

112TH CONGRESS
2D SESSION

H. R. 5998

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

JUNE 21, 2012

Mrs. BLACKBURN (for herself, Mr. BARROW, Mrs. CHRISTENSEN, and Mr. TERRY) 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 2012”.

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 re-
16 lated to the effectiveness and appropriateness of
17 clinical preventive services for the purpose of devel-
18 oping recommendations for primary care clinicians
19 and the health care community and updating pre-
20 vious clinical preventive recommendations.”;

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

24 (4) by inserting after paragraph (2) the fol-
25 lowing new paragraphs:

26 “(3) COMPOSITION.—

1 “(A) IN GENERAL.—The Task Force shall
2 be composed of individuals that collectively have
3 appropriate scientific expertise, including in
4 fields of health sciences research, health eco-
5 nomics, and clinical care. The Task Force shall
6 include balanced representation of practicing
7 primary and specialty care providers, patient
8 and health care consumers, and relevant stake-
9 holders from the medical products manufac-
10 turing community.

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

22 “(C) DISCLOSURE OF CONFLICTS OF IN-
23 TEREST.—The Director shall disclose conflicts
24 of interest (including personal as well as finan-
25 cial conflicts of interest) of any member of the

Task Force that have the potential to bias (or may be perceived as biasing) individual decisions of the Task Force.

“(4) REVIEW AND CONSULTATION.—

“(A) RESEARCH PLANS.—

“(i) IN GENERAL.—In conducting its reviews under paragraph (1), the Task Force, with the concurrence of the Director, 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. 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 (ii). The Agency shall provide for the publication in the Federal Register of a request for public comments on each plan and shall accept comments during a period of at least 60 days. Any final research plan shall be made available to the public and include a discussion of the comments received and responses to such comments. The Task

1 Force, with the concurrence of the Direc-
2 tor, may change such a research plan
3 through the same process as applied to the
4 initial adoption of such plan.

5 “(ii) CRITERIA.—The Director shall
6 design and regularly update guidelines for
7 proper methodological standards for incor-
8 poration into such research plans. Such
9 guidelines shall include measures for ap-
10 propriate validity, for risk adjustment, for
11 timeliness, for input from relevant experts
12 and peers in the respective communities,
13 for accounting for all relevant subpopula-
14 tions (including disparities by race, eth-
15 nicity, and socioeconomic status), and for
16 other health outcome measurements.

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

1 Cancer Institute, the National Institute on
2 Minority Health and Health Disparities,
3 the Centers for Disease Control and Pre-
4 vention, the Department of Defense, the
5 Department of Veterans Affairs, the Cen-
6 ters for Medicare & Medicaid Services, and
7 the Patient-Centered Outcomes Research
8 Institute.

9 “(iv) CONSULTATION ON DRAFT REC-
10 OMMENDATIONS.—Before voting on a draft
11 recommendation statement, the Task
12 Force shall consult with relevant stake-
13 holders, including provider groups, prac-
14 ticing specialists that treat the specific dis-
15 ease under review, and relevant patient
16 and disease advocacy organizations.

17 “(B) EVIDENCE REPORTS.—The Director
18 shall make publicly available each draft evi-
19 dence report and publish in the Federal Reg-
20 ister a request for public comments on such re-
21 ports. No such evidence report shall be pub-
22 lished prior to it being reviewed by a panel of
23 external subject matter experts that includes
24 provider and patient representatives. Each such
25 report shall include a description of the panel

1 that conducted such review. Such description
2 shall include information on each panel mem-
3 ber, including name, academic degree (or de-
4 grees), affiliations, and related expertise.

5 “(C) RECOMMENDATION STATEMENTS.—

6 “(i) PUBLICATION OF DRAFT REC-
7 OMMENDATIONS.—The Director shall make
8 publicly available each draft recommenda-
9 tion and shall provide for the publication
10 in the Federal Register of a request for
11 comments and accept comments during a
12 period of not less than 60 days.

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

24 “(iii) CONSIDERATION.—In publishing
25 recommendation statements, the Task

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

12 “(D) GRADING SYSTEM.—In publishing
13 recommendation statements, the Task Force
14 shall grade products and services consistent
15 with the following:

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

24 “(ii) GRADE B.—The Task Force con-
25 cludes that the current evidence is suffi-

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

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

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

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

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

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

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

22 (B) by striking “Guide’s recommenda-
23 tions” and inserting “recommendations of the
24 Task Force”;

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

3 “(6) PREVENTIVE SERVICES STAKEHOLDERS
4 BOARD.—

5 “(A) IN GENERAL.—The Task Force shall
6 convene a preventive services stakeholders
7 board (in this subsection referred to as the
8 ‘board’) composed of representatives of appro-
9 priate public and private entities with an inter-
10 est in clinical preventive services to advise the
11 Task Force on developing, updating, publishing,
12 and disseminating evidence-based recommenda-
13 tions on the use of clinical preventive services.

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

17 “(i) Patient groups.

18 “(ii) Providers of clinical preventive
19 services, including community-based pro-
20 viders and specialty physicians.

