▪ 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. 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.*

**The Key Questions**

*Key Question 1. Effectiveness and Comparative Effectiveness*

a. In patients with chronic pain, what is the effectiveness of nonopioid pharmacologic agents versus placebo for outcomes related to pain, function, and quality of life, after short-term treatment duration (3 to 6 months), intermediate-term treatment duration (6 to 12 months), and long-term treatment duration (≥12 months)?

b. In patients with chronic pain, what is the comparative effectiveness of nonopioid pharmacologic agents compared to other nonopioid pharmacologic agents for outcomes related to pain, function, and quality of life, after short-term treatment duration (3 to 6 months), intermediate-term treatment duration (6 to 12 months), and long-term treatment duration (≥12 months)?

c. *How does effectiveness or comparative effectiveness vary depending on:* (1) The specific type or cause of pain, (2) patient demographics, (3) patient comorbidities, (4) the dose of medication used, (5) the duration of treatment, and (6) dose titration, including tapering.

*Key Question 2. Harms and Adverse Events*

a. In patients with chronic pain, what are the risks of nonopioid pharmacologic agents for harms including overdose, misuse, dependence, withdrawals due to adverse events, and serious adverse events (including falls, fractures, motor vehicle accidents), and specific adverse events, according to drug class?

b. *How do harms vary depending on:* (1) The specific type or cause of pain, (2) patient demographics, (3) patient comorbidities, (4) the dose of medication used, (5) the duration of treatment, and (6) dose titration, including tapering.

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings) Population(s):

- *For all Key Questions (KQs):* Adults (age ≥18 years) with various types of chronic pain (defined as pain lasting >3 months), including patients with acute exacerbations of chronic pain, pregnant/breastfeeding women, and patients with opioid use disorder
- *For KQs 1c, 2b:* Subgroups of the above patient populations as defined by specific pain condition (neuropathic pain, musculoskeletal pain, fibromyalgia, inflammatory arthritis, and chronic headache), patient demographics (*e.g.,* age, race, ethnicity, and sex), comorbidities and degree of nociplasticity/central sensitization.

Interventions:

- Oral pharmacologic agents: Nonsteroidal anti-inflammatory drugs, acetaminophen, muscle relaxants (including benzodiazepines), antidepressants, and anticonvulsants
- Topical pharmacologic agents: diclofenac, capsaicin, and lidocaine
- Medical cannabis (any formulation)

Comparators:

- For KQ 1a/c and KQ2: Placebo (effectiveness)
- For KQ 1b/c and KQ2: Another included nonopioid pharmacologic agent, different doses, or treatment durations (comparative effectiveness)

Outcomes:

- KQ 1: Pain (intensity, severity, bothersomeness), function (physical disability, activity limitations, activity interference, work function), and quality of life (including depression)
  - o Only validated scales for assessments of pain, function, and quality of life
- KQ 2: For all drug classes: Overdose, misuse, dependence, withdrawals due to adverse events, and serious adverse events. Specific adverse events for each drug class, such as gastrointestinal events, cardiovascular events, and liver or kidney-related harms for non-steroidal anti-inflammatory drugs; weight gain, sedation, and cognitive effects for gabapentin and pregabalin, etc.

Timing:

- Short-term treatment duration (3 to 6 months), intermediate-term treatment duration (6 to 12 months), and long-term treatment duration (≥12 months)
- We will assess available literature to ensure that adequate evidence exists from studies of ≥3 months' treatment duration. If adequate evidence is not available for this shorter-duration, we will consider adding shorter-duration studies. If high-quality systematic reviews are available covering the scope of the review for shorter duration studies, we will summarize these in this case

Settings:

- Outpatient settings (*e.g.,* primary care, pain clinics, other specialty clinics)

**Gopal Khanna,**

*Director.*

[FR Doc. 2019–05142 Filed 3–18–19; 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: ''*Hospital Survey on Patient Safety Culture Comparative Database.*''

**DATES:** Comments on this notice must be received by May 20, 2019.

**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**

''*Hospital Survey on Patient Safety Culture Comparative Database.*''

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection. The Hospital Survey on Patient Safety Culture (Hospital SOPS) is designed to enable hospitals to assess provider and staff perspectives about patient safety issues, medical error, and error reporting. The Hospital SOPS includes 42 items that measure 12 composites of patient safety culture. AHRQ first made the Hospital SOPS publicly available, along with a Survey User's Guide and other toolkit materials, in November 2004 on the AHRQ website.

The Hospital Survey on Patient Safety Culture Comparative Database (Hospital SOPS Database) consists of data from the Hospital SOPS and may include reportable, non-required supplemental items. Hospitals in the U.S. can voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The Hospital SOPS Database (OMB NO. 0935–0162, last approved on September 30, 2016) was developed by AHRQ in 2006 in response to requests from hospitals interested in tracking their own survey results. Those organizations submitting data receive a feedback report, as well as a report of the aggregated de-identified findings of the other hospitals submitting data. These reports are used to assist hospital staff in their efforts to improve patient safety culture in their organizations.

**Rationale for the Information Collection**

The Hospital SOPS and the Hospital SOPS Database support AHRQ's goals of promoting improvements in the quality and safety of health care in hospital settings. The survey, toolkit materials, and database results are all made publicly available on AHRQ's website. Technical assistance is provided by AHRQ through its contractor at no charge to hospitals, to facilitate the use of these materials for hospital patient safety and quality improvement.

