

**MEETING MINUTES
OF THE
CENTERS FOR MEDICARE & MEDICAID SERVICES
MEDICARE EVIDENCE DEVELOPMENT & COVERAGE
ADVISORY COMMITTEE**

July 25, 2018

**Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland**

Medicare Evidence Development & Coverage Advisory Committee

July 25, 2018

Attendees

Committee Chair

Peter Bach, MD, MAPP

Committee Vice-Chair

Aloysius B. Cuyjet, MD, MPH

MEDCAC Members

Michael P. Cinquegrani, MD
Gregory Joseph Dehmer, MD
Anita Fernander, PhD, ABPBC
Naftali Zvi Frankel
Sandra J. Lewis, MD
Daniel A. Ollendorf, PhD
Zoltan Turi, MD, MSCAI

CMS Liaison

Daniel Arthur Canos, PhD, MPH

Industry Representative

Mark D. Carlson, MD, MA

Guest Panel Member

Patrice Desvigne-Nickens, MD

Invited Guest Speakers

Joseph E. Bavaria, MD
Aaron Horne, Jr., MD, MBA, MHS
Martin B. Leon, MD
Peter Pelikan, MD, FACC, FSCAI
Carl Tommaso, MD

Executive Secretary

Maria Ellis

Wednesday, July 25, 2018, 8:10 a.m.

The Medicare Evidence Development & Coverage Advisory Committee met on July 25, 2018, to discuss their appraisal and recommendations regarding the state of the evidence for procedural volume requirements, especially pertaining to surgical aortic valve replacement (SAVR), transcatheter aortic valve replacement (TAVR), and percutaneous coronary interventions (PCIs) for hospitals to begin and maintain TAVR programs.

The meeting began with a reading of a conflict of interest statement, welcoming remarks, and an introduction of the Committee.

CMS Presentation. A CMS representative presented information summarizing the current national coverage decision for TAVR, including the procedural volume requirements for institutions to begin or maintain provision of TAVR.

Presentations by Invited Guest Speakers. The panel heard presentations from the invited guest speakers. Dr. Pelikan urged that the time is right for CMS to lower the volume requirements in the NCD, arguing that the volume-quality relationship for the procedure no longer exists. Dr. Bavaria and Dr. Tommaso represented the American Association of Thoracic Surgeons, American College of Cardiology, Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgery; they summarized the 2018 multi-society consensus document, pointing out significant differences between the draft and final versions of the document. Dr. Leon presented a clinician's point of view on the questions before the panel. Dr. Horne highlighted disparities that exist racially and ethnically with the use of TAVR as an intervention.

Scheduled Public Comments. The panel heard from a total of ten scheduled speakers, including clinicians, society and industry representatives, and patients. These speakers informed the committee of their views on the consensus document, addressing their clinical, research and patient experience surrounding aortic stenosis and its treatments.

Open Public Comments. Nine members of the general public addressed the panel, including clinicians, a society representative, a representative of a patient advocacy group, a nurse practitioner, and a health care purchaser.

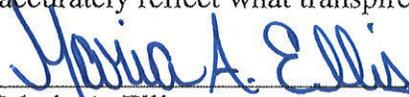
Questions to Presenters. The panel participated in a lengthy discussion and question and answer session with all of the presenters, which is recorded in the transcript.

Initial Open Panel Discussion, Formal Remarks and Voting Questions. The panel conducted an in depth discussion of the issues raised, before turning its attention to the discussion questions, followed by voting questions. There was a malfunction of the voting application during voting, and votes were recorded manually on sheets provided to the panelists, announced to the public, and were recorded by CMS staff. During the

the panelists, announced to the public, and were recorded by CMS staff. During the voting, the sound portion of the recording went out, so a portion of the transcript at the end of the meeting is missing.

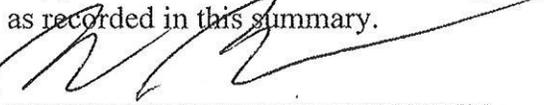
Adjournment. The meeting adjourned at 3:48 p.m.

I certify that I attended the meeting of the Medicare Evidence Development & Coverage Advisory Committee on July 25, 2018, and that these minutes accurately reflect what transpired.



Maria A. Ellis
Executive Secretary, MEDCAC, CMS

I approve the minutes of this meeting as recorded in this summary.



Peter Bach, MD, MAPP
MEDCAC Chair