

113TH CONGRESS
1ST SESSION

H. R. 2143

To amend title IX of the Public Health Service Act to revise the operations of the United States Preventive Services Task Force.

IN THE HOUSE OF REPRESENTATIVES

MAY 23, 2013

Mrs. BLACKBURN (for herself, Mr. BARROW of Georgia, Mr. TERRY, and Mrs. CHRISTENSEN) 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.

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 2013”.

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, patient and health
10 care consumers, and relevant stakeholders from
11 the medical products manufacturing commu-
12 nity.

13 “(B) NOTICE.—Before appointing mem-
14 bers to the Task Force, the Director shall give
15 persons an opportunity to nominate potential
16 members. The Director shall provide for the
17 publication in the Federal Register of a request
18 for comments on such members and shall pro-
19 vide a mechanism for persons to submit such
20 comments through the official website of the
21 Agency. The Director shall consider any com-
22 ments submitted in selecting the members of
23 the Task Force.

24 “(4) REVIEW AND CONSULTATION.—

25 “(A) RESEARCH PLANS.—

1 “(i) IN GENERAL.—In conducting its
2 reviews under paragraph (1), the Task
3 Force, with the concurrence of the Direc-
4 tor, shall publish one or more proposed re-
5 search plans (in this subsection referred to
6 as a ‘research plan’) to guide the Task
7 Force’s systematic review of the evidence.
8 Each such plan shall include an analytic
9 framework, key questions, and a literature
10 search strategy or research approach, and
11 shall incorporate the methodological guide-
12 lines developed under clause (ii). The
13 Agency shall provide for the publication in
14 the Federal Register of a request for pub-
15 lic comments on each plan and shall accept
16 comments during a period of at least 60
17 days. Any final research plan shall be
18 made available to the public and include a
19 discussion of the comments received and
20 responses to such comments. The Task
21 Force, with the concurrence of the Direc-
22 tor, may change such a research plan
23 through the same process as applied to the
24 initial adoption of such plan.

1 “(ii) 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 race, eth-
11 nicity, socioeconomic status, and geo-
12 graphic location), and for other health out-
13 come measurements.

14 “(iii) CONSULTATION ON RESEARCH
15 PLANS.—The Director shall facilitate co-
16 ordination and interaction with other agen-
17 cies and departments in the creation of re-
18 search plans (taking into consideration re-
19 search and findings by other agencies and
20 departments) and methodological stand-
21 ards under clause (ii), including with the
22 National Institutes of Health, the National
23 Cancer Institute, the National Institute on
24 Minority Health and Health Disparities,
25 the Centers for Disease Control and Pre-

1 vention, the Department of Defense, the
2 Department of Veterans Affairs, the Cen-
3 ters for Medicare & Medicaid Services, and
4 the Patient-Centered Outcomes Research
5 Institute.

6 “(B) EVIDENCE REPORTS.—The Director
7 shall make publicly available each draft evi-
8 dence report and publish in the Federal Reg-
9 ister a request for public comments on such re-
10 ports. No such evidence report shall be pub-
11 lished prior to it being reviewed by a panel of
12 external subject matter experts that includes
13 provider and patient representatives. Each such
14 report shall include a description of the panel
15 that conducted such review. Such description
16 shall include information on each panel mem-
17 ber, including name, academic degree (or de-
18 grees), affiliations, and related expertise.

19 “(C) RECOMMENDATION STATEMENTS.—

20 “(i) PUBLICATION OF DRAFT REC-
21 COMMENDATIONS.—The Director shall make
22 publicly available each draft recommenda-
23 tion and shall provide for the publication
24 in the Federal Register of a request for

1 comments and accept comments during a
2 period of not less than 60 days.

3 “(ii) CONSULTATION ON DRAFT REC-
4 COMMENDATIONS.—Before voting on a draft
5 recommendation statement, the Task
6 Force shall consult with relevant stake-
7 holders, including provider groups, prac-
8 ticing specialists that treat the specific dis-
9 ease under review, and relevant patient
10 and disease advocacy organizations.

