

113TH CONGRESS
2D SESSION

H. R. 4106

To provide for the development and dissemination of clinical practice guidelines and the establishment of a right of removal to Federal courts for defendants in medical malpractice actions involving a Federal payor, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 27, 2014

Mr. BARR (for himself and Mr. BERA of California) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, 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 provide for the development and dissemination of clinical practice guidelines and the establishment of a right of removal to Federal courts for defendants in medical malpractice actions involving a Federal payor, 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 “Saving Lives, Saving
5 Costs Act”.

1 **SEC. 2. PURPOSES.**

2 The purposes of this Act are:

3 (1) To offer physicians who document adher-
4 ence to certain evidence-based clinical-practice guide-
5 lines, and, when applicable, appropriate use criteria,
6 a safe harbor from medical-malpractice litigation.

7 (2) To reduce the practice of defensive medicine
8 and resulting health care costs.

9 (3) To increase adherence to evidence-based
10 clinical practice guidelines to reduce clinical vari-
11 ation in health care practice.

12 (4) To improve quality of care and patient safe-
13 ty.

14 (5) To permit organizations with relevant ex-
15 pertise to participate in the selection of clinical prac-
16 tice guidelines.

17 (6) To permit professionals with relevant exper-
18 tise to participate and benefit from liability reform.

19 **SEC. 3. REQUIREMENTS FOR SELECTION OF CLINICAL**
20 **PRACTICE GUIDELINES.**

21 (a) SELECTION.—Not later than 6 months after the
22 date of enactment of this Act, eligible professional organi-
23 zations that have established, published, maintained and
24 updated on a regular basis, clinical practice guidelines, in-
25 cluding when applicable, appropriate use criteria, that in-
26 corporate best practices, shall submit to the Secretary

1 those guidelines. Not later than 6 months after that sub-
2 mission date, the Secretary shall select and designate one
3 or more of those eligible professional organizations to pro-
4 vide and maintain such clinical practice guidelines on be-
5 half of the Secretary. To this end, not more than 6 months
6 after designating each such eligible professional organiza-
7 tion, the Secretary shall enter into an agreement with each
8 such eligible professional organization for maintenance
9 and updating of such clinical practice guidelines.

10 (b) MAINTENANCE.—

11 (1) PERIODIC REVIEW.—Not later than 5 years
12 after publication of guidelines, and every five years
13 thereafter, the Secretary shall review the clinical
14 practice guidelines and shall, as necessary, enter into
15 agreements with eligible professional organizations.

16 (2) UPDATE BY ELIGIBLE PROFESSIONAL ORGA-
17 NIZATION.—An eligible professional organization
18 that collaborated in the establishment of a clinical
19 practice guideline may submit amendments to that
20 clinical practice guideline at any time to the Sec-
21 retary, who shall review the amendments.

22 (3) NOTIFICATION REQUIRED FOR CERTAIN UP-
23 DATES.—In the case of an amendment under para-
24 graph (2) that adds, materially changes, or removes
25 a guideline from a set of guidelines, such update

1 shall not apply under this subsection unless notifica-
2 tion of such update is made available to applicable
3 eligible professionals.

4 **SEC. 4. DEVELOPMENT.**

5 (a) **GUIDELINE STANDARDS.**—To the extent possible,
6 the development of clinical practice guidelines should be
7 guided by the Institute of Medicine’s Standards for Devel-
8 oping Trustworthy Guidelines and should—

9 (1) be developed through a transparent process
10 that minimizes conflicts of interest;

11 (2) be developed by a knowledgeable, multidisci-
12 plinary panel of experts and representatives from
13 key affected groups;

14 (3) take into consideration important patient
15 subgroups and patient preferences as appropriate;

16 (4) be based on a systematic review of the exist-
17 ing evidence;

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

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

22 (7) be reconsidered and revised when new evi-
23 dence emerges; and

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

1 (b) REQUIRED DISCLOSURES FROM ELIGIBLE PRO-
2 FESSIONAL ORGANIZATIONS.—Any person who is affili-
3 ated with an eligible professional organization and who di-
4 rectly participated in the creation of a clinical practice
5 guideline shall disclose any conflicts of interest pertaining
6 to the development of the clinical practice guideline, in-
7 cluding any conflict of interest pertaining to any instru-
8 ment, medicine, drug, or any other substance, device, or
9 means included in the clinical practice guideline. Dislo-
10 sures by eligible professional organizations shall be made
11 promptly, upon submission of the guidelines, and during
12 every review of the guidelines, to the Secretary. Dislo-
13 sures shall additionally include the following:

14 (1) Scientific methodology and evidence that
15 supports clinical practice guidelines.

