

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 The draft guidance entitled "Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures: Submission Guidance for a 510(k)" will be available at 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on or before December 9, 1998, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance.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 The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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](mailto: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](mailto: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.*

[FR Doc. 98-24291 Filed 9-9-98; 8:45 am]

BILLING CODE 4120-01-P

## 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

Prevention; Director, National Institutes of Health; Administrator, Health Care Financing Administration; Administrator, Substance Abuse and Mental Health Services Administration; Administrator, Agency for Health Care Policy and Research (or their AIDS Coordinators or designees) and such additional officers of the U.S. Government as deemed necessary for the Committee to effectively carry out its functions; and 14 members selected by the Secretary.

Members shall be invited to serve as follows: nine shall be authorities knowledgeable in the fields of health care delivery, State health programs, clinical care, preventive and public health, medical education, health services and clinical research, and health care financing; five shall be members of the general public, and at least three shall be persons living with HIV/AIDS. Members shall be invited to serve for overlapping four-year terms; terms of more than two years are contingent upon the renewal of the Committee by appropriate action prior to its termination.

Dated: September 3, 1998.

**James J. Corrigan,**

*Associate Administrator for Management and Program Support.*

[FR Doc. 98-24244 Filed 9-9-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Center for Substance Abuse Treatment; Notice of Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of a Teleconference Meeting of the Center for Substance Abuse Treatment (CSAT) National Advisory Council to be held in September 1998.

The meeting will include the review, discussion and evaluation of grants and cooperative agreement applications. Therefore, the meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App. 2, § 10(d).

A summary of the meeting and roster of council members may be obtained from: Mrs. Marjorie Cashion, CSAT, National Advisory Council, Rockwall II Building, Suite 619, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443-8923.

Substantive program information may be obtained from the contact below

whose name and telephone number are listed.

*Committee name:*—Center for Substance Abuse Treatment, National Advisory Council.

*Meeting date:*—September 22, 1998.

*Place:*—Center for Substance Abuse Treatment, 5515 Security Lane, 6th Floor Conference Room, Suite 617, Rockville, MD 20852.

*Type:*—Closed: September 22, 1998—2:30–3:30 p.m.

*Contact:*—Marjorie M. Cashion, Executive Secretary, Telephone: (301) 443-8923, and FAX: (301) 480-6077.

This notice is being published less than fifteen days prior to meeting date due to urgent needs to meet timing limitation imposed by review and funding cycle.

Dated: September 3, 1998.

**Jeri Lipov,**

*Committee Management Officer, Substance Abuse and Mental Health Services Administration.*

[FR Doc. 98-24273 Filed 9-9-98; 8:45 am]

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## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Notice of Extension of Comment Period for Technical/Agency Draft Multi-Species Recovery Plan for the Threatened and Endangered Species of South Florida

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of extension of public comment period.

**SUMMARY:** The Fish and Wildlife Service (Service) announces the extension of the public comment period for Volume II of the draft multi-species recovery plan for the threatened and endangered species of South Florida. A notice announcing the availability of Volume II was published in the **Federal Register** on July 13, 1998 (63 FR 37584).

**DATES:** The comment period, which originally closed on September 30, 1998, is now extended until October 31, 1998 for Volume II only. The comment period for Volume I (63 FR 11304) still closes on September 30, 1998. Comments on the draft recovery plan must be received on or before these dates to ensure consideration by the Service.

**ADDRESSES:** Copies of the draft recovery plan can be obtained by contacting the U.S. Fish and Wildlife Service Publications Unit, National Conservation Training Center, c/o Aramark, Rt. 1 Box 166, Shepherd Grade Rd., Shepherdstown, West Virginia 25443. The Service is encouraging that

requests for copies be for the CD-ROM version as the hard copy of Volume II encompasses approximately 900 pages. Additionally, the entire document may be viewed or downloaded from the Service's South Florida Ecological Service's Field Office website at: <http://www.fws.gov/r4eao/wildlife/esvb.html>.

Written comments and materials regarding the plan should be addressed to Dawn Jennings, South Florida Field Office, 1360 U.S. Highway 1, Suite 5, Vero Beach, Florida 32960. Comments and materials received are available on request for public inspection, by appointment, during normal business hours at the South Florida Field Office.

#### FOR FURTHER INFORMATION CONTACT:

Dawn Jennings at the South Florida Field Office (561) 562-3909 for information on the recovery plan; the U.S. Fish and Wildlife Service Publications Unit (304) 876-7203 for additional copies of the draft recovery plan.

#### SUPPLEMENTARY INFORMATION:

##### Background

Restoring endangered or threatened animals and plants to the point where they are again secure, self-sustaining members of their ecosystems is a primary goal of the Fish and Wildlife Service's threatened and endangered species program. To help guide the recovery effort, the Service prepares recovery plans for most of the listed species native to the United States. Recovery plans describe actions that may be necessary for conservation of these species, establish criteria for the recovery levels for reclassification from endangered to threatened status or removal from the list, and estimate the time and cost for implementing the needed recovery measures.

The Endangered Species Act of 1973 (Act), as amended (16 U.S.C. *et seq.*) requires the development of recovery plans for listed species unless such a plan would not promote the conservation of a particular species. Section 4(f) of the Act requires that public notice and an opportunity for public review and comment be provided during the recovery plan development. The Service will consider all information presented during a public comment period prior to approval of each new or revised recovery plan. The Service and other Federal agencies will take these comments into account in the course of implementing approved recovery plans.

The Multi-Species Recovery Plan identifies the recovery and restoration needs of 68 threatened and endangered