

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “USPSTF Trans-
5 parency and Accountability Act of 2019”.

1 **SEC. 2. CHANGES TO UNITED STATES PREVENTIVE SERV-**
2 **ICES TASK FORCE.**

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

6 (1) by amending the heading to read as follows:

7 “UNITED STATES PREVENTIVE SERVICES TASK
8 FORCE”;

9 (2) by amending paragraph (1) to read as fol-
10 lows:

11 “(1) ESTABLISHMENT AND PURPOSE.—The Di-
12 rector may establish and periodically convene the
13 United States Preventive Services Task Force (in
14 this section referred to as the ‘Task Force’). The
15 Task Force shall review the scientific evidence and
16 new science related to the effectiveness and appro-
17 priateness of clinical preventive services for the pur-
18 pose of developing recommendations for primary
19 care clinicians and the health care community and
20 updating previous clinical preventive recommenda-
21 tions.”;

22 (3) by striking paragraph (3);

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

25 (5) by inserting after paragraph (2) the fol-
26 lowing new paragraphs:

1 “(3) COMPOSITION.—

2 “(A) IN GENERAL.—The Task Force shall
3 be composed of individuals that collectively have
4 appropriate scientific expertise, including in
5 fields of health sciences research, health eco-
6 nomics, health promotion, disease prevention,
7 and clinical care. The Task Force shall include
8 a balanced representation of practicing primary
9 and specialty care providers (including in the
10 fields of health services research, health eco-
11 nomics, and clinical care), patients, and health
12 care consumers.

13 “(B) NOTICE.—Before appointing mem-
14 bers to the Task Force, the Director shall pro-
15 vide notice in the Federal Register to give per-
16 sons an opportunity to nominate potential mem-
17 bers.

18 “(4) REVIEW AND CONSULTATION.—

19 “(A) RESEARCH PLANS.—

20 “(i) IN GENERAL.—In conducting its
21 reviews under paragraph (1), the Task
22 Force shall publish one or more proposed
23 research plans (in this subsection referred
24 to as a ‘research plan’) to guide the Task
25 Force’s systematic review of the evidence

1 referred to in such paragraph. Each such
2 plan shall include an analytic framework,
3 key questions, and a literature search
4 strategy or research approach, and shall
5 incorporate the methodological guidelines
6 developed under clause (iii).

7 “(ii) PUBLICATION; PUBLIC COMMENT
8 PERIOD.—The Task Force shall provide
9 for the publication in the Federal Register
10 of a request for public comments on each
11 research plan and shall accept comments
12 on such plan during a period of not less
13 than 45 days. The Director shall make
14 publicly available comments submitted in
15 response to a request for public comments.
16 Any final research plan shall be made
17 available to the public and include a dis-
18 cussion of the comments received with re-
19 spect to such plan and responses to such
20 comments. The Task Force, with the con-
21 currence of the Director, may change such
22 a research plan through the same process
23 as applied to the initial adoption of such
24 plan.

1 “(iii) CRITERIA.—The Director shall
2 design and regularly update guidelines for
3 proper methodological standards for incor-
4 poration into such research plans. Such
5 guidelines shall include measures for ap-
6 propriate validity, for risk adjustment, for
7 timeliness, for input from relevant experts
8 and peers in the respective communities,
9 for accounting for all relevant subpopula-
10 tions (including disparities by gender, race,
11 ethnicity, socioeconomic status, and geo-
12 graphic location), and for other health out-
13 come measurements. Such guidelines and
14 methodological standards shall ensure the
15 consideration of any evidence concerning
16 any relevant subpopulations (including dis-
17 parities by gender, race, ethnicity, genetic
18 predisposition, socioeconomic status, and
19 geographic location), any real world evi-
20 dence, any recent evidence, and any United
21 States-based studies.

22 “(iv) CONSULTATION ON RESEARCH
23 PLANS.—The Director shall facilitate co-
24 ordination and interaction with other agen-
25 cies and departments in the preparation

1 and publication of research plans (taking
2 into consideration research and findings by
3 other agencies and departments) and
4 methodological standards under clause
5 (iii), including with the National Institutes
6 of Health, the National Cancer Institute,
7 the National Institute on Minority Health
8 and Health Disparities, the Centers for
9 Disease Control and Prevention, the De-
10 partment of Defense, the Department of
11 Veterans Affairs, the Centers for Medicare
12 & Medicaid Services, and the Patient-Cen-
13 tered Outcomes Research Institute.

