108TH CONGRESS
1ST SESSION

S. 1374

To provide health care professionals with immediate relief from increased medical malpractice insurance costs and to deal with the root causes of the current medical malpractice insurance crisis.

IN THE SENATE OF THE UNITED STATES

JULY 8, 2003

Mr. DURBIN (for himself and Mr. GRAHAM of South Carolina) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To provide health care professionals with immediate relief from increased medical malpractice insurance costs and to deal with the root causes of the current medical malpractice insurance crisis.

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 ''Better HEALTH Act of 2003''.

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

TITLE I—ENHANCING PATIENT ACCESS TO CARE THROUGH DIRECT ASSISTANCE

SEC. 101. GRANTS AND CONTRACTS REGARDING HEALTH CARE PROFESSIONAL SHORTAGES.

Subpart I of part D of title III of the Public Health Service Act (42 U.S.C. 254b et seq.) is amended by adding at the end the following:

"SEC. 330L. HEALTH CARE PROFESSIONAL SHORTAGES RESULTING FROM COSTS OF MEDICAL MALPRACTICE INSURANCE.

''(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make awards of grants or contracts in accordance with this section for geographic areas that, as determined by the Secretary, have a shortage of one or more types of health care professionals as a result of the professional's making the decision to cease or curtail providing health care services in the geographic areas because of the costs of maintaining medical malpractice insurance.

''(b) RECIPIENTS OF AWARDS; EXPENDITURE.—In accordance with such criteria as the Secretary may establish:

''(1) Awards under subsection (a) may be made to health care professionals who agree to provide health care services (or to continue providing health care services, as the case may be) in geographic areas described in such subsection for the period during which payments under the awards are made to the health care professionals.

''(2) Health care professionals who receive such awards may expend the awards to assist the professionals with the costs of maintaining medical malpractice insurance for providing health care services in the geographic area for which the award is made.

''(c) DEFINITION.—For purposes of this section, the term 'health care professionals' means health care professionals, and organizations that provide health care services (including hospitals, clinics, and group practices), that meet applicable legal requirements to provide the health care services involved.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $10,000,000 for fiscal year 2004, and such sums as may be necessary for each subsequent fiscal year.''.

SEC. 102. HEALTH CARE PROFESSIONAL ASSIGNMENTS TO TRAUMA CENTERS THROUGH NATIONAL HEALTH SERVICE CORPS.

Section 338H of the Public Health Service Act (42 U.S.C. 254q) is amended by adding at the end the following:

''(d) TRAUMA CENTERS; SEPARATE AUTHORIZATION REGARDING SHORTAGES RESULTING FROM COSTS OF MEDICAL MALPRACTICE INSURANCE.—

''(1) IN GENERAL.—For the purpose of assigning Corps surgeons, obstetricians/gynecologists, and other health care professionals to trauma centers in health care professional shortage areas described in paragraph (2), there are authorized to be appropriated $10,000,000 for fiscal year 2004, and such sums as may be necessary for each of the fiscal years 2005 through 2007. Such authorization is in addition to any other authorization of appropriations that is available for such purpose.

''(2) DESCRIPTION OF AREAS.—A health professional shortage area referred to in paragraph (1) is such an area in which, as determined by the Secretary, a medical facility in the area has lost its designation as a trauma center or as a particular level of trauma center, or is at significant risk of losing such a designation, as a result of one or more sur-

geons, obstetricians/gynecologists, or other health care professionals making the decision to cease or curtail practicing at the facility because of the costs of maintaining medical malpractice insurance. For purposes of paragraph (1) the term 'trauma center' includes such a medical facility, the Secretary may adjust the criteria for designation as a health professional shortage area to the extent necessary to make funds appropriated under paragraph (1) available with respect to any medical facility to ensure that the facility does not lose any such designation as a result of such decisions by health care professionals.''.

TITLE II—INCENTIVES FOR PARTICIPATION IN MEDICARE, MEDICAID, AND SCHIP AND FINANCIAL ASSISTANCE FOR HEALTH CARE PROFESSIONALS

SEC. 201. INCENTIVES FOR PARTICIPATION IN MEDICARE, MEDICAID, AND SCHIP.

(a) IN GENERAL.—Punitive damages may not be awarded in a medical malpractice action against a qualified health professional, except upon proof of an intentional act, such as voluntary intoxication or impairment

by a physician, sexual abuse or misconduct, assault and battery, or falsification of records.

(b) CONSTRUCTION.—Subsection (a) shall not be construed to establish a cause of action for punitive damages and shall not preempt or supersede any other Federal or State law with respect to punitive damages.

(c) DEFINITIONS.—In this section:

(1) HEALTH CARE PROFESSIONAL.—The term ''health care professional'' means any individual who provides health care services in a State and who is required by the laws or regulations of the State to be licensed or certified by the State to provide such services in the State.

(2) MEDICAL MALPRACTICE ACTION.—The term ''medical malpractice action'' means an action in any Federal or State court or against a qualified health care professional that—

(A) arises under the law of the State involved;

(B) alleges the failure of such health care professional to adhere to the relevant professional standard of care for the service and specialty involved;

(C) alleges death or injury proximately caused by such failure; and

(D) seeks monetary damages, whether compensatory or punitive, as relief for such death or injury.

(3) QUALIFIED HEALTH CARE PROFESSIONAL.—The term ''qualified health care professional'' means a health care professional—

(A) who is licensed in the State in which such professional practices; and

(B) 25 percent or more of the patients of whom receive benefits under title XVIII, XIX, and XXI of the Social Security Act (42 U.S.C. 1395, 1396, and 1397aa et seq.).

SEC. 202. CREDIT FOR QUALIFIED EXPENDITURES FOR MEDICAL PROFESSIONAL MALPRACTICE INSURANCE.

(a) IN GENERAL.—Subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 (relating to business tax credits) is amended by adding at the end the following:

''SEC. 45G. CREDIT FOR EXPENDITURES FOR MEDICAL PROFESSIONAL MALPRACTICE INSURANCE.

''(a) GENERAL RULE.—For purposes of section 38, in the case of a taxpayer which is an eligible person, the medical malpractice insurance expenditure tax credit determined under this section for a covered year shall equal

the applicable percentage of the qualified medical malpractice insurance expenditures incurred by an eligible person during the covered year.

''(b) APPLICABLE PERCENTAGE.—For purposes of subsection (a), the applicable percentage is—

''(1) in the case of an eligible person described in subsection (c)(2)(A), 20 percent,

''(2) in the case of an eligible person described in subsection (c)(2)(B), 10 percent, and

''(3) in the case of an eligible person described in subsection (c)(2)(C), 15 percent.

''(c) DEFINITIONS.—In this section:

''(1) COVERED YEAR.—The term 'covered year' means taxable years beginning in 2004 and 2005.

''(2) ELIGIBLE PERSON.—The term 'eligible person' means—

''(A) any physician (as defined in section 213(d)(4)) who practices in any surgical specialty or subspecialty, emergency medicine, obstetrics, anesthesiology or who does intervention work which is reflected in medical malpractice insurance expenditures,

''(B) any physician (as so defined) who practices in general medicine, allergy, dermatology, or pathology, and

''(C) any hospital or clinic,

which meets applicable legal requirements to provide the health care services involved.

''(3) QUALIFIED MEDICAL MALPRACTICE INSURANCE EXPENDITURE.—The term 'qualified medical malpractice insurance expenditure' means so much of any professional insurance premium, surcharge, payment or other cost or expense required as a condition of State licensure which is incurred by an eligible person in a covered year for the sole purpose of providing or furnishing general medical malpractice liability insurance for such eligible person as does not exceed twice the Statewide average of such costs for similarly situated eligible persons.

''(d) SPECIAL RULES.—

''(1) IN GENERAL.—Except as provided in paragraph (2), the credit determined under this section shall be claimed by the eligible person incurring the qualified medical malpractice insurance expenditure.

''(2) CERTIFICATION.—Each State, through its board of medical licensure and State board (or agency) regulating insurance, annually shall provide such information to the Secretary of Health and Human Services as is necessary to permit the Secretary to calculate average costs for purposes of subsection

(c)(3) and to certify such average costs (rounded to the nearest whole dollar) to the Secretary of the Treasury on or before the 15th day of November of each year.

