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

performing the taper, and aid in providing follow-up and support during the taper. The clinician-facing CDS tools are meant to accomplish three goals: (1) Better monitor the patient's functional pain and opioid use, (2) visualize patient data, and (3) incorporate guidelines for prescribing and tapering opioids for chronic pain. The patient-facing CDS tool will be used to help patients at high-risk of harm from opioids track and manage chronic pain and daily function to support reduced opioid use. This goal will be achieved through the design, development, implementation, and evaluation of a CDS tool that facilitates continued patient provider engagement. This patient-facing CDS tool will deliver support in ways that enhance patient activation, education and engagement, and collaborative decisions and actions between patients and their care teams. The patient-facing CDS tool should enhance the quality of clinical discussion between healthcare providers and patients by allowing for continued patient engagement outside of the clinical setting.

This study is being conducted by AHRQ through its contractor, MedStar Health, pursuant to AHRQ's statutory authority to assist users of health information technology focused on CDS to promote the timely incorporation of comparative clinical effectiveness research into clinical practices. 42 U.S.C 299b–37(c).

Method of Collection

To achieve the goals of this project the following data collections will be implemented.

(1) Post-Use Survey with Primary Care Providers ''Evaluation Provider Survey'': This evaluation includes the collection of qualitative data through a short survey with primary care providers who used the clinician-facing CDS tool for chronic pain management (up to a maximum of 60). The research team will collect insights from providers on their experience of implementing and using the clinician-facing CDS tool for chronic pain management. The survey will be accessible in both online and paper formats.

(2) Post-Use Survey with Patients ''Evaluation Patient Survey'': This evaluation includes the collection of qualitative data through a short survey with patients who used the patient-facing CDS tool for pain management (up to a maximum of 150). The research team will collect insights from patients on their experience of implementing and using patient-facing CDS. The survey will be accessible in both online and paper formats.

(3) Post-Use Interview with Primary Care Providers ''Evaluation Provider Interview'': This evaluation component includes the collection of qualitative data through an in-depth thirty-minute interview with primary care providers who used the clinician-facing CDS tool for chronic pain management (up to a maximum of 10). The research team will collect insights from providers on their experience of implementing and using this clinician-facing CDS tool.

(4) Post-Use Interviews with Patients ''Evaluation Patient Interview'': This evaluation component includes the collection of qualitative data through an in-depth thirty-minute interview with patients who used the patient-facing CDS tool for pain management (up to a maximum of 20). The research team will collect insights from patients on their experience of implementing and using the patient-facing CDS tool.

(5) Post-Use Interviews with Site Champions ''Evaluation Site Champion Interview'': This evaluation component includes the collection of qualitative data through thirty-minute interviews with site leads (up to a maximum of 15) and site visits during which the research team will collect insights from providers and patients on their experience of implementing and using the clinical-facing and patient-facing CDS tools from the perspective of the site champions.

Estimated Annual Respondent Burden

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Post-Use Survey with Providers	60	1	0.25	15
Post-Use Survey with Patients	150	1	0.25	37.5
Post-Use Interview with Providers	10	1	0.5	5
Post-Use Interview with Patients	20	1	0.5	10
Post-Use Interview with Site Champions	15	1	0.5	7.5
Total	255	5	2	75

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Post-Use Survey with Providers	60	15	[b] $102.73	$1,540.95
Post-Use Survey with Patients	150	37.5	[a] 25.72	964.50
Post-Use Interview with Providers	10	5	[b] 102.73	513.65
Post-Use Interview with Patients	20	10	[a] 25.72	257.20
Post-Use Interview with Site Champions	15	7.5	[b] 102.73	770.48
Total	255	75	53.95	4,046.78

* National Compensation Survey: Occupational wages in the United States May 2019, ''U.S. Department of Labor, Bureau of Labor Statistics'', *https://www.bls.gov/oes/current/oes_nat.htm#b29-0000.htm.*

[a] Based on the mean wages for *all occupations (00–0000).*

[b] Based on the mean wages for *Family Medicine Physicians (29–1215).*

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: July 8, 2020.

Virginia L. Mackay-Smith,

Associate Director.

[FR Doc. 2020–15147 Filed 7–13–20; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1118]

Select Updates for Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Select Updates for Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH).'' FDA has developed this draft guidance to propose select updates to certain sections of the existing FDA guidance document ''Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH).'' This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by September 14, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–1118 for ''Select Updates for Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH).'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Select Updates for Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug