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(Original Signature of Member)

112TH CONGRESS
2D SESSION

H. R. _____

To amend title IX of the Public Health Service Act to revise the operations of the United States Preventive Services Task Force.

IN THE HOUSE OF REPRESENTATIVES

Mrs. BLACKBURN (for herself and Mr. BARROW) introduced the following bill; which was referred to the Committee on _____

A BILL

To amend title IX of the Public Health Service Act to revise the operations of the United States Preventive Services Task Force.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''USPSTF Transparency and Accountability Act of 2012''.

SEC. 2. CHANGES TO UNITED STATES PREVENTIVE SERVICES TASK FORCE.

(a) IN GENERAL.—Subsection (a) of section 915 of the Public Health Service Act (42 U.S.C. 299b–4) is amended—

(1) by amending the heading to read as follows: ''UNITED STATES PREVENTIVE SERVICES TASK FORCE'';

(2) by amending paragraph (1) to read as follows:

''(1) ESTABLISHMENT AND PURPOSE.—The Director may establish and periodically convene the United States Preventive Services Task Force (in this section referred to as the 'Task Force'). The Task Force shall review the scientific evidence related to the effectiveness and appropriateness of clinical preventive services for the purpose of developing recommendations for primary care clinicians and the health care community and updating previous clinical preventive recommendations.'';

(3) by redesignating paragraph (3) as paragraph (5) and paragraphs (4) through (7) as paragraphs (9) through (12), respectively;

(4) by inserting after paragraph (2) the following new paragraphs:

''(3) COMPOSITION.—

''(A) IN GENERAL.—The Task Force shall be composed of individuals that collectively have appropriate scientific expertise, including in fields of health sciences research, health economics, and clinical care. The Task Force shall include balanced representation of practicing primary and specialty care providers, patient and health care consumers, and relevant stakeholders from the medical products manufacturing community.

''(B) NOTICE.—Before appointing members to the Task Force, the Director shall give persons an opportunity to nominate potential members. The Director shall provide for the publication in the Federal Register of a request for comments on such members and shall provide a mechanism for persons to submit such comments through the official website of the Agency. The Director shall consider any comments submitted in selecting the members of the Task Force.

''(C) DISCLOSURE OF CONFLICTS OF INTEREST.—The Director shall disclose conflicts of interest (including personal as well as financial conflicts of interest) of any member of the

Task Force that have the potential to bias (or may be perceived as biasing) individual decisions of the Task Force.

''(4) REVIEW AND CONSULTATION.—

''(A) RESEARCH PLANS.—

''(i) IN GENERAL.—In conducting its reviews under paragraph (1), the Task Force, with the concurrence of the Director, shall publish one or more proposed research plans (in this subsection referred to as a 'research plan') to guide the Task Force's systematic review of the evidence. Each such plan shall include an analytic framework, key questions, and a literature search strategy or research approach, and shall incorporate the methodological guidelines developed under clause (ii). The Agency shall provide for the publication in the Federal Register of a request for public comments on each plan and shall accept comments during a period of at least 60 days. Any final research plan shall be made available to the public and include a discussion of the comments received and responses to such comments. The Task

Force, with the concurrence of the Director, may change such a research plan through the same process as applied to the initial adoption of such plan.

''(ii) CRITERIA.—The Director shall design and regularly update guidelines for proper methodological standards for incorporation into such research plans. Such guidelines shall include measures for appropriate validity, for risk adjustment, for timeliness, for input from relevant experts and peers in the respective communities, for accounting for all relevant subpopulations (including disparities by race, ethnicity, and socioeconomic status), and for other health outcome measurements.

''(iii) CONSULTATION ON RESEARCH PLANS.—The Director shall facilitate coordination and interaction with other agencies and departments in the creation of research plans (taking into consideration research and findings by other agencies and departments) and methodological standards under clause (ii), including with the National Institutes of Health, the National

Cancer Institute, the National Institute on Minority Health and Health Disparities, the Centers for Disease Control and Prevention, the Department of Defense, the Department of Veterans Affairs, the Centers for Medicare & Medicaid Services, and the Patient-Centered Outcomes Research Institute.

''(iv) CONSULTATION ON DRAFT RECOMMENDATIONS.—Before voting on a draft recommendation statement, the Task Force shall consult with relevant stakeholders, including provider groups, practicing specialists that treat the specific disease under review, and relevant patient and disease advocacy organizations.

