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,

and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* State Children's Health Insurance Program and Supporting Regulations; *Use:* States must submit title XXI plans and amendments for approval by the Secretary. We use the plan and its subsequent amendments to determine if the state has met the requirements of title XXI. Information provided in the state plan, state plan amendments, and from the other information we are collecting will be used by advocacy groups, beneficiaries, applicants, other governmental agencies, providers groups, research organizations, health care corporations, health care consultants. States will use the information collected to assess state plan performance, health outcomes and an evaluation of the amount of substitution of private coverage that occurs as a result of the subsidies and the effect of the subsidies on access to coverage. *Form Number:* CMS–R–308 (OCN: 0938–0841); *Frequency:* Yearly, Once, and Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 400; *Total Annual Hours:* 1,473,817. (For policy questions regarding this collection contact Judith Cash at 410–786–4473).

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Evaluation of the Rural Community Hospital Demonstration (RCHD); *Use:* Section 10313 of the Affordable Care Act of 2010 (ACA) extended and expanded the Rural Community Hospital Demonstration (RCHD). Originally authorized under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the RCHD provides enhanced reimbursement for inpatient services to small rural hospitals that do not qualify as critical access hospitals (CAHs). The RCHD is intended to increase the capability of these hospitals to meet the health care needs of rural beneficiaries in their service areas. As a demonstration, the RCHD aims to provide information that can be used to assess the feasibility and advisability of establishing a new category of rural community hospitals for reimbursement policy. As of January 2013, 23 hospitals from 11 states are participating in the RCHD. This number includes seven hospitals continuing from the original demonstration as authorized under the MMA and 15 new hospitals that joined under the expansion authorized under the ACA.

For the original demonstration, the MMA required a Report to Congress six months after the end of the demonstration, a requirement unchanged by the ACA. An initial evaluation was conducted between 2007 and 2011 toward preparing for a Report to Congress and focused on the 17 hospitals that had participated at some point between October 2004 and March 2011. Findings from this evaluation were reported to the Centers for Medicare and Medicaid Services (CMS) in the *Interim Evaluation Report of the Rural Community Hospital Demonstration* (an unpublished report).

The current five-year evaluation of the RCHD will extend and build on the prior evaluation and produce the Report to Congress required by the MMA. It will assess the impact of the RCHD in meeting its goals: to enable hospitals to achieve community benefits such as improved services for their communities (especially Medicare beneficiaries), meet their individual strategic goals, and improve the financial solvency and viability of the participating hospitals. In addition, the evaluation will determine if it is feasible and advisable to create a new payment category of rural hospitals. To achieve this objective, the evaluation will examine how RCHD hospitals responded to payment options and assess how the costs to Medicare under RCHD compare to existing alternative payment options.

The evaluation will also summarize the characteristics of the markets served by RCHD hospitals, including beneficiaries' proximity to inpatient providers and competition among providers in the area. The information will be used to assess the implications of expanding the RCHD payment system to hospitals in various market environments. In addition, the evaluation will examine the potential costs of expanding the RCHD payment methodology, accounting for alternative approaches to targeting rural hospitals. *Form Number:* CMS–10508 (OCN: 0938–NEW); *Frequency:* Annually; *Affected Public:* State, Local or Tribal Governments, Private sector (Business or other for-profit and Not-for-profit organizations); *Number of Respondents:* 57; *Total Annual Responses:* 101; *Total Annual Hours:* 245. (For policy questions regarding this collection contact Woolton Lee at 410–786–4942.)

Dated: January 16, 2014.

Martique Jones,

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

[FR Doc. 2014–01208 Filed 1–22–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1064]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Application for Participation in the Medical Device Fellowship Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by February 24, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: