• Clinical description of the service under discussion, with comparison to other services within the APC;

• Description of the resource inputs associated with the service under discussion, with a comparison to other services within the APC;

• Recommendations and rationale for change; and

• Expected outcome of change and potential consequences of no change.

Further details can be found on our web site at *http://www.hcfa.gov/fac/apcpage.htm*. Presentations submitted without the required data and information will not be considered.

In order to be scheduled to speak, this information must be received no later than 5 p.m., Tuesday, January 8, 2002 at the above address. Alternatively, the information may be sent electronically to the email address specified above. Because of staffing and resource limitations, we cannot accept this information by facsimile (FAX).

Presentations are limited to no more than 5 minutes and must be on the listed agenda topics only. The number of presentations may be limited by the time available.

In addition to formal presentations, there will be an opportunity during the meeting for public comment, limited to 1 minute for each individual or organization. The number of speakers may be limited by the time available.

Any persons wishing to attend this meeting located on Federal property must call the meeting coordinator, Angela Mason, at (410) 786–7452 to register at least 72 hours in advance. Persons attending must show a photographic identification to the Federal Protective Service or Guard Service personnel before they will be allowed to enter the building. Persons not registered in advance will not be permitted into the building and will not be permitted to attend the meeting. News media representatives should contact the CMS Press Office at (202) 690–6145.

Individuals requiring sign language interpretation for the hearing impaired or other special accommodations should contact the meeting coordinator at least 10 days before the meeting.

Authority: Section 1833 of the Social Security Act (42 U.S.C. 1395l) and section 10(a) of Public Law 92–463 (5 U.S.C. App. 2, section 10(a)); 45 CFR part 11)

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

Dated: December 11, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 01–30990 Filed 12–13–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers For Medicare & Medicaid Services

[CMS–4031–N]

Medicare Program; Open Public Meeting on January 16, 2002 to Discuss Activities Related to the Collection of Diagnostic Data from Medicare+Choice Organizations for Risk Adjustment

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting to provide Medicare+Choice Organizations (M+COs), providers, practitioners, and other interested parties an opportunity to ask questions and raise issues regarding the risk adjustment model that will be selected for use beginning in 2004 and reporting requirements for diagnostic information. The purpose of the meeting is to provide information about risk adjustment model options and associated data collection issues and to allow for public comment regarding the models and data collection.

DATES: The meeting is scheduled for January 16, 2002 from 9 a.m. until 4 p.m., EST.

ADDRESSES: The meeting will be held in the CMS Auditorium, 7500 Security Boulevard, Baltimore, Maryland, 21244–1850.

FOR FURTHER INFORMATION CONTACT: Bobbie Knickman at (410) 786–4161. To submit public comment no later than February 1, 2002, email: Bobbie Knickman at *bknickman@cms.hhs.gov* or fax to (410) 786–1048.

SUPPLEMENTARY INFORMATION:

Background

The Balanced Budget Act of 1997 (BBA) (Public Law 105–33) established the Medicare+Choice program that significantly expanded the health care options available to Medicare beneficiaries. Under the BBA, the Secretary of the Department of Health and Human Services (the Secretary) must implement a risk adjustment methodology that accounts for variations in per capita costs based on health status and other demographic factors for payment to Medicare+Choice organizations (M+COs). The BBA also gives the Secretary the authority to collect inpatient hospital data for discharges on or after July 1, 1997, and additional data for other services occurring on or after July 1, 1998. Risk adjustment implementation began January 1, 2000. Payments to M+COs are made at 10 percent risk adjusted rates and 90 percent demographically adjusted rates for years 2000 through 2003. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA), enacted in December 2000, stipulates that the risk adjustment methodology for 2004 and succeeding years should be based on data from inpatient hospital and ambulatory settings. BIPA contains a provision that phases in future risk adjusted payments as follows: 30 percent in 2004; 50 percent in 2005; 75 percent in 2006; and 100 percent in 2007. The collection of physician encounter data, which began on October 1, 2000, and hospital outpatient encounter data, which began on April 1, 2001, was suspended on May 25, 2001 through July 1, 2002. The Secretary indicated that we will be working closely with all interested parties to explore and implement a risk adjustment process for M+C payments that balances accuracy with administrative burden. The meeting will address the following topics:

• Risk adjustment models incorporating ambulatory and inpatient diagnoses;

• Collection/reporting of beneficiary and diagnostic information for Medicare+Choice enrollees in hospital inpatient, outpatient, and physician settings for use in risk adjustment models; and

• Data issues.

