Study participants will be persons between 25–70 years old who have health insurance and have had a visit to a doctor in the last 12 months. The quality information presented to study participants in this laboratory experiment evaluating design alternatives will consist of mock data on consumers' assessments of the care provided by their physicians. The quality information will contain measures of physician performance, with candidate measures including how well the doctor scored on (1) listening carefully to patients; (2) giving explanations that are easy to understand; (3) spending enough time with patients; and (4) treating patients with courtesy and respect. The quality information also will include ratings of doctor's staff, for example, office staff that are as helpful as they should be and office staff who treat patients with courtesy and respect.

Finally, the quality information will include measures of access to care, such as being able to make appointments as soon as needed, a reasonable amount of time waiting in the doctor's office, and access to extended hours of service. The exact quality measures on which we will present information will be determined during preliminary testing.

Data Confidentiality Provisions

To protect subject confidentiality, the following procedures will be employed:

- Upon arriving at the testing location and prior to participation, each subject will receive and sign the consent form, approved by the grantee's Institutional Review Boards, that contains information about their rights as a subject and the measures being taken to safeguard confidentiality. A test administrator will verbally repeat and explain the information in the form at the beginning of the testing session. Subjects will be informed that their participation is voluntary and that they have the right to refuse to answer any questions or to stop participating at any point during the testing session.
- All subject materials will be marked with a unique ID number, rather than the subject's names. Subjects' names will never be linked with their individual answers. Any information linking subject names and ID numbers will be kept in a secure location and will be accessible only to members of the project team. Subject names will not be shares with anyone outside of the project team.
- All information will be aggregated and reported at the group, rather than the individual, level.
- During portions of the testing session that will be video-taped (*i.e.*, the taping of the "choose a doctor'' and comprehension questions to gather timing data), we will refer to the subjects by first name only. The videotapes will be marked with subject ID numbers and will be stored in a secure location. The tapes will be used only for analysis purposes by project team members.
- Subjects will be informed that participation is voluntary.
- All completed subject materials (*e.g.*, recruitment screeners, questionnaires, tapes, consent forms, incentive receipt forms) will be kept in a secure location accessible only to members of the project team.
- All completed questionnaires, video tapes and other subject materials will be destroyed no later than 12 months following the end of the CAHPS II project.

Methods of Collection

The data will be collected using a pencil and paper.

Estimated Annual Respondent Burden

Survey	Number of respondents	Estimated time per respondent hours	Estimated total burden hours	Estimated annual cost to the government
A. Potential participants who did not enroll in study	100	.10	10	$1000
B. Potential participants who did enroll in study	350	.25	62.5	6250
C. Actual number of participants in laboratory experiment (subset of B)	210	2.0	420	39500
Total (A+B)	350	1.4	492.5	46,750

Request for Comments

In accordance with the above cited Paperwork Reduction Act legislation, comments on AHRQ's information collection 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 AHRQ, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including ours and cost) 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 upon the 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: April 2, 2004.

Carolyn M. Clancy,

Director

[FR Doc. 04–9191 Filed 4–22–04; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Section 1013: Suggest Priority Topics for Research

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice to suggest priority topics for research.

SUMMARY: AHRQ, on behalf of the Department of Health and Human Services, invites suggestions from interested organizations and knowledgeable individuals regarding the highest priorities for research, demonstration, and evaluation projects to support and improve the Medicare, Medicaid, and State Children Health Insurance (SCHIP) programs.

DATES: The statutory deadline for development of the initial priority list and the need to consider the FY 2006 priority list during this summer's budget development process requires expedited timelines for formulation of the initial and FY 2006 priority lists. Research recommendations must be received by May 7, 2004, to be considered for the initial priority list and by July 1, 2004,

to be considered for the FY 2006 priority list.

ADDRESSES: Recommendations for consideration and possible inclusion in the initial priority list and/or the FY 2006 priority list may be submitted to the Department through the U.S. Food and Drug Administration (FDA) Dockets Management Division at: *http://www.fda.gov/dockets/ecomments.*

The Docket ID for this request is 2004S–0170 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Section 1013: Suggest Priority Topics for Research.

FOR FURTHER INFORMATION CONTACT: Questions about the comment process should go to the FDA Dockets Management Division, (301) 827–6860. Hours are 9 a.m. to 4 p.m., Eastern Time, Monday through Friday.

Copies of E-Comments received through the FDA Dockets system are available on the FDA Web site at: *http://www.fda.gov/ohrms/dockets/dockets/dockets.htm.*

SUPPLEMENTARY INFORMATION:

1. Background

Section 1013 of Medicare Prescription Drug, Improvement, and Modernization Act of 2003 authorizes research, demonstrations, and evaluations to improve the quality, effectiveness, and efficiency of the Federally administered Medicare program and of two programs for which funding and administration is shared with the States: Medicaid and SCHIP.

The research and other activities undertaken and authorized by this provision may address:

(1) The outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs); and

(2) Strategies for improving the efficiency and effectiveness of Medicare, Medicaid, and SCHIP programs, including the ways in which health care items and services are organized, managed, and delivered under such programs.

The statute:

(a) Requires the establishment of a priority setting process for identifying the most important topics to address,

(b) Establishes a timetable for development of an initial priority list and completion of the research, and

(c) Requires ongoing consultation with relevant stakeholders.

To review the text of section 1013, ''Research on outcomes of health care items and services,'' go to: *http://www.medicare.gov/MedicareReform/108s1013.pdf.*

2. The Priority Setting Process

Recommendations for research that are made by the Centers for Medicare & Medicaid Services (CMS), the States, and other stakeholders will be reviewed and prioritized by a steering committee composed of representatives from the following components of the U.S. Department of Health and Human Services:

- Office of [the] Assistant Secretary for Budget, Technology, and Finance (ASBTF),
- Office of [the] Assistant Secretary for Planning and Evaluation (ASPE),
- Agency for Healthcare Research and Quality (AHRQ, the agency designated by the statute to carry out the research);
- Centers for Medicare & Medicaid Services (CMS);
- Food and Drug Administration (FDA); and,
- Other components of the Office of the Secretary.

If issues arise for which the expertise of other components of the U.S. Department of Health and Human Services or other Federal departments would be helpful in prioritizing suggested research topics, representatives from those entities will be added to, or consulted by the steering committee as warranted.

Steering committee staff will prepare a preliminary ranking of suggested topics for study, taking into consideration factors suggested by the terms of section 1013(a)(2)(C): *i.e.,* health care items or services that impose high costs on Medicare, Medicaid or SCHIP programs, those which may be underutilized or overutilized and those which may significantly improve the prevention, treatment or cure of diseases and conditions which impose high direct or indirect costs on patients or society.

3. Timetable

Section 1013 requires the development of an initial priority list six months after enactment of the legislation (June 2004) and completion of the initial research syntheses 18 months thereafter (December 2005), one month before the effective date of the prescription drug benefit.

The statute does not establish timetables for priority-setting after the initial list or the completion of subsequent research. Because the statute requires annual appropriations for funding the research and other activities authorized by this section, the Department will link the timetable for the priority-setting process for FY 2006 and subsequent years to its process for development of the Department's budget.

4. Stakeholder Consultation

The statute requires a broad, ongoing process of consultation with relevant stakeholders. Because two of the programs addressed by the statute are administered by the States, the Department will work with the States to develop an effective process for identifying their priority recommendations for research.

To meet the requirement for ongoing consultation with other stakeholders, the Department will issue a specific solicitation for research recommendations every year, will permit stakeholders to submit research recommendations throughout the year, and will host a series of listening sessions with different sectors of the health care community to provide additional opportunities for submitting recommendations. Information regarding the initial ''listening sessions'' will be announced shortly.

5. Requirements

Scope of recommendations: While the statute does not limit the scope of the initial priority list, recent congressional activity suggests that the initial priority list should be directed toward evaluating existing evidence regarding the comparative clinical effectiveness of prescription drugs in anticipation of the Medicare prescription drug benefit. Therefore, the Department requests that recommendations for the initial priority list focus on prescription drugs, although all recommendations will be considered. Submissions for the FY 2006 priority list may address other health care items or services as well, or program improvement strategies for organizing, managing, or delivering those items or services.

Justification: Because section 1013 is intended to fund research to improve the ''quality, effectiveness, and efficiency'' of the Medicare, Medicaid, and SCHIP programs, each submission must justify and explain how each recommended research project will contribute to that goal and why it should be considered a ''priority.'' With respect to research suggestions regarding prescription drugs, recommendations should include a rationale regarding potential impact of the research and might also address the most useful approaches for analyzing and presenting that evidence (*e.g.,* by disease or condition or by drug class and, if so, under which drug classification system).

Identification of affiliation: Individuals who are submitting recommendations on behalf of a ''stakeholder organization,'' such as a

provider, purchaser, supplier, or insurer of health care items or services, or those receiving services under the Medicare, Medicaid or SCHIP programs are invited to identify their organizational affiliation. This will enable the Department of assess the effectiveness of its efforts to ensure broad consultation with relevant stakeholders.

Dated: April 16, 2004.

Carolyn M. Clancy,

Director.

[FR Doc. 04–9190 Filed 4–22–04; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–04–44]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498–1210.

Comments are invited on: (a) Whether the proposed collection of information is 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. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–E11, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

Evaluation of Efficacy of Household Water Filtration/Treatment Devices in Households with Private Wells—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Approximately 42.4 million people in the United States are served by private wells. Unlike community water systems, private wells are not regulated by the U.S Environmental Protection Agency's (EPA) Safe Drinking Water Act (SDWA). Under the SDWA, EPA sets maximum contaminant levels (MCLs) for contaminants in drinking water. A 1997 U.S. General Accounting Office (GAO) report on drinking water concluded that users of private wells may face higher exposure levels to groundwater contaminants than users of community water systems. Increasingly, the public is concerned about drinking water quality, and the public's use of water treatment devices rose from 27% in 1995 to 41% in 2001 (*Water Quality Association, 2001 National Consumer Water Quality Survey*). Studies evaluating the efficacy of water treatment devices on removal of pathogens and other contaminants have assessed the efficacy of different treatment technologies.

The purpose of the proposed study is to evaluate how water treatment device efficacy is affected by user behaviors such as maintenance and selection of appropriate technologies. Working with public health authorities in Florida, Colorado, Maine, Missouri, Nebraska, New Jersey, and Wisconsin, NCEH will recruit 600 households to participate in a study to determine whether people using water treatment devices are protected from exposure to contaminants found in their well water. We plan to recruit households that own private wells and use filtration/treatment devices to treat their tap water for cooking and drinking. Study participants will be selected from geographical areas of each state where groundwater is known or suspected to contain contaminants of public health concern. We will administer a questionnaire at each household to obtain information on selection of water treatment type, adherence to suggested maintenance, and reasons for use of treatment device. We will also obtain samples of treated water and untreated well water at each household to analyze for contaminants of public health concern. There is no cost to respondents.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Participant Solicitation Telephone Questionnaire	1200	1	5/60	100
Household Questionnaire	600	1	20/60	200
Total				300

Dated: April 13, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–9211 Filed 4–22–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–04–45]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498–1210.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the