To be eligible to win a prize under this challenge, an individual or entity—

(1) Shall have registered to participate in the competition under the rules promulgated by HHS;

(2) Shall have complied with all the requirements under this section;

(3) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States; and

(4) May not be a Federal entity or Federal employee acting within the scope of their employment.

(5) Shall not be an HHS employee working on their applications or submissions during assigned duty hours.

(6) Shall not be in the reporting chain of Dr. Howard Koh in the Office of the Assistant Secretary for Health.

(7) Federal grantees may not use Federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award.

(8) Federal contractors may not use Federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge submission.

An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during a competition if the facilities and employees are made available to all individuals and entities participating in the competition on an equitable basis.

Challenge participants will be expected to sign a liability release as part of the contest registration process. The liability release will use the following language:

By participating in this competition, I agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from my participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise.

Registration Process for Participants:

Participants can register for the Challenge by visiting *http://www.health2challenge.org* or *http://www.challenge.gov.* Registration will be open from October 31, 2011 to March 15, 2012.

Amount of the Prize:

Challenge winners will be provided monetary cash prizes, totaling $15,000. The first place winner will receive $10,000. The second place winner will receive $3,000. And the third place winner will receive $2,000. Winners will be invited to demonstrate their apps at the 2012 Health Promotion Summit in Washington, DC.

Basis Upon Which Winner Will be Selected:

Challenge submissions will be reviewed by a panel of judges with relevant expertise in health IT and in Healthy People 2020. Winners will be selected based on the following criteria:

(1) Easy Access and Navigation.

(2) Platform Neutrality.

(3) User Appeal.

(4) Innovative Design.

(5) Broad Applicability.

(6) Integration of Health Data.

(7) Evidence of Co-Design and Collaboration.

Judges will also award bonus points to submissions that align with Section 508 of the Rehabilitation Act of 1973, and ones that incorporate plain language and health literacy principles.

Award Approving Official: Carter Blakey, Acting Director, Office of Disease Prevention and Health Promotion.

Additional Information: The Healthy People Web site, *http://www.HealthyPeople.gov,* contains objectives, targets, and baseline data for all of the Healthy People 2020 topic areas. From *healthypeople.gov,* challenge participants will also be able to access the corresponding leading health indicators from the HHS Health Indicators Warehouse.

Dated: October 18, 2011.

Carter Blakey,

Acting Director, Office of Disease Prevention and Health Promotion.

[FR Doc. 2011–27681 Filed 10–25–11; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Phototherapy for Treatment of Chronic Plaque Psoriasis

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 manufacturers of Phototherapy medical devices for treatment of chronic plaque psoriasis. Scientific information is being solicited to inform our Comparative Effectiveness Review of Biologic and Nonbiologic Systemic Agents and Phototherapy for Treatment of Chronic Plaque Psoriasis, 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 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 November 25, 2011.

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 of current studies and complete the form to upload your documents.

E-mail submissions: ehcsrc@ohsu.edu (please do not send zipped files—they are automatically deleted for security reasons).

Print submissions: Robin Paynter, Oregon Health and Science University, Oregon Evidence-based Practice Center, 3181 SW. Sam Jackson Park Road, Mail Code: BICC, Portland, OR 97239–3098.

FOR FURTHER INFORMATION CONTACT: Robin Paynter, Research Librarian, *Telephone:* 503–494–0147 or E-mail: *ehcsrc@ohsu.edu.*

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 the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness review of the evidence for Biologic and Nonbiologic Systemic Agents and Phototherapy for Treatment of Chronic Plaque Psoriasis.

