renewal request to OMB also cover the fully automated version of the OGE Form 201, available only through the OGE Web site at *www.oge.gov*. Initially launched in March 2012, this automated version of the access form enables a requestor to obtain immediately upon Web site submission of the completed form, those financial disclosure reports of individuals who have been nominated by the President to executive branch positions requiring Senate confirmation. In addition, OGE reviews the public financial disclosure report of individuals who have declared their candidacy for the Office of the President of the United States. Those certified reports may also be requested by submitting a completed automated OGE Form 201.

Request for Comments: OGE is publishing this first round notice of its intent to request paperwork clearance for a proposed modified OGE Form 201 Ethics Act Access Form. Agency and public comment is invited specifically on the need for and practical utility of this information collection, the accuracy of OGE's burden estimate, the enhancement of quality, utility and clarity of the information collected, and the minimization of burden (including the use of information technology). Comments received in response to this notice will be summarized for, and may be included with, the OGE request for extension of OMB paperwork approval. The comments will also become a matter of public record.

Approved: April 22, 2013.

Walter M. Shaub, Jr.,

Director, U.S. Office of Government Ethics.

[FR Doc. 2013–09932 Filed 4–25–13; 8:45 am]

BILLING CODE 6345–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request Therapies for Clinically Localized Prostate Cancer

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 medical device manufacturers with products falling within the following UMDNS product codes: Brachytherapy Systems [20–352]; Cyclotrons [15–818]; Radiotherapy Systems, Linear Accelerator [12–364]; Radiotherapy Systems, and Proton Beam [20–546]. Scientific information is being solicited to inform the update of our Comparative Effectiveness Review of Therapies for Clinically Localized Prostate Cancer which is currently being conducted by one of the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on this device will improve the quality of this comparative effectiveness review. AHRQ is requesting this scientific information and conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173.

DATES: Submission-Deadline-on or-before May 28, 2013.

ADDRESSES:

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 US Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT: Robin Paynter, Scientific Information Packet Coordinator, Telephone: 503–220–8262 x58652 or Email: *sips@epc-src.org.*

SUPPLEMENTARY INFORMATION: In accordance with Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, the Agency for Healthcare Research and Quality has commissioned one of the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness review of the evidence for Therapies for Clinically Localized Prostate Cancer: An Update of a 2008 Comparative Effectiveness Review.

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 (e.g., details of studies conducted) through public information requests, including via the **Federal Register** and direct postal and/or online solicitations. We are looking for studies that report on Therapies for Clinically Localized Prostate Cancer, including those that describe adverse events, as specified in the key questions detailed below. 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=1434#7270.*

This notice is a request for information about the following:

- A current product label, if applicable (preferably an electronic PDF file).
- Information identifying published randomized controlled trials and observational studies relevant to the clinical outcomes. AHRQ is interested in receiving both citations and reprints. Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. If possible, please provide a summary that includes 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 withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.
- Registered ClinicalTrials.gov studies. Please provide a list including the ClinicalTrials.gov identifier, condition, and intervention.

Your contribution is very beneficial to this-program. This is a-voluntary-request for information, and all costs for complying with this request must be borne by the submitter. You may wish to indicate whether or not the submission comprises all of the complete information available.

Please Note: The contents of all submissions, regardless of format, will be available to the public upon request unless prohibited by law.

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/.*

Scope and Key Questions

This update examines the same four key questions as in the original 2008 report on the comparative effectiveness of treatments for clinically localized prostate cancer. Although these key questions were reviewed and approved by AHRQ and discussed with Technical Expert Panel (TEP) members for the

original report, we presented them for discussion with a newly convened TEP for this update and made changes as necessary. This update will summarize the more recent evidence comparing the relative effectiveness and safety of treatment options for clinically localized prostate cancer. The key questions we will address are as follows:

Key Question 1

What are the comparative risks and benefits of the following therapies for clinically localized prostate cancer?

a. Radical prostatectomy, including open (retropubic and perineal) and laparoscopic (with or without robotic assistance) approaches.

b. External Beam Radiotherapy, including standard therapy and therapies designed to decrease exposure to normal tissues such as 3D conformal radiation therapy, intensity-modulated radiation therapy, proton beam therapy, and stereotactic body radiation therapy.

c. Interstitial brachytherapy.

d. Cryosurgery.

e. Watchful waiting.

f. Active surveillance.

g. Hormonal therapy as primary therapy, adjuvant, or neoadjuvant to other therapies.

h. High-intensity focused ultrasound.

Key Question 2

How do specific patient characteristics (e.g., age, race/ethnicity, presence or absence of comorbid illness, preferences such as trade-off of treatment-related adverse effects vs. potential for disease progression) affect the outcomes of these therapies overall and differentially?

Key Question 3

How do provider/hospital characteristics affect outcomes of these therapies overall and differentially (e.g., geographic region, case volume, learning curve)?

Key Question 4

How do tumor characteristics (e.g., Gleason score, tumor volume, screen-detected vs. clinically detected tumors, and PSA levels) affect the outcomes of these therapies overall and differentially?

Population, Interventions, Comparators, Outcomes, Timing, Settings Criteria Population

• Key Questions 1, 2, 3, and 4: Men considered to have clinically localized prostate cancer (T1 to T2, N0 to X, M0 to X) regardless of age, histologic grade, or PSA level. Articles will be excluded if men with disease stage higher than T2 were enrolled and outcomes were not stratified by stage.

Interventions

• For Key Questions 1, 2, 3, and 4, we will include treatment options for men with clinically localized prostate cancer: radical prostatectomy (including retropubic, perineal, laparoscopic, robotic-assisted), watchful waiting, active surveillance, External Beam Radiotherapy (including conventional radiation, Intensity Modulated Radiotherapy, 3D conformal radiation, proton beam, and stereotactic body radiation therapy), brachytherapy, androgen deprivation therapy, high-intensity focused ultrasound, and cryotherapy.

Comparators

• Any of the interventions of interest above or watchful waiting.

Outcomes

• The primary outcome is overall mortality or survival. Additional outcomes include prostate-cancer-specific mortality or survival, biochemical (PSA) progression, metastatic and/or clinical progression-free survival, health status, and quality of life. We will focus primarily on common and severe adverse events of treatment including bowel, bladder, and sexual dysfunction, as well as harms from biopsy such as bleeding and nosocomial infections.

• For Key Question 3, we plan to examine outcomes after radical prostatectomy, the most common treatment for localized prostate cancer, in association with provider location, case volume, and affiliation with academic centers.

Timing

• Duration of follow-up will be appropriate for the outcome under consideration.

Settings

• No restrictions by setting.

Dated: April 15, 2013.

Carolyn M. Clancy,

AHRQ, Director.

[FR Doc. 2013–09739 Filed 4–25–13; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Continuing Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation, Funding Opportunity Announcement (FOA) TS13–001, Initial Review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned SEP:

Time and Date: 12:00 p.m.–3:30 p.m., June 13, 2013 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''Continuing Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation, FOA TS13–001.''

Contact Person for More Information: Jane Suen, Dr.P.H, M.S., M.P.H., Scientific Review Officer, CDC, 4770 Buford Highway NE., Mailstop F63, Atlanta, Georgia 30341, Telephone: (770) 488–4281.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–09874 Filed 4–25–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH or Institute)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act