Request for Comments

In accordance with the Paperwork Reduction Act, 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 AHRQ health care research and health care information dissemination functions, 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 Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: September 10, 2013.

Richard Kronick,

Director.

[FR Doc. 2013–22578 Filed 9–16–13; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Medication Therapy Management

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

ACTION: Request for scientific information submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public on medication therapy management Scientific information is being solicited to inform our review of *Medication Therapy Management,* which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on medication therapy management will improve the quality of this review. AHRQ is conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, and Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: *Submission Deadline* on or before October 17, 2013.

ADDRESSES: *Online submissions: http://effectivehealthcareAHRQ.gov/index.cfm/submit-scientific-information-packets/.* Please select the study for which you are submitting information from the list to upload your documents.

Email submissions: SIPS@epc-src.org.

Print submissions:

Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, P.O. Box 69539, Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.): Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, 3710 SW., U.S. Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT: Robin Paynter, Research Librarian, Telephone: 503–220–8262 ext. 58652 or Email: *SIPS@epc-src.org.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a review of the evidence for Medication Therapy Management.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on medication therapy management, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: *http://www.effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=1601.*

This notice is to notify the public that the EHC program would find the following information on *medication therapy management* helpful:

- A list of completed studies your company has sponsored. In the list, *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies your company has sponsored.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your company for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can be made public. Materials that are considered confidential; marketing materials; study types not included in the review, such as cross-sectional studies, case series, case reports, before-and-after designs without a control group, and program evaluation data that does not include a comparison group; or information on indications not included in the review cannot be used by the Effective Health Care Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EHC program Web site and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions. The entire research protocol, is also available online at: *http://www.effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=1601.*

Question 1

What are the components and implementation features of MTM interventions?

Question 2

In adults with one or more chronic diseases who are taking prescription

medication, is MTM effective in improving the following:

a. Intermediate outcomes, including biometric and laboratory measures, drug therapy problems identified, drug therapy problems resolved, medication adherence, goals of therapy met, and patient engagement in medication management?

b. Patient-centered outcomes, such as disease-specific morbidity, disease-specific or all cause mortality, adverse drug events, health-related quality of life, activities of daily living, patient satisfaction with health care, work or school absenteeism, and patient and caregiver participation in medical care and decisionmaking?

c. Resource utilization, such as prescription drug costs, other health care costs, and health care utilization?

Question 3

Does the effectiveness of MTM differ by MTM components and implementation features?

Question 4

Does the effectiveness of MTM differ by patient characteristics, including but not limited to patient demographics and numbers and types of conditions and medications?

Question 5

Are there harms of MTM, and if so, what are they?

The PICOTS (Population(s), Interventions, Comparators, Outcomes, Timing, and Settings) criteria for the comparative effectiveness review are as follows:

Population(s)

- Patients ages 18 or older with one or more chronic conditions requiring the use of prescription medication to manage symptoms or prevent progression of chronic disease
- Patient characteristics that may influence intervention effectiveness:
  - Age, sex, race and ethnicity, socioeconomic status, health insurance status, education level, health literacy status, cognitive impairment, number and types of chronic conditions, social support, and urban/rural status

Interventions

- Explicitly termed *MTM* services, generally provided as a bundle of related services, that include at a *minimum* four of the following elements:
  - Comprehensive medication review
  - Patient-directed medication management action plan, with or without an equivalent prescriber-directed action plan
  - Patient-directed education and counseling or other resources to enhance understanding of the use of medication
  - Coordination of care, including prescriber-directed interventions; documentation of MTM services for use by the patient's other providers; and referral to other providers, clinicians, or resources when appropriate
- MTM-like services that are provided as a bundle or multicomponent intervention, even if not explicitly termed ''medication therapy management''

The following types of interventions generally are not considered MTM interventions and will not be included:

- Medication reconciliation interventions
- Integrated pharmacy services within inpatient settings
- One-time corrective actions related to medication management
- Disease management interventions
- Case or care management interventions
- The following types of interventions may include MTM services, but MTM may represent only one component of the overall intervention:
  - Patient-centered home health care-delivery model
  - Fully integrated, collaborative care models involving multiple disciplines and specialties

Studies should contain the same level of overall medical care/health care services among different study arms such that the effect of MTM interventions can be isolated. For example, a study with two arms that has one arm with a care management intervention that includes MTM services and the other arm that has the care management intervention without MTM services could be included. A study that includes a care management intervention with MTM in one arm and usual medical care (no care management intervention) in the other arm would not be included.

- Implementation features that may influence intervention effectiveness include the following:
  - Mode of delivery: telephonic, face to face, virtual (Web/online/Internet), and remote video
  - Type of professional providing initial and followup MTM service: pharmacist, nurse, physician, other clinician
  - Frequency and interval of followup for MTM services
  - Specific MTM components used
  - Fidelity in implementing MTM components: to what extent were services delivered as designed or intended
  - Establishing and communicating goals of drug therapy to patients and among care providers
  - Method of identifying patients for enrollment (e.g., population health data, provider referral for services, enrollment during a transition in care, targeting highly activated patients, targeting patients at time of high risk for event [e.g., when prescribing a new drug])
  - Level of integration of MTM with usual care, which includes access to real-time clinical information and laboratory values, and regular and consistent communication among prescribers and persons providing MTM services
  - Reimbursement characteristics (e.g., who is paying for cost of MTM services, who is reimbursed for MTM services, whether services are separately reimbursable)
  - Health system characteristics (e.g., are services being provided within an accountable care organization, patient-centered medical home, or some other unique system setting [e.g., the VHA, the Indian Health Service, non-U.S. single-payer system])

