

111<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 4138

To amend title XVIII of the Social Security Act to provide for an update under the Medicare physician fee schedule, to be fully paid for through medical liability reform, a pathway for biosimilar biological products, and other means.

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## IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 19, 2009

Mr. GINGREY of Georgia (for himself, Mr. CASSIDY, Mr. FLEMING, Mr. BOOZMAN, Mr. HERGER, Mr. SESSIONS, Mr. CULBERSON, Mr. HALL of Texas, Mr. WHITFIELD, Mr. SHIMKUS, Mr. BUYER, Mrs. MYRICK, Mr. PAULSEN, Mr. ROONEY, Ms. GRANGER, Mr. ROSKAM, Mrs. BLACKBURN, Mr. PRICE of Georgia, and Mr. ROE of Tennessee) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend title XVIII of the Social Security Act to provide for an update under the Medicare physician fee schedule, to be fully paid for through medical liability reform, a pathway for biosimilar biological products, and other means.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) **SHORT TITLE.**—This Act may be cited as the  
3 “Medicare SGR Improvement and Reform Act of 2009”.

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

Sec. 1. Short title; table of contents.

**TITLE I—ENSURING CONTINUED ACCESS TO PHYSICIANS IN  
MEDICARE**

Sec. 101. Improving Medicare physician payments.

Sec. 102. Statement of policy.

**TITLE II—DEFICIT PROTECTION AND FISCAL RESPONSIBILITY**

**Subtitle A—Enacting Real Medical Liability Reform**

Sec. 201. Encouraging speedy resolution of claims.

Sec. 202. Compensating patient injury.

Sec. 203. Maximizing patient recovery.

Sec. 204. Additional health benefits.

Sec. 205. Punitive damages.

Sec. 206. Authorization of payment of future damages to claimants in health  
care lawsuits.

Sec. 207. Definitions.

Sec. 208. Effect on other laws.

Sec. 209. State flexibility and protection of states’ rights.

Sec. 210. Applicability; effective date.

**Subtitle B—Application of Medicare Improvement Fund**

Sec. 211. Application of Medicare Improvement Fund.

**Subtitle C—Pathway for Biosimilar Biological Products**

Sec. 221. Licensure pathway for biosimilar biological products.

Sec. 222. Fees relating to biosimilar biological products.

Sec. 223. Amendments to certain patent provisions.

**Subtitle D—Administrative Simplification**

Sec. 231. Administrative simplification.

1 **TITLE I—ENSURING CONTINUED**  
2 **ACCESS TO PHYSICIANS IN**  
3 **MEDICARE**

4 **SEC. 101. IMPROVING MEDICARE PHYSICIAN PAYMENTS.**

5 Section 1848(d) of the Social Security Act (42 U.S.C.  
6 1395w-4(d)) is amended by adding at the end the fol-  
7 lowing new paragraphs:

8 “(10) 2 PERCENT ANNUAL UPDATE FOR YEARS  
9 2010 THROUGH 2013.—

10 “(A) IN GENERAL.—Subject to paragraphs  
11 (7)(B), (8)(B), and (9)(B) and subparagraph  
12 (B), in lieu of the update to the single conver-  
13 sion factor established in paragraph (1)(C) that  
14 would otherwise apply for each of 2010, 2011,  
15 2012, and 2013, the update to the single con-  
16 version factor shall be 2 percent.

17 “(B) NO EFFECT ON COMPUTATION OF  
18 CONVERSION FACTOR FOR 2014 AND SUBSE-  
19 QUENT YEARS.—The conversion factor under  
20 this subsection shall be computed under para-  
21 graph (1)(A) for 2014 and subsequent years as  
22 if subparagraph (A) had never applied, subject  
23 to paragraph (11).

24 “(11) UPDATE FOR 2014 AND POSSIBLE SUBSE-  
25 QUENT YEARS THROUGH 2019.—

1           “(A) IN GENERAL.—Subject to paragraphs  
2           (7)(B), (8)(B), and (9)(B) and subparagraph  
3           (B), in lieu of the update to the single conver-  
4           sion factor established in paragraph (1)(C) that  
5           would otherwise apply for 2014 and, at the Sec-  
6           retary’s discretion, for subsequent years ending  
7           not later than 2019, the update to the single  
8           conversion factor shall be such percentage for  
9           each such year as the Secretary determines will  
10          result in additional expenditures under this title  
11          in the aggregate for all such years of  
12          \$26,400,000,000. Not later than October 1,  
13          2013, the Secretary shall establish by regula-  
14          tion the method the Secretary will use in allo-  
15          cating the \$26,400,000,000 under the previous  
16          sentence between 2014 and subsequent years.  
17          Such allocation shall be designed in a manner  
18          so that the single conversion factor for a year  
19          is not less than 79 percent of the conversion  
20          factor for the previous year.

21           “(B) LIMITED EFFECT ON COMPUTATION  
22           OF CONVERSION FACTOR FOR SUBSEQUENT  
23           YEARS.—The conversion factor under this sub-  
24           section shall be computed under paragraph  
25           (1)(A) for subsequent years as if subparagraph

1 (A) had never applied, but taking into account  
2 the aggregate additional increase in expendi-  
3 tures permitted under such subparagraph.”.

4 **SEC. 102. STATEMENT OF POLICY.**

5 It is the policy of the Federal Government that the  
6 sustainable growth rate formula, upon which physician  
7 payments are based for the Medicare program, should be  
8 permanently repealed and replaced with a reimbursement  
9 policy that pays doctors an amount reflecting the true cost  
10 of services provided in a high-quality and efficient manner  
11 and uses a fiscally responsibly funding mechanism.

12 **TITLE II—DEFICIT PROTECTION**  
13 **AND FISCAL RESPONSIBILITY**  
14 **Subtitle A—Enacting Real Medical**  
15 **Liability Reform**

16 **SEC. 201. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.**

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

25 (1) upon proof of fraud;

1 (2) intentional concealment; or

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

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

15 **SEC. 202. COMPENSATING PATIENT INJURY.**

16 (a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL  
17 ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any  
18 health care lawsuit, nothing in this subtitle shall limit a  
19 claimant's recovery of the full amount of the available eco-  
20 nomic damages, notwithstanding the limitation in sub-  
21 section (b).

22 (b) ADDITIONAL NONECONOMIC DAMAGES.—In any  
23 health care lawsuit, the amount of noneconomic damages,  
24 if available, may be as much as \$250,000, regardless of  
25 the number of parties against whom the action is brought

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

3 (c) NO DISCOUNT OF AWARD FOR NONECONOMIC  
4 DAMAGES.—For purposes of applying the limitation in  
5 subsection (b), future noneconomic damages shall not be  
6 discounted to present value. The jury shall not be in-  
7 formed about the maximum award for noneconomic dam-  
8 ages. An award for noneconomic damages in excess of  
9 \$250,000 shall be reduced either before the entry of judg-  
10 ment, or by amendment of the judgment after entry of  
11 judgment, and such reduction shall be made before ac-  
12 counting for any other reduction in damages required by  
13 law. If separate awards are rendered for past and future  
14 noneconomic damages and the combined awards exceed  
15 \$250,000, the future noneconomic damages shall be re-  
16 duced first.

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

1 this section, the trier of fact shall determine the propor-  
2 tion of responsibility of each party for the claimant's  
3 harm.

4 **SEC. 203. MAXIMIZING PATIENT RECOVERY.**

5 (a) COURT SUPERVISION OF SHARE OF DAMAGES  
6 ACTUALLY PAID TO CLAIMANTS.—In any health care law-  
7 suit, the court shall supervise the arrangements for pay-  
8 ment of damages to protect against conflicts of interest  
9 that may have the effect of reducing the amount of dam-  
10 ages awarded that are actually paid to claimants. In par-  
11 ticular, in any health care lawsuit in which the attorney  
12 for a party claims a financial stake in the outcome by vir-  
13 tue of a contingent fee, the court shall have the power  
14 to restrict the payment of a claimant's damage recovery  
15 to such attorney, and to redirect such damages to the  
16 claimant based upon the interests of justice and principles  
17 of equity. In no event shall the total of all contingent fees  
18 for representing all claimants in a health care lawsuit ex-  
19 ceed the following limits—

20 (1) 40 percent of the first \$50,000 recovered by  
21 the claimant(s).

22 (2) 33 $\frac{1}{3}$  percent of the next \$50,000 recovered  
23 by the claimant(s).

24 (3) 25 percent of the next \$500,000 recovered  
25 by the claimant(s).



1           (4) 15 percent of any amount by which the re-  
2           covery by the claimant(s) is in excess of \$600,000.

3           (b) APPLICABILITY.—The limitations in this section  
4 shall apply whether the recovery is by judgment, settle-  
5 ment, mediation, arbitration, or any other form of alter-  
6 native dispute resolution. In a health care lawsuit involv-  
7 ing a minor or incompetent person, a court retains the  
8 authority to authorize or approve a fee that is less than  
9 the maximum permitted under this section. The require-  
10 ment for court supervision in the first two sentences of  
11 subsection (a) applies only in civil actions.

12 **SEC. 204. ADDITIONAL HEALTH BENEFITS.**

13           In any health care lawsuit involving injury or wrong-  
14 ful death, any party may introduce evidence of collateral  
15 source benefits. If a party elects to introduce such evi-  
16 dence, any opposing party may introduce evidence of any  
17 amount paid or contributed or reasonably likely to be paid  
18 or contributed in the future by or on behalf of the oppos-  
19 ing party to secure the right to such collateral source bene-  
20 fits. No provider of collateral source benefits shall recover  
21 any amount against the claimant or receive any lien or  
22 credit against the claimant's recovery or be equitably or  
23 legally subrogated to the right of the claimant in a health  
24 care lawsuit involving injury or wrongful death. This sec-  
25 tion shall apply to any health care lawsuit that is settled

1 as well as a health care lawsuit that is resolved by a fact  
2 finder. This section shall not apply to section 1862(b) (42  
3 U.S.C. 1395y(b)) or section 1902(a)(25) (42 U.S.C.  
4 1396a(a)(25)) of the Social Security Act.

