

FEDERAL COMMUNICATIONS COMMISSION

[FR ID 127534]

Deletion of Item From February 16, 2023 Open Meeting

The following item was released by the Commission on February 14, 2023

3	MEDIA	<i>Title:</i> Restricted Adjudicatory Matter. <i>Summary:</i> The Commission will consider a restricted adjudicatory matter.
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Federal Communications Commission.

Dated: February 14, 2023.

Marlene Dortch,*Secretary.*

[FR Doc. 2023-03465 Filed 2-16-23; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL RESERVE SYSTEM**Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company**

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551-0001, not later than March 6, 2023.

Federal Reserve Bank of Dallas (Karen Smith, Director, Mergers & Acquisitions) 2200 N Pearl St., Dallas, Texas 75201 or electronically: Comments.applications@dal.frb.org;

and deleted from the list of items scheduled for consideration at the Thursday, February 16, 2023, Open Meeting. The item was previously listed in the Commission's Sunshine Notice on Thursday, February 9, 2023.

1. *The Rumage Family Trust fbo Christopher Blain Rumage, C. Blain Rumage, as trustee, both of Jacksboro, Texas, Carl A. Ritchlin, as trust protector, Arlington, Texas, and Christy M. Peveto, as special trustee, Fort Worth, Texas; and The Rumage Family Trust fbo William Wakley Rumage, William W. Rumage, as trustee, both of Gunter, Texas, Carl A. Ritchlin, as trust protector, Arlington, Texas, and Christy M. Peveto, as special trustee, Fort Worth, Texas; to join the Voting Trust Control Group, a previously approved group acting in concert, to retain voting shares of Jacksboro National Bancshares, Inc., and thereby indirectly retain voting shares of Jacksboro National Bank, both of Jacksboro, Texas.*

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,*Deputy Associate Secretary of the Board.*

[FR Doc. 2023-03423 Filed 2-16-23; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Agency for Healthcare Research and Quality****Supplemental Evidence and Data Request on Behavioral Interventions for Migraine Prevention****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 Behavioral Interventions for Migraine Prevention, 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 March 20, 2023.**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 Behavioral Interventions for Migraine Prevention. AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

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 Behavioral Interventions for Migraine Prevention, including those that describe adverse events. The entire research protocol is available online at: <https://effectivehealthcare.ahrq.gov/products/behavioral-interventions-migraine-prevention/protocol>.

This is to notify the public that the EPC Program would find the following information on Behavioral Interventions for Migraine Prevention 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.

Key Questions (KQ)

KQ 1: What are the benefits and harms of behavioral interventions, either alone or in combination with other preventive strategies (including pharmacologic therapy), for migraine prevention compared to inactive control for children and adults?

KQ 1a: What are the benefits and harms of behavioral interventions delivered via telehealth and digital health (e/mHealth) technology compared to inactive control?

KQ 2: What is the comparative effectiveness and harms of a behavioral intervention for migraine prevention compared to either (a) a pharmacologic preventive agent or (b) another

behavioral intervention for children and adults?

KQ 2a: What is the comparative effectiveness and harms of behavioral interventions delivered via telehealth and digital health (e/mHealth) technology compared to (a) pharmacologic prevention or (b) other behavioral interventions?

KQ 3: For multicomponent or combined behavioral interventions, what are the effects of individual behavioral intervention components?

KQ 4: What are the benefits and harms of non-headache focused behavioral interventions (e.g., CBT for insomnia, CBT for depression/anxiety, parent training) for migraine prevention in children and adults with migraine?

KQ 5: For key questions 1–4, how do the findings vary by baseline biopsychosocial factors (e.g., sex, socioeconomic status, co-occurring mental health conditions)?

Contextual Questions

CQ 1: What evidence is available on the benefits of behavioral preventive treatments for children and adults with migraine that include intervention components targeting caregivers (e.g., parents, spouses, and other key support people)?

CQ 2: What are patient and provider perceptions of the benefits, harms, and barriers to engaging with behavioral treatments for migraine prevention in children and adults?

