

**MOTION TO RECOMMIT H.R. 3961, WITH
INSTRUCTIONS
OFFERED BY MR. GINGREY OF GEORGIA**

Mr. Gingrey moves to recommit the bill, H.R. 3961, to the Committee on Energy and Commerce with instructions to report the same back to the House forthwith with the following amendment:

Strike all after the enacting clause and insert the following:

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.

1 “(B) NO EFFECT ON COMPUTATION OF
2 CONVERSION FACTOR FOR 2014 AND SUBSE-
3 QUENT YEARS.—The conversion factor under
4 this subsection shall be computed under para-
5 graph (1)(A) for 2014 and subsequent years as
6 if subparagraph (A) had never applied, subject
7 to paragraph (11).

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

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 2014 and, at the Sec-
15 retary’s discretion, for subsequent years ending
16 not later than 2019, the update to the single
17 conversion factor shall be such percentage for
18 each such year as the Secretary determines will
19 result in additional expenditures under this title
20 in the aggregate for all such years of
21 \$26,400,000,000. Not later than October 1,
22 2013, the Secretary shall establish by regula-
23 tion the method the Secretary will use in allo-
24 cating the \$26,400,000,000 under the previous
25 sentence between 2014 and subsequent years.

1 Such allocation shall be designed in a manner
2 so that the single conversion factor for a year
3 is not less than 79 percent of the conversion
4 factor for the previous year.

5 “(B) LIMITED EFFECT ON COMPUTATION
6 OF CONVERSION FACTOR FOR SUBSEQUENT
7 YEARS.—The conversion factor under this sub-
8 section shall be computed under paragraph
9 (1)(A) for subsequent years as if subparagraph
10 (A) had never applied, but taking into account
11 the aggregate additional increase in expendi-
12 tures permitted under such subparagraph.”.

13 **SEC. 102. STATEMENT OF POLICY.**

14 It is the policy of the Federal Government that the
15 sustainable growth rate formula, upon which physician
16 payments are based for the Medicare program, should be
17 permanently repealed and replaced with a reimbursement
18 policy that pays doctors an amount reflecting the true cost
19 of services provided in a high-quality and efficient manner
20 and uses a fiscally responsibly funding mechanism.

1 **TITLE II—DEFICIT PROTECTION**
2 **AND FISCAL RESPONSIBILITY**
3 **Subtitle A—Enacting Real Medical**
4 **Liability Reform**

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

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

- 14 (1) upon proof of fraud;
15 (2) intentional concealment; or
16 (3) the presence of a foreign body, which has no
17 therapeutic or diagnostic purpose or effect, in the
18 person of the injured person.

19 Actions by a minor shall be commenced within 3 years
20 from the date of the alleged manifestation of injury except
21 that actions by a minor under the full age of 6 years shall
22 be commenced within 3 years of manifestation of injury
23 or prior to the minor's 8th birthday, whichever provides
24 a longer period. Such time limitation shall be tolled for
25 minors for any period during which a parent or guardian

1 and a health care provider or health care organization
2 have committed fraud or collusion in the failure to bring
3 an action on behalf of the injured minor.

4 **SEC. 202. COMPENSATING PATIENT INJURY.**

5 (a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL
6 ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any
7 health care lawsuit, nothing in this subtitle shall limit a
8 claimant's recovery of the full amount of the available eco-
9 nomic damages, notwithstanding the limitation in sub-
10 section (b).

11 (b) ADDITIONAL NONECONOMIC DAMAGES.—In any
12 health care lawsuit, the amount of noneconomic damages,
13 if available, may be as much as \$250,000, regardless of
14 the number of parties against whom the action is brought
15 or the number of separate claims or actions brought with
16 respect to the same injury.

17 (c) NO DISCOUNT OF AWARD FOR NONECONOMIC
18 DAMAGES.—For purposes of applying the limitation in
19 subsection (b), future noneconomic damages shall not be
20 discounted to present value. The jury shall not be in-
21 formed about the maximum award for noneconomic dam-
22 ages. An award for noneconomic damages in excess of
23 \$250,000 shall be reduced either before the entry of judg-
24 ment, or by amendment of the judgment after entry of
25 judgment, and such reduction shall be made before ac-

1 counting for any other reduction in damages required by
2 law. If separate awards are rendered for past and future
3 noneconomic damages and the combined awards exceed
4 \$250,000, the future noneconomic damages shall be re-
5 duced first.

