association, also of Marshfield, Wisconsin, and indirectly engage in real estate development and management activities pursuant to section 238.53(b)(4)–(8) of Regulation LL.

Board of Governors of the Federal Reserve System, July 9, 2020.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2020–15182 Filed 7–13–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Continuous Positive Airway Pressure Treatment for Obstructive Sleep Apnea in Medicare Eligible Patients

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data 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 on *Continuous Positive Airway Pressure Treatment of Obstructive Sleep Apnea in Medicare Eligible Patients,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before 30 days after date of publication of this Notice.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for Continuous Positive Airway Pressure Treatment of Obstructive Sleep Apnea in Medicare Eligible Patients. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

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 *Continuous Positive Airway Pressure Treatment of Obstructive Sleep Apnea in Medicare Eligible Patients,* including those that describe adverse events. The entire research protocol is available online at: *https://www.ahrq.gov/research/findings/ta/index.html#supplemental.*

This is to notify the public that the EPC Program would find the following information on *Continuous Positive Airway Pressure Treatment of Obstructive Sleep Apnea in Medicare Eligible Patients* 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,* 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 is very beneficial to the Program. Materials submitted must be publicly available or able to 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 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 email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

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.

Contextual and Key Questions (KQ)

Contextual Questions

CQ 1: What measures related to apneas and hypopneas (*e.g.,* apnea indices, hypopnea indices, and apnea-hypopnea indices with various measurements) or other measures (*e.g.,* time spent with oxygen saturation below 90% or other cutoffs, electrophysiologic signal analysis metrics such as time and frequency domain analyses of heart beats) are used in contemporary research and clinical settings? How have standard definitions of these measures changed over time and what is the explanation for such changes?

CQ 2: What are commonly used sleep questionnaires and how have they been validated?

CQ 3: What treatment modalities for OSA are currently being marketed in the U.S.? What OSA treatments (experimental or approved) are currently being investigated in ongoing trials for patients as an alternative to CPAP?

CQ 4: What are the variable features of marketed CPAP devices?

CQ 5: What are the patient-centered health outcome goals and symptom relief goals of CPAP devices?

Key Questions

KQ 1: What is the efficacy, effectiveness, comparative effectiveness, and harms of CPAP devices to improve *clinically significant outcomes*?

KQ 1a: How are respiratory disturbance events (apnea, hypopnea,

arousal) defined in each study? What are the diagnostic criteria for OSA (or criteria to treat with CPAP) in each study? How do the diagnostic criteria relate to time of AASM criteria? Do treatment effects of CPAP differ by the specific diagnostic criteria used within or across studies?

KQ 1b: What is the within-study concordance in CPAP trials among apnea and hypopnea indices (*e.g.,* AHI), sleep questionnaires (*e.g.,* Epworth Sleepiness Scale), and clinically significant outcomes?*

KQ 1c: Do the clinical effects or harms of specific CPAP devices differ by patient subgroups, duration of followup, or particular CPAP features?

KQ 1d: Summarize the methodological issues in the existing studies.

KQ 2: What is the evidence that apnea and hypopnea-based measures of sleep-disordered breathing (*e.g.,* apneic indices, hypopnea indices, and apnea-hypopnea indices) used in current practice and research are valid surrogate or intermediate measures for clinically significant outcomes?

KQ 2a: Summarize the methodological issues in the existing studies. What is the ideal study design for establishing the validity of a surrogate or intermediate measure?

* Note that the association between changes in apnea and hypopnea indices and clinical outcomes across a broader set of studies is primarily addressed in KQ 2.

Systematic Review Study Eligibility Criteria

Eligibility Criteria Relevant to Both KQs

Population

- Adults (>18 years)
- *Exclude* studies with any pregnant women
- *Exclude* studies in which any participants are reported to have, at baseline, central sleep apnea (from any cause including prior stroke, severe heart failure, among others), obesity hypoventilation syndrome (Pickwickian syndrome), neuromuscular disease, Parkinson disease, Down syndrome, Prader-Willi syndrome, major congenital skeletal abnormalities, narcolepsy, narcotic addiction, Alzheimer disease, epilepsy and or with mild cognitive impairment

