

111TH CONGRESS
1ST SESSION

H. R. 3459

To provide comprehensive reform regarding medical malpractice.

IN THE HOUSE OF REPRESENTATIVES

JULY 31, 2009

Mr. BAIRD 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 comprehensive reform regarding medical malpractice.

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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Comprehensive Medical Malpractice Reform Act of
6 2009”.

7 (b) TABLE OF CONTENTS.—The table of contents of
8 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—HEALTH CARE MALPRACTICE LIABILITY REFORM

- Sec. 101. Cap on non-economic damages.
- Sec. 102. Sanctions for meritless actions and pleadings.
- Sec. 103. Performance standards applicable to State medical boards.
- Sec. 104. Interstate patient reporting and physician tracking database.
- Sec. 105. Definitions.

TITLE II—HEALTH CARE MALPRACTICE LIABILITY MEDIATION PROGRAMS

- Sec. 201. Grants to States and health care entities for mediation programs.
- Sec. 202. Training and assistance for mediation programs.
- Sec. 203. Authorization of appropriations.

TITLE III—VOLUNTARY REPORTING OF MEDICAL SAFETY INCIDENTS

Subtitle A—Reporting by Individuals Involved in the Provision of Health Care

- Sec. 301. Amendments to Public Health Service Act.

Subtitle B—Liability Protection in Good-Faith Reporting

- Sec. 311. Liability protection for health care providers in good-faith reporting to State medical boards.

TITLE IV—INSURANCE REFORM

- Sec. 401. Uniform State requirements regarding proposed rate increases.
- Sec. 402. Reduction in premiums paid by physicians for medical malpractice insurance coverage.
- Sec. 403. Effective date.

TITLE V—EXCLUSION OF PHARMACEUTICALS AND DEVICES FROM LIABILITY REFORMS

- Sec. 501. Exclusion of pharmaceuticals and devices.

1 **TITLE I—HEALTH CARE MAL-**
 2 **PRACTICE LIABILITY RE-**
 3 **FORM**

4 **SEC. 101. CAP ON NON-ECONOMIC DAMAGES.**

5 (a) IN GENERAL.—When an individual is injured or
 6 dies as the result of health care malpractice, a person enti-
 7 tled to recover non-economic damages from a health care
 8 provider responsible for that malpractice may not recover
 9 such damages, in the aggregate from all such providers,

1 in an amount more than \$250,000, adjusted for inflation
2 from 1975 as provided in subsection (b). This limitation
3 applies separately to each person entitled to recover such
4 damages.

5 (b) ADJUSTMENT FOR INFLATION FROM 1975.—

6 (1) PUBLICATION BY SECRETARY OF LABOR.—

7 On or about December 1 of each year, the Secretary
8 of Labor shall publish in the Federal Register a dol-
9 lar amount determined by adjusting the dollar
10 amount specified in subsection (a) according to the
11 adjustments in the Consumer Price Index of the Bu-
12 reau of Labor Statistics of the Department of Labor
13 for the period beginning on or about October 1,
14 1975, and ending on or about October 1 of that
15 year.

16 (2) APPLICABILITY.—For purposes of sub-
17 section (a), the dollar amount that applies to a cal-
18 endar year is the dollar amount published on or
19 about December 1 of the preceding year.

20 (3) ESTIMATION.—Congress estimates that the
21 dollar amount that would apply to calendar year
22 2005 would be approximately \$878,000, though the
23 dollar amount published under paragraph (1), rather
24 than the estimation in this paragraph, is to be ap-
25 plied.

1 (c) APPLICABILITY.—

2 (1) IN GENERAL.—Subject to paragraph (2),
3 this section applies whenever the amount of a recov-
4 ery is made final in a calendar year after the date
5 of the enactment of this Act. In applying the dollar
6 amount to a recovery, all recoveries made final
7 (whether before or after the date of the enactment
8 of this Act) are included in the aggregate.

9 (2) NOT APPLICABLE WHEN STATE BOARD NOT
10 IN COMPLIANCE.—During a period in which a State
11 medical board is not in compliance with the vol-
12 untary performance standards developed under sec-
13 tion 103 or is failing to submit the information de-
14 scribed in paragraphs (2) and (3)(A) of section
15 104(b) (as determined by the Secretary under sec-
16 tion 103 or 104, respectively), the limitation in sub-
17 section (a) does not apply to liability arising under
18 the law of that State.

19 (d) RELATIONSHIP TO STATE LAW.—This section op-
20 erates on a case-by-case basis to provide a maximum re-
21 covery and to prevent State law from providing a recovery
22 above that maximum. It does not prevent State law from
23 providing a recovery below that maximum.

1 **SEC. 102. SANCTIONS FOR MERITLESS ACTIONS AND**
2 **PLEADINGS.**

3 (a) SIGNATURE REQUIRED.—Every pleading, written
4 motion, and other paper in any medical malpractice action
5 shall be signed by at least 1 attorney of record in the at-
6 torney's individual name, or, if the party is not rep-
7 resented by an attorney, shall be signed by the party. Each
8 paper shall state the signer's address and telephone num-
9 ber, if any. An unsigned paper shall be stricken unless
10 omission of the signature is corrected promptly after being
11 called to the attention of the attorney or party.

12 (b) CERTIFICATE OF MERIT.—

13 (1) IN GENERAL.—A medical malpractice action
14 shall be dismissed unless the attorney or unrepres-
15 ented party presenting the complaint certifies that,
16 to the best of the person's knowledge, information,
17 and belief, formed after an inquiry reasonable under
18 the circumstances—

19 (A) it is not being presented for any im-
20 proper purpose, such as to harass or to cause
21 unnecessary delay or needless increase in the
22 cost of litigation;

23 (B) the claims and other legal contentions
24 therein are warranted by existing law or by a
25 nonfrivolous argument for the extension, modi-

1 fication, or reversal of existing law or the estab-
2 lishment of new law; and

3 (C) the allegations and other factual con-
4 tentions have evidentiary support or, if specifi-
5 cally so identified, are likely to have evidentiary
6 support after a reasonable opportunity for fur-
7 ther investigation and discovery.

