### Sunshine Act Meetings

**TIME AND DATE:** Tuesday, September 25, 2018 at 10:00 a.m.

**PLACE:** 1050 First Street NE, Washington, DC.

**STATUS:** This Meeting will be Closed to the Public.

### MATTERS TO BE CONSIDERED:

- Compliance matters pursuant to 52 U.S.C. 30109.
- Matters concerning participation in civil actions or proceedings or arbitration.

**CONTACT PERSON FOR MORE INFORMATION:** Judith Ingram, Press Officer, Telephone: (202) 694–1220.

**FOR FURTHER INFORMATION CONTACT:** Jenae Benns, Telephone: 301–427–1496 or Email: epc@ahrq.hhs.gov.

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Agency for Healthcare Research and Quality**

**Supplemental Evidence and Data Request on Depression in Children: Systematic Review**

**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 of Depression in Children: Systematic Review, 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 October 22, 2018.

**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 06532, 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 0677D, Rockville, MD 20857.

**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 Depression in Children: Systematic Review. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a). 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 Depression in Children: Systematic Review, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: https://effectivehealthcare.ahrq.gov/topic/childhood-depression/protocol

This is to notify the public that the EPC Program would find the following...
The Key Questions (KQs)

1a. In adolescents and children, what are the benefits and harms of nonpharmacological interventions for depressive disorders (defined as MDD or PDD/DD)?

1b. How do these benefits and harms vary by subgroup (e.g., patient characteristics, parent/caregiver characteristics, disorder characteristics, history of previous treatment, comorbid condition, exposure to a traumatic life event)?

2a. In adolescents and children, what are the benefits and harms of pharmacological interventions for depressive disorders (defined as MDD or PDD/DD)?

2b. How do the benefits and harms vary by subgroup (e.g., patient characteristics, disorder characteristics, history of previous treatment, comorbid condition, exposure to a traumatic life event)?

3a. In adolescents and children, what are the benefits and harms of combination interventions for depressive disorders (defined as MDD or PDD/DD)?

3b. How do the benefits and harms vary by subgroup (e.g., patient characteristics, disorder characteristics, history of previous treatment, comorbid condition, exposure to a traumatic life event)?

4a: In adolescents and children, what are the benefits and harms of collaborative care interventions for depressive disorders (defined as MDD or PDD/DD)?

4b: How do the benefits and harms vary by subgroup (e.g., patient characteristics, disorder characteristics, history of previous treatment, comorbid condition, exposure to a traumatic life event)?

5a: In adolescents and children, what are the comparative benefits and harms of treatments (pharmacological, nonpharmacological, combined, collaborative care interventions) for depressive disorders (defined as MDD or PDD/DD)?

5b. How do these benefits and harms vary by subgroup (e.g., patient characteristics, disorder characteristics, history of previous treatment, comorbid condition, exposure to a traumatic life event)?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings) and Inclusion/Exclusion Criteria