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 systematically requesting information (*e.g.,* details of studies conducted) from medical device industry stakeholders through public information requests, including via the **Federal Register** and direct postal and/or online solicitations. We are looking

for studies that report on phototherapy for treatment of chronic plaque psoriasis, 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://effectivehealthcare.AHRQ.gov/index.cfm/search-forouides-reviews-and-reports/?pageaction=displayproduct&productid=793.*

This notice is a request for industry stakeholders to submit 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. Please provide both a list of citations and reprints if possible.
- 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/followup/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. AHRQ is not requesting and will not consider marketing material, health economics information, or information on other indications. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter. In addition to your scientific information please submit an index document outlining the relevant information in each file along with a statement regarding 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 e-mail list at: *http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/.*

Key Questions

Proposed Key Questions (KQs) were posted for public comments and were modified with consideration of the comments received. Since controversy surrounds the classification of psoriasis as mild or moderate-to-severe, moderate-to-severe disease was not included as an explicit inclusion criterion in the systematic search of the literature or in the comparative effectiveness review. As suggested in the public comments, we will consider when evaluating efficacy data whether patients were naïve to biologics, were treated previously with biologics, or were allowed drug holidays. Although a suggestion was made to evaluate combination therapy and to compare harms in patients without psoriasis or untreated controls with psoriasis, such an evaluation falls outside the scope of our review. We have now specified the measures that will be used for health-related quality of life in KQ.

1. The Psoriasis Area and Severity Index (PAST) score will be considered not only as a binary outcome but as a continuous outcome as suggested. Although we had proposed the Psoriasis Scalp Severity Index (PSSI) and the Nail Psoriasis Severity Index (NAPSI) scores as outcomes, patient-reported improvement in scalp pruritus and scalp pain were suggested as additional outcomes in KQ 1; scalp pruritus and scalp pain are not as commonly reported in the literature and are less likely to add extra value over the body-wide assessments. We have not listed specific malignancies (hepatosplenic T-cell lymphoma and other lymphomas) and infections (tuberculosis and histoplasmosis) in KQ 2 as suggested to be more comprehensive. Weight and impact of neutralizing antibodies have been added as characteristics that will be evaluated in KQ 3. We did not move major adverse cardiovascular events (MACE) from final health outcomes to harms, because this is an outcome of the disease process rather than of therapeutic interventions. Subgroup analyses based on duration of followup were discussed with the Technical Expert Panelists (TEP).

The acronyms used in the questions below are defined within the text and the list under Definitions of Terms.

Question 1

In patients with chronic plaque psoriasis, what is the comparative effectiveness of systemic biologic agents and systemic nonbiologic agents (between-class comparisons) or phototherapy when evaluating intermediate (plaque BSA measurement, PAST score, Patient's Assessment of Global Improvement, PGA, and individual symptom improvement) and final health outcomes (mortality, HRQoL [*e.g.,* DLQI, HAQ–DI, EQ–5D] and other patient-reported outcomes, MACE, diabetes, and psychological comorbidities [*e.g.,* depression, suicide])?

Question 2

In patients with chronic plaque psoriasis, what is the comparative safety of systemic biologic agents and systemic nonbiologic agents (between-class comparisons) or phototherapy (hepatotoxicity [*e.g.,* AST, ALT], nephrotoxicity [*e.g.,* SCr, GFR], hematologic toxicity [*e.g.,* TCP, anemia, neutropenia], hypertension, alteration in metabolic parameters [*e.g.,* glucose, lipids, weight, BMI, thyroid function], injection site reaction, malignancy, infection, and study withdrawal)?

Question 3

In patients with chronic plaque psoriasis treated with systemic biologic therapy, systemic nonbiologic therapy, or phototherapy, which patient or disease characteristics (*e.g.,* age, gender, race, weight, smoking status, psoriasis severity, presence or absence of concomitant psoriatic arthritis, disease duration, baseline disease severity, affected BSA, disease location, number and type of previous treatments, failure of previous treatments and presence of neutralizing antibodies) affect intermediate and final outcomes?

Details regarding the specific therapies considered in each class of interventions and comparators can be found in Tables 1–5. There are no specific requirements in terms of followup period that will be evaluated in these key questions. The setting will include inpatient, outpatient and home therapy.

Dated: October 14, 2011.

Carolyn M. Clancy,

Director, AHRQ.

[FR Doc. 2011–27563 Filed 10–25–11; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the