''(e) EFFECTIVE DATE.—This section shall apply to qualified medical malpractice expenditures incurred after December 31, 2002.''.

(b) CREDIT MADE PART OF GENERAL BUSINESS CREDIT.—Section 38(b) of the Internal Revenue Code of 1986 (relating to current year business credit) is amended by striking ''plus'' at the end of paragraph (14), by striking the period at the end of paragraph (15) and inserting '', plus'', and by adding at the end the following new paragraph:

''(16) the medical malpractice insurance expenditure tax credit determined under section 45G(a).''.

(c) LIMITATION ON CARRYBACK.—Section 39(d) of the Internal Revenue Code of 1986 (relating to transition rules) is amended by adding at the end the following new paragraph:

''(11) NO CARRYBACK OF MEDICAL MALPRACTICE INSURANCE EXPENDITURE TAX CREDIT BEFORE EFFECTIVE DATE.—No portion of the unused business credit for any taxable year which is

attributable to the credit determined under section 45G may be carried back to any taxable year beginning before 2004.''.

(d) DENIAL OF DOUBLE BENEFIT.—Section 280C of the Internal Revenue Code of 1986 (relating to certain expenses for which credits are allowable) is amended by adding at the end the following new subsection:

''(d) CREDIT FOR MEDICAL MALPRACTICE LIABILITY INSURANCE PREMIUMS.—

''(1) IN GENERAL.—No deduction shall be allowed for that portion of the qualified medical malpractice insurance expenditures otherwise allowable as a deduction for the taxable year which is equal to the amount of the credit allowable for the taxable year under section 45G (determined without regard to section 38(c)).

''(2) CONTROLLED GROUPS.—In the case of a corporation which is a member of a controlled group of corporations (within the meaning of section 41(f)(5)) or a trade or business which is treated as being under common control with other trades or business (within the meaning of section 41(f)(1)(B)), this subsection shall be applied under rules prescribed by the Secretary similar to the rules

applicable under subparagraphs (A) and (B) of section 41(f)(1).''.

(e) GRANTS TO NON-PROFIT HOSPITALS AND CLINICS.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration, shall award grants to eligible non-profit hospitals and clinics to assist such hospitals and clinics in defraying qualified medical malpractice insurance expenditures.

(2) ELIGIBLE NON-PROFIT HOSPITAL OR CLINIC.—To be eligible to receive a grant under paragraph (1) an entity shall—

(A) be a non-profit hospital or clinic;

(B) be unable to claim the tax credit described in section 45G of the Internal Revenue Code of 1986 for the year for which an application is submitted under subparagraph (C); and

(C) prepare and submit to the Secretary of Health and Human Services an application at such time, in such manner, and containing such information as the Secretary may require.

(3) AMOUNT OF GRANT.—The amount of a grant to a non-profit hospital or clinic under para-

graph (1) shall equal 15 percent of the amount of the qualified medical malpractice insurance expenditures of the hospital or clinic for the year involved.

(4) QUALIFIED MEDICAL MALPRACTICE INSURANCE EXPENDITURE.—In this subsection, the term ''qualified medical malpractice insurance expenditure'' means so much of any professional insurance premium, surcharge, payment or other cost or expense required as a condition of State licensure which is incurred by a non-profit hospital or clinic in a year for the sole purpose of providing or furnishing general medical malpractice liability insurance for such hospital or clinic as does not exceed twice the Statewide average of such costs for similarly situated hospitals or clinics.

(5) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for each of fiscal years 2004 and 2005.

(f) CLERICAL AMENDMENT.—The table of sections for subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

''Sec. 45G. Credit for expenditures for medical professional malpractice insurance.''.

(g) EFFECTIVE DATE.—The amendments made by this section shall apply to expenditures incurred after December 31, 2002.

SEC. 203. EXCLUSION FOR LOAN PAYMENTS UNDER NATIONAL HEALTH SERVICE CORPS LOAN REPAYMENT PROGRAM.

(a) IN GENERAL.—Section 117 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subsection:

''(e) LOAN PAYMENTS UNDER NATIONAL HEALTH SERVICE CORPS LOAN REPAYMENT PROGRAM.—Gross income shall not include any amount received under section 338B(g) of the Public Health Service Act.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to amounts received by an individual in taxable years beginning after December 31, 2002.

TITLE III—LIMITING FRIVOLOUS MEDICAL MALPRACTICE SUITS

SEC. 301. HEALTH CARE SPECIALIST AFFIDAVIT.

(a) REQUIRING SUBMISSION WITH COMPLAINT.—No medical malpractice liability action may be brought by any individual unless, at the time the individual brings the action (except as provided in subsection (b)(1)), it is accompanied by the affidavit of a qualified specialist that in-

cludes the specialist's statement of belief that, based on a review of the available medical record and other relevant material, there is a reasonable and meritorious cause for the filing of the action against the defendant.

(b) EXTENSION IN CERTAIN INSTANCES.—

(1) IN GENERAL.—Subject to paragraph (2), subsection (a) shall not apply with respect to an individual who brings a medical malpractice liability action without submitting an affidavit described in such subsection if, as of the time the individual brings the action, the individual has been unable to obtain adequate medical records or other information necessary to prepare the affidavit.

(2) DEADLINE FOR SUBMISSION WHERE EXTENSION APPLIES.—In the case of an individual who brings an action for which paragraph (1) applies, the action shall be dismissed unless the individual (or the individual's attorney) submits the affidavit described in subsection (a) not later than 90 days after obtaining the information described in such subparagraph.

(c) QUALIFIED SPECIALIST DEFINED.—In subsection (a), the term ''qualified specialist'' means, with respect to a medical malpractice liability action, a health

care professional who is reasonably believed by the individual bringing the action (or the individuals attorney)—

(1) to be knowledgeable in the relevant issues involved in the action;

(2) to practice (or to have practiced) or to teach (or to have taught) in the same area of health care or medicine that is at issue in the action; and

(3) in the case of an action against a physician, to be board certified in a specialty relating to that area of medicine.

(d) CONFIDENTIALITY OF SPECIALIST.—Upon a showing of good cause by a defendant, the court may ascertain the identity of a specialist referred to in subsection (a) while preserving confidentiality.

SEC. 302. SANCTIONS FOR FRIVOLOUS ACTIONS ANY PLEADINGS.

(a) SIGNATURE REQUIRED.—Every pleading, written motion, and other paper in any medical malpractice liability 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.—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—

(1) 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;

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

(3) 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 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).

SEC. 303. APPLICABILITY.

(a) IN GENERAL.—This title shall apply with respect to any medical malpractice liability action brought on or after the date of enactment of this Act in any State or Federal court, except that this title shall not apply to a

claim or action for damages arising from a vaccine-related injury or death to the extent that title XXI of the Public Health Service Act applies to the claim or action.

(b) EFFECT OF SOVEREIGN IMMUNITY AND CHOICE OF LAW OR VENUE.—Nothing in this title shall be construed to—

(1) waive or affect any defense of sovereign immunity asserted by any State under any provision of law;

(2) waive or affect any defense of sovereign immunity asserted by the United States;

(3) affect the applicability of any provision of the Foreign Sovereign Immunities Act of 1976;

(4) preempt State choice-of-law rules with respect to claims brought by a foreign nation or a citizen of a foreign nation; or

(5) affect the right of any court to transfer venue or to apply the law of a foreign nation or to dismiss a claim of a foreign nation or of a citizen of a foreign nation on the ground of inconvenient forum.

(c) FEDERAL COURT JURISDICTION NOT ESTABLISHED ON FEDERAL QUESTION GROUNDS.—Nothing in this title shall be construed to establish any jurisdiction in the district courts of the United States over medical

malpractice liability actions on the basis of section 1331 or 1337 of title 28, United States Code.

SEC. 304. DEFINITIONS.

In this title:

(1) HEALTH CARE PROFESSIONAL.—The term ''health care professional'' means any individual who provides health care services in a State and who is required by the laws or regulations of the State to be licensed or certified by the State to provide such services in the State.

(2) INJURY.—The term ''injury'' means any illness, disease, or other harm that is the subject of a medical malpractice liability action or a medical malpractice claim.

