

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.

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## 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.

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 Transparency 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 recomme-  
21          dations.”;

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.

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 employee 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.”.

○