Agenda items for these meetings are subject to change as priorities dictate.

Sharon B. Arnold,

Acting Director.

[FR Doc. 2017–02624 Filed 2–8–17; 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 the Fresenius Medical Care PSO, LLC

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 Act of 2005, 42 U.S.C. 299b–21 to b–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 70732–70814, establish a framework by which hospitals, doctors, and other health care providers may voluntarily report information to Patient Safety Organizations (PSOs), on a privileged and confidential basis, for the aggregation and analysis of patient safety events. The Patient Safety Rule authorizes AHRQ, on behalf of the Secretary of HHS, to list as a 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 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 Fresenius Medical Care PSO, LLC of its status as a PSO, and has delisted the PSO accordingly. The Fresenius Medical Care PSO, LLC submitted this request for voluntary relinquishment after receiving a Notice of Preliminary Finding of Deficiency.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight ET (2400) on January 6, 2017.

ADDRESSES: Both directories can be accessed electronically at the following HHS Web site: *http://www.pso.ahrq.gov/listed.*

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Room 06N94B, 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 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 the Fresenius Medical Care PSO, LLC, a component entity of Fresenius Medical Holdings, Inc., PSO number P0081, to voluntarily relinquish its status as a PSO. Accordingly, the Fresenius Medical Care PSO, LLC was delisted effective at 12:00 Midnight ET (2400) on January 6, 2017. AHRQ notes that the Fresenius Medical Care PSO, LLC submitted this request for voluntary relinquishment following receipt of the Notice of Preliminary Finding of Deficiency sent to the PSO on December 12, 2016.

Fresenius Medical Care PSO, LLC 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. In addition, according to sections 3.108(c)(2)(ii) and 3.108(b)(3) of the Patient Safety Rule regarding disposition of PSWP, the PSO has 90 days from the effective date of delisting and revocation to complete the disposition of PSWP that is currently in the PSO's possession.

More information on PSOs can be obtained through AHRQ's PSO Web site at *http://www.pso.ahrq.gov.*

Sharon B. Arnold,

Acting Director.

[FR Doc. 2017–02623 Filed 2–8–17; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Treatment-Resistant Depression: A Narrative and Systematic Review of Definitions and Methods in Clinical Research Studies

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

ACTION: Request for Scientific Information 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 of *Treatment-Resistant Depression: A Narrative and Systematic Review of Definitions and Methods in Clinical Research Studies,* 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. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: *Submission Deadline* on or before March 13, 2017.

ADDRESSES: *Email submissions: SEADS@epc-src.org.*

Print submissions:

Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, P.O. Box 69539, Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.): Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, 3710 SW U.S. Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT: Ryan McKenna, Telephone: 503–220–8262 ext. 51723 or Email: *SIPS@epc-src.org.*

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 *Treatment-Resistant Depression: A Narrative and Systematic Review of Definitions and Methods in Clinical Research Studies.*

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 *Treatment-Resistant Depression: A Narrative and Systematic Review of Definitions and Methods in Clinical Research Studies,* including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: *https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/topicrefinement/trdepression-protocol.pdf*

This is to notify the public that the EPC Program would find the following information on *Treatment-Resistant Depression (TRD): A Narrative and Systematic Review of Definitions and Methods in Clinical Research Studies* 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,* please provide 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 EPC Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can 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 Web site 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://subscriptions.ahrq.gov/accounts/USAHRQ/subscriber/new?topic_id=USAHRQ_18.*

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 entire research protocol, is available online at: *https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/topicrefinement/trdepression-protocol.pdf*

The Key Questions

Narrative Review Questions: Based on a literature search for consensus statements, guidelines, materials from the U.S. Food and Drug Administration (FDA), the U.S. National Institutes of Health (NIH), and the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA); systematic reviews; and on a review of UpToDate, an evidence-based, peer reviewed clinical information source, we will address the key questions (Key Questions [KQs] 1 through 5, with their subquestions) listed below. In addition, we will use information from the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) panel meeting on April 27, 2016, to augment our reporting on TRD definitions, study design issues, and the related topics. The specific issues are:

KQ 1. What definitions of TRD are found in this literature? What consensus, if any, exists about the best definition(s) for this condition?

KQ 2. What methods do investigators use to diagnose this condition in clinical research? What consensus, if any, exists about the best measure(s) to use? Does the setting of the medical visit influence the choices that investigators make about the diagnostic tool they use?

KQ 3. What measures have been developed to determine the success and failure of treatment in clinical research studies of TRD?