(3) MEDICAL MALPRACTICE CLAIM.—The term ''medical malpractice claim'' means a claim against a health care provider, a health care professional, or a blood or tissue bank licensed or registered by the Food and Drug Administration in which a claimant alleges that injury was caused by the provision of (or the failure to provide) health care services, except that such term does not include—

(A) any claim based on an allegation of an intentional tort; or

(B) any claim based on an allegation that a product is defective or unreasonably dangerous.

(4) MEDICAL MALPRACTICE LIABILITY ACTION.—The term ''medical malpractice liability action'' means a civil action brought in a State or Federal court against a health care provider, a health care professional, or a blood or tissue bank licensed or registered by the Food and Drug Administration in which the plaintiff alleges a medical malpractice claim.

(5) STATE.—The term ''State'' includes the District of Columbia and any commonwealth, territory, or possession of the United States.

TITLE IV—MEDICAL MALPRACTICE INSURANCE REFORM

SEC. 401. SHORT TITLE.

This title may be cited as the ''Medical Malpractice Insurance Antitrust Act of 2003''.

SEC. 402. PROHIBITION ON ANTI-COMPETITIVE ACTIVITIES.

Notwithstanding any other provision of law, nothing in the Act of March 9, 1945 (15 U.S.C. 1011 et seq., commonly known as the ''McCarran-Ferguson Act'') shall be construed to permit commercial insurers to engage in any

form of price fixing, bid rigging, or market allocations in connection with the conduct of the business of providing medical malpractice insurance.

SEC. 403. APPLICATION TO ACTIVITIES OF STATE COMMISSIONS OF INSURANCE AND OTHER STATE INSURANCE REGULATORY BODIES.

This title does not apply to the information gathering and rate setting activities of any State commissions of insurance, or any other State regulatory body with authority to set insurance rates.

SEC. 404. STUDY ON MEDICAL MALPRACTICE REINSURANCE.

(a) IN GENERAL.—The Secretary of the Treasury shall conduct a study of the feasibility and efficacy of establishing a Federal reinsurance fund for the payment of certain noneconomic damages in medical malpractice action. Such study shall address—

(1) the advantages, if any, that a federally-administered reinsurance fund would offer over private reinsurance;

(2) the level at which such fund should assume the liability for payment of noneconomic damages in medical malpractice actions;

(3) the administration of such payments of noneconomic damages by the fund;

(4) whether such a fund should be financed through the assessment of user fees on malpractice insurance issuers, and if so, the amount of such fee, and how to calculate such fee for each malpractice insurance issuer;

(5) whether individual malpractice insurance issuers should be permitted to negotiate their own terms (relating to fees and payments) with such fund; and

(6) whether such fund could use capital from the Federal Judgment Fund for the first year in which the fund is operating, and what the terms would be relating to the repayment of such capital.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of the Treasury shall submit to the appropriate committees of Congress a report concerning the results of the study conducted under subsection (a).

TITLE V—INDEPENDENT ADVISORY COMMISSION ON MEDICAL MALPRACTICE INSURANCE

SEC. 501. ESTABLISHMENT.

(a) FINDINGS.—The Congress finds as follows:

(1) The sudden rise in medical malpractice insurance premiums in regions of the United States can threaten patient access to health care professionals.

(2) Improving patient access to physicians and other health care professionals is a national priority.

(b) ESTABLISHMENT.—There is established a national commission to be known as the ''Independent Advisory Commission on Medical Malpractice Insurance'' (in this title referred to as the ''Commission'').

SEC. 502. DUTIES.

(a) IN GENERAL.—The Commission shall evaluate the causes and scope of the recent and dramatic increases in medical malpractice insurance premiums, including the correlation, if any, to changes in State tort law regarding medical malpractice, and formulate additional proposals to reduce such medical malpractice insurance premiums and make recommendations to avoid any dramatic increases in medical malpractice insurance premiums in the future.

(b) CONSIDERATIONS.—In formulating proposals under this section, the Commission shall, at a minimum, consider the following:

(1) Alternatives to the current medical malpractice liability system that would ensure adequate compensation for patients, preserve access to health

care professionals, and improve health care safety and quality.

(2) Modifications of, and alternatives to, the existing State and Federal regulations and oversight that affect, or could affect, medical malpractice lines of insurance.

(3) State and Federal reforms that would more evenly distribute the risk of medical malpractice across various categories of professionals.

(4) The effect of Federal medical malpractice reinsurance program administered by the Department of Health and Human Services on medical malpractice insurance availability and affordability.

(5) The effect on medical malpractice insurance availability and affordability of a Federal medical malpractice insurance program, administered by the Department of Health and Human Services, to provide medical malpractice insurance based on customary coverage terms and liability amounts in States where such insurance is unavailable or is unavailable at reasonable and customary terms, on medical malpractice insurance availability and affordability.

(6) Programs that would reduce medical errors and increase patient safety, including new innovations in technology and management.

(7) The effect on medical malpractice insurance availability and affordability of State policies under which—

(A) any health care professional licensed by the State has standing in any State administrative proceeding to challenge a proposed rate increase in medical malpractice insurance; and

(B) a provider of medical malpractice insurance in the State may not implement a rate increase in such insurance unless the provider, at minimum, first submits to the appropriate State agency a description of the rate increase and a substantial justification for the rate increase.

SEC. 503. REPORT.

(a) IN GENERAL.—The Commission shall transmit to Congress—

(1) an initial report not later than 180 days after the date of the initial meeting of the Commission; and

(2) a report not less than each year thereafter until the Commission terminates.

(b) CONTENTS.—Each report transmitted under this section shall contain a detailed statement of the findings and conclusions of the Commission, including proposals for addressing the current dramatic increases in medical malpractice insurance rates and recommendations for avoiding any such dramatic increases in the future.

(c) VOTING AND REPORTING REQUIREMENTS.—With respect to each proposal or recommendation contained in the report submitted under subsection (a), each member of the Commission shall vote on the proposal or recommendation, and the Commission shall include, by member, the results of that vote in the report.

SEC. 504. MEMBERSHIP.

(a) NUMBER AND APPOINTMENT.—The Commission shall be composed of 15 members appointed by the Comptroller General of the United States.

(b) MEMBERSHIP.—

(1) IN GENERAL.—The membership of the Commission shall include individuals with national recognition for their expertise in health finance and economics, actuarial science, medical malpractice insurance, insurance regulation, health care law, health care policy, health care access, allopathic and osteopathic physicians, other health care professionals of health care services, patient advocacy, and

other related fields, who provide a mix of different professionals, broad geographic representations, and a balance between urban and rural representatives.

(2) INCLUSION.—The membership of the Commission shall include the following:

(A) Two individuals with expertise in health finance and economics, including one with expertise in consumer protections in the area of health finance and economics.

(B) Two individuals with expertise in medical malpractice insurance, representing both commercial insurance carriers and physician-sponsored insurance carriers.

(C) An individual with expertise in State insurance regulation and State insurance markets.

(D) An individual representing physicians.

(E) An individual with expertise in issues affecting hospitals, nursing homes, nurses, and other health care professionals.

(F) Two individuals representing patient interests.

(G) Two individuals with expertise in health care law or health care policy.

(H) An individual with expertise in representing patients in medical malpractice claims.

(3) MAJORITY.—The total number of individuals who are directly involved with the provision or management of medical malpractice insurance, representing health care professionals, or representing professionals in malpractice lawsuits, shall not constitute a majority of the membership of the Commission.

(4) ETHICAL DISCLOSURE.—The Comptroller General of the United States shall establish a system for public disclosure by members of the Commission of financial or other potential conflicts of interest relating to such members.

(c) TERMS.—

(1) IN GENERAL.—The terms of the members of the Commission shall be for 3 years except that the Comptroller General of the United States shall designate staggered terms for the members first appointed.

(2) VACANCIES.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of

that term. A member may serve after the expiration of that member's term until a successor has taken office. A vacancy in the Commission shall be filled in the manner in which the original appointment was made.

(3) COMPENSATION.—Members of the Commission shall be compensated in accordance with section 1805(c)(4) of the Social Security Act.

(4) CHAIRPERSON; VICE CHAIRPERSON.—The Comptroller General of the United States shall designate at the time of appointment a member of the Commission as Chairperson and a member as Vice Chairperson. In the case of vacancy of the Chairpersonship or Vice Chairpersonship, the Comptroller General may designate another member for the remainder of that member's term.

