DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Planning and Evaluation; Medicare Program; Meeting of the Technical Advisory Panel on Medicare Trustee Reports

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces public meetings of the Technical Advisory Panel on Medicare Trustee Reports (Panel). Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). The Panel will discuss the short-term (10 year) projection methods and assumptions in projecting Medicare health spending for Parts A, B, C and D and may make recommendations to the Medicare Trustees on how the Trustees might more accurately estimate health spending in the short run. The Panel's discussion is expected to be very technical in nature and will focus on the actuarial and economic assumptions and methods by which Trustees might more accurately measure health spending. Although panelists are not limited in the topics they may discuss, the Panel is not expected to discuss or recommend changes in current or future Medicare provider payment rates or coverage policy.

DATES: July 7, 2011, 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at HHS headquarters at 200 Independence Ave., SW., Washington, DC 20201, Room 738G.

Comments: The meeting will allocate time on the agenda to hear public comments at the end of the meeting. In lieu of oral comments, formal written comments may be submitted for the record to Donald T. Oellerich, OASPE, 200 Independence Ave., SW., Washington, DC 20201, Room 405F. Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Donald T. Oellerich (202) 690–8410, *Don.oellerich@hhs.gov. Note:* Although the meeting is open to the public, procedures governing security procedures and the entrance to Federal buildings may change without notice. Those wishing to attend the meeting must call or e-mail Dr. Oellerich by Friday July 1, 2011, so that their name may be put on a list of expected attendees and forwarded to the security officers at HHS Headquarters.

SUPPLEMENTARY INFORMATION: Topics of the Meeting: The Panel is specifically charged with discussing and possibly making recommendations to the Medicare Trustees on how the Trustees might more accurately estimate health spending in the United States. The discussion is expected to focus on highly technical aspects of estimation involving economics and actuarial science. Panelists are not restricted, however, in the topics that they choose to discuss.

Procedure and Agenda: This meeting is open to the public. The Panel will likely hear presentations by panel members and HHS staff regarding short range projection methods and assumptions. After any presentations, the Panel will deliberate openly on the topic. Interested persons may observe the deliberations, but the Panel will not hear public comments during this time. The Panel will also allow an open public session for any attendee to address issues specific to the topic.

Authority: 42 U.S.C. 217a; Section 222 of the Public Health Services Act, as amended. The panel is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Sherry Glied,

Assistant Secretary for Planning and Evaluation.

[FR Doc. 2011–15515 Filed 6–21–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Statement of Organization, Functions, and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority for the U.S. Department of Health and Human Services is being amended at Chapter AA, Immediate Office of the Secretary, as last amended at 76 FR 4703, dated, January 26, 2011, and at Chapter AQ, Office of Global Health Affairs (OGHA), as last amended at 69 FR 51679–80, dated August 20, 2004, as follows:

I. Under Part A, Chapter AA, Section AA.10 Organization, replace ''Office of Global Health Affairs (AQ)'' with ''Office of Global Affairs (AQ).''

II. Under Part A, Chapter AQ, replace all references to the ''Office of Global Health Affairs'' with ''Office of Global Affairs'' and all references to ''OGHA'' with ''OGA.''

III. Delegation of Authority. All delegations and redelegations of authority made to officials and employees of the Office of Global Affairs will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

Dated: June 14, 2011.

E.J. Holland, Jr.,

Assistant Secretary for Administration.

[FR Doc. 2011–15517 Filed 6–21–11; 8:45 am]

BILLING CODE 4110–60–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Insulin Delivery and Glucose Monitoring Devices for Diabetes Mellitus

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 of insulin pumps and continuous glucose monitors. Scientific information is being solicited to inform our Comparative Effectiveness and Safety of Insulin Delivery and Glucose Monitoring Methods for Diabetes Mellitus review, 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 July 22, 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. 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 the Effectiveness and Safety of Insulin Delivery and Glucose Monitoring Methods for Diabetes Mellitus.

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 the Comparative Effectiveness and Safety of Insulin Delivery and Glucose Monitoring Methods for Diabetes Mellitus, 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-for-guides-reviews-and-reports/?PAGEaction=displayproduct&productid=689.*

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/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. 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.

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 website 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

Our draft Key Questions (KQs) were posted for public comment in October 2010 (see Appendix 1). Based on the public comments, we made the following changes to the KQs:

1. We will not include pregnant women with gestational diabetes in the review. There is a range of glucose abnormalities among women with gestational diabetes, and many women with gestational diabetes are not on intensive insulin therapy. Insulin pump therapy and CGM are more relevant to pregnant women with pre-existing diabetes. The population for this review will include patients with type 1 diabetes, patients with type 2 diabetes who are on insulin therapy, and pregnant women with pre-existing diabetes.

2. We will see if there are any studies that focused on older adults (age >65 years). Currently, there is no upper age limit on our proposed study populations, so we should be able to examine this group if data are available. Therefore, the age categories considered for this review will be very young children, adolescents and adults, including older adults (age >65 years).

3. KQ3 was made a subquestion of KQ 2.

There were several other relevant comments about the KQs and the protocol. These comments and our responses are summarized below.

1. We plan to abstract the following data to use in our analysis when available: measurement of adherence, MDI delivery method (pen vs. vial or syringe), study design, information about device use (e.g., analyses based on adherence to wearing the device, training of patient/staff, generation/model of devices), study participant characteristics, adjustment to insulin therapy, definitions of hypoglycemia, definitions of diabetes, assessment of quality of life, rt-CGM alarm threshold, and study length and followup time.

