itemizes the goods and services it offers; (2) show consumers a Casket Price List and an Outer Burial Container Price List at the outset of any discussion of those items or their prices, and in any event before showing consumers caskets or vaults; (3) provide price information from its price lists over the telephone; and (4) give consumers a Statement of Funeral Goods and Services Selected after determining the funeral arrangements with consumers. The Rule requires that funeral providers disclose this information to consumers and maintain records documenting their compliance with the Rule.

Affected Public: Private Sector: Businesses and other for-profit entities.

Estimated Number of Annual Respondents: 18,874.

Estimated Annual Burden Hours: 173,936.

Estimated Annual Labor Costs: $5,387,875.

Request for Comment:

On December 19, 2022, the FTC sought public comment on the information collection requirements in the Funeral Rule. 87 FR 77610 (Dec. 19, 2022). No relevant comments were received during the public comment period. Pursuant to OMB regulations, 5 CFR part 1320, that implement the PRA, 44 U.S.C. 3501 *et seq.,* the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for the Rule. For more details about the Rule requirements and the basis for the calculations summarized below, see 87 FR 77610.

Your comment—including your name and your state—will be placed on the public record of this proceeding. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone's Social Security number; date of birth; driver's license number or other state identification number or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for ensuring that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''[t]rade secret or any commercial or financial information which is . . . privileged or confidential''—as provided in section 6(f) of the FTC Act 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16CFR 4.10(a)(2)—including, in particular, competitively sensitive information, such as costs, sales statistics, inventories, formulas, patterns devices, manufacturing processes, or customer names.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2023–07186 Filed 4–5–23; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Psychosocial and Pharmacologic Interventions for Disruptive Behavior in Children and Adolescents

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 *Psychosocial and Pharmacologic Interventions for Disruptive Behavior in Children and Adolescents,* 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 May 8, 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 06E53A, 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 *Psychosocial and Pharmacologic Interventions for Disruptive Behavior in Children and Adolescents.* 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 Psychosocial and Pharmacologic Interventions for Disruptive Behavior in Children and Adolescents, including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/disruptive-behavior/protocol.*

This is to notify the public that the EPC Program would find the following information on Psychosocial and Pharmacologic Interventions for Disruptive Behavior in Children and Adolescents 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: In children under 18 years of age diagnosed with disruptive behaviors, which psychosocial interventions are more effective for improving short-term and long-term psychosocial outcomes compared to no treatment or other psychosocial interventions?

KQ 2: In children under 18 years of age diagnosed with disruptive behaviors, which pharmacologic interventions are more effective for improving short-term and long-term psychosocial outcomes compared to placebo or other pharmacologic interventions?

KQ 3: In children under 18 years of age diagnosed with disruptive behaviors, what is the relative effectiveness of psychosocial interventions alone compared with pharmacologic interventions alone for improving short-term and long-term psychosocial outcomes?

KQ 4: In children under 18 years of age diagnosed with disruptive behaviors, are combined psychosocial and pharmacologic interventions more effective for improving short-term and long-term psychosocial outcomes compared to either psychosocial or pharmacologic interventions alone?

KQ 5: What are the harms associated with treating children under 18 years of age for disruptive behaviors with either psychosocial, pharmacologic or combined interventions?

KQ 6a: Do interventions for disruptive behaviors vary in effectiveness and harms based on patient characteristics, including gender, age (including pubertal changes and use of oral contraceptives), racial/ethnic minority, LGBTQ+ status, English proficiency, health literacy, socioeconomic status, insurance status, rural versus urban, developmental status or delays, family history of disruptive behavior disorders or other mental health disorders, prenatal use of alcohol and drugs (specifically methamphetamine), history of trauma or Adverse Childhood Experiences (ACEs), parental ACEs, access to social supports (neighborhood assets, family social support, worship community, etc.), personal and family beliefs about mental health (*e.g.* stigma around mental health), or other social determinants of health?

KQ 6b: Do interventions for disruptive behaviors vary in effectiveness and harms based on clinical characteristics or manifestations of the disorder, including specific disruptive behavior (*e.g.,* stealing, fighting) or specific disruptive behavior disorder (*e.g.,* oppositional defiant disorder, conduct disorder), co-occurring behavioral disorders (*e.g.,* attention deficit hyperactivity disorder, autism spectrum disorder, internalizing disorders), related personality traits and symptom clusters, presence of non-behavioral comorbidities, age of onset, and duration?

KQ 6c: Do interventions for disruptive behaviors vary in effectiveness and harms based on treatment history of the patient?

KQ 6d: Do interventions for disruptive behaviors vary in effectiveness and harms based on characteristics of treatment, including setting (*e.g.,* group homes, residential treatment, family setting), duration, delivery, timing, and dose?

Contextual Question 1. What are the disparities in the diagnosis of disruptive behavior disorders (based on characteristics such as gender, race/ethnicity, socioeconomic status, other social determinants of health, or other factors) in children and adolescents?

Contextual Question 2. What are the disparities in the treatment of disruptive behaviors or disruptive behavior disorders (based on characteristics such as gender, race/ethnicity, socioeconomic status, other social determinants of health, or other factors) in children and adolescents?

Contextual Question 3. How do disparities in the diagnosis and treatment of disruptive behaviors or disruptive behavior disorders affect behavioral and functional outcomes (*e.g.,* compliance with teachers, contact with the juvenile justice system, substance abuse)?