(5) MEETINGS.—

(A) IN GENERAL.—The Commission shall meet at the call of the Chairperson.

(B) INITIAL MEETING.—The Commission shall hold an initial meeting not later than the date that is 1 year after the date of the enactment of this title, or the date that is 3 months after the appointment of all the members of the Commission, whichever occurs earlier.

SEC. 505. DIRECTOR AND STAFF; EXPERTS AND CONSULTANTS.

Subject to such review as the Comptroller General of the United States deems necessary to assure the efficient administration of the Commission, the Commission may—

(1) employ and fix the compensation of an Executive Director (subject to the approval of the Comptroller General) and such other personnel as may be necessary to carry out its duties (without regard to the provisions of title 5, United States Code, governing appointments in the competitive service);

(2) seek such assistance and support as may be required in the performance of its duties from appropriate Federal departments and agencies;

(3) enter into contracts or make other arrangements, as may be necessary for the conduct of the work of the Commission (without regard to section 3709 of the Revised Statutes (41 U.S.C. 5));

(4) make advance, progress, and other payments which relate to the work of the Commission;

(5) provide transportation and subsistence for persons serving without compensation; and

(6) prescribe such rules and regulations as it deems necessary with respect to the internal organization and operation of the Commission.

SEC. 506. POWERS.

(a) OBTAINING OFFICIAL DATA.—The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out this section. Upon request of the Chairperson, the head of that department or agency shall furnish that information to the Commission on an agreed upon schedule.

(b) DATA COLLECTION.—In order to carry out its functions, the Commission shall—

(1) utilize existing information, both published and unpublished, where possible, collected and assessed either by its own staff or under other arrangements made in accordance with this section;

(2) carry out, or award grants or contracts for, original research and experimentation, where existing information is inadequate; and

(3) adopt procedures allowing any interested party to submit information for the Commission's use in making reports and recommendations.

(c) ACCESS OF GENERAL ACCOUNTING OFFICE TO INFORMATION.—The Comptroller General of the United States shall have unrestricted access to all deliberations, records, and nonproprietary data of the Commission, immediately upon request.

(d) PERIODIC AUDIT.—The Commission shall be subject to periodic audit by the Comptroller General of the United States.

SEC. 507. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—There are authorized to be appropriated such sums as may be necessary to carry out this title for each of fiscal years 2004 through 2008.

(b) REQUESTS FOR APPROPRIATIONS.—The Commission shall submit requests for appropriations in the same manner as the Comptroller General of the United States submits requests for appropriations, but amounts appropriated for the Commission shall be separate from amounts appropriated for the Comptroller General.

TITLE VI—REDUCING MEDICAL MALPRACTICE BY PREVENTING MEDICAL ERRORS

SEC. 601. SHORT TITLE.

This title may be cited as the ''Patient Safety Improvement and Medical Injury Reduction Act''.

SEC. 602. PURPOSE.

It is the purpose of this title to improve patient safety by promoting the voluntary reporting of patient safety events and medical errors and other measures.

SEC. 603. PATIENT SAFETY IMPROVEMENTS.

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 E;

(3) by redesignating sections 921 through 928, as sections 941 through 948, respectively;

(4) in section 948(1) (as so redesignated), by striking "921" and inserting "941"; and

(5) by inserting after part B the following:

"PART C—PATIENT SAFETY IMPROVEMENT

"SEC. 921. DEFINITIONS.

"In this part:

"(1) CENTER.—The term 'Center' means the Center for Quality Improvement and Patient Safety established under section 922(a).

"(2) HEALTH CARE PROFESSIONAL.—The term 'health care professional' means an individual or entity licensed or otherwise authorized under State law to provide health care services, including—

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

"(B) a physician, physician assistant, nurse practitioner, clinical nurse specialist, cer-

tified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, or other individual health care practitioner;

''(C) a pharmacist; and

''(D) 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.

''(3) IDENTIFIABLE INFORMATION.—The term 'identifiable information' means information that is presented in a form and manner that allows the identification of any health care professional, patient, or reporter of patient safety information. 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).

''(4) NATIONAL PATIENT SAFETY DATABASE.—The term 'National Patient Safety Database' means the database of nonidentifiable information concerning patient safety that is coordinated by, and

developed in collaboration with, the Director under section 922(c)(3)(B).

''(5) NATIONAL PATIENT SAFETY RESEARCH DEMONSTRATION SYSTEM.—The term 'National Patient Safety Research Demonstration System' means a system under which the Director will enter into voluntary agreements with a geographically and institutionally diverse group of eligible entities to collect data for the purpose of conducting research on patient safety under section 922(c)(3)(C).

''(6) NONIDENTIFIABLE INFORMATION.—The term 'nonidentifiable information' means information that is presented in a form and manner that prevents the identification of any health care professional, patient, or reporter of patient safety information. 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).

''(7) PATIENT SAFETY INFORMATION.—The term 'patient safety information' means any reports, records, memoranda, analyses, deliberative work, statements, or root cause analyses that are collected

or developed to improve patient safety or health care quality and that—

"(A) are developed by a health care professional for the purpose of reporting to a patient safety organization and that are reported on a timely basis to such an organization; or

"(B) are collected or developed by a patient safety organization or by the National Patient Safety Database or National Patient Safety Research Demonstration System, regardless of whether the information is transmitted to the health care professional that reported the original information.

"(8) 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 Director under section 925, to perform each of the following activities:

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

''(B) The collection and analysis of patient safety information that is submitted by health care professionals.

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

''(D) The utilization of patient safety information 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 health care professionals to effectively minimize patient risk.

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

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

''(G) The submission of nonidentifiable information to the Agency consistent with standards established by the Director under section 924 for the National Patient Safety Database.

"SEC. 922. PRIVILEGE.

''(a) IN GENERAL.—Notwithstanding any other provision of law, patient safety information shall be privileged and confidential in accordance with this section.

''(b) SCOPE OF PRIVILEGE.—Subject to the succeeding provisions of this section, such information shall not be—

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

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

''(3) disclosed 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; or

''(4) admitted as evidence or otherwise disclosed in any Federal or State civil or administrative proceeding.

''(c) EXCEPTIONS TO PRIVILEGE.—The privilege provided for under this section shall not apply to—

''(1) records of a patient's medical diagnosis and treatment, patient or hospital records, other primary health care information or other documents, records, or data that exist separately from the process of collecting or developing information for the purposes of this part;

''(2) information merely by reason of its inclusion, report, or the fact of its submission, to a patient safety organization, the National Patient Safety Database, or the National Patient Safety Research Demonstration System; and

''(3) information available from sources other than a report or submission made under this part, which may be discovered or admitted in a Federal or State civil or administrative proceeding, if discoverable or admissible under applicable Federal or State law.

''(d) DISCLOSURES.—Nothing in this section shall be construed to prohibit any of the following disclosures:

''(1) The disclosure of nonidentifiable information by a health care professional, patient safety organization, or the Director.

''(2) The disclosure of identifiable information by a health care professional or patient safety organization, if such disclosure—

''(A) is authorized by the professional 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) The disclosure of patient safety information by a professional or patient safety organization to the Food and Drug Administration.

''(e) RULES OF CONSTRUCTION.—

''(1) IN GENERAL.—Nothing in this section shall be construed to limit or extend other privileges that are available under Federal or State laws, including peer review and confidentiality protections.

''(2) CONSTRUCTION REGARDING USE OF PATIENT SAFETY INFORMATION.—

''(A) INTERNAL USE PERMITTED TO IMPROVE PATIENT SAFETY, QUALITY, AND EFFICIENCY.—Nothing in this part shall be construed to limit a health care professional from using patient safety information within the professional to improve patient safety, health care quality, or administrative efficiency of the professional.

''(B) TREATMENT.—Information that is collected as patient safety information is not disqualified from being treated as patient safety

information because of its use for the purposes described in subparagraph (A) and such use shall not constitute a waiver of any privilege or protection established under this section or under State law.

''(3) STATE MANDATORY REPORTING REQUIREMENTS.—Nothing in this part shall be construed as preempting or otherwise affecting any mandatory reporting requirement for health care professionals under State law.