5 **SEC. 205. PUNITIVE DAMAGES.**

6 (a) IN GENERAL.—Punitive damages may, if other-  
7 wise permitted by applicable State or Federal law, be  
8 awarded against any person in a health care lawsuit only  
9 if it is proven by clear and convincing evidence that such  
10 person acted with malicious intent to injure the claimant,  
11 or that such person deliberately failed to avoid unneces-  
12 sary injury that such person knew the claimant was sub-  
13 stantially certain to suffer. In any health care lawsuit  
14 where no judgment for compensatory damages is rendered  
15 against such person, no punitive damages may be awarded  
16 with respect to the claim in such lawsuit. No demand for  
17 punitive damages shall be included in a health care lawsuit  
18 as initially filed. A court may allow a claimant to file an  
19 amended pleading for punitive damages only upon a mo-  
20 tion by the claimant and after a finding by the court, upon  
21 review of supporting and opposing affidavits or after a  
22 hearing, after weighing the evidence, that the claimant has  
23 established by a substantial probability that the claimant  
24 will prevail on the claim for punitive damages. At the re-

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

3 (1) whether punitive damages are to be award-  
4 ed and the amount of such award; and

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

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

12 (b) DETERMINING AMOUNT OF PUNITIVE DAM-  
13 AGES.—

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

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

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

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

24 (D) the number of products sold or med-  
25 ical procedures rendered for compensation, as

1 the case may be, by such party, of the kind  
2 causing the harm complained of by the claim-  
3 ant;

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

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

10 (2) MAXIMUM AWARD.—The amount of punitive  
11 damages, if awarded, in a health care lawsuit may  
12 be as much as \$250,000 or as much as two times  
13 the amount of economic damages awarded, which-  
14 ever is greater. The jury shall not be informed of  
15 this limitation.

16 **SEC. 206. AUTHORIZATION OF PAYMENT OF FUTURE DAM-**  
17 **AGES TO CLAIMANTS IN HEALTH CARE LAW-**  
18 **SUITS.**

19 (a) IN GENERAL.—In any health care lawsuit, if an  
20 award of future damages, without reduction to present  
21 value, equaling or exceeding \$50,000 is made against a  
22 party with sufficient insurance or other assets to fund a  
23 periodic payment of such a judgment, the court shall, at  
24 the request of any party, enter a judgment ordering that  
25 the future damages be paid by periodic payments. In any

1 health care lawsuit, the court may be guided by the Uni-  
2 form Periodic Payment of Judgments Act promulgated by  
3 the National Conference of Commissioners on Uniform  
4 State Laws.

5 (b) APPLICABILITY.—This section applies to all ac-  
6 tions which have not been first set for trial or retrial be-  
7 fore the effective date of this subtitle.

8 **SEC. 207. DEFINITIONS.**

9 In this subtitle:

10 (1) ALTERNATIVE DISPUTE RESOLUTION SYS-  
11 TEM; ADR.—The term “alternative dispute resolution  
12 system” or “ADR” means a system that provides  
13 for the resolution of health care lawsuits in a man-  
14 ner other than through a civil action brought in a  
15 State or Federal court.

16 (2) CLAIMANT.—The term “claimant” means  
17 any person who brings a health care lawsuit, includ-  
18 ing a person who asserts or claims a right to legal  
19 or equitable contribution, indemnity, or subrogation,  
20 arising out of a health care liability claim or action,  
21 and any person on whose behalf such a claim is as-  
22 serted or such an action is brought, whether de-  
23 ceased, incompetent, or a minor.

24 (3) COLLATERAL SOURCE BENEFITS.—The  
25 term “collateral source benefits” means any amount

1 paid or reasonably likely to be paid in the future to  
2 or on behalf of the claimant, or any service, product,  
3 or other benefit provided or reasonably likely to be  
4 provided in the future to or on behalf of the claim-  
5 ant, as a result of the injury or wrongful death, pur-  
6 suant to—

7 (A) any State or Federal health, sickness,  
8 income-disability, accident, or workers’ com-  
9 pensation law;

10 (B) any health, sickness, income-disability,  
11 or accident insurance that provides health bene-  
12 fits or income-disability coverage;

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

18 (D) any other publicly or privately funded  
19 program.

20 (4) COMPENSATORY DAMAGES.—The term  
21 “compensatory damages” means objectively  
22 verifiable monetary losses incurred as a result of the  
23 provision of, use of, or payment for (or failure to  
24 provide, use, or pay for) health care services or med-  
25 ical products, such as past and future medical ex-

1       penses, loss of past and future earnings, cost of ob-  
2       taining domestic services, loss of employment, and  
3       loss of business or employment opportunities, dam-  
4       ages for physical and emotional pain, suffering, in-  
5       convenience, physical impairment, mental anguish,  
6       disfigurement, loss of enjoyment of life, loss of soci-  
7       ety and companionship, loss of consortium (other  
8       than loss of domestic service), hedonic damages, in-  
9       jury to reputation, and all other nonpecuniary losses  
10      of any kind or nature. The term “compensatory  
11      damages” includes economic damages and non-  
12      economic damages, as such terms are defined in this  
13      section.

14           (5) CONTINGENT FEE.—The term “contingent  
15      fee” includes all compensation to any person or per-  
16      sons which is payable only if a recovery is effected  
17      on behalf of one or more claimants.

18           (6) ECONOMIC DAMAGES.—The term “economic  
19      damages” means objectively verifiable monetary  
20      losses incurred as a result of the provision of, use  
21      of, or payment for (or failure to provide, use, or pay  
22      for) health care services or medical products, such as  
23      past and future medical expenses, loss of past and  
24      future earnings, cost of obtaining domestic services,

1 loss of employment, and loss of business or employ-  
2 ment opportunities.

3 (7) HEALTH CARE LAWSUIT.—The term  
4 “health care lawsuit” means any health care liability  
5 claim concerning the provision of health care goods  
6 or services or any medical product affecting inter-  
7 state commerce, or any health care liability action  
8 concerning the provision of health care goods or  
9 services or any medical product affecting interstate  
10 commerce, brought in a State or Federal court or  
11 pursuant to an alternative dispute resolution system,  
12 against a health care provider, a health care organi-  
13 zation, or the manufacturer, distributor, supplier,  
14 marketer, promoter, or seller of a medical product,  
15 regardless of the theory of liability on which the  
16 claim is based, or the number of claimants, plain-  
17 tiffs, defendants, or other parties, or the number of  
18 claims or causes of action, in which the claimant al-  
19 leges a health care liability claim. Such term does  
20 not include a claim or action which is based on  
21 criminal liability; which seeks civil fines or penalties  
22 paid to Federal, State, or local government; or which  
23 is grounded in antitrust.

24 (8) HEALTH CARE LIABILITY ACTION.—The  
25 term “health care liability action” means a civil ac-



1       tion brought in a State or Federal court or pursuant  
2       to an alternative dispute resolution system, against  
3       a health care provider, a health care organization, or  
4       the manufacturer, distributor, supplier, marketer,  
5       promoter, or seller of a medical product, regardless  
6       of the theory of liability on which the claim is based,  
7       or the number of plaintiffs, defendants, or other par-  
8       ties, or the number of causes of action, in which the  
9       claimant alleges a health care liability claim.

10           (9) HEALTH CARE LIABILITY CLAIM.—The  
11       term “health care liability claim” means a demand  
12       by any person, whether or not pursuant to ADR,  
13       against a health care provider, health care organiza-  
14       tion, or the manufacturer, distributor, supplier, mar-  
15       keter, promoter, or seller of a medical product, in-  
16       cluding, but not limited to, third-party claims, cross-  
17       claims, counter-claims, or contribution claims, which  
18       are based upon the provision of, use of, or payment  
19       for (or the failure to provide, use, or pay for) health  
20       care services or medical products, regardless of the  
21       theory of liability on which the claim is based, or the  
22       number of plaintiffs, defendants, or other parties, or  
23       the number of causes of action.

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

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

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

13              (12) HEALTH CARE GOODS OR SERVICES.—The  
14      term “health care goods or services” means any  
15      goods or services provided by a health care organiza-  
16      tion, provider, or by any individual working under  
17      the supervision of a health care provider, that relates  
18      to the diagnosis, prevention, or treatment of any  
19      human disease or impairment, or the assessment or  
20      care of the health of human beings.

21              (13) MALICIOUS INTENT TO INJURE.—The  
22      term “malicious intent to injure” means inten-  
23      tionally causing or attempting to cause physical in-  
24      jury other than providing health care goods or serv-  
25      ices.

1           (14) MEDICAL PRODUCT.—The term “medical  
2           product” means a drug, device, or biological product  
3           intended for humans, and the terms “drug”, “de-  
4           vice”, and “biological product” have the meanings  
5           given such terms in sections 201(g)(1) and 201(h)  
6           of the Federal Food, Drug and Cosmetic Act (21  
7           U.S.C. 321(g)(1) and (h)) and section 351(a) of the  
8           Public Health Service Act (42 U.S.C. 262(a)), re-  
9           spectively, including any component or raw material  
10          used therein, but excluding health care services.

11          (15) NONECONOMIC DAMAGES.—The term  
12          “noneconomic damages” means damages for phys-  
13          ical and emotional pain, suffering, inconvenience,  
14          physical impairment, mental anguish, disfigurement,  
15          loss of enjoyment of life, loss of society and compan-  
16          ionship, loss of consortium (other than loss of do-  
17          mestic service), hedonic damages, injury to reputa-  
18          tion, and all other nonpecuniary losses of any kind  
19          or nature.