Intervention/Comparator

- *Exclude* studies of surgical interventions for OSA or bariatric surgery

Outcomes

- Hard clinical outcomes
  - Major clinical outcomes
    - Death
    - Cardiovascular and cerebrovascular events or incident diagnosis
    - Motor vehicle accidents
    - Composite outcomes that include only major clinical outcomes (*e.g.,* major adverse cardiovascular events defined as including all-cause mortality)
  - Other patient-centered and/or clinically significant outcomes
    - Other cardiovascular outcomes
    - Objective measures of cardiovascular severity (categorized, not continuous measures such as intima media thickness)
    - Incident hypertension (or regression to normotension)
    - Arrhythmias
    - Incident arrhythmias (or resolution of arrhythmias)
    - Clinically significant ventricular arrhythmias
    - Atrial fibrillation
    - New-onset diabetes mellitus or prediabetes (or regression to normoglycemia)
    - Mental health conditions, including depression, anxiety, and substance use disorder: Incident diagnosis or resolution
    - Cognitive function: Clinical diagnosis (*e.g.,* of dementia) or validated executive function measures
    - Quality of life and functional outcomes (validated measures)
    - Sexual function: Clinical diagnosis (*e.g.,* diagnosis of erectile dysfunction or anorgasmia) or their resolution
    - Sequelae of sleep deprivation (*e.g.,* trauma, missed work or school)
    - Other clinically significant outcomes reported in studies or as found for CQ 5
    - Exclude
    - Blood pressure
    - Asymptomatic arrhythmias or laboratory measures (*e.g.,* captured by electrophysiologic testing [heart rate variability, QTc interval, etc.])
    - Glycemia measures (*e.g.,* hemoglobin A1c, fasting blood glucose)
    - Instruments to measure severity of OSA (including AHI and sleepiness)
- Minimum duration for associations with death, incident cardiovascular events, *hypertension, or diabetes* is 1 year
- *Minimum duration for all other outcomes is 6 months*

Mediators of treatment effect (or association) (*e.g.,* factors to be evaluated in subgroup analyses) Note that *these are not eligibility criteria,* but are factors that will evaluated to potentially explain different findings across studies; *e.g.,* by subgroup analysis, regression, or other methods to evaluate heterogeneity of treatment effect)

- Body weight/obesity/neck circumference, etc.
- Weight change (loss or gain)
- Prior cardiovascular, cerebrovascular, or other major clinical disease/condition
- Sex/gender
- Race/ethnicity
- Severity of OSA (as defined by study)
- Other mediators as reported in primary studies

Setting

- Outpatient only (except for sleep laboratory setting for measurement of sleep and breathing measures)
- *Exclude* acute care hospital settings (including perioperative)

Additional Eligibility Criteria Specific to KQ 1

Populations

- As listed above, for both KQs

Intervention (CPAP)

- CPAP for treatment (not diagnosis or staging) of OSA
  - At least 1 month of prescribed (planned) treatment
- *Exclude* intervention designed only to improve CPAP compliance/adherence (*i.e.,* not an intervention of CPAP, *per se*)
- *Exclude* evaluations of accessories only (*e.g.,* nasal cannulas, head straps, humidifiers)
- *Exclude* evaluation of CPAP titration methods, *per se,* including specific parameters or modes (*e.g.,* starting pressures)
- *Exclude* evaluations of other features meant to improve comfort or adherence
- *Exclude* other non-CPAP interventions (*e.g.,* different times of monitoring, scoring), including noninvasive ventilation

Comparators

- No CPAP
- Non-CPAP active interventions for OSA (*e.g.,* mandibular advancement device)
  - *Exclude* bariatric surgery (as a comparator treatment)
  - *Exclude* surgical OSA procedure (as a comparator treatment)
- Other CPAP modality or protocol (*e.g.,* autoCPAP vs. bilevel CPAP)

Exclude comparisons with different accessories, titration methods, features to improve comfort or adherence, other non-CPAP interventions (*e.g.,* different times of monitoring, scoring), including noninvasive

Outcomes

- As listed above, for both KQs
- Sleep and breathing measures (*e.g.,* AHI) and validated sleep questionnaires (*e.g.,* Epworth Sleepiness Scale) (only for the purpose of addressing KQ 1b, not as outcomes of interest)
- Adverse events related to CPAP use

