

has been identified as a barrier to performance measurement for this goal. Therefore, the Office of Minority Health is proposing a study which will examine States' laws and policies concerning the collection and use of

racial and ethnic data by health insurers and managed care plans. The study involves visits to 20 States for an in-depth look at their policies and practices, interviews with State officials and representatives of the States' major

managed care plans and health insurance industry. *Respondents:* State or local governments; businesses or other for-profit; non-profit institutions.

BURDEN INFORMATION

Instrument	Number of respondents	Burden per response	Burden hours
Administrator Interview Guide	120	4	480

OMB Desk Officer: Allison Herron Eydtt.
Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 690-6207. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address:

Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street, NW., Washington, DC 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. Written comments should be received within 30 days of this notice.

Dated: May 29, 2002.

Kerry Weems,

Acting Deputy Assistant Secretary, Budget.

[FR Doc. 02-14284 Filed 6-6-02; 8:45 am]

BILLING CODE 4150-29-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request the Office of Management and Budget (OMB) to allow the proposed information collection project: "Enrollee Survey of Relationship Between Out-of-Pocket Costs and Use of Prescribed Medications". In accordance with the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C.

3506(c)(2)(A)), AHRQ invites the public to comment on this proposed information collection.

The proposed information collection was previously published in the **Federal Register** on April 3, 2002 and allowed 60 Days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 Days for public comment.

DATES: Comments on this notice must be received by July 8, 2002.

ADDRESSES: Written comments should be submitted to: OMB Desk Officer at the following address: Allison Eydtt, Human Resources and Housing Branch, Office of Information and Regulatory Affairs, OMB: New Executive Office Building, Room 10235; Washington, DC 20503.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of the proposed information collection. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Cynthia D. McMichael, AHRQ Reports Clearance Officer, (301) 594-3132.

SUPPLEMENTARY INFORMATION:

Proposed Project

"Enrollee Survey of Relationship Between Out-of-Pocket Costs and Use of Prescribed Medications"

The project is being conducted in response to an AHRQ task order entitled "Patient Safety and the Quality of Care: An Examination of Economic and Structural Characteristics, Working Conditions, and Technological Advances" (issued under Contract 290-00-0012: Accelerating the Cycle of Research through a Network of Integrated Delivery Systems with the Center for Health Care Policy and Evaluation, UnitedHealth Group, Minnetonka, MN).

Past research suggests that increases in out-of-pocket costs are associated with decreased medication use by the elderly patients who have a drug benefit.

Furthermore, reductions in medication use have been associated with increases in visits to physicians' offices and emergency departments and admissions to hospitals and long-term care facilities.

When Medicare beneficiaries alter their use of prescription medications in response to their out-of-pocket costs, patient safety and quality of care may be compromised.

As suggested by OMB, we have been in communication with the Center for Medicare & Medicaid Services (CMS) (contact: Frank Eppic Deputy Director, Information and Methods Group, ORDI, tel: 410-786-7950 or FEppic@hcfa.org) regarding the availability of data on this topic, particularly CMS's Medicare Current Beneficiary Survey (MCBS).

Examination of raw response frequencies on the 1999 MCBS survey indicate that fewer than 2% (319/16670 total respondents) cite costs or lack of coverage as primary reasons for not getting a prescription filled. This small percentage seems to be inconsistent with other reports on the inadequacy of drug benefits for the elderly. However, the MCBS does not inquire whether Medicare beneficiaries get prescriptions filled, but take less medication than prescribed because of out-of-pocket costs or caps on drug benefits. In addition, the amount of drug coverage is not ascertained. Since data to determine the prevalence of cost-related reductions in medication use under different drug benefits and subsequent worsening health or increased use of health care services are sparse, additional research on this important issue is warranted.

The proposed study will utilize the Center for Health Care Policy and Evaluation's administrative database that includes several Medicare+Choice health plans that have provided a limited drug benefit in 2002.

Data collected by survey will determine how often out-of-pocket costs or caps incurred under the available drug benefit caused Medicare beneficiaries to alter their use of prescription medicines including not

getting a prescription filled or refilled or taking reduced doses. These are the dependent variables for the study. Survey data will be used to identify medications that have not been taken or reduced and alternatives that have been used to make judgements about the potential clinical consequences of any changes in medication-taking behavior.