8 (2) PAPER CONSIDERED TO BE A CERTIFI-
9 CATION.—By presenting to the court (whether by
10 signing, filing, submitting, or later advocating) a
11 pleading, written motion, or other paper, an attorney
12 or unrepresented party is certifying that to the best
13 of the person’s knowledge, information and belief,
14 formed after an inquiry reasonable under the cir-
15 cumstances—

16 (A) it is not being presented for any im-
17 proper purpose, such as to harass or to cause
18 unnecessary delay or needless increase in the
19 cost of litigation;

20 (B) the claims, defenses, and other legal
21 contentions therein are warranted by existing
22 law or by a nonfrivolous argument for the ex-
23 tension, modification, or reversal of existing law
24 or the establishment of new law; and

1 (C) the allegations and other factual con-
2 tentions have evidentiary support or, if specifi-
3 cally so identified, are reasonable based on a
4 lack of information or belief.

5 (c) MANDATORY SANCTIONS.—

6 (1) FIRST VIOLATION.—If, after notice and a
7 reasonable opportunity to respond, a court, upon
8 motion or upon its own initiative, determines that
9 subsection (b) has been violated, the court shall find
10 each attorney or party in violation in contempt of
11 court and shall require the payment of costs and at-
12 torneys fees. The court may also impose additional
13 appropriate sanctions, such as striking the plead-
14 ings, dismissing the suit, and sanctions plus interest,
15 upon the person in violation, or upon both such per-
16 son and such person’s attorney or client (as the case
17 may be).

18 (2) SECOND VIOLATION.—If, after notice and a
19 reasonable opportunity to respond, a court, upon
20 motion or upon its own initiative, determines that
21 subsection (b) has been violated and that the attor-
22 ney or party with respect to which the determination
23 was made has committed one previous violation of
24 subsection (b) before this or any other court, the
25 court shall find each such attorney or party in con-

1 tempt of court and shall require the payment of
2 costs and attorneys fees, and require such person in
3 violation (or both such person and such person's at-
4 torney or client (as the case may be)) to pay a mon-
5 etary fine. The court may also impose additional ap-
6 propriate sanctions, such as striking the pleadings,
7 dismissing the suit and sanctions plus interest, upon
8 such person in violation, or upon both such person
9 and such person's attorney or client (as the case
10 may be).

11 (3) THIRD AND SUBSEQUENT VIOLATIONS.—If,
12 after notice and a reasonable opportunity to re-
13 spond, a court, upon motion or upon its own initia-
14 tive, determines that subsection (b) has been vio-
15 lated and that the attorney or party with respect to
16 which the determination was made has committed
17 more than one previous violation of subsection (b)
18 before this or any other court, the court shall find
19 each such attorney or party in contempt of court,
20 refer each such attorney to one or more appropriate
21 State bar associations for disciplinary proceedings,
22 require the payment of costs and attorneys fees, and
23 require such person in violation (or both such person
24 and such person's attorney or client (as the case
25 may be)) to pay a monetary fine. The court may

1 also impose additional appropriate sanctions, such as
2 striking the pleadings, dismissing the suit, and sanc-
3 tions plus interest, upon such person in violation, or
4 upon both such person and such person's attorney or
5 client (as the case may be).

6 (d) **CENTRAL TRACKING DATABASE.**—The Attorney
7 General shall establish and maintain a central tracking
8 database reporting system to which courts are to report
9 violations of subsection (b). The database shall include all
10 identifying information with respect to the attorney or the
11 party (if not represented by an attorney). The Attorney
12 General shall permit courts to consult the database to de-
13 termine the extent to which an attorney or party has vio-
14 lated subsection (b) previously.

15 **SEC. 103. PERFORMANCE STANDARDS APPLICABLE TO**
16 **STATE MEDICAL BOARDS.**

17 (a) **DEVELOPMENT.**—Not later than 1 year after the
18 date of the enactment of this Act, the Secretary of Health
19 and Human Services, in consultation with the Federation
20 of State Medical Boards, shall develop and make publicly
21 available voluntary performance standards applicable to
22 State medical boards.

23 (b) **CONTENTS.**—In developing performance stand-
24 ards under this section, the Secretary shall include stand-
25 ards to require the following:

1 (1) Processing patient complaints within a spec-
2 ified limited period of time.

3 (2) Maintaining a website or toll-free telephone
4 number to enable a patient submitting a complaint
5 to track the status of the complaint.

6 (3) Maintaining an adequate level of staff for
7 the activities of the State medical board.

8 (4) Ensuring that staff are qualified.

9 (5) Making the following information available
10 to the public for physicians:

11 (A) Each physician's education and train-
12 ing.

13 (B) Each physician's medical specialties.

14 (C) For each physician a description of
15 medical malpractice claims paid, hospital dis-
16 ciplinary actions taken, criminal convictions oc-
17 curring, and disciplinary actions taken by the
18 State medical board, within the previous 10
19 years.

20 (D) At the option of a State medical
21 board, each physician's professional demo-
22 graphics (such as business address, insurance
23 plan and hospital affiliations, and available
24 translation services), professional or community

1 awards received, and research or other profes-
2 sional publications.

3 (6) Issuing an annual report that includes ag-
4 gregate disciplinary statistics, including—

5 (A) statistics on the number and type of
6 complaints received; and

7 (B) with respect to physicians, statistics on
8 the number and type of complaints received,
9 disaggregated by the medical school and grad-
10 uate medical education program completed by
11 the physicians involved.

12 (7) Such other issues as the Secretary deter-
13 mines appropriate.

14 (c) DETERMINATION REQUIRED.—For the period be-
15 ginning 3 years after the date of the enactment of this
16 Act, the Secretary shall determine whether the State med-
17 ical board of each State is in compliance with the vol-
18 untary performance standards developed under subsection
19 (a).

