they were produced, including any code if applicable. The processes can be submitted in text document.

In order for an entry to be eligible to win this Challenge, it must meet the following requirements:

1. Acceptable platforms—The tool must be designed for use with existing Web, mobile Web, electronic health record, or other platform.

2. Section 508 Compliance—Contestants must acknowledge that they understand that, as a prerequisite to any subsequent acquisition by FAR contract or other method, they are required to make their proposed solution compliant with Section 508 accessibility and usability requirements at their own expense. Any electronic information technology that is ultimately obtained by HHS for its use, development, or maintenance must meet Section 508 accessibility and usability standards. Past experience has demonstrated that it can be costly for solution-providers to ''retrofit'' solutions if remediation is later needed. The HHS Section 508 Evaluation Product Assessment Template, available at *http://www.hhs.gov/od/vendors/index.html,* provides a useful roadmap for developers to review. It is a simple, web-based checklist utilized by HHS officials to allow vendors to document how their products do or do not meet the various Section 508 requirements.

3. No HHS or OBMT logo—The app must not use HHS' or OBMT's logos or official seals in the Submission, and must not claim endorsement.

4. Functionality/Accuracy—A submission may be disqualified if it fails to function as expressed in the description provided by the user, or if it provides inaccurate or incomplete information.

5. Security—Submissions must be free of malware. Contestant agrees that OBMT may conduct testing on the app to determine whether malware or other security threats may be present. OBMT may disqualify the Submission if, in OBMT's judgment, the app may damage government or others' equipment or operating environment.

Additional Information

General Conditions: OBMT reserves the right to cancel, suspend, and/or modify the Contest, or any part of it, for any reason, at OBMT's sole discretion.

Intellectual Property

- Each entrant retains full ownership and title in and to their submission. Entrants expressly reserve all intellectual property rights not expressly granted under the challenge agreement.
- By participating in the challenge, each entrant hereby irrevocably grants to OBMT a limited, non-exclusive, royalty-free, worldwide license and right to reproduce, publically perform, publically display, and use the submission for internal HHS business and to the extent necessary to administer the challenge, and to publically perform and publically display the Submission, including, without limitation, for advertising and promotional purposes relating to the challenge.

Dated: July 11, 2014.

E.J. Holland, Jr.,

Assistant Secretary for Administration, U.S. Department of Health and Human Services.

[FR Doc. 2014–17065 Filed 7–18–14; 8:45 am]

BILLING CODE 4151–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Behavioral Programs 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 the public. Scientific information is being solicited to inform our review of Behavioral Programs for Diabetes Mellitus, 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 will improve the quality of this review. AHRQ is conducting this systematic review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, and Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: Submission Deadline on or before August 20, 2014.

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 to upload your documents.

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

FOR FURTHER INFORMATION CONTACT: Ryan McKenna, Telephone: 503–220–8262 ext. 58653 or Email: *SIPS@epc-src.org.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a review of the evidence for Behavioral Programs 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 requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on Behavioral Programs for Diabetes Mellitus, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: *http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1917.*

This notice is to notify the public that the EHC Program would find the following information on Behavioral Programs for Diabetes Mellitus helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.
- For completed studies that do not have results on ClinicalTrials.gov, please provide a summary, including 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 follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- A list of ongoing studies that your organization has sponsored for this indication. In the list, please provide the ClinicalTrials.gov trial number or, if the

trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

• Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EHC Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EHC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

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/.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions. The entire research protocol is also available online at: *http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1917.*

The Key Questions

Question 1

For patients with Type 1 Diabetes Mellitus (T1DM), are behavioral programs implemented in a community health setting effective compared with usual or standard care, or active comparators in, a) improving behavioral, clinical, and health outcomes, b) improving diabetes-related health care utilization, and c) achieving program acceptability as measured by participant attrition rates?