''(f) APPLICATION OF PRIVACY REGULATIONS.—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)—

''(1) patient safety organizations that collect or receive identifiable information shall be treated as covered entities; and

''(2) activities of such organizations described in section 923(b)(2)(A) in relation to a health care professional are deemed to be health care operations of the professional.

Nothing in this section shall be construed to alter or affect the implementation of such regulation or such section 264(c).

''(g) WAIVERS.—

''(1) IN GENERAL.—Nothing in this part shall be construed as precluding a health care professional from waiving the privilege established under this section.

''(2) LIMITATION.—The disclosure of patient safety information pursuant to this part shall not constitute a waiver of any other Federal or State privilege.

''(h) CONTINUATION OF PRIVILEGE.—Patient safety information 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 until the information is otherwise disposed of in accordance with section 925(g).

''(i) PENALTY.—

''(1) PROHIBITION.—Except as provided in this part, and subject to paragraph (2), it shall be unlawful for any person to disclose patient safety information in violation of this section.

''(2) RELATION TO HIPAA.—The penalty under this subsection for a disclosure described in paragraph (1) shall not apply if the person making such

disclosure is 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 such disclosure.

''(3) AMOUNT.—Any person who violates paragraph (1) shall be subject to a civil monetary penalty of not more than $25,000 for each such violation involved. Such penalty shall be imposed and collected in the same manner as civil money penalties are imposed and collected under subsection (a) of section 1128A of the Social Security Act.

''(j) SURVEY AND REPORT.—

''(1) SURVEY.—The Comptroller General of the United States shall conduct a survey of State laws that relate to patient safety information peer review systems, including laws that establish an evidentiary privilege applicable to information developed in such systems, and shall review the manner in which such laws have been interpreted by the courts and the effectiveness of such laws in promoting patient safety.

''(2) REPORT.—Not later than 9 months after the date of enactment of this part, the Comptroller General shall prepare and submit to Congress a re-

port concerning the results of the survey conducted under paragraph (1).

"SEC. 923. REPORTER PROTECTION.

''(a) IN GENERAL.—A health care professional may not take an adverse employment action, as described in subsection (b), against an individual based upon the fact that the individual in good faith reported—

''(1) to the professional with the intention of having it reported to a patient safety organization, or

''(2) directly to a patient safety organization,

information that would constitute patient safety information if the professional were to have submitted it on a timely basis to a patient safety organization in accordance with this part.

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

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

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

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

''(c) REMEDIES.—The provisions of the first sentence of section 1128A(a) of the Social Security Act shall apply with respect to a health care professional's violation of subsection (a) in the same manner as they apply to an act referred to in section 1128A(a)(7) of such Act.

''(d) PENALTY.—Any person who violated the provisions of this section shall be subject to a fine of not more than $25,000, imprisonment for not more than 6 months, or both, per disclosure and payment of the costs of prosecution.

''SEC. 924. CENTER FOR QUALITY IMPROVEMENT AND PATIENT SAFETY.

''(a) IN GENERAL.—The Director shall establish a center to be known as the Center for Quality Improvement and Patient Safety to carry out the duties described in subsection (b).

''(b) DUTIES.—

''(1) IN GENERAL.—The Center shall carry out the following duties:

''(A) Conduct and support research, demonstrations, and evaluations of the quality of health care and the promotion of patient safety, and the measurement of health care quality.

"(B) Develop, evaluate, and disseminate methods for identifying and promoting effective patient safety programs.

"(C) Provide for the certification and recertification of patient safety organizations in accordance with section 925.

"(D) Establish a National Patient Safety Database to collect, support, and coordinate the analysis of nonidentifiable information submitted to the Database in accordance with subsection (d).

"(E) Establish a National Patient Safety Research Demonstration System under which the Director will enter into voluntary agreements with a geographically and institutionally diverse group of eligible entities to collect data for the purpose of conducting research on patient safety.

"(F) Facilitate the development of consensus, including through annual meetings, among health care professionals, patients, and other interested parties concerning patient safety and recommendations to improve patient safety.

''(G) Provide technical assistance and support to States that have (or are developing) medical errors reporting systems, assist States in developing standardized methods for data collection, and collect data from State reporting systems for inclusion in the National Patient Safety Database.

''(2) CONSULTATION.—In carrying out the duties under paragraph (1) (including the establishment of the Database), the Director shall consult with and develop partnerships, as appropriate, with health care organizations, health care professionals, public and private sector entities, patient safety organizations, health care consumers, and other relevant experts to improve patient safety.

''(c) IMPLEMENTATION AND CONSULTATION.—In carrying out this section, the Director shall—

''(1) facilitate the development of patient safety goals and track the progress made in meeting those goals; and

''(2) ensure that information submitted by a patient safety organization to the National Patient Safety Database, as provided for under subsection (d), is comparable and useful for research and analysis and that the research findings and patient safe-

ty alerts that result from such analyses are presented in clear and consistent formats that enhance the usefulness of such alerts.

''(d) NATIONAL PATIENT SAFETY DATABASE.—

''(1) IN GENERAL.—The Director shall—

''(A) establish a National Patient Safety Database to collect nonidentifiable information concerning patient safety that is reported on a voluntary basis which shall be used to analyze national, regional, and State trends and patterns in patient safety and medical errors; and

''(B) establish common formats for the voluntary reporting of information under subparagraph (A), including the establishment of necessary data elements, common and consistent definitions, and a standardized computer interface for the processing of such data.

To the extent practicable, formats established under subparagraph (A) shall be consistent with the administrative simplification provisions of part C of title XI of the Social Security Act.

''(2) DATABASE.—In carrying out this subsection, the Director—

''(A) shall establish and modify as necessary criteria to determine the organizations

that may voluntarily contribute to, and the data that comprises, the National Patient Safety Database;

"(B) shall ensure that the National Patient Safety Database is only used by qualified entities or individuals for purposes of research, education, and enhancing patient safety as determined appropriate by the Director in accordance with criteria applied by the Director;

"(C) may enter into contracts for the administration of the Database with private and public entities with experience in the administration of similar databases;

"(D) shall ensure that the methodologies for the collection of nonidentifiable patient safety information for the National Patient Safety Database include the methodologies developed or recommended by the Patient Safety Task Force of the Department of Health and Human Services; and

"(E) may, to the extent practicable, facilitate the direct link of information between health care professionals and patient safety organizations and between patient safety organi-

zations and the National Patient Safety Database.

''(3) NATIONAL PATIENT SAFETY RESEARCH DEMONSTRATION SYSTEM.—

''(A) ESTABLISHMENT.—

''(i) IN GENERAL.—Not later than 1 year after the date of enactment of this part, the Director shall establish a National Patient Safety Research Demonstration System under which the Director will enter into voluntary agreements with a geographically and institutionally diverse group of eligible entities to collect information for the purpose of conducting research on patient safety. The Director may contract with other organizations to carry out this paragraph.

''(ii) PURPOSE.—The purpose of the demonstration system established under clause (i) is to conduct targeted research on patient safety and to test promising systems and methods of improving patient safety.

''(iii) NUMBER AND TYPES OF ORGANIZATIONS.—In carrying out clause (i), the

Director shall determine the number and types of health care organizations with which to enter into agreements, as well as the types of patient safety events the particular health care organizations with which the Director enters into an agreement should identify and the types of analyses that such organizations should perform.

''(B) ELIGIBILITY.—To be eligible to enter into an agreement under subparagraph (A) an entity shall—

''(i) be a health care organization; and

''(ii) prepare and submit to the Director an application at such time, in such manner, and containing such information as the Director may require.

''(C) SUBMISSION OF REPORTS.—

''(i) IN GENERAL.—A health care organization that enters into a voluntary agreement under subparagraph (A) shall, with respect to such organization, submit reports of patient safety events, or reports of specific types of patient safety events if so prescribed by the agreement, and shall

submit, if prescribed by the agreement, root cause analyses concerning such events (using standards developed by the Director), and corrective action plans to the Director.

''(ii) PROCESSING OF INFORMATION.—The Director shall process the reports submitted under clause (i) in the same manner as reports are processed through the National Patient Safety Database.

''(iii) PROVISION OF RECOMMENDATIONS.—The Director shall provide feedback concerning patient safety event reports directly to the health care organizations that are participating in the demonstration system under this paragraph.

