

committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before July 31, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: April 9, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96-16663 Filed 6-28-96; 8:45 am]

BILLING CODE 4160-01-F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current

information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Advisory Committee for Reproductive Health Drugs

Date, time, and place. July 19, 1996, 9 a.m., FDA Technical Center, 16071 Industrial Dr., Gaithersburg, MD. Attendees should allow time to proceed through security procedures. Admission to the facility by public participants will be available on a first come, first serve basis, and will be limited to approximately 200, the number of seats available to the public in the conference room. There will be an overflow room with both audio and video link to the meeting. The overflow room is located at the Hilton Hotel, 620 Perry Pkwy., Gaithersburg, MD.

Type of meeting and contact person. Open committee discussion, 9 a.m. to 1:30 p.m.; open public hearing, 1:30 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 3:30 p.m. to 5 p.m.; Philip A. Corfman, Center for Drug Evaluation and Research (HFD-580), Food and Drug Administration, 5600 Fishers Lane, rm. 14B-04, Rockville, MD 20857, 301-443-3510, FAX 301-443-9282, or e-mail july19@cder.fda.gov. Information concerning the meeting is available from FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Advisory Committee for Reproductive Health Drugs, code 12537. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology, and related specialties.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in

writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person in writing by mail, e-mail, or fax no later than 5 p.m., EDT on July 12, 1996, with a brief statement of the general nature of the evidence or arguments they wish to present, the names, telephone numbers, and addresses of proposed participants, and an indication of the approximate time required to make their comments. The time for presentations will be allotted equitably, and will depend on how many individuals give advance notice within the time indicated of their intention to speak. In the interest of time, the agency may require persons with common interests to make joint presentations.

Open committee discussion. The committee will discuss the new drug application for mifepristone for the interruption of early pregnancy.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published

in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above in writing, prior to the meeting.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: June 25, 1996.
Michael A. Friedman,
Deputy Commissioner for Operations.
[FR Doc. 96-16770 Filed 6-28-96; 8:45 am]
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Health Care Financing Administration

[BPD-847-CN]

RIN 0938-AH34

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1997 Rates; Correction

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

ACTION: Correction notice.

SUMMARY: On May 31, 1996, we published a proposed rule (61 FR 27444) that would revise the Medicare hospital inpatient prospective payment

systems for operating costs and capital-related costs to implement necessary changes arising from our continuing experience with the systems. In the addendum to the proposed rule, we announced the prospective payment rates for Medicare hospital inpatient services for operating costs and capital-related costs that would apply to discharges occurring on or after October 1, 1996, and set forth the factors for determining the rate-of-increase limits for hospital and hospital units excluded from the prospective payment system. This notice corrects errors made in that document.

FOR FURTHER INFORMATION CONTACT: Tzvi Hefter, (410) 786-1304.

SUPPLEMENTARY INFORMATION: In the May 31, 1996 proposed rule (61 FR 27444), we indicated that the addendum would discuss our proposed update of the factors for determining the rate-of-increase limits for cost reporting periods beginning in Federal fiscal year 1997 for hospitals and hospital units excluded from the prospective payment system. This discussion was inadvertently omitted from the published document.

In addition, there were errors in our calculations of the Geographic Adjustment Factors (GAFs) in tables 4a and 4b. The tables are reprinted in their entirety in this document. The GAFs set forth in table 4c are correct.

The proposed rule also contained other technical and typographical errors. Therefore, we are making the following corrections to the May 31, 1996 proposed rule:

1. On page 27474, in the table entitled Initial Residency Period, after "Allopathy" and before "ANESTHESIOLOGY" insert the following row:

ALLERGY AND IMMUNOLOGY3.

2. On page 27504, in the second column before "V. Tables", the following information should be inserted:

IV. Proposed Rate-of-Increase Percentages for Excluded Hospitals and Hospital Units

The inpatient operating costs of hospitals and hospital units excluded from the prospective payment system are subject to rate-of-increase limits established under the authority of section 1886(b) of the Act, which is implemented in § 413.40 of the regulations. Under these limits, an annual target amount (expressed in terms of the inpatient operating cost per discharge) is set for each hospital, based on the hospital's own historical cost

experience trended forward by the applicable rate-of-increase percentages (update factors). The target amount is multiplied by the number of Medicare discharges in a hospital's cost reporting period, yielding the ceiling on aggregate Medicare inpatient operating costs for the cost reporting period.

Effective with cost reporting periods beginning on or after October 1, 1991, a hospital that has Medicare inpatient operating costs in excess of its ceiling is paid its ceiling plus 50 percent of its costs in excess of the ceiling. Total payment may not exceed 110 percent of the ceiling. A hospital that has inpatient operating costs less than its ceiling is paid its costs plus the lower of—

- Fifty percent of the difference between the allowable inpatient operating costs and the ceiling; or
- Five percent of the ceiling.

Each hospital's target amount is adjusted annually, at the beginning of its cost reporting period, by an applicable rate-of-increase percentage. Section 1886(b)(3)(B) of the Act provides that for cost reporting periods beginning on or after October 1, 1993, and before October 1, 1994, the applicable rate-of-increase percentage is the market basket percentage increase minus the lesser of 1 percentage point or the percentage point difference between 10 percent and the hospital's "update adjustment percentage" of at least 10 percent. The rate-of-increase percentage for hospitals in the latter case is the market basket percentage increase. The "update adjustment percentage" is the percentage by which a hospital's allowable inpatient operating costs exceeds the hospital's ceiling for the cost reporting period beginning in Federal fiscal year (FY) 1990. For cost reporting periods beginning on or after October 1, 1994, and before October 1, 1997, the update adjustment percentage is the update adjustment percentage from the previous year plus the previous year's applicable reduction. The applicable reduction and applicable rate-of-increase percentage are then determined in the same manner as for FY 1994. The most recent forecasted market basket increase for FY 1997 for hospitals and hospital units excluded from the prospective payment system is 2.7 percent.

3. On pages 27521 to 27527, Table 4a—Wage Index and Capital Geographic Adjustment Factor (GAF) for Urban Areas is corrected by replacing the table with the following table: