

availability, costs, and scope of private health insurance benefits among Americans;

- Examining the effects of changes in how chronic care and disability are managed and financed;
- Evaluating the growing impact of managed care and of enrollment in different types of managed care plans; and
- Examining access to and costs of health care for common diseases and conditions, prescription drug use, and other health issues.

Statisticians and researchers will use these data to make important generalizations on the civilian noninstitutionalized population of the United States, as well as to conduct research in which the family is the unit of analysis.

Method of Collection

The data will be collected using a combination of modes. For example, the AHCPR intends to introduce study participants to the survey through advance mailings. The first contact will provide the household with information regarding the importance and uses of the information obtained. The AHCPR will then conduct five (in-person) interviews with each household to obtain health care use and expense data. Lastly, the AHCPR will conduct one telephone interview with each household to obtain tax and asset information. Data will be collected using a computer-assisted personal interviewing method (CAPI). In certain cases, AHCPR will conduct interviews over the telephone, if necessary. Burden estimates follow:

Initial Number of Respondents:
10,000.

Panel 3: 4800.
Panel 4: 5200.

Number of Surveys Per Respondent: 6.
Average Burden Per Respondent: 9.0 hours.

Estimated Burden Total: 81,100 hours.

Panel 3: 39,050 hours.
Panel 4: 42,050 hours.

Request for Comments

Comments are invited on: (a) the necessity of the proposed collection; (b) the accuracy of the Agency's estimate of 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 the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or

included in the request for OMB approval of this information collection.

Copies of these proposed collection plans and instruments can be obtained from the AHCPR Reports Clearance Officer (see above).

Dated: November 4, 1997.

John M. Eisenberg,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Notice of Meetings

In accordance with section 10(a) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2) announcement is made of the following advisory subcommittees scheduled to meet during November 1997:

Name: Health Services Research Initial Review Group (Subcommittees: Health Systems Research, Health Care Quality and Effectiveness Research, Health Care Technology and Decision Sciences, and Health Research Dissemination and Implementation).

Date and Time: November 19, 1997, 8:00 a.m.

Place: Bethesda Hyatt Hotel, One Metro Plaza, Bethesda, Maryland 20816.

Open November 19, 8:00 a.m. to 8:30 a.m.

Closed for remainder of meetings.

Purpose: The Health Systems Research Subcommittee is charged with the initial review of research applications relating to cost and financing of health care, health care markets, organizational and delivery system issues, and the provider workforce. The Health Research Dissemination and Implementation Subcommittee is charged with the initial review of research applications relating to behavior change, demonstrations and interventions, consumer decision-making, dissemination, health professional and consumer education, and translation of research findings. The Health Care Technology and Decision Sciences Subcommittee is charged with the initial review of research applications relating to the development, refinement, assessment, cost-effectiveness, and application of health care technologies. The Health Care Quality and Effectiveness Research Subcommittee is charged with the initial review of research applications relating to clinical outcomes and effectiveness, quality and

cost-effectiveness of health care, effectiveness research, evidence-based medicine, and quality of care research.

Agenda: The open sessions of these meetings on November 19, from 8:00 a.m. to 8:30 a.m., will be devoted to business meetings covering administrative matters and reports. During the closed sessions, the Subcommittees will be reviewing research and demonstration grant applications relating to the delivery, organization, and financing of health services. In accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C., 552b(c)(6), the Administrator, AHCPR, has made a formal determination that these latter sessions will be closed because the discussions are likely to reveal personal information concerning individuals associated with the applications. This information is exempt from mandatory disclosure.

Anyone wishing to obtain rosters of members, minutes of the meetings, or other relevant information should contact Sheila S. Simmons, Committee Management Officer, Agency for Health Care Policy and Research, Suite 400, Executive Office Center, 2101 East Jefferson Street, Rockville, Maryland 20852, Telephone (301) 594-1452 ext. 1627.

Agenda items for all meetings are subject to change as priorities dictate.

Dated: November 4, 1997.

John M. Eisenberg,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Exchange of Letters Between the Food and Drug Administration and the Australian Therapeutic Goods Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of an exchange of letters (EOL) between FDA and the Australian Therapeutic Goods Administration. The purpose of the EOL is to facilitate the exchange of documents and information concerning a drug or biological preparation that is considered for orphan status.

DATES: The agreement became effective August 12, 1997.