113TH CONGRESS
1ST SESSION

S. 1860

To reform the medical liability system, improve access to health care for rural and indigent patients, enhance access to affordable prescription drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 19, 2013

Mr. HELLER introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To reform the medical liability system, improve access to health care for rural and indigent patients, enhance access to affordable prescription drugs, and for other purposes.

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 ''Steps Toward Access and Reform Act of 2013'' or the ''STAR Act of 2013''.

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

TITLE I—MEDICAL LIABILITY REFORM

SEC. 101. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.

The time for the commencement of a health care lawsuit shall be 3 years after the date of manifestation of injury or 1 year after the claimant discovers, or through the use of reasonable diligence should have discovered, the injury, whichever occurs first. In no event shall the time for commencement of a health care lawsuit exceed 3 years after the date of manifestation of injury unless tolled for any of the following—

(1) upon proof of fraud;

(2) intentional concealment; or

(3) the presence of a foreign body, which has no therapeutic or diagnostic purpose or effect, in the body of the injured person.

Actions by a minor shall be commenced within 3 years from the date of the alleged manifestation of injury except that actions by a minor under the full age of 6 years shall be commenced within 3 years of manifestation of injury or prior to the minor's 8th birthday, whichever provides a longer period. Such time limitation shall be tolled for minors for any period during which a parent or guardian and a health care provider or health care organization have committed fraud or collusion in the failure to bring an action on behalf of the injured minor.

SEC. 102. COMPENSATING PATIENT INJURY.

(a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any health care lawsuit, nothing in this title shall limit a claimant's recovery of the full amount of the available economic damages, notwithstanding the limitation in subsection (b).

(b) ADDITIONAL NONECONOMIC DAMAGES.—In any health care lawsuit, the amount of noneconomic damages, if available, shall not exceed $250,000, regardless of the number of parties against whom the action is brought or

the number of separate claims or actions brought with respect to the same injury.

(c) NO DISCOUNT OF AWARD FOR NONECONOMIC DAMAGES.—For purposes of applying the limitation in subsection (b), future noneconomic damages shall not be discounted to present value. The jury shall not be informed about the maximum award for noneconomic damages. An award for noneconomic damages in excess of $250,000 shall be reduced either before the entry of judgment, or by amendment of the judgment after entry of judgment, and such reduction shall be made before accounting for any other reduction in damages required by law. If separate awards are rendered for past and future noneconomic damages and the combined awards exceed $250,000, the future noneconomic damages shall be reduced first.

(d) FAIR SHARE RULE.—In any health care lawsuit, each party shall be liable for that party's several share of any damages only and not for the share of any other person. Each party shall be liable only for the amount of damages allocated to such party in direct proportion to such party's percentage of responsibility. Whenever a judgment of liability is rendered as to any party, a separate judgment shall be rendered against each such party for the amount allocated to such party. For purposes of

this section, the trier of fact shall determine the proportion of responsibility of each party for the claimant's harm.

SEC. 103. MAXIMIZING PATIENT RECOVERY.

(a) COURT SUPERVISION OF SHARE OF DAMAGES ACTUALLY PAID TO CLAIMANTS.—In any health care lawsuit, the court shall supervise the arrangements for payment of damages to protect against conflicts of interest that may have the effect of reducing the amount of damages awarded that are actually paid to claimants. In particular, in any health care lawsuit in which the attorney for a party claims a financial stake in the outcome by virtue of a contingent fee, the court shall have the power to restrict the payment of a claimant's damage recovery to such attorney, and to redirect such damages to the claimant based upon the interests of justice and principles of equity. In no event shall the total of all contingent fees for representing all claimants in a health care lawsuit exceed the following limits:

(1) 40 percent of the first $50,000 recovered by the claimants.

(2) 33⅓ percent of the next $50,000 recovered by the claimants.

(3) 25 percent of the next $500,000 recovered by the claimants.

(4) 15 percent of any amount by which the recovery by the claimants is in excess of $600,000.

(b) APPLICABILITY.—The limitations in this section shall apply whether the recovery is by judgment, settlement, mediation, arbitration, or any other form of alternative dispute resolution. In a health care lawsuit involving a minor or incompetent person, a court retains the authority to authorize or approve a fee that is less than the maximum permitted under this section. The requirement for court supervision in the first two sentences of subsection (a) applies only in civil actions.

SEC. 104. ADDITIONAL COLLATERAL SOURCE BENEFITS.

In any health care lawsuit involving injury or wrongful death, any party may introduce evidence of collateral source benefits. If a party elects to introduce such evidence, any opposing party may introduce evidence of any amount paid or contributed or reasonably likely to be paid or contributed in the future by or on behalf of the opposing party to secure the right to such collateral source benefits. No provider of collateral source benefits shall recover any amount against the claimant or receive any lien or credit against the claimant's recovery or be equitably or legally subrogated to the right of the claimant in a health care lawsuit involving injury or wrongful death. This section shall apply to any health care lawsuit that is settled

as well as a health care lawsuit that is resolved by a fact finder. This section shall not apply to section 1862(b) (42 U.S.C. 1395y(b)) or section 1902(a)(25) (42 U.S.C. 1396a(a)(25)) of the Social Security Act.

SEC. 105. PUNITIVE DAMAGES.

(a) IN GENERAL.—Punitive damages may, if otherwise permitted by applicable State or Federal law, be awarded against any person in a health care lawsuit only if it is proven by clear and convincing evidence that such person acted with malicious intent to injure the claimant, or that such person deliberately failed to avoid unnecessary injury that such person knew the claimant was substantially certain to suffer. In any health care lawsuit where no judgment for compensatory damages is rendered against such person, no punitive damages may be awarded with respect to the claim in such lawsuit. No demand for punitive damages shall be included in a health care lawsuit as initially filed. A court may allow a claimant to file an amended pleading for punitive damages only upon a motion by the claimant and after a finding by the court, upon review of supporting and opposing affidavits or after a hearing, after weighing the evidence, that the claimant has established by a substantial probability that the claimant will prevail on the claim for punitive damages. At the re-

quest of any party in a health care lawsuit, the trier of fact shall consider in a separate proceeding—

(1) whether punitive damages are to be awarded and the amount of such award; and

(2) the amount of punitive damages following a determination of punitive liability.

