10638, March 4, 1998). Tracking orders were also issued on December 14, 1998, to tissue banks that manufacture and distribute dura mater.

On March 4, 1998, FDA announced the availability of the ''Guidance on Medical Device Tracking'' (63 FR 10638 at 10640). This final draft guidance was issued as a Level 1 guidance under the agency's Good Guidance Practices (GGP's) (62 FR 8961, February 27, 1997). The guidance explained: (1) Revised tracking criteria in section 519(e) of the act, as amended by FDAMA; (2) patients' rights to refuse information disclosure; (3) FDA's discretion in issuing tracking orders; (4) FDA's review and reconsideration of devices subject to FDAMA tracking criteria; and (5) the regulatory application of tracking requirements in 21 CFR part 821.

Through the January 1998 meeting and the March 1998 **Federal Register** notices, FDA solicited public comment on what factors in addition to the revised statutory criteria the agency should consider in exercising its discretion to require, or not to require, the tracking of devices. As a consequence of these comments, FDA believes it should consider the following factors, as ascertained from available premarket and postmarket information, in determining whether to issue a tracking order for a particular type of device: (1) Likelihood of sudden, catastrophic failure; (2) likelihood of significant adverse clinical outcome; and (3) need for prompt professional intervention.

This revised final guidance replaces the March 1998 guidance and reflects the factors FDA may consider in determining which devices should be tracked. The list of tracked devices identified in the March 1998 guidance also has been revised in this final guidance, based on the additional factors noted previously and identifies 14 categories of devices that have been released from FDAMA tracking requirements under the tracking requirement rescission orders issued by FDA in August 1998. It also identifies the 16 categories of devices currently subject to tracking orders. The agency added one category, dura mater, which was the subject of tracking orders issued by the agency which became effective on December 14, 1998. The remaining 15 device types were the subject of tracking orders issued by the agency which became effective on February 19, 1998. Upon further review and reconsideration, FDA has determined that these particular devices meet the statutory tracking criteria under section 519(e) of the act and, upon failure, would likely exhibit the factors noted previously that FDA believes warrants their tracking. The agency may add or remove devices from the list of tracked devices as a result of its review of premarket applications, recall data, medical device reporting, inspections, petitions, postmarket surveillance, or other information.

II. Significance of Guidance

This guidance document represents the agency's current thinking on medical device tracking requirements, as amended by FDAMA. 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 applicable statute, regulations, or both.

The agency has adopted GGP's, which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Guidance on Medical Device Tracking'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (169) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the revised final guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes ''Guidance on Medical Device Tracking,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. ''Guidance on Medical Device Tracking'' will be available at ''http://www.fda.gov/cdrh/ochome.html''.

IV. Comments

Interested persons may, at any time, submit to the contact person (address above) written comments regarding this guidance. Such comments will be considered when determining whether to amend the current 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 guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 3, 1999.

Linda S. Kahan,

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

[FR Doc. 99–3437 Filed 2–11–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1064–N]

RIN 0938–AJ38

Medicare Program; March 15, 1999, Meeting of the Practicing Physicians Advisory Council

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

ACTION: Notice of a meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Practicing Physicians Advisory Council (the Council) on March 15, 1999. This meeting is open to the public.

The Council is mandated by section 1868 of the Social Security Act and meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services.

DATES: The meeting is scheduled for March 15, 1999, from 8:30 a.m. until 5 p.m., e.s.t.

ADDRESSES: The meeting will be held in Room 800, 8th Floor, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C. 20201.

FOR FURTHER INFORMATION CONTACT: Aron Primack, M.D., M.A., F.A.C.P., Executive Director, Practicing Physicians Advisory Council, Room 435–H, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC, 20201, (202) 690–7874. News media representatives should contact the HCFA Press Office (202) 690–6145.

SUPPLEMENTARY INFORMATION: The Secretary of the Department of Health and Human Services (the Secretary) is mandated by section 1868 of the Social Security Act to appoint a Practicing Physicians Advisory Council (the Council) based on nominations submitted by medical organizations representing physicians.

The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of HCFA no later than December 31 of each year.

The Council consists of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under Medicare or Medicaid in the previous year. Members of the Council include both participating and nonparticipating physicians, as well as physicians practicing in rural and underserved urban areas. At least 11 members must be doctors of medicine or osteopathy authorized to practice medicine and surgery by the States in which they practice.

Members have been invited to serve for overlapping 4-year terms. In accordance with section 14 of the Federal Advisory Committee Act, terms of more than 2 years are contingent upon the renewal of the Council by appropriate action before the end of the 2-year term.

The current members are: Jerold M. Aronson, M.D.; Richard Bronfman, D.P.M. (renominated—pending selection); Wayne R. Carlsen, D.O.; Gary C. Dennis, M.D.; Mary T. Herald, M.D.; Ardis D. Hoven, M.D.; Sandral Hullett, M.D.; Jerilynn S. Kaibel, D.C.; Marie G. Kuffner, M.D.; Marc Lowe, M.D. (renominated—pending selection); Derrick K. Latos, M.D.; Sandra B. Reed, M.D.; Susan Schooley, M.D.; Maisie Tam, M.D.; and Kenneth M. Viste, Jr., M.D. The chairperson is Kenneth M. Viste, Jr., M.D. The vice chairperson is Marie G. Kuffner, M.D.

The next meeting of the Council is scheduled for March 15, 1999, from 8:30 a.m. until 5 p.m., e.s.t. This meeting is open to the public and will be held in Room 800, 8th Floor, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington DC, 20201. The meeting is open to the public, but attendance is limited to the space available.

At this meeting the Council members will be updated on the status of items discussed at previous meetings. In addition, new members will be sworn in to serve on the Council. The agenda will provide for discussion and comment on the following topic:

Physicians Regulatory Issues Team (PRIT) Testimony is requested from physicians and medical organizations representing physicians regarding the regulatory requirements placed on practicing physicians. Testimony should address methods of improving a physician's administrative process, while maintaining the integrity of Federal administrative systems.

Individual physicians or medical organizations that represent physicians that wish to make 5-minute oral presentations on the agenda issue should contact the Executive Director by 12 noon, February 19, 1999, to be scheduled. The number of oral presentations may be limited by the time available. A written copy of the presenters' oral remarks should be submitted to the Executive Director no later than 12 noon, February 26, 1999, for distribution to the Council members.

Any interested member of the public may submit written comments to the Executive Director and Council members for review. Comments should be received by the Executive Director by 12 noon, February 26, 1999, for distribution.

(Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Public Law 92–463 (5 U.S.C. App. 2, section 10(a)); 45 CFR Part 11)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 1, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 99–3558 Filed 2–11–99; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group, Subcommittee G—Education.

Date: March 10–12, 1999.

Time: 12:00 pm to 4:00 pm.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Georgetown, 2101 Wisconsin Ave. NW., Washington, DC 20007.

Contact Person: Harvey Stein, PhD, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard, Rockville, MD 20892, 301–496–7481.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.298, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 5, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–3478 Filed 2–11–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, SBIR Topic 173.