I

109TH CONGRESS
1ST SESSION

H. R. 2657

To provide comprehensive reform regarding medical malpractice.

IN THE HOUSE OF REPRESENTATIVES

MAY 26, 2005

Mr. BAIRD (for himself, Mr. MORAN of Virginia, and Mr. RUPPERSBERGER) 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

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A BILL

To provide comprehensive reform regarding medical malpractice.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Comprehensive Medical Malpractice Reform Act of 2005''.

(b) TABLE OF CONTENTS.—The table of contents of 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. Reduction in premiums paid by physicians for medical malpractice insurance coverage.
Sec. 103. Sanctions for meritless actions and pleadings.
Sec. 104. Performance standards applicable to State medical boards.
Sec. 105. Interstate patient reporting and physician tracking database.
Sec. 106. Report on modification of malpractice procedures relating to mandated care under EMTALA.
Sec. 107. 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.

TITLE I—HEALTH CARE MALPRACTICE LIABILITY REFORM

SEC. 101. CAP ON NON-ECONOMIC DAMAGES.

(a) IN GENERAL.—When an individual is injured or dies as the result of health care malpractice, a person entitled to recover non-economic damages from a health care

provider responsible for that malpractice may not recover such damages, in the aggregate from all such providers, in an amount more than $250,000, adjusted for inflation from 1975 as provided in subsection (b). This limitation applies separately to each person entitled to recover such damages.

(b) ADJUSTMENT FOR INFLATION FROM 1975.—

(1) PUBLICATION BY SECRETARY OF LABOR.—On or about December 1 of each year, the Secretary of Labor shall publish in the Federal Register a dollar amount determined by adjusting the dollar amount specified in subsection (a) according to the adjustments in the Consumer Price Index of the Bureau of Labor Statistics of the Department of Labor for the period beginning on or about October 1, 1975, and ending on or about October 1 of that year.

(2) APPLICABILITY.—For purposes of subsection (a), the dollar amount that applies to a calendar year is the dollar amount published on or about December 1 of the preceding year.

(3) ESTIMATION.—Congress estimates that the dollar amount that would apply to calendar year 2005 would be approximately $878,000, though the dollar amount published under paragraph (1), rather

than the estimation in this paragraph, is to be applied.

(c) APPLICABILITY.—

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

(2) NOT APPLICABLE WHEN STATE BOARD NOT IN COMPLIANCE.—During a period in which a State medical board is not in compliance with the voluntary performance standards developed under section 104 or is failing to submit the information described in paragraphs (2) and (3)(A) of section 105(b) (as determined by the Secretary under section 104 or 105, respectively), the limitation in subsection (a) does not apply to liability arising under the law of that State.

(d) RELATIONSHIP TO STATE LAW.—This section operates on a case-by-case basis to provide a maximum recovery and to prevent State law from providing a recovery above that maximum. It does not prevent State law from providing a recovery below that maximum.

SEC. 102. REDUCTION IN PREMIUMS PAID BY PHYSICIANS FOR MEDICAL MALPRACTICE INSURANCE COVERAGE.

(a) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, each medical malpractice liability insurance company shall—

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

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

(3) submit to the Secretary of Health and Human Services (in this subsection referred to as the ''Secretary'') a written certification that the company has complied with subparagraphs (A) and (B).

(b) REPORTS.—Not later than one year after the date of the enactment of this Act and annually thereafter, each medical malpractice liability insurance company shall submit to the Secretary a report that identifies the percentage by which the company has reduced medical malpractice coverage premiums relative to the date of the enactment of this Act.

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

(d) DEFINITION.—For purposes of this subsection, the term ''medical malpractice liability insurance company'' means an entity in the business of providing an insurance policy under which the entity makes payment in settlement (or partial settlement) of, or in satisfaction of a judgment in, a medical malpractice action or claim.

SEC. 103. SANCTIONS FOR MERITLESS ACTIONS AND PLEADINGS.