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)

PICOTS	Inclusion	Exclusion
Patients	<p>All KQs:</p> <ul style="list-style-type: none"> Children (age 6 to 11), adolescents (12 to 17), and adults (18 or older) with migraine headache (episodic or chronic). <p>We will not require studies to only include individuals with an International Classification of Headache Disorders diagnosis of migraine headache.</p> <ul style="list-style-type: none"> ≥80% of study participants had migraine headache, or the study reports a subgroup analysis comprised of at least 80% migraine patients. We will include studies with participants with other headache types (e.g., medication overuse headache, tension type headache, cluster headache, etc.) in addition to migraine, as long as ≥80% of participants have migraine. 	<p>All KQs:</p> <p>Studies conducted exclusively</p> <ul style="list-style-type: none"> Among individuals in institutions (e.g., psychiatric inpatients, long-term care facilities, incarcerated populations). Parents, for studies with interventions targeting children and adolescents. Individuals with psychotic disorders.
Interventions	<p>KQs 1–3.</p> <p>Migraine-focused behavioral interventions used for prevention, administered either alone or with pharmacotherapy, delivered in-person, via telehealth, or with e- or mHealth.</p> <p>1. CBT.</p> <ul style="list-style-type: none"> Cognitive behavioral therapy. 	<p>We will exclude studies focused solely on the following interventions:</p>

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

PICOTS	Inclusion	Exclusion
<p>Comparisons</p>	<ul style="list-style-type: none"> • Cognitive therapy • Behavioral therapy • Stress management training (SMT) • Coping skills training • “Learning to cope with triggers” (LCT) • Parent/caregiver operant training (parent or caregiver reinforces coping behaviors). • Problem-solving training. <p>2. Biofeedback.</p> <ul style="list-style-type: none"> • Thermal/temperature biofeedback (Hand warming/Thermal biofeedback) (often feedback of skin temperature from finger). • Electromyographic (EMG) biofeedback (feedback of electrical activity from muscles of scalp, neck, or upper body). • Heart rate variability biofeedback. • Electrocardio biofeedback. • Pulse. • Blood Volume Pulse. • Respiratory. • Electroencephalography (EEG)/Neurofeedback. <p>3. Relaxation.</p> <ul style="list-style-type: none"> • Diaphragmatic Breathing. • Progressive muscle relaxation (alternatively tensing/relaxing selected muscles). • Autogenic feedback (use of calm, self-soothing statements to promote a state of deep relaxation). • Autogenic training. <p>4. Mindfulness based stress reduction.</p> <ul style="list-style-type: none"> • Meditation (use of silently repeated word or sound to promote mental calm and relaxation). • Transcendental meditation. • Guided imagery/Guided visual imagery. <p>5. Third wave CBT.</p> <ul style="list-style-type: none"> • Acceptance and commitment therapy. <p>6. Education.</p> <ul style="list-style-type: none"> • Education (skills, lifestyle, exercise, nutrition, hydration, stress management, sleep hygiene). • Neuroscience education therapy. • Healthy lifestyle counseling. • Sleep counseling. • Trigger avoidance. • Weight management (informational). • Diary/tracking. <p>7. Hypnotherapy.</p> <p>8. Trauma-informed therapy.</p> <ul style="list-style-type: none"> • Eye movement desensitization and reprocessing (EMDR). • Trauma-focused therapy. <p>9. Dialectical behavioral therapy (DBT).</p> <p>10. Motivational interviewing and stages of change.</p> <p>11. Professionally led support groups/peer support.</p> <p>12. Combination therapies.</p> <p>KQ1a and KQ2a: The above interventions delivered via telehealth or with e- or mHealth.</p> <p>KQ 4.</p> <p>Non-headache focused behavioral interventions, <i>e.g.</i>,</p> <ul style="list-style-type: none"> • CBT for insomnia or depression/anxiety. • Sleep hygiene counseling. • Parent/caregiver operant training (parent or caregiver reinforces adaptive sleep behaviors). • Healthy lifestyle counseling. <p>KQ5 Interventions included for KQs 1–4.</p> <p>KQs 1</p> <ul style="list-style-type: none"> • No intervention (<i>e.g.</i>, waitlist, usual care) • Minimal intervention (<i>e.g.</i>, educational materials without skills training). • Most active: Attention control, sham, or placebo <p>KQs 2–4.</p> <p>A different eligible behavioral intervention.</p>	<ul style="list-style-type: none"> • Physical therapy. • Exercise. • Catharsis therapy (<i>e.g.</i>, written emotional disclosure). • Occupational therapy. • Creative arts therapy (art therapy, music therapy, dance therapy). <p>Comparators not listed as included.</p>

