

economics, information systems, law, ethics, business, or public policy; and, (7) in representing the interests of patients and consumers of health care. 42 U.S.C. 299c(c)(2). Individuals are particularly sought with experience and success in activities specified in the summary above.

**DATES:** Nominations should be received on or before 60 days after date of publication.

**ADDRESSES:** Nominations should be sent to Ms. Karen Brooks, AHRQ, 540 Gaither Road, Room 3006, Rockville, Maryland 20850. Nominations may also be emailed to [Karen.Brooks@ahrq.hhs.gov](mailto:Karen.Brooks@ahrq.hhs.gov).

**FOR FURTHER INFORMATION CONTACT:** Ms. Karen Brooks, AHRQ, at (301) 427-1801.

**SUPPLEMENTARY INFORMATION:** 42 U.S.C. 299e provides that the Secretary shall appoint to the National Advisory Council for Healthcare Research and Quality twenty one appropriately qualified individuals. At least seventeen members shall be representatives of the public and at least one member shall be a specialist in the rural aspects of one or more of the professions or fields listed in the above summary. In addition, the Secretary designates, as ex officio members, representatives from other Federal agencies, principally agencies that conduct or support health care research, as well as Federal officials the Secretary may consider appropriate. 42 U.S.C. 299c(c)(3). The Council meets in the Washington, DC, metropolitan area, generally in Rockville, Maryland, approximately three times a year to provide broad guidance to the Secretary and AHRQ's Director on the direction of and programs undertaken by AHRQ.

Seven individuals will be selected presently by the Secretary to serve on the Council beginning with the meeting in the spring of 2015. Members generally serve 3-year terms. Appointments are staggered to permit an orderly rotation of membership.

Interested persons may nominate one or more qualified persons for membership on the Council. Self-nominations are accepted. Nominations shall include: (1) A copy of the nominee's resume or curriculum vitae; and (2) a statement that the nominee is willing to serve as a member of the Council. Selected candidates will be asked to provide detailed information concerning their financial interests, consultant positions and research grants and contracts, to permit evaluation of possible sources of conflict of interest. Please note that once you are nominated, AHRQ may consider your

nomination for future positions on the Council. Federally registered lobbyists are not permitted to serve on this advisory board pursuant to the Presidential Memorandum entitled "Lobbyists on Agency Boards and Commissions" dated June 10, 2010, and the Office of Management and Budget's "Final Guidance on Appointment of Lobbyists to Federal Boards and Commissions," 76 Fed. Reg. 61756 (October 5, 2011).

The Department seeks a broad geographic representation. In addition, AHRQ conducts and supports research concerning priority populations, which include: low-income groups; minority groups; women; children; the elderly; and individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care. See 42 U.S.C. 299(c). Nominations of persons with expertise in health care for these priority populations are encouraged.

Dated: May 29 2014.

**Richard Kronick,**  
AHRQ Director.

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**BILLING CODE 4160-90-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Scientific Information Request on Diagnosis and Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)

**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. Scientific information is being solicited to inform our review of Diagnosis and Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS), 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 will improve the quality of this review. AHRQ is conducting this systematic 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 July 17, 2014.

**ADDRESSES:** Online submissions: <http://effectivehealthcare.AHRQ.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](mailto:SIPS@epc-src.org).

#### Print Submissions

Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, PO 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:** Ryan McKenna, Telephone: 503-220-8262 ext. 58653 or Email: [SIPS@epcsrc.org](mailto:SIPS@epcsrc.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 Diagnosis and Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS).

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 Diagnosis and Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS), including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: <http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1906#8766>.

This notice is to notify the public that the EHC program would find the following information on Diagnosis and Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS).

- A list of completed studies your company has sponsored for this indication. 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 for this indication. 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; 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://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1906#8766>.

#### Key Questions (KQs)

1. What methods are available to clinicians to diagnose ME/CFS and how

do the use of these methods vary by patient subgroups?

A. What are widely accepted diagnostic methods and what conditions are required to be ruled out or excluded before assigning a diagnosis of ME/CFS?

B. What is the accuracy and concordance of diagnostic methods?

C. What harms are associated with diagnosing ME/CFS?

2. What are the (a) benefits and (b) harms of therapeutic interventions for patients with ME/CFS and how do they vary by patient subgroups?

A. What are the characteristics of responders and non-responders to interventions?

#### PICOTS (Population, Intervention, Comparator(s), Outcomes, Timing, Setting)

##### Population(s)

1. Include:

A. For KQ 1: Symptomatic adults (aged 18 years or older) with fatigue

B. For KQ 2: Adults aged 18 years or older, with ME/CFS, without other underlying diagnosis

2. Exclude:

A. Children and adolescents

B. Patients with other underlying diagnosis

##### Interventions

1. Include:

A. For KQ1: Case definitions: e.g., Fukuda/CDC, Canadian, International and others

For KQ2: symptom-based medication management (immune modulators, beta blockers, antidepressants, anxiolytics, stimulants), forms of counseling and behavior therapy, graded exercise programs, complementary and alternative medicine (acupuncture, relaxation, massage, or other), and transcutaneous electrical nerve stimulation.

##### Comparators

1. Include:

A. For KQ1: Diagnostic accuracy studies and diagnostic concordance studies with comparators

B. For KQ2: Placebo or no treatment/ usual care, other active interventions (including combination therapies and head-to-head trials)

##### Outcomes

1. Include:

A. For KQ1: Sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, negative likelihood ratio, C statistic (AUROC), net reclassification

index; concordance, any potential harm from diagnosis (such as psychological harms, labeling, risk from diagnostic test, misdiagnosis, other)

B. For KQ2: Overall function (i.e., 36-item Short Form Survey [SF-36]), quality of life, days spent at work/school, proportion working full or part time, fatigue (Multidimensional Fatigue Inventory [MFI] or similar), adverse effects of interventions, withdrawals and withdrawals due to adverse events, rates of adverse events due to interventions

##### Timing

1. Include: 12 weeks or longer

##### Setting

1. Include: Clinical settings

Dated: June 3, 2014.

**Richard Kronick,**

*AHRQ Director.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

#### Privacy Act of 1974; Report of New System of Records

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

**ACTION:** Notice of New System of Records (SOR).

**SUMMARY:** In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new SOR, titled "CMS Encounter Data System (EDS)", System No. 09-70-0506. CMS intends to collect encounter data, or data on each item or service delivered to enrollees of Medicare Advantage (MA) plans offered by MA organizations as defined at Title 42, Code of Federal Regulation (CFR), § 422.4. Pursuant to 42 CFR 422.310, each MA organization must submit encounter data to CMS that is used to determine the risk adjustment factors for payment, updating the risk adjustment model, calculating Medicare Disproportionate Share Hospital (DSH) percentages, Medicare coverage purposes, and quality review and improvement activities. Encounter data will be collected and maintained in the EDS.

Under the authority granted in Section 1115 of the Social Security Act (the Act), CMS is authorized to conduct experimental, pilot or demonstration