identified with the docket number found in the brackets in the heading of this guidance document. A copy of the guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document using the Internet. For Internet access, connect to CBER at http://www.fda.gov/cber/guidelines.htm.

Dated: March 1, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–6283 Filed 3–14–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3032–N]

Medicare Program; Meeting of the Medical and Surgical Procedures Panel of the Medicare Coverage Advisory Committee—April 12 and 13, 2000

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting of the Medical and Surgical Procedures Panel of the Medicare Coverage Advisory Committee (MCAC). The panel provides advice and recommendations to the agency about clinical coverage issues. The panel will hear and discuss presentations from interested persons regarding the treatment of non-neurogenic urinary incontinence in adults. The meeting will focus on two treatment options: biofeedback and pelvic floor electrical stimulation. 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:* The meeting will be held on April 12, 2000 from 8:00 a.m. until 5:15 p.m. and on April 13, 2000, from 8:00 a.m. until 3:00 p.m. E.S.T.

Deadline for Presentations and Comments: March 22, 2000, 5 p.m.

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 March 31, 2000.

ADDRESSES:

The Meeting: The meeting will be held at The Baltimore Convention Center, One West Pratt Street, Baltimore, MD 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, 1–877–449–5699 (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. This notice announces the following public meeting of the MCAC:

Current Panel Members:

Alan M. Garber, M.D.; Michael D. Maves, M.D.; Angus M. McBryde, M.D.; H. Logan Holtgrewe, M.D.; Kenneth P. Brin, M.D.; Les J. Zendle, M.D.; Bruce Sigsbee, M.D.; Linda D. Bradley, M.D.; James P. Rathmell, M.D.; Arnold M. Epstein, M.D.; Phyllis E. Greenberger, M.S.W.; Marshall S. Stanton, M.D.

Meeting Topic:

The Panel will hear and discuss presentations from interested persons regarding the treatment of non-neurogenic urinary incontinence in adults. The meeting will focus on two treatment options: biofeedback the first day and pelvic floor electrical stimulation the second day.

Procedure and Agenda:

This meeting is open to the public. The panel will hear oral presentations from the public for approximately 2 hours and 30 minutes on each day of the meeting. The Panel 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 person, 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 or not 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 Panel. After our presentation, the Panel will deliberate openly on the topic. Interested persons may observe the deliberations, but the Panel will not hear further comments during this time except at the request of the chairperson. At the end of the Panel deliberations each day, the Panel will allow approximately a 30-minute open public session for any attendee to address issues specific to the topic. After which, the members will vote and the Panel 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: February 29, 2000.

Jeffrey L. Kang,

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

[FR Doc. 00–6421 Filed 3–14–00; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding the Section 340B Drug Pricing Program—Program Guidance Clarification

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Section 602 of Public Law 102–585, the ''Veterans Health Care Act of 1992,'' enacted section 340B of the Public Health Service Act, ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible (covered) entities must sign a pharmaceutical pricing agreement with the Secretary of HHS in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

The purpose of this notice is to clarify section 340B program guidance related to the mechanism to prevent duplicate discounts (i.e., the generation of a