6 (d) FAIR SHARE RULE.—In any health care lawsuit,
7 each party shall be liable for that party's several share
8 of any damages only and not for the share of any other
9 person. Each party shall be liable only for the amount of
10 damages allocated to such party in direct proportion to
11 such party's percentage of responsibility. Whenever a
12 judgment of liability is rendered as to any party, a sepa-
13 rate judgment shall be rendered against each such party
14 for the amount allocated to such party. For purposes of
15 this section, the trier of fact shall determine the propor-
16 tion of responsibility of each party for the claimant's
17 harm.

18 **SEC. 203. MAXIMIZING PATIENT RECOVERY.**

19 (a) COURT SUPERVISION OF SHARE OF DAMAGES
20 ACTUALLY PAID TO CLAIMANTS.—In any health care law-
21 suit, the court shall supervise the arrangements for pay-
22 ment of damages to protect against conflicts of interest
23 that may have the effect of reducing the amount of dam-
24 ages awarded that are actually paid to claimants. In par-
25 ticular, in any health care lawsuit in which the attorney

1 for a party claims a financial stake in the outcome by vir-
2 tue of a contingent fee, the court shall have the power
3 to restrict the payment of a claimant's damage recovery
4 to such attorney, and to redirect such damages to the
5 claimant based upon the interests of justice and principles
6 of equity. In no event shall the total of all contingent fees
7 for representing all claimants in a health care lawsuit ex-
8 ceed the following limits:

9 (1) 40 percent of the first \$50,000 recovered by
10 the claimant(s).

11 (2) 33 $\frac{1}{3}$ percent of the next \$50,000 recovered
12 by the claimant(s).

13 (3) 25 percent of the next \$500,000 recovered
14 by the claimant(s).

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

17 (b) APPLICABILITY.—The limitations in this section
18 shall apply whether the recovery is by judgment, settle-
19 ment, mediation, arbitration, or any other form of alter-
20 native dispute resolution. In a health care lawsuit involv-
21 ing a minor or incompetent person, a court retains the
22 authority to authorize or approve a fee that is less than
23 the maximum permitted under this section. The require-
24 ment for court supervision in the first two sentences of
25 subsection (a) applies only in civil actions.

1 **SEC. 204. ADDITIONAL HEALTH BENEFITS.**

2 In any health care lawsuit involving injury or wrong-
3 ful death, any party may introduce evidence of collateral
4 source benefits. If a party elects to introduce such evi-
5 dence, any opposing party may introduce evidence of any
6 amount paid or contributed or reasonably likely to be paid
7 or contributed in the future by or on behalf of the oppos-
8 ing party to secure the right to such collateral source bene-
9 fits. No provider of collateral source benefits shall recover
10 any amount against the claimant or receive any lien or
11 credit against the claimant's recovery or be equitably or
12 legally subrogated to the right of the claimant in a health
13 care lawsuit involving injury or wrongful death. This sec-
14 tion shall apply to any health care lawsuit that is settled
15 as well as a health care lawsuit that is resolved by a fact
16 finder. This section shall not apply to section 1862(b) (42
17 U.S.C. 1395y(b)) or section 1902(a)(25) (42 U.S.C.
18 1396a(a)(25)) of the Social Security Act.

19 **SEC. 205. PUNITIVE DAMAGES.**

20 (a) IN GENERAL.—Punitive damages may, if other-
21 wise permitted by applicable State or Federal law, be
22 awarded against any person in a health care lawsuit only
23 if it is proven by clear and convincing evidence that such
24 person acted with malicious intent to injure the claimant,
25 or that such person deliberately failed to avoid unneces-
26 sary injury that such person knew the claimant was sub-