2. Because insulin regimens may change over time, it may be difficult to determine if the current delivery method is responsible for the long-term outcomes. Therefore, we will abstract data on the length of use of current technology, changes in the mode of insulin delivery over time, and changes in the type of insulin used over time if available.

3. The list of process measures and intermediate outcomes will not change. Some of the suggested outcomes were either beyond the scope of the review (e.g., changes in carbohydrate counting, diet, and physical activity) or only applied to a particular insulin-delivery device or blood glucose-monitoring technique (e.g., time spent in the hypoglycemic range).

The finalized KQs are:

KQ 1

In patients receiving intensive insulin therapy, does mode of delivery (multiple daily injections [MDI] vs. continuous subcutaneous insulin infusion [CSII]) have a differential effect on process measures, intermediate outcomes, and clinical outcomes in patients with diabetes mellitus? (Process measures, intermediate outcomes, and clinical outcomes of interest are summarized below in Table 1.) Do these effects differ by:

a. Type 1 or type 2 diabetes status?

b. Age: Very young children, adolescents, and adults, including older adults (age >65 years)?

c. Pregnancy status: Pre-existing type 1 or type 2 diabetes?

KQ 2

In patients using intensive insulin therapy (MDI or CSII), does the type of glucose monitoring (real-time continuous glucose monitoring [rt-CGM] vs. self-monitoring of blood glucose [SMBG]) have a differential effect on process measures, intermediate outcomes, and clinical outcomes (see Table 1) in patients with diabetes mellitus (*i.e.,* what is the incremental benefit of rt-CGM in patients already using intensive insulin therapy on process and outcome measures)? Do these effects differ by:

a. Type 1 or type 2 diabetes status?

b. Age: Very young children, adolescents, and adults, including older adults (age >65 years)?

c. Pregnancy status: Pre-existing type 1 or type 2 diabetes?

d. Intensive insulin delivery: MDI or CSII?

TABLE 1—SUMMARY OF PROCESS MEASURES AND INTERMEDIATE AND CLINICAL OUTCOMES

Process measures	Intermediate outcomes	Clinical outcomes

• Ratio of basal to bolus insulin
• Frequency of adjusting insulin therapy
• Adherence to insulin therapy/sensor use
• Frequency of professional or allied health visits.
	• Primary
	  • Hemoglobin $A1_c$
	• Secondary
	  • Hyperglycemia
	  • Weight gain
	  • Hypoglycemia frequency
		• Microvascular*
		  • Retinopathy
		  • Nephropathy
		  • Neuropathy
		• Macrovascular*
		  • Coronary heart disease
		  • Cerebrovascular disease
		  • Peropheral arterial disease
		• Severe hypoglycemia
		• Quality of life
		• Fetal outcomes †
		• Maternal pregnancy outcomes
		  • C-section rates

* We will only include objective assessments of microvascular and macrovascular outcomes (i.e., we will be excluding patient self-reported microvascular and macrovascular outcomes).

† Fetal outcomes include gestational age, birth weight, frequency of neonatal hypoglycemia, birth trauma, major and minor anomalies, and admission to a neonatal intensive care unit.

For each KQ we will identify:

Population(s):

Adults, adolescents, and children with type 1 or type 2 diabetes mellitus and pregnant women with pre-existing diabetes treated with insulin therapy.

1. We will use age ranges prescribed by the Juvenile Diabetes Research Foundation (<8 years [very young children], 8–14 years [children], 14–25 years [adolescent], and >25 years [adults]); however, our final definitions will be guided by those used in the literature that is reviewed.

2. If available, we will examine data among populations of older adult (>65 years).

Interventions:

The interventions of interest are CSII (see Appendix 2 for a list of insulin pumps and models) and rt-CGM (see Appendix 3 for a list of monitors).

1. We will not be including the following devices because they are no longer used in the United States:

a. GlucoWatch continuous glucose meter

b. Insulin pumps with regular insulin

Comparators:

All studies must have a concurrent comparison group.

1. CSII would be compared with MDI, which will be defined as at least three injections of basal and rapid-acting insulin per day.

2. rt-CGM would be compared with SMBG, which will be defined as at least three fingersticks per day.

Outcomes measures for each KQ:

1. Process measures

a. Ratio of basal to bolus insulin

b. Frequency of adjustments to insulin therapy

c. Adherence to insulin therapy/sensor use

d. Frequency of professional or allied health visits Intermediate outcomes

- HbA1c

a. Hyperglycemia

b. Weight gain

c. Hypoglycemia frequency

Clinical Outcomes

- Objective assessments of microvascular outcomes (retinopathy, nephropathy, and neuropathy)

a. Objective assessments of macrovascular outcomes (coronary heart disease, cerebrovascular disease, and peripheral arterial disease)

b. Severe hypoglycemia

c. Quality of life

d. Fetal outcomes (gestational age, birth weight, frequency of neonatal hypoglycemia, birth trauma, major and minor anomalies, and admission to a neonatal intensive care unit)

e. Maternal pregnancy outcomes (cesarean section rates)

Timing: Usage of a device for at least 24 hours.

Settings: Outpatient setting.

Dated: June 10, 2011.

Carolyn M. Clancy,

AHRQ, Director.

[FR Doc. 2011–15580 Filed 6–21–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0110]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Prescription Drug Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Prescription Drug Advertisements'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 24, 2011 (76 FR 4117), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0686. The approval expires on June 30, 2014. A