20          (16) PUNITIVE DAMAGES.—The term “punitive  
21          damages” means damages awarded, for the purpose  
22          of punishment or deterrence, and not solely for com-  
23          pensatory purposes, against a health care provider,  
24          health care organization, or a manufacturer, dis-  
25          tributor, or supplier of a medical product. Punitive

1 damages are neither economic nor noneconomic  
2 damages.

3 (17) RECOVERY.—The term “recovery” means  
4 the net sum recovered after deducting any disburse-  
5 ments or costs incurred in connection with prosecu-  
6 tion or settlement of the claim, including all costs  
7 paid or advanced by any person. Costs of health care  
8 incurred by the plaintiff and the attorneys’ office  
9 overhead costs or charges for legal services are not  
10 deductible disbursements or costs for such purpose.

11 (18) STATE.—The term “State” means each of  
12 the several States, the District of Columbia, the  
13 Commonwealth of Puerto Rico, the Virgin Islands,  
14 Guam, American Samoa, the Northern Mariana Is-  
15 lands, the Trust Territory of the Pacific Islands, and  
16 any other territory or possession of the United  
17 States, or any political subdivision thereof.

18 **SEC. 208. EFFECT ON OTHER LAWS.**

19 (a) VACCINE INJURY.—

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

24 (A) this subtitle does not affect the appli-  
25 cation of the rule of law to such an action; and

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

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

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

15 **SEC. 209. STATE FLEXIBILITY AND PROTECTION OF**  
16 **STATES' RIGHTS.**

17 (a) HEALTH CARE LAWSUITS.—The provisions gov-  
18 erning health care lawsuits set forth in this subtitle pre-  
19 empt, subject to subsections (b) and (c), State law to the  
20 extent that State law prevents the application of any pro-  
21 visions of law established by or under this subtitle. The  
22 provisions governing health care lawsuits set forth in this  
23 subtitle supersede chapter 171 of title 28, United States  
24 Code, to the extent that such chapter—

1           (1) provides for a greater amount of damages  
2           or contingent fees, a longer period in which a health  
3           care lawsuit may be commenced, or a reduced appli-  
4           cability or scope of periodic payment of future dam-  
5           ages, than provided in this subtitle; or

6           (2) prohibits the introduction of evidence re-  
7           garding collateral source benefits, or mandates or  
8           permits subrogation or a lien on collateral source  
9           benefits.

10          (b) PROTECTION OF STATES' RIGHTS AND OTHER  
11          LAWS.—(1) Any issue that is not governed by any provi-  
12          sion of law established by or under this subtitle (including  
13          State standards of negligence) shall be governed by other-  
14          wise applicable State or Federal law.

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

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

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

1 satory or punitive damages (or the total amount of  
2 damages) that may be awarded in a health care law-  
3 suit, regardless of whether such monetary amount is  
4 greater or lesser than is provided for under this sub-  
5 title, notwithstanding section 202(a); or

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

9 **SEC. 210. APPLICABILITY; EFFECTIVE DATE.**

10 This subtitle shall apply to any health care lawsuit  
11 brought in a Federal or State court, or subject to an alter-  
12 native dispute resolution system, that is initiated on or  
13 after the date of the enactment of this Act, except that  
14 any health care lawsuit arising from an injury occurring  
15 prior to the date of the enactment of this Act shall be  
16 governed by the applicable statute of limitations provisions  
17 in effect at the time the injury occurred.

18 **Subtitle B—Application of**  
19 **Medicare Improvement Fund**

20 **SEC. 211. APPLICATION OF MEDICARE IMPROVEMENT**  
21 **FUND.**

22 Section 1898(b)(1) of the Social Security Act (42  
23 U.S.C. 1395iii(b)(1)) is amended by striking “for services  
24 furnished” and all that follows and inserting “for services  
25 furnished on or after January 1, 2010, \$0.”.

1 **Subtitle C—Pathway for Biosimilar**  
2 **Biological Products**

3 **SEC. 221. LICENSURE PATHWAY FOR BIOSIMILAR BIOLOGI-**  
4 **CAL PRODUCTS.**

5 (a) LICENSURE OF BIOLOGICAL PRODUCTS AS BIO-  
6 SIMILAR OR INTERCHANGEABLE.—Section 351 of the  
7 Public Health Service Act (42 U.S.C. 262) is amended—

8 (1) in subsection (a)(1)(A), by inserting “under  
9 this subsection or subsection (k)” after “biologics li-  
10 cense”; and

11 (2) by adding at the end the following:

12 “(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIO-  
13 SIMILAR OR INTERCHANGEABLE.—

14 “(1) IN GENERAL.—Any person may submit an  
15 application for licensure of a biological product  
16 under this subsection.

17 “(2) CONTENT.—

18 “(A) IN GENERAL.—

19 “(i) REQUIRED INFORMATION.—An  
20 application submitted under this subsection  
21 shall include information demonstrating  
22 that—

23 “(I) the biological product is bio-  
24 similar to a reference product based  
25 upon data derived from—



1           “(aa) analytical studies that  
2           demonstrate that the biological  
3           product is highly similar to the  
4           reference product notwith-  
5           standing minor differences in  
6           clinically inactive components;

7           “(bb) animal studies (includ-  
8           ing the assessment of toxicity);  
9           and

10           “(cc) a clinical study or  
11           studies (including the assessment  
12           of immunogenicity and phar-  
13           macokinetics                            or  
14           pharmacodynamics) that are suf-  
15           ficient to demonstrate safety, pu-  
16           rity, and potency in 1 or more  
17           appropriate conditions of use for  
18           which the reference product is li-  
19           censed and intended to be used  
20           and for which licensure is sought  
21           for the biological product;

22           “(II) the biological product and  
23           reference product utilize the same  
24           mechanism or mechanisms of action  
25           for the condition or conditions of use

1 prescribed, recommended, or sug-  
2 gested in the proposed labeling, but  
3 only to the extent the mechanism or  
4 mechanisms of action are known for  
5 the reference product;

6 “(III) the condition or conditions  
7 of use prescribed, recommended, or  
8 suggested in the labeling proposed for  
9 the biological product have been pre-  
10 viously approved for the reference  
11 product;

12 “(IV) the route of administra-  
13 tion, the dosage form, and the  
14 strength of the biological product are  
15 the same as those of the reference  
16 product; and

17 “(V) the facility in which the bio-  
18 logical product is manufactured, proc-  
19 essed, packed, or held meets stand-  
20 ards designed to assure that the bio-  
21 logical product continues to be safe,  
22 pure, and potent.

23 “(ii) DETERMINATION BY SEC-  
24 RETARY.—The Secretary may determine,  
25 in the Secretary’s discretion, that an ele-

1           ment described in clause (i)(I) is unneces-  
2           sary in an application submitted under this  
3           subsection.

4           “(iii) ADDITIONAL INFORMATION.—  
5           An application submitted under this sub-  
6           section—

7                   “(I) shall include publicly avail-  
8                   able information regarding the Sec-  
9                   retary’s previous determination that  
10                  the reference product is safe, pure,  
11                  and potent; and

12                   “(II) may include any additional  
13                   information in support of the applica-  
14                   tion, including publicly available infor-  
15                   mation with respect to the reference  
16                   product or another biological product.

17           “(B) INTERCHANGEABILITY.—An applica-  
18           tion (or a supplement to an application) sub-  
19           mitted under this subsection may include infor-  
20           mation demonstrating that the biological prod-  
21           uct meets the standards described in paragraph  
22           (4).

23           “(3) EVALUATION BY SECRETARY.—Upon re-  
24           view of an application (or a supplement to an appli-  
25           cation) submitted under this subsection, the Sec-

1       retary shall license the biological product under this  
2       subsection if—

3               “(A) the Secretary determines that the in-  
4               formation submitted in the application (or the  
5               supplement) is sufficient to show that the bio-  
6               logical product—

7                       “(i) is biosimilar to the reference  
8                       product; or

9                       “(ii) meets the standards described in  
10                      paragraph (4), and therefore is inter-  
11                      changeable with the reference product; and

12               “(B) the applicant (or other appropriate  
13               person) consents to the inspection of the facility  
14               that is the subject of the application, in accord-  
15               ance with subsection (c).

16               “(4) SAFETY STANDARDS FOR DETERMINING  
17               INTERCHANGEABILITY.—Upon review of an applica-  
18               tion submitted under this subsection or any supple-  
19               ment to such application, the Secretary shall deter-  
20               mine the biological product to be interchangeable  
21               with the reference product if the Secretary deter-  
22               mines that the information submitted in the applica-  
23               tion (or a supplement to such application) is suffi-  
24               cient to show that—

25                       “(A) the biological product—

1           “(i) is biosimilar to the reference  
2           product; and

3           “(ii) can be expected to produce the  
4           same clinical result as the reference prod-  
5           uct in any given patient; and

6           “(B) for a biological product that is ad-  
7           ministered more than once to an individual, the  
8           risk in terms of safety or diminished efficacy of  
9           alternating or switching between use of the bio-  
10          logical product and the reference product is not  
11          greater than the risk of using the reference  
12          product without such alternation or switch.

13          “(5) GENERAL RULES.—

14               “(A) ONE REFERENCE PRODUCT PER AP-  
15               PLICATION.—A biological product, in an appli-  
16               cation submitted under this subsection, may not  
17               be evaluated against more than 1 reference  
18               product.

19               “(B) REVIEW.—An application submitted  
20               under this subsection shall be reviewed by the  
21               division within the Food and Drug Administra-  
22               tion that is responsible for the review and ap-  
23               proval of the application under which the ref-  
24               erence product is licensed.

1           “(C) RISK EVALUATION AND MITIGATION  
2 STRATEGIES.—The authority of the Secretary  
3 with respect to risk evaluation and mitigation  
4 strategies under the Federal Food, Drug, and  
5 Cosmetic Act shall apply to biological products  
6 licensed under this subsection in the same man-  
7 ner as such authority applies to biological prod-  
8 ucts licensed under subsection (a).

