SUMMARY: Notice is hereby given of the names of the members of the Performance Review Board.

FOR FURTHER INFORMATION CONTACT: William ''Todd'' Cole, Director Office of Human Resources, Federal Maritime Commission, 800 North Capitol Street NW., Washington, DC 20573.

SUPPLEMENTARY INFORMATION: Sec. 4314(c) (1) through (5) of title 5, U.S.C., requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more performance review boards. The board shall review and evaluate the initial appraisal of a senior executive's performance by the supervisor, along with any recommendations to the appointing authority relative to the performance of the senior executive.

THE MEMBERS OF THE PERFORMANCE REVIEW BOARD ARE:

1. Rebecca F. Dye, Commissioner
2. Richard A. Lidinsky, Jr., Commissioner
3. Michael A. Khouri, Commissioner
4. William P. Doyle, Commissioner
5. Clay G. Guthridge, Chief Administrative Law Judge
6. Erin M. Wirth, Administrative Law Judge
7. Florence A. Carr, Director, Bureau of Trade Analysis
8. Rebecca A. Fenneman, Director, Office of Consumer Affairs & Dispute Resolution Services
9. Karen V. Gregory, Managing Director
10. Peter J. King, Director, Assistant Managing Director
11. Sandra L. Kusumoto, Director, Bureau of Certification and Licensing
12. Mary T. Hoang, Chief of Staff
13. Tyler J. Wood, General Counsel

Rachel E. Dickon,

Assistant Secretary.

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BILLING CODE 6731–AA–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Short and Long Term Outcomes After Bariatric Therapies in the Medicare Population

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 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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@epc-src.org.

Print submissions:

Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, P.O. 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. 51723 or Email: *SIPS@epc-src.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. 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 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:

http://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/topicrefinement/bariatric-surgery-protocol.pdf.

KQ 1: What are the theorized mechanisms of action of bariatric procedures on weight loss and on type 2 diabetes in the Medicare population?

KQ 2: 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?

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?

PICOTS (Population, Intervention, Comparator, Outcome, Timing, Setting)

Population: Medicare-eligible population to include those age 65 and older and the disabled.

Interventions: Bariatric treatments including anatomic alteration, FDA-approved device placements, open surgical procedures, as well as laparoscopic and endoscopic procedures

I. Surgical bariatric therapies
- A. Adjustable gastric banding (AGB)
- 1. LAP-band, pars flaccida technique
- 2. LAP-band, perigastric technique
- 3. Swedish-band (also known as REALIZE-band), pars flaccida technique
- 4. Swedish-band (also known as REALIZE-band), pars flaccida technique, single bolus filling
- 5. Gastroplasties
- B. Horizontal banded gastroplasty
- C. Vertical banded gastroplasty
- D. Endoluminal vertical gastroplasty
- 1. Sleeve gastrectomy
- 2. Gastric plication (also referred to as gastric greater curvature plication or gastric imbrication)
- 3. Jejunoileal bypass
- 4. Biliopancreatic diversion (BPD)
- E. Biliopancreatic diversion (BPD) with RYGB (BPD–RYGB)
- F. BPD with duodenal switch (BPD–DS)
- 1. Roux-en-Y Gastric Bypass (RYGB)
- 2. Mini-gastric bypass
- 3. Single Anastomosis Duodeno-Ileostomy (SADI)
- 4. Vagal blockade
- 5. Omentum removal (omentectomy)
- 6. Gastric stimulation (also referred to as gastric pacing)
- 7. Mucosal ablation

II. Endoscopic bariatric therapies
- A. Space-occupying endoscopic bariatric therapies
- 1. Intragastric balloons
- B. Nonballoon devices
- 1. Aspiration therapy
- 2. Endoscopic sleeve gastroplasty
- 3. Endoscopic gastrointestinal bypass devices
- C. Duodenojejunal bypass sleeve
- D. Gastroduodenojejunal bypass sleeve
- 1. Duodenal mucosal resurfacing
- 2. Self-assembling magnets for endoscopy

