

primary endpoints for trials of drug products.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on the development of drugs for the treatment of FSD. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 12, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.
[FR Doc. 00-12594 Filed 5-18-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-3034-N]

Medicare Program; Meeting of the Executive Committee of the Medicare Coverage Advisory Committee—June 6, 2000

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting of the Executive Committee (the Committee) of the Medicare Coverage Advisory Committee (MCAC). The Committee will hear reports from the Medical and Surgical Procedures Panel meeting of April 12 and 13, 2000, during which biofeedback and pelvic floor electrical stimulation in the treatment of urinary incontinence were deliberated. The Committee will also discuss presentations from interested persons regarding procedural aspects of future public meetings of the medical specialty panels of the MCAC. Notice of this meeting is given under the Federal Advisory Committee Act (5

U.S.C. App. 2, section 10(a)(1) and (a)(2)).

DATES:

The Meeting: June 6, 2000, from 8 a.m. until 3 p.m., E.D.T.

Deadline for Presentations and Comments: May 17, 2000, 5 p.m., E.D.T.

Special Accommodations: Persons attending the meeting who are hearing impaired and require sign language interpretation, or have a condition that requires other special assistance or accommodations, are asked to notify the Executive Secretary by May 25, 2000.

ADDRESSES:

The Meeting: The meeting will be held at the Baltimore Convention Center, One West Pratt Street, Baltimore, Maryland 21201.

Presentations and Comments: Submit formal presentations and written comments to Constance A. Conrad, Executive Secretary; Office of Clinical Standards and Quality; Health Care Financing Administration; 7500 Security Boulevard; Mail Stop S3-02-01; Baltimore, MD 21244.

Website: You may access up-to-date information on this meeting at www.hcfa.gov/quality/8b.htm.

Hotline: You may access up-to-date information on this meeting on the HCFA Advisory Committee Information Hotline, 1-877-449-5659 (toll free) or in the Baltimore area (410) 786-9379.

FOR FURTHER INFORMATION CONTACT:

Constance A. Conrad, Executive Secretary, 410-786-4631.

SUPPLEMENTARY INFORMATION: On August 13, 1999, we published a notice (64 FR 44231) to describe the MCAC, which provides advice and recommendations to us about clinical issues.

Current Panel Members

Harold C. Sox, MD (Chairperson); Thomas V. Holohan; Leslie P. Francis; John H. Ferguson; Robert L. Murray; Alan M. Garber; Michael D. Maves; Frank J. Papatheofanis; Ronald M. Davis; Daisy Alford-Smith; Joe W. Johnson; Robert H. Brook; Linda A. Berghold; Randel E. Richner.

Meeting Topic

The Committee will hear reports from the Medical and Surgical Procedures Panel meeting of April 12 and 13, 2000, during which biofeedback and pelvic floor electrical stimulation in the treatment of urinary incontinence. The Committee will also hear and discuss presentations from interested persons regarding procedural aspects of future public meetings of the medical specialty panels of the MCAC.

Procedure and Agenda

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 1 hour. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations you must notify the For Further Information Contact, and submit the following by the Deadline for Presentations and Comments date listed in the **DATES** section of this notice: a brief statement of the general nature of the evidence or arguments you wish to present, the names and addresses of proposed participants, and an estimate of the time required to make the presentation. We will request that you declare at the meeting whether you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

After the public presentation, we will make a presentation to the Committee. After our presentation, the Committee will deliberate openly. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. Prior to the review of the Medical Specialty Panel recommendation, the Committee will allow approximately a 30-minute open public session for any attendee to address issues specific to the topic. After the open session, the members will vote and the Committee will make its recommendation.

Authority: 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 11, 2000.

Jeffrey L. Kang,

Director Office of Clinical Standards and Quality, Health Care Financing Administration.

[FR Doc. 00-12686 Filed 5-18-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-1136-N]

Medicare Program; June 5, 2000, Meeting of the Practicing Physicians Advisory Council

AGENCY: Health Care Financing Administration (HCFA), HHS.