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

PICOTS	Inclusion	Exclusion
Outcomes	<p>KQ 2–4. Medications from the following drug classes (see Table 2):</p> <ul style="list-style-type: none"> • Alpha agonists. • Angiotensin-converting enzyme inhibitors/Angiotensin receptor blockers. • Antiepileptics. • Antihistamines (for child and adolescents only). • Beta-blockers. • Botulinum toxin type A. • Calcitonin gene–related peptide antagonists. • Calcium channel blockers. • Other antidepressants. • Serotonin norepinephrine reuptake inhibitors (SNRIs). • Tricyclic antidepressants. <p>KQ5 Comparators in KQs 1–4.</p> <p>All KQs. Migraine/Headache frequency:</p> <ul style="list-style-type: none"> • Migraine/headache count: Migraine days per month, migraine attacks per month, headache days per month, or headaches per month.. • Responder rate: 50% or more reduction in one of the above quantities. <p>Functional Status/Disability.</p> <ul style="list-style-type: none"> • MIDAS, PedMIDAS, HANA, MIBS, FIS, FDI (Parent form), FDI-(child and adolescent), IMPAC). <p>Quality of Life (QOL).</p> <ul style="list-style-type: none"> • Migraine Specific: HIT–6, MSQoL v2.1, MSQ • General: SF–36, EQ–5, SF–12, PedsQL. <p>Adverse effects such as dropout and any reported.</p> <p>Emotional Status.</p> <ul style="list-style-type: none"> • Anxiety symptoms (e.g., GAD–7, PROMIS Pediatric—Anxiety, HADS). • Depression symptoms (e.g., PHQ4, PHQ 9, CDI, PROMIS Pediatric-Depression, HADS). <p>Other:</p> <ul style="list-style-type: none"> • Most bothersome symptoms. • Headache pain intensity (VAS, NRS). • Acute headache medication use. • Discontinuation of preventive medication. <p>KQ 4. Additional outcomes:</p> <ul style="list-style-type: none"> • Anxiety (e.g., GAD–7, PROMIS Pediatric—Anxiety). • Depression (e.g., PHQ 4, PHQ 9, CDI, PROMIS Pediatric-Depression). • Sleep outcomes (sleep onset latency, wake after sleep onset, total sleep time, sleep efficiency). 	
Study Design Criteria	<p>All KQs:</p> <ul style="list-style-type: none"> • Randomized controlled trials reporting outcomes for ≥10 participants per treatment arm. • Period 1 data from crossover RCTs • Published in English-language • Published 1975 or after <p>For KQ1–4, we will require studies to report at least one of four primary outcomes: Migraine/Headache frequency, migraine-related disability, migraine-specific quality of life, and/or adverse events.</p>	<p>All KQs:</p> <ul style="list-style-type: none"> • Exclude crossover trials not reporting period 1 data separately. • Exclude reviews, letters, guidelines, position statements and commentaries. • Exclude single arm or non-randomized controlled studies. <p>SRs will only be used to identify potential RCTs for inclusion.</p>
Setting	<ul style="list-style-type: none"> • Any non-inpatient setting • Trials conducted in countries rated as “very high” on the 2022 Human Development Index (as defined by the United Nations Development Programme). 	<p>Hospitalized patients.</p>

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

PICOTS	Inclusion	Exclusion
Timing	Studies must report a primary outcome at 4 weeks or longer after treatment initiation.	

