Nebraska, and thereby engage in extending credit, activities related to extending credit, community development activities, and data processing activities, pursuant to sections 225.28(b)(1), (b)(2), (b)(12), and (b)(14) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–14575 Filed 7–1–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Mindfulness-Based Interventions for Mental Health and Wellbeing in Children and Adolescents: A Systematic Review

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

ACTION: Request for supplemental evidence and data submission.

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 *Mindfulness-Based Interventions for Mental Health and Wellbeing in Children and Adolescents: A Systematic Review,* which is currently being conducted by 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 August 1, 2024.

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: Kelly Carper, telephone: 301–427–1656 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 *Mindfulness-Based Interventions for Mental Health and Wellbeing in Children and Adolescents: A Systematic Review.* AHRQ is conducting this 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 *Mindfulness-Based Interventions for Mental Health and Wellbeing in Children and Adolescents: A Systematic Review.* The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/ped-mindfulness/protocol*

This is to notify the public that the EPC Program would find the following information on *Mindfulness-Based Interventions for Mental Health and Wellbeing in Children and Adolescents: A Systematic Review* helpful:

- A list of completed studies that your organization has sponsored for this topic. 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, if relevant: study number, study period, design, methodology, indication and diagnosis, 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 topic.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including, if relevant, a study number, the study period, design, methodology, indication and diagnosis, 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 topic 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 topics 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://effectivehealthcare.ahrq.gov/email-updates.*

The 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 mindfulness-based interventions in the general child and adolescent populations?

KQ 2. What are the benefits and harms of mindfulness-based interventions in children and adolescents diagnosed with anxiety and/or depression?

KQ 3. What are the benefits and harms of mindfulness-based interventions in children and adolescents with a chronic condition who are at risk for elevated symptoms of anxiety and/or depression?

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

	Inclusion criteria	Exclusion criteria
Population	KQ 1. Children and adolescents aged 3 to 18 years *without* known anxiety and/or depression. KQ 2. Children and adolescents aged 3 to 18 years *with* a diagnosis of depression and/or anxiety. KQ 3. Children and adolescents aged 3 to 18 years *with* a chronic condition who are at risk for elevated symptoms of or being diagnosed with anxiety and/or depression. Definition of chronic physical conditions: Medical physical conditions (*i.e.,* conditions that primarily affect the body's systems and functions) that persist for one year or longer and require ongoing medical attention, limit activities of daily living, or both.	Studies with ≥20% of participants in the following groups and do not report findings by population. • In institutions (*e.g.,* psychiatric inpatients, long-term care facilities). • Diagnosed with advanced neurodevelopmental disorders (*e.g.,* severe autism spectrum disorders [for example, level 3 on DSM–5], severe attention-deficit/hyperactivity disorder [*e.g.,* based on DSM–5 definition], severe learning disorders [*e.g.,* more than 2 standard deviations below the mean in one or more areas of cognitive processing related to the specific learning disorder]). • With major behavioral or emotional dysregulation (*e.g.,* conduct disorder, oppositional defiant disorder, disruptive mood dysregulation disorder).[a] • With substance use disorder. We will exclude studies with MBIs designed and/or administered only to parents/caregivers, as well as interventions administered by parents/caregivers. We will exclude studies designed to treat test or sports performance anxiety, anxiety associated with medical/dental procedures and with interventions for specific high-risk exposures such as for post-sexual assault or another traumatic event.
Interventions	KQ 1–3 In addition to the minimum requirements identified above: • Mindfulness-based intervention, provided alone or in addition to other therapies. • Mindfulness is the primary component for multicomponent interventions (as a part of behavioral and similar non-pharmacological strategies), meaning that the intervention must be centered around mindfulness (*e.g.,* the majority of the sessions or focus are mindfulness-based). • A mindfulness instructor (*e.g.,* therapist, teacher) must have some training in providing mindfulness. We do not specify the required minimum training. • Clear specification of repeated practice (*e.g.,* more than one session with an instructor, or repeated self-directed exercises after at least one initial session with an instructor). Examples of other therapies include structured mindfulness programs and mindfulness-based therapies such as: • Mindfulness-based Stress Reduction • Mindfulness-based Cognitive Therapy • Acceptance and Commitment Therapy Components of programs, if they are intentionally used to promote mindfulness principles and meet other criteria, may include: • Relaxation techniques • Meditation • Mindful breathing • Guided imagery • Visualization	Pharmacologic interventions or traditional psychotherapies alone (*e.g.,* cognitive-behavioral therapy, play therapy, dialectical behavior therapy, parent-child interaction therapy) and integrative therapies alone including acupuncture/acupressure, expressive therapies, exercise, yoga, Tai Chi, biofeedback, hypnotherapy, massage, chiropractic care, homeopathy, diets (*e.g.,* gluten-free diet), traditional Chinese medicine, and Ayurveda.
Comparators	KQ 1. Usual care, enhanced usual care, waitlist control, sham, attention control, or no active intervention. KQ 2–3. Usual care, enhanced usual care, waitlist control, sham, attention control, no active intervention, or conventional therapies (*i.e.,* pharmacotherapy for anxiety and/or depression [see Table 2], behavioral interventions[b]).	Other interventions not listed in the ''included'' list. Other mindfulness-based interventions (*i.e.,* comparative effectiveness of MBIs).
Outcomes	KQ 1–3 Primary outcomes (children and adolescents outcomes) • Quality of life (*e.g.,* PedsQL, KIDSCREEN, CHQ, ITQOL, PQ–LES–Q). • General and social functioning (*e.g.,* SDQ, SSIS, CGI–I, CGAS), including behavior problems (*e.g.,* ECBI, CBCL, SDQ), coping skills (*e.g.,* CSI–CA, CCSC, RSQ), executive functioning (*e.g.,* BRIEF), academic performance (*e.g.,* WIAT, Woodcock-Johnson Tests of Achievement). • Disability (*e.g.,* VABS, FDI, days of missed school). • Depression (*e.g.,* CDI, BDI, MFQ, CES–D, CDRS–R, RADS, PHQ–A, PI–ED), diagnosis (KQs 2 and 3 only), and remission and response (KQs 1 and 3). • Anxiety (*e.g.,* SCARED, MASC, SCAS, CAIS, GAD–7, PHQ–A, PI–ED), diagnosis (KQs 2 and 3 only), and remission and response (KQs 1 and 3). • Any reported adverse events or unintended negative consequences attributed to treatment. Additional outcomes (children and adolescents outcomes). • Acceptance of experiences in the present moment (*e.g.,* CAMM). • Autonomic arousal (*e.g.,* SCL, HRV). • Executive functioning (*e.g.,* BRIEF). • Subjective well-being (*e.g.,* PANAS–C, SLSS). • Substance use.	Other outcomes, parent/caregiver outcomes.