9           “(D) RESTRICTIONS ON BIOLOGICAL PROD-  
10 UCTS CONTAINING DANGEROUS INGREDI-  
11 ENTS.—If information in an application sub-  
12 mitted under this subsection, in a supplement  
13 to such an application, or otherwise available to  
14 the Secretary shows that a biological product—

15           “(i) is, bears, or contains a select  
16 agent or toxin listed in section 73.3 or  
17 73.4 of title 42, section 121.3 or 121.4 of  
18 title 9, or section 331.3 of title 7, Code of  
19 Federal Regulations (or any successor reg-  
20 ulations); or

21           “(ii) is, bears, or contains a controlled  
22 substance in schedule I or II of section  
23 202 of the Controlled Substances Act, as  
24 listed in part 1308 of title 21, Code of

1 Federal Regulations (or any successor reg-  
2 ulations);  
3 the Secretary shall not license the biological  
4 product under this subsection unless the Sec-  
5 retary determines, after consultation with ap-  
6 propriate national security and drug enforce-  
7 ment agencies, that there would be no increased  
8 risk to the security or health of the public from  
9 licensing such biological product under this sub-  
10 section.

11 “(6) EXCLUSIVITY FOR FIRST INTERCHANGE-  
12 ABLE BIOLOGICAL PRODUCT.—Upon review of an  
13 application submitted under this subsection relying  
14 on the same reference product for which a prior bio-  
15 logical product has received a determination of inter-  
16 changeability for any condition of use, the Secretary  
17 shall not make a determination under paragraph (4)  
18 that the second or subsequent biological product is  
19 interchangeable for any condition of use until the  
20 earlier of—

21 “(A) 1 year after the first commercial  
22 marketing of the first interchangeable bio-  
23 similar biological product to be approved as  
24 interchangeable for that reference product;

25 “(B) 18 months after—

1           “(i) a final court decision on all pat-  
2           ents in suit in an action instituted under  
3           subsection (l)(5) against the applicant that  
4           submitted the application for the first ap-  
5           proved interchangeable biosimilar biological  
6           product; or

7           “(ii) the dismissal with or without  
8           prejudice of an action instituted under sub-  
9           section (l)(5) against the applicant that  
10          submitted the application for the first ap-  
11          proved interchangeable biosimilar biological  
12          product; or

13          “(C)(i) 42 months after approval of the  
14          first interchangeable biosimilar biological prod-  
15          uct if the applicant that submitted such appli-  
16          cation has been sued under subsection (l)(5)  
17          and such litigation is still ongoing within such  
18          42-month period; or

19          “(ii) 18 months after approval of the first  
20          interchangeable biosimilar biological product if  
21          the applicant that submitted such application  
22          has not been sued under subsection (l)(5).

23          For purposes of this paragraph, the term ‘final court  
24          decision’ means a final decision of a court from  
25          which no appeal (other than a petition to the United



1 States Supreme Court for a writ of certiorari) has  
2 been or can be taken.

3 “(7) EXCLUSIVITY FOR REFERENCE PROD-  
4 UCT.—

5 “(A) EFFECTIVE DATE OF BIOSIMILAR AP-  
6 PPLICATION APPROVAL.—Approval of an applica-  
7 tion under this subsection may not be made ef-  
8 fective by the Secretary until the date that is  
9 12 years after the date on which the reference  
10 product was first licensed under subsection (a).

11 “(B) FILING PERIOD.—An application  
12 under this subsection may not be submitted to  
13 the Secretary until the date that is 4 years  
14 after the date on which the reference product  
15 was first licensed under subsection (a).

16 “(C) FIRST LICENSURE.—Subparagraphs  
17 (A) and (B) shall not apply to a license for or  
18 approval of—

19 “(i) a supplement for the biological  
20 product that is the reference product; or

21 “(ii) a subsequent application filed by  
22 the same sponsor or manufacturer of the  
23 biological product that is the reference  
24 product (or a licensor, predecessor in inter-  
25 est, or other related entity) for—

1                   “(I) a change (not including a  
2                   modification to the structure of the bi-  
3                   ological product) that results in a new  
4                   indication, route of administration,  
5                   dosing schedule, dosage form, delivery  
6                   system, delivery device, or strength; or

7                   “(II) a modification to the struc-  
8                   ture of the biological product that  
9                   does not result in a change in safety,  
10                  purity, or potency.

11                  “(8) PEDIATRIC STUDIES.—

12                  “(A) EXCLUSIVITY.—If, before or after li-  
13                  censure of the reference product under sub-  
14                  section (a) of this section, the Secretary deter-  
15                  mines that information relating to the use of  
16                  such product in the pediatric population may  
17                  produce health benefits in that population, the  
18                  Secretary makes a written request for pediatric  
19                  studies (which shall include a timeframe for  
20                  completing such studies), the applicant or hold-  
21                  er of the approved application agrees to the re-  
22                  quest, such studies are completed using appro-  
23                  priate formulations for each age group for  
24                  which the study is requested within any such  
25                  timeframe, and the reports thereof are sub-

1           mitted and accepted in accordance with section  
2           505A(d)(3) of the Federal Food, Drug, and  
3           Cosmetic Act the period referred to in para-  
4           graph (7)(A) of this subsection is deemed to be  
5           12 years and 6 months rather than 12 years.

6           “(B) EXCEPTION.—The Secretary shall  
7           not extend the period referred to in subpara-  
8           graph (A) of this paragraph if the determina-  
9           tion under section 505A(d)(3) of the Federal  
10          Food, Drug, and Cosmetic Act is made later  
11          than 9 months prior to the expiration of such  
12          period.

13          “(C) APPLICATION OF CERTAIN PROVI-  
14          SIONS.—The provisions of subsections (a), (d),  
15          (e), (f), (h), (j), (k), and (l) of section 505A of  
16          the Federal Food, Drug, and Cosmetic Act  
17          shall apply with respect to the extension of a  
18          period under subparagraph (A) of this para-  
19          graph to the same extent and in the same man-  
20          ner as such provisions apply with respect to the  
21          extension of a period under subsection (b) or  
22          (c) of section 505A of the Federal Food, Drug,  
23          and Cosmetic Act.

24          “(9) GUIDANCE DOCUMENTS.—

1           “(A) IN GENERAL.—The Secretary may,  
2           after opportunity for public comment, issue  
3           guidance in accordance, except as provided in  
4           subparagraph (B)(i), with section 701(h) of the  
5           Federal Food, Drug, and Cosmetic Act with re-  
6           spect to the licensure of a biological product  
7           under this subsection. Any such guidance may  
8           be general or specific.

9           “(B) PUBLIC COMMENT.—

10           “(i) IN GENERAL.—The Secretary  
11           shall provide the public an opportunity to  
12           comment on any proposed guidance issued  
13           under subparagraph (A) before issuing  
14           final guidance.

15           “(ii) INPUT REGARDING MOST VALU-  
16           ABLE GUIDANCE.—The Secretary shall es-  
17           tablish a process through which the public  
18           may provide the Secretary with input re-  
19           garding priorities for issuing guidance.

20           “(C) NO REQUIREMENT FOR APPLICATION  
21           CONSIDERATION.—The issuance (or non-  
22           issuance) of guidance under subparagraph (A)  
23           shall not preclude the review of, or action on,  
24           an application submitted under this subsection.

1           “(D) REQUIREMENT FOR PRODUCT CLASS-  
2 SPECIFIC GUIDANCE.—If the Secretary issues  
3 product class-specific guidance under subpara-  
4 graph (A), such guidance shall include a de-  
5 scription of—

6           “(i) the criteria that the Secretary will  
7 use to determine whether a biological prod-  
8 uct is highly similar to a reference product  
9 in such product class; and

10           “(ii) the criteria, if available, that the  
11 Secretary will use to determine whether a  
12 biological product meets the standards de-  
13 scribed in paragraph (4).

14           “(E) CERTAIN PRODUCT CLASSES.—

15           “(i) GUIDANCE.—The Secretary may  
16 indicate in a guidance document that the  
17 science and experience, as of the date of  
18 such guidance, with respect to a product or  
19 product class (not including any recom-  
20 binant protein) does not allow approval of  
21 an application for a license as provided  
22 under this subsection for such product or  
23 product class.

24           “(ii) MODIFICATION OR REVERSAL.—  
25 The Secretary may issue a subsequent

1 guidance document under subparagraph  
2 (A) to modify or reverse a guidance docu-  
3 ment under clause (i).

4 “(iii) NO EFFECT ON ABILITY TO  
5 DENY LICENSE.—Clause (i) shall not be  
6 construed to require the Secretary to ap-  
7 prove a product with respect to which the  
8 Secretary has not indicated in a guidance  
9 document that the science and experience,  
10 as described in clause (i), does not allow  
11 approval of such an application.

12 “(10) NAMING.—The Secretary shall ensure  
13 that the labeling and packaging of each biological  
14 product licensed under this subsection bears a name  
15 that uniquely identifies the biological product and  
16 distinguishes it from the reference product and any  
17 other biological products licensed under this sub-  
18 section following evaluation against such reference  
19 product.

20 “(1) PATENT NOTICES; RELATIONSHIP TO FINAL AP-  
21 PROVAL.—

22 “(1) DEFINITIONS.—For the purposes of this  
23 subsection, the term—

1           “(A) ‘biosimilar product’ means the bio-  
2           logical product that is the subject of the appli-  
3           cation under subsection (k);

4           “(B) ‘relevant patent’ means a patent  
5           that—

6                   “(i) expires after the date specified in  
7                   subsection (k)(7)(A) that applies to the  
8                   reference product; and

9                   “(ii) could reasonably be asserted  
10                  against the applicant due to the unauthor-  
11                  ized making, use, sale, or offer for sale  
12                  within the United States, or the importa-  
13                  tion into the United States of the bio-  
14                  similar product, or materials used in the  
15                  manufacture of the biosimilar product, or  
16                  due to a use of the biosimilar product in  
17                  a method of treatment that is indicated in  
18                  the application;

19           “(C) ‘reference product sponsor’ means the  
20           holder of an approved application or license for  
21           the reference product; and

22           “(D) ‘interested third party’ means a per-  
23           son other than the reference product sponsor  
24           that owns a relevant patent, or has the right to

1           commence or participate in an action for in-  
2           fringement of a relevant patent.