Question 2

For patients with T1DM, do behavioral programs implemented in the community health setting differ in effectiveness for behavioral, clinical, and health outcomes, their effect on diabetes-related health care utilization, or program acceptability, for subgroups of patients based on: Age (i.e., children and adolescents [≤18 years] and their families, young adults [19–30 years], adults [31–64 years], older adults [≥65 years]); race or ethnicity; socioeconomic status (e.g., family income, education level, literacy); time since diagnosis (i.e., ≤1 year vs. >1 year); and, level of glycemic control (e.g., HbA1c <7 vs. ≥7 percent)?

Question 3

For patients with T1DM, does the effectiveness of behavioral programs differ based on the: (a) Components; (b) intensity (i.e., program duration, frequency/periodicity of interactions); (b) delivery personnel (e.g., dietitian, exercise specialist, physician, nurse practitioner, certified diabetes educator, lay health worker); (c) method of communication (e.g., individual vs. group, face-to-face, interactive behavior change technology, social media); (d) degree of tailoring based on needs assessment (e.g., educational/behavioral deficits, age or other demographics, readiness to change); or (e) level and nature of community engagement?

Question 4

For patients with T1DM, what are the associated harms (i.e., activity-related injury) of behavioral programs implemented in a community health setting compared with usual care, standard care, or active comparators?

Question 5

Among behavioral programs targeted at adults with Type 2 Diabetes Mellitus (T2DM) implemented in a community health setting, what factors contribute to: (a) Their effectiveness for behavioral, clinical, and health outcomes; (b) their effect on diabetes-related health care utilization; and (c) program acceptability as measured by participant attrition rates? Factors include program components, program intensity, delivery personnel, methods of delivery and communication, degree of tailoring, and community engagement.

Question 6

Do the factors that contribute to program effectiveness for patients with T2DM vary across the following subpopulations: Age (i.e., young adults [19–30 years], adults [31–64 years], older adults [≥65 years]); race or ethnicity; socioeconomic status (e.g., family income, education level, literacy); time since diagnosis (i.e., ≤1 year vs. >1 year); and, level of glycemic control (i.e., HbA1c <7 vs. ≥7 percent)?

PICOTS (Patients, Interventions, Comparators, Outcomes, Timing, and Setting) Criteria

PICOTS frameworks are presented below for the Key Questions that relate to Type 1 Diabetes Mellitus (T1DM) and Type 2 Diabetes Mellitus (T2DM). These frameworks will guide all the stages of the systematic review, including literature searching, study selection, and data abstraction.

Key Questions 1–4

Population

Patients with T1DM (any age) who have undergone basic diabetes education.

Interventions

- Multicomponent behavioral program that includes at least one of:
  - Diabetes self-management education; OR
  - Structured dietary intervention (related to any of weight loss, glycemic control, or reducing risk for complications) together with one or more additional components; OR
  - Structured exercise/physical activity intervention together with one or more additional components.
  - Additional components may include interventions related to: Diet or physical activity, behavioral change (including but not limited to: Goal setting, problem solving, motivational interviewing, coping skills training, cognitive behavioral therapy strategies), relaxation or stress reduction, blood glucose awareness, medication adherence, or self-monitoring for diabetic complications (foot, eye, and renal tests).
- Repeated provision by one or more trained individuals
- Duration of intervention: minimum 4 weeks

Comparators

- Usual or standard care or an active comparator (e.g., behavioral program or intervention) as reported for studies
- Delivery methods (personnel, intensity, communication methods, etc.) as reported for studies

Outcomes

- Behavioral outcomes
  - Self-regulation of insulin based on diet, physical activity, and glucose monitoring results
  - Change in physical activity (e.g., volume of activity per week) or fitness (e.g., cardiorespiratory fitness, strength)

- Change in dietary or nutrient intake (i.e., energy intake, saturated fat consumption)
- Adherence to treatment, including self-monitoring and medication

