

**[DISCUSSION DRAFT]**114<sup>TH</sup> CONGRESS  
2<sup>D</sup> 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.

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**IN THE HOUSE OF REPRESENTATIVES**

Mrs. BLACKBURN introduced the following bill; which was referred to the Committee on \_\_\_\_\_

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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 Trans-  
5 parency and Accountability Act of 2016”.

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 redesignating paragraph (3) as para-  
23 graph (5) and paragraphs (4) through (7) as para-  
24 graphs (9) through (12), respectively;

25 (4) 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 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), and patient and  
12 health 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 Each such plan shall include an analytic  
2 framework, key questions, and a literature  
3 search strategy or research approach, and  
4 shall incorporate the methodological guide-  
5 lines developed under clause (ii). The  
6 Agency shall provide for the publication in  
7 the Federal Register of a request for pub-  
8 lic comments on each plan and shall accept  
9 comments during a period of at least [45  
10 days]. Any final research plan shall be  
11 made available to the public and include a  
12 discussion of the comments received and  
13 responses to such comments. The Task  
14 Force, with the concurrence of the Direc-  
15 tor, may change such a research plan  
16 through the same process as applied to the  
17 initial adoption of such plan.

18 “(ii) CRITERIA.—The Director shall  
19 design and regularly update guidelines for  
20 proper methodological standards for incor-  
21 poration into such research plans. Such  
22 guidelines shall include measures for ap-  
23 propriate validity, for risk adjustment, for  
24 timeliness, for input from relevant experts  
25 and peers in the respective communities,

1 for accounting for all relevant subpopula-  
2 tions (including disparities by race, eth-  
3 nicity, socioeconomic status, and geo-  
4 graphic location), and for other health out-  
5 come measurements.

6 “(iii) CONSULTATION ON RESEARCH  
7 PLANS.—The Director shall facilitate co-  
8 ordination and interaction with other agen-  
9 cies and departments in the creation of re-  
10 search plans (taking into consideration re-  
11 search and findings by other agencies and  
12 departments) and methodological stand-  
13 ards under clause (ii), including with the  
14 National Institutes of Health, the National  
15 Cancer Institute, the National Institute on  
16 Minority Health and Health Disparities,  
17 the Centers for Disease Control and Pre-  
18 vention, the Department of Defense, the  
19 Department of Veterans Affairs, the Cen-  
20 ters for Medicare & Medicaid Services, and  
21 the Patient-Centered Outcomes Research  
22 Institute.

23 “(B) EVIDENCE REPORTS.—The Director  
24 shall make publicly available each draft evi-  
25 dence report and publish in the Federal Reg-

1           ister a request for public comments on such re-  
2           ports. No such evidence report shall be pub-  
3           lished prior to it being reviewed by a panel of  
4           external subject matter experts that includes  
5           provider and patient representatives. Each such  
6           report shall include a description of the panel  
7           that conducted such review. Such description  
8           shall include information on each panel mem-  
9           ber, including name, academic degree (or de-  
10          grees), affiliations, and related expertise.

11                   “(C) RECOMMENDATION STATEMENTS.—

12                           “(i) PUBLICATION OF DRAFT REC-  
13                           COMMENDATIONS.—The Director shall make  
14                           publicly available each draft recommenda-  
15                           tion and shall provide for the publication  
16                           in the Federal Register of a request for  
17                           comments and accept comments during a  
18                           period of not less than **[45 days]**.

19                           “(ii) CONSULTATION ON DRAFT REC-  
20                           COMMENDATIONS.—Before voting on a draft  
21                           recommendation statement, the Task  
22                           Force shall consult with relevant stake-  
23                           holders, including provider groups, prac-  
24                           ticing specialists that treat the specific dis-

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

3 “(iii) PUBLIC AVAILABILITY OF COM-  
4 MENTS AND INCLUSION OF DESCRIPTION  
5 OF COMMENTS IN FINAL STATEMENT.—  
6 The Director shall make such comments  
7 received publicly available. Any final rec-  
8 ommendation statement shall include a de-  
9 scription of comments received on the draft  
10 recommendation statement and rec-  
11 ommendations of other Federal agencies or  
12 organizations relating to the topic of the  
13 statement.