3           “(2) HANDLING OF CONFIDENTIAL INFORMA-  
4           TION.—Any entity receiving confidential information  
5           pursuant to this subsection shall designate one or  
6           more individuals to receive such information. Each  
7           individual so designated shall execute an agreement  
8           in accordance with regulations promulgated by the  
9           Secretary. The regulations shall require each such  
10          individual to take reasonable steps to maintain the  
11          confidentiality of information received pursuant to  
12          this subsection and use the information solely for  
13          purposes authorized by this subsection. The obliga-  
14          tions imposed on an individual who has received con-  
15          fidential information pursuant to this subsection  
16          shall continue until the individual returns or de-  
17          stroys the confidential information, a court imposes  
18          a protective order that governs the use or handling  
19          of the confidential information, or the party pro-  
20          viding the confidential information agrees to other  
21          terms or conditions regarding the handling or use of  
22          the confidential information.

23          “(3) PUBLIC NOTICE BY SECRETARY.—Within  
24          30 days of acceptance by the Secretary of an appli-



1 cation filed under subsection (k), the Secretary shall  
2 publish a notice identifying—

3 “(A) the reference product identified in the  
4 application; and

5 “(B) the name and address of an agent  
6 designated by the applicant to receive notices  
7 pursuant to paragraph (4)(B).

8 “(4) EXCHANGES CONCERNING PATENTS.—

9 “(A) EXCHANGES WITH REFERENCE  
10 PRODUCT SPONSOR.—

11 “(i) Within 30 days of the date of ac-  
12 ceptance of the application by the Sec-  
13 retary, the applicant shall provide the ref-  
14 erence product sponsor with a copy of the  
15 application and information concerning the  
16 biosimilar product and its production. This  
17 information shall include a detailed de-  
18 scription of the biosimilar product, its  
19 method of manufacture, and the materials  
20 used in the manufacture of the product.

21 “(ii) Within 60 days of the date of re-  
22 ceipt of the information required to be pro-  
23 vided under clause (i), the reference prod-  
24 uct sponsor shall provide to the applicant  
25 a list of relevant patents owned by the ref-

1           erence product sponsor, or in respect of  
2           which the reference product sponsor has  
3           the right to commence an action of in-  
4           fringement or otherwise has an interest in  
5           the patent as such patent concerns the bio-  
6           similar product.

7           “(iii) If the reference product sponsor  
8           is issued or acquires an interest in a rel-  
9           evant patent after the date on which the  
10          reference product sponsor provides the list  
11          required by clause (ii) to the applicant, the  
12          reference product sponsor shall identify  
13          that patent to the applicant within 30 days  
14          of the date of issue of the patent, or the  
15          date of acquisition of the interest in the  
16          patent, as applicable.

17          “(B) EXCHANGES WITH INTERESTED  
18          THIRD PARTIES.—

19          “(i) At any time after the date on  
20          which the Secretary publishes a notice for  
21          an application under paragraph (3), any  
22          interested third party may provide notice  
23          to the designated agent of the applicant  
24          that the interested third party owns or has  
25          rights under 1 or more patents that may

1 be relevant patents. The notice shall iden-  
2 tify at least 1 patent and shall designate  
3 an individual who has executed an agree-  
4 ment in accordance with paragraph (2) to  
5 receive confidential information from the  
6 applicant.

7 “(ii) Within 30 days of the date of re-  
8 ceiving notice pursuant to clause (i), the  
9 applicant shall send to the individual des-  
10 ignated by the interested third party the  
11 information specified in subparagraph  
12 (A)(i), unless the applicant and interested  
13 third party otherwise agree.

14 “(iii) Within 90 days of the date of  
15 receiving information pursuant to clause  
16 (ii), the interested third party shall provide  
17 to the applicant a list of relevant patents  
18 which the interested third party owns, or  
19 in respect of which the interested third  
20 party has the right to commence or partici-  
21 pate in an action for infringement.

22 “(iv) If the interested third party is  
23 issued or acquires an interest in a relevant  
24 patent after the date on which the inter-  
25 ested third party provides the list required

1 by clause (iii), the interested third party  
2 shall identify that patent within 30 days of  
3 the date of issue of the patent, or the date  
4 of acquisition of the interest in the patent,  
5 as applicable.

6 “(C) IDENTIFICATION OF BASIS FOR IN-  
7 FRINGEMENT.—For any patent identified under  
8 clause (ii) or (iii) of subparagraph (A) or under  
9 clause (iii) or (iv) of subparagraph (B), the ref-  
10 erence product sponsor or the interested third  
11 party, as applicable—

12 “(i) shall explain in writing why the  
13 sponsor or the interested third party be-  
14 lieves the relevant patent would be in-  
15 fringed by the making, use, sale, or offer  
16 for sale within the United States, or im-  
17 portation into the United States, of the  
18 biosimilar product or by a use of the bio-  
19 similar product in treatment that is indi-  
20 cated in the application;

21 “(ii) may specify whether the relevant  
22 patent is available for licensing; and

23 “(iii) shall specify the number and  
24 date of expiration of the relevant patent.

1           “(D) CERTIFICATION BY APPLICANT CON-  
2           CERNING IDENTIFIED RELEVANT PATENTS.—  
3           Not later than 45 days after the date on which  
4           a patent is identified under clause (ii) or (iii) of  
5           subparagraph (A) or under clause (iii) or (iv) of  
6           subparagraph (B), the applicant shall send a  
7           written statement regarding each identified pat-  
8           ent to the party that identified the patent. Such  
9           statement shall either—

10                   “(i) state that the applicant will not  
11                   commence marketing of the biosimilar  
12                   product and has requested the Secretary to  
13                   not grant final approval of the application  
14                   before the date of expiration of the noticed  
15                   patent; or

16                   “(ii) provide a detailed written expla-  
17                   nation setting forth the reasons why the  
18                   applicant believes—

19                           “(I) the making, use, sale, or  
20                           offer for sale within the United  
21                           States, or the importation into the  
22                           United States, of the biosimilar prod-  
23                           uct, or the use of the biosimilar prod-  
24                           uct in a treatment indicated in the ap-

1                   plication, would not infringe the pat-  
2                   ent; or

3                   “(II) the patent is invalid or un-  
4                   enforceable.

5                   “(5) ACTION FOR INFRINGEMENT INVOLVING  
6                   REFERENCE PRODUCT SPONSOR.—If an action for  
7                   infringement concerning a relevant patent identified  
8                   by the reference product sponsor under clause (ii) or  
9                   (iii) of paragraph (4)(A), or by an interested third  
10                  party under clause (iii) or (iv) of paragraph (4)(B),  
11                  is brought within 60 days of the date of receipt of  
12                  a statement under paragraph (4)(D)(ii), and the  
13                  court in which such action has been commenced de-  
14                  termines the patent is infringed prior to the date ap-  
15                  plicable under subsection (k)(7)(A) or (k)(8), the  
16                  Secretary shall make approval of the application ef-  
17                  fective on the day after the date of expiration of the  
18                  patent that has been found to be infringed. If more  
19                  than one such patent is found to be infringed by the  
20                  court, the approval of the application shall be made  
21                  effective on the day after the date that the last such  
22                  patent expires.

23                  “(6) NOTIFICATION OF AGREEMENTS.—

24                  “(A) REQUIREMENTS.—

1           “(i) AGREEMENT BETWEEN BIO-  
2           SIMILAR PRODUCT APPLICANT AND REF-  
3           ERENCE PRODUCT SPONSOR.—If a bio-  
4           similar product applicant under subsection  
5           (k) and the reference product sponsor  
6           enter into an agreement described in sub-  
7           paragraph (B), the applicant and sponsor  
8           shall each file the agreement in accordance  
9           with subparagraph (C).

10           “(ii) AGREEMENT BETWEEN BIO-  
11           SIMILAR PRODUCT APPLICANTS.—If 2 or  
12           more biosimilar product applicants submit  
13           an application under subsection (k) for bio-  
14           similar products with the same reference  
15           product and enter into an agreement de-  
16           scribed in subparagraph (B), the appli-  
17           cants shall each file the agreement in ac-  
18           cordance with subparagraph (C).

19           “(B) SUBJECT MATTER OF AGREEMENT.—  
20           An agreement described in this subparagraph—

21           “(i) is an agreement between the bio-  
22           similar product applicant under subsection  
23           (k) and the reference product sponsor or  
24           between 2 or more biosimilar product ap-

1 applicants under subsection (k) regarding the  
2 manufacture, marketing, or sale of—

3 “(I) the biosimilar product (or  
4 biosimilar products) for which an ap-  
5 plication was submitted; or

6 “(II) the reference product;

7 “(ii) includes any agreement between  
8 the biosimilar product applicant under sub-  
9 section (k) and the reference product spon-  
10 sor or between 2 or more biosimilar prod-  
11 uct applicants under subsection (k) that is  
12 contingent upon, provides a contingent  
13 condition for, or otherwise relates to an  
14 agreement described in clause (i); and

15 “(iii) excludes any agreement that  
16 solely concerns—

17 “(I) purchase orders for raw ma-  
18 terial supplies;

19 “(II) equipment and facility con-  
20 tracts;

21 “(III) employment or consulting  
22 contracts; or

23 “(IV) packaging and labeling  
24 contracts.