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

	Inclusion criteria	Exclusion criteria
Timing	• Psychological flexibility (*e.g.,* AFQ–Y, AAQ). • Healthcare utilization. • A minimum of 4 weeks since the beginning of the intervention or baseline assessment (if the intervention start cannot be determined) for all outcomes except for harms. • We will extract harms reported at any followup, regardless of the duration since the intervention start or baseline assessment.	Mid-intervention assessment times.
Setting	KQ 1–3 • Administered in outpatient health care or community settings (*e.g.,* schools, residential). • Trials conducted in countries rated as ''very high'' on the 2019 Human Development Index (as defined by the United Nations Development Program).	In-patient, ED/EMS, and psychiatric subacute settings (*e.g.,* partial hospitalization programs, intensive outpatient programs).
Study Design	• Randomized controlled trials (individually or site-randomized), with individually randomized trials reporting outcomes for a minimum of 10 participants per treatment arm. • Period 1 data from crossover RCTs. • Published in English-language. • Published in 2010 or later.	Other study designs.

Abbreviations: AAQ = Acceptance and Action Questionnaire; AFQ–Y = Avoidance and Fusion Questionnaire for Youth; BDI = Beck Depression Inventory; BRIEF = Behavior Rating Inventory of Executive Function; CAIS = Child Anxiety Impact Scale; CAMM = Child and Adolescent Mindfulness Measure; CBCL = Child Behavior Checklist; CCSC = Children's Coping Strategies Checklist; CDI = Children's Depression Inventory; CDRS–R = Children's Depression Rating Scale–Revised; CES–D = Center for Epidemiologic Studies Depression Scale; CGAS = Children's Global Assessment Scale; CGI–I = Clinical Global Impression-Improvement Scale; CHQ = Child Health Questionnaire; CSI–CA = Coping Strategies Inventory for Children and Adolescents; ED/EMS = emergency department/emergency medical services; ECBI = Eyberg Child Behavior Inventory; FDI = Functional Disability Inventory Child Form; GAD–7 = Generalized Anxiety Disorder scale; HRV = heart rate variability; ITQOL = Infant/Toddler Quality of Life Questionnaire; KQ = Key Question; MASC = Multidimensional Anxiety Scale for Children; MFQ = Mood and Feelings Questionnaire; NA = not applicable; PedsQL = Pediatric Quality of Life Inventory; PHQ–A = Patient Health Questionnaire for Adolescents; PICOTS = population, interventions, comparators, outcomes, timing, and setting; PI–ED = Paediatric Index of Emotional Distress; PQ–LES–Q = Perceived Quality of Life Scale; RADS = Reynolds Adolescent Depression Scale; RSQ = Responses to Stress Questionnaire; SCARED = Screen for Child Anxiety Related Emotional Disorders; SCAS = Spence Children's Anxiety Scale; SCL = Skin Conductance Level; SDQ = Strengths and Difficulties Questionnaire; SLSS = Students' Life Satisfaction Scale; SSIS = Social Skills Improvement System; PANAS–C = Positive and Negative Affect Schedule for Children; SWLS = Satisfaction with Life Scale; VABS = Vineland Adaptive Behavior Scales; WIAT = Wechsler Individual Achievement Test; WISC = Wechsler Intelligence Scale for Children.

[a] These are reviewed in other AHRQ systematic reviews.

[b] We defined behavioral interventions as nonpharmacologic strategies intended to enhance outcomes by modifying behavior and/or ways of thinking (*e.g.,*cognitive behavioral therapy, coping skills training, behavioral therapy, biofeedback, dialectical behavioral therapy).

Dated: June 27, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024–14573 Filed 7–1–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10849 and CMS–10516]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by September 3, 2024.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10849—Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request

CMS–10516—Program Integrity: Exchange, Premium Stabilization