''(D) TECHNICAL ASSISTANCE.—The Director shall provide health care organizations participating in the demonstration system under this paragraph with technical support and may provide technology support, including computer software and hardware, through the patient safety improvement grants under section 932 and section 934.

''(E) EVALUATION.—Upon the expiration of the 5-year period beginning on the date on which the demonstration system is established under this paragraph, the Director shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—

''(i) information on the types of data collected through the demonstration system;

''(ii) research conducted with data collected through the demonstration system; and

''(iii) the identification of promising systems and methods of reducing patient safety events.

''(F) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed to preempt Federal or State mandatory reporting or sentinel surveillance systems in effect on the date of enactment of this part, or Federal or State mandatory reporting or sentinel surveillance systems developed after such date of enactment.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out this section.

''SEC. 925. PATIENT SAFETY ORGANIZATIONS.

''(a) CERTIFICATION AND RECERTIFICATION.—

''(1) IN GENERAL.—The initial certification and recertification of a patient safety organization under section 924 shall be made under a process that is approved by the Director and is consistent with criteria published by the Director.

''(2) REVOCATION.—Such a certification or recertification of a patient safety organization may be revoked by the Director upon a showing of cause (including the disclosure of information in violation of section 922).

''(3) TERMINATION.—Such a certification provided for a patient safety organization shall terminate (subject to recertification) on the earlier of—

''(A) the date that is 3 years after the date on which such certification was provided; or

''(B) the date on which the Director revokes the certification.

''(b) ORGANIZATION REQUIREMENTS.—A patient safety organization shall meet the following criteria as conditions for certification:

''(1) The mission of the organization shall be to conduct activities to improve patient safety and the quality of health care delivery.

''(2) The organization shall collect and analyze patient safety information that is voluntarily reported by more than one health care professional on a local, regional, State, or national basis.

''(3) The organization shall have appropriately qualified staff, including licensed or certified medical professionals.

''(4) The organization is managed, controlled, and operated independently from health care professionals that report patient safety information to it under this part, and the organization—

''(A) does not have a material familial or financial relationship (except for fees charged to health care professionals) with any health care professional from whom it receives patient safety information;

''(B) does not otherwise have a conflict of interest with such a health care professional (as determined under regulations); and

''(C) is not a health insurer or other entity that offers a group health plan or health insur-

ance coverage, or a component of such an entity.

''(5) The organization seeks to collect data from health care professionals in a standardized manner that permits valid comparisons of similar cases among similar health care professionals.

''(6) The organization meets such other requirements as the Director may by regulation require.

''(c) LIMITATION ON USE OF PATIENT SAFETY INFORMATION BY PATIENT SAFETY ORGANIZATIONS.—A patient safety organization may not use patient safety information reported by a health care professional in accordance with this part to take regulatory or enforcement actions it otherwise performs (or is responsible for performing) in relation to such professional.

''(d) TECHNICAL ASSISTANCE.—The Director may provide technical assistance to patient safety organizations in providing recommendations and advice to health care professionals reporting patient safety information under this part. Such assistance shall include advice with respect to methodology, communication, dissemination of information, data collection, security, and confidentiality concerns.

''(e) COMPONENT ORGANIZATIONS.—If a patient safety organization is a component of a larger organization, the patient safety organization shall—

''(1) maintain patient safety information within the component, separately from the rest of the larger organization, and establish appropriate security measures to maintain the confidentiality of the patient safety information;

''(2) not disclose patient safety information to the larger organization; and

''(3) not create a conflict of interest with the larger organization.

''(f) CONSTRUCTION.—Nothing in this part shall be construed to limit or discourage the reporting of information relating to patient safety within a health care professional.

''(g) TREATMENT OF INFORMATION.—If an organization no longer qualifies as a patient safety organization under this section, with respect to any patient safety information that such organization received from a health care professional, the organization shall comply with one of the following:

''(1) With the approval of the professional and another patient safety organization, the organization shall transfer such information to such other organization.

''(2) If practicable, the organization shall return the information to the professional.

''(3) The organization shall destroy the patient safety information.

"PART D—PATIENT SAFETY IMPROVEMENT GRANTS

"SEC. 931. GRANTS FOR COMMUNITY PARTNERSHIPS FOR HEALTH CARE IMPROVEMENT.

''(a) IN GENERAL.—The Secretary shall award grants to eligible entities to enable such entities to establish, enhance or improve community partnerships for health care improvement among professionals within a community for the purpose of improving the quality of medical care, including the prescribing, dispensing, and use of prescription drugs, within such community.

''(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant under subsection (a) an entity shall—

''(1) be a—

''(A) hospital;

''(B) health care clinic;

''(C) skilled nursing facility;

''(D) non-profit entity, or component thereof, established for the purpose of establishing, enhancing or improving a community partnership for health care improvement; or

''(E) consortium of any of the entities described in subparagraphs (A) through (D); and

''(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may reasonably require, including assurances satisfactory to the Secretary that the community partnership for health care improvement in connection with which the entity is submitting the application does, at the time of application, or will, within a reasonable amount of time from the date of application, include the substantive participation of a broad range of entities (that may include professionals, payers, patients, and governmental entities) involved in the delivery of health care within the community.

''(c) LIMITATIONS.—In carrying out subsection (a), the Secretary shall not—

''(1) award any single entity more than $2,000,000 in any single fiscal year; or

''(2) award grants under this section to any single entity for more than 3 fiscal years.

''(d) DEFINITION.—In this section, the term 'community partnership for health care improvement' means a formal cooperative arrangement including health care facilities and nonprofit organizations within a community that—

''(1) is entered into for the purpose of significantly reducing the incidence of patient safety events or significantly improving the quality of health care, including the appropriate use of prescription drugs, at health care facilities participating in such partnership using one or more quantifiable indicators of such improvement;

''(2) collects quantifiable data on the incidence of patient safety events or on the quality of health care in connection with one or more specific medical procedures conducted at the health care facilities participating in such partnerships;

''(3) makes available to the health care facilities participating in such partnership the data described in paragraph (2); and

''(4) promotes cooperation and communication among professionals employed by the health care facilities participating in such partnership for the purposes described in paragraph (1).

''(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $50,000,000 for fiscal year 2004, and such sums as may be necessary for each subsequent fiscal year.

"SEC. 932. TECHNICAL STANDARDS FOR HEALTH CARE INFORMATION TECHNOLOGY SYSTEMS.

''(a) IN GENERAL.—By not later than 2 years after the date of the enactment of this part, the Secretary shall develop or adopt (and shall periodically review and update) voluntary, national standards—

''(1) that promote the interoperability of health care information technology systems across all health care settings; and

''(2) for computerized physician order entry systems, including standards relating to—

''(A) data formats or other methods of encoding medical information that facilitate transfer of data among such systems;

''(B) the protection of the confidentiality of individually identifiable health information contained within such systems from unauthorized access or disclosure;

''(C) procedures for issuing warnings when prescribing errors may be imminent;

''(D) procedures for ensuring that recommendations or warnings issued by such systems reflect good medical practice; and

''(E) other matters determined appropriate by the Secretary.

''(b) COST AND INCREASED EFFICIENCY.—In promulgating regulations to carry out this section, the Secretary shall take into account the cost that meeting the standards under subsection (a) would have on providing health care in the United States and the increased efficiencies in providing such care achieved under the standards.

''(c) CONSULTATION AND COORDINATION.—The Secretary shall develop and update the standards under subsection (a) in consultation with (and with coordination between)—

''(1) the National Committee for Vital and Health Statistics;

''(2) the Medical Information Technology Advisory Board (established under section 933); and

''(3) the Secretary of Veterans Affairs and the Secretary of Defense.

''(d) DISSEMINATION.—The Secretary shall provide for the dissemination of the standards developed and updated under this section.

''(e) LIMITATION.—Effective beginning on the date that is 4 years after the date of enactment of this part, the Secretary may not purchase any health care information technology system unless such system conforms to the standards developed or adopted under subsection (a), to

the extent that such standards have been developed or adopted.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out this section.

''SEC. 933. MEDICAL INFORMATION TECHNOLOGY ADVISORY BOARD.

''(a) ESTABLISHMENT.—

''(1) IN GENERAL.—Not later than 3 months after the date of the enactment of this part, the Secretary shall appoint an advisory board to be known as the 'Medical Information Technology Advisory Board' (in this section referred to as the 'MITAB').