If a separate proceeding is requested, evidence relevant only to the claim for punitive damages, as determined by applicable State law, shall be inadmissible in any proceeding to determine whether compensatory damages are to be awarded.

(b) DETERMINING AMOUNT OF PUNITIVE DAMAGES.—

(1) FACTORS CONSIDERED.—In determining the amount of punitive damages, if awarded, in a health care lawsuit, the trier of fact shall consider only the following—

(A) the severity of the harm caused by the conduct of such party;

(B) the duration of the conduct or any concealment of it by such party;

(C) the profitability of the conduct to such party;

(D) the number of products sold or medical procedures rendered for compensation, as

the case may be, by such party, of the kind causing the harm complained of by the claimant;

(E) any criminal penalties imposed on such party, as a result of the conduct complained of by the claimant; and

(F) the amount of any civil fines assessed against such party as a result of the conduct complained of by the claimant.

(2) MAXIMUM AWARD.—The amount of punitive damages, if awarded, in a health care lawsuit may not exceed $250,000 or two times the amount of economic damages awarded, whichever is greater. The jury shall not be informed of this limitation.

(c) NO PUNITIVE DAMAGES FOR PRODUCTS THAT COMPLY WITH FDA STANDARDS.—

(1) IN GENERAL.—

(A) No punitive damages may be awarded against the manufacturer or distributor of a medical product, or a supplier of any component or raw material of such medical product, based on a claim that such product caused the claimant's harm where—

(i)(I) such medical product was subject to premarket approval, clearance, or li-

censure by the Food and Drug Administration with respect to the safety of the formulation or performance of the aspect of such medical product which caused the claimant's harm or the adequacy of the packaging or labeling of such medical product; and

(II) such medical product was so approved, cleared, or licensed; or

(ii) such medical product is generally recognized among qualified experts as safe and effective pursuant to conditions established by the Food and Drug Administration and applicable Food and Drug Administration regulations, including without limitation those related to packaging and labeling, unless the Food and Drug Administration has determined that such medical product was not manufactured or distributed in substantial compliance with applicable Food and Drug Administration statutes and regulations.

(B) RULE OF CONSTRUCTION.—Subparagraph (A) may not be construed as establishing the obligation of the Food and Drug Adminis-

tration to demonstrate affirmatively that a manufacturer, distributor, or supplier referred to in such subparagraph meets any of the conditions described in such subparagraph.

(2) LIABILITY OF HEALTH CARE PROVIDERS.—A health care provider who prescribes, or who dispenses pursuant to a prescription, a medical product approved, licensed, or cleared by the Food and Drug Administration shall not be named as a party to a product liability lawsuit involving such product and shall not be liable to a claimant in a class action lawsuit against the manufacturer, distributor, or seller of such product. Nothing in this paragraph prevents a court from consolidating cases involving health care providers and cases involving products liability claims against the manufacturer, distributor, or product seller of such medical product.

(3) PACKAGING.—In a health care lawsuit for harm which is alleged to relate to the adequacy of the packaging or labeling of a drug which is required to have tamper-resistant packaging under regulations of the Secretary of Health and Human Services (including labeling regulations related to such packaging), the manufacturer or product seller of the drug shall not be held liable for punitive dam-

ages unless such packaging or labeling is found by the trier of fact by clear and convincing evidence to be substantially out of compliance with such regulations.

(4) EXCEPTION.—Paragraph (1) shall not apply in any health care lawsuit in which—

(A) a person, before or after premarket approval, clearance, or licensure of such medical product, knowingly misrepresented to or withheld from the Food and Drug Administration information that is required to be submitted under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or section 351 of the Public Health Service Act (42 U.S.C. 262) that is material and is causally related to the harm which the claimant allegedly suffered; or

(B) a person made an illegal payment to an official of the Food and Drug Administration for the purpose of either securing or maintaining approval, clearance, or licensure of such medical product.

SEC. 106. AUTHORIZATION OF PAYMENT OF FUTURE DAMAGES TO CLAIMANTS IN HEALTH CARE LAWSUITS.

(a) IN GENERAL.—In any health care lawsuit, if an award of future damages, without reduction to present value, equaling or exceeding $50,000 is made against a party with sufficient insurance or other assets to fund a periodic payment of such a judgment, the court shall, at the request of any party, enter a judgment ordering that the future damages be paid by periodic payments. In any health care lawsuit, the court may be guided by the Uniform Periodic Payment of Judgments Act promulgated by the National Conference of Commissioners on Uniform State Laws.

(b) APPLICABILITY.—This section applies to all actions which have not been first set for trial or retrial before the effective date of this Act.

SEC. 107. EFFECT ON OTHER LAWS.

(a) VACCINE INJURY.—

(1) To the extent that title XXI of the Public Health Service Act establishes a Federal rule of law applicable to a civil action brought for a vaccine-related injury or death—

(A) this title does not affect the application of the rule of law to such an action; and

(B) any rule of law prescribed by this title in conflict with a rule of law of such title XXI shall not apply to such action.

(2) If there is an aspect of a civil action brought for a vaccine-related injury or death to which a Federal rule of law under title XXI of the Public Health Service Act does not apply, then this title or otherwise applicable law (as determined under this title) will apply to such aspect of such action.

(b) OTHER FEDERAL LAW.—Except as provided in this section, nothing in this title shall be deemed to affect any defense available to a defendant in a health care lawsuit or action under any other provision of Federal law.

SEC. 108. STATE FLEXIBILITY AND PROTECTION OF STATES' RIGHTS.