''(B) EVIDENCE REPORTS.—The Director shall make publicly available each draft evidence report and publish in the Federal Register a request for public comments on such reports. No such evidence report shall be published prior to it being reviewed by a panel of external subject matter experts that includes provider and patient representatives. Each such report shall include a description of the panel

that conducted such review. Such description shall include information on each panel member, including name, academic degree (or degrees), affiliations, and related expertise.

''(C) RECOMMENDATION STATEMENTS.—

''(i) PUBLICATION OF DRAFT RECOMMENDATIONS.—The Director shall make publicly available each draft recommendation and shall provide for the publication in the Federal Register of a request for comments and accept comments during a period of not less than 60 days.

''(ii) PUBLIC AVAILABILITY OF COMMENTS AND INCLUSION OF DESCRIPTION OF COMMENTS IN FINAL STATEMENT.—The Director shall make such comments received publicly available. Any final recommendation statement shall include a description of comments received on the draft recommendation statement and recommendations of other Federal agencies or organizations relating to the topic of the statement.

''(iii) CONSIDERATION.—In publishing recommendation statements, the Task

Force shall consider the impact of its recommendations on the health care community, whether a preventive service is beneficial for some individuals and the need to encourage a discussion of benefits and risks for those individuals, and how its specific assignment of a grade to a product or service may affect coverage and access to such product or service under Federal programs and private health insurance coverage.

''(D) GRADING SYSTEM.—In publishing recommendation statements, the Task Force shall grade products and services consistent with the following:

''(i) GRADE A.—The Task Force concludes that the current evidence is sufficient to assess the balance of benefits and risks of the product or service, and, on the basis of such evidence, recommends the product or service and determines that there is high certainty that the net benefit from the product or service is substantial.

''(ii) GRADE B.—The Task Force concludes that the current evidence is suffi-

cient to assess the balance of benefits and risks of the product or service, and, on the basis of such evidence, recommends the product or service and determines that there is high certainty that the net benefit of the product or service is moderate or there is moderate certainty that the net benefit of the product or service is moderate to substantial.

''(iii) GRADE C.—The Task Force concludes that the current evidence is sufficient to assess the balance of benefits and risks of the product or service, and, on the basis of such evidence, does not make a recommendation of the product or service and clinicians may provide this product or service to selected patients depending on individual circumstances. However, for most individuals without signs or symptoms there is likely to be only a small benefit from this product or service.

''(iv) GRADE D.—The Task Force concludes that the current evidence is sufficient to assess the balance of benefits and risks of the product or service, and, on the

basis of such evidence, recommends against the product or service and determines that there is moderate or high certainty that the product or service has no net benefit or that the harm of the product or service outweighs the benefits. Recommendations against a preventive service shall only be issued in concurrence with the Secretary after consultation with other Federal health agencies and relevant patient and provider groups.

''(v) GRADE I.—The Task Force concludes that the current evidence is not sufficient to assess the balance of benefits and risks of the product or service.'';

(5) in paragraph (5), as redesignated by paragraph (3)—

(A) by striking ''dissemination of the recommendations of the Task Force'' and inserting ''dissemination of its recommendation statements''; and

(B) by striking ''Guide's recommendations'' and inserting ''recommendations of the Task Force'';

(6) by inserting after paragraph (5), as so redesignated, the following new paragraphs:

''(6) PREVENTIVE SERVICES STAKEHOLDERS BOARD.—

''(A) IN GENERAL.—The Task Force shall convene a preventive services stakeholders board (in this subsection referred to as the 'board') composed of representatives of appropriate public and private entities with an interest in clinical preventive services to advise the Task Force on developing, updating, publishing, and disseminating evidence-based recommendations on the use of clinical preventive services.

''(B) MEMBERSHIP.—The members of the board shall include representatives of the following:

''(i) Patient groups.

''(ii) Providers of clinical preventive services, including community-based providers and specialty physicians.

''(iii) Federal departments and agencies, including—

''(I) appropriate health agencies and offices in the Department, including the National Institutes of Health,

the National Cancer Institute, the National Institute on Minority Health and Health Disparities, the Centers of Disease Control and Prevention, the Administration on Aging, the Health Resources and Services Administration, the Centers for Medicare & Medicaid Services, the Office of the Surgeon General of the Public Health Service, the Office of Minority Health, and the Office on Women's Health; and

''(II) as appropriate, other Federal departments and agencies the programs of which have a significant impact upon health, including the Congressionally Directed Medical Research Programs, Veterans Health Administration and others (as determined by the Secretary).