16 (2) Outside collaborators.

17 (3) Endorsements.

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

19 The Secretary of Health and Human Services shall
20 publish all clinical practice guidelines on the Internet
21 through the National Guideline Clearinghouse or other ap-
22 propriate sites or sources, including all data and method-
23 ology used in the development and selection of the guide-
24 lines in compliance with data disclosure standards in the

1 Health Insurance Portability and Accountability Act of
2 1996.

3 **SEC. 6. STATE FLEXIBILITY AND PROTECTION OF STATES'**
4 **RIGHTS.**

5 (a) LIMITATION.—This Act shall not preempt or su-
6 persede any State or Federal law that imposes greater
7 procedural or substantive protections for health care pro-
8 viders and health care organizations from liability, loss,
9 or damages than those provided by this title or create a
10 cause of action.

11 (b) STATE FLEXIBILITY.—No provision of this Act
12 shall be construed to preempt any defense available to a
13 party in a health care liability action under any other pro-
14 vision of State or Federal law.

15 **SEC. 7. RIGHT OF REMOVAL.**

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

18 “(g) CERTAIN ACTIONS AGAINST MEDICAL PROFES-
19 SIONALS.—(1) Any health care liability action brought in
20 a State court against an applicable eligible professional or
21 health care provider may be removed by any defendant
22 or the defendants to the district court of the United States
23 for the district and division embracing the place where
24 such action is pending.

1 “(2) For purposes of this subsection the terms ‘appli-
2 cable eligible professional’, ‘health care provider’, ‘health
3 care liability action’, and ‘health care liability claim’ have
4 the meaning given such term in section 10 of the Saving
5 Lives, Saving Costs Act of 2014.”.

6 **SEC. 8. MANDATORY REVIEW BY INDEPENDENT MEDICAL**
7 **REVIEW PANEL.**

8 (a) IN GENERAL.—If, in any health care liability ac-
9 tion against an applicable eligible professional, the appli-
10 cable eligible professional alleges, in any response to the
11 claimant’s filing, that the applicable eligible professional
12 adhered to an applicable clinical practice guideline in the
13 provision of health care goods or services to the claimant,
14 then the court shall suspend further proceedings on the
15 health care liability action prior to discovery proceedings,
16 until the completion of a review of the action by an inde-
17 pendent medical review panel.

18 (b) INDEPENDENT MEDICAL REVIEW PANEL.—

19 (1) COMPOSITION.—An independent medical re-
20 view panel under this section shall be composed of
21 3 members who are experts in the relevant field of
22 clinical practice.

23 (2) REQUIREMENTS FOR MEMBER ELIGI-
24 BILITY.—To be eligible to serve on an independent
25 medical review panel, a member shall—

1 (A) be an experienced physician certified
2 by a board recognized by the American Board
3 of Medical Specialties;

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

12 (C) be approved by his or her specialty so-
13 ciety.

14 When possible, members should be from the region
15 where the case in question originates to account for
16 geographical practice variation.

17 (3) NO CIVIL LIABILITY FOR MEMBERS.—No
18 civil action shall be brought in any court against any
19 member for any act done, failure to act, or state-
20 ment or opinion made, within the scope of his or her
21 duties as a member of the independent medical re-
22 view panel.

23 (4) CONSIDERATIONS IN MAKING DETERMINA-
24 TIONS.—The members of the independent medical
25 review panel shall acknowledge the ability of physi-

1 cians to depart from the recommendations in clinical
2 practice guidelines, when appropriate, in the care of
3 individual patients.

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

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

3 (2) RECORD FOR REVIEW.—The review panel
4 shall make a preliminary finding based solely upon
5 the pre-discovery evidence submitted to it pursuant
6 to Rule 26 of the Federal Rules of Civil Procedure
7 and the applicable prescribed clinical practice guide-
8 lines.