(a) HEALTH CARE LAWSUITS.—The provisions governing health care lawsuits set forth in this title preempt, subject to subsections (b) and (c), State law to the extent that State law prevents the application of any provisions of law established by or under this title. The provisions governing health care lawsuits set forth in this title supersede chapter 171 of title 28, United States Code, to the extent that such chapter—

(1) provides for a greater amount of damages or contingent fees, a longer period in which a health care lawsuit may be commenced, or a reduced applicability or scope of periodic payment of future damages, than provided in this title; or

(2) prohibits the introduction of evidence regarding collateral source benefits, or mandates or permits subrogation or a lien on collateral source benefits.

(b) PROTECTION OF STATES' RIGHTS AND OTHER LAWS.—(1) Any issue that is not governed by any provision of law established by or under this title (including State standards of negligence) shall be governed by otherwise applicable State or Federal law.

(2) This title shall not preempt or supersede any State or Federal law that imposes greater procedural or substantive protections for health care providers and health care organizations from liability, loss, or damages than those provided by this title or create a cause of action.

(c) STATE FLEXIBILITY.—No provision of this title shall be construed to preempt—

(1) any State law (whether effective before, on, or after the date of the enactment of this Act) that specifies a particular monetary amount of compen-

satory or punitive damages (or the total amount of damages) that may be awarded in a health care lawsuit, regardless of whether such monetary amount is greater or lesser than is provided for under this title, notwithstanding section 104(a); or

(2) any defense available to a party in a health care lawsuit under any other provision of State or Federal law.

SEC. 109. APPLICABILITY; EFFECTIVE DATE.

This title shall apply to any health care lawsuit brought in a Federal or State court, or subject to an alternative dispute resolution system, that is initiated on or after the date of the enactment of this Act, except that any health care lawsuit arising from an injury occurring prior to the date of the enactment of this Act shall be governed by the applicable statute of limitations provisions in effect at the time the injury occurred.

SEC. 110. SENSE OF CONGRESS.

It is the sense of Congress that a health insurer should be liable for damages for harm caused when it makes a decision as to what care is medically necessary and appropriate.

SEC. 111. DEFINITIONS.

In this title:

(1) ALTERNATIVE DISPUTE RESOLUTION SYSTEM; ADR.—The term ''alternative dispute resolution system'' or ''ADR'' means a system that provides for the resolution of health care lawsuits in a manner other than through a civil action brought in a State or Federal court.

(2) CLAIMANT.—The term ''claimant'' means any person who brings a title, including a person who asserts or claims a right to legal or equitable contribution, indemnity, or subrogation, arising out of a health care liability claim or action, and any person on whose behalf such a claim is asserted or such an action is brought, whether deceased, incompetent, or a minor.

(3) COLLATERAL SOURCE BENEFITS.—The term ''collateral source benefits'' means any amount paid or reasonably likely to be paid in the future to or on behalf of the claimant, or any service, product, or other benefit provided or reasonably likely to be provided in the future to or on behalf of the claimant, as a result of the injury or wrongful death, pursuant to—

(A) any State or Federal health, sickness, income-disability, accident, or workers' compensation law;

(B) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(C) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income-disability benefits; and

(D) any other publicly or privately funded program.

(4) COMPENSATORY DAMAGES.—The term ''compensatory damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities, damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses

of any kind or nature. The term ''compensatory damages'' includes economic damages and non-economic damages, as such terms are defined in this section.

(5) CONTINGENT FEE.—The term ''contingent fee'' includes all compensation to any person or persons which is payable only if a recovery is effected on behalf of one or more claimants.

(6) ECONOMIC DAMAGES.—The term ''economic damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities.

(7) HEALTH CARE LAWSUIT.—The term ''health care lawsuit'' means any health care liability claim concerning the provision of health care goods or services or any medical product affecting interstate commerce, or any health care liability action concerning the provision of health care goods or services or any medical product affecting interstate commerce, brought in a State or Federal court or

pursuant to an alternative dispute resolution system, against a health care provider, a health care organization, or the manufacturer, distributor, supplier, marketer, promoter, or seller of a medical product, regardless of the theory of liability on which the claim is based, or the number of claimants, plaintiffs, defendants, or other parties, or the number of claims or causes of action, in which the claimant alleges a health care liability claim. Such term does not include a claim or action which is based on criminal liability; which seeks civil fines or penalties paid to Federal, State, or local government; or which is grounded in antitrust.

(8) HEALTH CARE LIABILITY ACTION.—The term ''health care liability action'' means a civil action brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider, a health care organization, or the manufacturer, distributor, supplier, marketer, promoter, or seller of a medical product, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action, in which the claimant alleges a health care liability claim.

(9) HEALTH CARE LIABILITY CLAIM.—The term ''health care liability claim'' means a demand by any person, whether or not pursuant to ADR, against a health care provider, health care organization, or the manufacturer, distributor, supplier, marketer, promoter, or seller of a medical product, including, but not limited to, third-party claims, cross-claims, counter-claims, or contribution claims, which are based upon the provision of, use of, or payment for (or the failure to provide, use, or pay for) health care services or medical products, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action.

(10) HEALTH CARE ORGANIZATION.—The term ''health care organization'' means any person or entity which is obligated to provide or pay for health benefits under any health plan, including any person or entity acting under a contract or arrangement with a health care organization to provide or administer any health benefit.

(11) HEALTH CARE PROVIDER.—The term ''health care provider'' means any person or entity required by State or Federal laws or regulations to be licensed, registered, or certified to provide health

care services, and being either so licensed, registered, or certified, or exempted from such requirement by other statute or regulation.

(12) HEALTH CARE GOODS OR SERVICES.—The term ''health care goods or services'' means any goods or services provided by a health care organization, provider, or by any individual working under the supervision of a health care provider, that relates to the diagnosis, prevention, or treatment of any human disease or impairment, or the assessment or care of the health of human beings.

