

114TH CONGRESS
1ST SESSION

S. 1475

To provide for the creation of a safe harbor for defendants in medical malpractice actions who demonstrate adherence to clinical practice guidelines.

IN THE SENATE OF THE UNITED STATES

JUNE 2, 2015

Mr. BARRASSO (for himself and Mrs. CAPITO) introduced the following bill;
which was read twice and referred to the Committee on the Judiciary

A BILL

To provide for the creation of a safe harbor for defendants in medical malpractice actions who demonstrate adherence to clinical practice guidelines.

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 “Saving Lives, Saving
5 Costs Act”.

6 **SEC. 2. REQUIREMENTS FOR SELECTION OF CLINICAL**
7 **PRACTICE GUIDELINES.**

8 (a) SELECTION.—Not later than 6 months after the
9 date of enactment of this Act, eligible professional organi-
10 zations that have established, published, maintained, and

1 updated on a regular basis, clinical practice guidelines, in-
2 cluding when applicable, appropriate use criteria, that in-
3 corporate best practices, may submit such guidelines to
4 the Secretary. Not later than 6 months after the last day
5 for submitting such guidelines, the Secretary shall select
6 and designate one or more eligible professional organiza-
7 tions to provide and maintain such clinical practice guide-
8 lines on behalf of the Secretary. Not later than 6 months
9 after designating each such eligible professional organiza-
10 tion, the Secretary shall enter into an agreement with each
11 such eligible professional organization for maintenance,
12 publication, and updating of such clinical practice guide-
13 lines.

14 (b) MAINTENANCE.—

15 (1) PERIODIC REVIEW.—Not later than 5 years
16 after the Secretary enters into an agreement with
17 each eligible professional organization under sub-
18 section (a), and every 5 years thereafter, the Sec-
19 retary shall review the clinical practice guidelines of
20 such organization and shall, as necessary, enter into
21 agreements with additional eligible professional orga-
22 nizations, as appropriate, in accordance with sub-
23 section (a).

24 (2) UPDATE BY ELIGIBLE PROFESSIONAL ORGA-
25 NIZATION.—An eligible professional organization

1 that collaborated in the establishment of a clinical
2 practice guideline may submit amendments to that
3 clinical practice guideline at any time to the Sec-
4 retary for review by the Secretary.

5 (3) NOTIFICATION REQUIRED FOR CERTAIN UP-
6 DATES.—An amendment under paragraph (2) may
7 not add, materially change, or remove a guideline
8 from a set of guidelines, unless notification of such
9 update is made available to applicable eligible profes-
10 sionals.

11 **SEC. 3. DEVELOPMENT.**

12 (a) GUIDELINE STANDARDS.—The Secretary shall
13 ensure that, to the extent practicable, the development of
14 clinical practice guidelines are guided by the Standards
15 for Developing Trustworthy Clinical Practice Guidelines of
16 the Institute of Medicine and—

17 (1) are developed through a transparent process
18 that minimizes conflicts of interest;

19 (2) are developed by a knowledgeable, multi-
20 disciplinary panel of experts and representatives
21 from key affected groups;

22 (3) take into consideration important patient
23 subgroups and patient preferences, as appropriate;

24 (4) are based on a systematic review of the ex-
25 isting evidence;

1 (5) provide a clear explanation of the relation-
2 ship between care options and health outcomes;

3 (6) provide ratings of both the quality of evi-
4 dence and strength of recommendation;

5 (7) are reconsidered and revised when new evi-
6 dence emerges; and

7 (8) clearly identify any exceptions to the appli-
8 cation of the clinical practice guideline.

9 (b) REQUIRED DISCLOSURES FROM ELIGIBLE PRO-
10 FESSIONAL ORGANIZATIONS.—Any person who is affili-
11 ated with an eligible professional organization and who di-
12 rectly participated in the creation of a clinical practice
13 guideline shall disclose any conflicts of interest pertaining
14 to the development of the clinical practice guideline, in-
15 cluding any conflict of interest pertaining to any instru-
16 ment, medicine, drug, or any other substance, device, or
17 means included in the clinical practice guideline. Disclo-
18 sures to the Secretary by eligible professional organiza-
19 tions shall be made promptly, upon submission of the
20 guidelines, and during every review of the guidelines. Dis-
21 closures shall include the following:

22 (1) Scientific methodology and evidence that
23 supports clinical practice guidelines.

24 (2) Outside collaborators.

25 (3) Endorsements.

1 **SEC. 4. NO LIABILITY FOR GUIDELINE PRODUCERS.**

2 Neither an eligible professional organization nor the
3 participants in its guideline development and approval
4 process, may be held liable for any injury alleged to be
5 caused by adhering to a clinical practice guideline to which
6 they contributed.