- Clinical outcomes
  - Glycemic control (Hemoglobin Alt)
  - Change in body composition (i.e., weight, Body Mass Index, waist circumference, % body fat)
  - Episodes of severe hypoglycemia
  - Treatment for hyperglycemia (ketoacidosis)
  - Control of blood pressure and lipids
  - Development or control of depression or anxiety
- Health outcomes
  - Quality of life (e.g., validated tools for health-related quality of life, life satisfaction, psychosocial adaptation to illness, patient satisfaction)
  - Development of micro- and macrovascular complications (i.e., retinopathy, nephropathy, neuropathy, cardiovascular outcomes)
  - Mortality (all-cause)
- Diabetes-related health care utilization
  - Hospital admissions
  - Length of stay in hospital
  - Emergency department admissions
  - Visits to specialist clinics
- Program acceptability as measured by participant attrition rates
- Harms from program as reported for studies
- Activity-related injury

Timing

Any length of followup

Study Design

Prospective comparative studies using a best evidence approach based on hierarchy of evidence: randomized controlled trials, nonrandomized controlled trials, prospective cohort studies, controlled before-after studies

Settings

- Community health setting (i.e., ambulatory care clinics, outpatient clinics, primary care clinics, family physician clinics, Community Health Centers, Rural Health Centers)
- United States or other high-income countries with a very high Human Development Index

Key Questions 5–6

Population

Adults (≥18 years) with T2DM who have undergone primary diabetes education

Interventions

- Multicomponent behavioral programs that include at least one of:
  - Diabetes self-management education; OR
  - Structured dietary intervention (related to any of weight loss, glycemic control, or reducing risk for complications) together with one or more additional components; OR
  - Structured exercise/physical activity intervention together with one or more additional components.
  - Additional components may include interventions related to: diet or physical activity, behavioral change (including but not limited to: Goal setting, problem solving, motivational interviewing, coping skills training, cognitive behavioral therapy strategies), relaxation or stress reduction, blood glucose awareness, medication adherence, or self-monitoring for diabetic complications (foot, eye, and renal tests).
- Repeated provision by one or more trained individuals
- Duration of intervention: Minimum 4 weeks

Comparators

- Usual or standard care or an active comparator (e.g., behavioral program or intervention) as reported for studies
- Delivery methods (personnel, intensity, communication methods etc.) as reported for studies

Outcomes

- Behavioral outcomes
  - Change in physical activity (e.g., volume of activity per week) or fitness (e.g., cardiorespiratory fitness, strength)
  - Change in dietary or nutrient intake (i.e., energy intake, saturated fat consumption)
  - Adherence to medication
- Clinical outcomes
  - Glycemic control (Hemoglobin Mc)
  - Change in body composition (i.e., weight, Body Mass Index, waist circumference, % body fat)
  - Control of blood pressure and lipids
  - Sleep apnea or sleep quality
  - Development or control of depression or anxiety
- Health outcomes
  - Quality of life (e.g., validated tools for health-related quality of life, life satisfaction, psychosocial adaptation to illness, patient satisfaction)
  - Development of micro- and macrovascular complications (i.e., retinopathy, nephropathy, neuropathy, cardiovascular outcomes)
  - Mortality (all-cause)
- Diabetes-related health care utilization
  - Hospital admissions
  - Length of stay in hospital
  - Emergency department admissions
  - Visits to specialist clinics
- Program acceptability as measured by participant attrition rates

Timing

Any length of followup

Study design

Randomized controlled trials

Settings

- Community health setting (i.e., ambulatory care clinics, outpatient clinics, primary care clinics, family physician clinics, Community Health Centers, Rural Health Centers)
- United States or other high-income country with a very high Human Development Index

Language

English

Dated: July 3, 2014.

Richard Kronick,

AHRQ Director.

[FR Doc. 2014–16669 Filed 7–18–14; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Statement of Organization, Functions, and Delegations of Authority

Part E, Chapter E (Agency for Healthcare Research and Quality), of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (61 FR 15955–58, April 10, 1996, most recently amended at 78 FR 38981, on June 28, 2013) is amended to reflect recent organizational changes. The specific amendments are as follows:

I. Under Section E–10, Organization, delete all components and replace with the following:

A. Office of the Director.

B. Center for Delivery, Organization, and Markets.

C. Center for Financing, Access, and Cost Trends.

D. Center for Evidence and Practice Improvement.