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[DISCUSSION DRAFT]

114TH 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, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mrs. BLACKBURN 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, and for other purposes.

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 2016''.

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 and new science 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, health promotion, disease prevention, and clinical care. The Task Force shall include balanced representation of practicing primary and specialty care providers (including in the fields of health services research, health economics, and clinical care), and patient and health care consumers.

''(B) NOTICE.—Before appointing members to the Task Force, the Director shall provide notice in the Federal Register to give persons an opportunity to nominate potential members.

''(4) REVIEW AND CONSULTATION.—

''(A) RESEARCH PLANS.—

''(i) IN GENERAL.—In conducting its reviews under paragraph (1), the Task Force, 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 [45 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, socioeconomic status, and geographic location), 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.

''(B) EVIDENCE REPORTS.—The Director shall make publicly available each draft evidence report and publish in the Federal Reg-

ister 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 [45 days].

''(ii) 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 dis-

ease under review, and relevant patient and disease advocacy organizations.

''(iii) 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.

''(iv) 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 pro-

grams and private health insurance coverage.

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

''(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 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 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.

''(v) GRADE I.—The Task Force concludes that the current evidence is not suf-

ficient to assess the balance of benefits and risks of the product or service.

''(E) CHANGES IN GRADING SYSTEM.—

''(i) IN GENERAL.—The Director may provide, by regulation, for changes in the grading system described in subparagraph (D).

''(ii) IMPACT OF CHANGES.—If the Director makes a change in the grading system under clause (i) for a particular grade, the Task Force shall review and regrade the services previously classified within that grade. Such review and regrade may be done through an expedited process but any such change in grade shall not take effect before such review process is completed.'';

(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 ADVISORY BOARD.—

''(A) IN GENERAL.—The Task Force shall convene a preventive services advisory 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 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 for 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 Department of Defense, the Department of Veterans Affairs, the Patient-Centered Outcomes Research Institute, 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.

"(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 the research plan, the evidence report, and 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.

"(D) MEETINGS.—The Preventive Services Advisory Board shall meet as the Chair of the Board determines to be appropriate to fulfill the responsibilities described in paragraph (C), but not fewer than 2 times each year.

"(7) DISCLOSURE AND CONFLICTS OF INTEREST.—Prior to participating in a meeting of the Task Force or board, each member of the Task Force or board, respectively, shall disclose to the Director any potential, relevant financial interests in the same manner and to the same extent as an employee of the executive branch of the United States,

if the employee were participating in such meeting, would be required to disclose such interests under section 208 of title 18, United States Code.

''(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 FACA.—The Task Force shall conduct its activities in compliance with the Federal Advisory Committee Act (5 U.S.C. App.).''.

(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 guidelines 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) An organization may request the Task Force to review such previous recommendations or guidelines if such organization has additional peer-reviewed scientific evidence that provides new information relevant to the previous recommendation or guideline.

(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 con-

firm 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)) 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''.

(e) APPLICATION TO 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)) is amended by adding at the end the following flush sentence: ''Effective on [the date of enactment of the USPSTF Transparency and Accountability Act of 2016], the Secretary may only use the authority under this subsection to modify or eliminate cov-

erage of a preventive service based on the recommendation or grade of the United States Preventive Services Task Force with respect to the service if such recommendation or grade was developed or updated in accordance with the amendments made by section 2(a) of such Act and if the Secretary [has concurred with] such recommendation or grade after consultation with [other Federal health agencies] and relevant patient and [provider] groups.''.

(f) APPLICATION TO PHYSICIAN QUALITY MEASURES UNDER THE MEDICARE PROGRAM.—Section 1848 of the Social Security Act (42 U.S.C. 1395w–4) is amended by adding at the end the following new subsection:

''(t) MEASURES RELATED TO USPSTF RECOMMENDATIONS.—Effective on [the date of enactment of the USPSTF Transparency and Accountability Act of 2016], notwithstanding any other provision of this title, a quality measure related to a recommendation of the United States Preventive Services Task Force may only be applied under this section if such recommendation was developed or updated in accordance with the amendments made by section 2(a) of such Act and if the Secretary [has concurred with] such recommendation or grade after consultation with [other Federal health agencies] and relevant patient and [provider] groups.''.