1 stantially certain to suffer. In any health care lawsuit
2 where no judgment for compensatory damages is rendered
3 against such person, no punitive damages may be awarded
4 with respect to the claim in such lawsuit. No demand for
5 punitive damages shall be included in a health care lawsuit
6 as initially filed. A court may allow a claimant to file an
7 amended pleading for punitive damages only upon a mo-
8 tion by the claimant and after a finding by the court, upon
9 review of supporting and opposing affidavits or after a
10 hearing, after weighing the evidence, that the claimant has
11 established by a substantial probability that the claimant
12 will prevail on the claim for punitive damages. At the re-
13 quest of any party in a health care lawsuit, the trier of
14 fact shall consider in a separate proceeding—

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

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

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

24 (b) DETERMINING AMOUNT OF PUNITIVE DAM-
25 AGES.—

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

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

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

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

11 (D) the number of products sold or med-
12 ical procedures rendered for compensation, as
13 the case may be, by such party, of the kind
14 causing the harm complained of by the claim-
15 ant;

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

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

22 (2) MAXIMUM AWARD.—The amount of punitive
23 damages, if awarded, in a health care lawsuit may
24 be as much as \$250,000 or as much as two times
25 the amount of economic damages awarded, which-

1 ever is greater. The jury shall not be informed of
2 this limitation.

3 **SEC. 206. AUTHORIZATION OF PAYMENT OF FUTURE DAM-**
4 **AGES TO CLAIMANTS IN HEALTH CARE LAW-**
5 **SUITS.**

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

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

20 **SEC. 207. DEFINITIONS.**

21 In this subtitle:

22 (1) ALTERNATIVE DISPUTE RESOLUTION SYS-
23 TEM; ADR.—The term “alternative dispute resolution
24 system” or “ADR” means a system that provides
25 for the resolution of health care lawsuits in a man-

1 ner other than through a civil action brought in a
2 State or Federal court.

3 (2) CLAIMANT.—The term “claimant” means
4 any person who brings a health care lawsuit, includ-
5 ing a person who asserts or claims a right to legal
6 or equitable contribution, indemnity, or subrogation,
7 arising out of a health care liability claim or action,
8 and any person on whose behalf such a claim is as-
9 serted or such an action is brought, whether de-
10 ceased, incompetent, or a minor.

11 (3) COLLATERAL SOURCE BENEFITS.—The
12 term “collateral source benefits” means any amount
13 paid or reasonably likely to be paid in the future to
14 or on behalf of the claimant, or any service, product,
15 or other benefit provided or reasonably likely to be
16 provided in the future to or on behalf of the claim-
17 ant, as a result of the injury or wrongful death, pur-
18 suant to—

19 (A) any State or Federal health, sickness,
20 income-disability, accident, or workers’ com-
21 pensation law;

22 (B) any health, sickness, income-disability,
23 or accident insurance that provides health bene-
24 fits or income-disability coverage;

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

6 (D) any other publicly or privately funded
7 program.

8 (4) COMPENSATORY DAMAGES.—The term
9 “compensatory damages” means objectively
10 verifiable monetary losses incurred as a result of the
11 provision of, use of, or payment for (or failure to
12 provide, use, or pay for) health care services or med-
13 ical products, such as past and future medical ex-
14 penses, loss of past and future earnings, cost of ob-
15 taining domestic services, loss of employment, and
16 loss of business or employment opportunities, dam-
17 ages for physical and emotional pain, suffering, in-
18 convenience, physical impairment, mental anguish,
19 disfigurement, loss of enjoyment of life, loss of soci-
20 ety and companionship, loss of consortium (other
21 than loss of domestic service), hedonic damages, in-
22 jury to reputation, and all other nonpecuniary losses
23 of any kind or nature. The term “compensatory
24 damages” includes economic damages and non-

1 economic damages, as such terms are defined in this
2 section.

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

7 (6) ECONOMIC DAMAGES.—The term “economic
8 damages” means objectively verifiable monetary
9 losses incurred as a result of the provision of, use
10 of, or payment for (or failure to provide, use, or pay
11 for) health care services or medical products, such as
12 past and future medical expenses, loss of past and
13 future earnings, cost of obtaining domestic services,
14 loss of employment, and loss of business or employ-
15 ment opportunities.