Mediators of treatment effect (*e.g.,* subgroup analyses; see note above about mediators)

- As listed above, for both KQs
- New or prior OSA diagnosis
- Treatment naïve versus failed prior treatment
- First versus second or more use of CPAP
- Treatment (CPAP) compliance
- Treatment (CPAP) discontinuation

Design

- Randomized controlled trials (RCT)
  - Consider whether study met power calculation for the outcome(s) of interest (including adverse events)
- Nonrandomized comparative studies (NRCS)
  - Restrict to studies that use modeling or other analytic methods to minimize confounding bias (due to inherent differences between people who receive one or the other intervention)
  - *Exclude* case-control design
  - *Exclude* ''pre-post'' design (comparison of before and after CPAP treatment in a single group of participants)
- Longitudinal
  - *Exclude* cross-sectional

Additional Eligibility Criteria Specific to KQ 2

For KQ 2, we will include studies that measure a change in the intermediate/surrogate measure (*e.g.,* AHI) over a period of time and report on outcomes of interest. We will include studies that provide formal evaluation of validity of the intermediate/surrogate measure for the clinical outcome and other studies that report sufficient data to analyze a potential association between the change in the measure and the clinical outcome.

Population

- Adults
  - Do not require a diagnosis of OSA (for evaluations of associations of measures)
  - *Exclude* populations as described under ''Eligibility Criteria relevant to Both KQs''

Intermediate/Surrogate measures (variables of interest evaluated regarding their association with clinical outcomes)

- Sleep and breathing measures
  - Indices based on apneas or hypopneas (*e.g.,* AHI, RDI) or other respiratory events such as RERAs, oxygen desaturations
- *Exclude* evaluations of isolated neurophysiologic parameters of sleep (*e.g.,* respiratory effort, heart rate, air flow, pulse oximetry alone) and cardiac electrophysiology indices (*e.g.,* heart rate variability)

Outcomes

- As listed above, for both KQs
- Each study must report both one or more intermediate/surrogate measures (*i.e.,* sleep and breathing measures) *and* one or more outcomes of interest

Additional mediators of association (*e.g.,* analyzed by subgroup analyses)

- As listed above, for both KQs
- Definition of sleep and breathing measure

Study Design

- Longitudinal studies informing on person-level associations of sleep and breathing measure(s) with outcome(s)
  - Patient-level association between *change* in measure and *change or incident* outcome (*i.e.,* evaluation of association reported within study)
  - *Exclude* cross-sectional studies
- Comparative or noncomparative (single group) studies
- N ≥ 30 analyzed for a given association between intermediate/surrogate measure and outcome

Dated: July 9, 2020.

Virginia Mackay-Smith,

Associate Director.

[FR Doc. 2020–15172 Filed 7–13–20; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project ''Clinical Decision Support (CDS) for Chronic Pain Management.''

DATES: Comments on this notice must be received by 60 days after date of publication of this notice.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by emails at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Clinical Decision Support (CDS) for Chronic Pain Management

Prescription opioid pain medication overuse, misuse, and abuse have been a significant contributing factor in the opioid epidemic. The goal of this project is to develop, implement, disseminate, and evaluate clinical decision support (CDS) tools for both patients and clinicians in the management of chronic pain. The CDS tools are intended to be interoperable and publicly-shareable, and will be designed to meet the needs of patients and clinicians through both patient-facing and clinician-facing channels and formats.

The development and deployment of CDS tools designed to optimize opioid dose reduction is intended to support primary care physicians who are not pain-management specialists as they care for patients who are at high risk of harm from opioids. This goal will be achieved through the design, development, implementation, and evaluation of a clinician-facing CDS tool for chronic pain management that optimize presentation of patient data and evidence-based guidelines to support opioid tapering. The clinician-facing CDS tool will help non-pain specialists detect patients at high risk of harm from opioids, provide personalized evidence-based guidelines to support opioid tapering, optimize the presentation of patient data, and reduce unnecessary variation in clinical practice.

The clinician-facing CDS tool will also assist non-pain specialists in determining if an opioid taper is necessary for a specific patient, aid in