20 (d) DETERMINATION OF NONCOMPLIANCE.—Before
21 making a determination under subsection (c) that a State
22 medical board is not in compliance with the voluntary per-
23 formance standards developed under subsection (a), the
24 Secretary shall—

25 (1) propose a determination of noncompliance;

1 (2) identify the reasons for such noncompliance;
2 and

3 (3) give the State medical board an opportunity
4 to correct such noncompliance.

5 (e) REVISION OF DETERMINATIONS.—The Secretary
6 shall periodically review and, as necessary, revise deter-
7 minations of compliance and noncompliance under sub-
8 section (c).

9 (f) REPORT BY SECRETARY.—Not later than 5 years
10 after the date of the enactment of this Act, and annually
11 thereafter, the Secretary shall submit a report to the Con-
12 gress on the activities of the Secretary under this section,
13 including a listing of the State medical boards determined
14 by the Secretary to be in compliance or not in compliance
15 with the voluntary standards developed under subsection
16 (a).

17 **SEC. 104. INTERSTATE PATIENT REPORTING AND PHYSI-**
18 **CIAN TRACKING DATABASE.**

19 (a) ESTABLISHMENT.—The Secretary of Health and
20 Human Services shall establish and maintain an interstate
21 patient reporting and physician tracking database (in this
22 section referred to as the “database”).

23 (b) DATABASE CONTENTS.—

1 (1) IN GENERAL.—The database shall consist of
2 information about physicians voluntarily submitted
3 to the database by—

4 (A) State medical boards; and

5 (B) patients.

6 (2) SUBMISSIONS BY STATE MEDICAL
7 BOARDS.—The database shall encourage the State
8 medical board of each State to submit, with respect
9 to each physician licensed by the State, the fol-
10 lowing:

11 (A) The physician’s identity.

12 (B) The physician’s education and train-
13 ing.

14 (C) The physician’s medical specialties.

15 (D) A description of medical malpractice
16 claims paid, hospital disciplinary actions taken,
17 criminal convictions occurring, and disciplinary
18 actions taken by the State medical board, with-
19 in the previous 10 years.

20 (3) PATIENT COMPLAINTS.—The database
21 shall—

22 (A) encourage the State medical board of
23 each State to submit, with respect to each phy-
24 sician licensed by the State, a description of

1 pending patient complaints about the physician;
2 and

3 (B) allow patients to submit complaints
4 about physicians directly to the database.

5 (c) AVAILABILITY OF INFORMATION.—

6 (1) IN GENERAL.—The information submitted
7 to the database pursuant to subsection (b)(2) shall
8 be available to the public, including by means of the
9 Internet and a toll-free telephone number.

10 (2) PATIENT COMPLAINTS.—

11 (A) CONFIDENTIALITY.—Any patient com-
12 plaint about a physician submitted to the data-
13 base shall be kept confidential and shall not be
14 subject to disclosure under section 552 of title
15 5, United States Code. Except as provided in
16 subparagraph (B), the database may disclose
17 information derived from such a patient com-
18 plaint only if the information is not individually
19 identifiable.

20 (B) TRACKING PATIENT COMPLAINTS.—

21 The database shall—

22 (i) assign a tracking number to each
23 patient complaint submitted to the data-
24 base pursuant to subsection (b)(3);

1 (ii) provide notice and a description of
2 each patient complaint submitted pursuant
3 to subsection (b)(3)(B) to the applicable
4 State medical board; and

5 (iii) allow the patient making any
6 complaint submitted to the database pur-
7 suant to subsection (b)(3) to track the sta-
8 tus of the complaint, including by means of
9 the Internet and a toll-free telephone num-
10 ber.

11 (C) ANALYSIS.—Subject to subparagraph
12 (A), the Secretary of Health and Human Serv-
13 ices shall conduct analysis of patient complaints
14 submitted to the database, including complaints
15 that do not result in disciplinary action, and
16 use the data and conclusions derived from such
17 analysis to provide timely public health safety
18 information to health care consumers and prac-
19 tioners.

20 (d) TECHNICAL ASSISTANCE.—The Secretary of
21 Health and Human Services shall provide technical assist-
22 ance to States to facilitate the exchange of information
23 between State medical boards and the database.

24 (e) DETERMINATION REQUIRED.—For the period be-
25 ginning 3 years after the date of the enactment of this

1 Act, the Secretary shall determine whether the State med-
2 ical board of each State is failing to submit the informa-
3 tion described in subsections (b)(2) and (b)(3)(A).

4 (f) DETERMINATION OF NONCOMPLIANCE.—Before
5 making a determination under subsection (e) that a State
6 medical board is failing to submit such information, the
7 Secretary shall—

8 (1) propose a determination of noncompliance;

9 (2) identify the reasons for such noncompliance;

10 and

11 (3) give the State medical board an opportunity
12 to correct such noncompliance.

13 (g) REVISION OF DETERMINATIONS.—The Secretary
14 shall periodically review and, as necessary, revise deter-
15 minations of compliance and noncompliance under sub-
16 section (e).

17 (h) ASSESSMENT.—Not later than 3 years after the
18 date of the enactment of this Act, the Secretary shall—

19 (1) conduct an assessment of the database, in-
20 cluding an assessment of the value of the database
21 to patients and the effect of the database on physi-
22 cians; and

23 (2) submit a report to the Congress on the re-
24 sults of the assessment, including any recommenda-
25 tions for improvement of the database.

1 **SEC. 105. DEFINITIONS.**

2 In this title:

3 (1) The term “State medical board” means a
4 State entity responsible for licensing physicians or a
5 subdivision of such an entity.

6 (2) The term “health care malpractice” means
7 the negligence or other fault of a health care pro-
8 vider.

9 (3) The term “health care provider” means—

10 (A) any individual who is engaged in the
11 delivery of health care services in a State and
12 who is required by State law or regulation to be
13 licensed or certified by the State to engage in
14 the delivery of such services in the State; and

15 (B) any entity that is engaged in the deliv-
16 ery of health care services in a State and that,
17 if it is required by State law or regulation to be
18 licensed or certified by the State to engage in
19 the delivery of such services in the State, is so
20 licensed.