(13) MALICIOUS INTENT TO INJURE.—The term ''malicious intent to injure'' means intentionally causing or attempting to cause physical injury other than providing health care goods or services.

(14) MEDICAL PRODUCT.—The term ''medical product'' means a drug, device, or biological product intended for humans, and the terms ''drug'', ''device'', and ''biological product'' have the meanings given such terms in sections 201(g)(1) and 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1) and (h)) and section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), re-

spectively, including any component or raw material used therein, but excluding health care services.

(15) NONECONOMIC DAMAGES.—The term ''noneconomic damages'' means damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature.

(16) PUNITIVE DAMAGES.—The term ''punitive damages'' means damages awarded, for the purpose of punishment or deterrence, and not solely for compensatory purposes, against a health care provider, health care organization, or a manufacturer, distributor, or supplier of a medical product. Punitive damages are neither economic nor noneconomic damages.

(17) RECOVERY.—The term ''recovery'' means the net sum recovered after deducting any disbursements or costs incurred in connection with prosecution or settlement of the claim, including all costs paid or advanced by any person. Costs of health care incurred by the plaintiff and the attorneys' office

overhead costs or charges for legal services are not deductible disbursements or costs for such purpose.

(18) STATE.—The term ''State'' means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and any other territory or possession of the United States, or any political subdivision thereof.

TITLE II—IMPROVING ACCESS FOR RURAL AND INDIGENT PATIENTS

SEC. 201. IMPROVING ACCESS FOR RURAL AND INDIGENT PATIENTS.

(a) LOAN FORGIVENESS FOR PRIMARY CARE PROVIDERS.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall carry out a program of entering into contracts with eligible individuals under which—

(A) the individual agrees to serve for a period of not less than 4 years as a primary care provider in a medically underserved community (as defined in section 799B of the Public Health Service Act (42 U.S.C. 295p)); and

(B) in consideration of such service, the Secretary agrees to pay not more than $100,000 on the principal and interest on the individual's graduate educational loans.

(2) ELIGIBILITY.—To be eligible to enter into a contract under subsection (1), an individual must—

(A) have a graduate degree in medicine, osteopathic medicine, or another health profession from an accredited (as determined by the Secretary of Health and Human Services) institution of higher education; and

(B) have practiced as a primary care provider for a period (excluding any residency or fellowship training period) of not less than 3 years in a medically underserved community (as defined in section 799B of the Public Health Service Act (42 U.S.C. 295p)).

(3) INSTALLMENTS.—Payments under this section may be made in installments of not more than $25,000 for each year of service described in paragraph (1) (A).

(4) APPLICABILITY OF CERTAIN PROVISIONS.—The provisions of subpart III of part D of title III of the Public Health Service Act shall, except as inconsistent with this section, apply to the program es-

tablished under this section in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established in such subpart.

(b) PERMITTING STATE DESIGNATION OF CRITICAL ACCESS HOSPITALS.—Section 1820(c)(2)(B)(i)(II) of the Social Security Act (42 U.S.C. 1395i–4(c)(2)(B)(i)(II)) is amended by inserting ''or on or after the date of enactment of the Steps Toward Access and Reform Act of 2013'' after ''January 1, 2006,''.

(c) PATIENT FAIRNESS AND INDIGENT CARE PROMOTION.—

(1) IN GENERAL.—Section 166 of the Internal Revenue Code of 1986 (relating to bad debts) is amended by redesignating subsection (f) as subsection (g) and by inserting after subsection (e) the following new subsection:

''(f) UNPAID MEDICAL CARE PROVIDED TO LOW-INCOME INDIVIDUALS.—

''(1) IN GENERAL.—In the case of a taxpayer to whom this subsection applies, the deduction under subsection (a) for worthless qualified medical care debt shall not be less than 75 percent of the taxpayer's charge for such care.

''(2) TAXPAYER TO WHOM SUBSECTION APPLIES.—This subsection shall apply to any taxpayer who is engaged in the trade or business of providing medical care other than as an employee and who used the cash receipts and disbursements method of accounting.

''(3) QUALIFIED MEDICAL CARE DEBT.—For purposes of this subsection, the term 'qualified medical care debt' means any debt for medical care provided by the taxpayer to a low-income individual who is a citizen or legal resident of the United States.

''(4) DETERMINATION OF CHARGE.—The amount of the taxpayer's charge which may be taken into account—

''(A) shall not exceed the amount of the charge that would be recognized for purposes of title XVIII of the Social Security Act, and

''(B) shall not include any amount for which the taxpayer is not entitled to reimbursement from the low-income individual.

''(5) LOW-INCOME INDIVIDUAL.—For purposes of this subsection, the term 'low-income individual' means an individual who, at the time the medical care attributable to the debt is provided, has an annual household income below 135 percent of the pov-

erty line (as defined in section 673 of the Community Services Block Grant Act (42 U.S.C. 9902)) applicable to the size of the family involved, and is a citizen or legal resident of the United States.

''(6) MEDICAL CARE.—For purposes of this subsection, the term 'medical care' has the meaning given to such term by section 213(d).

''(7) REGULATIONS.—The Secretary shall prescribe such regulations as may be necessary or appropriate to carry out this section, including regulations providing for methods of establishing that an individual is a low-income individual for purposes of this section.''.

(2) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after the date of the enactment of this Act.

TITLE III—PROVIDING FOR AFFORDABLE PRESCRIPTION DRUGS

SEC. 301. PROVIDING FOR AFFORDABLE PRESCRIPTION DRUGS.

Notwithstanding any other provision of law, the Food and Drug Administration shall not take any action to prevent an individual not in the business of importing a prescription drug (within the meaning of section 801(g) of

the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(g))) from importing a prescription drug from Canada that complies with the Federal Food, Drug, and Cosmetic Act.

