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.

This proposed information collection was previously published in the **Federal Register** on December 1, 2006 and allowed 60 days for public comment.

The purpose of this notice is to publish prior comments received and agency responses as well as allow an additional 30 days for public comment.

Public comments were received and are included at the end of this notice, along with responses to the comments.

DATES: Comments on this notice must be received by June 18, 2007.

ADDRESSES: Written comments should be submitted to: Karen Matsuoka by fax at (202) 395–6974 (*attention:* AHRQ's desk office) or by e-mail at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer). 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 Privacy and Security regulations of the Health Insurance Protection and Portability Act, 45 CFR Parts 160, 162 and 164 and with 45 CFR part 46, the ''Common rule'' regarding the Conduct of Research Involving Human Subjects. An informed consent with 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, health service use, health status, adverse drug events, satisfaction with the MTMP, and demographics. Study pharmacists will assess subject's medication use, the appropriateness of each prescribed medication using a validated scale, and will provide information about their own satisfactions 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. 299 c–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 of the study 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, data 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 Chat Review and Abstraction.	400	2	1	800

Respondents and response type	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total burden (hours)
Study Investigators and Personnel/Preparing Electronic Pharmacy Records.	4 (from 4 different sites).	2	4	32
Total				2232

** Refers to time on the part of investigators and study personnel in obtaining informed consent from subjects.

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 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 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.

Comments on the 60 Day Notice Federal Register Notice

Comment a: Study design favors self selection of patients who are mobile, able to accurately self-report data elements and have sufficient cognitive function and health status to benefit from patient education and participate for the study duration. How then will this study design inform about how to intervene for the oldest and sickest beneficiaries?

Response: Clearly no single study can address all patient populations that might benefit from medication therapy management (MTM). In order for this study to be both practical and generalizable to the broadest range of Medicare beneficiaries, we have targeted those that are mobile, able to accurately self-report the required data elements and have sufficient cognitive function and health status to benefit from the intervention and participate for the study duration. Nevertheless, we recognize that certain patients may be at higher risk than others. Therefore, the protocol has been revised to focus on those beneficiaries at greater risk of drug related problems (DRPs) and adverse drug events (ADEs)—and thus presumably in the greatest need for medication therapy management (MTM). Entry criteria in the revised protocol include (1). must be least 65 years old as of August 1, 2007; (2). must have 3 or more comorbid conditions associated with increased healthcare utilization (conditions include diabetes mellitus, heart failure, asthma, hypertension, dyslipidemia, COPD, coronary artery disease, chronic renal failure, arthritis, depression, dementia, chronic pain, and conditions requiring anticoagulation); (3). must have visited a physician at one or more of the clinics on a regular basis (defined as 2 or more clinic visits over 1 year prior to the study start) for these condition; (4). must have received 8 or more different chronic prescription medications over the 6 months prior to the enrollment period; (5) must have a telephone line and agree to maintain it for at least 6 months; and (6). must have one of the following situations placing him/her at risk for a DRP: (a) ER visit in past 30 days, (b) new physician in past 30 days, (c) hospitalization in past 30 days, (d) change in mediation in past 30 days, or (e) 3 or more providers.

Comment b: Although five specific services are identified, they are not standardized. Lack of a standardized intervention means that it will be impossible to draw valid comparisons between the control and intervention groups.

Response: The intervention has been revised to focus on medication reconciliation and DRP assessment. The intervention will be well-defined, with specific tools or ''aids'' for implementation, and it will be standardized across the study sites. A ''toolkit'' will be produced that will allow the intervention to be reproduced once the study is completed.

Comment c: The identified interventions do not address the most critical element of MTM—assessment of the appropriateness of medications, including identification of untreated indications that would be followed by recommendations to prescribers. In the proposed study, while pharmacists will be addressing continuity of care, the assumption appears to be that the initial prescription choice is always appropriate. We believe this is a major weakness of the study protocol.

Response: Assessment of untreated indications is clearly one type of DRP that will be assessed as part of this study. Follow-up recommendations will be provided to prescribers.

Comment d: Of the five interventions identified in the study protocol, several fall outside the purview of a pharmacist's traditional training such as scheduling follow-up doctor's appointments, obtaining transportation to the clinic or motivating patients to take their medications using motivational interviewing techniques. We are concerned about the feasibility and cost of training pharmacists to undertake these tasks.

Response: The purpose for this study is to assess components of MTM. Providers of MTM may include pharmacists or other healthcare professionals. Thus, a ''pharmacist's traditional training'' is not necessarily relevant to the design of the intervention. Nevertheless, as mentioned above, the intervention has been revised to focus on medication reconciliation and DAP assessment—two activities which are likely within the purview of most pharmacists.

