

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

May 16, 2012

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

Medicare Evidence Development & Coverage Advisory Committee

May 16, 2012

Attendees

Chairperson

Clifford Goodman, PhD

Vice-Chair

Steve E. Phurrough, MD

Voting Members

Rene' Cabral-Daniels, JD, MPH

Mark D. Grant, MD, MPH

Robert McDonough, MD, JD

James Min, MD

Sharon-Lise T. Normand, PhD

Jeffrey B. Rich, MD

Ryan H. Saadi, MD, MPH

J. Sanford Schwartz, MD

Art Sedrakyan, MD, PhD

Industry Representative

Peter Juhn, MD, MPH

Guest Panel Members

Steven Goodman, MD, MHS, PhD

Jack W. Lasersohn

Peter J. Neumann, ScD

Invited Guest Speakers

Allan Korn, MD, FACP

Rick Kuntz, MD

Mark McClellan, MD

Lewis G. Sandy, MD, FACP

Sean Tunis, MD, FACP

CMS Liaison

Tamara Syrek Jensen, JD

Executive Secretary

Maria Ellis

Wednesday, May 16, 2012, 8:10 a.m.

The Medicare Evidence Development & Coverage Advisory Committee met on May 16, 2012, to discuss desirable characteristics of evidence appropriate for coverage with evidence development.

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

CMS Presentation and Voting Questions. Dr. Louis Jacques of CMS informed the panel and audience of the goals for today's meeting, explained the history of coverage with evidence development (CED) within the Agency, provided certain definitions of terms that would be used during the discussion and voting, and then read the voting and discussion questions to be considered by the panel.

Scheduled Public Comments. The panel heard from a total of nine scheduled speakers, including professional society representatives and counsel representing manufacturers.

Invited Guest Speaker Presentation, Discussion and Voting on Question 1. The panel heard a presentation from Dr. Korn regarding Question 1. Following the presentation, the panel asked questions of him, conducted further discussion, heard comments from the other invited guest speakers, and voted on the question. The vice chair then summarized the discussion and points raised.

Open Public Comments. The panel heard from one member of the public, representing a provider of orthopedic products.

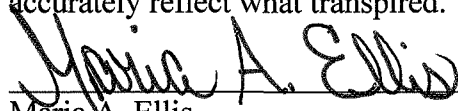
Presentation by Guest Speaker. Dr. McClellan made a presentation to the panel, summarizing his experiences with CED while at CMS and FDA, and sharing his opinions and recommendations on the questions before the panel.

Invited Guest Speaker Presentations, Discussion and Voting on Questions 2-5. For each of the remaining questions, the panel heard from one of the invited guest speakers, i.e., Dr. Tunis for Question 2, Dr. Schwartz for Questions 3 and 4, and Dr. Kuntz for Question 5. Following the respective presentations, the panel conducted further discussion, heard from each of the guest speakers, and voted on the respective questions. After the presentations and discussion, the chair asked each panelist to share his or her key point on that particular topic, and these points were summarized by the vice chair.

Final Comments. Following presentations and discussion on each specific question, each panelist was asked by the chair to express his or her recommendation regarding a single important point that they would take from the day's discussion on which CMS should focus as future decisions are made regarding use and implementation of CED in the context of Medicare coverage decision-making.


Adjournment. The meeting adjourned at 4:27 p.m.

I certify that I attended the meeting
of the Medicare Evidence Development &
Coverage Advisory Committee on
May 16, 2012, 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.



Clifford Goodman, PhD
Chairperson