In addition, respondents' perceptions of the effects of any changes in medication use on their health status and utilization of other services (physician visits, emergency department visits and hospital admissions) will be ascertained. Several potential correlates will be assessed as well, most of which are based on previous studies of medication use in elderly population. Other key variables will be extracted from administrative (enrollment and claims) data including age, gender, identity of the health plan, duration of enrollment, number of prescription claims, types of medications, prescription co-payments, number of physician visits and hospital admissions during the period prior to the survey.

Data Confidentiality Provisions

Assurances of confidentiality will be given to participants within the informed consent form that each person will sign prior to participation (see Appendix 1). These assurances explain the applicability of AHRQ's confidentiality statute, 42 U.S.C. 299c-3(c). (see Appendix 2). The consent form will be reviewed, modified if requested and approved by an Institutional Review Board and sent to survey recipients along with the survey (see Appendix 3).

The Center for Health Care Policy and Evaluation has an extensive security program in place to safeguard the privacy and confidentiality of data. This multi-tiered program, comprised of both policies and specific procedures, promotes compliance with all legal and regulatory requirements for privacy protection of individually identifiable health information. Building and office access cards and computer identification codes and passwords are in operation. Encryption and authentication are utilized where control over sensitive information is required including file transfers (e.g., FTP) and data processing applications. Automated monitoring (network and platform intrusion detection) and system firewalls are established for all major network interface points.

Additional confidentiality procedures include: (1) Written agreements with a subcontractor hired to administer the questionnaire; (2) use of key-code processes and encryption to protect

individual identity of data records in the Center for Health Care Policy and Evaluation's administrative database; (3) use of study-specific keys for data transmission and linkage of sample information and survey data; (4) efforts to ensure that the least sensitive level of data possible is used or transmitted in the conduct of research;

(5) destruction of data files after completion of the research project, approximately one year after the final report is filed under the task order or one year after a journal article is published based upon the final report, whichever is later (to allow access to assist other scientists seeking to validate or replicate results); and (6) written policies and procedures and training of employees in regards to protection of human subjects and data confidentiality.

Data Products

Data will be produced in the following forms:

1. A file will be developed comprising the sample from the Center for Health Care Policy and Evaluation's database of enrollment and claims to be used to collect the survey data. The sample file will contain an investigator-assigned, study specific case identity code that will allow the survey results file to be linked back to the administrative data.

2. A second file will include information on the final disposition of all cases and survey responses along with variables derived from administrative data. This file will be analyzed to generate research reports. The proportion (probability) that an individual in the study population altered his/her prescription medication-taking behavior because of out-of-pocket costs or limits on drug benefits will be estimated with 95% confidence intervals.

The probabilities of altered medication use secondary to out-of-pocket costs or caps on drug benefits will be analyzed separately. Since the sampling design provides equal probabilities of selection without cluster techniques, design effects do not need to be taken into consideration during estimation of the probabilities and confidence intervals (variance).

The finite population correction factor should also be negligible. Missing data on partially completed surveys will be imputed. Estimates and tests of potential explanatory variable will be generated by two-step regression models in an effort to control non-response bias.

The data are intended to be used for purposes such as:

1. Providing information about the extent and correlates of reduced

prescriptions drug use to help define the circumstances when out-of-pocket costs might become a quality/safety issue.

2. Helping to inform policymakers about how current drug benefits being provided by Medicare+Choice plans affect patients' quality of care.

3. Informing the design of drug benefits for Medicare beneficiaries that foster quality care by considering financial barriers to effective use of pharmaceuticals.

Method of Collection

The population to be studied consists of individuals enrolled in the Center for Health Care Policy and Evaluation's UnitedHealthcare Medicare+Choice health plans that provide a drug benefit in 2002, from which sample will be drawn and surveyed.

The Center for Health Care Policy & Evaluation maintains a database comprised of enrollment and claims data generated by these health plans. Actual 2002 enrollment will be used for sampling. None of drug benefits being studied require a deductible and all will use the same formulary or preferred drug list.