TITLE IV—EXPANDING CHOICES BY ALLOWING AMERICANS TO BUY HEALTH CARE COVERAGE ACROSS STATE LINES

SEC. 401. INTERSTATE PURCHASING OF HEALTH INSURANCE.

(a) IN GENERAL.—Title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.) is amended by adding at the end the following:

"PART D—COOPERATIVE GOVERNING OF INDIVIDUAL HEALTH INSURANCE COVERAGE

"SEC. 2795. DEFINITIONS.

''In this part:

''(1) PRIMARY STATE.—The term 'primary State' means, with respect to individual health insurance coverage offered by a health insurance issuer, the State designated by the issuer as the State whose covered laws shall govern the health insurance issuer in the sale of such coverage under this part. An issuer, with respect to a particular policy, may only designate one such State as its primary State

with respect to all such coverage it offers. Such an issuer may not change the designated primary State with respect to individual health insurance coverage once the policy is issued, except that such a change may be made upon renewal of the policy. With respect to such designated State, the issuer is deemed to be doing business in that State.

''(2) SECONDARY STATE.—The term 'secondary State' means, with respect to individual health insurance coverage offered by a health insurance issuer, any State that is not the primary State. In the case of a health insurance issuer that is selling a policy in, or to a resident of, a secondary State, the issuer is deemed to be doing business in that secondary State.

''(3) HEALTH INSURANCE ISSUER.—The term 'health insurance issuer' has the meaning given such term in section 2791(b)(2), except that such an issuer must be licensed in the primary State and be qualified to sell individual health insurance coverage in that State.

''(4) INDIVIDUAL HEALTH INSURANCE COVERAGE.—The term 'individual health insurance coverage' means health insurance coverage offered in

the individual market, as defined in section 2791(e)(1).

''(5) APPLICABLE STATE AUTHORITY.—The term 'applicable State authority' means, with respect to a health insurance issuer in a State, the State insurance commissioner or official or officials designated by the State to enforce the requirements of this title for the State with respect to the issuer.

''(6) HAZARDOUS FINANCIAL CONDITION.—The term 'hazardous financial condition' means that, based on its present or reasonably anticipated financial condition, a health insurance issuer is unlikely to be able—

''(A) to meet obligations to policyholders with respect to known claims and reasonably anticipated claims; or

''(B) to pay other obligations in the normal course of business.

''(7) COVERED LAWS.—

''(A) IN GENERAL.—The term 'covered laws' means the laws, rules, regulations, agreements, and orders governing the insurance business pertaining to—

''(i) individual health insurance coverage issued by a health insurance issuer;

''(ii) the offer, sale, rating (including medical underwriting), renewal, and issuance of individual health insurance coverage to an individual;

''(iii) the provision to an individual in relation to individual health insurance coverage of health care and insurance related services;

''(iv) the provision to an individual in relation to individual health insurance coverage of management, operations, and investment activities of a health insurance issuer; and

''(v) the provision to an individual in relation to individual health insurance coverage of loss control and claims administration for a health insurance issuer with respect to liability for which the issuer provides insurance.

''(B) EXCEPTION.—Such term does not include any law, rule, regulation, agreement, or order governing the use of care or cost management techniques, including any requirement related to provider contracting, network access or

adequacy, health care data collection, or quality assurance.

''(8) STATE.—The term 'State' means the 50 States and includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

''(9) UNFAIR CLAIMS SETTLEMENT PRACTICES.—The term 'unfair claims settlement practices' means only the following practices:

''(A) Knowingly misrepresenting to claimants and insured individuals relevant facts or policy provisions relating to coverage at issue.

''(B) Failing to acknowledge with reasonable promptness pertinent communications with respect to claims arising under policies.

''(C) Failing to adopt and implement reasonable standards for the prompt investigation and settlement of claims arising under policies.

''(D) Failing to effectuate prompt, fair, and equitable settlement of claims submitted in which liability has become reasonably clear.

''(E) Refusing to pay claims without conducting a reasonable investigation.

''(F) Failing to affirm or deny coverage of claims within a reasonable period of time after

having completed an investigation related to those claims.

''(G) A pattern or practice of compelling insured individuals or their beneficiaries to institute suits to recover amounts due under its policies by offering substantially less than the amounts ultimately recovered in suits brought by them.

''(H) A pattern or practice of attempting to settle or settling claims for less than the amount that a reasonable person would believe the insured individual or his or her beneficiary was entitled by reference to written or printed advertising material accompanying or made part of an application.

''(I) Attempting to settle or settling claims on the basis of an application that was materially altered without notice to, or knowledge or consent of, the insured.

''(J) Failing to provide forms necessary to present claims within 15 calendar days of a request with reasonable explanations regarding their use.

''(K) Attempting to cancel a policy in less time than that prescribed in the policy or by the law of the primary State.

''(10) FRAUD AND ABUSE.—The term 'fraud and abuse' means an act or omission committed by a person who, knowingly and with intent to defraud, commits, or conceals any material information concerning, one or more of the following:

''(A) Presenting, causing to be presented or preparing with knowledge or belief that it will be presented to or by an insurer, a reinsurer, broker or its agent, false information as part of, in support of or concerning a fact material to one or more of the following:

''(i) An application for the issuance or renewal of an insurance policy or reinsurance contract.

''(ii) The rating of an insurance policy or reinsurance contract.

''(iii) A claim for payment or benefit pursuant to an insurance policy or reinsurance contract.

''(iv) Premiums paid on an insurance policy or reinsurance contract.

''(v) Payments made in accordance with the terms of an insurance policy or reinsurance contract.

''(vi) A document filed with the commissioner or the chief insurance regulatory official of another jurisdiction.

''(vii) The financial condition of an insurer or reinsurer.

''(viii) The formation, acquisition, merger, reconsolidation, dissolution or withdrawal from one or more lines of insurance or reinsurance in all or part of a State by an insurer or reinsurer.