7 **SEC. 5. INTERNET PUBLICATION OF GUIDELINES.**

8 The Secretary shall publish on the Internet through
9 the National Guideline Clearinghouse or other appropriate
10 sites or sources, all clinical practice guidelines, including
11 all data and methodology used in the development and se-
12 lection of the guidelines in compliance with data disclosure
13 standards in the Health Insurance Portability and Ac-
14 countability Act of 1996 (Public Law 104–191).

15 **SEC. 6. STATE FLEXIBILITY AND PROTECTION OF STATES’**
16 **RIGHTS.**

17 (a) **LIMITATION.**—This Act shall not preempt or su-
18 perse any State or Federal law that—

19 (1) imposes procedural or substantive protec-
20 tions for health care providers and health care orga-
21 nizations from liability, loss, or damages greater
22 than such protections provided by this title; or

23 (2) creates a cause of action related to the pro-
24 vision of health care goods or services.

25 (b) **STATE FLEXIBILITY.**—No provision of this Act
26 shall be construed to preempt any defense available to a

1 party in a health care liability action under any other pro-
 2 vision of State or Federal law.

3 **SEC. 7. FEDERAL CAUSE OF ACTION.**

4 (a) IN GENERAL.—Chapter 85 of title 28, United
 5 States Code, is amended by adding at the end the fol-
 6 lowing:

7 **“§ 1370. Health care liability claims**

8 “(a) DEFINITIONS.—In this section, the terms ‘appli-
 9 cable eligible professional’, ‘health care goods or services’,
 10 ‘health care liability action’, ‘health care liability claim’,
 11 ‘health care organization’, and ‘health care provider’ have
 12 the meaning given such terms in section 10 of the Saving
 13 Lives, Saving Costs Act.

14 “(b) JURISDICTION OF CLAIMS.—The district courts
 15 shall have original jurisdiction of a health care liability ac-
 16 tion against an applicable eligible professional, health care
 17 provider, or health care organization.

18 “(c) SUBSTANTIVE LAW.—The substantive law for
 19 decision in a health care liability action brought under
 20 subsection (b) shall be derived from the law, including
 21 choice of law principles, of the State in which the provision
 22 of, use of, or payment for (or the failure to provide, use,
 23 or pay for) health care goods or services giving rise to
 24 the health care liability claim occurred unless such law is
 25 inconsistent with or preempted by Federal law.”.

1 (b) TECHNICAL AND CONFORMING AMENDMENT.—
 2 The table of sections for chapter 85 of title 28, United
 3 States Code, is amended by adding at the end the fol-
 4 lowing:

“1370. Health care liability claims.”.

5 **SEC. 8. RIGHT OF REMOVAL.**

6 Section 1441 of title 28, United States Code, is
 7 amended by adding at the end the following:

8 “(g) CERTAIN ACTIONS AGAINST MEDICAL PROFES-
 9 SIONALS.—(1) A health care liability action brought in a
 10 State court against an applicable eligible professional,
 11 health care provider, or health care organization may be
 12 removed by any defendant or the defendants to the district
 13 court of the United States for the district and division em-
 14 bracing the place where such action is pending.

15 “(2) In this subsection, the terms ‘applicable eligible
 16 professional’, ‘health care liability action’, ‘health care or-
 17 ganization’, and ‘health care provider’ have the meaning
 18 given such terms in section 10 of the Saving Lives, Saving
 19 Costs Act.”.

20 **SEC. 9. MANDATORY REVIEW BY INDEPENDENT MEDICAL**
 21 **PANEL.**

22 (a) IN GENERAL.—If, in any health care liability ac-
 23 tion removed to Federal court pursuant to section 1441(g)
 24 of title 28, United States Code, against an applicable eligi-
 25 ble professional, health care provider, or health care orga-

1 nization, the applicable eligible professional, health care
2 provider, or health care organization alleges, in response
3 to a filing of the claimant, that the applicable eligible pro-
4 fessional, health care provider, or health care organization
5 adhered to an applicable clinical practice guideline in the
6 provision of health care goods or services to the claimant,
7 then the court shall suspend further proceedings on the
8 health care liability action prior to discovery proceedings,
9 until the completion of a review of the action by an inde-
10 pendent medical review panel.

11 (b) INDEPENDENT MEDICAL REVIEW PANEL.—

12 (1) COMPOSITION.—An independent medical re-
13 view panel under this section shall be composed of
14 3 members who are experts in the relevant field of
15 clinical practice, appointed in accordance with para-
16 graph (5).

