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

Medicaid rebate on a section 340B discounted drug). Any covered entity that purchases its non-Medicaid drugs through the 340B program but its Medicaid drugs through other avenues must provide the Office of Drug Pricing (ODP) notice of this type of dual purchasing activity. The ODP will place a notation ''non-applicable'' (N/A) by the covered entity name on the eligibility list so that any reimbursement requests for its Medicaid drugs will continue to generate manufacturer rebates. For appropriate Medicaid drug reimbursement procedures, the Health Resources and Services Administration (HRSA) refers the covered entity to its respective State Medicaid agency for guidance.

FOR FURTHER INFORMATION CONTACT: Captain Robert Staley, Office of Drug Pricing, Bureau of Primary Health Care, Health Resources and Services Administration, 10th Floor, East-West Towers, 4350 East-West Highway, Bethesda, MD 20814; Phone (800) 628–6297; Fax (301) 594–4982.

SUPPLEMENTARY INFORMATION: Section 340B(a)(5)(A) required HHS to develop a mechanism to prevent a section 340B drug discount and a Medicaid rebate on the same drug (*i.e.,* prevention of double discounting). HRSA, together with the Medicaid Rebate Program, Health Care Financing Administration, developed a process to prevent this potential double price reduction and published the final notice of this mechanism on June 23, 1993, at 58 FR 34058. The mechanism, which focuses only on 340B covered outpatient drugs, requires a covered entity that bills Medicaid on a cost basis (e.g., community health centers using fee for service and not all inclusive rates) to submit to ODP its Pharmacy Medicaid Number (*i.e.,* the number used to bill Medicaid for the drugs). This information is placed by the name of the covered entity on the master electronic eligibility list. Using this Medicaid number, the State Medicaid agency creates a separate provider file for claims from that covered entity. This computer file then excludes data from this provider file when generating the rebate bills to the manufacturers. In this way, the mechanism prevents double discounting.

An entity which utilizes a Medicaid billing system that includes pharmacy in an all-inclusive rate or does not submit Medicaid claims for covered outpatient drugs would not generate Medicaid rebates. Consequently, these entities do not have to provide their pharmacy numbers (58 FR 34059). However, such entities were instructed to provide ODP with notice of such purchasing practices so that this information could be provided to participating manufacturers and appropriate State Medicaid agencies (59 FR 25112, May 13, 1994).

It has come to our attention that there may be some confusion concerning the appropriate reporting procedures for an entity not participating in the 340B Program for its Medicaid drugs (i.e., purchasing its non-Medicaid drugs through the 340B Program and its Medicaid drugs outside the Program). Because drugs purchased outside of the 340B Program are not considered covered 340B outpatient drugs, an entity that only purchases non-Medicaid drugs through the 340B Program would not request Medicaid reimbursement for its covered outpatient drugs (i.e., non-Medicaid drugs discounted through the 340B program). Consequently, the covered entity would not provide ODP its Medicaid Pharmacy number. However, this entity still must notify ODP of this type of purchasing practice. ODP will place N/A by the name of the covered entity, signaling no Medicaid reimbursement requests on drugs purchased with discounts under section 340B. In this way, Medicaid rebates will continue to be generated on its Medicaid drugs purchased outside the 340B program.

Covered entities that have submitted Medicaid Pharmacy provider numbers now included in the covered entity database but are purchasing drugs for their Medicaid patients on the open market should contact ODP as soon as possible to request that their Medicaid Pharmacy numbers be replaced by N/A in the covered entity database. An entity that has purchased Medicaid drugs outside of the 340B Program but submitted its Medicaid provider number to ODP should attempt to preserve any documentation of such purchasing activity. The entity should contact its State Medicaid agency about these past drug purchases so that the agency can bill manufacturers for rebates that were excluded from past rebate claims.

On behalf of the Medicaid Drug Rebate Program, HRSA provided notice to covered entities regarding appropriate procedures for requesting Medicaid reimbursement for covered outpatient drugs (58 FR 27293 and 59 FR 25112 regarding ''actual acquisition cost''). Currently, HRSA is reviewing that portion of the guidance and recommends that covered entities refer to their respective Medicaid State agency drug reimbursement guidelines for applicable billing limits.

Dated: March 9, 2000.

Claude Earl Fox,

Administrator.

[FR Doc. 00–6287 Filed 3–14–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub.L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of April 2000.

Name: Advisory Committee on Training in Primary Care Medicine and Dentistry.

Date and Time: April 20, 2000; 8 a.m.–5:30 p.m.; April 21, 2000; 8 a.m.–3:00 p.m.

Place: Hilton Washington and Towers, 1919 Connecticut Avenue, NW, Washington, DC 20009.

The meeting is open to the public.

Purpose: The Advisory Committee shall (1) Provide advice and recommendations to the Secretary concerning policy and program development and other matters of significance concerning activities under section 747 of the Public Health Service (PHS) Act; and (2) Prepare and submit to the Secretary, the Committee on Labor and Human Resources of the Senate, and the Committee on Commerce of the House of Representatives, a report describing the activities of the Advisory Committee, including findings and recommendations made by the Committee concerning the activities under section 747 of the PHS Act. The Advisory Committee will meet twice each year and submit its first report to the Secretary and the Congress by November 2001.

Agenda: Discussion of the focus of the programs and activities authorized under section 747 of the PHS Act; responses to questions on the programs under section 747 of the PHS Act; project requirements; funding priorities; outcomes data; and the peer review process. Strategic planning for the Committee.

Anyone interested in obtaining a roster of members, minutes of the meeting, or other relevant information should write or contact Barbara Brookmyer, Deputy Executive Secretary, Advisory Committee on Training in Primary Care Medicine and Dentistry,