21 (4) The term “State” includes the District of
22 Columbia, the Commonwealth of Puerto Rico, and
23 other territories and possessions of the United
24 States.

1 **TITLE II—HEALTH CARE MAL-**
2 **PRACTICE LIABILITY MEDI-**
3 **ATION PROGRAMS**

4 **SEC. 201. GRANTS TO STATES AND HEALTH CARE ENTITIES**
5 **FOR MEDIATION PROGRAMS.**

6 (a) GRANTS AUTHORIZED.—From amounts made
7 available to carry out this section, the Attorney General
8 shall carry out a program under which the Attorney Gen-
9 eral makes grants to States and health care entities to
10 carry out mediation programs described in subsection (b).

11 (b) MEDIATION PROGRAMS.—A mediation program
12 referred to in subsection (a) is a program, based on the
13 Rush model, under which an allegation that an individual
14 has been injured or has died as the result of health care
15 malpractice is mediated by those parties consenting to do
16 so in an effort to resolve the matter without litigation.

17 (c) RUSH MODEL.—For purposes of this section, a
18 program is based on the Rush model if the program satis-
19 fies each of the following:

20 (1) Participation by the parties in the medi-
21 ation is voluntary.

22 (2) The mediator is neutral, having no interest
23 in or power to determine the outcome of the pro-
24 ceedings.

1 (3) The site of the mediation conference is held
2 in a neutral setting, one that the parties mutually
3 agree upon.

4 (4) At the commencement of a mediation, the
5 parties enter into a mediation agreement that—

6 (A) states that the parties—

7 (i) will not request or subpoena the
8 mediator to testify or produce any docu-
9 ments or other information in any pro-
10 ceeding related to the mediation; and

11 (ii) will defend and indemnify the me-
12 diator in connection with any summons or
13 subpoena arising out of the mediation pro-
14 ceeding;

15 (B) provides for confidentiality of the me-
16 diation proceedings; and

17 (C) states that any apology or expression
18 of remorse by a health care provider or other
19 entity at any time during the mediation pro-
20 ceedings will be kept confidential and will not
21 be used in any subsequent legal proceeding.

22 (5) The program is similar to the mediation
23 program carried out as of January 1, 2005, at
24 Rush-Presbyterian-St. Luke's Medical Center in Chi-
25 cago, Illinois.

1 (d) DEFINITIONS.—In this section:

2 (1) The term “health care entity” means an en-
3 tity covered by section 105(3)(B).

4 (2) The term “health care malpractice” has the
5 meaning given such term in section 105.

6 (3) The term “State” has the meaning given
7 such term in section 105.

8 **SEC. 202. TRAINING AND ASSISTANCE FOR MEDIATION**
9 **PROGRAMS.**

10 From amounts made available to carry out this sec-
11 tion, the Attorney General shall carry out a program
12 under which the Attorney General provides training and
13 assistance to recipients of grant amounts under section
14 201 to carry out mediation programs under that section.

15 **SEC. 203. AUTHORIZATION OF APPROPRIATIONS.**

16 There are authorized to be appropriated to the Attor-
17 ney General such sums as may be necessary to carry out
18 sections 201 and 202.

1 **TITLE III—VOLUNTARY REPORT-**
2 **ING OF MEDICAL SAFETY IN-**
3 **CIDENTS**

4 **Subtitle A—Reporting by Individ-**
5 **uals Involved in the Provision**
6 **of Health Care**

7 **SEC. 301. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.**

8 (a) IN GENERAL.—Title IX of the Public Health
9 Service Act (42 U.S.C. 299 et seq.) is amended—

10 (1) in section 912(c), by inserting “, in accord-
11 ance with part C,” after “The Director shall”;

12 (2) by redesignating part C as part D;

13 (3) by redesignating sections 921 through 928,
14 as sections 931 through 938, respectively;

15 (4) in section 938(1) (as so redesignated), by
16 striking “921” and inserting “931”; and

17 (5) by inserting after part B the following:

18 **“PART C—PATIENT SAFETY IMPROVEMENT**

19 **“SEC. 921. DEFINITIONS.**

20 “In this part:

21 “(1) IDENTIFIABLE INFORMATION.—The term
22 ‘identifiable information’ means information that is
23 presented in a form and manner that allows the
24 identification of any provider, patient, or reporter of
25 patient safety work product. With respect to pa-

1 tients, such information includes any individually
2 identifiable health information as that term is de-
3 fined in the regulations promulgated pursuant to
4 section 264(c) of the Health Insurance Portability
5 and Accountability Act of 1996 (Public Law 104–
6 191; 110 Stat. 2033).

7 “(2) NONIDENTIFIABLE INFORMATION.—The
8 term ‘nonidentifiable information’ means informa-
9 tion that is presented in a form and manner that
10 prevents the identification of any provider, patient,
11 or reporter of patient safety work product. With re-
12 spect to patients, such information must be de-iden-
13 tified consistent with the regulations promulgated
14 pursuant to section 264(c) of the Health Insurance
15 Portability and Accountability Act of 1996 (Public
16 Law 104–191; 110 Stat. 2033).

17 “(3) PATIENT SAFETY EVALUATION SYSTEM.—
18 The term ‘patient safety evaluation system’ means a
19 process that involves the collection, management, or
20 analysis of information for submission to or by a pa-
21 tient safety organization.

22 “(4) PATIENT SAFETY ORGANIZATION.—The
23 term ‘patient safety organization’ means a private or
24 public organization or component thereof that is cer-
25 tified, through a process to be determined by the

1 Secretary under section 925, to perform each of the
2 following activities:

3 “(A) The conduct, as the organization or
4 component’s primary activity, of efforts to im-
5 prove patient safety and the quality of health
6 care delivery.

7 “(B) The collection and analysis of patient
8 safety work product that is submitted by pro-
9 viders.