14 “(B) EVIDENCE REPORTS.—

15 “(i) INITIAL PUBLICATION.—The Di-
16 rector shall make publicly available each
17 systematic evidence review and any related
18 reports that serve as the foundation for
19 any recommendation of the Task Force
20 and publish in the Federal Register a re-
21 quest for public comments on such review
22 or related reports.

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

1 clause (i) during a period of at least 45
2 days. The Director shall make publicly
3 available comments submitted in response
4 to a request for public comment. Each
5 final evidence review shall include a de-
6 scription of comments submitted on the
7 draft evidence review and the response of
8 the Task Force to such comments.

9 “(iii) REVIEW BY EXTERNAL EX-
10 PERTS.—No such evidence report shall be
11 published prior to it being reviewed by a
12 panel of external subject matter experts
13 that includes provider and patient rep-
14 resentatives. Each such report shall in-
15 clude a description of the panel that con-
16 ducted such review. Such description shall
17 include information on each panel member,
18 including name, academic degree (or de-
19 grees), affiliations, and related expertise.

20 “(C) RECOMMENDATION STATEMENTS.—

21 “(i) PUBLICATION OF DRAFT REC-
22 OMMENDATIONS.—The Director shall make
23 publicly available each draft recommenda-
24 tion statement (as that term is used for
25 purposes of section 7 of the U.S. Preven-

1 tive Services Task Force Procedure Man-
2 ual, as in effect on April 1, 2019) and
3 shall provide for the publication in the
4 Federal Register of a request for com-
5 ments and accept comments during a pe-
6 riod of not less than 45 days.

7 “(ii) CONSULTATION ON REC-
8 COMMENDATIONS.—Before voting on a draft
9 or final recommendation statement (as
10 that term is used for purposes of section 7
11 of the procedure manual referred to in
12 clause (i)), the Task Force shall—

13 “(I) consult with relevant stake-
14 holders, including provider groups,
15 practicing specialists that treat the
16 specific disease under review, and rel-
17 evant patient and disease advocacy or-
18 ganizations; and

19 “(II) take into account the feed-
20 back provided by the board.

21 “(iii) PUBLIC AVAILABILITY OF COM-
22 MENTS AND INCLUSION OF DESCRIPTION
23 OF COMMENTS IN FINAL STATEMENT.—
24 The Director shall make comments re-
25 ceived pursuant to clause (i) publicly avail-

1 able. Any final recommendation statement
2 shall include a description of comments re-
3 ceived on the draft recommendation state-
4 ment and recommendations of other Fed-
5 eral agencies or organizations relating to
6 the topic of the statement. The Director
7 shall make final recommendation state-
8 ments publicly available, including through
9 publication in the Federal Register.

10 “(iv) CONSIDERATION.—In publishing
11 draft or final recommendation statements
12 (as those terms are used for purposes of
13 section 7 of the procedure manual referred
14 to in clause (i)), the Task Force shall con-
15 sider—

16 “(I) the impact of its rec-
17 ommendations on the health care
18 community;

19 “(II) whether a preventive service
20 is beneficial for some individuals and
21 the need to encourage a discussion of
22 benefits and risks for those individ-
23 uals; and

24 “(III) how its specific assignment
25 of a grade to a product or service may

1 affect coverage and access to such
2 product or service under Federal pro-
3 grams and private health insurance
4 coverage.

5 “(v) DISSEMINATION OF EVIDENCE-
6 BASED RECOMMENDATIONS.—The Task
7 Force shall publish and disseminate the
8 evidence-based recommendations after con-
9 sultation with the following:

10 “(I) Relevant patient organiza-
11 tions.

12 “(II) Providers of clinical serv-
13 ices, including community-based pro-
14 viders and specialty physicians.

15 “(III) The Department of Vet-
16 erans Affairs, the Centers for Medi-
17 care & Medicaid Services, and the
18 Centers for Disease Control and Pre-
19 vention.

20 “(D) GRADING SYSTEM.—Subject to sub-
21 paragraph (E), in publishing recommendation
22 statements (as that term is used for purposes
23 of section 7 of the procedure manual referred to
24 in clause (i)), the Task Force shall grade prod-
25 ucts and services consistent with the following:

1 “(i) GRADE A.—The Task Force shall
2 assign a product or service Grade A if the
3 Task Force concludes that the current evi-
4 dence is sufficient to assess the balance of
5 benefits and risks of the product or service,
6 and, on the basis of such evidence, rec-
7 ommends the product or service and deter-
8 mines that there is high certainty that the
9 net benefit from the product or service is
10 substantial.