11 “(iii) PUBLIC AVAILABILITY OF COM-
12 MENTS AND INCLUSION OF DESCRIPTION
13 OF COMMENTS IN FINAL STATEMENT.—
14 The Director shall make such comments
15 received publicly available. Any final rec-
16 ommendation statement shall include a de-
17 scription of comments received on the draft
18 recommendation statement and rec-
19 ommendations of other Federal agencies or
20 organizations relating to the topic of the
21 statement.

22 “(iv) CONSIDERATION.—In publishing
23 recommendation statements, the Task
24 Force shall consider the impact of its rec-
25 ommendations on the health care commu-

1 nity, whether a preventive service is bene-
2 ficial for some individuals and the need to
3 encourage a discussion of benefits and
4 risks for those individuals, and how its spe-
5 cific assignment of a grade to a product or
6 service may affect coverage and access to
7 such product or service under Federal pro-
8 grams and private health insurance cov-
9 erage.

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

14 “(i) GRADE A.—The Task Force con-
15 cludes that the current evidence is suffi-
16 cient to assess the balance of benefits and
17 risks of the product or service, and, on the
18 basis of such evidence, recommends the
19 product or service and determines that
20 there is high certainty that the net benefit
21 from the product or service is substantial.

22 “(ii) GRADE B.—The Task Force con-
23 cludes that the current evidence is suffi-
24 cient to assess the balance of benefits and
25 risks of the product or service, and, on the

1 basis of such evidence, recommends the
2 product or service and determines that
3 there is high certainty that the net benefit
4 of the product or service is moderate or
5 there is moderate certainty that the net
6 benefit of the product or service is mod-
7 erate to substantial.

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

20 “(iv) GRADE D.—The Task Force
21 concludes that the current evidence is suf-
22 ficient to assess the balance of benefits and
23 risks of the product or service, and, on the
24 basis of such evidence, recommends
25 against the product or service and deter-

1 mines that there is moderate or high cer-
2 tainty that the product or service has no
3 net benefit or that the harm of the product
4 or service outweighs the benefits. Rec-
5 ommendations against a preventive service
6 shall only be issued in concurrence with
7 the Secretary after consultation with other
8 Federal health agencies and relevant pa-
9 tient and provider groups.

10 “(v) GRADE I.—The Task Force con-
11 cludes that the current evidence is not suf-
12 ficient to assess the balance of benefits and
13 risks of the product or service.

14 “(E) CHANGES IN GRADING SYSTEM.—

15 “(i) IN GENERAL.—The Director may
16 provide, by regulation, for changes in the
17 grading system described in subparagraph
18 (D).

19 “(ii) IMPACT OF CHANGES.—If the
20 Director makes a change in the grading
21 system under clause (i) for a particular
22 grade, the Task Force shall review and re-
23 grade the services previously classified
24 within that grade. Such review and regrade
25 may be done through an expedited process

1 but any such change in grade shall not
2 take effect before such review process is
3 completed.”;

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

6 (A) by striking “dissemination of the rec-
7 ommendations of the Task Force” and inserting
8 “dissemination of its recommendation state-
9 ments”; and

10 (B) by striking “Guide’s recommenda-
11 tions” and inserting “recommendations of the
12 Task Force”;

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

15 “(6) PREVENTIVE SERVICES ADVISORY
16 BOARD.—

17 “(A) IN GENERAL.—The Task Force shall
18 convene a preventive services advisory board (in
19 this subsection referred to as the ‘board’) com-
20 posed of representatives of appropriate public
21 and private entities with an interest in clinical
22 preventive services to advise the Task Force on
23 developing, updating, publishing, and dissemi-
24 nating evidence-based recommendations on the
25 use of clinical preventive services.

1 “(B) MEMBERSHIP.—The members of the
2 board shall include representatives of the fol-
3 lowing:

4 “(i) Patient groups.

5 “(ii) Providers of clinical services, in-
6 cluding community-based providers and
7 specialty physicians.