I. What consensus, if any, exists about the best measure(s) to investigate treatments for TRD? What are the main points of agreement about such measures?
II. Are these measures physician-reported or patient-reported?
III. What are the psychometric properties of these measures? Is the minimum significant clinical difference defined for these measures?
IV. Compare and contrast these measures in how they describe:
  A. Change in depression scores as measured by depression scales
  B. Change in depressive symptomatology (*e.g.,* sleep disorders, fatigue, weight change, cognition)
  C. Change in measures of anhedonia
  D. Change in measures of functional capacity (*e.g.,* physical functioning, ability to care for self)
  E. Change in measures of quality of life
  F. Change in measures of suicide ideation
  G. Change in suicide attempts
  H. Other

KQ 4. What types of research designs are used to study TRD?

I. What consensus, if any, exists about the type of study design that best minimizes bias and the placebo effect in this field?
II. If no consensus exists about study designs to accomplish these goals, what are the trends in study designs for assessing interventions for TRD? Do these trends reflect long-lasting (*e.g.,* traditional) designs or short-lived, evolving, or newly emerging designs?
III. What consensus, if any, exists about the appropriate length of a trial?

KQ 5. What are the risk factors for TRD?

Systematic Review Questions: From a systematic literature search for individual studies on TRD. We will address the KQs 6 through 11 with their subquestions as listed below.

KQ 6. What variables were considered for TRD patients in these studies? Specify at least the factors listed below.

I. Patient Characteristics:
  A. Age
  B. Type of depressive episode (unipolar, bipolar, psychotic, atypical, other)
  C. Number of depression relapses and time to relapse
  D. Psychiatric comorbidities

E. Medical comorbidities (*e.g.,* diabetes, cardiac disease, renal disease, dementia and other cognitive abnormalities)
F. Suicidal ideation
G. Suicide attempts
H. Duration of symptoms
I. Screening tools used to make the diagnosis
J. Diagnostic tools to confirm the diagnosis

II. Prior Treatments:
A. The number, duration, dosage, or classes of antidepressants attempted for each trial of therapy
B. The number of failed trials of adequate therapy
C. The number of prior treatment trials that patients did not tolerate
D. The use of augmentation and combination pharmacological therapies for each attempted treatment trial
E. The use of electroconvulsive therapy
F. The use of psychotherapy

III. Diagnostic characteristics
A. The use of structured versus unstructured diagnostic assessments
B. Scores on standardized and validated depression rating instruments
C. Setting in which the diagnosis was made (*i.e.,* primary care, generalized psychiatric setting, specialty psychiatric setting, other)

KQ 7. How do these inclusion criteria compare or contrast with the definition(s) of TRD noted in the Narrative Questions?

KQ 8. What were primary characteristics of included studies?

I. What was the main design of each included study (*e.g.,* randomized controlled trial with blinding; interrupted time series; use of placebo, wait-list, or sham procedure)?
II. Were run-in or wash-out periods (or both) used in included studies? If so, how long were they?
III. How long was each included study?

KQ 9. How were included studies designed to account for the risk factors for TRD (see Narrative Question #5)? If the following characteristics are not noted above as risk factors, how did included studies account for at least the following: Age, sex, race, socioeconomic status, duration of symptoms, disease severity, co-existing medical and psychiatric conditions, and placebo effect?

KQ 10. What are relationships between risk factors and various results of included studies?

I. Using regression analysis or other statistical techniques, determine whether the risk factors for Narrative Review Question #5 and Systematic Review Question # 9 can be correlated with study results (*i.e.,* the magnitude of treatment effects)?
II. What is the influence of placebo response on the magnitude of treatment effects for different types of interventions?
III. Does study duration moderate the influence of placebo response?

KQ 11. What variables or information did included studies report? Specifically:

I. What measures are used to define end points in these TRD trials?
II. In addition to the measures noted for Narrative Review Question #3, did these studies record:
A. Adherence to treatment
B. Attrition from care
C. Changes in patient-selected factors of importance (*i.e.,* outcome measures identified by patient as important)
D. Changes in employment or disability status
E. Changes in use of medical resources (*e.g.,* hospitalizations, emergency room or physician visits)
F. Time to relapse

PICOTS (Populations, Interventions, Comparators, Outcomes, Time Frames, Settings)

Population(s)

All adults (>18 years old) identified as having a depressive episode (including major depressive disorder [MDD] and bipolar disorder) who have not responded to treatment(s). The depressive episode must be part of a major depressive disorder or a bipolar disorder. Studies of people without a primary diagnosis of major depressive disorder or bipolar disorder, or without evidence of treatment nonresponse, will be excluded.