16 (7) HEALTH CARE LAWSUIT.—The term
17 “health care lawsuit” means any health care liability
18 claim concerning the provision of health care goods
19 or services or any medical product affecting inter-
20 state commerce, or any health care liability action
21 concerning the provision of health care goods or
22 services or any medical product affecting interstate
23 commerce, brought in a State or Federal court or
24 pursuant to an alternative dispute resolution system,
25 against a health care provider, a health care organi-

1 zation, or the manufacturer, distributor, supplier,
2 marketer, promoter, or seller of a medical product,
3 regardless of the theory of liability on which the
4 claim is based, or the number of claimants, plain-
5 tiffs, defendants, or other parties, or the number of
6 claims or causes of action, in which the claimant al-
7 leges a health care liability claim. Such term does
8 not include a claim or action which is based on
9 criminal liability; which seeks civil fines or penalties
10 paid to Federal, State, or local government; or which
11 is grounded in antitrust.

12 (8) HEALTH CARE LIABILITY ACTION.—The
13 term “health care liability action” means a civil ac-
14 tion brought in a State or Federal court or pursuant
15 to an alternative dispute resolution system, against
16 a health care provider, a health care organization, or
17 the manufacturer, distributor, supplier, marketer,
18 promoter, or seller of a medical product, regardless
19 of the theory of liability on which the claim is based,
20 or the number of plaintiffs, defendants, or other par-
21 ties, or the number of causes of action, in which the
22 claimant alleges a health care liability claim.

23 (9) HEALTH CARE LIABILITY CLAIM.—The
24 term “health care liability claim” means a demand
25 by any person, whether or not pursuant to ADR,

1 against a health care provider, health care organiza-
2 tion, or the manufacturer, distributor, supplier, mar-
3 keter, promoter, or seller of a medical product, in-
4 cluding, but not limited to, third-party claims, cross-
5 claims, counter-claims, or contribution claims, which
6 are based upon the provision of, use of, or payment
7 for (or the failure to provide, use, or pay for) health
8 care services or medical products, regardless of the
9 theory of liability on which the claim is based, or the
10 number of plaintiffs, defendants, or other parties, or
11 the number of causes of action.

12 (10) HEALTH CARE ORGANIZATION.—The term
13 “health care organization” means any person or en-
14 tity which is obligated to provide or pay for health
15 benefits under any health plan, including any person
16 or entity acting under a contract or arrangement
17 with a health care organization to provide or admin-
18 ister any health benefit.

19 (11) HEALTH CARE PROVIDER.—The term
20 “health care provider” means any person or entity
21 required by State or Federal laws or regulations to
22 be licensed, registered, or certified to provide health
23 care services, and being either so licensed, reg-
24 istered, or certified, or exempted from such require-
25 ment by other statute or regulation.

1 (12) HEALTH CARE GOODS OR SERVICES.—The
2 term “health care goods or services” means any
3 goods or services provided by a health care organiza-
4 tion, provider, or by any individual working under
5 the supervision of a health care provider, that relates
6 to the diagnosis, prevention, or treatment of any
7 human disease or impairment, or the assessment or
8 care of the health of human beings.

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

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

24 (15) NONECONOMIC DAMAGES.—The term
25 “noneconomic damages” means damages for phys-

1 ical and emotional pain, suffering, inconvenience,
2 physical impairment, mental anguish, disfigurement,
3 loss of enjoyment of life, loss of society and compan-
4 ionship, loss of consortium (other than loss of do-
5 mestic service), hedonic damages, injury to reputa-
6 tion, and all other nonpecuniary losses of any kind
7 or nature.

8 (16) PUNITIVE DAMAGES.—The term “punitive
9 damages” means damages awarded, for the purpose
10 of punishment or deterrence, and not solely for com-
11 pensatory purposes, against a health care provider,
12 health care organization, or a manufacturer, dis-
13 tributor, or supplier of a medical product. Punitive
14 damages are neither economic nor noneconomic
15 damages.

16 (17) RECOVERY.—The term “recovery” means
17 the net sum recovered after deducting any disburse-
18 ments or costs incurred in connection with prosecu-
19 tion or settlement of the claim, including all costs
20 paid or advanced by any person. Costs of health care
21 incurred by the plaintiff and the attorneys’ office
22 overhead costs or charges for legal services are not
23 deductible disbursements or costs for such purpose.