25 “(C) FILING.—



1           “(i) IN GENERAL.—The text of an  
2 agreement required to be filed by subpara-  
3 graph (A) shall be filed with the Assistant  
4 Attorney General and the Federal Trade  
5 Commission not later than—

6                   “(I) 10 business days after the  
7 date on which the agreement is exe-  
8 cuted; and

9                   “(II) prior to the date of the first  
10 commercial marketing of, for agree-  
11 ments described in subparagraph  
12 (A)(i), the biosimilar product that is  
13 the subject of the application or, for  
14 agreements described in subparagraph  
15 (A)(ii), any biosimilar product that is  
16 the subject of an application described  
17 in such subparagraph.

18           “(ii) IF AGREEMENT NOT REDUCED  
19 TO TEXT.—If an agreement required to be  
20 filed by subparagraph (A) has not been re-  
21 duced to text, the persons required to file  
22 the agreement shall each file written de-  
23 scriptions of the agreement that are suffi-  
24 cient to disclose all the terms and condi-  
25 tions of the agreement.

1           “(iii) CERTIFICATION.—The chief ex-  
2           ecutive officer or the company official re-  
3           sponsible for negotiating any agreement re-  
4           quired to be filed by subparagraph (A)  
5           shall include in any filing under this para-  
6           graph a certification as follows: ‘I declare  
7           under penalty of perjury that the following  
8           is true and correct: The materials filed  
9           with the Federal Trade Commission and  
10          the Department of Justice under section  
11          351(l)(6) of the Public Health Service Act,  
12          with respect to the agreement referenced in  
13          this certification: (1) represent the com-  
14          plete, final, and exclusive agreement be-  
15          tween the parties; (2) include any ancillary  
16          agreements that are contingent upon, pro-  
17          vide a contingent condition for, or are oth-  
18          erwise related to, the referenced agree-  
19          ment; and (3) include written descriptions  
20          of any oral agreements, representations,  
21          commitments, or promises between the  
22          parties that are responsive to such section  
23          and have not been reduced to writing.’.

24           “(D) DISCLOSURE EXEMPTION.—Any in-  
25          formation or documentary material filed with

1 the Assistant Attorney General or the Federal  
2 Trade Commission pursuant to this paragraph  
3 shall be exempt from disclosure under section  
4 552 of title 5, United States Code, and no such  
5 information or documentary material may be  
6 made public, except as may be relevant to any  
7 administrative or judicial action or proceeding.  
8 Nothing in this subparagraph prevents disclo-  
9 sure of information or documentary material to  
10 either body of the Congress or to any duly au-  
11 thorized committee or subcommittee of the Con-  
12 gress.

13 “(E) ENFORCEMENT.—

14 “(i) CIVIL PENALTY.—Any person  
15 that violates a provision of this paragraph  
16 shall be liable for a civil penalty of not  
17 more than \$11,000 for each day on which  
18 the violation occurs. Such penalty may be  
19 recovered in a civil action—

20 “(I) brought by the United  
21 States; or

22 “(II) brought by the Federal  
23 Trade Commission in accordance with  
24 the procedures established in section

1                   16(a)(1) of the Federal Trade Com-  
2                   mission Act.

3                   “(ii) COMPLIANCE AND EQUITABLE  
4                   RELIEF.—If any person violates any provi-  
5                   sion of this paragraph, the United States  
6                   district court may order compliance, and  
7                   may grant such other equitable relief as  
8                   the court in its discretion determines nec-  
9                   essary or appropriate, upon application of  
10                  the Assistant Attorney General or the Fed-  
11                  eral Trade Commission.

12                  “(F) RULEMAKING.—The Federal Trade  
13                  Commission, with the concurrence of the Assist-  
14                  ant Attorney General and by rule in accordance  
15                  with section 553 of title 5, United States Code,  
16                  consistent with the purposes of this para-  
17                  graph—

18                         “(i) may define the terms used in this  
19                         paragraph;

20                         “(ii) may exempt classes of persons or  
21                         agreements from the requirements of this  
22                         paragraph; and

23                         “(iii) may prescribe such other rules  
24                         as may be necessary and appropriate to  
25                         carry out the purposes of this paragraph.

1           “(G) SAVINGS CLAUSE.—Any action taken  
2           by the Assistant Attorney General or the Fed-  
3           eral Trade Commission, or any failure of the  
4           Assistant Attorney General or the Commission  
5           to take action, under this paragraph shall not  
6           at any time bar any proceeding or any action  
7           with respect to any agreement between a bio-  
8           similar product applicant under subsection (k)  
9           and the reference product sponsor, or any  
10          agreement between biosimilar product appli-  
11          cants under subsection (k), under any other  
12          provision of law, nor shall any filing under this  
13          paragraph constitute or create a presumption of  
14          any violation of any competition laws.”.

15          (b) DEFINITIONS.—Section 351(i) of the Public  
16          Health Service Act (42 U.S.C. 262(i)) is amended—

17                 (1) by striking “In this section, the term ‘bio-  
18                 logical product’ means” and inserting the following:

19                 “In this section:

20                         “(1) The term ‘biological product’ means”;

21                         (2) in paragraph (1), as so designated, by in-  
22                         serting “protein (except any chemically synthesized  
23                         polypeptide),” after “allergenic product,”; and

24                         (3) by adding at the end the following:

1           “(2) The term ‘biosimilar’ or ‘biosimilarity’, in  
2 reference to a biological product that is the subject  
3 of an application under subsection (k), means—

4           “(A) that the biological product is highly  
5 similar to the reference product notwith-  
6 standing minor differences in clinically inactive  
7 components; and

8           “(B) there are no clinically meaningful dif-  
9 ferences between the biological product and the  
10 reference product in terms of the safety, purity,  
11 and potency of the product.

12           “(3) The term ‘interchangeable’ or ‘inter-  
13 changeability’, in reference to a biological product  
14 that is shown to meet the standards described in  
15 subsection (k)(4), means that the biological product  
16 may be substituted for the reference product without  
17 the intervention of the health care provider who pre-  
18 scribed the reference product.

19           “(4) The term ‘reference product’ means the  
20 single biological product licensed under subsection  
21 (a) against which a biological product is evaluated in  
22 an application submitted under subsection (k).”.

23           (c) PRODUCTS PREVIOUSLY APPROVED UNDER SEC-  
24 TION 505.—

1           (1) REQUIREMENT TO FOLLOW SECTION 351.—  
2       Except as provided in paragraph (2), an application  
3       for a biological product shall be submitted under  
4       section 351 of the Public Health Service Act (42  
5       U.S.C. 262) (as amended by this Act).

6           (2) EXCEPTION.—An application for a biological  
7       product may be submitted under section 505 of  
8       the Federal Food, Drug, and Cosmetic Act (21  
9       U.S.C. 355) if—

10           (A) such biological product is in a product  
11       class for which a biological product in such  
12       product class is the subject of an application  
13       approved under such section 505 not later than  
14       the date of enactment of this Act; and

15           (B) such application—

16           (i) has been submitted to the Sec-  
17       retary of Health and Human Services (re-  
18       ferred to in this Act as the “Secretary”)  
19       before the date of enactment of this Act;  
20       or

21           (ii) is submitted to the Secretary not  
22       later than the date that is 10 years after  
23       the date of enactment of this Act.

24           (3) LIMITATION.—Notwithstanding paragraph  
25       (2), an application for a biological product may not

1 be submitted under section 505 of the Federal Food,  
2 Drug, and Cosmetic Act (21 U.S.C. 355) if there is  
3 another biological product approved under sub-  
4 section (a) of section 351 of the Public Health Serv-  
5 ice Act that could be a reference product with re-  
6 spect to such application (within the meaning of  
7 such section 351) if such application were submitted  
8 under subsection (k) of such section 351.

9 (4) DEEMED APPROVED UNDER SECTION 351.—  
10 An approved application for a biological product  
11 under section 505 of the Federal Food, Drug, and  
12 Cosmetic Act (21 U.S.C. 355) shall be deemed to be  
13 a license for the biological product under such sec-  
14 tion 351 on the date that is 10 years after the date  
15 of enactment of this Act.

16 (5) DEFINITIONS.—For purposes of this sub-  
17 section, the term “biological product” has the mean-  
18 ing given such term under section 351 of the Public  
19 Health Service Act (42 U.S.C. 262) (as amended by  
20 this Act).

21 **SEC. 222. FEES RELATING TO BIOSIMILAR BIOLOGICAL**  
22 **PRODUCTS.**

23 Subparagraph (B) of section 735(1) of the Federal  
24 Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)) is  
25 amended by inserting “, including licensure of a biological



1 product under section 351(k) of such Act” before the pe-  
2 riod at the end.

3 **SEC. 223. AMENDMENTS TO CERTAIN PATENT PROVISIONS.**

4 (a) Section 271(e)(2) of title 35, United States Code  
5 is amended—

6 (1) in subparagraph (A), by striking “or” after  
7 “patent,”;

8 (2) in subparagraph (B), by adding “or” after  
9 the comma at the end;

10 (3) by inserting the following after subpara-  
11 graph (B):

12 “(C) a statement under section  
13 351(l)(4)(D)(ii) of the Public Health Service  
14 Act,”; and

15 (4) in the matter following subparagraph (C)  
16 (as added by paragraph (3)), by inserting before the  
17 period the following: “, or if the statement described  
18 in subparagraph (C) is provided in connection with  
19 an application to obtain a license to engage in the  
20 commercial manufacture, use, or sale of a biological  
21 product claimed in a patent or the use of which is  
22 claimed in a patent before the expiration of such  
23 patent”.

1 (b) Section 271(e)(4) of title 35, United States Code,  
 2 is amended by striking “in paragraph (2)” in both places  
 3 it appears and inserting “in paragraph (2)(A) or (2)(B)”.