The agenda will include presentations by our staff and a question and answer sessions. Written public comments are preferred following the meeting and will be accepted until February 1, 2002.

Registration

Registration for this public meeting is required and will be on a first-come, first-serve basis, limited to two attendees per organization. A waiting list will be available for additional requests. The registration deadline will be January 11, 2002 at 5:00 pm. EST. Registration will be done via the Internet at *http://www.hcfa.gov/events/events.htm*. A confirmation notice will be sent to attendees upon finalization of registration.

Persons who are not registered in advance will not be permitted into the Federal Building and thus not be able to attend the meeting. Persons attending the meeting will be required to show a photographic identification, preferably a valid drivers' license before entering the building. Please note that if the meeting is cancelled we will post that information on our website.

Attendees will be provided with meeting materials at the time of the meeting. Written meeting materials will be posted on the CMS website before the January 16, 2002 meeting at: *http://www.hcfa.gov* and *http://www.cms.hhs.gov.* We will accept written questions about meeting logistics or requests for meeting materials either before the meeting or up to 14 days after the meeting. Written submissions must be sent to:

Aspen Systems Corporation, ATTN: Kim Slaughter, 2275 Research Boulevard, Mail Stop 5W, Rockville, Maryland 20850.

You may also contact Encounter Data Representative: Kim Slaughter, Telephone Number: (301) 519–5388, Fax Number: (301) 519–6360, E-mail: *encounterdata@aspensys.com.*

Written public comments will be accepted until February 1, 2002. Written public comments should be sent to Bobbie Knickman at bknickman@cms.hhs.gov or fax to (410) 786–1048.

(Authority: Sections 1851 through 1859 of the Social Security Act (42 U.S.C. 1395w–21 through 1395w–28))

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

Dated: December 11, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 01–30991 Filed 12–13–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0393]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Prescription Drug Product Labeling; Medication Guide Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by January 14, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug Product Labeling; Medication Guide Requirements (OMB Control No. 0910–0393)—Extension

FDA regulations require the distribution of patient labeling, called Medication Guides, for certain prescription human drug and biological products used primarily on an outpatient basis that pose a serious and significant public health concern requiring distribution of FDA-approved patient medication information. These Medication Guides inform patients about the most important information they should know about these products in order to use them safely and effectively. Included are information such as the drug's approved uses, contraindications, adverse drug reactions, and cautions for specific populations, with a focus on why the particular product requires a Medication Guide. These regulations are intended to improve the public health by providing information necessary for patients to use certain medication safely and effectively.

The regulations contain the following reporting requirements that are subject to the PRA. The estimates for the burden hours imposed by the following regulations are listed in table 1 of this document:

21 CFR 208.20—Applicants must submit draft Medication Guides for FDA approval according to the prescribed content and format.

21 CFR 314.70(b)(3)(ii) and 601.12(f)—Application holders must submit changes to Medication Guides to FDA for prior approval as supplements to their applications.

21 CFR 208.24(e)—Each authorized dispenser of a prescription drug product for which a Medication Guide is required, when dispensing the product to a patient or to a patient's agent, must provide a Medication Guide directly to each patient unless an exemption applies under § 208.26 (21 CFR 208.26).

Section 208.26(a)—Requests may be submitted for exemption or deferral from particular Medication Guide content or format requirements.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
208.20	8	1	8	242	1,936
314.70(b)(3)(ii) and 601.12(f)	3	1	3	24	72
208.24(e)	55,000	8.3	460,000	.0014	644
208.26(a)	1	1	1	4	4
Total					2,656

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In the **Federal Register** of September 25, 2001 (66 FR 49024), the agency requested comments on the proposed collections of information. FDA received one comment on the September 25, 2001, notice. The