17 (2) REQUIREMENTS FOR MEMBER ELIGI-
18 BILITY.—

19 (A) IN GENERAL.—To be eligible to serve
20 on an independent medical review panel, a
21 member shall—

22 (i) be an experienced physician cer-
23 tified by a board recognized by the Amer-
24 ican Board of Medical Specialties;

1 (ii) not earlier than 2 years prior to
2 the date of selection to the board, have
3 been in active medical practice or devoted
4 a substantial portion of his or her time to
5 teaching at an accredited medical school,
6 or have been engaged in university-based
7 research in relation to the medical care
8 and type of treatment at issue; and

9 (iii) be approved by his or her spe-
10 cialty society.

11 (B) REGIONAL PREFERENCE.—When pos-
12 sible, members should be from the region where
13 the case in question originates to account for
14 geographical practice variation.

15 (3) NO CIVIL LIABILITY FOR MEMBERS.—No
16 civil action shall be brought in any court against any
17 member for any act, failure to act, or statement or
18 opinion made, within the scope of his or her duties
19 as a member of the independent medical review
20 panel.

21 (4) CONSIDERATIONS IN MAKING DETERMINA-
22 TIONS.—The members of the independent medical
23 review panel shall acknowledge that, under certain
24 circumstances, it may be appropriate for a physician

1 to depart from the recommendations in clinical prac-
2 tice guidelines in the care of individual patients.

3 (5) SELECTION OF MEMBERS.—Each member
4 of the independent medical review panel shall be
5 jointly selected by the parties. A member whose se-
6 lection one party does not concur in may not serve
7 on the panel, except that, if, not later than 30 days
8 after a response to the health care liability action is
9 filed, 3 members have not been selected by the par-
10 ties, the court shall appoint any remaining members.

11 (6) COMPENSATION OF MEMBERS.—The costs
12 of compensation to the members of the independent
13 medical review panel shall be shared between the
14 parties equally, unless otherwise agreed to by the
15 parties.

16 (c) TERMS OF REVIEW.—A review by an independent
17 medical review panel under this section shall comply with
18 the following:

19 (1) STANDARD OF CONDUCT.—The mandatory
20 independent medical review panel that is charged
21 with the responsibility of making a preliminary find-
22 ing as to liability of the defendant applicable eligible
23 professional shall deem the prescribed clinical prac-
24 tice guidelines as the standard of conduct, care, and
25 skill expected of members of the medical profession

1 engaged in the defendant's field of practice under
2 the same or similar circumstances, subject to the
3 provisions of subsection (b)(4).

4 (2) RECORD FOR REVIEW.—The independent
5 medical review panel shall make a preliminary find-
6 ing based solely upon the pre-discovery evidence sub-
7 mitted to it pursuant to Rule 26 of the Federal
8 Rules of Civil Procedure, any medical records that
9 would be discoverable if the lawsuit advances to
10 trial, and the applicable prescribed clinical practice
11 guidelines.

12 (3) LIMITATION.—The independent medical re-
13 view panel shall not make a finding of negligence
14 from the mere fact that a treatment or procedure
15 was unsuccessful or failed to bring the best result,
16 or that the patient died.

17 (4) USE AT TRIAL OF WORK PRODUCT OF RE-
18 VIEW PANEL.—No preliminary finding by the inde-
19 pendent medical review panel that the defendant ap-
20 plicable eligible professional breached the standard
21 of care as set forth under the prescribed clinical
22 practice guidelines shall constitute negligence per se
23 or conclusive evidence of liability, but findings, opin-
24 ions, and conclusions of the review panel shall be ad-
25 missible as evidence in any and all subsequent pro-

1 proceedings before the court, including for purposes of
2 motions for summary judgment and at trial.

3 (d) RESULTS OF REVIEW.—

4 (1) IN GENERAL.—Not later than 60 days after
5 all members of the independent medical review panel
6 have been selected, the panel shall complete a review
7 of the record of the liability action and shall make
8 a finding under this subsection.

9 (2) FINDING DESCRIBED.—A finding under this
10 subsection shall include the following:

11 (A) A determination of whether there are
12 any applicable clinical practice guidelines to the
13 health care liability action that substantively
14 pertains to the injury suffered by the claimant.

15 (B) Whether the applicable eligible profes-
16 sional has alleged adherence to any such guide-
17 line.

18 (C) Whether the applicable eligible profes-
19 sional adhered to any such guideline.

20 (D) Whether there is a reasonable prob-
21 ability that—

22 (i) the applicable eligible professional
23 violated the applicable clinical practice
24 guideline;

1 (ii) that violation proximately caused
2 the claimant's alleged injury; and

3 (iii) the claimant suffered damages as
4 a result of the injury.