''(ix) The issuance of written evidence of insurance.

''(x) The reinstatement of an insurance policy.

''(B) Solicitation or acceptance of new or renewal insurance risks on behalf of an insurer reinsurer or other person engaged in the business of insurance by a person who knows or should know that the insurer or other person responsible for the risk is insolvent at the time of the transaction.

''(C) Transaction of the business of insurance in violation of laws requiring a license, certificate of authority or other legal authority for the transaction of the business of insurance.

''(D) Attempt to commit, aiding or abetting in the commission of, or conspiracy to commit the acts or omissions specified in this paragraph.

''SEC. 2796. APPLICATION OF LAW.

''(a) IN GENERAL.—The covered laws of the primary State shall apply to individual health insurance coverage offered by a health insurance issuer in the primary State and in any secondary State, but only if the coverage and issuer comply with the conditions of this section with respect to the offering of coverage in any secondary State.

''(b) EXEMPTIONS FROM COVERED LAWS IN A SECONDARY STATE.—Except as provided in this section, a health insurance issuer with respect to its offer, sale, rating (including medical underwriting), renewal, and issuance of individual health insurance coverage in any secondary State is exempt from any covered laws of the secondary State (and any rules, regulations, agreements, or orders sought or issued by such State under or related to such covered laws) to the extent that such laws would—

''(1) make unlawful, or regulate, directly or indirectly, the operation of the health insurance issuer operating in the secondary State, except that any secondary State may require such an issuer—

''(A) to pay, on a nondiscriminatory basis, applicable premium and other taxes (including high risk pool assessments) which are levied on insurers and surplus lines insurers, brokers, or policyholders under the laws of the State;

''(B) to register with and designate the State insurance commissioner as its agent solely for the purpose of receiving service of legal documents or process;

''(C) to submit to an examination of its financial condition by the State insurance commissioner in any State in which the issuer is doing business to determine the issuer's financial condition, if—

''(i) the State insurance commissioner of the primary State has not done an examination within the period recommended by the National Association of Insurance Commissioners; and

''(ii) any such examination is conducted in accordance with the examiners'

handbook of the National Association of Insurance Commissioners and is coordinated to avoid unjustified duplication and unjustified repetition;

''(D) to comply with a lawful order issued—

''(i) in a delinquency proceeding commenced by the State insurance commissioner if there has been a finding of financial impairment under subparagraph (C); or

''(ii) in a voluntary dissolution proceeding;

''(E) to comply with an injunction issued by a court of competent jurisdiction, upon a petition by the State insurance commissioner alleging that the issuer is in hazardous financial condition;

''(F) to participate, on a nondiscriminatory basis, in any insurance insolvency guaranty association or similar association to which a health insurance issuer in the State is required to belong;

''(G) to comply with any State law regarding fraud and abuse (as defined in section

2795(10)), except that if the State seeks an injunction regarding the conduct described in this subparagraph, such injunction must be obtained from a court of competent jurisdiction;

''(H) to comply with any State law regarding unfair claims settlement practices (as defined in section 2795(9)); or

''(I) to comply with the applicable requirements for independent review under section 2798 with respect to coverage offered in the State;

''(2) require any individual health insurance coverage issued by the issuer to be countersigned by an insurance agent or broker residing in that Secondary State; or

''(3) otherwise discriminate against the issuer issuing insurance in both the primary State and in any secondary State.

''(c) CLEAR AND CONSPICUOUS DISCLOSURE.—A health insurance issuer shall provide the following notice, in 12-point bold type, in any insurance coverage offered in a secondary State under this part by such a health insurance issuer and at renewal of the policy, with the 5 blank spaces therein being appropriately filled with the name of the health insurance issuer, the name of primary

State, the name of the secondary State, the name of the secondary State, and the name of the secondary State, respectively, for the coverage concerned:

THIS POLICY IS ISSUED BY _____ AND IS GOVERNED BY THE LAWS AND REGULATIONS OF THE STATE OF _____, AND IT HAS MET ALL THE LAWS OF THAT STATE AS DETERMINED BY THAT STATE'S DEPARTMENT OF INSURANCE. THIS POLICY MAY BE LESS EXPENSIVE THAN OTHERS BECAUSE IT IS NOT SUBJECT TO ALL OF THE INSURANCE LAWS AND REGULATIONS OF THE STATE OF _____, INCLUDING COVERAGE OF SOME SERVICES OR BENEFITS MANDATED BY THE LAW OF THE STATE OF _____. ADDITIONALLY, THIS POLICY IS NOT SUBJECT TO ALL OF THE CONSUMER PROTECTION LAWS OR RESTRICTIONS ON RATE CHANGES OF THE STATE OF _____. AS WITH ALL INSURANCE PRODUCTS, BEFORE PURCHASING THIS POLICY, YOU SHOULD CAREFULLY REVIEW THE POLICY AND DETERMINE WHAT HEALTH CARE SERVICES THE POLICY COVERS AND WHAT BENEFITS IT PRO-

VIDES, INCLUDING ANY EXCLUSIONS, LIMITATIONS, OR CONDITIONS FOR SUCH SERVICES OR BENEFITS.

''(d) PROHIBITION ON CERTAIN RECLASSIFICATIONS AND PREMIUM INCREASES.—

''(1) IN GENERAL.—For purposes of this section, a health insurance issuer that provides individual health insurance coverage to an individual under this part in a primary or secondary State may not upon renewal—

''(A) move or reclassify the individual insured under the health insurance coverage from the class such individual is in at the time of issue of the contract based on the health-status related factors of the individual; or

''(B) increase the premiums assessed the individual for such coverage based on a health status-related factor or change of a health status-related factor or the past or prospective claim experience of the insured individual.