CDI = Children's Depression Inventory, EQ-5D = EuroQol-5D, FDI-Child Form = Functional Disability Inventory—Child and Adolescent Form, FDI-Parent Form = Functional Disability Inventory—Parent Form, FIS = Fatigue Impact Scale, GAD-7 = General Anxiety Disorder-7, HADS = Hospital Anxiety and Depression Scale, HANA = Headache Needs Assessment, HIT-6™ = Headache Impact Test, IMPAC = Impact of Migraine on Partners and Adolescent Children, MIBS = Migraine Interictal Burden Scale, MIDAS = Migraine Disability Assessment, MSQ = Migraine Specific Quality of Life Questionnaire v. 2.1, NRS = Numeric Rating Scale, PedMIDAS = Pediatric Migraine-Specific Disability Assessment, PedsQL = Pediatric Quality of Life Inventory, PHQ = Patient Health Questionnaire—Depression, PQ-LES-Q = Pediatric quality of life enjoyment and satisfaction, SF-12 = 12-Item Short Form Survey, SF-36 = 36-Item Short Form Survey, VAS = Visual Analogue Scale.

Dated: February 14, 2023.

Marquita Cullom,
Associate Director.

[FR Doc. 2023-03406 Filed 2-16-23; 8:45 am]

BILLING CODE 4160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting for Software Developers on the Common Formats for Patient Safety Data Collection

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

ACTION: Notice of public meeting.

SUMMARY: AHRQ coordinates the development of sets of standardized definitions and formats (Common Formats) that make it possible to collect, aggregate, and analyze uniformly structured information about health care quality and patient safety for local, regional, and national learning. The Common Formats include technical specifications to facilitate the collection of electronically comparable data by Patient Safety Organizations (PSOs) and other entities. Additional information about the Common Formats can be obtained through AHRQ's PSO website at <https://pso.ahrq.gov/common-formats> and the PSO Privacy Protection Center's website at https://www.psoppc.org/psoppc_web/publicpages/commonFormatsOverview. The purpose of this notice is to announce a meeting to discuss implementation of the Common Formats with software developers and other interested parties. This meeting is designed as an interactive forum where software developers can provide input on use of the formats. AHRQ especially requests participation by and input from those entities which have used AHRQ's technical specifications and implemented, or plan to implement, the Common Formats electronically.

DATES: The meeting will be held from 2:00 to 2:45 p.m. Eastern on Thursday, March 16, 2023.

ADDRESSES: The meeting will be held virtually.

FOR FURTHER INFORMATION CONTACT: Dr. Hamid Jalal, Medical Officer, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, 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: psa@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 to 299b-26 (Patient Safety Act), and the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, 73 FR 70731-70814, provide for the Federal listing of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information (patient safety work product) regarding the quality and safety of health care delivery.

The Patient Safety Act requires PSOs, to the extent practical and appropriate, to collect patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers. (42 U.S.C. 299b-24(b)(1)(F)). The Patient Safety Act also authorizes the development of data standards, known as the Common Formats, to facilitate the aggregation and analysis of non-identifiable patient safety data collected by PSOs and reported to the network of patient safety databases (NPSD). (42 U.S.C. 299b-23(b)). The Patient Safety Act and Patient Safety Rule can be accessed at: <http://www.pso.ahrq.gov/legislation/>.

AHRQ has issued Common Formats for Event Reporting (CFER) for three settings of care—hospitals, nursing homes, and community pharmacies. AHRQ has also issued Common Formats

for Event Reporting—Diagnostic Safety (CFER-DS) designed for use in all healthcare settings.

Federally listed PSOs can meet the requirement to collect patient safety work product in a standardized manner to the extent practical and appropriate by using AHRQ's Common Formats. The Common Formats are also available in the public domain to encourage their widespread adoption. An entity does not need to be listed as a PSO or working with one to use the Common Formats. However, the Federal privilege and confidentiality protections only apply to information developed as patient safety work product by providers and PSOs working under the Patient Safety Act.

Agenda, Registration, and Other Information About the Meeting

The Agency for Healthcare Research and Quality (AHRQ) will be hosting this fully virtual meeting to discuss implementation of the Common Formats with members of the public, including software developers and other interested parties. Agenda topics will include discussion of the Network of Patient Safety Databases, including the Falls 2022 Supplemental Dashboard. Active participation and discussion by meeting participants is encouraged.

AHRQ requests that interested persons send an email to SDMeetings@infinityconferences.com for registration information. Before the meeting, an agenda and logistical information will be provided to registrants.

Dated: February 13, 2023.

Marquita Cullom,
Associate Director.

[FR Doc. 2023-03328 Filed 2-16-23; 8:45 am]

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