5 (3) USE AT TRIAL.—The finding under this
6 subsection may be received into evidence by the
7 court. If the independent medical review panel made
8 any finding under paragraph (2)(D) that there was
9 no reasonable probability of the matters described in
10 clauses (i) through (iii), the court may issue a sum-
11 mary judgment in favor of the applicable eligible
12 professional unless the claimant is able to show oth-
13 erwise by clear and convincing evidence. If the panel
14 made a finding under subparagraphs (A) through
15 (C) of paragraph (2) that there was an applicable
16 clinical practice guideline that the defendant adhered
17 to, the court shall issue summary judgment in favor
18 of the applicable eligible professional unless the
19 claimant is able to show otherwise by clear and con-
20 vincing evidence. Any preliminary finding that the
21 defendant applicable eligible professional did not
22 breach the standard of care as set forth under the
23 prescribed medical practice guidelines or that the de-
24 fendant applicable eligible professional's nonadher-
25 ence to the applicable standard was neither the

1 cause in fact nor the proximate cause of the plain-
2 tiff's injury or that the plaintiff did not incur any
3 damages as a result shall be given deference by the
4 court and shall entitle the defendant applicable eligi-
5 ble professional to summary judgment unless the
6 plaintiff is able to show by clear and convincing evi-
7 dence that the independent medical review panel was
8 in error and that there is a genuine issue as to a
9 material fact in the case.

10 **SEC. 10. DEFINITIONS.**

11 In this Act:

12 (1) **APPLICABLE ELIGIBLE PROFESSIONAL.**—

13 The term “applicable eligible professional” means a
14 physician practicing within clinical practice guide-
15 lines submitted by an eligible professional organiza-
16 tion and includes employees and agents of a physi-
17 cian.

18 (2) **APPROPRIATE USE CRITERIA.**—The term

19 “appropriate use criteria” means established evi-
20 dence-based guidelines developed or endorsed by an
21 eligible professional organization that specify when
22 the health benefits of a procedure or service exceed
23 the expected health risks by a significantly wide
24 margin.

1 (3) CLINICAL PRACTICE GUIDELINE.—The term
2 “clinical practice guideline” means systematically de-
3 veloped statements based on the review of clinical
4 evidence for assisting a health care provider to de-
5 termine the appropriate health care in specific clin-
6 ical circumstances.

7 (4) ELIGIBLE PROFESSIONAL ORGANIZATION.—
8 The term “eligible professional organization” means
9 a national or State medical society or medical spe-
10 cialty society.

11 (5) FEDERAL PAYOR.—The term “Federal
12 payor” includes reimbursements made under the
13 Medicare program under title XVIII of the Social
14 Security Act or the Medicaid program under title
15 XIX of the Social Security Act, premium tax credits
16 under section 36B of the Internal Revenue Code of
17 1986 or cost-sharing reductions under section 1402
18 of the Patient Protection and Affordable Care Act,
19 or medical screenings, treatments, or transfer serv-
20 ices provided pursuant to section 1867 of the Social
21 Security Act is not made by the individual or any
22 non-Federal third party on behalf of the individual.

23 (6) HEALTH CARE GOODS OR SERVICES.—The
24 term “health care goods or services” means any
25 goods or services provided by a health care organiza-

1 tion, provider, or by any individual working under
2 the supervision of a health care provider, that relates
3 to the diagnosis, prevention, or treatment of any
4 human disease or impairment, or the assessment or
5 care of the health of human beings.

6 (7) HEALTH CARE LIABILITY ACTION.—The
7 term “health care liability action” means a civil ac-
8 tion against an applicable eligible professional, a
9 health care provider, or a health care organization,
10 regardless of the theory of liability on which the
11 claim is based, or the number of plaintiffs, defend-
12 ants, or other parties, or the number of causes of ac-
13 tion, in which the claimant alleges a health care li-
14 ability claim.

15 (8) HEALTH CARE LIABILITY CLAIM.—The
16 term “health care liability claim” means a claim by
17 any person against an applicable eligible profes-
18 sional, a health care provider, or a health care orga-
19 nization which is based upon the provision of, use of,
20 or payment for (or the failure to provide, use, or pay
21 for) health care goods or services for which at least
22 partial payment was made by a Federal payor or
23 which was mandated by Federal law, regardless of
24 the theory of liability on which the claim is based.

1 (9) HEALTH CARE ORGANIZATION.—The term
2 “health care organization” means any person or en-
3 tity which is obligated to provide or pay for health
4 benefits under any health plan, including any person
5 or entity acting under a contract or arrangement
6 with a health care organization to provide or admin-
7 ister any health benefit.

8 (10) HEALTH CARE PROVIDER.—The term
9 “health care provider” means any person or entity
10 required by State or Federal laws or regulations to
11 be licensed, registered, or certified to provide health
12 care services, and being either so licensed, reg-
13 istered, or certified, or exempted from such require-
14 ment by other statute or regulation.

15 (11) SECRETARY.—The term “Secretary”
16 means the Secretary of Health and Human Services.

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