''(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed to prohibit a health insurance issuer—

"(A) from terminating or discontinuing coverage or a class of coverage in accordance with subsections (b) and (c) of section 2742;

"(B) from raising premium rates for all policy holders within a class based on claims experience;

"(C) from changing premiums or offering discounted premiums to individuals who engage in wellness activities at intervals prescribed by the issuer, if such premium changes or incentives—

"(i) are disclosed to the consumer in the insurance contract;

"(ii) are based on specific wellness activities that are not applicable to all individuals; and

"(iii) are not obtainable by all individuals to whom coverage is offered;

"(D) from reinstating lapsed coverage; or

"(E) from retroactively adjusting the rates charged an insured individual if the initial rates were set based on material misrepresentation by the individual at the time of issue.

"(e) PRIOR OFFERING OF POLICY IN PRIMARY STATE.—A health insurance issuer may not offer for sale

individual health insurance coverage in a secondary State unless that coverage is currently offered for sale in the primary State.

''(f) LICENSING OF AGENTS OR BROKERS FOR HEALTH INSURANCE ISSUERS.—Any State may require that a person acting, or offering to act, as an agent or broker for a health insurance issuer with respect to the offering of individual health insurance coverage obtain a license from that State, with commissions or other compensation subject to the provisions of the laws of that State, except that a State may not impose any qualification or requirement which discriminates against a nonresident agent or broker.

''(g) DOCUMENTS FOR SUBMISSION TO STATE INSURANCE COMMISSIONER.—Each health insurance issuer issuing individual health insurance coverage in both primary and secondary States shall submit—

''(1) to the insurance commissioner of each State in which it intends to offer such coverage, before it may offer individual health insurance coverage in such State—

''(A) a copy of the plan of operation or feasibility study or any similar statement of the policy being offered and its coverage (which

shall include the name of its primary State and its principal place of business);

"(B) written notice of any change in its designation of its primary State; and

"(C) written notice from the issuer of the issuer's compliance with all the laws of the primary State; and

"(2) to the insurance commissioner of each secondary State in which it offers individual health insurance coverage, a copy of the issuer's quarterly financial statement submitted to the primary State, which statement shall be certified by an independent public accountant and contain a statement of opinion on loss and loss adjustment expense reserves made by—

"(A) a member of the American Academy of Actuaries; or

"(B) a qualified loss reserve specialist.

"(h) POWER OF COURTS TO ENJOIN CONDUCT.—Nothing in this section shall be construed to affect the authority of any Federal or State court to enjoin—

"(1) the solicitation or sale of individual health insurance coverage by a health insurance issuer to any person or group who is not eligible for such insurance; or

''(2) the solicitation or sale of individual health insurance coverage that violates the requirements of the law of a secondary State which are described in subparagraphs (A) through (H) of section 2796(b)(1).

''(i) POWER OF SECONDARY STATES TO TAKE ADMINISTRATIVE ACTION.—Nothing in this section shall be construed to affect the authority of any State to enjoin conduct in violation of that State's laws described in section 2796(b)(1).

''(j) STATE POWERS TO ENFORCE STATE LAWS.—

''(1) IN GENERAL.—Subject to the provisions of subsection (b)(1)(G) (relating to injunctions) and paragraph (2), nothing in this section shall be construed to affect the authority of any State to make use of any of its powers to enforce the laws of such State with respect to which a health insurance issuer is not exempt under subsection (b).

''(2) COURTS OF COMPETENT JURISDICTION.—If a State seeks an injunction regarding the conduct described in paragraphs (1) and (2) of subsection (h), such injunction must be obtained from a Federal or State court of competent jurisdiction.

''(k) STATES' AUTHORITY TO SUE.—Nothing in this section shall affect the authority of any State to bring action in any Federal or State court.

''(l) GENERALLY APPLICABLE LAWS.—Nothing in this section shall be construed to affect the applicability of State laws generally applicable to persons or corporations.

''(m) GUARANTEED AVAILABILITY OF COVERAGE TO HIPAA ELIGIBLE INDIVIDUALS.—To the extent that a health insurance issuer is offering coverage in a primary State that does not accommodate residents of secondary States or does not provide a working mechanism for residents of a secondary State, and the issuer is offering coverage under this part in such secondary State which has not adopted a qualified high risk pool as its acceptable alternative mechanism (as defined in section 2744(c)(2)), the issuer shall, with respect to any individual health insurance coverage offered in a secondary State under this part, comply with the guaranteed availability requirements for eligible individuals in section 2741.

''SEC. 2797. PRIMARY STATE MUST MEET FEDERAL FLOOR BEFORE ISSUER MAY SELL INTO SECONDARY STATES.

''A health insurance issuer may not offer, sell, or issue individual health insurance coverage in a secondary

State if the State insurance commissioner does not use a risk-based capital formula for the determination of capital and surplus requirements for all health insurance issuers.

"SEC. 2798. INDEPENDENT EXTERNAL APPEALS PROCEDURES.

''(a) RIGHT TO EXTERNAL APPEAL.—A health insurance issuer may not offer, sell, or issue individual health insurance coverage in a secondary State under the provisions of this title unless—

''(1) both the secondary State and the primary State have legislation or regulations in place establishing an independent review process for individuals who are covered by individual health insurance coverage, or

''(2) in any case in which the requirements of subparagraph (A) are not met with respect to the either of such States, the issuer provides an independent review mechanism substantially identical (as determined by the applicable State authority of such State) to that prescribed in the 'Health Carrier External Review Model Act' of the National Association of Insurance Commissioners for all individuals who purchase insurance coverage under the terms of this part, except that, under such mechanism, the review

is conducted by an independent medical reviewer, or a panel of such reviewers, with respect to whom the requirements of subsection (b) are met.