(a) SIGNATURE REQUIRED.—Every pleading, written motion, and other paper in any medical malpractice action shall be signed by at least 1 attorney of record in the attorney's individual name, or, if the party is not represented by an attorney, shall be signed by the party. Each paper shall state the signer's address and telephone number, if any. An unsigned paper shall be stricken unless

omission of the signature is corrected promptly after being called to the attention of the attorney or party.

(b) CERTIFICATE OF MERIT.—

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

(A) it is not being presented for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation;

(B) the claims and other legal contentions therein are warranted by existing law or by a nonfrivolous argument for the extension, modification, or reversal of existing law or the establishment of new law; and

(C) the allegations and other factual contentions have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation and discovery.

(2) PAPER CONSIDERED TO BE A CERTIFICATION.—By presenting to the court (whether by

signing, filing, submitting, or later advocating) a pleading, written motion, or other paper, an attorney or unrepresented party is certifying that to the best of the person's knowledge, information and belief, formed after an inquiry reasonable under the circumstances—

(A) it is not being presented for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation;

(B) the claims, defenses, and other legal contentions therein are warranted by existing law or by a nonfrivolous argument for the extension, modification, or reversal of existing law or the establishment of new law; and

(C) the allegations and other factual contentions have evidentiary support or, if specifically so identified, are reasonable based on a lack of information or belief.

(c) MANDATORY SANCTIONS.—

(1) FIRST VIOLATION.—If, after notice and a reasonable opportunity to respond, a court, upon motion or upon its own initiative, determines that subsection (b) has been violated, the court shall find each attorney or party in violation in contempt of

court and shall require the payment of costs and attorneys fees. The court may also impose additional appropriate sanctions, such as striking the pleadings, dismissing the suit, and sanctions plus interest, upon the person in violation, or upon both such person and such person's attorney or client (as the case may be).

(2) SECOND VIOLATION.—If, after notice and a reasonable opportunity to respond, a court, upon motion or upon its own initiative, determines that subsection (b) has been violated and that the attorney or party with respect to which the determination was made has committed one previous violation of subsection (b) before this or any other court, the court shall find each such attorney or party in contempt of court and shall require the payment of costs and attorneys fees, and require such person in violation (or both such person and such person's attorney or client (as the case may be)) to pay a monetary fine. The court may also impose additional appropriate sanctions, such as striking the pleadings, dismissing the suit and sanctions plus interest, upon such person in violation, or upon both such person and such person's attorney or client (as the case may be).

(3) THIRD AND SUBSEQUENT VIOLATIONS.—If, after notice and a reasonable opportunity to respond, a court, upon motion or upon its own initiative, determines that subsection (b) has been violated and that the attorney or party with respect to which the determination was made has committed more than one previous violation of subsection (b) before this or any other court, the court shall find each such attorney or party in contempt of court, refer each such attorney to one or more appropriate State bar associations for disciplinary proceedings, require the payment of costs and attorneys fees, and require such person in violation (or both such person and such person's attorney or client (as the case may be)) to pay a monetary fine. The court may also impose additional appropriate sanctions, such as striking the pleadings, dismissing the suit, and sanctions plus interest, upon such person in violation, or upon both such person and such person's attorney or client (as the case may be).

(d) CENTRAL TRACKING DATABASE.—The Attorney General shall establish and maintain a central tracking database reporting system to which courts are to report violations of subsection (b). The database shall include all identifying information with respect to the attorney or the

party (if not represented by an attorney). The Attorney General shall permit courts to consult the database to determine the extent to which an attorney or party has violated subsection (b) previously.

SEC. 104. PERFORMANCE STANDARDS APPLICABLE TO STATE MEDICAL BOARDS.

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

(b) CONTENTS.—In developing performance standards under this section, the Secretary shall include standards to require the following:

(1) Processing patient complaints within a specified limited period of time.

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

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

(4) Ensuring that staff are qualified.

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

(A) Each physician's education and training.

(B) Each physician's medical specialties.

(C) For each physician a description of medical malpractice claims paid, hospital disciplinary actions taken, criminal convictions occurring, and disciplinary actions taken by the State medical board, within the previous 10 years.