8 “(iii) Federal departments and agen-
9 cies, including—

10 “(I) appropriate health agencies
11 and offices in the Department, includ-
12 ing the National Institutes of Health,
13 the National Cancer Institute, the Na-
14 tional Institute on Minority Health
15 and Health Disparities, the Centers
16 for Disease Control and Prevention,
17 the Administration on Aging, the
18 Health Resources and Services Ad-
19 ministration, the Centers for Medicare
20 & Medicaid Services, the Office of the
21 Surgeon General of the Public Health
22 Service, the Department of Defense,
23 the Department of Veterans Affairs,
24 the Patient-Centered Outcomes Re-
25 search Institute, the Office of Minor-

1 ity Health, and the Office on Wom-
2 en’s Health; and

3 “(II) as appropriate, other Fed-
4 eral departments and agencies the
5 programs of which have a significant
6 impact upon health.

7 “(iv) Private health care payors.

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

10 “(i) recommend clinical preventive
11 services for review by the Task Force;

12 “(ii) suggest scientific evidence for
13 consideration by the Task Force related to
14 reviews undertaken by the Task Force;

15 “(iii) provide feedback regarding the
16 research plan, the evidence report, and
17 draft recommendations by the Task Force;
18 and

19 “(iv) assist with efforts regarding dis-
20 semination of recommendations by the Di-
21 rector of the Agency for Healthcare Re-
22 search and Quality.

23 “(7) DISCLOSURE AND CONFLICTS OF INTER-
24 EST.—Members of the Task Force or the board shall
25 not be considered employees of the Federal Govern-

1 ment by reason of service on the Task Force or the
2 board, except members of the Task Force or the
3 board shall be considered to be special Government
4 employees within the meaning of section 107 of the
5 Ethics in Government Act of 1978 (5 U.S.C. App.)
6 and section 208 of title 18, United States Code, for
7 the purposes of disclosure and management of con-
8 flicts of interest under those sections.

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

16 (7) by amending paragraph (10), as redesignig-
17 nated by paragraph (3), to read as follows:

18 “(10) APPLICATION OF FACA.—The Task Force
19 shall conduct its activities in compliance with the
20 Federal Advisory Committee Act (5 U.S.C. App.).”.

21 (b) EFFECTIVE DATE; TRANSITION.—

22 (1) IN GENERAL.—Except as otherwise pro-
23 vided, the amendments made by subsection (a) shall
24 take effect on the date of the enactment of this Act.

25 The United States Preventive Services Task Force

1 shall not publish any draft or final recommendations
2 on or after such date except in accordance with such
3 amendments.

4 (2) RECONSTITUTION OF TASK FORCE.—Not
5 later than 180 days after the date of the enactment
6 of this Act, the Director of the Agency for
7 Healthcare Research and Quality shall take steps to
8 reconstitute the membership of the Task Force con-
9 sistent with section 915(a)(3) of the Public Health
10 Service Act, as amended by subsection (a).

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

19 (A) Interested parties may request the
20 Task Force to review such previous rec-
21 ommendations or guidelines.

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

1 (C) Such process shall include public no-
2 tice through the Federal Register and oppor-
3 tunity for comment and a determination to con-
4 firm or modify such recommendations or guide-
5 lines.

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

10 (c) GAO EVALUATION AND REPORT.—Not later than
11 1 year after the date of enactment of this Act, the Comp-
12 troller General of the United States shall submit to Con-
13 gress a report that contains the following:

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

19 (2) A comparison of such recommendations and
20 relevant recommendations of other Federal health
21 agencies, including the Centers for Disease Control
22 and Prevention, the Centers for Medicare & Med-
23 icaid Services, the Department of Defense, the De-
24 partment of Veterans Affairs, and the Patient-Cen-
25 tered Outcomes Research Institute, as well as rel-

1 evant recommendations from national medical pro-
2 fessional societies and relevant patient and disease
3 advocacy organizations.

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

8 (d) ELIMINATION OF SECRETARIAL DISCRETION TO
9 REMOVE CERTAIN PREVENTIVE SERVICES UNDER THE
10 MEDICARE PROGRAM.—Section 1834(n) of the Social Se-
11 curity Act (42 U.S.C. 1395m(n)), as added by section
12 4105(a) of Public Law 111–148, is amended—

13 (1) by striking paragraph (2);

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

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

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

○