Comparators

- Usual care, as defined by the studies
- Individual components of MTM services (e.g., MTM services with four components vs. a single component)
- Different bundles of MTM services
- Same MTM services provided by different health care professionals (e.g., pharmacist, physician, nurse, other)
- Same bundles of MTM services delivered by different modes (e.g., telephone or in person)
- Same MTM services provided at different intensities, frequencies, or level of integration with prescribers

Outcomes

- Intermediate Outcomes
  - Disease-specific laboratory or biometric outcomes (e.g., hemoglobin A1c; blood pressure; total, low-density lipoprotein, or high-density lipoprotein cholesterol; pulmonary function; renal function; left ventricular ejection fraction; or other lab or biometric outcome specific to diseases covered)
  - Drug therapy problems identified as defined by primary studies but typically including the following:

medications being taken but not indicated; medications indicated but not prescribed; patient adherence issues; supratherapeutic doses; subtherapeutic doses; generic, formulary, or therapeutic substitution issues; complex regimen that can be simplified with same therapeutic benefit; and potential for drug-drug interactions or adverse events.
- Drug therapy problems that resolved as defined by primary studies but typically including the following: needed drug initiated; unnecessary drug discontinued; change in drug dose, form, or frequency; or generic, formulary, or therapeutic substitution
- Medication adherence
- Goals of therapy met
- Patient engagement (e.g., initial and continuing patient participation in the MTM program)

- Patient-Centered Outcomes
- Disease-specific morbidity, including falls and fall-related morbidity and outcomes specific to the patient's underlying chronic conditions (e.g., Patient Health Questionnaire 9 [PHQ9], disease-specific symptoms, reduced number of disease-specific acute exacerbations or events)
- Disease-specific or all-cause mortality, including fall-related mortality
- Reduced (actual) adverse drug events (frequency and/or severity)
- Health-related quality of life as measured by generally accepted generic health-related quality-of-life measures (e.g., short-form questionnaires, EuroQOL) or disease-specific measures
- Activities of daily living as measured by generally accepted standardized measures of basic and/or instrumental activities of daily living (e.g., Katz, Lawton, or Bristol instruments) or with instruments that have demonstrated validity and reliability
- Patient satisfaction with care
- Work or school absenteeism
- Patient and caregiver participation in medical care and decisionmaking

- Resource Utilization
- Prescription drug costs and appropriate prescription drug expenditures
- Other health care costs
- Health care utilization (hospitalizations, emergency department visits, and physician office visits)

- Harms
- Care fragmentation
- Patient confusion
- Patient decisional conflict
- Patient anxiety
- Increased (actual) adverse drug events
- Patient dissatisfaction with care
- Prescriber confusion
- Prescriber dissatisfaction

Timing

- Interventions should have at least two separately identifiable episodes of care (either patient or provider directed or both), but there is no certain amount of time in between those episodes.
- For studies that report outcomes at different points in time, we will only consider outcomes measured after the second episode of care.

Settings

- Patients must have been seen in ambulatory settings (e.g., outpatient clinics or private physician offices, long-term care, or retail pharmacy settings).
- However, the MTM intervention itself may be delivered by telephone, via the Web, or in other non-face-to-face modalities, such as video teleconferencing.
- MTM services that are delivered mostly in inpatient settings will not be included.
- Interventions conducted in the United States and other countries and are published in English will be included.

Dated: September 6, 2013.

Richard Kronick,

AHRQ Director.

[FR Doc. 2013–22579 Filed 9–16–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting of the Community Preventive Services Task Force

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: The Centers for Disease Control and Prevention (CDC) announces the next meeting of the Community Preventive Services Task Force (Task Force). The Task Force is an independent, nonfederal, and uncompensated panel. Its members represent a broad range of research, practice, and policy expertise in prevention, wellness and health promotion, and public health, and are appointed by the CDC Director. The Task Force was convened in 1996 by the Department of Health and Human Services (HHS) to identify community preventive programs, services, and policies that increase healthy longevity, save lives and dollars and improve Americans' quality of life. During this meeting, the Task Force will consider the findings of systematic reviews on existing research and issue recommendations. These recommendations provide evidence-based options from which decision makers in communities, companies, health departments, health plans and healthcare systems, non-governmental organizations, and at all levels of government can choose what best meets the needs, preferences, available resources, and constraints of their constituents. The Task Force's recommendations, along with the systematic reviews of the scientific evidence on which they are based, are compiled in the *Guide to Community Preventive Services (Community Guide).*

DATES: The meeting will be held on Wednesday, October 23, 2013 from 8:30 a.m. to 5:30 p.m. EDT and Thursday, October 24, 2013 from 8:30 a.m. to 1:00 p.m. EDT.

ADDRESSES: The Task Force Meeting will be held at CDC Edward R. Roybal Campus, Tom Harkin Global Communications Center (Building 19), 1600 Clifton Road NE., Atlanta, GA 30333. You should be aware that the meeting location is in a Federal government building; therefore, Federal security measures are applicable. For additional information, please see Roybal Campus Security Guidelines under **SUPPLEMENTARY INFORMATION**. Information regarding meeting logistics will be available on the Community Guide Web site (*www.thecommunityguide.org*), Wednesday, September 25, 2013.

FOR FURTHER INFORMATION CONTACT: Andrea Baeder, The Community Guide Branch, Division of Epidemiology, Analysis, and Library Services (proposed), Center for Surveillance, Epidemiology and Laboratory Services (proposed), Office of Public Health Scientific Services (proposed), Centers for Disease Control and Prevention, 1600 Clifton Road, MS–E–69, Atlanta, GA 30333, phone: (404) 498–498–6876, email: *CPSTF@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The purpose of the meeting is for the Task Force to consider the findings of systematic reviews and issue findings and recommendations to help inform decision making about policy, practice, and research in a wide range of U.S. settings.