

or benefits of any product are scientifically or clinically proven or about the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Provision IV is a provision for FDA-approved claims.

Provision V prohibits misrepresentations in connection with the marketing, advertising, or promoting of any product, service, or program that paid commercial advertising is independent programming.

Provision VI prohibits any representation about any user, consumer, or endorser of a covered product without disclosing, clearly and conspicuously, and in close proximity to that representation, any unexpected material connection between such endorser and (1) any respondent; or (2) any other individual or entity affiliated with the product. "Unexpected material connection" means any relationship that might materially affect the weight or credibility of the testimonial or endorsement and that would not reasonably be expected by consumers.

Provision VII prohibits misrepresentations regarding the status of any endorser or person providing a review of a product, including a misrepresentation that the endorser or reviewer is an independent or ordinary user of the product.

Provision VIII prohibits respondents from providing the means and instrumentalities to make any false or misleading statement of material fact, including the representations prohibited by Provisions I to III. "Means and instrumentalities" mean any information, document, or article referring or relating to any covered product, including any advertising, labeling, promotional, or purported substantiation materials, for use by a licensee to market or sell any covered product.

Provision IX, triggered when the human clinical testing requirement in Provisions I or II applies, requires that respondents secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, such as protocols, instructions, participant-specific data, statistical analyses, and contracts with the test's researchers. There is an exception for a reliably reported test (defined as a test that is published in a peer-reviewed journal) that was not conducted, controlled, or sponsored by, with, or on behalf of any respondent or by any supplier or manufacturer of the product. Also, the published report must provide sufficient information about the test for experts in the relevant

field to assess the reliability of the results.

Provision X mandates that respondents acknowledge receipt of the order, distribute the order to principals, officers, and certain employees and agents, and obtain signed acknowledgments from them.

Provision XI requires that respondents submit compliance reports to the FTC 60 days after the order's issuance and submit notifications when certain events occur for 10 years.

Provision XII requires that respondents create and retain certain records for 10 years.

Provision XIII provides for the FTC's continued compliance monitoring of respondents' activities during the order's effective dates.

Provision XIV requires that respondents notify their licensees, monitor their highest-selling licensees' advertising to ensure compliance with Provisions I through III, and suspend any licensee who makes any prohibited claims. Respondents must terminate any licensee who continues to make prohibited claims. There are two limited exceptions to the monitoring requirement: (1) Representations during private consultations between a licensee and one of the licensee's patients about the potential safety, health benefits, performance, efficacy, or side effects of a covered product; and (2) representations about the potential safety, health benefits, performance, efficacy, or side effects of a covered product by a licensee who has purchased a covered product solely for incorporation into the licensee's own product and markets that product without any involvement by respondents.

Provision XV requires that respondents send a notice to all customers who purchased directly from them TA-65MD or TA-65 Skin within one year prior to the issuance of the order or through a currently active enrollment in a continuity or autoshop program.

Provision XVI provides that, with exceptions, the order will terminate in 20 years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.

By direction of the Commission.

Donald S. Clark,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Request for Information Regarding Patient-Reported Outcome Measures

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

ACTION: Request for information.

SUMMARY: AHRQ is seeking information submissions from the public.

Information is being solicited to inform our work on patient-reported outcomes (PROs). Access to information regarding physical function PRO measure use will assist the selection of measures for AHRQ's efforts to develop and implement user-friendly technical tools to collect and integrate PRO data in electronic health records or other health information technology products.

DATES: Submission must be received by April 1, 2018.

ADDRESSES: Electronic responses are preferred and should be addressed to Janey.hsiao@ahrq.hhs.gov. Non-electronic responses will also be accepted. Please mail to: Janey Hsiao, Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, Mailstop: 06E73A.

FOR FURTHER INFORMATION CONTACT: Janey Hsiao, Health Scientist Administrator, Center for Evidence and Practice Improvement, Janey.hsiao@ahrq.hhs.gov, (301) 427-1335.

SUPPLEMENTARY INFORMATION: AHRQ plans to conduct a Challenge Competition in Fall 2018 to develop user-friendly technical tools to collect and integrate patient-reported outcome (PRO) data in electronic health records or other health information technology products. The technical tools will be intended for use in ambulatory care settings including primary care and specialty care. For this competition, AHRQ will choose a physical function PRO measure as a use case for the tool development. More information about the Challenge Competition is available at <https://www.gpo.gov/fdsys/pkg/FR-2017-12-26/pdf/2017-27663.pdf>. AHRQ will also conduct another project to pilot test whether the specified standards used in the Challenge Competition can be adapted for data collection utilizing other PRO measures or domains. AHRQ is interested in learning what physical function PRO measures are being used, and about experiences with these measures in clinical practice. We are also interested in methods used to collect these PROs, including computer adaptive testing

(CAT). The information will inform AHRQ's decision in selecting physical function PRO measures for the Challenge Competition and the subsequent pilot test.

Your contribution will be very beneficial to AHRQ's PRO projects. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

This RFI is for planning purposes only and should not be construed as a policy, solicitation for applications, or as an obligation on the part of the Government to provide support for any ideas identified in response to it. AHRQ will use the information submitted in response to this RFI at its discretion and will not provide comments to any responder's submission. However, responses to the RFI may be reflected in future solicitation(s) or policies. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s). The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or able to be made public.

Submission Instructions

Specific questions of interest to AHRQ include, but are not limited to:

1. What *physical function* PRO measures does your health system/practice currently use to collect PRO data? Which PRO measures in use do you find most useful with respect to clinical management, quality improvement, population health, or for other uses?

2. What is the type of care setting (primary care or specialty care) within which these physical function PRO data are collected? Are similar measures used in other settings (e.g., acute care, post-acute care, rehabilitation, home care, long term care)?

3. How are the PRO data collected? Is the PRO data collection via paper or an electronic mechanism? Please specify the electronic mechanism (e.g., patient portal, tablet) and whether the electronic mechanism is internal or external to an electronic health records system. Is CAT used? What is the typical workflow for collecting PRO data?

4. How are the PRO data used (e.g., patient assessment, shared decision

making, quality improvement, research?) What has been your experience with the use of these measures?

AHRQ is interested in all of the questions listed above, but respondents are welcome to address as many or as few as they choose and to address additional areas of interest not listed. Submission of copies of existing documentation or reports describing the measure and its properties, existing data sources, etc., is highly desirable but not required.

Gopal Khanna,

Director.

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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: All nominations submitted in writing or electronically will be considered for appointment to the USPSTF. Nominations must be received by May 15th of a given year to be considered for appointment to begin in January 2019.

Nomination Submissions

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

1. The applicant's current curriculum vitae and contact information, including mailing address, email address, and telephone number; 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 could

include 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 minority 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 May 15, 2017, 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
- Behavioral medicine
- 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.

ADDRESSES: Submit your responses either in writing or electronically to: Lydia Hill, ATTN: USPSTF Nominations, Center for Evidence and Practice Improvement, Agency for