POPULATION, INTERVENTION, COMPARATOR, OUTCOME, TIMING, SETTING/STUDY DESIGN (PICOTS)

PICOTS	Inclusion	Exclusion
Population	KQs 1–6. Children under 18 years of age who are being treated for disruptive behavior or a disruptive behavior disorder that includes oppositional defiant disorder, conduct disorder, and intermittent explosive disorder; children with a co-occurring diagnosis (e.g., ADHD, ASD) provided the disruptive behavior treated is due to a DBD will be included.	—Asymptomatic children. —At-risk children. —Treatment of disruptive behavior secondary to other conditions (e.g., substance abuse, developmental delay, intellectual disability, pediatric bipolar disorder, ADHD).
Interventions	KQs 1, 3–6. Psychosocial interventions for child, parents/family or both including: .. —Social skills training. —Functional behavioral interventions. —Parent training. —Psychotherapy (e.g., cognitive behavior therapy, interpersonal psychotherapy, psychodynamic therapy, dialectical behavior therapy, equine-assisted psychotherapy with mental health provider). —Contingency management methods. —Behavior management training. KQs 2–6. Pharmacologic interventions that are FDA approved medications used on or off label, including the following class of drugs: —Alpha-agonists. —Anticonvulsants —Second-generation (i.e., atypical) antipsychotics. —Beta-adrenergic blocking agents (i.e., beta-blockers). —Central nervous system stimulants. —First-generation antipsychotics. —Selective serotonin reuptake inhibitors. —Selective norepinephrine reuptake inhibitors. —Mood stabilizers. —Antihistamines.	—Preventive interventions for at-risk populations. —Preventive interventions for caregiver health. —Interventions that do not target disruptive behaviors. —Specialized diet or dietary supplements. —Speech, occupational, physical therapy. —Complimentary and Integrative Health interventions (e.g., acupuncture, herbal remedies). —Exercise programs as the sole intervention. —Massage, chiropractic care. —Invasive medical interventions (e.g., surgery, deep brain stimulation).

POPULATION, INTERVENTION, COMPARATOR, OUTCOME, TIMING, SETTING/STUDY DESIGN (PICOTS)—Continued

PICOTS	Inclusion	Exclusion
	KQs 4–6. Combined psychosocial and pharmacologic interventions included for KQs 1–3.	
Comparators	—Other included psychosocial and/or pharmacologic interventions —Inactive treatment, including waitlist control, no treatment and placebo.	No comparison group, excluded interventions.
Outcomes	KQs 1–4, 6. Behavioral outcomes: —Aggressive behavior. —Temper outbursts (not considered age-appropriate). —Violent behavior. —Delinquent behavior. —Fighting, property destruction, and rule violations. —Compliance with parents, teachers, and institutional rules. —Affective or mood elements of DBD. —Treatment satisfaction. —Other patient-centered outcomes. KQs 1–4, 6. Functional outcomes: —Family functioning/cohesion. —School performance/attendance. —Interpersonal/social function and competence/need for special accommodations. —Interactions with legal/juvenile justice systems. —Out of home placement. —Health care system utilization. —Substance abuse. —Parenting stress. —Logistical family outcomes (days of work lost, etc.). —Health-related quality of life (e.g., mental health, physical health). —Other patient-centered outcomes. KQ 5. Adverse effects/harms: —Metabolic effects: weight gain, hyperglycemia and diabetes, hyperlipidemia. —Extrapyramidal effects: parkinsonism, acute dystonia, akathisia, tardive dyskinesia. —Cardiac adverse effects: prolonged QT/arrhythmias, hypotension, cardiomyopathy. —Prolactin-related effects. —Neutropenia as a potential adverse effect of atypical antipsychotics. —Allergic reaction. —Sleep disruption, fatigue. —Sudden death. —Suicide. —Over-medication or inappropriate medication. —Negative effects on family dynamics. —Acne. —Stigma. —Harms/barriers to utilization of care related to psychosocial interventions (e.g., time investment, limited access to trained providers, and lower acceptability based on a misperception that family-focused psychosocial interventions carry implicit judgements about the quality of their parenting). —Study withdrawal due to medication adverse effects.	Unvalidated outcomes measures.
Timing	KQs 1–6. Any length of follow-up.	
Setting	KQs 1–6. Clinical setting, including medical or psychosocial care that is delivered to individuals by clinical professionals (including telehealth), as well as individually focused programs to which clinicians refer their patients; may include classroom settings when intervention is directed to treat disruptive behavior(s) in a specific child (not the whole class) as part of that child's treatment plan.	Exclude school wide or system wide settings (e.g., juvenile justice system) wherein interventions are targeted more widely.
Study Design	Randomized controlled trials (no sample size limit), comparative nonrandomized controlled trials that adjust for confounding variables (N≥100), published in English on or after 1994.	Published before 1994.

Abbreviations: ADHD=Attention-deficit/hyperactivity disorder; ASD=Autism Spectrum Disorder; DBD=Disruptive Behavior Disorders; FDA=U.S. Food and Drug Administration; KQ=Key Question.

Dated: March 30, 2023.

Marquita Cullom,

Associate Director.

[FR Doc. 2023–07129 Filed 4–5–23; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0112]

Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Draft Guidance for Industry; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice announcing the availability of a draft guidance for industry that appeared in the **Federal Register** of February 13, 2023. In that notice, FDA requested comments on the draft guidance for industry entitled ''Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development.'' The