methodology, controls, clinical endpoints, and data analysis. The committee will also discuss issues related to the development of guidance for refractive implants (phakic IOL's and corneal implants). The topics for discussion will include the scope of the proposed guidance, the maintenance of endothelial cell counts, and cataractogenesis due to the presence of an implant. As the materials become available, background information, questions for the panel, a bibliography for the PCO discussion, and an overview of the proposed clinical study section and questions for the panel for the refractive implants discussion will be made available to the public on FDA's website at http://www.fda.gov/ohrms/dockets/ac/cdrh00.htm#ophthalmicdevices.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 1, 2000. Oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:45 a.m. on May 11, 2000, and between approximately 8:45 a.m. and 9:15 a.m. on May 12, 2000. On May 11, 2000, near the end of the committee deliberations on the PMA, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 1, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 30, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–8600 Filed 4–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1128–N]

RIN 0938–AK01

Medicare Program; Process for Requesting Recognition of New Technologies and Certain Drugs, Biologicals, and Medical Devices for Special Payment Under the Hospital Outpatient Prospective Payment System

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

ACTION: Notice.

SUMMARY: We expect to implement a prospective payment system for hospital outpatient services for the Medicare program on July 1, 2000. This system will recognize new technology as discrete payment groups within the ambulatory payment classification (APC) system. This payment system will also provide for additional payments to hospitals at amounts higher than the amounts that would otherwise be paid for certain specified items, such as: orphan drugs; drugs, biologic agents, and brachytherapy devices used for the treatment of cancer; radiopharmaceutical drugs and biologic products; and certain new or innovative medical devices. We have identified items or services for inclusion in the new technology APC groups, as well as items potentially eligible for special additional payments. This notice addresses the process that interested parties must use to submit additional items for consideration.

FOR FURTHER INFORMATION CONTACT: Diane Milstead, (410) 786–3355.

SUPPLEMENTARY INFORMATION: We expect to implement a prospective payment system (PPS) for hospital outpatient services for Medicare on July 1, 2000. One aspect of this system will be to develop a process to recognize new technologies on an ongoing basis in a timely manner, and to establish special payments for a number of specified items, in accordance with section 201 of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), enacted on November 29, 1999. New technologies refer to services and items that have emerged since 1996, and therefore are not reflected in the cost data that are being used to develop our PPS. Additionally, section 201(b) of the BBRA requires us to make additional payments to hospitals for a period of 2 to 3 years for specific items at amounts higher than the amounts that would otherwise be paid under the hospital outpatient PPS for items in the following categories: (a) current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; (b) current drugs, biologic agents, and brachytherapy devices used for the treatment of cancer; (c) current radiopharmaceutical drugs and biologicals; and (d) new or innovative medical devices, new drugs, and biologic agents, in instances when we were not paying for the item as a hospital outpatient service as of December 31, 1996, and when the cost is ''not insignificant'' in relation to the hospital outpatient PPS payment amount. In this context, ''current'' refers to those items for which we are making hospital outpatient payment on the first date the new PPS is implemented.

We will include these items and services within payment groups called ambulatory payment classifications (APCs), which will be used in the payment system for hospital outpatient services. In addition to the APC-related payments, however, hospitals may receive additional payment for specified items. In order to appropriately assign items to the new technology APCs and make special payments for the relevant drugs, biologicals, and medical devices, we must be able to identify the specific items and services, and ensure that HCFA Common Procedure Coding System (HCPCS) codes are established for them. To facilitate this activity, we have placed on our Internet site at *http://www.hcfa.gov/medicare/hopsmain.htm* the following information:

(a) A list of those items and services that we have already identified as potentially eligible for special payments or treatment as a new technology service; and

(b) The procedures interested parties must follow to bring to our attention additional items that may be eligible.

If you cannot access this information on our Internet site, you may request a paper copy by contacting Joan Briscoe in the Division of Practitioner and Ambulatory Care at (410) 786–4495.

Authority: Section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)).

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

Dated: February 21, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Approved: March 31, 2000.

Donna E. Shalala,

Secretary.

[FR Doc. 00–8744 Filed 4–6–00; 8:45 am]

BILLING CODE 4120–01–P