Comment e: What is the method of that will be used to achieve an equal or roughly proportional number of enrollees in each group?

Response: Stratified randomization.

Comment f: Similarly, how is the site effect controlled for, particularly since a disproportionate number of subjects may be enrolled at the University of Illinois at Chicago site (100 patients)?

Response: There will be an equal number of subjects enrolled at each site.

Comment g: How will be the investigators account for failure to enroll beneficiaries in either group?

Response: Each study site draws from a large pool of eligible participants and includes experienced investigators who have successfully recruited patients for similar types of studies. Given the relatively low burden for participation, the study is anticipated to enroll an

adequate sample. However, should the initial recruitment efforts be unsuccessful we will intensify efforts by contacting physicians to refer patients, posting advertisements, and screening patients seen in applicable clinics. Also, if failure to enroll at one site is a problem we can increase enrollment at other sites to compensate.

Comment h: Presumably, participants in the control group will be receiving some level of MTM by virtue of Part D enrollment. How will ''usual care'', which could contain widely variable applications of MTM, be defined, measured, controlled, and distinguished from the ''intervention''?

Response: Patients already enrolled in an MTM program where medication reconciliation and/or assessment of DRPs has occurred in the previous 12 months will be excluded.

Comment i: What methodology will be employed to control for potential confounders residing with the pharmacist; for example, pharmacist tenure/experience with MTM service?

Response: There will be a small number of pharmacists at each site (1 or 2) and all of the pharmacists will be of similar tenure/experience. Training will be provided to all pharmacists so that the protocol is implemented in a standard manner.

Comment j: How will non-adherence to scheduled monthly MTM program visits and subsequent missing data be accounted for? Will this be a last-observation-carried-forward study? Will beneficiaries who do not keep appointments for some percentage of their scheduled follow-up visits be excluded or treated as controls? Is there a procedure for identifying why patients leave the study?

Response: The intervention has been changed from monthly visits to just 2 visits. With this reduced number of visits we do not anticipate significant non-compliance. An intent-to-treat analysis will be conducted, meaning that the analysis will be based on the group to which subjects were originally/randomly assigned.

Comment k: Will pharmacists evaluate all of the beneficiary's medications or just those that are Part D covered? Presumably, one would assume the former; however, this should be explicitly stated. And again, how does this differ from ''usual care''? Likewise, how will non-Part D medications, particularly samples and OTC medications, be accounted for regarding medication adherence (patient self-report, pharmacy claims, both)?

Response: The program will evaluate all medications. Medication adherence has been removed as an outcome measure for the study.

Comment l: It seems unlikely that when assessed for 12-month recall of adverse events at the close of the study, participants will be able to relate an accurate history. A participant log or dairy might support recall of events.

Response: The protocol has been changed and we will now assess this at day 90 and 180 for only the preceding 3 months, using a structured interview. In order to assist with recall, we will provide participants with a patient log or diary to record drug related problems.

Comment m: We believe that the investigators may have underestimated the time required to collect information from study participants and to abstract data from clinical records, particularly given the number of tools and measurements that will be employed. Additionally, there appears to be no formal training of pharmacists in the utilization and application of these instruments, which may further underestimate burden.

Response: Significant changes have now been made to reduce the patient and investigator time. A formal training session will be held for pharmacists who will provide the intervention and tools have been developed to standardize the intervention as mentioned above.

Comment n: As we have communicated in the list of questions/concerns about design (above), we believe that the study could be strengthened by clearer definitions of the intervention ''MTM program'' and the ''dose'' (that is, the specific type and amount of services that the treating pharmacist elects to provide a given beneficiary). If doses are not standard across beneficiaries, as one would expect, what characteristics/criteria will be used to determine dose?

Response: The revised protocol may contain more data upon which to assess these issues. The intervention has been more clearly defined and narrowed in scope, and the number of visits has been reduced.

Comment o: The study could be strengthened by explication of techniques for accrual, randomization, and follow up on missed appointments and handling of missing data.

Response: All of these items are included in the revised protocol.

Comment p: While we strongly favor and actively use electronic clinical records for MTM, we have found that automated data collection techniques (such as interactive voice response, or IVR) are frequently impractical for collecting data from older adults who may have difficulty hearing, need more time to respond than is typically programmed, and need to have items repeated. However, data collection via telephone with a ''live'' data collector and web-enabled medication management devices that also track adherence and present questions/collect information from patients are potentially very useful in terms of data accuracy and completeness. One caution exists in terms of interpretation and generalizability of the findings: Automated data collection techniques might ''cue'' the beneficiary in a way that inflates the effect; as such, cues would presumably not be present in standard (non-experimental) application of MTM programs. This could lead to inflation of effect and potential Type 1 error. Studies are needed that explore the feasibility and utility of automated data collection with older adults who are at risk for medication-related problems and poor outcomes.

