To improve the safety of processed human dura mater, and based upon the committee's recommendations, on March 6, 1998, FDA sent letters to providers of processed human dura mater requesting that they implement specific measures that may be beyond their standard operating procedures. On April 16, 1998, FDA presented to the FDA TSE Advisory Committee proposed revisions to the committee recommendations from the October 6, 1997, meeting. These revisions took into consideration the responses from the processed human dura mater suppliers to the FDA letter of March 6, 1998. This guidance was prepared to replace the existing FDA guidance ''Guide for 510(k) Review of Processed Human Dura Mater'' dated June 26, 1990, and to incorporate the recommendations received from the FDA TSE Advisory Committee and the responses from manufacturers.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the preparation of a premarket notification for processed human dura mater. 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 This draft guidance document is issued as a Level 1 guidance consistent with GGP's. Public comment prior to implementation of this guidance document is not required because the guidance is needed to address a significant public health issue. However, the agency did solicit input from the FDA TSE Advisory Committee and processed human dura mater suppliers provided comments on FDA's approach in response to FDA's March 6, 1998, letter.

III. Electronic Access

In order to receive the ''Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater'' 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 the second voice prompt press 2, and then enter the document number (054) followed by the pound sign(#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW).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 web. Updated on a regular basis, the CDRH home page includes ''Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater,'' 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. The ''Guidance for the Preparation of a Premarket Notification Application for Process Human Dura Mater'' will be available at http://www.fda.gov/cdrh/ode/054.pdf.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1999.

Linda S. Kahan,

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

[FR Doc. 99–26720 Filed 10–13–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0262]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* The Adjusted Community Rate Proposal (ACRP) M+C Plan Benefit Package and Supporting Regulations in 42 CFR 417.401, 422.1–.10, 422.50–.80, 422.100–.132, 422.300–.312, 422.400–.404, and 422.560–.622; *Form No.:* HCFA–R–0262 (OMB #0938–0763); *Use:* The plan year 2000 pilot collection effort will be used to verify that the information collection instrument will produce the data HCFA needs to approve M+C plans in the future. Respondents include any M+C organization that intends to offer an M+C plan in calendar year 2000.

This collection will also allow the Agency to provide a totally automated submission and review capability, replace text with data format, establish a standard set of benefit descriptions/definitions, provide a framework to describe benefits, reduce variation in benefit descriptions, collect benefit information and Medicare Compare data with a single instrument, and eliminate the need to validate Medicare Compare data.; *Frequency:* Annual; *Affected Public:* Business or other for-profit, and Not-for-profit institution.; *Number of Respondents:* 300; *Total Annual Responses:* 300; *Total Annual Hours:* 600.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and

recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards; Attention: Julie Brown, Room N2–15–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850

Dated: October 5, 1999.

John Parmigiani,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–26829 Filed 10–13–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1092–N]

Medicare Program; October 29, 1999, Meeting of the Competitive Pricing Advisory Committee

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

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Competitive Pricing Advisory Committee (the CPAC) on October 29, 1999. The Balanced Budget Act of 1997 (BBA) requires the Secretary of the Department of Health and Human Services (the Secretary) to establish a demonstration project under which payments to Medicare+Choice organizations in designated areas are determined in accordance with a competitive pricing methodology. The BBA requires the Secretary to create the CPAC to make recommendations on demonstration area designation and appropriate research designs for the project. The CPAC meetings are open to the public.

DATES: The meeting is scheduled to meet on October 29, 1999, from 10 a.m. until 4 p.m., e.d.s.t.

ADDRESSES: The meeting will be held at the Marriott Wardman Park Hotel, 2660 Woodley Road, NW, Washington, DC 20008.

FOR FURTHER INFORMATION CONTACT: Sharon Arnold, Ph.D., Executive Director, Competitive Pricing Advisory Committee, Health Care Financing Administration, 7500 Security Boulevard C4–14–17, Baltimore, Maryland 21244–1850, (410) 786–6451.

