SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions to inform our review of Short and Long Term Outcomes after Bariatric Therapies in the Medicare Population, which is currently being conducted by the AHRQ’s Evidence-based Practice Centers (EPC) Programs. Access to published and unpublished pertinent scientific information will improve the quality of this review. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: Submission Deadline on or before January 9, 2017.

ADDRESSES: Email submissions: SEADS@epcsrc.org.
Print submissions:
Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, P.O. Box 69539, Portland, OR 97229
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. 51723 or Email: SIPS@epcsrc.org.

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Programs to complete a review of the evidence for Short and Long Term Outcomes after Bariatric Therapies in the Medicare Population.

The EPC 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 Short and Long Term Outcomes after Bariatric Therapies in the Medicare Population, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: http://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/topicrefinement/bariatric-surgery-protocol.pdf.

This notice is to notify the public that the EPC Program would find the following information on Short and Long Term Outcomes after Bariatric Therapies in the Medicare Population 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 EPC 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 EPC Program.

The draft of this review will be posted on AHRQ’s EPC 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: https://subscriptions.ahrq.gov/accounts/USAHRQ/subscriber/new?topic_id=USAHRQ_18.

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 available online at:
I. In Medicare-eligible patients, what is the effect of different bariatric therapies (contrasted between them or vs. non-bariatric therapies) on weight outcomes (including failure to achieve at least minimal weight loss)?

II. What patient—(KQ2 I) and intervention-level characteristics (KQ2 II) modify the effect of bariatric therapies on weight outcomes (including failure to achieve at least minimal weight loss)?

III. In Medicare-eligible patients who have undergone bariatric therapy, what is the frequency and the predictors of failing to achieve at least minimal weight loss?

KQ 3:

I. In Medicare-eligible patients, what is the effect of different bariatric therapies (contrasted between them or vs. non-bariatric therapies) on weight outcomes (including failure to achieve at least minimal weight loss)?

II. What patient—(KQ2 I) and intervention-level characteristics (KQ2 II) modify the effect of bariatric therapies on weight outcomes (including failure to achieve at least minimal weight loss)?

III. In Medicare-eligible patients who have undergone bariatric therapy, what is the frequency and the predictors of failing to achieve at least minimal weight loss?

KQ 4:

I. In Medicare-eligible patients, what is the comparative effectiveness and safety of different bariatric interventions (contrasted between them or vs. non-bariatric interventions) with respect to the outcomes in KQ2 III?

II. What patient—(KQ2 I) and intervention-level (KQ2 II) characteristics modify the effect of the bariatric therapies on the outcomes in KQ2 III?

KQ 5:

I. In Medicare-eligible patients who have undergone bariatric therapy, what is the association between weight outcomes and eligible short- and long-term outcomes (other than weight outcomes)?

II. In Medicare-eligible patients, what proportion of the bariatric intervention effect on eligible short- and long-term outcomes (other than weight outcomes) is accounted for by changes in weight outcomes?

KQ 6: What are the theorized mechanisms of action of bariatric procedures on weight loss and on type 2 diabetes in the Medicare population?

KQ 7: In studies that are applicable to the Medicare population and enroll patients who have undergone bariatric therapy, what are

I. the characteristics and indications of the patients including descriptives of age, BMI, and comorbid conditions

II. the characteristics of the interventions, including the bariatric procedures themselves as well as pre- and/or post-surgical surgical work-ups (e.g., psychiatric evaluations, behavioral and nutritional counseling)

III. the outcomes that have been measured, including peri-operative (i.e., 90 days or less after bariatric surgery), short-term (2 years or less from surgery), mid-term (more than 2 but 5 or less years), and long-term (more than 5 years after surgery) outcomes?

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I. In Medicare-eligible patients, what is the effect of different bariatric therapies (contrasted between them or vs. non-bariatric therapies) on weight outcomes (including failure to achieve at least minimal weight loss)?

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I. In Medicare-eligible patients who have undergone bariatric therapy, what is the association between weight outcomes and eligible short- and long-term outcomes (other than weight outcomes)?

II. In Medicare-eligible patients, what proportion of the bariatric intervention effect on eligible short- and long-term outcomes (other than weight outcomes) is accounted for by changes in weight outcomes?
A. Sexual functioning
B. Ability to participate in an exercise program
C. Ability to return to work
D. Physical performance test pain (joint pain, joint aches)
E. Regular daily activities
F. Polypharmacy
G. Admission to a skilled-nurse facility

XVII. Access to plastic surgery
XVIII. Readmissions/rehospitalizations

Prevention Programs

The surveillance system is focused on behaviors directly related to HIV transmission and those that are amenable to intervention through prevention programs. Information collected through the NHBS System allows CDC to: (a) Describe the prevalence of and trends in risk behaviors; (b) describe the prevalence of and trends in HIV testing and HIV infection; (c) describe the prevalence of and trends in use of HIV prevention services; and (d) identify met and unmet needs for HIV prevention services in order to inform health departments, community-based organizations, community planning groups and other stakeholders. No other federal agency systematically collects this type of information from persons at risk for HIV infection.

Venue-based sampling methods are used to identify respondents for the MSM information collection cycle and respondent-driven sampling methods are used to identify respondents for the IDU cycle and the HET cycle. Consistent with these methods, persons who participate in the IDU and HET interviews may be trained to recruit additional respondents. Each person who serves as a peer recruiter will be asked to participate in a short debriefing interview.

CDC requests OMB approval to continue information collection for three years, with revisions. Selected questions in the eligibility screener and the behavioral assessment interview instruments will be updated to improve usability and data quality, and new questions will be added to provide measures of high priority emerging issues including pre-exposure prophylaxis, treatment as prevention, and opioid use and abuse. Lower priority questions and repetitive content will be deleted in order to manage project cost and respondent burden. There are no changes to the estimated burden per response for any information collection instrument. However, total burden will decrease due to a reduction in the number of health departments funded to participate in the NHBS System (from 25 to 22). Compared to the previous period of OMB approval, this will reduce the total estimated number of interviews for each cycle from 12,500 (4,167 annualized) to 11,000 (3,667 annualized).

Information collected through the NHBS has a substantial impact on the design and delivery of HIV prevention programs aimed at reducing new HIV infections and evaluating