FEDERAL COMMUNICATIONS COMMISSION

Radio Broadcasting Services; AM or FM Proposals To Change the Community of License

AGENCY: Federal Communications Commission.

ACTION: Notice.

DATES: The agency must receive comments on or before January 21, 2020.


FOR FURTHER INFORMATION CONTACT: Rolanda F. Smith, 202–418–2054.

SUPPLEMENTARY INFORMATION: The following applicants filed AM or FM proposals to change the community of license: OMNI BROADCASTING, LLC, WTKP(FM), Fac. ID No. 67579, Channel 229C3, From: YOUNGSTOWN, FL, To: PORT ST. JOE, FL, File No. 0000082907; SUN MEDIA, INC., WJLI(FM), Fac. ID No. 63817, Channel 252C1, From: PADUCAH, KY, To: METROPOLIS, IL, File No. 0000082340; HI-LINE RADIO FELLOWSHIP INC., KZLM(FM), Fac. ID No. 171025, Channel 300A, From: HARLOWTON, MT, To: LEWISTOWN, MT, File No. 0000082340, Fac. ID No. BPED–20190815ABG; KIZART MEDIA PARTNERSHIP, INC., WBZW(AM), Fac. ID No. 63166–2034. Comments can also be sent electronically via the Media Bureau's prod/app_search.htm. The full text of these applications is available for inspection and copying at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

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 indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

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 December 20, 2019.

A. Federal Reserve Bank of St. Louis (David L. Hubbard, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to Comments.applications@stls.frb.org.

1. Citizens Union Bancorp of Shelbyville, Inc., Shelbyville, Kentucky; to merge with Owenton Bancorp, Inc., and thereby indirectly acquire Peoples Bank & Trust Company, both of Owenton, Kentucky.

Board of Governors of the Federal Reserve System, November 18, 2019.

Yao-Chin Chao,
Assistant Secretary of the Board.
conducted). We are looking for studies that report on Management of Primary Headache during Pregnancy, including those that describe adverse events. The entire research protocol is available online at: https://effectivehealthcare.ahrq.gov/products/headaches-pregnancy/protocol.

This is to notify the public that the EPC Program would find the following information on Management of Primary Headache during Pregnancy 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 (comparative) benefits and harms of interventions to prevent attacks of primary headache in women who are pregnant (or attempting to become pregnant), postpartum, or breastfeeding?

**KQ 1a**: Do the (comparative) benefits and harms vary by phase (i.e., preconception, first trimester of pregnancy, second trimester of pregnancy, third trimester of pregnancy, postpartum, breastfeeding)?

**KQ 1b**: Do the (comparative) benefits and harms vary by type of primary headache (i.e., migraine, tension headache, cluster headache, and other trigeminal autonomic cephalgias)?

**KQ 2**: What are the (comparative) benefits and harms of interventions to treat acute attacks of primary headache in women who are pregnant (or attempting to become pregnant), postpartum, or breastfeeding?

**KQ 2a**: Do the (comparative) benefits and harms vary by phase (i.e., preconception, first trimester of pregnancy, second trimester of pregnancy, third trimester of pregnancy, postpartum, breastfeeding)?

**KQ 2b**: Do the (comparative) benefits and harms vary by type of primary headache (i.e., migraine, tension headache, cluster headache, and other trigeminal autonomic cephalgias)?

**Contextual Question**

What is the available evidence concerning levels in maternal serum/blood, fetal/infant serum/blood, breast milk, amniotic fluid, meconium, cord blood, or child urine of drugs used to prevent or treat attacks of primary headache in women who are pregnant (or attempting to become pregnant), postpartum, or breastfeeding?

**Study Eligibility Criteria**

We had discussions with a Technical Expert Panel (TEP) during which we reviewed the specific eligibility criteria. As part of the discussions, we asked the TEP to provide guidance on prioritizing outcomes and selecting among harms/adverse events of interest.

**KQ 1 (Prevention of Primary Headache)**

**Population(s):**

- Women who are pregnant (or attempting to become pregnant/in the preconception phase), postpartum (defined as up to 12 months post-delivery), or breastfeeding (for any length of time) with history of primary headache
- Migraine, tension headache, cluster headache or other trigeminal autonomic cephalgia (TACs)
- Women attempting to become pregnant include those actively planning pregnancy, by any method, who may wish to use only treatments found to be safe and effective during pregnancy.