SUPPLEMENTARY INFORMATION: Section 4011 of the Balanced Budget Act of 1997 (BBA) (Public Law 105–33), requires the Secretary of the Department of Health and Human Services (the Secretary) to establish a demonstration project under which payments to Medicare+Choice organizations in designated areas are determined in accordance with a competitive pricing methodology. Section 4012(a) of the BBA requires the Secretary to appoint a Competitive Pricing Advisory Committee (the CPAC) to meet periodically and make recommendations to the Secretary concerning the designation of areas for inclusion in the project and appropriate research design for implementing the project. The CPAC has previously met on May 7, 1998, June 24 and 25, 1998, September 23 and 24, 1998, October 28, 1998, January 6, 1999, May 13, 1999, July 22, 1999, and September 16, 1999.

The CPAC consists of 15 individuals who are independent actuaries, experts in competitive pricing and the administration of the Federal Employees Health Benefit Program, and representatives of health plans, insurers, employers, unions, and beneficiaries. The CPAC members are: James Cubbin, Executive Director, General Motors Health Care Initiative; Robert Berenson, M.D., Director, Center for Health Plans and Providers, HCFA; John Bertko, Actuary Principal, Reden & Anders Ltd.; David Durenberger, Vice President, Public Policy Partners; Gary Goldstein, M.D., Samuel Havens, Healthcare Consultant; Margaret Jordan, Healthcare Consultant; Chip Kahn, President, The Health Insurance Association of America; Cleve Killingsworth, President and CEO, Health Alliance Plan; Nancy Kichak, Director, Office of Actuaries, Office of Personnel Management; Len Nichols, Principal Research Associate, The Urban Institute; Robert Reischauer, Senior Fellow, The Brookings Institute; John Rother, Director, Legislation and Public Policy, American Association of Retired Persons; Andrew Stern, President, Service Employees International Union, AFL–CIO; and Jay Wolfson, Director, The Florida Information Center, University of South Florida. The chairperson is James Cubbin and the co-chairperson is Robert Berenson, M.D. In accordance with section 4012(a)(5) of the BBA, the CPAC will terminate on December 31, 2004.

The agenda for the October 29, 1999, meeting will include the following:

- A discussion on the status of the Kansas City and Phoenix Area Advisory Committee activities.
- Reports from the CPAC subcommittees.
- A review of the current implementation schedules.
- A discussion of the evaluation of the competitive pricing demonstration.

Individuals or organizations that wish to make 5-minute oral presentations on the agenda issues should contact the Executive Director, by 12 noon, October 26, 1999, to be scheduled. The number of oral presentations may be limited by the time available. A written copy of the oral remarks should be submitted to the Executive Director, no later than 12 noon, October 27, 1999. Anyone who is not scheduled to speak may submit written comments to the Executive Director, by 12 noon, October 27, 1999.

This meeting is open to the public, but attendance is limited to the space available.

(Section 4012 of the Balanced Budget Act of 1997, Public Law 105–33 (42 U.S.C.1395w–23 note) and section 10(a) of Public Law 92–463 (5 U.S.C. App.2, section 10(a))

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

Dated: October 7, 1999.

Michael M. Hash,

Deputy Administrator, Health Care Financing Administration.

[FR Doc. 99–26751 Filed 10–13–99; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3023–N]

Medicare Program; Meeting of the Laboratory and Diagnostic Services Panel of the Medicare Coverage Advisory Committee—November 15 and 16, 1999

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a meeting of the Laboratory and Diagnostic Services Panel (the Panel) of the Medicare Coverage Advisory Committee. The Panel will discuss presentations from interested persons regarding human tumor assay systems. This meeting is open to the public and complies with the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)).

DATES: *The Meeting:* November 15, 1999 from 8 a.m. to 4 p.m. and on November 16, 1999, from 8 a.m. to 12 noon, E.S.T.