4 **Subtitle D—Administrative**  
 5 **Simplification**

6 **SEC. 231. ADMINISTRATIVE SIMPLIFICATION.**

7 (a) OPERATING RULES FOR HEALTH INFORMATION  
 8 TRANSACTIONS.—

9 (1) DEFINITION OF OPERATING RULES.—Sec-  
 10 tion 1171 of the Social Security Act (42 U.S.C.  
 11 1320d) is amended by adding at the end the fol-  
 12 lowing:

13 “(9) OPERATING RULES.—The term ‘operating  
 14 rules’ means the necessary business rules and guide-  
 15 lines for the electronic exchange of information that  
 16 are not defined by a standard or its implementation  
 17 specifications as adopted for purposes of this part.”.

18 (2) OPERATING RULES AND COMPLIANCE.—  
 19 Section 1173 of the Social Security Act (42 U.S.C.  
 20 1320d–2) is amended—

21 (A) in subsection (a)(2), by adding at the  
 22 end the following new subparagraph:

23 “(J) Electronic funds transfers.”; and

24 (B) by adding at the end the following new  
 25 subsections:

1 “(g) OPERATING RULES.—

2 “(1) IN GENERAL.—The Secretary shall adopt  
3 a single set of operating rules for each transaction  
4 described in subsection (a)(2) with the goal of cre-  
5 ating as much uniformity in the implementation of  
6 the electronic standards as possible. Such operating  
7 rules shall be consensus-based and reflect the nec-  
8 essary business rules affecting health plans and  
9 health care providers and the manner in which they  
10 operate pursuant to standards issued under Health  
11 Insurance Portability and Accountability Act of  
12 1996.

13 “(2) OPERATING RULES DEVELOPMENT.—In  
14 adopting operating rules under this subsection, the  
15 Secretary shall rely on recommendations for oper-  
16 ating rules developed by a qualified nonprofit entity,  
17 as selected by the Secretary, that meets the fol-  
18 lowing requirements:

19 “(A) The entity focuses its mission on ad-  
20 ministrative simplification.

21 “(B) The entity demonstrates an estab-  
22 lished multi-stakeholder and consensus-based  
23 process for development of operating rules, in-  
24 cluding representation by or participation from  
25 health plans, health care providers, vendors, rel-

1           evant Federal agencies, and other standard de-  
2           velopment organizations.

3           “(C) The entity has established a public  
4           set of guiding principles that ensure the oper-  
5           ating rules and process are open and trans-  
6           parent.

7           “(D) The entity coordinates its activities  
8           with the HIT Policy Committee and the HIT  
9           Standards Committee (as established under  
10          title XXX of the Public Health Service Act)  
11          and complements the efforts of the Office of the  
12          National Healthcare Coordinator and its related  
13          health information exchange goals.

14          “(E) The entity incorporates national  
15          standards, including the transaction standards  
16          issued under Health Insurance Portability and  
17          Accountability Act of 1996.

18          “(F) The entity supports nondiscrimina-  
19          tion and conflict of interest policies that dem-  
20          onstrate a commitment to open, fair, and non-  
21          discriminatory practices.

22          “(G) The entity allows for public review  
23          and updates of the operating rules.

1           “(3) REVIEW AND RECOMMENDATIONS.—The  
2 National Committee on Vital and Health Statistics  
3 shall—

4           “(A) review the operating rules developed  
5 by a nonprofit entity described under paragraph  
6 (2);

7           “(B) determine whether such rules rep-  
8 resent a consensus view of the health care in-  
9 dustry and are consistent with and do not alter  
10 current standards;

11           “(C) evaluate whether such rules are con-  
12 sistent with electronic standards adopted for  
13 health information technology; and

14           “(D) submit to the Secretary a rec-  
15 ommendation as to whether the Secretary  
16 should adopt such rules.

17           “(4) IMPLEMENTATION.—

18           “(A) IN GENERAL.—The Secretary shall  
19 adopt operating rules under this subsection, by  
20 regulation in accordance with subparagraph  
21 (C), following consideration of the rules devel-  
22 oped by the non-profit entity described in para-  
23 graph (2) and the recommendation submitted  
24 by the National Committee on Vital and Health

1           Statistics under paragraph (3)(D) and having  
2           ensured consultation with providers.

3           “(B) ADOPTION REQUIREMENTS; EFFEC-  
4           TIVE DATES.—

5                   “(i) ELIGIBILITY FOR A HEALTH  
6                   PLAN AND HEALTH CLAIM STATUS.—The  
7                   set of operating rules for transactions for  
8                   eligibility for a health plan and health  
9                   claim status shall be adopted not later  
10                  than July 1, 2011, in a manner ensuring  
11                  that such rules are effective not later than  
12                  January 1, 2013, and may allow for the  
13                  use of a machine readable identification  
14                  card.

15                  “(ii) ELECTRONIC FUNDS TRANSFERS  
16                  AND HEALTH CARE PAYMENT AND REMIT-  
17                  TANCE ADVICE.—The set of operating  
18                  rules for electronic funds transfers and  
19                  health care payment and remittance advice  
20                  shall be adopted not later than July 1,  
21                  2012, in a manner ensuring that such  
22                  rules are effective not later than January  
23                  1, 2014.

24                  “(iii) OTHER COMPLETED TRANS-  
25                  ACTIONS.—The set of operating rules for

1           the remainder of the completed trans-  
2           actions described in subsection (a)(2), in-  
3           cluding health claims or equivalent encoun-  
4           ter information, enrollment and  
5           disenrollment in a health plan, health plan  
6           premium payments, and referral certifi-  
7           cation and authorization, shall be adopted  
8           not later than July 1, 2014, in a manner  
9           ensuring that such rules are effective not  
10          later than January 1, 2016.

11           “(C) EXPEDITED RULEMAKING.—The Sec-  
12          retary shall promulgate an interim final rule  
13          applying any standard or operating rule rec-  
14          ommended by the National Committee on Vital  
15          and Health Statistics pursuant to paragraph  
16          (3). The Secretary shall accept public comments  
17          on any interim final rule published under this  
18          subparagraph for 60 days after the date of such  
19          publication.

20          “(h) COMPLIANCE.—

21               “(1) HEALTH PLAN CERTIFICATION.—

22                   “(A) ELIGIBILITY FOR A HEALTH PLAN,  
23                   HEALTH CLAIM STATUS, ELECTRONIC FUNDS  
24                   TRANSFERS, HEALTH CARE PAYMENT AND RE-  
25                   MITTANCE ADVICE.—Not later than December

1           31, 2013, a health plan shall file a statement  
2           with the Secretary, in such form as the Sec-  
3           retary may require, certifying that the data and  
4           information systems for such plan are in com-  
5           pliance with any applicable standards (as de-  
6           scribed under paragraph (7) of section 1171)  
7           and operating rules (as described under para-  
8           graph (9) of such section) for electronic funds  
9           transfers, eligibility for a health plan, health  
10          claim status, and health care payment and re-  
11          mittance advice, respectively.

12           “(B)   OTHER   COMPLETED   TRANS-  
13          ACTIONS.—Not later than December 31, 2015,  
14          a health plan shall file a statement with the  
15          Secretary, in such form as the Secretary may  
16          require, certifying that the data and informa-  
17          tion systems for such plan are in compliance  
18          with any applicable standards and operating  
19          rules for the remainder of the completed trans-  
20          actions described in subsection (a)(2), including  
21          health claims or equivalent encounter informa-  
22          tion, enrollment and disenrollment in a health  
23          plan, health plan premium payments, and refer-  
24          ral certification and authorization, respectively.

25          A health plan shall provide the same level of



1 documentation to certify compliance with such  
2 transactions as is required to certify compliance  
3 with the transactions specified in subparagraph  
4 (A).

5 “(2) DOCUMENTATION OF COMPLIANCE.—A  
6 health plan shall provide the Secretary, in such form  
7 as the Secretary may require, with adequate docu-  
8 mentation of compliance with the standards and op-  
9 erating rules described under paragraph (1). A  
10 health plan shall not be considered to have provided  
11 adequate documentation and shall not be certified as  
12 being in compliance with such standards, unless the  
13 health plan—

14 “(A) demonstrates to the Secretary that  
15 the plan conducts the electronic transactions  
16 specified in paragraph (1) in a manner that  
17 fully complies with the regulations of the Sec-  
18 retary; and

19 “(B) provides documentation showing that  
20 the plan has completed end-to-end testing for  
21 such transactions with their partners, such as  
22 hospitals and physicians.

23 “(3) SERVICE CONTRACTS.—A health plan shall  
24 be required to comply with any applicable certifi-  
25 cation and compliance requirements (and provide the

1 Secretary with adequate documentation of such com-  
2 pliance) under this subsection for any entities that  
3 provide services pursuant to a contract with such  
4 health plan.

5 “(4) CERTIFICATION BY OUTSIDE ENTITY.—  
6 The Secretary may contract with an independent,  
7 outside entity to certify that a health plan has com-  
8 plied with the requirements under this subsection,  
9 provided that the certification standards employed  
10 by such entities are in accordance with any stand-  
11 ards or rules issued by the Secretary.

12 “(5) COMPLIANCE WITH REVISED STANDARDS  
13 AND RULES.—A health plan (including entities de-  
14 scribed under paragraph (3)) shall comply with the  
15 certification and documentation requirements under  
16 this subsection for any interim final rule promul-  
17 gated by the Secretary under subsection (i) that  
18 amends any standard or operating rule described  
19 under paragraph (1) of this subsection. A health  
20 plan shall comply with such requirements not later  
21 than the effective date of the applicable interim final  
22 rule.

23 “(6) AUDITS OF HEALTH PLANS.—The Sec-  
24 retary shall conduct periodic audits to ensure that  
25 health plans (including entities described under

1 paragraph (3)) are in compliance with any standards  
2 and operating rules that are described under para-  
3 graph (1).