- **Exclude**: Women with history of secondary headache of any origin

**Interventions:**

- Pharmacologic interventions
- Tricyclic antidepressants (e.g., amitriptyline, nortriptyline, imipramine)
- Beta blockers (e.g., metoprolol, propranolol, nadolol, atenolol, timolol, nebivolol)
- Calcium channel blockers (e.g., verapamil, nifedipine, nifedipine, nicardipine)
- Other antihypertensive medications (e.g., lisinopril, candesartan, clonidine)
- Antiiepileptic drugs (e.g., divalproex sodium, sodium valproate, valproic acid, topiramate, gabapentin, carbamazepine, lamotrigine)
- Serotonin and norepinephrine reuptake inhibitors (SSSNRs) (e.g., venlafaxine, duloxetine)
- Benzodiazepines (e.g., clonazepam)
- N-methyl-D-aspartate (NMDA) receptor antagonists (e.g., memantine)
- Calcitonin gene-related peptide (CGRP) inhibitors (e.g., erenumab, fremanezumab, galcanezumab)
- Antihistamines (e.g., cyproheptadine)
- Antimanic agents (e.g., lithium)
- Tetracyclic antidepressants (e.g., mirtazapine)
- Corticosteroids (e.g., methylprednisolone, triamcinolone acetonide, combinations of local anesthetics and corticosteroids)
- Other pharmacologic interventions used to prevent primary headache (whether or not available or approved in the United States)

- **Non-pharmacologic interventions**
  - Supplements (e.g., riboflavin, magnesium, coenzyme Q10, melatonin, feverfew, butterbur, frankincense)
  - Nerve blocks (e.g., occipital nerve blocks, sphenopalatine ganglion blocks, trigger point injections)
  - Chemodenervation (e.g., onabotulinum toxin A, abobotulinum toxin A)
  - Physical therapy
  - Hydration
  - Noninvasive neuromodulation devices (e.g., transcutaneous

- **Inclusion/Exclusion Criteria**
  - Study eligibility criteria
  - Blood, fetal/infant serum/blood, breast milk, amniotic fluid, meconium, cord blood, or child urine of drugs used to prevent or treat attacks of primary headache in women who are pregnant (or attempting to become pregnant), postpartum, or breastfeeding
  - 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.
electrical nerve stimulation, transcranial magnetic stimulation, transcutaneous vagal stimulation, remote electrical neurostimulation

- Behavioral therapy (e.g., cognitive behavioral therapy, diet therapy, sleep therapy, exercise therapy, support group therapy)
- Complementary therapies (e.g., biofeedback, acupuncture, mindfulness-based stress reduction)
- Other non-pharmacologic interventions used to prevent primary headache

Comparators:
- Pharmacologic interventions
  - Other class
  - Other drug within class
  - Same drug(s), different route, treatment duration, initiation time, or other aspect
  - As comparator to nonpharmacologic intervention
- Nonpharmacologic interventions
  - Other nonpharmacologic intervention class
  - Other nonpharmacologic intervention, within class
  - As comparator to pharmacologic intervention
- No pharmacologic or nonpharmacologic interventions
  - Placebo
  - No intervention

Outcomes: (* denotes important outcomes that will be used when developing Strength of Evidence tables)
- Acute headache attacks*
  - Occurrence of acute headache attacks
  - Frequency of acute headache attacks
  - Severity of acute headache attacks
  - Duration of acute headache attacks
- Headache-related symptoms (e.g., nausea/vomiting, photosensitivity, dizziness)*
  - Occurrence of headache-related symptoms
  - Frequency of headache-related symptoms
  - Severity of headache-related symptoms
  - Duration of headache-related symptoms
  - Most bothersome symptom
- Emergency department visits, clinic visits, or hospitalizations*
- Quality of life*
- Functional outcomes
  - Impact on family life
  - Employment/school attendance
  - Time spent managing disease
- Resource use
- Acceptability of intervention by patients
- Patient satisfaction with intervention
- Number of prescribed medications
- Number of days with acute medication use
- Adverse events
  - Maternal
    - Serious maternal adverse events*
    - “Serious” adverse events (including those that are composite outcomes), as defined by study authors
    - Cardiovascular outcomes, such as stroke, myocardial infarction
    - Non-serious maternal adverse events
  - Nonobstetrical (e.g., maternal weight gain, tachycardia, hypertension, gastrointestinal)
  - Preterm labor, cesarean section
  - Reduced breast milk production
  - Symptoms related to withdrawal of medication
  - Discontinuation of intervention (or of study participation) due to maternal adverse events*
  - Fetal/infant
    - Serious fetal/infant adverse events*
    - “Serious” adverse events (including those that are composite outcomes), as defined by study authors
    - Death—spontaneous abortion, stillbirth, infant death
    - Preterm birth
    - Low birth weight for gestational age
    - Congenital anomalies or other newborn abnormalities
    - Perinatal complications, e.g., low APGAR score, respiratory distress, neonatal intensive care unit time
    - Neurodevelopmental—social, emotional, or cognitive delay or disability
    - Non-serious fetal/infant adverse events
    - Breastfeeding—delayed initiation, cessation, reduced frequency, reduced volume of breast milk
    - Poor infant attachment/bonding
    - Symptoms related to withdrawal of medication
    - Discontinuation of intervention (or of study participation) due to fetal/infant adverse events*