21 “(iii) Federal departments and agen-
22 cies, including—

23 “(I) appropriate health agencies
24 and offices in the Department, includ-
25 ing the National Institutes of Health,

1 the National Cancer Institute, the Na-
2 tional Institute on Minority Health
3 and Health Disparities, the Centers of
4 Disease Control and Prevention, the
5 Administration on Aging, the Health
6 Resources and Services Administra-
7 tion, the Centers for Medicare & Med-
8 icaid Services, the Office of the Sur-
9 geon General of the Public Health
10 Service, the Office of Minority Health,
11 and the Office on Women’s Health;
12 and

13 “(II) as appropriate, other Fed-
14 eral departments and agencies the
15 programs of which have a significant
16 impact upon health, including the
17 Congressionally Directed Medical Re-
18 search Programs, Veterans Health
19 Administration and others (as deter-
20 mined by the Secretary).

21 “(iv) Private health care payors.

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

24 “(i) recommend clinical preventive
25 services for review by the Task Force;

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

4 “(iii) provide feedback regarding draft
5 recommendations by the Task Force; and

6 “(iv) assist with efforts regarding dis-
7 semination of recommendations by the Di-
8 rector of the Agency for Healthcare Re-
9 search and Quality.

10 “(7) DISCLOSURE AND CONFLICTS OF INTER-
11 EST.—Members of the Task Force or the board shall
12 not be considered employees of the Federal Govern-
13 ment by reason of service on the Task Force or the
14 board, except members of the Task Force or the
15 board shall be considered to be special Government
16 employees within the meaning of section 107 of the
17 Ethics in Government Act of 1978 (5 U.S.C. App.)
18 and section 208 of title 18, United States Code, for
19 the purposes of disclosure and management of con-
20 flicts of interest under those sections.

21 “(8) NO PAY; RECEIPT OF TRAVEL EX-
22 PENSES.—Members of the Task Force or the board
23 shall not receive any pay for service on the Task
24 Force or board, but may receive travel expenses, in-
25 cluding a per diem, in accordance with applicable

1 provisions of subchapter I of chapter 57 of title 5,
2 United States Code.”; and

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

5 “(10) APPLICATION OF APA.—The Task Force
6 shall conduct its activities in compliance with chap-
7 ter 5 of title 5, United States Code (commonly
8 known as the Administrative Procedures Act).”.

9 (b) EFFECTIVE DATE; TRANSITION.—

10 (1) IN GENERAL.—Except as otherwise pro-
11 vided, the amendments made by subsection (a) shall
12 take effect on the date of the enactment of this Act.
13 The United States Preventive Services Task Force
14 shall not publish any draft or final recommendations
15 on or after such date except in accordance with such
16 amendments.

17 (2) RECONSTITUTION OF TASK FORCE.—Not
18 later than 180 days after the date of the enactment
19 of this Act, the Director of the Agency for
20 Healthcare Research and Quality shall take steps to
21 reconstitute the membership of the Task Force con-
22 sistent with section 915(a)(3) of the Public Health
23 Service Act, as amended by subsection (a).

24 (3) PREVIOUSLY PUBLISHED RECOMMENDA-
25 TIONS.—With respect to recommendations or guide-

1 lines published by such Task Force before the date
2 of the enactment of this Act, under procedures es-
3 tablished by the Director of the Agency for
4 Healthcare Research and Quality, the reconstituted
5 Task Force shall undertake a review process con-
6 sistent with the following:

7 (A) Interested parties may request the
8 Task Force to review such previous rec-
9 ommendations or guidelines.

10 (B) Based upon such requests, the Task
11 Force shall establish a process for the review of
12 previous recommendations or guidelines.

13 (C) Such process shall include public no-
14 tice through the Federal Register and oppor-
15 tunity for comment and a determination to con-
16 firm or modify such recommendations or guide-
17 lines.

18 (D) The process shall, to the extent fea-
19 sible, be consistent with the procedures applied
20 under the amendments made by subsection (a)
21 for the promulgation of new recommendations.

22 (c) GAO EVALUATION AND REPORT.—Not later than
23 1 year after the date of enactment of this Act, the Comp-
24 troller General of the United States shall submit to Con-
25 gress a report that contains the following:

1 (1) A listing of the recommendations of the
2 United States Preventive Services Task Force as of
3 the such date, including the date final recommenda-
4 tions and any subsequent updates were posted or
5 published.

6 (2) A comparison of such recommendations and
7 relevant recommendations of other Federal health
8 agencies, including the Centers for Disease Control
9 and Prevention, the Centers for Medicare & Med-
10 icaid Services, the Department of Defense, the De-
11 partment of Veterans Affairs, and the Patient-Cen-
12 tered Outcomes Research Institute, as well as rel-
13 evant recommendations from national medical pro-
14 fessional societies and relevant patient and disease
15 advocacy organizations.

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

20 (d) ELIMINATION OF 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 added by section
24 4105(a) of Public Law 111–148, is amended—

25 (1) by striking paragraph (2);

- 1 (2) by striking “; and” at the end of paragraph
2 (1)(B) and inserting a period;
3 (3) by redesignating subparagraphs (A) and
4 (B) of paragraph (1) as paragraphs (1) and (2), re-
5 spectively, and moving their margins 2 ems to the
6 left; and
7 (4) by striking “may” and all that follows
8 through “modify” and inserting “may modify”.

○