10 “(C) The development and dissemination
11 of evidence-based information to providers with
12 respect to improving patient safety, such as rec-
13 ommendations, protocols, or information re-
14 garding best practices.

15 “(D) The utilization of patient safety work
16 product to carry out activities limited to those
17 described under this paragraph and for the pur-
18 poses of encouraging a culture of safety and of
19 providing direct feedback and assistance to pro-
20 viders to effectively minimize patient risk.

21 “(E) The maintenance of confidentiality
22 with respect to identifiable information.

23 “(F) The provision of appropriate security
24 measures with respect to patient safety work
25 product.

1 “(G) The submission of nonidentifiable in-
2 formation to the Agency consistent with stand-
3 ards established by the Secretary under section
4 923(b) for any National Patient Safety Data-
5 base.

6 “(5) PATIENT SAFETY WORK PRODUCT.—

7 “(A) The term ‘patient safety work prod-
8 uct’ means any document or communication
9 (including any information, report, record,
10 memorandum, analysis, deliberative work, state-
11 ment, or root cause analysis) that—

12 “(i) except as provided in subpara-
13 graph (B), is developed by a provider for
14 the purpose of reporting to a patient safety
15 organization, and is reported to a patient
16 safety organization;

17 “(ii) is created by a patient safety or-
18 ganization; or

19 “(iii) would reveal the deliberations or
20 analytic process of a patient safety evalua-
21 tion system (as defined in paragraph (3)).

22 “(B)(i) Patient safety work product de-
23 scribed in subparagraph (A)(i)—

24 “(I) does not include any separate in-
25 formation described in clause (ii); and

1 “(II) shall not be construed to include
2 such separate information merely by rea-
3 son of inclusion of a copy of the document
4 or communication involved in a submission
5 to, or the fact of submission of such a copy
6 to, a patient safety organization.

7 “(ii) Separate information described in this
8 clause is a document or communication (includ-
9 ing a patient’s medical record or any other pa-
10 tient or hospital record) that is developed or
11 maintained, or exists, separately from any pa-
12 tient safety evaluation system.

13 “(C) Information available from sources
14 other than a patient safety work product under
15 this section may be discovered or admitted in a
16 civil or administrative proceeding, if discover-
17 able or admissible under applicable law.

18 “(6) PROVIDER.—The term ‘provider’ means—

19 “(A) an individual or entity licensed or
20 otherwise authorized under State law to provide
21 health care services, including—

22 “(i) a hospital, nursing facility, com-
23 prehensive outpatient rehabilitation facil-
24 ity, home health agency, and hospice pro-
25 gram;

1 “(ii) a physician, physician assistant,
2 nurse practitioner, clinical nurse specialist,
3 certified nurse midwife, nurse anesthetist,
4 psychologist, certified social worker, reg-
5 istered dietitian or nutrition professional,
6 physical or occupational therapist, or other
7 individual health care practitioner;

8 “(iii) a pharmacist; and

9 “(iv) a renal dialysis facility, ambula-
10 tory surgical center, pharmacy, physician
11 or health care practitioner’s office, long-
12 term care facility, behavioral health resi-
13 dential treatment facility, clinical labora-
14 tory, or community health center; or

15 “(B) any other person or entity specified
16 in regulations by the Secretary after public no-
17 tice and comment.

18 **“SEC. 922. PRIVILEGE FOR PATIENT SAFETY WORK PROD-**
19 **UCT.**

20 “(a) PRIVILEGE.—Notwithstanding any other provi-
21 sion of law and subject to subsection (c), patient safety
22 work product shall not be—

23 “(1) subject to a civil or administrative sub-
24 poena or order;

1 “(2) subject to discovery in connection with a
2 civil or administrative proceeding;

3 “(3) subject to disclosure pursuant to section
4 552 of title 5, United States Code (commonly known
5 as the Freedom of Information Act), or any other
6 similar Federal or State law;

7 “(4) required to be admitted as evidence or oth-
8 erwise disclosed in any State or Federal civil or ad-
9 ministrative proceeding; or

10 “(5) if the patient safety work product is identi-
11 fiable information and is received by a national ac-
12 creditation organization in its capacity as a patient
13 safety organization—

14 “(A) used by a national accreditation orga-
15 nization in an accreditation action against the
16 provider that reported the information;

17 “(B) shared by such organization with its
18 survey team; or

19 “(C) required as a condition of accredita-
20 tion by a national accreditation association.

21 “(b) REPORTER PROTECTION.—

22 “(1) IN GENERAL.—A provider may not use
23 against an individual in an adverse employment ac-
24 tion described in paragraph (2) the fact that the in-
25 dividual in good faith reported information—

1 “(A) to the provider with the intention of
2 having the information reported to a patient
3 safety organization; or

4 “(B) directly to a patient safety organiza-
5 tion.

6 “(2) ADVERSE EMPLOYMENT ACTION.—For
7 purposes of this subsection, an ‘adverse employment
8 action’ includes—

9 “(A) the failure to promote an individual
10 or provide any other employment-related benefit
11 for which the individual would otherwise be eli-
12 gible;

13 “(B) an adverse evaluation or decision
14 made in relation to accreditation, certification,
15 credentialing, or licensing of the individual; and

16 “(C) a personnel action that is adverse to
17 the individual concerned.

18 “(3) REMEDIES.—Any provider that violates
19 this subsection shall be subject to a civil monetary
20 penalty of not more than \$20,000 for each such vio-
21 lation involved. Such penalty shall be imposed and
22 collected in the same manner as civil money pen-
23 alties under subsection (a) of section 1128A of the
24 Social Security Act are imposed and collected.

1 “(c) DISCLOSURES.—Nothing in this section pro-
2 hibits any of the following disclosures:

3 “(1) Voluntary disclosure of nonidentifiable in-
4 formation.