Potential Modifiers:
- Phase
  - Preconception
  - First trimester
  - Second trimester
  - Third trimester
  - Postpartum
  - Breastfeeding
- Type of primary headache
  - Migraine
  - Tension headache
  - Cluster headache
  - Other TACs

Timing:
- Any
- Setting:
  - Any

Design:
- Randomized controlled trials
- Nonrandomized comparative studies, including pre-post studies
- Single group studies
- N-of-1 studies
- Case-control studies
- Case reports or series of case reports
- Cross-sectional studies/surveys
  - Prospective or retrospective (all applicable study types)

For harms, we will start by searching for existing systematic reviews of interventions used during pregnancy, postpartum, or breastfeeding, regardless of their indication (i.e., for any disease/condition, not only primary headaches). We will not enforce a date restriction when screening for eligible systematic reviews, but when multiple eligible systematic reviews exist for a certain drug/class of drugs, we will use the most recent or most complete one.

We will subsequently search for, and include, large primary studies of interventions not adequately covered by the existing systematic reviews of harms. The specific eligibility criteria (particularly pertaining to study design, minimum sample size, and publication date) will be determined based on available EPC resources, the number of interventions without adequate existing systematic reviews, and the volume of potentially eligible studies.

For harms, we will also search the U.S. Food and Drug Administration, other international equivalent agencies, and pharmacopoeia.

KQ 2 (Treatment of Primary Headache)

Population(s):
- Women who are pregnant (or attempting to become pregnant/in the preconception phase), postpartum (defined as up to 12 months post-delivery), or breastfeeding (for any length of time) with acute attacks of primary headache
  - Migraine, tension headache, cluster headache, or other trigeminal autonomic cephalalgia (TACs)
  - Women attempting to become pregnant include those actively planning pregnancy, by any method, who may wish to use only treatments found to be safe and effective during pregnancy.
  - Exclude: Women with attacks of secondary headache of any origin

Interventions:
- Pharmacologic interventions
  - Analgesics/antipyretics (e.g., acetaminophen)
Non-pharmacologic interventions

- Hydration
- Physical therapy
- Procedures (e.g., occipital nerve blocks, sphenopalantine ganglion blocks, trigger point injections)
- Noninvasive neuromodulation devices (e.g., transcutaneous electrical nerve stimulation, transcranial magnetic stimulation, transcutaneous vaginal stimulation, remote electrical neurostimulation)
- Behavioral therapy (e.g., cognitive behavioral therapy, diet therapy, sleep therapy, exercise therapy, support group therapy)
- Supplements (e.g., magnesium, cannabidiol)
- Complementary therapies (e.g., biofeedback, acupuncture, mindfulness-based stress reduction)
- Other non-pharmacologic interventions used to treat acute attacks of primary headache

Comparators:

- Pharmacologic interventions
  - Other class
  - Other drug within class
  - Same drug(s), different route, treatment duration, initiation time, or other aspect
  - As comparator to nonpharmacologic intervention
- Nonpharmacologic interventions
  - Other nonpharmacologic intervention class
  - Other nonpharmacologic intervention, within class
  - As comparator to pharmacologic intervention
- No pharmacologic or nonpharmacologic interventions
  - Placebo
  - No intervention