14 “(iv) CONSIDERATION.—In publishing  
15 recommendation statements, the Task  
16 Force shall consider the impact of its rec-  
17 ommendations on the health care commu-  
18 nity, whether a preventive service is bene-  
19 ficial for some individuals and the need to  
20 encourage a discussion of benefits and  
21 risks for those individuals, and how its spe-  
22 cific assignment of a grade to a product or  
23 service may affect coverage and access to  
24 such product or service under Federal pro-

1           grams and private health insurance cov-  
2           erage.

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

7                   “(i) GRADE A.—The Task Force con-  
8                   cludes that the current evidence is suffi-  
9                   cient to assess the balance of benefits and  
10                  risks of the product or service, and, on the  
11                  basis of such evidence, recommends the  
12                  product or service and determines that  
13                  there is high certainty that the net benefit  
14                  from the product or service is substantial.

15                  “(ii) GRADE B.—The Task Force con-  
16                  cludes that the current evidence is suffi-  
17                  cient to assess the balance of benefits and  
18                  risks of the product or service, and, on the  
19                  basis of such evidence, recommends the  
20                  product or service and determines that  
21                  there is high certainty that the net benefit  
22                  of the product or service is moderate or  
23                  there is moderate certainty that the net  
24                  benefit of the product or service is mod-  
25                  erate to substantial.

1           “(iii) GRADE C.—The Task Force  
2 concludes that the current evidence is suf-  
3 ficient to assess the balance of benefits and  
4 risks of the product or service, and, on the  
5 basis of such evidence, does not make a  
6 recommendation of the product or service  
7 and clinicians may provide this product or  
8 service to selected patients depending on  
9 individual circumstances. However, for  
10 most individuals without signs or symp-  
11 toms there is likely to be only a small ben-  
12 efit from this product or service.

13           “(iv) GRADE D.—The Task Force  
14 concludes that the current evidence is suf-  
15 ficient to assess the balance of benefits and  
16 risks of the product or service, and, on the  
17 basis of such evidence, recommends  
18 against the product or service and deter-  
19 mines that there is moderate or high cer-  
20 tainty that the product or service has no  
21 net benefit or that the harm of the product  
22 or service outweighs the benefits.

23           “(v) GRADE I.—The Task Force con-  
24 cludes that the current evidence is not suf-

1           efficient to assess the balance of benefits and  
2           risks of the product or service.

3           “(E) CHANGES IN GRADING SYSTEM.—

4                   “(i) IN GENERAL.—The Director may  
5           provide, by regulation, for changes in the  
6           grading system described in subparagraph  
7           (D).

8                   “(ii) IMPACT OF CHANGES.—If the  
9           Director makes a change in the grading  
10          system under clause (i) for a particular  
11          grade, the Task Force shall review and re-  
12          grade the services previously classified  
13          within that grade. Such review and regrade  
14          may be done through an expedited process  
15          but any such change in grade shall not  
16          take effect before such review process is  
17          completed.”;

18           (5) in paragraph (5), as redesignated by para-  
19          graph (3)—

20                   (A) by striking “dissemination of the rec-  
21          ommendations of the Task Force” and inserting  
22          “dissemination of its recommendation state-  
23          ments”; and

1 (B) by striking “Guide’s recommenda-  
2 tions” and inserting “recommendations of the  
3 Task Force”;

4 (6) by inserting after paragraph (5), as so re-  
5 designated, the following new paragraphs:

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

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

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

20 “(i) Patient groups.

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

24 “(iii) Federal departments and agen-  
25 cies, including—

1           “(I) appropriate health agencies  
2           and offices in the Department, includ-  
3           ing the National Institutes of Health,  
4           the National Cancer Institute, the Na-  
5           tional Institute on Minority Health  
6           and Health Disparities, the Centers  
7           for Disease Control and Prevention,  
8           the Administration on Aging, the  
9           Health Resources and Services Ad-  
10          ministration, the Centers for Medicare  
11          & Medicaid Services, the Office of the  
12          Surgeon General of the Public Health  
13          Service, the Department of Defense,  
14          the Department of Veterans Affairs,  
15          the Patient-Centered Outcomes Re-  
16          search Institute, the Office of Minor-  
17          ity Health, and the Office on Wom-  
18          en’s Health; and

19                   “(II) as appropriate, other Fed-  
20                   eral departments and agencies the  
21                   programs of which have a significant  
22                   impact upon health.