9 (3) LIMITATION.—The review panel shall not
10 make a finding of negligence from the mere fact that
11 a treatment or procedure was unsuccessful, failed to
12 bring the best result or that the patient died.

13 (4) USE AT TRIAL OF WORK PRODUCT OF RE-
14 VIEW PANEL.—No preliminary finding by the review
15 panel that the defendant applicable eligible profes-
16 sional breached the standard of care as set forth
17 under the prescribed clinical practice guidelines shall
18 constitute negligence per se or conclusive evidence of
19 liability. However, said findings, opinions and con-
20 clusions of the review panel shall be admissible as
21 evidence in any and all subsequent proceedings be-
22 fore the court, including for purposes of motions for
23 summary judgment and at trial.

24 (d) RESULTS OF REVIEW.—

1 (1) IN GENERAL.—Not later than 60 days after
2 all members of the panel have been selected, the
3 panel shall complete a review of the record of the li-
4 ability action and shall make a finding under this
5 subsection.

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

8 (A) A determination of whether or not
9 there are any applicable clinical practice guide-
10 lines to the health care liability action that sub-
11 stantively pertains to the injury suffered by the
12 claimant.

13 (B) If the applicable eligible professional
14 has alleged adherence to any such guideline.

15 (C) If the applicable eligible professional
16 did adhere to any such guideline.

17 (D) Whether there is a reasonable prob-
18 ability that—

19 (i) the applicable eligible professional
20 violated the applicable standard of care;

21 (ii) that violation proximately caused
22 the claimant’s alleged injury; and

23 (iii) the claimant suffered damages as
24 a result of the injury.

1 (3) USE AT TRIAL.—The finding under this
2 subsection may be received into evidence by the
3 court. If the panel made any finding under para-
4 graph (2)(D) that there was no reasonable prob-
5 ability, the court may issue a summary judgment in
6 favor of the applicable eligible professional unless
7 the claimant is able to show otherwise by clear and
8 convincing evidence. If the panel made a finding
9 under subparagraphs (A) through (C) that there was
10 an applicable clinical practice guideline that the de-
11 fendant adhered to, the court shall issue summary
12 judgment in favor of the applicable eligible profes-
13 sional unless the claimant is able to show otherwise
14 by clear and convincing evidence. Any preliminary
15 finding that the defendant applicable eligible profes-
16 sional did not breach the standard of care as set
17 forth under the prescribed medical practice guide-
18 lines or that the defendant applicable eligible profes-
19 sional’s failure to conform to the required standard
20 was neither the cause in fact nor the proximate
21 cause of the plaintiff’s injury or that the plaintiff
22 did not incur any damages as a result shall be given
23 deference by the court and shall entitle the defend-
24 ant applicable eligible professional to summary judg-
25 ment unless the plaintiff is able to show by clear and

1 convincing evidence that the independent medical re-
2 view panel was in error and that there is a genuine
3 issue as to a material fact in the case.

4 **SEC. 9. RECOVERY OF COSTS.**

5 If the defendant applicable eligible professional pre-
6 vails subsequent to a preliminary finding in his or her
7 favor by the independent medical review panel, the defend-
8 ant may recover costs and attorneys' fees from the plain-
9 tiff.

10 **SEC. 10. DEFINITIONS.**

11 In this Act:

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

13 The term “applicable eligible professional” means
14 physicians 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 a health care provider or a health care
9 organization, regardless of the theory of liability on
10 which the claim is based, or the number of plaintiffs,
11 defendants, or other parties, or the number of
12 causes of action, in which the claimant alleges a
13 health care liability claim.

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

24 (9) HEALTH CARE ORGANIZATION.—The term
25 “health care organization” means any person or en-

1 tity which is obligated to provide or pay for health
2 benefits under any health plan, including any person
3 or entity acting under a contract or arrangement
4 with a health care organization to provide or admin-
5 ister any health benefit.

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

13 (11) PERFORMANCE PERIOD.—The term “per-
14 formance period” means the period of time during
15 which the final rule establishing a clinical practice
16 guideline is in effect.

17 (12) SECRETARY.—The term “Secretary”
18 means the Secretary of Health and Human Services.

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