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- Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes.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primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to withdrawn/followup/analyzed, and effectiveness/efficacy and safety results.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

Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 76 FR 50223—50224, dated August 12, 2011) is amended to reflect the reorganization of the Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows:

After item (7) in the functional statement for the Office of Public Health Preparedness and Response (CG), Division of Strategic National Stockpile (CGE), Office of the Director (CGE1), insert the following: And (8) provides leadership, guidance, and technical assistance to state, tribal and local territories for healthcare preparedness and emergency response and for the integration of preparedness planning across the public health, healthcare, and emergency management sectors.

Dated: October 14, 2011.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–27497 Filed 10–25–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–3180–N2]

Food and Drug Administration

[Docket No. FDA–2010–N–0308]

Pilot Program for Parallel Review of Medical Products; Correction

AGENCY: Food and Drug Administration, Centers for Medicare and Medicaid Services, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) are correcting a notice that appeared in the **Federal Register** of October 11, 2011 (76 FR 62808). The document announced a pilot program for sponsors of innovative device technologies to participate in a program of parallel FDA–CMS review. The document was published with an incorrect Web page address and an incorrect email address. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Jean Olson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4434, Silver Spring, MD 20993–0002, 301–796–6579.

SUPPLEMENTARY INFORMATION: In FR Doc. 2011–25907, appearing on page 62808 in the **Federal Register** of Tuesday, October 11, 2011, the following corrections are made:

1. On page 62808, in the third column, under the heading ''A. *Parallel Review Proposal,*'' the Web site address ''*http://www.parallel-review.fda.gov*'' is corrected to read ''*http://www.fda.gov/parallel-review*''.

2. On page 62809, in the second column, under the heading ''B. *Appropriate Candidates,*'' the e-mail address ''*parallel-review@fda.gov*'' is corrected to read ''*parallel-review@fda.hhs.gov*''.

3. On page 62809, in the third column, under the heading ''1. *Nomination,*'' the Web site address ''*http://www.parallel-review.fda.gov*'' is corrected to read ''*http://www.fda.gov/parallel-review*''.

Dated: October 17, 2011.

Jacquelyn Y. White,

Director, Office of Strategic Operations and Regulatory Affairs. Centers for Medicare & Medicaid Services.

Dated: October 19, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy, Food and Drug Administration.

[FR Doc. 2011–27694 Filed 10–25–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Affordable Care Act Tribal Maternal, Infant and Early Childhood Home Visiting Program Annual Report.

OMB No.: New.

Description

Section 511(h)(2)(A) of Title V of the Social Security Act, as added by Section 2951 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, Affordable Care Act or ACA), authorizes the Secretary of HHS to award grants to Indian Tribes (or a consortium of Indian Tribes), Tribal Organizations, or Urban Indian Organizations to conduct an early childhood home visiting program.

The legislation sets aside 3 percent of the total ACA Maternal, Infant, and Early Childhood Home Visiting Program appropriation (authorized in Section 511(j)) for grants to Tribal entities and requires that the Tribal grants, to the greatest extent practicable, be consistent with the requirements of the Maternal, Infant, and Early Childhood Home Visiting Program grants to States and territories (authorized in Section 511(c)), and include (1) Conducting a needs assessment similar to the assessment required for all States under the legislation and (2) establishing quantifiable, measurable 3- and 5-year benchmarks consistent with the legislation.

The Administration for Children and Families, Office of Child Care, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau, has awarded grants for the Tribal Maternal, Infant, and Early Childhood Home Visiting Program (Tribal Home Visiting). The Tribal Home Visiting grant awards support 5-year cooperative agreements to conduct community needs assessments, plan for and implement (in accordance with an Implementation Plan submitted at the end of Year 1) high-quality, culturally-relevant, evidence-based and promising home visiting programs in at-risk Tribal communities, and participate in research and evaluation activities to build the knowledge base on home visiting among Native populations.

In the Affordable Care Act Tribal Maternal, Infant, and Early Childhood Home Visiting Program Needs Assessment and Plan for Responding to Identified Needs (''Implementation Plan Guidance'') (OMB Control No. 0970–0389, Expiration Date 6/30/14), grantees were notified that in Years 2–5 of their grant they must comply with the requirement for submission of an Annual Report to the Secretary regarding the program and activities carried out under the program.

This Report Shall Address the Following

Home Visiting Program Goals and Objectives.

Implementation of Home Visiting Program in Targeted Community(ies).

Progress toward Meeting Legislatively Mandated Benchmark Requirements.

Research and Evaluation Update.

Home Visiting Program Continuous Quality Improvement (CQI) Efforts.

Administration of Home Visiting Program.

Technical Assistance Needs.

Respondents