

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 questions below. This information is provided as background and AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

KQ 1a: Which medications are efficacious for improving consumption outcomes for adults with alcohol-use disorders in outpatient settings?

KQ 1b: How do medications for adults with alcohol-use disorders compare for improving consumption outcomes in outpatient settings?

KQ 2a: Which medications are efficacious for improving health outcomes (including functioning and quality-of-life outcomes) for adults with alcohol-use disorders in outpatient settings?

KQ 2b: How do medications for adults with alcohol-use disorders compare for improving health outcomes (including functioning and quality-of-life outcomes) in outpatient settings?

KQ 3a: What adverse effects are associated with medications for adults with alcohol-use disorders in outpatient settings?

KQ 3b: How do medications for adults with alcohol-use disorders compare for adverse effects in outpatient settings?

KQ 4: Are medications for treating adults with alcohol-use disorders effective in primary care settings?

KQ 5: Are any of the medications more or less effective than other medications for older adults, younger adults, smokers, or those with co-occurring disorders?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, and Setting)

• Population(s)

○ Adults (age 18 years or older) with alcohol-use disorders.

• Interventions

○ Pharmacotherapy for relapse prevention. This includes:

■ Medications approved by FDA for treating alcohol dependence:

- Acamprosate
- disulfiram
- naltrexone (oral or injectable)

■ Certain medications in use off label that are available in the United States:

- Baclofen
- gabapentin
- ondansetron

- topiramate
- prazosin
- varenicline

○ Studies evaluating pharmacotherapy that used co-interventions with other treatments for AUDs (e.g., behavioral counseling, cognitive behavioral therapy, motivational enhancement therapy, psychosocial treatments, or self-help such as 12-step programs [e.g., Alcoholics Anonymous]) will be eligible for inclusion, as long as they meet other inclusion/exclusion criteria.

○ This review will not include pharmacotherapy for alcohol withdrawal.

• Comparators

○ Studies must compare one of the medications listed above with placebo or another eligible medication.

• Outcomes

○ Consumption outcomes:

- Abstinence/any drinking
 - rates of continuous abstinence
 - percentage of days abstinent
 - time to first drink/lapse
 - time to heavy drinking/relapse
- reduction in alcohol consumption
 - number of heavy drinking days
 - percentage of subjects with no heavy drinking days
 - number of drinking days
 - drinks per drinking day
 - drinks per week

○ Health outcomes:

- Accidents
- injuries
- quality of life
- function
- mortality
 - Adverse effects of intervention(s):
- Withdrawals due to adverse events
- nausea/vomiting
- diarrhea
- anorexia
- alptitions
- headache
- dizziness
- cognitive dysfunction
- taste abnormalities
- paresthesias (numbness, tingling)
- metabolic acidosis
- glaucoma
- vision changes
- suicidal ideation
- insomnia
- anxiety
- rash
- tiredness
- weakness
- constipation

• Timing

○ Studies with at least 12 weeks of planned pharmacologic treatment and

followup from the time of medication initiation.

• Setting

○ Outpatient healthcare settings; KQ 4 applies to primary care settings only (i.e., internal medicine, family medicine, obstetrics/gynecology, or college and university health clinics).

Dated: May 12, 2022.

Marquita Cullom,

Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Plan for Foster Care and Adoption Assistance—Title IV–E (OMB #0970–0433)

AGENCY: Children's Bureau, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Children's Bureau (CB), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting a 3-year extension of the Plan for Foster Care and Adoption Assistance—Title IV–E, (OMB#: 0970–0433, expiration 11/30/2022). This plan also incorporates the plan requirements for the optional Guardianship Assistance program, the Title IV–E Prevention Services plan and the Title IV–E Kinship Navigator program. There are no changes requested to the form.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. You can also obtain copies of the proposed collection of information by emailing infocollection@acf.hhs.gov. Identify all emailed

requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: A title IV–E plan is required by section 471, part IV–E of the Social Security Act (the Act) for each public child welfare agency requesting federal funding for foster care, adoption assistance, and guardianship assistance under the Act. Section 479B of the Act provides for an Indian tribe, tribal organization, or tribal consortium (tribe) to operate a title IV–E program in the same manner as a state with minimal exceptions. The tribe must have an approved Title IV–E Plan. The Title IV–E Plan provides assurances the programs will be administered in conformity with the specific requirements stipulated in Title IV–E. The plan must include all applicable state or tribal statutory, regulatory, or policy references and citations for each requirement as well as supporting documentation. A title IV–E agency may use the pre-print format prepared by CB, or a different format, on the condition that the format used includes all of the Title IV–E Plan requirements.

Title IV–E of the Act was amended by Public Law 115–123, which included

the Family First Prevention Services Act (FFPSA). FFPSA authorized new optional Title IV–E funding for time-limited (1 year) prevention services for mental health/substance abuse and in-home parent skill-based programs for (1) a child who is a candidate for foster care (as defined in section 475(13) of the Act), (2) pregnant/parenting foster youth, and (3) the parents/kin caregivers of those children and youth (sections 471(e), 474(a)(6), and 475(13) of the Act). Title IV–E prevention services must be rated as promising, supported, or well supported in accordance with HHS criteria and be approved by HHS (section 471(e)(4)(C) of the Act) as part of the Title IV–E Prevention Services Clearinghouse (section 476(d)(2) of the Act). A state or tribal Title IV–E agency electing to participate in the program must submit a 5-year Title IV–E Prevention Program Plan that meets the statutory requirements. (See Program Instructions ACYF–CB–PI–18–09 and ACYF–CB–PI–18–10 for more information.)

FFPSA also amended section 474(a)(7) of the Act to reimburse state and tribal Title IV–E agencies for a portion of the costs of operating kinship

navigator programs that meet certain criteria. To qualify for funding under the Title IV–E Kinship Navigator Program, the program must meet the requirements of a kinship navigator program described in section 427(a)(1) of the Act. The Kinship Navigator Program must meet practice criteria of promising, supported, or well-supported in accordance with HHS criteria and be approved by HHS (section 471(e)(4)(C) of the Act). To begin participation in the Title IV–E Kinship Navigator Program, a Title IV–E agency must submit an attachment to its Title IV–E plan that specifies the kinship navigator model it has chosen to implement and the date on which the provision of program services began or will begin, and provide an assurance that the model meets the requirements of section 427(a)(1) of the Act, as well as a brief narrative describing how the program will be operated. (Please see Program Instruction ACYF–CB–PI–18–11 for additional information: <https://www.acf.hhs.gov/cb/policy-guidance/pi-18-11>.)

Respondents: State and tribal title IV–E agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Title IV–E Plan	17	1	16	272
Title IV–E prevention services plan	12	1	5	60
Attachment to Title IV–E plan for Kinship Navigator Program	15	1	1	15

Estimated Total Annual Burden Hours: 347.

Authority: Title IV–E of the Social Security Act as amended by Public Law 115–123 enacted February 9, 2018.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0001]

Science Board to the Food and Drug Administration Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Science Board to the Food and Drug Administration. The Science Board provides advice to the Commissioner of Food and Drugs and other appropriate officials on specific, complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice to the Agency on keeping pace with technical and scientific developments, including in regulatory science, input into the Agency’s research agenda, and on upgrading its scientific and research facilities and training opportunities. It will also provide, where requested, expert review of Agency-sponsored intramural and extramural scientific research programs. The meeting will be open to the public.

DATES: The meeting will be held virtually on June 14, 2022, from 9 a.m. to 4 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT: Rakesh Raghuvanshi, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3309, Silver Spring, MD 20993, 301–796–4769, Rakesh.Raghuvanshi@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute