

II. Additional Information on PDUFA

There are several sources of information on FDA's Web site that may be useful for interested stakeholders to better understand the history and evolution of the PDUFA program and its current status:

- Information on the April 2010 public meeting on PDUFA Reauthorization, the **Federal Register** notice announcing the meeting, and the transcript of the meeting are available at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm117890.htm>. The slide presentations from the meeting can be found at <http://www.regulations.gov> using Docket No. FDA-2010-N-0128.

- FDA created a webinar on the PDUFA program, drug development, and FDA's drug review in PDUFA IV. These presentations are available at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm207597.htm>.

- Key **Federal Register** documents, PDUFA-related guidances, legislation, performance reports, and financial reports and plans are posted at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm>.

- Specific information on the FDA Amendments Act of 2007 is available at: <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm>.

III. How To Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 3, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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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 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).

The USPSTF, a standing, independent panel of non-Federal experts that makes evidence-based recommendations to the health care community and the public regarding the provision of clinical preventive services, *see* 42 U.S.C. 299b-4(a), is composed of members appointed to serve for four-year terms with an option for a one-year or two-year extension. New members are selected each year to replace those members who are completing their appointments. Individuals nominated but not appointed in previous years, as well as those newly nominated, are considered in the annual selection process.

USPSTF members meet three times a year for two days in the Washington, DC area. Between meetings, member duties include reviewing and preparing comments (off site) on systematic evidence reviews prior to discussing and making recommendations on preventive services, drafting final recommendation documents, and participating in workgroups on specific topics or methods.

A diversity of perspectives is valuable to the work of the USPSTF. To help obtain a diversity of perspectives among nominees, AHRQ particularly encourages nominations of women, members of minority populations, and persons with disabilities. Interested individuals can self nominate. Organizations and individuals may nominate one or more persons qualified for membership on the USPSTF.

Qualification Requirements: The mission of the USPSTF is to review the scientific evidence related to the effectiveness and appropriateness of clinical preventive services for the purpose of developing recommendations for the health care community. Therefore, in order to qualify for the USPSTF, an applicant or nominee **MUST** demonstrate the following:

1. Knowledge and experience in the critical evaluation of research published in peer reviewed literature and in the methods of evidence review;

2. Understanding and experience in the application of synthesized evidence to clinical decisionmaking and/or policy;

3. Expertise in disease prevention and health promotion;

4. Ability to work collaboratively with peers; and,

5. Clinical expertise in the primary health care of children and/or adults, and/or expertise in counseling and behavioral interventions for primary care patients.

Some USPSTF members without primary health care clinical experience may be selected based on their expertise in methodological issues such as medical decisionmaking, clinical epidemiology, behavioral medicine, health equity, and health economics. For individuals with clinical expertise in primary health care, additional qualifications in one or more of these areas would enhance their candidacy.

Consideration will be given to individuals who are recognized nationally for scientific leadership within their field of expertise. Applicants must have no substantial conflicts of interest, whether financial, professional, or other conflicts, that would impair the scientific integrity of the work of the USPSTF.

DATES: Nominations are welcome at any time. To be considered for appointment in 2011, complete nominations must be received by November 29, 2010.

Nominated individuals will be selected for the USPSTF on the basis of their qualifications (in particular, those that address the required qualifications, outlined above) and the current expertise needs of the USPSTF. All individuals with complete nominations will be considered. AHRQ will retain and consider for future vacancies the nominations of those not selected during this cycle.

ADDRESSES: Submit your responses either in writing or electronically to: Gloria Washington, **ATTN:** USPSTF Nominations, Center for Primary Care, Prevention, and Clinical Partnerships, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850, USPSTFnominations@AHRQ.hhs.gov.

Nomination Submissions

Nominations may be submitted in writing or electronically, but must include:

- (1) The applicant's current curriculum vitae and contact information, including

mailing address, e-mail address, and telephone number and

(2) A letter explaining how this individual meets the qualification requirements and how he/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 persons under serious consideration for 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, and research grants or contracts.

Nominee Selection

Appointments to the USPSTF will be made on the basis of qualifications as outlined above (see Qualification Requirements) and the current expertise needs of the USPSTF.

Arrangement for Public Inspection

Nominations and applications are kept on file at the Center for Primary care, Prevention, and Clinical Partnerships, AHRQ and are available for review during business hours. AHRQ does not reply to individual nominations, but considers all nominations in selecting members. Information regarded as private and personal, such as a nominee's Social Security number, home and e-mail addresses, home telephone and fax numbers, or names of family members will not be disclosed to the public. This is in accord with AHRQ confidentiality policies and Department of Health and Human Services regulations (45 CFR 5.67).

FOR FURTHER INFORMATION CONTACT:
Gloria Washington at
USPSTFnominations@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

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, and improvements in the organization,

financing, and delivery of health care services. See 42 U.S.C. 299(b).

The USPSTF is a panel of non-Federal experts that makes independent evidence-based recommendations regarding the provision of clinical preventive services. See 42 U.S.C. 299b-4(a). The USPSTF was first established in 1984 under the auspices of the U.S. Public Health Service. Currently, the USPSTF is convened by the Director of AHRQ, and AHRQ provides ongoing administrative, research and technical support for the USPSTF's operation. The USPSTF is charged with rigorously evaluating the effectiveness and appropriateness of clinical preventive services and formulating or updating recommendations for primary care clinicians regarding the appropriate provision of preventive services. See 42 U.S.C. 299b-4(a)(1). Current USPSTF recommendations and associated evidence reviews are available on the Internet (<http://USPreventiveServicesTaskForce.org>).

Dated: November 1, 2010.

Carolyn M. Clancy,
AHRQ Director.

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DEPARTMENT OF HOMELAND SECURITY

United States Immigration and Customs Enforcement

Agency Information Collection Activities: Revision of an Existing Information Collection; Comment Request

ACTION: 60-Day Notice of Information Collection for Review; Student and Exchange Visitor Information System (SEVIS); OMB Control No. 1653-0038.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (ICE), will be submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until January 10, 2011.

Written comments and suggestions regarding items contained in this notice,

and especially with regard to the estimated public burden and associated response time should be directed to the Department of Homeland Security (DHS), Joseph M. Gerhart, Chief, Records Management Branch, U.S. Immigration and Customs Enforcement, 500 12th Street, SW., STOP 5705, Washington, DC 20536-5705.

Comments are encouraged and will be accepted for sixty days until January 10, 2011. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency's, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Revision of a currently approved information collection.

(2) *Title of the Form/Collection:* Student and Exchange Visitor Information System (SEVIS).

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Forms I-17 and I-20; U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Not-for-profit institutions and individuals or households.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*