This database will:

1. Present results from hospitals that voluntarily submit their data,

2. provide data to hospitals to facilitate internal assessment and learning in the patient safety improvement process, and

3. provide supplemental information to help hospitals identify their strengths and areas with potential for improvement in patient safety culture.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to surveys and database development. 42 U.S.C. 299a(a)(1) and (8)

**Method of Collection**

To achieve the goal of this project the following activities and data collections will be implemented:

1. Eligibility and Registration Form—The hospital point-of-contact (POC) completes a number of data submission steps and forms, beginning with the completion of an online Eligibility and Registration Form. The purpose of this form is to collect basic demographic information about the hospital and initiate the registration process.

2. Data Use Agreement—The purpose of the data use agreement, completed by the hospital POC, is to state how data submitted by hospitals will be used and provide privacy assurances.

3. Hospital Site Information Form—The purpose of the site information form, also completed by the hospital POC, is to collect background characteristics of the hospital. This information will be used to analyze data collected with the Hospital SOPS survey.

4. Data Files Submission—POCs upload their data file(s), using hospital data file specifications, to ensure that users submit standardized and consistent data in the way variables are named, coded, and formatted. The number of submissions to the database is likely to vary each year because hospitals do not administer the survey and submit data every year. Data submission is typically handled by one POC who is either a patient safety manager in the hospital or a survey vendor who contracts with a hospital to collect and submit their data. POCs submit data on behalf of 3 hospitals, on average, because many hospitals are part of a health system that includes many hospitals, or the POC is a vendor that is submitting data for multiple hospitals.

**Estimated Annual Respondent Burden**

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in the database. An estimated 340 POCs, each representing an average of 3 individual hospitals each, will complete the database submission steps and forms annually. Each POC will submit the following:

- Eligibility and registration form (completion is estimated to take about 3 minutes).
- Data Use Agreement (completion is estimated to take about 3 minutes).
- Hospital Information Form (completion is estimated to take about 5 minutes).
- Survey data submission will take an average of one hour.

The total annual burden hours are estimated to be 459 hours. Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be $26,572 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

| Form name | Number of respondents/ POCs | Number of responses per POC | Hours per response | Total burden hours |
|---|---|---|---|---|
| Eligibility/Registration Form | 340 | 1 | 3/60 | 17 |
| Data Use Agreement | 340 | 1 | 3/60 | 17 |
| Hospital Information Form | 340 | 3 | 5/60 | 85 |
| Data Files Submission | 340 | 1 | 1 | 340 |
| Total | N/A | N/A | N/A | 459 |

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

| Form name | Number of respondents/ POCs | Total burden hours | Average hourly wage rate * | Total cost burden |
|---|---|---|---|---|
| Eligibility/Registration Form | 340 | 17 | $57.89 | $984 |
| Data Use Agreement | 340 | 17 | 57.89 | 984 |
| Hospital Information Form | 340 | 85 | 57.89 | 4,921 |
| Data Files Submission | 340 | 340 | 57.89 | 19,683 |
| Total | N/A | N/A | N/A | 26,572 |

* Mean hourly wage of $57.89 for Medical and Health Services Managers (SOC code 11–9111) was obtained from the May 2017 National Industry-Specific Occupational Employment and Wage Estimates NAICS 622000—Hospitals, located at *http://www.bls.gov/oes/current/naics3_622000.htm.*

**Request for Comments**

In accordance with the Paperwork Reduction Act, 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.

**Gopal Khanna,**

*Director.*

[FR Doc. 2019–05140 Filed 3–18–19; 8:45 am]

**BILLING CODE 4160–90–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

### Patient Safety Organizations: Voluntary Relinquishment From Quality Alliance Patient Safety Organization

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

**ACTION:** Notice of delisting.

**SUMMARY:** The Patient Safety and Quality Improvement Final Rule (Patient Safety Rule) authorizes AHRQ, on behalf of the Secretary of HHS, to list as a patient safety organization (PSO) an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' by the Secretary if it is found to no longer meet the requirements of the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. AHRQ has accepted a notification of voluntary relinquishment from the Quality Alliance Patient Safety Organization, PSO number P0163, of its status as a PSO, and has delisted the PSO accordingly.

**DATES:** The delisting was effective at 12:00 Midnight ET (2400) on December 31, 2018.

**ADDRESSES:** The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. Both directories can be accessed electronically at the following HHS website: *http://www.pso.ahrq.gov/listed.*

**FOR FURTHER INFORMATION CONTACT:** Cathryn Bach, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, MS 06N100B, Rockville, MD 20857; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *pso@ahrq.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

**Background**

The Patient Safety Act, 42 U.S.C. 299b–21 to 299b–26, and the related Patient Safety Rule, 42 CFR part 3, published in the **Federal Register** on November 21, 2008, 73 FR 70732–70814, establish a framework by which individuals and entities that meet the definition of provider in the Patient Safety Rule may voluntarily report information to PSOs listed by AHRQ, on a privileged and confidential basis, for the aggregation and analysis of patient safety events.

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

AHRQ has accepted a notification from Quality Alliance Patient Safety Organization, a component entity of Memorial Health System, Midwest Healthcare Quality Alliance, Southern Illinois University HealthCare and Springfield Clinic, LLP, to voluntarily relinquish its status as a PSO. Accordingly, Quality Alliance Patient Safety Organization, P0163, was delisted effective at 12:00 Midnight ET (2400) on December 31, 2018.

Quality Alliance Patient Safety Organization has patient safety work product (PSWP) in its possession. The PSO will meet the requirements of section 3.108(c)(2)(i) of the Patient Safety Rule regarding notification to providers that have reported to the PSO and of section 3.108(c)(2)(ii) regarding disposition of PSWP consistent with section 3.108(b)(3). According to section 3.108(b)(3) of the Patient Safety Rule, the PSO has 90 days from the effective