SUPPLEMENTARY INFORMATION:

I. Background

Reuse of SUD's is the practice of cleaning, disinfecting, sterilizing, and reusing medical devices that are intended for only one use. Reuse has raised concerns regarding patient safety, informed consent, and equitable regulation of reuse under the Federal Food, Drug and Cosmetic Act. On May 5 and 6, 1999, FDA and the Association for the Advancement of Medical Instrumentation cosponsored a conference on reuse of single-use devices to help examine policy alternatives regarding the practice of reuse. As a result of that meeting, FDA made the draft guidance entitled ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' available on November 3, 1999. Risk categorization of SUD's was one topic of discussion at an open meeting held by FDA on December 14, 1999. This document was the basis for the discussion at that meeting and is now being made more widely available for public comment. FDA expects to issue an updated draft of this guidance shortly and will also make that draft available for public comment.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the categorization of risk for SUD's. It does not create or confer any rights for or on any person and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 Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the draft guidance entitled ''Reprocessing and Reuse of Single-Use Devices: Risk Categorization Scheme'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at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 1156 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer. Updated on a regular basis, the CDRH home page includes ''Reprocessing and Reuse of Single-Use Devices: Risk Categorization Scheme,'' 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. ''Reprocessing and Reuse of Single-Use Devices: Risk Categorization Scheme'' will be available at http://www.fda.gov/cdrh/Reuse.

IV. Comments

Interested persons may, on or before May 2, 2000, submit to 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 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: January 23, 2000.

Linda S. Kahan,

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

[FR Doc. 00–2244 Filed 2–1–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3031–N]

Medicare Program; Meeting of the Executive Committee of the Medicare Coverage Advisory Committee—March 1, 2000

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting of the Executive Committee of the Medicare Coverage Advisory Committee (MCAC). The Committee provides advice and recommendations to us about clinical coverage issues. The Committee will hear reports from its subcommittee, and will discuss and consider the levels of evidence (including the types and presentation format of information) that it believes should be considered by the medical specialty panels of the MCAC at future public meetings. 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:* March 1, 2000, from 8 a.m. until 4 p.m., E.D.T.

Deadline for Presentation Submissions: February 10, 2000.

Special Accommodations: Persons attending the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance or accommodations, must notify the Executive Secretary by February 15, 2000.

ADDRESSES: *The Meeting:* The meeting will be held at the Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244.

Presentations and Comments: Submit formal presentations and written comments to Sharon Lappalainen, 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.

FOR FURTHER INFORMATION CONTACT: Sharon Lappalainen, Executive Secretary, (410) 786–9262.

SUPPLEMENTARY INFORMATION: On August 13, 1999, we published a notice (64 FR 44231) describing the Medicare Coverage Advisory Committee (MCAC), which provides advice and recommendations to us about clinical coverage issues. This notice announces the following public meeting of the MCAC:

Current Members of the Panel

Harold C. Sox, MD (Chairperson); Thomas V. Holohan, MD (FACP); Leslie P. Francis, JD, PhD; John H. Ferguson, MD; Robert L. Murray, PhD; Alan M. Garber, MD, PhD; Michael D. Maves, MD, MBA; David M. Eddy, MD, PhD; Frank J. Papatheofanis, MD, PhD; Ronald M. Davis, MD; Daisy Alford-Smith, PhD; Joe W. Johnson, DC; Robert H. Brook, MD, ScD; Linda A. Bergthold, PhD; Randel E. Richner, MPH.

Topic of the Meeting

The Committee will hear reports from its subcommittee, and will discuss and consider the levels of evidence (including the types and presentation

format of information) that it believes should be considered by the medical specialty panels of the MCAC at future public meetings.

Procedure and Agenda

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately one hour. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make a formal presentation, you must notify the For Further Information Contact, 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 Committee. After our presentation, the Committee will deliberate openly on the topic. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. At the end of the Committee deliberations, the Committee will allow a 30-minute open public session for any attendee to address issues specific to the topic. After which, the members will vote and the Committee 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: January 18, 2000.

Jeffrey L. Kang,

Director, Office of Clinical Standards and Quality, Health Care Financing Administration.

[FR Doc. 00–2313 Filed 2–1–00; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: State Prevention Needs Assessments: Alcohol and Other Drugs, Cohort V (New)—SAMHSA's Center for Substance Abuse Prevention (CSAP) has awarded contracts to several States (Cohort V) to collect data to assess the nature and extent of substance abuse prevention services needs. The data collection by these States will bring to 30 (Cohorts I–V) the number of States that have implemented a family of prevention needs assessment studies, and will constitute the third cohort to apply the core set of measures, instruments, and methodologies developed and standardized under prior State needs assessment State contracts.

Data will be collected in school surveys and community resource assessments (CRA). The information collected in this project will be combined with existing information from other sources; States may use multiple approaches to assess statewide and substate distributions of risk and protective factors for substance use, of prevention resources, and of prevention services needs. These needs assessment studies will permit cross-State comparison of risk and protection variables to assist State services planning and allocation of State Block Grant funds, and to assist Federal response to the Government Performance and Results Act (GPRA). The estimated annualized burden for the three-year project is shown below.

Respondents	Number of respondents	Responses per respondent	Average burden per response (hours)	Annualized burden hours
Students	137,500	1	0.75	103,125
Program Providers	1,410	1	1.00	1,410
Total	138,910	.....	.....	104,535
3-year Average	46,303	.....	.....	34,845

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16–105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 24, 2000.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 00–2213 Filed 2–1–00; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of Application for Endangered Species Permit

AGENCY: Fish and Wildlife Service, Interior.