11 “(ii) GRADE B.—The Task Force
12 shall assign a product or service Grade B
13 if the Task Force concludes that the cur-
14 rent evidence is sufficient to assess the bal-
15 ance of benefits and risks of the product or
16 service, and, on the basis of such evidence,
17 recommends the product or service and de-
18 termines that there is high certainty that
19 the net benefit of the product or service is
20 moderate or there is moderate certainty
21 that the net benefit of the product or serv-
22 ice is moderate to substantial.

23 “(iii) GRADE C.—The Task Force
24 shall assign a product or service Grade C
25 if the Task Force concludes that—

1 “(I) the current evidence is suffi-
2 cient to assess the balance of benefits
3 and risks of the product or service;

4 “(II) on the basis of such evi-
5 dence, does not make a recommenda-
6 tion of the product or service and cli-
7 nicians may provide this product or
8 service to selected patients depending
9 on individual circumstances; and

10 “(III) for most individuals with-
11 out signs or symptoms of a particular
12 disease or condition there is at least
13 moderate certainty that the net ben-
14 efit is small.

15 “(iv) GRADE D.—The Task Force
16 shall assign a product or service Grade D
17 if the Task Force concludes that the cur-
18 rent evidence is sufficient to assess the bal-
19 ance of benefits and risks of the product or
20 service, and, on the basis of such evidence,
21 recommends against the product or service
22 and determines that there is moderate or
23 high certainty that the product or service
24 has no net benefit or that the harm of the
25 product or service outweighs the benefits.

1 “(v) GRADE I.—The Task Force shall
2 assign a product or service Grade I if the
3 Task Force concludes that the current evi-
4 dence is not sufficient to assess the bal-
5 ance of benefits and risks of the product or
6 service.

7 “(E) CHANGES IN GRADING SYSTEM.—

8 “(i) IN GENERAL.—The Director may
9 provide, by regulation, for changes in the
10 grading system described in subparagraph
11 (D).

12 “(ii) IMPACT OF CHANGES.—If the
13 Director makes a change in the grading
14 system under clause (i) for a particular
15 grade, the Task Force shall review and re-
16 grade the products or services previously
17 classified within that grade. Any such re-
18 view and regrading may be done through
19 an expedited process so long as any change
20 in grade does not take effect before the re-
21 view of that change in grade is completed.

22 “(5) ROLE OF AGENCY.—The Agency shall pro-
23 vide ongoing administrative, research, and technical
24 support for the operations of the Task Force, includ-
25 ing coordinating and supporting the dissemination of

1 its recommendation statements, ensuring adequate
2 staff resources, and assistance to those organizations
3 requesting it for implementation of the recommenda-
4 tions of the Task Force.

5 “(6) PREVENTIVE SERVICES ADVISORY
6 BOARD.—

7 “(A) IN GENERAL.—The Task Force shall
8 convene a preventive services advisory board (in
9 this subsection referred to as the ‘board’) com-
10 posed of representatives of appropriate public
11 and private entities with an interest in clinical
12 preventive services to advise the Task Force
13 throughout the development of evidence-based
14 recommendations on the use of clinical preven-
15 tive services.

16 “(B) MEMBERSHIP.—The members of the
17 board shall include representatives of the fol-
18 lowing:

19 “(i) Patient groups.

20 “(ii) Providers of clinical services, in-
21 cluding community-based providers and
22 specialty physicians.

23 “(iii) Federal departments and agen-
24 cies that have expertise in the clinical pre-
25 ventive service being reviewed.

1 “(C) RESPONSIBILITIES.—The board
2 shall—

3 “(i) recommend clinical preventive
4 services for review by the Task Force;

5 “(ii) suggest scientific evidence for
6 consideration by the Task Force related to
7 reviews undertaken by the Task Force;

8 “(iii) provide feedback regarding the
9 research plan, the evidence report, and
10 draft recommendations by the Task Force;
11 and

12 “(iv) assist with efforts regarding dis-
13 semination of recommendations by the Di-
14 rector.

15 “(D) MEETINGS.—The board shall meet as
16 the chair of the board determines to be appro-
17 priate to fulfill the responsibilities described in
18 paragraph (C), but not fewer than 2 times each
19 year.

20 “(7) DISCLOSURE AND CONFLICTS OF INTER-
21 EST.—Prior to participating in a meeting of the
22 Task Force or board, each member of the Task
23 Force or board, respectively, shall disclose to the Di-
24 rector any potential, relevant financial interests in
25 the same manner and to the same extent as an em-

1 ployee of the executive branch of the United States,
2 if the employee were participating in such meeting,
3 would be required to disclose such interests under
4 section 208 of title 18, United States Code.

