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, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) allow the proposed information collection project: ''Evaluation of a Medication Therapy Management Program to Improve Patient Safety in Medicare Beneficiaries.'' 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.

DATES: Comments on this notice must be received by January 30, 2007.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, 540 Gaither Road, Room #5036, Rockville, MD 20850.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from AHRQ's Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ, Reports Clearance Officer, (301) 427–1477.

SUPPLEMENTARY INFORMATION:

Proposed Project

''Evaluation of a Medication Therapy Management Program (MTMP) To Improve Patient Safety in Medicare Beneficiaries''

The Medicare Modernization Act of 2003 (MMA) requires Medicare prescription drug plans to have a MTMP that is developed in cooperation with licensed and practicing pharmacists and physicians for targeted beneficiaries. MTMP is defined in the MMA as a program of drug therapy management that is designed to assure, with respect to targeted beneficiaries, that covered part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions.

The proposed MTMP research project will prospectively evaluate the effects of a specific drug therapy management program on health outcomes and patient safety in a group of research subjects aged 65 or older, living with multiple chronic health conditions and taking multiple part D medications. The evaluation will be designed as a randomized, controlled study with subjects recruited from multiple ambulatory care or family practice medical clinics in the States of Illinois, North Carolina, and Texas. The study will be coordinated by clinical scientists, physicians, and pharmacists affiliated with AHRQ, Baylor Health Care System, Duke University, RTI International, and the University of Illinois at Chicago.

The study protocol and data collection procedures for the MTMP research evaluation will be reviewed by the official Institutional Review Boards at each participating study site. The study will be conducted in accordance with the rules and regulations of the Health Insurance Protection and Portability Act and with the ''Guidelines for the Conduct of Research Involving Human Subjects.'' An informed consent will be obtained (see Table below) prior to subject enrollment in the study. For individuals who consent to participate, confidential identifiable information will be collected as described in the informed consent document. Subjects will be asked to provide information about medication use, adherence to prescription instructions, health services use, health status, adverse drug events, satisfaction with the MTMP, and demographics. Study pharmacists will assess subjects' medication use, the appropriateness of each prescribed medication using a validated scale, and will provide information about their own satisfaction with the MTMP. All study information will be entered and maintained in a secure, password-protected database and will be protected in accordance with AHRQ's confidentiality statute, Section 934(c) of the Public Health Service Act (42 U.S.C. 299c–3(c)).

Methods of Collection

The data will be collected using several methods at study entry and at the end of the study. Questionnaire data will be obtained via direct patient interview by clinical investigators who will record the information on a paper form. In addition, a self-administered paper patient survey will be collected during scheduled patient study visits in both the intervention and control arms to assess the effects of participation in the medication therapy management program. All survey forms will be entered and maintained in a secure, password-protected database. Patient health, medication history, and hospitalization information will be obtained through a review of the subjects' electronic or paper medical records. Information on prescriptions filled (*e.g.*, number of tablets, directions, date filled) and refill frequency will be obtained through electronic pharmacy records, when these records are available and when access is authorized by the subject.

Estimated Annual Respondent Burden

The Table below indicates the total time burden required to obtain all of the data required to meet the study's objectives. The Table does not include time required to analyze the data and prepare it for statistical reporting, analysis and publication.

Respondents and response type	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total burden (hours)
Study Participants/Informed Consent	400	1	0.25	100
Study Participants/Patient Survey	400	2	0.75	600
Study Investigators and Personnel/Informed Consent	400	1	0.25	100
Study Investigators and Personnel/Patient Survey	400	2	0.75	600
Study Investigators and Personnel/Medical Chart Review and Abstraction.	400	2	1	800
Study Investigators and Personnel/Preparing Electronic Pharmacy Records.	4 (from 4 different sites).	2	4	32
Total				2232

Estimated Costs to the Federal Government

The cost estimate to the federal government is $1,400,000.

Request for Comments

In accordance with the above-cited 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 health care research and information dissemination functions of AHRQ, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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: November 20, 2006.

Carolyn M. Clancy,

Director.

[FR Doc. 06–9485 Filed 11–30–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meeting

In accordance with section 10(d) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of a Health Care Policy and Research Special Emphasis Panel (SEP) meeting.

A Special Emphasis Panel is a group of experts in fields related to health care research who are invited by the Agency for Healthcare Research and Quality (AHRQ), and agree to be available, to conduct on an as needed basis, scientific reviews of applications for AHRQ support. Individual members of the Panel do not attend regularly scheduled meetings and do not serve for fixed terms or a long period of time. Rather, they are asked to participate in particular review meetings which require their type of expertise.

Substantial segments of the upcoming SEP meeting listed below will be closed to the public 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). Grant applications for the Announcement of Availability of Funds for Grants regarding Adolescent Family Life (AFL) Research are to be reviewed and discussed at this meeting. This program is sponsored by the Office of Population Affairs. These discussions are likely to reveal personal information concerning individuals associated with the applications. This information is exempt from mandatory disclosure under the above-cited statutes.

SEP Meeting on: Announcement of Availability of Funds for Grants regarding Adolescent Family Life (AFL) Research.

Date: December 11, 2006 (Open on December 11 from 8:30 a.m. to 8:45 a.m. and closed for the remainder of the meeting).

Place: John M. Eisenberg Building, AHRQ Conference Center, 540 Gaither Road, Rockville, Maryland 20850.

Contact Person: Anyone wishing to obtain a roster of members, agenda or minutes of the non-confidential portions of this meeting should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research, Education and Priority Populations, AHRQ, 540 Gaither Road, Room 2038, Rockville, Maryland 20850, Telephone (301) 427–1554.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: November 20, 2006.

Carolyn M. Clancy,

Director.

[FR Doc. 06–9486 Filed 11–30–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Itemized Undistributed Collections (Schedule UDC).

OMB No.: 0970–0268.

Description: State agencies administering the Child Support Enforcement Program under Title IV–D of the Social Security Act are required to provide information each fiscal quarter to the Office of Child Support Enforcement (OCSE) concerning administrative expenditures and the receipt and disposition of child support payments from non-custodial parents (Forms OCSE–396A and OCSE–34A—OMB NO. 0970–0181). Together with a third quarterly report, ''Itemized Undistributed Collections,'' these forms provide information from each State that is used to compute the quarterly grant awards, the annual incentive payments and provide valuable information on program finances. This information is also included in a published annual statistical and financial report, available to the general public.

Public Law 109–171, the Deficit Reduction Act of 2005, contains a number of provisions that will impact the States' completion and submission of these quarterly financial reports. These changes become effective in fiscal years 2006, 2007 and 2008. These changes require revisions to some of the data entry lines and reporting instructions currently contained on these forms. In addition, a periodic review of the data currently requested on these forms will assure that OCSE collects the information needed in the most efficient format feasible.

Respondents: State agencies administering the Child Support Enforcement Program.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Schedule UDC	54	4	4	864