(D) At the option of a State medical board, each physician's professional demographics (such as business address, insurance plan and hospital affiliations, and available translation services), professional or community awards received, and research or other professional publications.

(6) Issuing an annual report that includes aggregate disciplinary statistics, including—

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

(B) with respect to physicians, statistics on the number and type of complaints received, disaggregated by the medical school and graduate medical education program completed by the physicians involved.

(7) Such other issues as the Secretary determines appropriate.

(c) DETERMINATION REQUIRED.—For the period beginning 3 years after the date of the enactment of this Act, the Secretary shall determine whether the State medical board of each State is in compliance with the voluntary performance standards developed under subsection (a).

(d) DETERMINATION OF NONCOMPLIANCE.—Before making a determination under subsection (c) that a State medical board is not in compliance with the voluntary performance standards developed under subsection (a), the Secretary shall—

(1) propose a determination of noncompliance;

(2) identify the reasons for such noncompliance; and

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

(e) REVISION OF DETERMINATIONS.—The Secretary shall periodically review and, as necessary, revise determinations of compliance and noncompliance under subsection (c).

(f) REPORT BY SECRETARY.—Not later than 5 years after the date of the enactment of this Act, and annually thereafter, the Secretary shall submit a report to the Con-

gress on the activities of the Secretary under this section, including a listing of the State medical boards determined by the Secretary to be in compliance or not in compliance with the voluntary standards developed under subsection (a).

SEC. 105. INTERSTATE PATIENT REPORTING AND PHYSICIAN TRACKING DATABASE.

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

(b) DATABASE CONTENTS.—

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

(A) State medical boards; and

(B) patients.

(2) SUBMISSIONS BY STATE MEDICAL BOARDS.—The database shall encourage the State medical board of each State to submit, with respect to each physician licensed by the State, the following:

(A) The physician's identity.

(B) The physician's education and training.

(C) The physician's medical specialties.

(D) A description of medical malpractice claims paid, hospital disciplinary actions taken, criminal convictions occurring, and disciplinary actions taken by the State medical board, within the previous 10 years.

(3) PATIENT COMPLAINTS.—The database shall—

(A) encourage the State medical board of each State to submit, with respect to each physician licensed by the State, a description of pending patient complaints about the physician; and

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

(c) AVAILABILITY OF INFORMATION.—

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

(2) PATIENT COMPLAINTS.—

(A) CONFIDENTIALITY.—Any patient complaint about a physician submitted to the database shall be kept confidential and shall not be subject to disclosure under section 552 of title

5, United States Code. Except as provided in subparagraph (B), the database may disclose information derived from such a patient complaint only if the information is not individually identifiable.

(B) TRACKING PATIENT COMPLAINTS.—The database shall—

(i) assign a tracking number to each patient complaint submitted to the database pursuant to subsection (b)(3);

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

(iii) allow the patient making any complaint submitted to the database pursuant to subsection (b)(3) to track the status of the complaint, including by means of the Internet and a toll-free telephone number.

(C) ANALYSIS.—Subject to subparagraph (A), the Secretary of Health and Human Services shall conduct analysis of patient complaints submitted to the database, including complaints that do not result in disciplinary action, and

use the data and conclusions derived from such analysis to provide timely public health safety information to health care consumers and practitioners.

(d) TECHNICAL ASSISTANCE.—The Secretary of Health and Human Services shall provide technical assistance to States to facilitate the exchange of information between State medical boards and the database.

(e) DETERMINATION REQUIRED.—For the period beginning 3 years after the date of the enactment of this Act, the Secretary shall determine whether the State medical board of each State is failing to submit the information described in subsections (b)(2) and (b)(3)(A).

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

(1) propose a determination of noncompliance;

(2) identify the reasons for such noncompliance; and

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

(g) REVISION OF DETERMINATIONS.—The Secretary shall periodically review and, as necessary, revise deter-

minations of compliance and noncompliance under subsection (e).

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

(1) conduct an assessment of the database, including an assessment of the value of the database to patients and the effect of the database on physicians; and

(2) submit a report to the Congress on the results of the assessment, including any recommendations for improvement of the database.

SEC. 106. REPORT ON MODIFICATION OF MALPRACTICE PROCEDURES RELATING TO MANDATED CARE UNDER EMTALA.

(a) ANALYSIS.—The Secretary of Health and Human Services shall conduct a study on alternatives to the present medical malpractice litigation and compensation process in resolving health care malpractice claims arising out of a screening examination or treatment provided to comply with the requirements of section 1867 of the Social Security Act (42 U.S.C. 1395dd), commonly referred to as EMTALA.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall submit to the Congress a report on the study conducted under

subsection (a). The Secretary shall include in such report alternatives to medical malpractice litigation and compensation, including medical liability insurance premium tax credits, no-fault medical liability insurance, and medical malpractice health courts.

SEC. 107. DEFINITIONS.

In this title:

(1) The term ''State medical board'' means a State entity responsible for licensing physicians or a subdivision of such an entity.

(2) The term ''health care malpractice'' means the negligence or other fault of a health care provider.

(3) The term ''health care provider'' means—

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

(B) any entity that is engaged in the delivery of health care services in a State and that, if it is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State, is so licensed.

(4) The term ''State'' includes the District of Columbia, the Commonwealth of Puerto Rico, and other territories and possessions of the United States.

TITLE II—HEALTH CARE MALPRACTICE LIABILITY MEDIATION PROGRAMS

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

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

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

(c) RUSH MODEL.—For purposes of this section, a program is based on the Rush model if the program satisfies each of the following:

(1) Participation by the parties in the mediation is voluntary.

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

(A) states that the parties—

(i) will not request or subpoena the mediator to testify or produce any documents or other information in any proceeding related to the mediation; and

(ii) will defend and indemnify the mediator in connection with any summons or subpoena arising out of the mediation proceeding;

(B) provides for confidentiality of the mediation proceedings; and

(C) states that any apology or expression of remorse by a health care provider or other entity at any time during the mediation proceedings will be kept confidential and will not be used in any subsequent legal proceeding.

(3) The program is similar to the mediation program carried out as of January 1, 2005, at Rush-Presbyterian-St. Luke's Medical Center in Chicago, Illinois.

(d) DEFINITIONS.—In this section:

(1) The term ''health care entity'' means an entity covered by section 105(3)(B).

(2) The term ''health care malpractice'' has the meaning given such term in section 105.

(3) The term ''State'' has the meaning given such term in section 105.

SEC. 202. TRAINING AND ASSISTANCE FOR MEDIATION PROGRAMS.

From amounts made available to carry out this section, the Attorney General shall carry out a program under which the Attorney General provides training and assistance to recipients of grant amounts under section 201 to carry out mediation programs under that section.

SEC. 203. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to the Attorney General such sums as may be necessary to carry out sections 201 and 202.

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.

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

(1) in section 912(c), by inserting ", in accordance with part C," after "The Director shall";

(2) by redesignating part C as part D;

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

(4) in section 938(1) (as so redesignated), by striking "921" and inserting "931"; and

(5) by inserting after part B the following:

"PART C—PATIENT SAFETY IMPROVEMENT

"SEC. 921. DEFINITIONS.

"In this part:

"(1) IDENTIFIABLE INFORMATION.—The term 'identifiable information' means information that is presented in a form and manner that allows the identification of any provider, patient, or reporter of patient safety work product. With respect to patients, such information includes any individually identifiable health information as that term is defined in the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033).

"(2) NONIDENTIFIABLE INFORMATION.—The term 'nonidentifiable information' means information that is presented in a form and manner that

prevents the identification of any provider, patient, or reporter of patient safety work product. With respect to patients, such information must be de-identified consistent with the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033).

''(3) PATIENT SAFETY EVALUATION SYSTEM.—The term 'patient safety evaluation system' means a process that involves the collection, management, or analysis of information for submission to or by a patient safety organization.