Investigators will use the enrollment and claims database to define the sampling frame for the study. Pharmacy claims will not be used for sample selection because they would be missing if enrollees do not get prescriptions filled, and selecting people because they had a pharmacy claim could bias estimates of cost-altered medication use. Since medication use and out-of-pocket prescription costs are related to the presence of chronic conditions, selection of enrollees will be based on diagnoses listed in the administrative data. The focus will be on medical conditions that are common in the elderly population for which medications are often prescribed including hypertension, hyperlipidemia (high cholesterol), coronary artery disease, congestive heart failure, diabetes, arthritis, glaucoma and gastrointestinal ulcers.

The presence of one or more of these diagnoses on claims from physician visits or hospital admissions that occur in the first quarter of 2002 will be used to create a sampling frame. This will help assure that sampled enrollees have recently seen a physician who has acknowledged the presence of the condition and a high likelihood of having been prescribed medication. Eligible health plan members must also be enrolled during the entire first quarter of 2002 to facilitate collection of administrative variables for the analysis.

The sample of eligible enrollees will be stratified by health plan and a simple

random sample will be selected from each health plan using a proportionate (uniform) sampling fraction.

Mission sampling frame elements are not expected to be a problem, and anyone excluded from the sampling frame because of missing diagnoses due to claims lags will be considered missing at random because physician and hospital claim lags should be totally independent of cost-related changes in medication-taking behavior.

The sample file will contain an investigator-assigned, study specific case identity code that will allow the survey results file to be linked back to

the administrative data. Checks for changes in address will be made and survey packets prepared. A cover letter from the investigators will invite Medicare beneficiaries enrolled in UnitedHealthcare Medicare+Choice health plans to participate in the study, and a written consent form approved by a duly constituted Institutional Review Board will be sent along with the survey questionnaire. Two mailings with a postcard reminder sent in the interim period and follow-up calls to non-responders after the second survey mailing are planned to obtain a response rate similar to the Medicare Consumers

Assessment of Health Plans Survey response rate of 75% to 82%. Respondents will not receive any gifts or payments as incentives to respond.

Estimated Annual Respondent Burden

This is a one-time survey with 24 multiple choice questions, plus one question that asks respondents to name any medication(s) they did not use as prescribed because of cost, plus one question that asks respondents to name the medication(s), if any, that they used as alternative(s) to the medication(s) that cost too much. The survey will be conducted in 2002.

Survey year	Number of respondents	Estimated time per respondent in hours	Estimated total burden hours	Estimated cost to the government
2002	1,125	.25	281	\$35,000

Request for Comments

In accordance with the above cited legislation, comments on the AHRQ information collection proposal are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden (including hours and costs) 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 the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: May 15, 2002.

Carolyn M. Clancy,
Acting Director.

[FR Doc. 02-14382 Filed 6-6-02; 8:45 am]

BILLING CODE 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Cooperative Agreements for Prevention Research Centers, Program Announcements 98047 and 01101

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements for Prevention Research Centers, Program Announcements 98047 and 01101, meeting.

Times and Dates: 8:30 a.m.—8:55 a.m., June 25, 2002 (Open); 9 a.m.—5 p.m., June 25, 2002 (Closed); 8 a.m.—5 p.m., June 26, 2001 (Closed).

Place: Sheraton Colony Hotel, 188 14th Street, N.E., Atlanta, GA 30361.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Deputy Director for Program Management, CDC, pursuant to Public Law 92-463.

Matters to Be Discussed: The meeting will include the review, discussion, and evaluation of award applications received in response to Program Announcements #98047 and 01101.

For Further Information Contact: Mike Waller, Deputy Branch Chief, Healthcare and Aging Studies Branch, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 4770 Buford Highway, m/s K45,

Atlanta, GA., 30341. Telephone 770.488.5269, e-mail mnw1@cdc.gov.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: June 3, 2002.

Joseph E. Salter,

Acting Director, Management Analysis and Services Office, CDC.

[FR Doc. 02-14323 Filed 6-6-02; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Community-Based Participatory Prevention Research, Program Announcement #02003

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Community-Based Participatory Prevention Research, Program Announcement #02003.

Times and Dates: 5 p.m.—6 p.m., June 24, 2002 (Open); 6:15 p.m.—8 p.m., June 24, 2002 (Closed); 8 a.m.—5 p.m., June 25, 2002 (Closed); 8 a.m.—4 p.m., June 26, 2002 (Closed).

Place: Holiday Inn Select, 130 Clairmont Avenue, Decatur, Georgia.