4 “(i) REVIEW AND AMENDMENT OF STANDARDS AND  
5 RULES.—

6 “(1) ESTABLISHMENT.—Not later than Janu-  
7 ary 1, 2014, the Secretary shall establish a review  
8 committee (as described under paragraph (4)).

9 “(2) EVALUATIONS AND REPORTS.—

10 “(A) HEARINGS.—Not later than April 1,  
11 2014, and not less than biennially thereafter,  
12 the Secretary, acting through the review com-  
13 mittee, shall conduct hearings to evaluate and  
14 review the existing standards and operating  
15 rules established under this section.

16 “(B) REPORT.—Not later than July 1,  
17 2014, and not less than biennially thereafter,  
18 the review committee shall provide rec-  
19 ommendations for updating and improving such  
20 standards and rules. The review committee  
21 shall recommend a single set of operating rules  
22 per transaction standard and maintain the goal  
23 of creating as much uniformity as possible in  
24 the implementation of the electronic standards.

25 “(3) INTERIM FINAL RULEMAKING.—

1           “(A) IN GENERAL.—Any recommendations  
2 to amend existing standards and operating  
3 rules that have been approved by the review  
4 committee and reported to the Secretary under  
5 paragraph (2)(B) shall be adopted by the Sec-  
6 retary through promulgation of an interim final  
7 rule not later than 90 days after receipt of the  
8 committee’s report.

9           “(B) PUBLIC COMMENT.—

10           “(i) PUBLIC COMMENT PERIOD.—The  
11 Secretary shall accept public comments on  
12 any interim final rule published under this  
13 paragraph for 60 days after the date of  
14 such publication.

15           “(ii) EFFECTIVE DATE.—The effective  
16 date of any amendment to existing stand-  
17 ards or operating rules that is adopted  
18 through an interim final rule published  
19 under this paragraph shall be 25 months  
20 following the close of such public comment  
21 period.

22           “(4) REVIEW COMMITTEE.—

23           “(A) DEFINITION.—For the purposes of  
24 this subsection, the term ‘review committee’  
25 means a committee within the Department of

1 Health and Human services that has been des-  
2 ignated by the Secretary to carry out this sub-  
3 section, including—

4 “(i) the National Committee on Vital  
5 and Health Statistics; or

6 “(ii) any appropriate committee as de-  
7 termined by the Secretary.

8 “(B) COORDINATION OF HIT STAND-  
9 ARDS.—In developing recommendations under  
10 this subsection, the review committee shall con-  
11 sider the standards approved by the Office of  
12 the National Coordinator for Health Informa-  
13 tion Technology.

14 “(j) PENALTIES.—

15 “(1) PENALTY FEE.—

16 “(A) IN GENERAL.—Not later than April  
17 1, 2014, and annually thereafter, the Secretary  
18 shall assess a penalty fee (as determined under  
19 subparagraph (B)) against a health plan that  
20 has failed to meet the requirements under sub-  
21 section (h) with respect to certification and doc-  
22 umentation of compliance with the standards  
23 (and their operating rules) as described under  
24 paragraph (1) of such subsection.

1           “(B) FEE AMOUNT.—Subject to subpara-  
2           graphs (C), (D), and (E), the Secretary shall  
3           assess a penalty fee against a health plan in the  
4           amount of \$1 per covered life until certification  
5           is complete. The penalty shall be assessed per  
6           person covered by the plan for which its data  
7           systems for major medical policies are not in  
8           compliance and shall be imposed against the  
9           health plan for each day that the plan is not in  
10          compliance with the requirements under sub-  
11          section (h).

12          “(C) ADDITIONAL PENALTY FOR MIS-  
13          REPRESENTATION.—A health plan that know-  
14          ingly provides inaccurate or incomplete informa-  
15          tion in a statement of certification or docu-  
16          mentation of compliance under subsection (h)  
17          shall be subject to a penalty fee that is double  
18          the amount that would otherwise be imposed  
19          under this subsection.

20          “(D) ANNUAL FEE INCREASE.—The  
21          amount of the penalty fee imposed under this  
22          subsection shall be increased on an annual basis  
23          by the annual percentage increase in total na-  
24          tional health care expenditures, as determined  
25          by the Secretary.

1           “(E) PENALTY LIMIT.—A penalty fee as-  
2           sessed against a health plan under this sub-  
3           section shall not exceed, on an annual basis—

4                   “(i) an amount equal to \$20 per cov-  
5                   ered life under such plan; or

6                   “(ii) an amount equal to \$40 per cov-  
7                   ered life under the plan if such plan has  
8                   knowingly provided inaccurate or incom-  
9                   plete information (as described under sub-  
10                  paragraph (C)).

11           “(F) DETERMINATION OF COVERED INDI-  
12           VIDUALS.—The Secretary shall determine the  
13           number of covered lives under a health plan  
14           based upon the most recent statements and fil-  
15           ings that have been submitted by such plan to  
16           the Securities and Exchange Commission.

17           “(2) NOTICE AND DISPUTE PROCEDURE.—The  
18           Secretary shall establish a procedure for assessment  
19           of penalty fees under this subsection that provides a  
20           health plan with reasonable notice and a dispute res-  
21           olution procedure prior to provision of a notice of as-  
22           sessment by the Secretary of the Treasury (as de-  
23           scribed under paragraph (4)(B)).

24           “(3) PENALTY FEE REPORT.—Not later than  
25           May 1, 2014, and annually thereafter, the Secretary

1 shall provide the Secretary of the Treasury with a  
2 report identifying those health plans that have been  
3 assessed a penalty fee under this subsection.

4 “(4) COLLECTION OF PENALTY FEE.—

5 “(A) IN GENERAL.—The Secretary of the  
6 Treasury, acting through the Financial Man-  
7 agement Service, shall administer the collection  
8 of penalty fees from health plans that have been  
9 identified by the Secretary in the penalty fee re-  
10 port provided under paragraph (3).

11 “(B) NOTICE.—Not later than August 1,  
12 2014, and annually thereafter, the Secretary of  
13 the Treasury shall provide notice to each health  
14 plan that has been assessed a penalty fee by the  
15 Secretary under this subsection. Such notice  
16 shall include the amount of the penalty fee as-  
17 sessed by the Secretary and the due date for  
18 payment of such fee to the Secretary of the  
19 Treasury (as described in subparagraph (C)).

20 “(C) PAYMENT DUE DATE.—Payment by a  
21 health plan for a penalty fee assessed under  
22 this subsection shall be made to the Secretary  
23 of the Treasury not later than November 1,  
24 2014, and annually thereafter.



1           “(D) UNPAID PENALTY FEES.—Any  
2 amount of a penalty fee assessed against a  
3 health plan under this subsection for which pay-  
4 ment has not been made by the due date pro-  
5 vided under subparagraph (C) shall be—

6                   “(i) increased by the interest accrued  
7 on such amount, as determined pursuant  
8 to the underpayment rate established  
9 under section 6601 of the Internal Rev-  
10 enue Code of 1986; and

11                   “(ii) treated as a past-due, legally en-  
12 forceable debt owed to a Federal agency  
13 for purposes of section 6402(d) of the In-  
14 ternal Revenue Code of 1986.

15           “(E) ADMINISTRATIVE FEES.—Any fee  
16 charged or allocated for collection activities con-  
17 ducted by the Financial Management Service  
18 will be passed on to a health plan on a pro-rata  
19 basis and added to any penalty fee collected  
20 from the plan.”.

21 (b) PROMULGATION OF RULES.—

22           (1) UNIQUE HEALTH PLAN IDENTIFIER.—The  
23 Secretary shall promulgate a final rule to establish  
24 a unique health plan identifier (as described in sec-  
25 tion 1173(b) of the Social Security Act (42 U.S.C.

1 1320d–2(b)) based on the input of the National  
2 Committee of Vital and Health Statistics. The Sec-  
3 retary may do so on an interim final basis and such  
4 rule shall be effective not later than October 1,  
5 2012.

6 (2) ELECTRONIC FUNDS TRANSFER.—The Sec-  
7 retary shall promulgate a final rule to establish a  
8 standard for electronic funds transfers (as described  
9 in section 1173(a)(2)(J) of the Social Security Act,  
10 as added by subsection (a)(2)(A)). The Secretary  
11 may do so on an interim final basis and shall adopt  
12 such standard not later than January 1, 2012, in a  
13 manner ensuring that such standard is effective not  
14 later than January 1, 2014.

15 (c) EXPANSION OF ELECTRONIC TRANSACTIONS IN  
16 MEDICARE.—Section 1862(a) of the Social Security Act  
17 (42 U.S.C. 1395y(a)) is amended—

18 (1) in paragraph (23), by striking the “or” at  
19 the end;

20 (2) in paragraph (24), by striking the period  
21 and inserting “; or”; and

22 (3) by inserting after paragraph (24) the fol-  
23 lowing new paragraph:

24 “(25) not later than January 1, 2014, for  
25 which the payment is other than by electronic funds

1 transfer (EFT) or an electronic remittance in a form  
2 as specified in ASC X12 835 Health Care Payment  
3 and Remittance Advice or subsequent standard.”.

4 (d) MEDICARE AND MEDICAID COMPLIANCE RE-  
5 PORTS.—Not later than July 1, 2013, the Secretary of  
6 Health and Human Services shall submit a report to the  
7 Chairs and Ranking Members of the Committee on Ways  
8 and Means and the Committee on Energy and Commerce  
9 of the House of Representatives and the Chairs and Rank-  
10 ing Members of the Committee on Health, Education,  
11 Labor, and Pensions and the Committee on Finance of  
12 the Senate on the extent to which the Medicare program  
13 and providers that serve beneficiaries under that program,  
14 and State Medicaid programs and providers that serve  
15 beneficiaries under those programs, transact electronically  
16 in accordance with transaction standards issued under the  
17 Health Insurance Portability and Accountability Act of  
18 1996, part C of title XI of the Social Security Act, and  
19 regulations promulgated under such Acts.

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