''(b) QUALIFICATIONS OF INDEPENDENT MEDICAL REVIEWERS.—In the case of any independent review mechanism referred to in subsection (a)(2)—

''(1) IN GENERAL.—In referring a denial of a claim to an independent medical reviewer, or to any panel of such reviewers, to conduct independent medical review, the issuer shall ensure that—

''(A) each independent medical reviewer meets the qualifications described in paragraphs (2) and (3);

''(B) with respect to each review, each reviewer meets the requirements of paragraph (4) and the reviewer, or at least 1 reviewer on the panel, meets the requirements described in paragraph (5); and

''(C) compensation provided by the issuer to each reviewer is consistent with paragraph (6).

''(2) LICENSURE AND EXPERTISE.—Each independent medical reviewer shall be a physician (allopathic or osteopathic) or health care professional who—

''(A) is appropriately credentialed or licensed in 1 or more States to deliver health care services; and

''(B) typically treats the condition, makes the diagnosis, or provides the type of treatment under review.

''(3) INDEPENDENCE.—

''(A) IN GENERAL.—Subject to subparagraph (B), each independent medical reviewer in a case shall—

''(i) not be a related party (as defined in paragraph (7));

''(ii) not have a material familial, financial, or professional relationship with such a party; and

''(iii) not otherwise have a conflict of interest with such a party (as determined under regulations).

''(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

''(i) prohibit an individual, solely on the basis of affiliation with the issuer, from serving as an independent medical reviewer if—

''(I) a non-affiliated individual is not reasonably available;

''(II) the affiliated individual is not involved in the provision of items or services in the case under review;

''(III) the fact of such an affiliation is disclosed to the issuer and the enrollee (or authorized representative) and neither party objects; and

''(IV) the affiliated individual is not an employee of the issuer and does not provide services exclusively or primarily to or on behalf of the issuer;

''(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as an independent medical reviewer merely on the basis of such affiliation if the affiliation is disclosed to the issuer and the enrollee (or authorized representative), and neither party objects; or

''(iii) prohibit receipt of compensation by an independent medical reviewer from an entity if the compensation is provided consistent with paragraph (6).

''(4) PRACTICING HEALTH CARE PROFESSIONAL IN SAME FIELD.—

''(A) IN GENERAL.—In a case involving treatment, or the provision of items or services—

''(i) by a physician, a reviewer shall be a practicing physician (allopathic or osteopathic) of the same or similar specialty, as a physician who, acting within the appropriate scope of practice within the State in which the service is provided or rendered, typically treats the condition, makes the diagnosis, or provides the type of treatment under review; or

''(ii) by a non-physician health care professional, the reviewer, or at least 1 member of the review panel, shall be a practicing non-physician health care professional of the same or similar specialty as the non-physician health care professional who, acting within the appropriate scope of practice within the State in which the service is provided or rendered, typically treats the condition, makes the diag-

nosis, or provides the type of treatment under review.

''(B) PRACTICING DEFINED.—For purposes of this paragraph, the term 'practicing' means, with respect to an individual who is a physician or other health care professional, that the individual provides health care services to individual patients on average at least 2 days per week.

''(5) PEDIATRIC EXPERTISE.—In the case of an external review relating to a child, a reviewer shall have expertise under paragraph (2) in pediatrics.

''(6) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by the issuer to an independent medical reviewer in connection with a review under this section shall—

''(A) not exceed a reasonable level; and

''(B) not be contingent on the decision rendered by the reviewer.

''(7) RELATED PARTY DEFINED.—For purposes of this section, the term 'related party' means, with respect to a denial of a claim under a coverage relating to an enrollee, any of the following:

''(A) The issuer involved, or any fiduciary, officer, director, or employee of the issuer.

''(B) The enrollee (or authorized representative).

''(C) The health care professional that provides the items or services involved in the denial.

''(D) The institution at which the items or services (or treatment) involved in the denial are provided.

''(E) The manufacturer of any drug or other item that is included in the items or services involved in the denial.

''(F) Any other party determined under any regulations to have a substantial interest in the denial involved.

''(8) DEFINITIONS.—For purposes of this subsection:

''(A) ENROLLEE.—The term 'enrollee' means, with respect to health insurance coverage offered by a health insurance issuer, an individual enrolled with the issuer to receive such coverage.

''(B) HEALTH CARE PROFESSIONAL.—The term 'health care professional' means an individual who is licensed, accredited, or certified under State law to provide specified health care

services and who is operating within the scope of such licensure, accreditation, or certification.

"SEC. 2799. ENFORCEMENT.

"(a) IN GENERAL.—Subject to subsection (b), with respect to specific individual health insurance coverage the primary State for such coverage has sole jurisdiction to enforce the primary State's covered laws in the primary State and any secondary State.

"(b) SECONDARY STATE'S AUTHORITY.—Nothing in subsection (a) shall be construed to affect the authority of a secondary State to enforce its laws as set forth in the exception specified in section 2796(b)(1).

"(c) COURT INTERPRETATION.—In reviewing action initiated by the applicable secondary State authority, the court of competent jurisdiction shall apply the covered laws of the primary State.

"(d) NOTICE OF COMPLIANCE FAILURE.—In the case of individual health insurance coverage offered in a secondary State that fails to comply with the covered laws of the primary State, the applicable State authority of the secondary State may notify the applicable State authority of the primary State.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to individual health insurance

coverage offered, issued, or sold after the date that is one year after the date of the enactment of this Act.

(c) GAO ONGOING STUDY AND REPORTS.—

(1) STUDY.—The Comptroller General of the United States shall conduct an ongoing study concerning the effect of the amendment made by subsection (a) on—

(A) the number of uninsured and under-insured;

(B) the availability and cost of health insurance policies for individuals with preexisting medical conditions;

(C) the availability and cost of health insurance policies generally;

(D) the elimination or reduction of different types of benefits under health insurance policies offered in different States; and

(E) cases of fraud or abuse relating to health insurance coverage offered under such amendment and the resolution of such cases.

(2) ANNUAL REPORTS.—The Comptroller General shall submit to Congress an annual report, after the end of each of the 5 years following the effective

date of the amendment made by subsection (a), on the ongoing study conducted under paragraph (1).

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