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<tr>
<th>PICOTS</th>
<th>Inclusion</th>
<th>Exclusion</th>
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<tr>
<td>Population</td>
<td>Children and adolescents (≤18 years old) with a depressive disorder (MDD or PDD/DD) as indicated by a diagnosis made from an established taxonomy (e.g., DSM, ICD) via administration of a structured or semi-structured clinical interview (CIDI, DISC, SCID, PRIME–MD, Kinder-DIPS, K–SADS, DICA, CAS, SADS, DAWBA, SCAN), use of a cutoff indicative of clinical MDD or PDD/DD as measured by a clinically validated depression scale (BDI, CDI, CESD, PHQ, MFS, Child–S), or via a clinician diagnosis. Subgroups of interest (KQs 1b, 2b, 3b, 4b, 5b) include those distinguished by patient characteristics (e.g., developmental age—child or adolescent, gender, race/ethnicity), parent/caregiver characteristics (e.g., type, severity), history of previous treatment, comorbid condition, and exposure to a traumatic life event.</td>
<td>All other children and adolescents (≤18 years old); all adults &gt;18 years old.</td>
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<td>Intervention</td>
<td>Nonpharmacological interventions: Cognitive behavioral therapy, rational emotive behavior therapy, behavioral activation, other behavioral therapy, interpersonal therapy, directive counseling, Katathymianthotic Psychotherapy, family therapy, parent education, self-help groups, problem-solving therapy, autonomic training, combined-modality therapy, psychological adaptation therapies.</td>
<td>All other interventions.</td>
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<td>PICOTS</td>
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<td><strong>Lifestyle:</strong> Exercise (physical activity), diet therapy, mindfulness (including mindfulness-based stress reduction), meditation (including mindfulness mediation), relaxation therapy, massage therapy, music therapy, art therapy, integrative restoration, visualization, tai-chi, yoga, spirituality, acupuncture.</td>
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<td><strong>Supplements:</strong> St. John’s Wort, SAMe, fish oil, melatonin, L-tryptophan, folic acid, 5-HTP, zinc, chromium, gingko biloba, vitamin E, omega-3 fatty acids, hypericum, inositol, selenium.</td>
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<td><strong>Other:</strong> Electroconvulsive therapy, transcranial magnetic stimulation, light therapy (phototherapy), hypnotherapy (including self-hypnotherapy), neurofeedback, deep brain stimulation, biofeedback.</td>
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<td><strong>Pharmacological interventions:</strong></td>
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<td><em>Selective serotonin reuptake inhibitors (SSRIs):</em> Citalopram, escitalopram, fluvoxamine, paroxetine, sertraline, vilazodone.</td>
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<td><em>Serotonin and norepinephrine reuptake inhibitors (SNRIs):</em> Duloxetine, venlafaxine.</td>
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<td><em>Tricyclic antidepressants:</em> Amitriptyline, desipramine, imipramine, nortriptyline, doxepin, clomipramine.</td>
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<td><em>Monoamine oxidase inhibitors:</em> Rasagiline, selegiline, isocarboxazid, phenelzine, tranylcypromine.</td>
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<td><em>Atypical antidepressants:</em> Bupropion, mirtazapine, nefazodone, trazodone, vortioxetine.</td>
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<td><strong>Combination interventions:</strong> Any combined treatment that includes two or more types of nonpharmacological, pharmacological, and/or collaborative care interventions, either started together or given as augment to initial treatment types.</td>
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<td><strong>Collaborative care interventions:</strong> Collaborative care, integrated care, integrative care, stepped care, coordinated care, co-managed care, co-located care.</td>
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| Comparator | KQ 1: Treatment as usual, sham, attention control, wait list control ... | All other comparators. |
| Comparator | KQ 2: Placebo, treatment as usual, attention control, wait list control. | |
| Comparator | KQ 3: Treatment as usual, placebo, sham, attention control, wait list control. | |
| Comparator | KQ 4: Treatment as usual, placebo, sham, attention control, wait list control. | |
| Comparator | KQ 5: Any nonpharmacologic, pharmacologic, or collaborative care intervention alone or in combination. | |

| Outcomes | Harms: Any AEs of intervention (e.g., death, serious adverse events). |

| Time frame | Less than 6 weeks of treatment. |
| Time frame | At least 6 weeks of treatment. |

| Settings | Outpatient care in countries with a very high Human Development Index **. |
| Settings | Inpatient care, studies conducted in countries without a very high Human Development Index. |

| Study design | For benefits: Adolescents (sample age >12 and ≤18): randomized controlled trials (RCTs). Children (sample age ≤12): RCTs or controlled clinical trials (CCTs). For harms: RCTs, CCTs, and observational studies ***. Reference lists of relevant systematic reviews published in 2013 or later will be used to ensure our search strategies captured all relevant studies. |
| Study design | All other designs and studies using included designs that do not meet the sample size criterion. |

| Language | Studies published in English. |
| Language | Studies published in languages other than English. |

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* In the absence of clear, clinically validated cutoffs of depression scales used to indicate a either MDD or PDD/DD, the research team will consult two recent systematic reviews on the topic and discuss required thresholds with the Technical Expert Panel (TEP) for each scale.


*** The research team will evaluate the yield for harms. When studies with sample sizes of 1,000 or more participants are available for a given intervention and comparator, the team plans to restrict the analysis to that group. If large samples are not available, the team plans to include studies with smaller sample sizes.
The research team anticipates grading all outcomes but if needed (based on the volume of evidence), they may seek input from the TEP on prioritizing outcomes for strength of evidence grading.

AE = adverse event; BDI = Beck Depression Inventory; CAS: The Child Assessment Schedule; CBT = cognitive behavioral therapy; CCT = controlled clinical trial; CDI = Composite International Diagnostic Interview; CDI–S: Children’s Depression Inventory; CES–D = Center for Epidemiological Studies Depression Scale; Child–S: Children’s Depression Screener; DAWBA = The Development and Wellbeing Assessment; DD = dysthyemic disorder; DICA = Diagnostic Interview for Children and Adolescents; SADS = The Schedule for Affective Disorders and Schizophrenia for School-Age Children; MDD = major depressive disorder; PDD = persistent depressive disorder; PHQ = Patient Health Questionnaire; PICOTS = populations, interventions, comparators, outcomes, timing, and setting; PRIME–MD = The Primary Care Evaluation of Mental Disorders; RCT = randomized controlled trial; SADS = The Schedule for Affective Disorders and Schizophrenia; SCAN = Schedules for Clinical Assessment in Neuropsychiatry; SCID = Structured Clinical Interview for DSM disorders.

