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116TH CONGRESS
1ST SESSION

H. R. 3534

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

JUNE 27, 2019

Mr. RUSH (for himself, Mr. DAVID P. ROE of Tennessee, Ms. JUDY CHU of California, and Mr. DUNN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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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 2019''.

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 striking paragraph (3);

(4) by redesignating paragraphs (4) through (7) as paragraphs (9) through (12), respectively;

(5) 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 a balanced representation of practicing primary and specialty care providers (including in the fields of health services research, health economics, and clinical care), patients, 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

referred to in such paragraph. 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 (iii).

''(ii) PUBLICATION; PUBLIC COMMENT PERIOD.—The Task Force shall provide for the publication in the Federal Register of a request for public comments on each research plan and shall accept comments on such plan during a period of not less than 45 days. The Director shall make publicly available comments submitted in response to a request for public comments. Any final research plan shall be made available to the public and include a discussion of the comments received with respect to such plan 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.

"(iii) 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 gender, race, ethnicity, socioeconomic status, and geographic location), and for other health outcome measurements. Such guidelines and methodological standards shall ensure the consideration of any evidence concerning any relevant subpopulations (including disparities by gender, race, ethnicity, genetic predisposition, socioeconomic status, and geographic location), any real world evidence, any recent evidence, and any United States-based studies.

"(iv) CONSULTATION ON RESEARCH PLANS.—The Director shall facilitate coordination and interaction with other agencies and departments in the preparation

and publication of research plans (taking into consideration research and findings by other agencies and departments) and methodological standards under clause (iii), 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.—

''(i) INITIAL PUBLICATION.—The Director shall make publicly available each systematic evidence review and any related reports that serve as the foundation for any recommendation of the Task Force and publish in the Federal Register a request for public comments on such review or related reports.

''(ii) PUBLIC COMMENT PERIOD.—The Director shall accept comments on any draft evidence report published under

clause (i) during a period of at least 45 days. The Director shall make publicly available comments submitted in response to a request for public comment. Each final evidence review shall include a description of comments submitted on the draft evidence review and the response of the Task Force to such comments.

''(iii) REVIEW BY EXTERNAL EXPERTS.—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 statement (as that term is used for purposes of section 7 of the U.S. Preven-

tive Services Task Force Procedure Manual, as in effect on April 1, 2019) 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 RECOMMENDATIONS.—Before voting on a draft or final recommendation statement (as that term is used for purposes of section 7 of the procedure manual referred to in clause (i)), the Task Force shall—

''(I) consult with relevant stakeholders, including provider groups, practicing specialists that treat the specific disease under review, and relevant patient and disease advocacy organizations; and

''(II) take into account the feedback provided by the board.

''(iii) PUBLIC AVAILABILITY OF COMMENTS AND INCLUSION OF DESCRIPTION OF COMMENTS IN FINAL STATEMENT.—The Director shall make comments received pursuant to clause (i) publicly avail-

able. 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. The Director shall make final recommendation statements publicly available, including through publication in the Federal Register.

''(iv) CONSIDERATION.—In publishing draft or final recommendation statements (as those terms are used for purposes of section 7 of the procedure manual referred to in clause (i)), the Task Force shall consider—

''(I) the impact of its recommendations on the health care community;

''(II) whether a preventive service is beneficial for some individuals and the need to encourage a discussion of benefits and risks for those individuals; and

''(III) 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.

"(v) DISSEMINATION OF EVIDENCE-BASED RECOMMENDATIONS.—The Task Force shall publish and disseminate the evidence-based recommendations after consultation with the following:

"(I) Relevant patient organizations.

"(II) Providers of clinical services, including community-based providers and specialty physicians.

"(III) The Department of Veterans Affairs, the Centers for Medicare & Medicaid Services, and the Centers for Disease Control and Prevention.

"(D) GRADING SYSTEM.—Subject to subparagraph (E), in publishing recommendation statements (as that term is used for purposes of section 7 of the procedure manual referred to in clause (i)), the Task Force shall grade products and services consistent with the following:

''(i) GRADE A.—The Task Force shall assign a product or service Grade A if 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 shall assign a product or service Grade B if 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 shall assign a product or service Grade C if the Task Force concludes that—

"(I) the current evidence is sufficient to assess the balance of benefits and risks of the product or service;

"(II) 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; and

"(III) for most individuals without signs or symptoms of a particular disease or condition there is at least moderate certainty that the net benefit is small.

"(iv) GRADE D.—The Task Force shall assign a product or service Grade D if 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 shall assign a product or service Grade I if the Task Force concludes that the current evidence is not sufficient 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 products or services previously classified within that grade. Any such review and regrading may be done through an expedited process so long as any change in grade does not take effect before the review of that change in grade is completed.

''(5) ROLE OF AGENCY.—The Agency shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of

its recommendation statements, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of the recommendations of the Task Force.

''(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 throughout the development of 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 that have expertise in the clinical preventive service being reviewed.

"(C) RESPONSIBILITIES.—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.

"(D) MEETINGS.—The 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 em-

ployee 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

(6) by amending paragraph (10), as redesignated by paragraph (4), to read as follows:

''(10) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the Task Force except that section 14 of such Act (relating to termination of advisory committees) shall not apply to the Task Force.''.

(b) EFFECTIVE DATE; TRANSITION.—

(1) IN GENERAL.—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 any such previous recommendation or guideline 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) 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''.

(d) 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)), as amended by subsection (c), is further amended by adding at the end the following flush sentence: ''Effective on the date of enact-

ment of the USPSTF Transparency and Accountability Act of 2019, the Secretary may use the authority under this subsection only to modify coverage 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.''.

(e) 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 2019, notwithstanding any other provision of this title, a quality measure related to a recommendation of the United States Preventive Services Task Force may be applied under this section only 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 con-

sultation with other Federal health agencies and relevant patient and provider groups.''.

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