Response: This study uses no automated collection techniques.

Comment q: ACCP recommends that inclusion of additional survey questions that would investigate the process by which beneficiaries are being informed and educated about the availability of MTMPs for eligible enrollees, and how the plans are promoting MTMPs among their enrollees.

Response: The purpose of the proposed study is to evaluate a specific MTM intervention. While important questions, a survey of MTM providers about the process by which beneficiaries are being informed and educated about the availability of MTMPs for eligible enrollees, and how the plans are promoting MTMPs among their enrollees is not within the scope of the study.

Comment r: We strongly believe that any research in the area of MTMP will be very helpful in determining the effect of these programs, but it appears in the proposed project that community pharmacy sites are being excluded from the study. Community pharmacy must be represented in any study evaluating the effectiveness of MTMP, so as to determine potential strengths and/or barriers to providing these programs in the community pharmacy setting. We question the broad applicability of this research project based on the sites from which study subjects will be recruited and we strongly encourage the involvement of community pharmacy practice sites in this project.

Response: AHRQ recognizes the importance of community pharmacy as one site in which MTM may be provided. No study can be designed to include all aspects of diversity in the site of provision of MTM. For this study

we attempted to obtain a balance between availability of data needed to assess the impact of the intervention, and the generalizability of the setting of care. In revisions made to the protocol we have focused on developing an intervention that could be conducted in a community pharmacy, and as such may be generalizable to community pharmacies.

Dated: May 10, 2007.

Carolyn M. Clancy,

Director.

[FR Doc. 07–2481 Filed 5–17–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10233, CMS–10234 and CMS–10236]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Regional Preferred Provider Organization (RPPO) Reconciliation Cost Report; *Form Number:* CMS–10233 (OMB#: 0938–New); *Use:* The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Title II, Subtitle C (Offering of Medicare Advantage Regional Plans; Medicare Advantage Competition) provided for the establishment of Medicare Advantage Regional Plans. Subsequently, the Regional Preferred Provider Organization (RPPO) program was developed and began contracting with Managed Care Organizations (MCOs) and enrolling beneficiaries for the 2006 contract year. Section 1858 of the Social Security Act provides for risk sharing with RPPOs to be in place for contract years 2006 and 2007. The Code of Federal Regulations at 42 CFR 422.458 provides specific direction with respect to how the Centers for Medicare and Medicaid Services (CMS) will share risk with the RPPOs. The regulations require CMS to collect Allowable Cost data, and to compare this data to Target Amounts. If the comparison demonstrates that there were either savings or losses in the contract year, the regulations provide specific risk corridors to be used in determining the Risk Sharing Reconciliation amount due to either the plan or CMS. The Risk Sharing Reconciliation cost report will be used to collect the information necessary to accurately reconcile the payments made to RPPOs for the 2006 and 2007 contract years. *Frequency:* Reporting—Annually; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 14; *Total Annual Responses:* 14; T*otal Annual Hours:* 1,120.

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* State Plan Pre-print implementing Section 6087 of the Deficit Reduction Act: Optional Self-Direction Personal Assistance Services (PAS) Program (Cash and Counseling); *Form Number:* CMS–10234 (OMB#: 0938–New); *Use:* Information submitted via the State Plan Amendment (SPA) pre-print will be used by the Centers for Medicare & Medicaid Services (CMS) Central and Regional Offices to analyze a State's proposal to implement Section 6087 of the Deficit Reduction Act (DRA). State Medicaid Agencies will complete the SPA pre-print, and submit it to CMS for a comprehensive analysis. The pre-print contains assurances, check-off items, and areas for States to describe policies and procedures for subjects such as quality assurance, risk management, and voluntary and involuntary disenrollment; *Frequency:* Reporting—Once; *Affected Public:* State, Local, or Tribal Government; *Number of Respondents:* 56; *Total Annual Responses:* 30; Total Annual Hours: 600.

3. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Disclosure of Financial Relationships Report (''DFRR''); *Form Number:* CMS–10236 (OMB#: 0938–New); *Use:* Section 1877(f) of the Social Security Act requires that each entity providing covered items or services for which payment may be made shall provide the Secretary with information concerning the entity's ownership, investment, and compensation arrangements, in such form, manner, and at such times as the Secretary shall specify. DFRR is a new collection instrument that will be used by CMS to obtain information necessary to analyze each hospital's compliance with Section 1877 of the Social Security Act (''the physician self-referral law''), and implementing regulations (42 Code of Federal Regulations, Subpart J). *Frequency:* Reporting—Once; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 2,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on July 17, 2007.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—B, Attention: William N. Parham, III, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: May 11, 2007.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–265–94 and CMS–460]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the