''(4) PATIENT SAFETY ORGANIZATION.—The term 'patient safety organization' means a private or public organization or component thereof that is certified, through a process to be determined by the Secretary under section 925, to perform each of the following activities:

''(A) The conduct, as the organization or component's primary activity, of efforts to improve patient safety and the quality of health care delivery.

''(B) The collection and analysis of patient safety work product that is submitted by providers.

''(C) The development and dissemination of evidence-based information to providers with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

''(D) The utilization of patient safety work product to carry out activities limited to those described under this paragraph and for the purposes of encouraging a culture of safety and of providing direct feedback and assistance to providers to effectively minimize patient risk.

''(E) The maintenance of confidentiality with respect to identifiable information.

''(F) The provision of appropriate security measures with respect to patient safety work product.

''(G) The submission of nonidentifiable information to the Agency consistent with standards established by the Secretary under section 923(b) for any National Patient Safety Database.

''(5) PATIENT SAFETY WORK PRODUCT.—

''(A) The term 'patient safety work product' means any document or communication (including any information, report, record,

memorandum, analysis, deliberative work, statement, or root cause analysis) that—

"(i) except as provided in subparagraph (B), is developed by a provider for the purpose of reporting to a patient safety organization, and is reported to a patient safety organization;

"(ii) is created by a patient safety organization; or

"(iii) would reveal the deliberations or analytic process of a patient safety evaluation system (as defined in paragraph (3)).

"(B)(i) Patient safety work product described in subparagraph (A)(i)—

"(I) does not include any separate information described in clause (ii); and

"(II) shall not be construed to include such separate information merely by reason of inclusion of a copy of the document or communication involved in a submission to, or the fact of submission of such a copy to, a patient safety organization.

"(ii) Separate information described in this clause is a document or communication (including a patient's medical record or any other pa-

tient or hospital record) that is developed or maintained, or exists, separately from any patient safety evaluation system.

''(C) Information available from sources other than a patient safety work product under this section may be discovered or admitted in a civil or administrative proceeding, if discoverable or admissible under applicable law.

''(6) PROVIDER.—The term 'provider' means—

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

''(i) a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, and hospice program;

''(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified nurse midwife, nurse anesthetist, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, or other individual health care practitioner;

''(iii) a pharmacist; and

''(iv) a renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long-term care facility, behavioral health residential treatment facility, clinical laboratory, or community health center; or

''(B) any other person or entity specified in regulations by the Secretary after public notice and comment.

"SEC. 922. PRIVILEGE FOR PATIENT SAFETY WORK PRODUCT.

''(a) PRIVILEGE.—Notwithstanding any other provision of law and subject to subsection (c), patient safety work product shall not be—

''(1) subject to a civil or administrative subpoena or order;

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

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

''(4) required to be admitted as evidence or otherwise disclosed in any State or Federal civil or administrative proceeding; or

''(5) if the patient safety work product is identifiable information and is received by a national accreditation organization in its capacity as a patient safety organization—

''(A) used by a national accreditation organization in an accreditation action against the provider that reported the information;

''(B) shared by such organization with its survey team; or

''(C) required as a condition of accreditation by a national accreditation association.

''(b) REPORTER PROTECTION.—

''(1) IN GENERAL.—A provider may not use against an individual in an adverse employment action described in paragraph (2) the fact that the individual in good faith reported information—

''(A) to the provider with the intention of having the information reported to a patient safety organization; or

''(B) directly to a patient safety organization.

''(2) ADVERSE EMPLOYMENT ACTION.—For purposes of this subsection, an 'adverse employment action' includes—

''(A) the failure to promote an individual or provide any other employment-related benefit for which the individual would otherwise be eligible;

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

''(C) a personnel action that is adverse to the individual concerned.

''(3) REMEDIES.—Any provider that violates this subsection shall be subject to a civil monetary penalty of not more than $20,000 for each such violation involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A of the Social Security Act are imposed and collected.

''(c) DISCLOSURES.—Nothing in this section prohibits any of the following disclosures:

''(1) Voluntary disclosure of nonidentifiable information.