5 “(8) NO PAY; RECEIPT OF TRAVEL EX-
6 PENSES.—Members of the Task Force or the board
7 shall not receive any pay for service on the Task
8 Force or board, but may receive travel expenses, in-
9 cluding a per diem, in accordance with applicable
10 provisions of subchapter I of chapter 57 of title 5,
11 United States Code.”; and

12 (6) by amending paragraph (10), as redesign-
13 nated by paragraph (4), to read as follows:

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

19 (b) EFFECTIVE DATE; TRANSITION.—

20 (1) IN GENERAL.—The United States Preven-
21 tive Services Task Force shall not publish any draft
22 or final recommendations on or after such date ex-
23 cept in accordance with such amendments.

24 (2) RECONSTITUTION OF TASK FORCE.—Not
25 later than 180 days after the date of the enactment

1 of this Act, the Director of the Agency for
2 Healthcare Research and Quality shall take steps to
3 reconstitute the membership of the Task Force con-
4 sistent with section 915(a)(3) of the Public Health
5 Service Act, as amended by subsection (a).

6 (3) PREVIOUSLY PUBLISHED RECOMMENDA-
7 TIONS.—With respect to recommendations or guide-
8 lines published by such Task Force before the date
9 of the enactment of this Act, under procedures es-
10 tablished by the Director of the Agency for
11 Healthcare Research and Quality, the reconstituted
12 Task Force shall undertake a review process con-
13 sistent with the following:

14 (A) An organization may request the Task
15 Force to review any such previous recommenda-
16 tion or guideline if such organization has addi-
17 tional peer-reviewed scientific evidence that pro-
18 vides new information relevant to the previous
19 recommendation or guideline.

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

23 (C) Such process shall include public no-
24 tice through the Federal Register and oppor-
25 tunity for comment and a determination to con-

1 firm or modify such recommendations or guide-
 2 lines.

3 (D) The process shall, to the extent fea-
 4 sible, be consistent with the procedures applied
 5 under the amendments made by subsection (a)
 6 for the promulgation of new recommendations.

7 (c) ELIMINATION OF SECRETARIAL DISCRETION TO
 8 REMOVE CERTAIN PREVENTIVE SERVICES UNDER THE
 9 MEDICARE PROGRAM.—Section 1834(n) of the Social Se-
 10 curity Act (42 U.S.C. 1395m(n)) is amended—

11 (1) by striking paragraph (2);

12 (2) by striking “; and” at the end of paragraph
 13 (1)(B) and inserting a period;

14 (3) by redesignating subparagraphs (A) and
 15 (B) of paragraph (1) as paragraphs (1) and (2), re-
 16 spectively, and moving their margins 2 ems to the
 17 left; and

18 (4) by striking “may” and all that follows
 19 through “modify” and inserting “may modify”.

20 (d) APPLICATION TO SECRETARIAL DISCRETION TO
 21 REMOVE CERTAIN PREVENTIVE SERVICES UNDER THE
 22 MEDICARE PROGRAM.—Section 1834(n) of the Social Se-
 23 curity Act (42 U.S.C. 1395m(n)), as amended by sub-
 24 section (c), is further amended by adding at the end the
 25 following flush sentence: “Effective on the date of enact-

1 ment of the USPSTF Transparency and Accountability
2 Act of 2019, the Secretary may use the authority under
3 this subsection only to modify coverage of a preventive
4 service based on the recommendation or grade of the
5 United States Preventive Services Task Force with respect
6 to the service if such recommendation or grade was devel-
7 oped or updated in accordance with the amendments made
8 by section 2(a) of such Act and if the Secretary has con-
9 curred with such recommendation or grade after consulta-
10 tion with other Federal health agencies and relevant pa-
11 tient and provider groups.”.

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

16 “(t) MEASURES RELATED TO USPSTF REC-
17 OMMENDATIONS.—Effective on the date of enactment of
18 the USPSTF Transparency and Accountability Act of
19 2019, notwithstanding any other provision of this title, a
20 quality measure related to a recommendation of the
21 United States Preventive Services Task Force may be ap-
22 plied under this section only if such recommendation was
23 developed or updated in accordance with the amendments
24 made by section 2(a) of such Act and if the Secretary has
25 concurred with such recommendation or grade after con-

- 1 sultation with other Federal health agencies and relevant
- 2 patient and provider groups.”.

