 1, 2022 and December 31, 2022 the DRCF shall be completed, signed and submitted by March 1, 2023.
- (3) 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.
- (4) 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 128745, Health and Safety Code. Reference: Sections 128745 and 128748, Health and Safety Code.

§ 97150. Compliance.

- (1) TAVR hospitals that do not meet the requirements specified in § 97145 (1), (2), and (3) shall be deemed and reported as non-compliant in the annual outcomes report.

§ 97155. Hospital Data Contact.

(1) 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.

(2) 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 128745, Health and Safety Code. Reference: Sections 128745 and 128748, Health and Safety Code.

§ 97160. Audit Procedure.

(1) 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.

(2) 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.

(3) 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.

(4) 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 128745, Health and Safety Code. Reference: Sections 128745 and 128748, Health and Safety Code.

**DATA RELEASE CONSENT FORM (revised 6/21/2022) AND
ADDENDUM TO THE TVT REGISTRY PARTICIPATION AGREEMENT
BETWEEN THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION, THE SOCIETY
OF THORACIC SURGEONS AND PARTICIPANT**

This Data Release Consent Form and Addendum (“Addendum”) to the TVT Registry Participation Agreement (“Participation Agreement”) between the undersigned Hospital Participant (“Hospital Participant”), the undersigned Surgeon (“Surgeon Participant”), the undersigned Cardiologist (“Cardiologist Participant”), the American College of Cardiology Foundation (“ACCF”) and The Society of Thoracic Surgeons (“STS”) is entered into and made effective on the latest date signed below (“Effective Date”). The Hospital Participant, Surgeon Participant, and Cardiologist Participant shall be referred to herein collectively as “Participant.” ACCF and STS shall be referred to herein collectively as “ACCF/STS”. ACCF/STS and Participant shall each be referred to herein as a “Party” and collectively as the “Parties.” All existing terms and conditions of the Participation Agreement shall remain in full force and effect.

For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties further acknowledge and agree as follows:

SAMPLE – DO NOT USE

1. Participant has entered into a Participation Agreement and a Business Associate Contract and Data Use Agreement (“BAC/DUA”) with ACCF/STS to provide certain transcatheter valve therapies patient-level data to ACCF/STS (“TVT Data”) and to receive certain comparative and benchmark reports from ACCF/STS. TVT Data include certain required patient identifiers and such data include Protected Health Information (“PHI”) as defined under the regulations issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA regulations”).

2. Pursuant to Sections 97140-97160 of Title 22 of the California Code of Regulations, as amended, Participant is required to participate in the TVT Registry and confer the right to transfer the TAVR data submitted by the Participant to the California Department of Health Care Access and Information (“HCAI”). To fulfill such requirement, Participant agrees to permit the transmission by ACCF/STS to HCAI of Participant’s data submitted to the TVT Registry, and to further permit the disclosure of Participant’s PHI to HCAI.

3. Participant acknowledges that it has been informed that ACCF/STS and HCAI have entered or will enter into an agreement, the purposes of such agreement being to provide to HCAI in a secure manner reports, including Participant’s row-level data and aggregate data, to HCAI.

4. Participant authorizes and directs ACCF/STS to transmit Participant’s TVT Registry data to HCAI for the purposes described in Paragraph 3 above.

SAMPLE – DO NOT USE

5. This Addendum shall be effective for the duration of Participant’s participation in the TVT Registry unless earlier terminated as permitted herein. This Addendum may be terminated by Participant or ACCF/STS upon written notice to the other Party at any time. Termination of this Addendum shall not constitute a termination of the Participation Agreement, unless otherwise agreed to by Participant or ACCF/STS.

6. As amended by this Addendum, the Participation Agreement is in all respects ratified and confirmed, and the Participation Agreement and this Addendum shall be read, taken, and construed as one and the same instrument. If there is any inconsistency between (a) the Participation Agreement and/or the

BAC/DUA and (b) this Addendum, then the terms of the Participation Agreement and/or the BAC/DUA shall control and prevail.

7. This Addendum may be executed in one or more counterparts, each of which shall be deemed an original and all of which taken together shall constitute one and the same instrument.

IN WITNESS WHEREOF, each of the Parties hereto has caused this Addendum to be executed as of the ____ day of _____, 20__ :

SAMPLE – DO NOT USE

HOSPITAL PARTICIPANT	ACCF/STS
Signature: _____	Signature: _____
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____
E-Mail Address: _____	
Phone: _____	
SURGEON PARTICIPANT	
Signature: _____	
Name: _____	
Title: _____	
Date: _____	
E-mail Address: _____	
CARDIOLOGIST PARTICIPANT	
Signature: _____	
Name: _____	
Title: _____	
Date: _____	
E-Mail Address: _____	