''(iv) Private health care payors.

''(C) RESPONSIBILITIES.—In accordance with subsection (b)(5), the board shall—

''(i) recommend clinical preventive services for review by the Task Force;

''(ii) suggest scientific evidence for consideration by the Task Force related to reviews undertaken by the Task Force;

''(iii) provide feedback regarding draft recommendations by the Task Force; and

''(iv) assist with efforts regarding dissemination of recommendations by the Director of the Agency for Healthcare Research and Quality.

''(7) DISCLOSURE AND CONFLICTS OF INTEREST.—Members of the Task Force or the board shall not be considered employees of the Federal Government by reason of service on the Task Force or the board, except members of the Task Force or the board shall be considered to be special Government employees within the meaning of section 107 of the Ethics in Government Act of 1978 (5 U.S.C. App.) and section 208 of title 18, United States Code, for the purposes of disclosure and management of conflicts of interest under those sections.

''(8) NO PAY; RECEIPT OF TRAVEL EXPENSES.—Members of the Task Force or the board shall not receive any pay for service on the Task Force or board, but may receive travel expenses, including a per diem, in accordance with applicable

provisions of subchapter I of chapter 57 of title 5, United States Code.''; and

(7) by amending paragraph (10), as redesignated by paragraph (3), to read as follows:

''(10) APPLICATION OF APA.—The Task Force shall conduct its activities in compliance with chapter 5 of title 5, United States Code (commonly known as the Administrative Procedures Act).''.

(b) EFFECTIVE DATE; TRANSITION.—

(1) IN GENERAL.—Except as otherwise provided, the amendments made by subsection (a) shall take effect on the date of the enactment of this Act. The United States Preventive Services Task Force shall not publish any draft or final recommendations on or after such date except in accordance with such amendments.

(2) RECONSTITUTION OF TASK FORCE.—Not later than 180 days after the date of the enactment of this Act, the Director of the Agency for Healthcare Research and Quality shall take steps to reconstitute the membership of the Task Force consistent with section 915(a)(3) of the Public Health Service Act, as amended by subsection (a).

(3) PREVIOUSLY PUBLISHED RECOMMENDATIONS.—With respect to recommendations or guide-

lines published by such Task Force before the date of the enactment of this Act, under procedures established by the Director of the Agency for Healthcare Research and Quality, the reconstituted Task Force shall undertake a review process consistent with the following:

(A) Interested parties may request the Task Force to review such previous recommendations or guidelines.

(B) Based upon such requests, the Task Force shall establish a process for the review of previous recommendations or guidelines.

(C) Such process shall include public notice through the Federal Register and opportunity for comment and a determination to confirm or modify such recommendations or guidelines.

(D) The process shall, to the extent feasible, be consistent with the procedures applied under the amendments made by subsection (a) for the promulgation of new recommendations.

(c) GAO EVALUATION AND REPORT.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report that contains the following:

(1) A listing of the recommendations of the United States Preventive Services Task Force as of the such date, including the date final recommendations and any subsequent updates were posted or published.

(2) A comparison of such recommendations and relevant recommendations of other Federal health agencies, including the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, the Department of Defense, the Department of Veterans Affairs, and the Patient-Centered Outcomes Research Institute, as well as relevant recommendations from national medical professional societies and relevant patient and disease advocacy organizations.

(3) An analysis of the impact of the recommendations of the Task Force on public and private insurance coverage, access, and outcomes, including impact on morbidity and mortality.

(d) ELIMINATION OF SECRETARIAL DISCRETION TO REMOVE CERTAIN PREVENTIVE SERVICES UNDER THE MEDICARE PROGRAM.—Section 1834(n) of the Social Security Act (42 U.S.C. 1395m(n)), as added by section 4105(a) of Public Law 111–148, is amended—

(1) by striking paragraph (2);

(2) by striking ''; and'' at the end of paragraph (1)(B) and inserting a period;

(3) by redesignating subparagraphs (A) and (B) of paragraph (1) as paragraphs (1) and (2), respectively, and moving their margins 2 ems to the left; and

(4) by striking ''may'' and all that follows through ''modify'' and inserting ''may modify''.