Comparisons: Comparisons of interest include comparisons between different surgical interventions, or between surgical and non-surgical interventions

Outcomes: Outcomes will be classified as 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). The following outcome categories are of interest:

I. Mortality
II. Weight loss
III. Reoperations/need for revisional bariatric surgery
IV. Postoperative complications including mortality
V. Metabolic/diabetes-related outcomes
- A. Correction of glucose tolerance, including elimination of all medications with Hemoglobin A1c (HbA1c) <6
- B. Diabetes: New onset diabetes; treatment of diabetes; diabetic complications (microvascular disease, kidney disease, retinopathy)
- C. Hypoglycemic-like syndromes such as nesidioblastosis, post-gastric surgery hypoglycemia, and dumping syndrome
- D. Non-alcoholic steatohepatitis (NASH) and/or non-alcoholic fatty liver disease (NAFLD)

VI. Reflux
VII. Cardiovascular outcomes
- A. Myocardial infarction
- B. Stroke
- C. Hypertension

VIII. Respiratory disease
- A. Asthma
- B. COPD

IX. Orthopedic outcomes
- A. Fractures
- B. Falls
- C. Osteoporosis/bone-mineral density (DEXA, DEEG)

X. Sleep apnea including the discontinuation of CPAP or BiPAP
XI. Incidence of specific cancers (breast, colorectal cancer, endometrial cancer, esophageal adenocarcinoma, gall bladder cancer, and renal cell cancer)
XII. Nutritional deficiencies including zinc, iron, thiamine, and vitamin D, and associated disorders such as neuropathy and bone disease
XIII. Renal function as measured by creatinine clearance or urinary albumin excretion
XIV. Compliance to follow-up
XV. Mental health outcomes. Incidence of suicide and suicide attempts
- A. Incidence of depression
- B. Alcohol addiction after surgery/Substance abuse
- C. Psychiatric hospitalizations
- D. Anxiety
- E. Panic disorder
- F. Borderline personality disorder
- G. PTSD
- H. Bipolar disorder

XVI. Function and quality of life (validated measurements only), *e.g.,*
- i. Cognitive functioning

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
Timing:
No time limit
Setting:
Any

Sharon B. Arnold,

AHRQ Deputy.

[FR Doc. 2016–29408 Filed 12–7–16; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–17–0770]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

National HIV Behavioral Surveillance System ((NHBS), OMB Control No. 0920–0770, exp. 03/31/2017)—Revision—National Center for HIV, Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC currently sponsors the National HIV Behavioral Surveillance (NHBS) System. The system is designed to describe and monitor the HIV risk behaviors, HIV seroprevalence and incidence, and HIV prevention experiences of persons at highest risk for HIV infection in the United States. NHBS awardees are state and local health departments that provide HIV-related services, conduct NHBS interviews, and submit non-identifiable information to CDC. To be eligible for NHBS funding, a health department must serve one of the 30 Metropolitan Statistical Areas (MSA) in the U.S. with high HIV prevalence. Twenty-two (22) programs receive NHBS funding and technical assistance from CDC at this time. Burden estimates are based on current availability of funds and recruitment targets for 22 CDC-funded NHBS awardees. If additional funding is received to support the participation of additional sites, CDC will submit a Change Request to make the appropriate adjustments to the total estimated annualized burden.

Information collection is based on rotating annual ''cycles'' of surveillance with three populations: Men who have sex with men (MSM), injecting drug users (IDUs), and heterosexuals at increased risk of HIV (HET). Screening interviews and specialized behavioral assessment interviews are conducted once every three years with each population: MSM in year 1, IDU in year 2, and HET in year 3. The target number of annual interviews for each NHBS-funded awardee is 500. Due to differences in the risk characteristics of the MSM, IDU and HET groups, the behavioral assessment is customized for each group. In addition, an HIV test and pre-test counseling session are offered to all persons who participate in an NHBS interview.

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 targeted prevention programs aimed at reducing new HIV infections and evaluating