5 “(2) Voluntary disclosure of identifiable infor-
6 mation by a provider or patient safety organization,
7 if such disclosure—

8 “(A) is authorized by the provider for the
9 purposes of improving quality and safety;

10 “(B) is to an entity or person subject to
11 the requirements of section 264(c) of the
12 Health Insurance Portability and Accountability
13 Act of 1996 (Public Law 104–191; 110 Stat.
14 2033), or any regulation promulgated under
15 such section; and

16 “(C) is not in conflict with such section or
17 any regulation promulgated under such section.

18 “(3) Disclosure as required by law by a pro-
19 vider to the Food and Drug Administration, or on
20 a voluntary basis by a provider to a federally estab-
21 lished patient safety program, with respect to an Ad-
22 ministration-regulated product or activity for which
23 that entity has responsibility, for the purposes of ac-
24 tivities related to the quality, safety, or effectiveness
25 of such Administration-regulated product or activity.

1 “(4) Disclosures of patient safety work product
2 in accordance with this part by a provider to a pa-
3 tient safety organization.

4 “(d) EFFECT OF TRANSFER, DISCLOSURE.—The fol-
5 lowing shall not be treated as a waiver of any privilege
6 or protection established under this part:

7 “(1) The transfer of any patient safety work
8 product between a provider and a patient safety or-
9 ganization.

10 “(2) Disclosure of patient safety work product
11 as described in subsection (c).

12 “(3) The unauthorized disclosure of patient
13 safety work product.

14 “(e) PENALTY.—

15 “(1) PROHIBITION.—Except as provided in this
16 part, and subject to paragraphs (2) and (4), it shall
17 be unlawful for any person to disclose patient safety
18 work product in violation of this section, if such dis-
19 closure constitutes a negligent or knowing breach of
20 confidentiality.

21 “(2) RELATION TO HIPAA.—The penalty under
22 paragraph (3) for a disclosure in violation of para-
23 graph (1) does not apply if the person would be sub-
24 ject to a penalty under section 264(c) of the Health
25 Insurance Portability and Accountability Act of

1 1996 (Public Law 104–191; 110 Stat. 2033), or any
2 regulation promulgated under such section, for the
3 same disclosure.

4 “(3) AMOUNT.—Any person who violates para-
5 graph (1) shall be subject to a civil monetary penalty
6 of not more than \$10,000 for each such violation in-
7 volved. Such penalty shall be imposed and collected
8 in the same manner as civil money penalties under
9 subsection (a) of section 1128A of the Social Secu-
10 rity Act are imposed and collected.

11 “(4) SUBSEQUENT DISCLOSURE.—Paragraph
12 (1) applies only to the first person that breaches
13 confidentiality with respect to particular patient
14 safety work product.

15 “(f) RELATION TO HIPAA.—

16 “(1) IN GENERAL.—For purposes of applying
17 the regulations promulgated pursuant to section
18 264(c) of the Health Insurance Portability and Ac-
19 countability Act of 1996 (Public Law 104–191; 110
20 Stat. 2033)—

21 “(A) patient safety organizations shall be
22 treated as business associates; and

23 “(B) activities of such organizations de-
24 scribed in section 921(4) in relation to a pro-

1 vider are deemed to be health care operations
2 (as defined in such regulations) of the provider.

3 “(2) RULE OF CONSTRUCTION.—Nothing in
4 this section shall be construed to alter or affect the
5 implementation of such regulations or such section
6 264(c).

7 “(g) NO LIMITATION OF OTHER PRIVILEGES.—
8 Nothing in this section shall be construed to affect privi-
9 leges, including peer review and confidentiality protec-
10 tions, that are otherwise available under Federal or State
11 laws.

12 “(h) NO LIMITATION ON CONTRACTS.—Nothing in
13 this section shall be construed to limit the power of a pro-
14 vider and a patient safety organization, or a patient safety
15 organization and the Agency or any National Patient
16 Safety Database, consistent with the provisions of this Act
17 and other applicable law, to enter into a contract requiring
18 greater confidentiality or delegating authority to make an
19 authorized disclosure.

20 “(i) RELATION TO STATE REPORTING REQUIRE-
21 MENTS.—Nothing in this part shall be construed as pre-
22 empting or otherwise affecting any State law requiring a
23 provider to report information, including information de-
24 scribed in section 921(5)(B), that is not patient safety
25 work product.

1 “(j) CONTINUATION OF PRIVILEGE.—Patient safety
2 work product of an organization that is certified as a pa-
3 tient safety organization shall continue to be privileged
4 and confidential, in accordance with this section, if the or-
5 ganization’s certification is terminated or revoked or if the
6 organization otherwise ceases to qualify as a patient safety
7 organization.

8 “(k) REPORTS ON STRATEGIES TO IMPROVE PA-
9 TIENT SAFETY.—

10 “(1) DRAFT REPORT.—Not later than the date
11 that is 18 months after any National Patient Safety
12 Database is operational, the Secretary, in consulta-
13 tion with the Director, shall prepare a draft report
14 on effective strategies for reducing medical errors
15 and increasing patient safety. The draft report shall
16 include any measure determined appropriate by the
17 Secretary to encourage the appropriate use of such
18 strategies, including use in any federally funded pro-
19 grams. The Secretary shall make the draft report
20 available for public comment and submit the draft
21 report to the Institute of Medicine for review.

22 “(2) FINAL REPORT.—Not later than 1 year
23 after the date described in paragraph (1), the Sec-
24 retary shall submit a final report to the Congress
25 that includes, in an appendix, any findings by the

1 Institute of Medicine concerning research on the
2 strategies discussed in the draft report and any
3 modifications made by the Secretary based on such
4 findings.

5 **“SEC. 923. NATIONAL PATIENT SAFETY DATABASE.**

6 “(a) AUTHORITY.—

7 “(1) IN GENERAL.—In conducting activities
8 under this part, the Secretary shall provide for the
9 establishment and maintenance of a database to re-
10 ceive relevant nonidentifiable patient safety work
11 product, and may designate entities to collect rel-
12 evant nonidentifiable patient safety work product
13 that is voluntarily reported by patient safety organi-
14 zations upon the request of the Secretary. Any data-
15 base established or designated under this paragraph
16 may be referred to as a ‘National Patient Safety
17 Database’.