''(2) CHAIRPERSON.—The Secretary shall designate one member of the MITAB to serve as the chairperson. The chairperson shall be an individual affiliated with an organization having expertise creating American National Standards Institute (ANSI) accepted standards in health care information technology and a member of the National Committee for Vital and Health Statistics.

''(b) COMPOSITION.—

''(1) IN GENERAL.—The MITAB shall consist of not more than 17 members that include—

"(A) experts from the fields of medical information, information technology, medical continuous quality improvement, medical records security and privacy, individual and institutional health care clinical professionals, health researchers, and health care purchasers;

"(B) one or more staff experts from each of the following: the Centers for Medicare & Medicaid Services, the Agency for Healthcare Research and Quality, and the Institute of Medicine of the National Academy of Sciences;

"(C) representatives of private organizations with expertise in medical informatics;

"(D) a representative of a teaching hospital;

"(E) one or more representatives of the health care information technology industry; and

"(F) a representative of an organization representing health care consumers.

"(2) TERMS OF APPOINTMENT.—The term of any appointment under paragraph (1) to the MITAB shall be for 2 years. Such an appointment may be renewed for one additional term.

''(3) MEETINGS.—The MITAB shall meet at the call of its chairperson or a majority of its members.

''(4) VACANCIES.—A vacancy on the MITAB shall be filled in the same manner in which the original appointment was made not later than 30 days after the MITAB is given notice of the vacancy and shall not affect the power of the remaining members to execute the duties of the MITAB.

''(5) COMPENSATION.—Members of the MITAB shall receive no additional pay, allowances, or benefits by reason of their service on the MITAB.

''(6) EXPENSES.—Each member of the MITAB shall receive travel expenses and per diem in lieu of subsistence in accordance with sections 5702 and 5703 of title 5, United States Code.

''(c) DUTIES.—

''(1) IN GENERAL.—The MITAB shall on an ongoing basis advise, and make recommendations to, the Secretary regarding medical information technology, including the following:

''(A) The best current practices in medical information technology.

''(B) Methods for the adoption (not later than 2 years after the date of the enactment of

this part) of a uniform health care information system interface between and among old and new computer systems.

''(C) Recommendations for health care vocabulary, messaging, and other technology standards (including a common lexicon for computer technology) necessary to achieve the interoperability of health care information systems for the purposes described in subparagraph (E).

''(D) Methods of implementing—

''(i) health care information technology interoperability standardization; and

''(ii) records security.

''(E) Methods to promote information exchange among health care professionals so that long-term compatibility among information systems is maximized, in order to do one or more of the following:

''(i) To maximize positive outcomes in clinical care—

''(I) by providing decision support for diagnosis and care; and

''(II) by assisting in the emergency treatment of a patient presenting at a facility where there is no medical record for the patient.

''(ii) To contribute to (and be consistent with) the development of the patient assessment instrument provided for under section 545 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, and to assist in minimizing the need for new and different records as patients move from professional to professional.

''(iii) To reduce or eliminate the need for redundant records, paperwork, and the repetitive taking of patient histories and administering of tests.

''(iv) To minimize medical errors, such as administration of contraindicated drugs.

''(v) To provide a compatible information technology architecture that facilitates future quality and cost-saving needs and that avoids the financing and development

of information technology systems that are not readily compatible.

''(2) REPORTS.—

''(A) INITIAL REPORT.—Not later than 18 months after the date of the enactment of this part, the MITAB shall submit to Congress and the Secretary an initial report concerning the matters described in paragraph (1). The report shall include—

''(i) the practices described in paragraph (1)(A), including the status of health care information technology standards being developed by private sector and public-private groups;

''(ii) recommendations for accelerating the development of common health care terminology standards;

''(iii) recommendations for completing development of health care information system messaging standards; and

''(iv) progress toward meeting the deadline described in paragraph (1)(B) for adoption of methods described in such paragraph.

''(B) SUBSEQUENT REPORTS.—During each of the 2 years after the year in which the report is submitted under subparagraph (A), the MITAB shall submit to Congress and the Secretary an annual report relating to additional recommendations, best practices, results of information technology improvements, analyses of private sector efforts to implement the interoperability standards established in section 1184 of the Social Security Act, and such other matters as may help ensure the most rapid dissemination of best practices in health care information technology.

''(d) STAFF AND SUPPORT SERVICES.—

''(1) EXECUTIVE DIRECTOR.—

''(A) APPOINTMENT.—The Chairperson shall appoint an executive director of the MITAB.

''(B) COMPENSATION.—The executive director shall be paid the rate of basic pay for level V of the Executive Schedule.

''(2) STAFF.—With the approval of the MITAB, the executive director may appoint such personnel as the executive director considers appropriate.

''(3) APPLICABILITY OF CIVIL SERVICE LAWS.—The staff of the MITAB shall be appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title (relating to classification and General Schedule pay rates).

''(4) EXPERTS AND CONSULTANTS.—With the approval of the MITAB, the executive director may procure temporary and intermittent services under section 3109(b) of title 5, United States Code.

''(e) POWERS.—

''(1) HEARINGS AND OTHER ACTIVITIES.—For the purpose of carrying out its duties, the MITAB may hold such hearings and undertake such other activities as the MITAB determines to be necessary to carry out its duties.

''(2) DETAIL OF FEDERAL EMPLOYEES.—Upon the request of the MITAB, the head of any Federal agency is authorized to detail, without reimbursement, any of the personnel of such agency to the MITAB to assist the MITAB in carrying out its duties. Any such detail shall not interrupt or otherwise

affect the civil service status or privileges of the Federal employee.

''(3) TECHNICAL ASSISTANCE.—Upon the request of the MITAB, the head of a Federal agency shall provide such technical assistance to the MITAB as the MITAB determines to be necessary to carry out its duties.

''(4) OBTAINING INFORMATION.—The MITAB may secure directly from any Federal agency information necessary to enable it to carry out its duties, if the information may be disclosed under section 552 of title 5, United States Code. Upon request of the Chairperson of the MITAB, the head of such agency shall furnish such information to the MITAB.

''(f) TERMINATION.—The MITAB shall terminate 30 days after the date of submission of its final report under subsection (c)(2)(B).

''(g) TESTING.—The Secretary, in consultation with the MITAB, shall test the efficacy, usability, and scalability, of standards within a variety of clinical settings that may include a rural hospital or community health center, a community hospital, a children's hospital, and an urban academic center.

''(h) APPLICABILITY OF FACA.—The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the MITAB.

''(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary of Health and Human Services such sums as are necessary to carry out this section.

''SEC. 934. GRANTS FOR COMPUTERIZED PHYSICIAN ORDER ENTRY SYSTEMS.

''(a) IN GENERAL.—The Secretary may award grants to eligible entities to enable such entities to develop, install, or train personnel in the use of, computerized physician order entry systems.

''(b) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), an entity shall—

''(1) be a nonprofit hospital, health care clinic, community health center, skilled nursing facility, or other nonprofit entity determined to be eligible by the Secretary;

''(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a description of the computerized medication prescribing system that the entity in-

tends to implement using amounts received under the grant; and

''(3) provide assurances that are satisfactory to the Secretary that any computerized physician order entry systems, for which amounts are to be expended under an award made under subsection (a), conform to the technical standards established by the Secretary for such systems under section 932(a)(2).

''(c) MATCHING REQUIREMENT.—

''(1) IN GENERAL.—The Secretary may not make a grant to an entity under subsection (a) unless that entity agrees that, with respect to the costs to be incurred by the entity in carrying out the activities for which the grant is being awarded, the entity will make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount equal to $1 for each $2 of Federal funds provided under the grant.

''(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including equipment or services. Amounts provided by the Federal Government, or services as-

sisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

''(d) STUDY.—

''(1) IN GENERAL.—The Secretary, acting through The Director of the Agency for Healthcare Research and Quality, shall support a study to assess existing scientific evidence regarding the effectiveness and cost-effectiveness of the use of electronic prescription programs intended to improve the efficiency of prescription ordering and the safe and effective use of prescription drugs. The study shall address the following:

''(A) The ability of such programs to reduce medical errors and improve the quality and safety of patient care.

''(B) The impact of the use of such programs on physicians, pharmacists, and patients, including such factors as direct and indirect costs, changes in productivity, and satisfaction.

''(C) The effectiveness of strategies for overcoming barriers to the use of electronic prescription programs.

''(2) REPORT.—The Secretary shall ensure that, not later than 18 months after the date of enactment of this part, a report containing the findings of the study under paragraph (1) is submitted to the appropriate committees of the Congress.

''(3) DISSEMINATION OF FINDINGS.—The Secretary shall disseminate the findings of the study under paragraph (1) to appropriate public and private entities.

''(e) DEFINITIONS.—In this section and section 932:

''(1) COMPUTERIZED PHYSICIAN ORDER ENTRY SYSTEM.—The term 'computerized physician order entry system' means an information technology system that—

''(A) shall—

''(i) permit a qualified practitioner who wishes to enter a medication order for a patient to enter such order via a computer that is linked to a database capable of accessing the medical record of the patient who is intended to receive such medication;

''(ii) incorporate prescribing error prevention software so that a warning (including documentation regarding the cause of

such warning) is generated by such system if a medication order is entered that is likely to lead to an adverse drug event; and

''(iii) require documented acknowledgment that a qualified practitioner entering a medication order that has generated the warning described in clause (ii) has read the appropriate documentation regarding the cause of such warning prior to overriding such warning; and

''(B) may allow for the electronic submission of prescriptions to pharmacies or pharmacy benefit managers and the processing of such submissions by pharmacies.

''(2) QUALIFIED PRACTITIONER.—The term 'qualified practitioner' means a practitioner licensed to administer prescription drugs.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $100,000,000 for fiscal year 2004, and such sums as may be necessary for each of fiscal years 2005 through 2008.

''SEC. 935. GRANTS FOR INFORMATICS SYSTEMS.

''(a) IN GENERAL.—The Secretary may establish a program to make grants to eligible entities for the purpose of assisting such entities in offsetting the costs related to

purchasing, leasing, licensing, developing, and implementing standardized clinical health care informatics systems, other than computerized prescriber order entry systems, that are designed to improve patient safety and reduce adverse events and health care complications resulting from medication errors.

''(b) COSTS DEFINED.—In this section, the term 'costs' includes total expenditures incurred for—

''(1) purchasing, leasing, licensing, and installing computer software and hardware;

''(2) making improvements to existing computer software and hardware;

''(3) purchasing or leasing communications capabilities necessary for clinical data access, storage, and exchange; and

''(4) providing education and training to eligible entity staff on computer patient safety information systems.

''(c) ELIGIBILITY.—To be eligible to receive a grant under this section, an entity shall—

''(1) be a hospital, health care clinic, community health center, skilled nursing facility, patient safety organization, or other entity determined to be eligible by the Secretary; and

''(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a description of the type of informatics system that the entity intends to implement using amounts received under the grant.

''(d) TYPES OF IMFORMATICS SYSTEMS.—

''(1) IN GENERAL.—Not later than 6 months after the date of enactment of this part, the Secretary shall identify the informatics systems, other than computerized physician order entry systems, and other information technology or telecommunications systems demonstrated to improve patient safety and reduce adverse events and health care complications resulting from medication errors, that may be adopted and applied by eligible entities through funds under this section.

''(2) SYSTEMS.—The systems described in paragraph (1) may include bar coding, software to collect and analyze medication errors, clinical decision-support systems, software to detect inappropriately prescribed drugs or doses, drug utilization review programs, and disease management systems.

''(e) MATCHING REQUIREMENT.—

''(1) IN GENERAL.—The Secretary may not make a grant to an entity under subsection (a) unless that entity agrees that, with respect to the costs to be incurred by the entity in carrying out the activities for which the grant is being awarded, the entity will make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount equal to $1 for each $1 of Federal funds provided under the grant.

''(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including equipment or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

''(f) ADDITIONAL INFORMATION.—An eligible entity receiving a grant under this section shall furnish the Secretary with such information as the Secretary may require to—

''(1) evaluate the project for which the grant is made, including how the project has improved pa-

tient safety and has reduced patient safety events and health care complications resulting from medication errors; and

''(2) ensure that funding provided under the grant is expended for the purposes for which it is made.

''(g) REPORTS.—

''(1) INTERIM REPORTS.—

''(A) IN GENERAL.—The Secretary shall submit, at least annually, a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the grant program established under this section.

''(B) CONTENTS.—A report submitted pursuant to subparagraph (A) shall include information on—

''(i) the number of grants made;

''(ii) the nature of the projects for which funding is provided under the grant program;

''(iii) the geographic distribution of grant recipients; and

''(iv) such other matters as the Secretary determines appropriate.

''(2) FINAL REPORT.—Not later than 5 years after the date of enactment of this part, the Secretary shall submit a final report to the committees referred to in paragraph (1)(A) on the grant program.

''(h) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $50,000,000 for fiscal year 2004, and such sums as may be necessary for each subsequent fiscal year.''.

''SEC. 936. GRANTS FOR PATIENT SAFETY RESEARCH.

''(a) IN GENERAL.—The Secretary may conduct research and award grants to promote research on patient safety.

''(b) PROCESS.—The Secretary shall establish a formal process to gather information on priorities, methodologies and approaches for medical errors, including medication errors, and patient safety research. In gathering such information, the Secretary shall ensure that input is obtained from a wide range of individuals and organizations who will use and can benefit from the availability of such information.

''(c) COORDINATION.—The Secretary shall ensure that activities are carried out under subsection (a) in co-

operation and coordination with existing research initiatives, programs, and activities.

''(d) OTHER INDUSTRIES.—In carrying out this section, the Secretary shall consider the experiences of other industries in reducing errors within such industries and the processes that such industries employ to reduce errors.

''(e) ISSUES.—The issues to be addressed with respect to the research to be conducted and supported under this subsection may include—

''(1) the types and causes of errors in the provision of health care, both in the United States and internationally, such as those identified by the reporting system developed by the Linnaeus Collaboration and the United States Pharmacopeia;

''(2) the identification and comparison of trends in errors in geographically and demographically diverse health care facilities;

''(3) training requirements for health care professionals to ensure that such professionals provide quality health care generally, in specific settings, and for specific practices;

''(4) the development of effective communication methods and tools between disciplines to improve patient safety;

''(5) the use of interdisciplinary teams to improve patient safety;

''(6) the barriers to medical error reduction strategies;

''(7) the use of standardized processes in providing medication, including the application of these processes in demographically diverse health care facilities;

''(8) the application of a national standardized taxonomy for medication errors;

''(9) the effect of educational programs on the consistent application of standardized definitions, terminology, and formats; and

''(10) other areas determined appropriate by the Secretary.

''(f) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), an entity shall—

''(1) be a patient safety organization, health care professional, health care professional association, research organization, university, or other entity determined to be eligible by the Secretary; and

''(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $50,000,000 for fiscal year 2004, and such sums as may be necessary for each subsequent fiscal year.''.

SEC. 604. REQUIRED USE OF PRODUCT IDENTIFICATION TECHNOLOGY.

The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) in section 502, by adding at the end the following:

''(u) If it is a drug or biological product, unless it includes a unique product identifier for the drug or biological product as required by regulations under section 510(o).''; and

(2) in section 510, by adding at the end the following:

''(o)(1) The Secretary shall issue, and may periodically revise, regulations requiring the manufacturer of any drug or biological product, or the packager or labeler of a drug or biological product, to include a unique product identifier on the packaging of the drug or biological product.

''(2) For purposes of this subsection, the term 'unique product identifier' means an identification that—

''(A) is affixed by the manufacturer, labeler, or packager to each drug or biological product described in paragraph (1);

''(B) uniquely identifies the item and meets the standards required by this section; and

''(C) can be read by a scanning device or other technology acceptable to the Secretary.

''(3) A unique product identifier required by regulations issued or revised under paragraph (1) shall be based on—

''(A) the National Drug Code maintained by the Food and Drug Administration;

''(B) commercially accepted standards established by organizations that are accredited by the American National Standards Institute, such as the Health Industry Business Communication Council or the Uniform Code Council; or

''(C) other identification formats that the Secretary deems appropriate.

''(4) The Secretary may, at the Secretary's discretion, waive the requirements of this subsection, or add additional provisions that are necessary to safeguard the public health.''.

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