

submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. The draft guidance entitled "Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures: Submission Guidance for a 510(k)" will be available at <http://www.fda.gov/cdrh/ode/ed—rp.html>.

IV. Comments

Interested persons may, on or before December 9, 1998, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance.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 The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 25, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98-24243 Filed 9-9-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-3432-N]

Medicare Program; September 25, 1998, Open Town Hall Meeting To Discuss the Medicare Coverage Process

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a meeting to solicit comments from the public on proposed revisions to the process we use to make administrative coverage decisions in the Medicare program. Advance registration is required due to space limitations.

DATES: The meeting is scheduled for September 25, 1998 from 8:30 a.m. until 5:30 p.m., e.s.t.

ADDRESSES: The meeting will be held in the HCFA headquarters auditorium, 7500 Security Boulevard, Baltimore, Maryland, 21244.

FOR FURTHER INFORMATION CONTACT: Ron Milhorn (410) 786-5663

SUPPLEMENTARY INFORMATION: At present, in accordance with section 1862(a)(1)(A) of the Social Security Act,

we use a variety of mechanisms to make coverage decisions, including internal staff review, meetings and discussions with medical experts, and technology assessments. Until last year, we also used a Technology Advisory Committee, comprised of both HCFA and non-HCFA personnel, to discuss and receive advice about coverage issues. We disbanded the Technology Advisory Committee last year following concerns raised by the General Accounting Office about whether the Committee complies with the Federal Advisory Committee Act. We have developed a plan for establishing a new committee that fully complies with the Federal Advisory Committee Act. This committee will be more open and responsive to public participation. We are also taking other steps to make the coverage review process more open and to offer a more accessible and systematic means for advising the public about ongoing actions regarding coverage issues.

The meeting will consist of short HCFA presentations on several major topics central to the development of revisions to the coverage process followed by public discussion. The meeting will conclude with a question and answer session during which the public may raise any issues related to the topics discussed. While the meeting is open to the public, attendance is limited to space available. Therefore, individuals must register in advance, as described below.

Registration

Casals and Associates in Arlington, Virginia will handle registration for the meeting. Individuals may register by contacting Stacey Young at Casals and Associates by mail, fax, or Internet electronic mail. Please provide your name, title, firm name, address, telephone, fax, and Internet electronic mail address (if applicable).

- For mail registration, the address is: Casals and Associates, 2231 Crystal Drive, Suite 814, Arlington, Virginia, 22202, Attention: Stacey Young.

- For fax registration, the number is 703-920-5750.

- For registration by Internet electronic mail, the address is SYoung@Casals.com.

Casals and Associates will provide all registrants with a confirmation packet and background papers prior to the meeting.

We will accept written questions, comments, or other materials, either prior to, or within 14 days after the meeting. Address comments to: Ron Milhorn (S3-02-01), HCFA, 7500 Security Blvd., Baltimore, Md. 21244,

Telephone: 410-786-5663, FAX: 410-786-6857, E-Mail: Rmilhorn@hcfa.gov

There is no special format for the materials; however, we request that commenters be clear about the issue or aspect of the proposed process on which they have a question, comment, or suggestion.

After reviewing and analyzing the comments and suggestions we receive, we intend to prepare a notice for publication in the **Federal Register** setting forth the process for making administrative coverage decisions. Although our plans are to publish this notice in final form, we anticipate that we will provide a comment period and make any necessary revisions in the notice based on the comments we receive.

Authority: Federal Advisory Committee Act (5 U.S.C. App.2)

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

Dated: August 26, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council Notice of Re-establishment

Pursuant to the Federal Advisory Committee Act, Public Law 92-463 (5 U.S.C. Appendix 2), the Secretary, Department of Health and Human Services, announces the re-establishment of the following advisory committee.

Designation: HRSA AIDS Advisory Committee.

Purpose: Advises the Secretary and the Health Resources and Services Administration (HRSA) on its activities related to the support of health care services to persons living with HIV/AIDS and education of health professionals about HIV/AIDS. The Committee will support the Agency's process of identifying and responding to the health service delivery needs of affected communities and to the needs of individuals living with this disease.

Structure: The Committee shall consist of the Administrator, HRSA as Chair; ex-officio members: Director, Centers for Disease Control and