18 “(2) USE OF INFORMATION.—Information re-
19 ported to any National Patient Safety Database
20 shall be used to analyze national and regional statis-
21 tics, including trends and patterns of health care er-
22 rors. The information resulting from such analyses
23 may be included in the annual quality reports pre-
24 pared under section 913(b)(2).

1 “(3) ADVISORY ROLE.—The Secretary shall
2 provide scientific support to patient safety organiza-
3 tions, including the dissemination of methodologies
4 and evidence-based information related to root
5 causes and quality improvement.

6 “(b) STANDARDS.—In establishing or designating a
7 database under subsection (a)(1), the Secretary shall, in
8 consultation with representatives of patient safety organi-
9 zations, the provider community, and the health informa-
10 tion technology industry, determine common formats for
11 the voluntary reporting of nonidentifiable patient safety
12 work product, including necessary elements, common and
13 consistent definitions, and a standardized computer inter-
14 face for the processing of the work product. To the extent
15 practicable, such standards shall be consistent with the
16 administrative simplification provisions of part C of title
17 XI of the Social Security Act.

18 “(c) CERTAIN METHODOLOGIES FOR COLLECTION.—
19 The Secretary shall ensure that the methodologies for the
20 collection of nonidentifiable patient safety work product
21 for any National Patient Safety Database include the
22 methodologies developed or recommended by the Patient
23 Safety Task Force of the Department of Health and
24 Human Services.

1 “(d) FACILITATION OF INFORMATION EXCHANGE.—
2 To the extent practicable, the Secretary may facilitate the
3 direct link of information between providers and patient
4 safety organizations and between patient safety organiza-
5 tions and any National Patient Safety Database.

6 “(e) RESTRICTION ON TRANSFER.—Only nonidentifi-
7 able information may be transferred to any National Pa-
8 tient Safety Database.

9 **“SEC. 924. TECHNICAL ASSISTANCE.**

10 “(a) IN GENERAL.—The Secretary, acting through
11 the Director, may—

12 “(1) provide technical assistance to patient
13 safety organizations, and to States with reporting
14 systems for health care errors; and

15 “(2) provide guidance on the type of data to be
16 voluntarily submitted to any National Patient Safety
17 Database.

18 “(b) ANNUAL MEETINGS.—Assistance provided
19 under subsection (a) may include annual meetings for pa-
20 tient safety organizations to discuss methodology, commu-
21 nication, information collection, or privacy concerns.

22 **“SEC. 925. CERTIFICATION OF PATIENT SAFETY ORGANIZA-**
23 **TIONS.**

24 “(a) IN GENERAL.—Not later than 6 months after
25 the date of enactment of the Patient Safety and Quality

1 Improvement Act, the Secretary shall establish a process
2 for certifying patient safety organizations.

3 “(b) PROCESS.—The process established under sub-
4 section (a) shall include the following:

5 “(1) Certification of patient safety organiza-
6 tions by the Secretary or by such other national or
7 State governmental organizations as the Secretary
8 determines appropriate.

9 “(2) If the Secretary allows other governmental
10 organizations to certify patient safety organizations
11 under paragraph (1), the Secretary shall establish a
12 process for approving such organizations. Any such
13 approved organization shall conduct certifications
14 and reviews in accordance with this section.

15 “(3) A review of each certification under para-
16 graph (1) (including a review of compliance with
17 each criterion in this section and any related imple-
18 menting standards as determined by the Secretary
19 through rulemaking) not less often than every 3
20 years, as determined by the Secretary.

21 “(4) Revocation of any such certification by the
22 Secretary or other such governmental organization
23 that issued the certification, upon a showing of
24 cause.

1 “(c) CRITERIA.—A patient safety organization must
2 meet the following criteria as conditions of certification:

3 “(1) The mission of the patient safety organiza-
4 tion is to conduct activities that are to improve pa-
5 tient safety and the quality of health care delivery
6 and is not in conflict of interest with the providers
7 that contract with the patient safety organization.

8 “(2) The patient safety organization has appro-
9 priately qualified staff, including licensed or certified
10 medical professionals.

11 “(3) The patient safety organization, within any
12 2-year period, contracts with more than 1 provider
13 for the purpose of receiving and reviewing patient
14 safety work product.

15 “(4) The patient safety organization is not a
16 component of a health insurer or other entity that
17 offers a group health plan or health insurance cov-
18 erage.

19 “(5) The patient safety organization is man-
20 aged, controlled, and operated independently from
21 any provider that contracts with the patient safety
22 organization for reporting patient safety work prod-
23 uct.

24 “(6) To the extent practical and appropriate,
25 the patient safety organization collects patient safety

1 work product from providers in a standardized man-
2 ner that permits valid comparisons of similar cases
3 among similar providers.

4 “(d) ADDITIONAL CRITERIA FOR COMPONENT ORGA-
5 NIZATIONS.—If a patient safety organization is a compo-
6 nent of another organization, the patient safety organiza-
7 tion must, in addition to meeting the criteria described
8 in subsection (c), meet the following criteria as conditions
9 of certification:

10 “(1) The patient safety organization maintains
11 patient safety work product separately from the rest
12 of the organization, and establishes appropriate se-
13 curity measures to maintain the confidentiality of
14 the patient safety work product.

15 “(2) The patient safety organization does not
16 make an unauthorized disclosure under this Act of
17 patient safety work product to the rest of the orga-
18 nization in breach of confidentiality.

19 “(3) The mission of the patient safety organiza-
20 tion does not create a conflict of interest with the
21 rest of the organization.”.

22 (b) AUTHORIZATION OF APPROPRIATIONS.—Section
23 937 of the Public Health Service Act (as redesignated by
24 subsection (a)) is amended by adding at the end the fol-
25 lowing:

1 “(e) PATIENT SAFETY AND QUALITY IMPROVE-
2 MENT.—For the purpose of carrying out part C, there are
3 authorized to be appropriated such sums as may be nec-
4 essary for each of the fiscal years 2010 through 2014.”.