Interventions

Any pharmacologic intervention tested as a treatment for TRD as a primary therapy or as an augmentation agent to an existing primary therapy.

I. Antidepressants (*e.g.,* selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, tricyclic antidepressants, monoamine oxidase inhibitors atypical agents)
II. Atypical antipsychotics
III. Anticonvulsants
IV. Mood stabilizers
V. Psychostimulants
VI. Agents approved by the FDA for other indications but tested in TRD populations (*e.g.,* ketamine, levothyroxine [T3], clonidine)

Any nonpharmacologic device or procedure tested as a treatment for TRD as a primary therapy or as augmentation to an existing primary therapy and identified as a TRD option by a consensus statement, guideline, the MEDCAC panel, or systematic review (*e.g.,* ECT, repetitive transcranial magnetic stimulation, vagus nerve stimulation, deep brain stimulation, cranial electrotherapy stimulation).

Any nonpharmacologic intervention tested as a treatment for TRD as a primary therapy or as augmentation to an existing primary therapy and identified as a TRD option by a consensus statement, guideline, the MEDCAC panel, or systematic review.

I. Complementary and alternative medication therapies
II. Psychotherapy
III. Exercise

Comparators

All comparative studies with a concurrent control group or a control group from an interrupted time-series study. These designs exclude pre/post studies that did not conduct interrupted time-series analyses.

Outcomes

Mental health outcomes identified in previous depression comparative effectiveness review work as either critical or important for decision making:

I. Benefits that are reported as primary endpoints (or outcomes) for a trial. Such outcomes could include: Reduction in suicidal ideation or suicide attempts
A. Quality of life
B. Response to treatment
C. Remission
D. Change in depressive severity
E. Functional capacity (physical and cognitive functioning measured by validated scales)
F. Speed of remission
G. Speed of response
H. Intervention durability (rates or counts of recurrence of a depressive episode for those who have remitted)
II. Adverse events from the intervention identified as either critical or important for decision making. Serious adverse events per FDA definition (rates or counts)
A. Overall adverse events (rates or counts)
B. Treatment discontinuations attributed to adverse events (rates or counts)

Time Frames

I. Any study duration.

Settings

I. All settings.

Our population of interest is adults 18 years of age or older with depression who have not responded to treatment(s). The depressive illness can be part of either major depressive disorder or a bipolar disorder, but one of these diagnoses must be a primary diagnosis. For example, schizophrenia with a secondary diagnosis of MDD, or dysthymia, would not be eligible for this report. If a study involves both eligible and ineligible patients and does not report data separately, that whole study will be excluded. Populations with no evidence of treatment nonresponse (*e.g.,* a study in which the absence of treatment response is not part of the selection criteria) will not be eligible.

Eligible interventions include those that have both been tested as a treatment targeting TRD in adults and been identified by guidelines, consensus statements, the MEDCAC panel, or systematic reviews as alternatives for TRD treatment. These criteria ensure consideration of interventions with a minimum threshold amount of data addressing its effectiveness in TRD populations. Comparison groups include concurrent control groups (*e.g.,* active, sham, or placebo) and a control group from an interrupted time series.

We will require outcomes to have been identified previously as the most meaningful to depression management decision making. In our earlier comparative effectiveness work on depression, we asked our Technical Expert Panel and Key Informants to rank the relative importance of these outcomes following a process proposed by the GRADE Working Group.30 We used SurveyMonkey© for an anonymous ranking of the relative importance of outcomes. Participants used a 9-point Likert scale to rank outcomes into three categories: (1) Critical for decision making, (2) important but not critical for decision making, and (3) of low importance for decision making. They identified six outcomes as critical and five as important, and they supported the inclusion of an additional depressive outcome (change in depressive severity). For one of the adverse events outcomes, serious adverse events, we will use the FDA definition and will consider physical, psychological, and cognitive events. We will require relevant studies for the current project to report on at least 1 of these 12 outcomes.

All study durations and all settings are eligible. Pre/post studies that do not use interrupted time series analyses will be excluded, because potential confounding from multiple sources renders questionable the ability of these study designs to support causal inferences. We will include English-language articles and exclude studies that are not published fully in English.

Sharon B. Arnold,

Acting Director.

[FR Doc. 2017–02622 Filed 2–8–17; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS (the Secretary) is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place NW., Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857; (301) 443–6593, or visit our Web site at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that ''[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.'' Set forth below is a list of petitions received by HRSA on December 1, 2016, through December 31, 2016. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and
2. Any allegation in a petition that the petitioner either:
   a. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by'' one of the vaccines referred to in the Table, or
   b. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the