**References**


Francis D. Chesley, Jr.,
Deputy Director.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Performance Review Board Members**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC) located within the Department of Health and Human Services (HHS) is publishing the names of the Performance Review Board Members who are reviewing performance for Fiscal Year 2018.

**FOR FURTHER INFORMATION CONTACT:** Sandra DeShields, Chief, Compensation and Performance Management Team, Executive and Scientific Resources Office, Human Resources Office, Centers for Disease Control and Prevention, 11 Corporate Square Blvd., Mailstop US11–2, Atlanta, Georgia 30341, Telephone (770) 486–0252.

**SUPPLEMENTARY INFORMATION:** Title 5, U.S.C. Section 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires that the appointment of Performance Review Board Members be published in the Federal Register. The following persons will serve on the CDC Performance Review Boards or Panels, which will oversee the evaluation of performance appraisals of Senior Executive Service members for the Fiscal Year 2018 review period:

- Dean, Hazel Co-Chair
- Shelton, Dana Co-Chair
- Arispe, Irma
- Boyle, Coleen
- Branche, Christine
- Curlee, Robert C.
- Kosmos, Christine
- Peeples, Amy
- Quarters, Judith
- Ruiz, Roberto
- Smagh, Kalwant

Dated: September 17, 2018.

Sandra Cashman,
Executive Secretary, Centers for Disease Control and Prevention.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**[CMS–4184–N]**

**Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2019**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the annual adjustment in the amount in controversy (AIC) threshold amounts for Administrative Law Judge (ALJ) hearings and judicial review under the Medicare appeals process. The adjustment to the AIC threshold amounts will be effective for requests for ALJ hearings and judicial review filed on or after January 1, 2019. The calendar year 2019 AIC threshold amounts are $1,000 for ALJ hearings and $1,000, respectively, for Medicare Part A and Part B appeals. Section 940 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), amended section 1869(b)(1)(E) of the Act to require the AIC threshold amounts for ALJ hearings and judicial review to be adjusted annually. Beginning in January 2005, the AIC threshold amounts are to be adjusted by the percentage increase in the medical care component of the consumer price index (CPI) for all urban consumers (U.S. city average) for July 2003 to July of the year preceding the year involved and rounded to the nearest multiple of $10. Section 940(b)(2) of the MMA provided conforming amendments to apply the AIC adjustment requirement to Medicare Part C/Medicare Advantage (MA) appeals and certain health maintenance organization and competitive health plan appeals. Health care prepayment plans are also subject to MA appeals rules, including the AIC adjustment requirement. Section 101 of the MMA provides for the application of the AIC adjustment requirement to Medicare Part D appeals.

**A. Medicare Part A and Part B Appeals**

The statutory formula for the annual adjustment to the AIC threshold amounts for ALJ hearings and judicial review of Medicare Part A and Part B appeals, set forth at section 1869(b)(1)(E) of the Act, is included in the applicable implementing regulations, 42 CFR §§405.1003 and 405.1006(b) and (c). The regulations require the Secretary of Health and Human Services (the

**FOR FURTHER INFORMATION CONTACT:** Liz Hosna (Katherine.Hosna@cms.hhs.gov), (410) 786–4993.

**SUPPLEMENTARY INFORMATION:**

I. Background

Section 1869(b)(1)(E) of the Social Security Act (the Act), as amended by section 521 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), established the amount in controversy (AIC) threshold amounts for Administrative Law Judge (ALJ) hearings and judicial review at $100 and $1,000, respectively, for Medicare Part A and Part B appeals. Section 940 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), amended section 1869(b)(1)(E) of the Act to require the AIC threshold amounts for ALJ hearings and judicial review to be adjusted annually. Beginning in January 2005, the AIC threshold amounts are to be adjusted by the percentage increase in the medical care component of the consumer price index (CPI) for all urban consumers (U.S. city average) for July 2003 to July of the year preceding the year involved and rounded to the nearest multiple of $10. Section 940(b)(2) of the MMA provided conforming amendments to apply the AIC adjustment requirement to Medicare Part C/Medicare Advantage (MA) appeals and certain health maintenance organization and competitive health plan appeals. Health care prepayment plans are also subject to MA appeals rules, including the AIC adjustment requirement. Section 101 of the MMA provides for the application of the AIC adjustment requirement to Medicare Part D appeals.