such as sign language interpretation or other reasonable accommodations, should notify Esther Yoo by telephone at (202) 233–3960, or email at *Esther.Yoo@bioethics.gov* in advance of the meeting. The Commission will make every effort to accommodate persons who need special assistance.

Dated: January 9, 2014.

Lisa M. Lee,

Executive Director, Presidential Commission for the Study of Bioethical Issues.

[FR Doc. 2014–01344 Filed 1–22–14; 8:45 am]

BILLING CODE 4154–06–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Diagnostic Tests of Right Lower Quadrant Pain (Suspected Acute Appendicitis)

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 medical devices used for the diagnosis of right lower quadrant pain (suspected acute appendicitis), for example: Magnetic resonance imaging (MRI), computed tomography (CT), ultrasound (US), laparoscopic equipment, or assays. Scientific information is being solicited to inform our review of *Diagnosis of Right Lower Quadrant Pain (Suspected Acute Appendicitis),* 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 Access to published and unpublished pertinent scientific information on medical devices used for the diagnosis of suspected acute appendicitis will improve the quality of this review.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 February 24, 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.

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: 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 *Diagnosis of Right Lower Quadrant Pain (Suspected Acute Appendicitis).*

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 the *Diagnosis of Right Lower Quadrant Pain (Suspected Acute Appendicitis),* 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=1827.*

This notice is to notify the public that the EHC program would find the following information on devices for the *Diagnosis of Right Lower Quadrant Pain (Suspected Acute Appendicitis)* helpful:

- 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=1827.*

Key Questions (KQ)

KQ 1

What is the performance of alternative diagnostic tests, alone or in combination, for patients with right lower quadrant (RLQ) pain and suspected acute appendicitis?

I. What is the performance and comparative performance of alternative diagnostic tests in the following patient populations:

A. Children

B. Adults

C. Non pregnant women of reproductive age

D. Pregnant women
E. The elderly (age greater than or equal to 65 years)
II. What factors modify the test performance and comparative test performance of available diagnostic tests in these populations?

KQ 2

What is the comparative effectiveness of alternative diagnostic tests, alone or in combination, for patients with RLQ pain and suspected acute appendicitis?
I. For the populations listed under Key Question 1a, what is the effect of alternative testing strategies on diagnostic thinking, therapeutic decision making, clinical outcomes, and resource utilization?
II. What factors modify the comparative effectiveness of testing for patients with RLQ pain and suspected acute appendicitis?

KQ 3

What are the harms of diagnostic tests per se, and what are the treatment-related harms of test-directed treatment for tests used to diagnose RLQ pain and suspected acute appendicitis?

PICOTS (Population, Interventions, Comparators, Outcomes, Timing, Setting)

Population(s)

I. Patients with acute RLQ abdominal pain (less than or equal to 7 days duration) for whom appendicitis is considered in the differential diagnosis
II. Separate analyses will be performed for the following populations:
A. Children (age less than 18 years); additional analyses will be performed for younger children (less than 2 years and 2–5 years of age)
B. Adults (age greater than or equal to 18 years)
C. Non pregnant women of reproductive age
D. Pregnant women
E. Elderly (age greater than or equal to 65 years)

Interventions

I. Diagnostic tests (alone or in combination) for diagnosing appendicitis
A. Clinical signs (e.g., psoas sign, obturator sign, Rovsing sign, McBurney sign)
B. Clinical symptoms (e.g., fever, migrating pain, guarding)
C. Laboratory tests (e.g., white blood cell count, C-reactive protein concentration, left shift)
D. Clinical prediction or decision rules (e.g., Alvarado score, Pediatric Appendicitis Score, other predictive models)
E. Imaging tests (e.g., US; multidetector or helical CT with or without contrast administered orally, rectally, or intravenously; MRI with or without contrast; abdominal X-ray)
F. Nuclear imaging studies
G. Diagnostic laparoscopy

Comparators

Alternative tests or test combinations (as listed above), clinical observation

Outcomes

I. Test performance (e.g., sensitivity, specificity, accuracy, proportion of ''negative'' appendectomies) using pathology or clinical followup as the reference standard
II. Intermediate outcomes
A. Impact on diagnostic thinking (e.g., change in diagnosis after testing; change in subsequent diagnostic approach after obtaining initial test results)
B. Impact on therapeutic decision making (e.g., change in treatment plan after testing; time from admission to surgery)
III. Final health or patient-centered outcomes
A. Bowel perforation (ruptured appendix)
B. Fistula formation
C. Infectious complications (abscess formation, peritonitis, sepsis, stump appendicitis)
D. Delay in diagnosis (time from presentation to definitive diagnosis; time from presentation to initiation of treatment; time from presentation to resolution of pain)
E. Length of hospital stay
F. Fetal/maternal outcomes (for pregnant women; including premature labor, pregnancy loss, fetal morbidity, fetal mortality, maternal morbidity, maternal mortality)
G. Mortality
IV. Adverse effects of intervention(s)
A. Direct harms of testing (e.g., harms from exposure to ionizing radiation, allergic reactions/kidney injury caused by contrast agents)
B. Harms of test-directed treatment (indirect)

Timing

Studies will be considered regardless of duration of followup.

Setting

All health care settings will be considered.

Dated: January 14, 2014.

Richard Kronick,

AHRQ Director.

[FR Doc. 2014–01241 Filed 1–22–14; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–308 and CMS–10508]

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

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the 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.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by February 24, 2014.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR* Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number,