

sales statistics, inventories, formulas, patterns devices, manufacturing processes, or customer names.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Solicitation for Nominations for Members of the U.S. Preventive Services Task Force (USPSTF)

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

ACTION: Solicits nominations for new members of the USPSTF.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) invites nominations of individuals qualified to serve as members of the U.S. Preventive Services Task Force (USPSTF).

DATES: Nominations must be received electronically by March 15th of a given year to be considered for appointment to begin in January of the following year.

ADDRESSES: Submit your responses electronically via: <https://uspstfnominations.ahrq.gov/register>.

FOR FURTHER INFORMATION CONTACT: Lydia Hill at (301) 427-1587.

SUPPLEMENTARY INFORMATION:

Arrangement for Public Inspection

Nominations and applications are kept on file at the Center for Evidence and Practice Improvement, AHRQ, and are available for review during business hours. AHRQ does not reply to individual nominations, but considers all nominations in making recommendation for appointment. Information regarded as private and personal, such as a nominee's social security number, home and email addresses, home telephone and fax numbers, or names of family members will not be disclosed to the public in accord with the Freedom of Information Act. 5 U.S.C. 552(b)(6); 45 CFR 5.31(f).

Nomination Submissions

Nominations must be submitted electronically, and should include:

1. The applicant's current curriculum vitae and contact information, including mailing address, and email address; and
2. A letter explaining how this individual meets the qualification requirements and how he or she would contribute to the USPSTF. The letter

should also attest to the nominee's willingness to serve as a member of the USPSTF.

AHRQ will later ask people under serious consideration for USPSTF membership to provide detailed information that will permit evaluation of possible significant conflicts of interest. Such information will concern matters such as financial holdings, consultancies, non-financial scientific interests, and research grants or contracts.

To obtain a diversity of perspectives, AHRQ particularly encourages nominations of women, members of underrepresented populations, and persons with disabilities. Interested individuals can nominate themselves. Organizations and individuals may nominate one or more people qualified for membership on the USPSTF at any time. Individuals nominated prior to March 15, 2023, who continue to have interest in serving on the USPSTF should be re-nominated.

Qualification Requirements

To qualify for the USPSTF and support its mission, an applicant or nominee should, at a minimum, demonstrate knowledge, expertise, and national leadership in the following areas:

1. The critical evaluation of research published in peer-reviewed literature and in the methods of evidence review;
2. Clinical prevention, health promotion and primary health care; and
3. Implementation of evidence-based recommendations in clinical practice including at the clinician-patient level, practice level, and health-system level.

Additionally, the Task Force benefits from members with expertise in the following areas:

- Public Health
- Health Equity and The Reduction of Health Disparities
- Application of Science to Health Policy
- Decision modeling
- Dissemination and Implementation
- Behavioral Medicine/Clinical Health Psychology
- Communication of Scientific Findings to Multiple Audiences Including Health Care Professionals, Policy Makers, and the General Public.

Candidates with experience and skills in any of these areas should highlight them in their nomination materials.

Applicants must have no substantial conflicts of interest, whether financial, professional, or intellectual, that would impair the scientific integrity of the work of the USPSTF and must be willing to complete regular conflict of interest disclosures.

Applicants must have the ability to work collaboratively with a team of diverse professionals who support the mission of the USPSTF. Applicants must have adequate time to contribute substantively to the work products of the USPSTF.

Nominee Selection

Nominated individuals will be selected for the USPSTF on the basis of how well they meet the required qualifications and the current expertise needs of the USPSTF. It is anticipated that new members will be invited to serve on the USPSTF beginning in January, 2025. All nominated individuals will be considered; however, strongest consideration will be given to individuals with demonstrated training and expertise in the areas of Internal Medicine, Family Medicine, and Obstetrics and Gynecology. AHRQ will retain and may consider for future vacancies nominations received this year and not selected during this cycle.

Some USPSTF members without primary health care clinical experience may be selected based on their expertise in methodological issues such as meta-analysis, analytic modeling, or clinical epidemiology. For individuals with clinical expertise in primary health care, additional qualifications in methodology would enhance their candidacy.

Background

Under title IX of the Public Health Service Act, AHRQ is charged with enhancing the quality, appropriateness, and effectiveness of health care services and access to such services. 42 U.S.C. 299(b). AHRQ accomplishes these goals through scientific research and promotion of improvements in clinical practice, including clinical prevention of diseases and other health conditions. See 42 U.S.C. 299(b).

The USPSTF, an independent body of experts in prevention and evidence-based medicine, works to improve the health of people nationwide by making evidence-based recommendations about the effectiveness of clinical preventive services and health promotion. The recommendations made by the USPSTF address clinical preventive services for adults and children, and include screening tests, counseling services, and preventive medications.

The USPSTF was first established in 1984 under the auspices of the U.S. Public Health Service. AHRQ provides ongoing scientific, administrative, and dissemination support for the USPSTF's operation. See 42 U.S.C. 299b-4(a)(3). Members are appointed by the Secretary of the U.S. Department of Health and

Human Services to serve four-year terms. New members are selected each year to replace those members who are completing their appointments.

The USPSTF rigorously evaluates the effectiveness of clinical preventive services and formulating or updating recommendations regarding the appropriate provision of preventive services. Current USPSTF recommendations and associated evidence reviews are available on the internet (www.uspreventiveservices.taskforce.org).

USPSTF members meet three times a year for two days in the Washington, DC area or virtually if necessary. A significant portion of the USPSTF's work occurs between meetings during conference calls and via email discussions. Member duties include prioritizing topics, designing research plans, reviewing and commenting on systematic evidence reviews, discussing evidence and making recommendations on preventive services, reviewing stakeholder comments, drafting final recommendation documents, and participating in workgroups on specific topics and methods. Members can expect to receive frequent emails, can expect to participate in multiple conference calls each month, and can expect to have periodic interaction with stakeholders. AHRQ estimates that members devote approximately 250 hours a year outside of in-person meetings to their USPSTF duties. The members are all volunteers and do not receive any compensation beyond support for travel to attend the thrice yearly meetings and trainings.

Dated: December 27, 2023.

Marquita Cullom,
Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-5653]

Food and Drug Administration's Draft Report and Plan on Best Practices for Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability, request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled "Food and Drug

Administration's Draft Report and Plan on Best Practices for Guidance." This draft report responds to the Consolidated Appropriations Act of 2023, which directs FDA to issue a report identifying best practices for the efficient prioritization, development, issuance, and use of guidance documents and a plan for implementation of such best practices. It also directs FDA to publish a draft report and plan no later than 1 year after enactment of the Consolidated Appropriations Act and to consult with stakeholders in developing the report and implementation plan.

DATES: Submit either electronic or written comments on the draft report and plan by March 4, 2024.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-N-5653 for "Draft Report and Plan on Best Practices for Guidance." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft report and plan.

FOR FURTHER INFORMATION CONTACT: Julie Finegan, Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4252, Silver Spring, MD 20993-0002, 301-827-4830.