''(2) Voluntary disclosure of identifiable information by a provider or patient safety organization, if such disclosure—

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

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

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

''(3) Disclosure as required by law by a provider to the Food and Drug Administration, or on a voluntary basis by a provider to a federally established patient safety program, with respect to an Administration-regulated product or activity for which that entity has responsibility, for the purposes of activities related to the quality, safety, or effectiveness of such Administration-regulated product or activity.

''(4) Disclosures of patient safety work product in accordance with this part by a provider to a patient safety organization.

''(d) EFFECT OF TRANSFER, DISCLOSURE.—The following shall not be treated as a waiver of any privilege or protection established under this part:

''(1) The transfer of any patient safety work product between a provider and a patient safety organization.

''(2) Disclosure of patient safety work product as described in subsection (c).

''(3) The unauthorized disclosure of patient safety work product.

''(e) PENALTY.—

''(1) PROHIBITION.—Except as provided in this part, and subject to paragraphs (2) and (4), it shall be unlawful for any person to disclose patient safety work product in violation of this section, if such disclosure constitutes a negligent or knowing breach of confidentiality.

''(2) RELATION TO HIPAA.—The penalty under paragraph (3) for a disclosure in violation of paragraph (1) does not apply if the person would be subject to a penalty under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033), or any regulation promulgated under such section, for the same disclosure.

''(3) AMOUNT.—Any person who violates paragraph (1) shall be subject to a civil monetary penalty of not more than $10,000 for each such violation involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under

subsection (a) of section 1128A of the Social Security Act are imposed and collected.

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

''(f) RELATION TO HIPAA.—

''(1) IN GENERAL.—For purposes of applying the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033)—

''(A) patient safety organizations shall be treated as business associates; and

''(B) activities of such organizations described in section 921(4) in relation to a provider are deemed to be health care operations (as defined in such regulations) of the provider.

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

''(g) NO LIMITATION OF OTHER PRIVILEGES.—Nothing in this section shall be construed to affect privileges, including peer review and confidentiality protec-

tions, that are otherwise available under Federal or State laws.

''(h) NO LIMITATION ON CONTRACTS.—Nothing in this section shall be construed to limit the power of a provider and a patient safety organization, or a patient safety organization and the Agency or any National Patient Safety Database, consistent with the provisions of this Act and other applicable law, to enter into a contract requiring greater confidentiality or delegating authority to make an authorized disclosure.

''(i) RELATION TO STATE REPORTING REQUIREMENTS.—Nothing in this part shall be construed as preempting or otherwise affecting any State law requiring a provider to report information, including information described in section 921(5)(B), that is not patient safety work product.

''(j) CONTINUATION OF PRIVILEGE.—Patient safety work product of an organization that is certified as a patient safety organization shall continue to be privileged and confidential, in accordance with this section, if the organization's certification is terminated or revoked or if the organization otherwise ceases to qualify as a patient safety organization.

''(k) REPORTS ON STRATEGIES TO IMPROVE PATIENT SAFETY.—

''(1) DRAFT REPORT.—Not later than the date that is 18 months after any National Patient Safety Database is operational, the Secretary, in consultation with the Director, shall prepare a draft report on effective strategies for reducing medical errors and increasing patient safety. The draft report shall include any measure determined appropriate by the Secretary to encourage the appropriate use of such strategies, including use in any federally funded programs. The Secretary shall make the draft report available for public comment and submit the draft report to the Institute of Medicine for review.

''(2) FINAL REPORT.—Not later than 1 year after the date described in paragraph (1), the Secretary shall submit a final report to the Congress that includes, in an appendix, any findings by the Institute of Medicine concerning research on the strategies discussed in the draft report and any modifications made by the Secretary based on such findings.

''SEC. 923. NATIONAL PATIENT SAFETY DATABASE.

''(a) AUTHORITY.—

''(1) IN GENERAL.—In conducting activities under this part, the Secretary shall provide for the establishment and maintenance of a database to re-

ceive relevant nonidentifiable patient safety work product, and may designate entities to collect relevant nonidentifiable patient safety work product that is voluntarily reported by patient safety organizations upon the request of the Secretary. Any database established or designated under this paragraph may be referred to as a 'National Patient Safety Database'.

''(2) USE OF INFORMATION.—Information reported to any National Patient Safety Database shall be used to analyze national and regional statistics, including trends and patterns of health care errors. The information resulting from such analyses may be included in the annual quality reports prepared under section 913(b)(2).

''(3) ADVISORY ROLE.—The Secretary shall provide scientific support to patient safety organizations, including the dissemination of methodologies and evidence-based information related to root causes and quality improvement.

''(b) STANDARDS.—In establishing or designating a database under subsection (a)(1), the Secretary shall, in consultation with representatives of patient safety organizations, the provider community, and the health information technology industry, determine common formats for

the voluntary reporting of nonidentifiable patient safety work product, including necessary elements, common and consistent definitions, and a standardized computer interface for the processing of the work product. To the extent practicable, such standards shall be consistent with the administrative simplification provisions of part C of title XI of the Social Security Act.

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

''(d) FACILITATION OF INFORMATION EXCHANGE.—To the extent practicable, the Secretary may facilitate the direct link of information between providers and patient safety organizations and between patient safety organizations and any National Patient Safety Database.

''(e) RESTRICTION ON TRANSFER.—Only nonidentifiable information may be transferred to any National Patient Safety Database.

''SEC. 924. TECHNICAL ASSISTANCE.

''(a) IN GENERAL.—The Secretary, acting through the Director, may—

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

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

''(b) ANNUAL MEETINGS.—Assistance provided under subsection (a) may include annual meetings for patient safety organizations to discuss methodology, communication, information collection, or privacy concerns.

''SEC. 925. CERTIFICATION OF PATIENT SAFETY ORGANIZATIONS.

''(a) IN GENERAL.—Not later than 6 months after the date of enactment of the Patient Safety and Quality Improvement Act, the Secretary shall establish a process for certifying patient safety organizations.

''(b) PROCESS.—The process established under subsection (a) shall include the following:

''(1) Certification of patient safety organizations by the Secretary or by such other national or State governmental organizations as the Secretary determines appropriate.

''(2) If the Secretary allows other governmental organizations to certify patient safety organizations under paragraph (1), the Secretary shall establish a

process for approving such organizations. Any such approved organization shall conduct certifications and reviews in accordance with this section.

''(3) A review of each certification under paragraph (1) (including a review of compliance with each criterion in this section and any related implementing standards as determined by the Secretary through rulemaking) not less often than every 3 years, as determined by the Secretary.

''(4) Revocation of any such certification by the Secretary or other such governmental organization that issued the certification, upon a showing of cause.

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

''(1) The mission of the patient safety organization is to conduct activities that are to improve patient safety and the quality of health care delivery and is not in conflict of interest with the providers that contract with the patient safety organization.

''(2) The patient safety organization has appropriately qualified staff, including licensed or certified medical professionals.

''(3) The patient safety organization, within any 2 year period, contracts with more than 1 provider

for the purpose of receiving and reviewing patient safety work product.

''(4) The patient safety organization is not a component of a health insurer or other entity that offers a group health plan or health insurance coverage.

''(5) The patient safety organization is managed, controlled, and operated independently from any provider that contracts with the patient safety organization for reporting patient safety work product.

''(6) To the extent practical and appropriate, the patient safety organization collects patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers.

''(d) ADDITIONAL CRITERIA FOR COMPONENT ORGANIZATIONS.—If a patient safety organization is a component of another organization, the patient safety organization must, in addition to meeting the criteria described in subsection (c), meet the following criteria as conditions of certification:

''(1) The patient safety organization maintains patient safety work product separately from the rest of the organization, and establishes appropriate se-

curity measures to maintain the confidentiality of the patient safety work product.

''(2) The patient safety organization does not make an unauthorized disclosure under this Act of patient safety work product to the rest of the organization in breach of confidentiality.

''(3) The mission of the patient safety organization does not create a conflict of interest with the rest of the organization.''.

(b) AUTHORIZATION OF APPROPRIATIONS.—Section 937 of the Public Health Service Act (as redesignated by subsection (a)) is amended by adding at the end the following:

''(e) PATIENT SAFETY AND QUALITY IMPROVEMENT.—For the purpose of carrying out part C, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2006 through 2010.''.

Subtitle B—Liability Protection in Good-faith Reporting

SEC. 311. LIABILITY PROTECTION FOR HEALTH CARE PROVIDERS IN GOOD-FAITH REPORTING TO STATE MEDICAL BOARDS.

(a) IN GENERAL.—Notwithstanding any other provision of law, no health care provider providing information (including by making a report, filing charges, or pre-

senting evidence) to a State medical board regarding the competence or professional conduct of a physician shall be held, by reason of having provided such information, to be liable in damages under any law of the United States or of any State (or political subdivision thereof) unless such information is false and the person providing the information knew that the information was false.

(b) ATTORNEY FEES.—If a health care provider establishes in a civil action that the health care provider is not liable in damages because of the application of subsection (a), the court shall award to the provider any attorney fees and costs incurred by the provider in establishing the application of subsection (a).

(c) DEFINITION.—In this section, the term ''State medical board'' means a State entity responsible for licensing physicians or a subdivision of such an entity.

TITLE IV—INSURANCE REFORM

SEC. 401. UNIFORM STATE REQUIREMENTS REGARDING PROPOSED RATE INCREASES.

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

(1) a provider of medical malpractice insurance in the State may not implement any increase in the rate for such insurance that would result in such rate increasing more than a certain percentage, as

specified in such laws or regulations, within a certain period of time, as specified in such laws or regulations, unless, before such increase takes effect—

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

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

(2) any determination referred to in paragraph (1)(B) regarding an increase in medical malpractice insurance rates is made pursuant to an administrative hearing held by the appropriate State agency; and

(3) any individual or institution that is involved in the provision of health care and is licensed by the State to provide such care has standing, in any administrative proceeding of the State regarding a proposed increase in the rate for medical malpractice insurance (including a hearing referred to in paragraph (2)), to challenge such increase.

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

(1) conduct and complete a survey of the laws and regulations of the States to determine the extent

to which the States have in effects laws or regulations described in subsection (a); and

(2) submit a report to the Congress setting forth the results of the survey, describing such laws and regulations of the various States, and describing the extent of the uniformity of such laws and regulations.

(c) DEFINITION.—For purposes of this section, the term ''State'' has the meaning given such term in section 105.

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

SEC. 402. REDUCTION IN PREMIUMS PAID BY PHYSICIANS FOR MEDICAL MALPRACTICE INSURANCE COVERAGE.

(a) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, each medical malpractice liability insurance company shall—

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

(2) develop and implement a plan to annually dedicate at least 50 percent of such annual savings to reduce the amount of premiums that the company

charges physicians for medical malpractice liability coverage; and

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

(b) REPORTS.—Not later than one year after the date of the enactment of this Act and annually thereafter, each medical malpractice liability insurance company shall submit to the Secretary a report that identifies the percentage by which the company has reduced medical malpractice coverage premiums relative to the date of the enactment of this Act.

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

(d) DEFINITION.—For purposes of this section, the term ''medical malpractice liability insurance company'' means an entity in the business of providing an insurance

policy under which the entity makes payment in settlement (or partial settlement) of, or in satisfaction of a judgment in, a medical malpractice action or claim.

SEC. 403. EFFECTIVE DATE.

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

TITLE V—EXCLUSION OF PHARMACEUTICALS AND DEVICES FROM LIABILITY REFORMS

SEC. 501. EXCLUSION OF PHARMACEUTICALS AND DEVICES.

For purposes of title I and II of this Act, the manufacturer or distributor of a pharmaceutical or device is not a health care provider, and health care malpractice does not include responsibility based on products liability.

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