23                   “(iv) Private health care payors.

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

1 “(i) recommend clinical preventive  
2 services for review by the Task Force;

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

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

10 “(iv) assist with efforts regarding dis-  
11 semination of recommendations by the Di-  
12 rector of the Agency for Healthcare Re-  
13 search and Quality.

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

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

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

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

11 (7) by amending paragraph (10), as redesign-  
12 nated by paragraph (3), to read as follows:

13 “(10) APPLICATION OF FACCA.—The Task Force  
14 shall conduct its activities in compliance with the  
15 Federal Advisory Committee Act (5 U.S.C. App.).”.

16 (b) EFFECTIVE DATE; TRANSITION.—

17 (1) IN GENERAL.—Except as otherwise pro-  
18 vided, the amendments made by subsection (a) shall  
19 take effect on **the date of the enactment of this**  
20 **Act**. The United States Preventive Services Task  
21 Force shall not publish any draft or final rec-  
22 ommendations on or after such date except in ac-  
23 cordance 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 such previous recommendations  
16 or guidelines if such organization has additional  
17 peer-reviewed scientific evidence that provides  
18 new information relevant to the previous rec-  
19 ommendation 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) GAO EVALUATION AND REPORT.—Not later than  
8 **[1 year after the date of enactment of this Act]**, the  
9 Comptroller General of the United States shall submit to  
10 Congress a report that contains the following:

11 (1) A listing of the recommendations of the  
12 United States Preventive Services Task Force as of  
13 the such date, including the date final recommenda-  
14 tions and any subsequent updates were posted or  
15 published.

16 (2) A comparison of such recommendations and  
17 relevant recommendations of other Federal health  
18 agencies, including the Centers for Disease Control  
19 and Prevention, the Centers for Medicare & Med-  
20 icaid Services, the Department of Defense, the De-  
21 partment of Veterans Affairs, and the Patient-Cen-  
22 tered Outcomes Research Institute, as well as rel-  
23 evant recommendations from national medical pro-  
24 fessional societies and relevant patient and disease  
25 advocacy organizations.

1           (3) An analysis of the impact of the rec-  
2           ommendations of the Task Force on public and pri-  
3           vate insurance coverage, access, and outcomes, in-  
4           cluding impact on morbidity and mortality.

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

9           (1) by striking paragraph (2);

10           (2) by striking “; and” at the end of paragraph

11           (1)(B) and inserting a period;

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

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

18           (e) APPLICATION TO SECRETARIAL DISCRETION TO  
19 REMOVE CERTAIN PREVENTIVE SERVICES UNDER THE  
20 MEDICARE PROGRAM.—Section 1834(n) of the Social Se-  
21 curity Act (42 U.S.C. 1395m(n)) is amended by adding  
22 at the end the following flush sentence: “Effective on [the  
23 date of enactment of the USPSTF Transparency and Ac-  
24 countability Act of 2016], the Secretary may only use the  
25 authority under this subsection to modify or eliminate cov-

1 erage of a preventive service based on the recommendation  
2 or grade of the United States Preventive Services Task  
3 Force with respect to the service if such recommendation  
4 or grade was developed or updated in accordance with the  
5 amendments made by section 2(a) of such Act and if the  
6 Secretary [has concurred with] such recommendation or  
7 grade after consultation with [other Federal health agen-  
8 cies] and relevant patient and [provider] groups.”.

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

13 “(t) MEASURES RELATED TO USPSTF REC-  
14 OMMENDATIONS.—Effective on [the date of enactment of  
15 the USPSTF Transparency and Accountability Act of  
16 2016], notwithstanding any other provision of this title,  
17 a quality measure related to a recommendation of the  
18 United States Preventive Services Task Force may only  
19 be applied under this section if such recommendation was  
20 developed or updated in accordance with the amendments  
21 made by section 2(a) of such Act and if the Secretary [has  
22 concurred with] such recommendation or grade after con-  
23 sultation with [other Federal health agencies] and rel-  
24 evant patient and [provider] groups.”.