5 **Subtitle B—Liability Protection in**
6 **Good-Faith Reporting**

7 **SEC. 311. LIABILITY PROTECTION FOR HEALTH CARE PRO-**
8 **VIDERS IN GOOD-FAITH REPORTING TO**
9 **STATE MEDICAL BOARDS.**

10 (a) IN GENERAL.—Notwithstanding any other provi-
11 sion of law, no health care provider providing information
12 (including by making a report, filing charges, or pre-
13 senting evidence) to a State medical board regarding the
14 competence or professional conduct of a physician shall
15 be held, by reason of having provided such information,
16 to be liable in damages under any law of the United States
17 or of any State (or political subdivision thereof) unless
18 such information is false and the person providing the in-
19 formation knew that the information was false.

20 (b) ATTORNEY FEES.—If a health care provider es-
21 tablishes in a civil action that the health care provider is
22 not liable in damages because of the application of sub-
23 section (a), the court shall award to the provider any at-
24 torney fees and costs incurred by the provider in estab-
25 lishing the application of subsection (a).

1 (c) DEFINITION.—In this section, the term “State
2 medical board” means a State entity responsible for li-
3 censing physicians or a subdivision of such an entity.

4 **TITLE IV—INSURANCE REFORM**

5 **SEC. 401. UNIFORM STATE REQUIREMENTS REGARDING** 6 **PROPOSED RATE INCREASES.**

7 (a) IN GENERAL.—The Congress intends that each
8 State have in effect laws or regulations providing that—

9 (1) a provider of medical malpractice insurance
10 in the State may not implement any increase in the
11 rate for such insurance that would result in such
12 rate increasing more than a certain percentage, as
13 specified in such laws or regulations, within a cer-
14 tain period of time, as specified in such laws or reg-
15 ulations, unless, before such increase takes effect—

16 (A) the provider submits to an appropriate
17 State agency a description and justification of
18 the rate increase; and

19 (B) such agency makes a determination
20 that the increase is justified; and

21 (2) any determination referred to in paragraph
22 (1)(B) regarding an increase in medical malpractice
23 insurance rates is made pursuant to an administra-
24 tive hearing held by the appropriate State agency;
25 and

1 (3) any individual or institution that is involved
2 in the provision of health care and is licensed by the
3 State to provide such care has standing, in any ad-
4 ministrative proceeding of the State regarding a pro-
5 posed increase in the rate for medical malpractice
6 insurance (including a hearing referred to in para-
7 graph (2)), to challenge such increase.

8 (b) REPORT.—Not later than 2 years after the date
9 of the enactment of this Act, the Secretary of Health and
10 Human Services shall—

11 (1) conduct and complete a survey of the laws
12 and regulations of the States to determine the extent
13 to which the States have in effects laws or regula-
14 tions described in subsection (a); and

15 (2) submit a report to the Congress setting
16 forth the results of the survey, describing such laws
17 and regulations of the various States, and describing
18 the extent of the uniformity of such laws and regula-
19 tions.

20 (c) DEFINITION.—For purposes of this section, the
21 term “State” has the meaning given such term in section
22 105.

23 (d) EFFECTIVE DATE.—This section shall take effect
24 on the date of the enactment of this Act.

1 **SEC. 402. REDUCTION IN PREMIUMS PAID BY PHYSICIANS**
2 **FOR MEDICAL MALPRACTICE INSURANCE**
3 **COVERAGE.**

4 (a) IN GENERAL.—Not later than 180 days after the
5 date of the enactment of this Act, each medical mal-
6 practice liability insurance company shall—

7 (1) develop a reasonable estimate of the annual
8 amount of financial savings that will be achieved by
9 the company as a result of section 101;

10 (2) develop and implement a plan to annually
11 dedicate at least 50 percent of such annual savings
12 to reduce the amount of premiums that the company
13 charges physicians for medical malpractice liability
14 coverage; and

15 (3) submit to the Secretary of Health and
16 Human Services (in this subsection referred to as
17 the “Secretary”) a written certification that the
18 company has complied with paragraphs (1) and (2).

19 (b) REPORTS.—Not later than one year after the date
20 of the enactment of this Act and annually thereafter, each
21 medical malpractice liability insurance company shall sub-
22 mit to the Secretary a report that identifies the percentage
23 by which the company has reduced medical malpractice
24 coverage premiums relative to the date of the enactment
25 of this Act.

1 (c) ENFORCEMENT.—A medical malpractice liability
2 insurance company that violates a provision of this section
3 is liable to the United States for a civil penalty in an
4 amount assessed by the Secretary, not to exceed \$11,000
5 for each such violation. The provisions of paragraphs (3)
6 through (5) of section 303(g) of the Federal Food, Drug,
7 and Cosmetic Act apply to such a civil penalty to the same
8 extent and in the same manner as such paragraphs apply
9 to a civil penalty under such section.

10 (d) DEFINITION.—For purposes of this section, the
11 term “medical malpractice liability insurance company”
12 means an entity in the business of providing an insurance
13 policy under which the entity makes payment in settlement
14 (or partial settlement) of, or in satisfaction of a judgment
15 in, a medical malpractice action or claim.

16 **SEC. 403. EFFECTIVE DATE.**

17 Except as provided in section 401(d), this title shall
18 take effect 1 year after the date of the enactment of this
19 Act.

1 **TITLE V—EXCLUSION OF PHAR-**
2 **MACEUTICALS AND DEVICES**
3 **FROM LIABILITY REFORMS**

4 **SEC. 501. EXCLUSION OF PHARMACEUTICALS AND DE-**
5 **VICES.**

6 For purposes of title I and II of this Act, the manu-
7 facturer or distributor of a pharmaceutical or device is not
8 a health care provider, and health care malpractice does
9 not include responsibility based on products liability.

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