Outcomes (* denotes important outcomes that will be used when developing Strength of Evidence tables):

- Acute headache attack*
- Severity of acute headache attack
- Resolution of acute headache attack
- Duration of acute headache attack
- Headache-related symptoms (e.g., nausea/vomiting, photosensitivity)*
- Severity of headache-related symptoms
- Resolution of headache-related symptoms
- Duration of headache-related symptoms
- Most bothersome symptom
- Emergency department visits, clinic visits, or hospitalizations*
- Quality of life*
- Functional outcomes
  - Impact on family life
  - Employment/school attendance
  - Time spent managing disease
  - Resource use
- Acceptability of intervention by patients
- Patient satisfaction with intervention
- Number of prescribed medications
- Adverse events
  - Maternal
  - Serious maternal adverse events*
  - “Serious” adverse events (including those that are composite outcomes), as defined by study authors

Potential Modifiers:

- Phase
  - Preconception
  - First trimester
  - Second trimester
  - Third trimester
  - Postpartum
  - Breastfeeding
- Type of primary headache
  - Migraine
  - Tension headache
  - Cluster headache
  - Other TACs
  - Breastfeeding—delayed initiation, cessation, reduced frequency, reduced volume of breast milk
  - Poor infant attachment/bonding
  - Symptoms related to withdrawal of medication
- Discontinuation of intervention (or of study participation) due to maternal adverse events*

Timing:

- Any
  - Any
- Setting:
  - Any
- Design:
  - Randomized controlled trials
  - Nonrandomized comparative studies, including pre-post studies
  - Single group studies
  - N-of-1 studies
  - Case-control studies
• Case reports or series of case reports
• Cross-sectional studies/surveys
  ○ Prospective or retrospective (all applicable study types)
• For harms, we will start by searching for existing systematic reviews of interventions used during pregnancy, postpartum, or breastfeeding, regardless of their indication (i.e., for any disease/condition, not only primary headaches). We will not enforce a date restriction when screening for eligible systematic reviews, but when multiple eligible systematic reviews exist for a certain drug/class of drugs, we will use the most recent or most complete one.
  ○ We will subsequently search for, and include, large primary studies of interventions not adequately covered by the existing systematic reviews of harms. The specific eligibility criteria (particularly pertaining to study design, minimum sample size, and publication date) will be determined based on available EPC resources, the number of interventions without adequate existing systematic reviews, and the volume of potentially eligible studies.
  ○ For harms, we will also search the U.S. Food and Drug Administration, other international equivalent agencies, and pharmacopoeia.

Dated: November 19, 2019.
Virginia Mackay-Smith, Associate Director.
[FR Doc. 2019–25414 Filed 11–21–19; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC); Notice of Charter Renewal
AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).
ACTION: Notice of charter renewal.
SUMMARY: This gives notice under the Federal Advisory Committee Act of October 6, 1972, that the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC), Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through November 5, 2021.
FOR FURTHER INFORMATION CONTACT: Kimberly Lochner, ScD, Designated Federal Officer, BSC, CPR, Centers for Disease Control and Prevention, Department of Health and Human Services, 1600 Clifton Road NE, Mailstop H21–6, Atlanta, Georgia 30329–4027, telephone (404) 718–3420; Email address KDL4@cdc.gov.
The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.
Kalwant Smagh, Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.
[FR Doc. 2019–25352 Filed 11–21–19; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
Board of Scientific Counselors, Center for Preparedness and Response (BSC, CPR); (Formerly Known as the Board of Scientific Counselors, Office of Public Health Preparedness and Response (BSC, OPHPR)); Notice of Charter Renewal
AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).
ACTION: Notice of charter renewal.
SUMMARY: This gives notice under the Federal Advisory Committee Act of October 6, 1972, that the Board of Scientific Counselors, Center for Preparedness and Response (BSC, CPR); (formerly known as the Board of Scientific Counselors, Office of Public Health Preparedness and Response (BSC, OPHPR)), Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through October 31, 2021.
FOR FURTHER INFORMATION CONTACT: Sarah Wiley, MPH, Designated Federal Officer, BSC, DDID, Centers for Disease Control and Prevention, Department of Health and Human Services, 1600 Clifton Road NE, Mailstop H24–12, Atlanta, Georgia 30329–4027, telephone (404) 639–2100; email address SWiley@cdc.gov.
The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for