24 (18) STATE.—The term “State” means each of
25 the several States, the District of Columbia, the

1 Commonwealth of Puerto Rico, the Virgin Islands,
2 Guam, American Samoa, the Northern Mariana Is-
3 lands, the Trust Territory of the Pacific Islands, and
4 any other territory or possession of the United
5 States, or any political subdivision thereof.

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

7 (a) VACCINE INJURY.—

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

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

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

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

24 (b) OTHER FEDERAL LAW.—Except as provided in
25 this section, nothing in this subtitle shall be deemed to

1 affect any defense available to a defendant in a health care
2 lawsuit or action under any other provision of Federal law.

3 **SEC. 209. STATE FLEXIBILITY AND PROTECTION OF**
4 **STATES' RIGHTS.**

5 (a) HEALTH CARE LAWSUITS.—The provisions gov-
6 erning health care lawsuits set forth in this subtitle pre-
7 empt, subject to subsections (b) and (c), State law to the
8 extent that State law prevents the application of any pro-
9 visions of law established by or under this subtitle. The
10 provisions governing health care lawsuits set forth in this
11 subtitle supersede chapter 171 of title 28, United States
12 Code, to the extent that such chapter—

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

18 (2) prohibits the introduction of evidence re-
19 garding collateral source benefits, or mandates or
20 permits subrogation or a lien on collateral source
21 benefits.

22 (b) PROTECTION OF STATES' RIGHTS AND OTHER
23 LAWS.—(1) Any issue that is not governed by any provi-
24 sion of law established by or under this subtitle (including

1 State standards of negligence) shall be governed by other-
2 wise applicable State or Federal law.

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

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

11 (1) any State law (whether effective before, on,
12 or after the date of the enactment of this Act) that
13 specifies a particular monetary amount of compen-
14 satory or punitive damages (or the total amount of
15 damages) that may be awarded in a health care law-
16 suit, regardless of whether such monetary amount is
17 greater or lesser than is provided for under this sub-
18 title, notwithstanding section 202(a); or

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

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

23 This subtitle shall apply to any health care lawsuit
24 brought in a Federal or State court, or subject to an alter-
25 native dispute resolution system, that is initiated on or

1 after the date of the enactment of this Act, except that
2 any health care lawsuit arising from an injury occurring
3 prior to the date of the enactment of this Act shall be
4 governed by the applicable statute of limitations provisions
5 in effect at the time the injury occurred.

6 **Subtitle B—Application of** 7 **Medicare Improvement Fund**

8 **SEC. 211. APPLICATION OF MEDICARE IMPROVEMENT** 9 **FUND.**

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

14 **Subtitle C—Pathway for Biosimilar** 15 **Biological Products**

16 **SEC. 221. LICENSURE PATHWAY FOR BIOSIMILAR BIOLOGI-** 17 **CAL PRODUCTS.**

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

21 (1) in subsection (a)(1)(A), by inserting “under
22 this subsection or subsection (k)” after “biologics li-
23 cense”; and

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

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

3 “(1) IN GENERAL.—Any person may submit an
4 application for licensure of a biological product
5 under this subsection.

6 “(2) CONTENT.—

7 “(A) IN GENERAL.—

8 “(i) REQUIRED INFORMATION.—An
9 application submitted under this subsection
10 shall include information demonstrating
11 that—

12 “(I) the biological product is bio-
13 similar to a reference product based
14 upon data derived from—

15 “(aa) analytical studies that
16 demonstrate that the biological
17 product is highly similar to the
18 reference product notwith-
19 standing minor differences in
20 clinically inactive components;

21 “(bb) animal studies (includ-
22 ing the assessment of toxicity);
23 and

24 “(cc) a clinical study or
25 studies (including the assessment

1 of immunogenicity and phar-
2 macokinetics or
3 pharmacodynamics) that are suf-
4 ficient to demonstrate safety, pu-
5 rity, and potency in 1 or more
6 appropriate conditions of use for
7 which the reference product is li-
8 censed and intended to be used
9 and for which licensure is sought
10 for the biological product;

11 “(II) the biological product and
12 reference product utilize the same
13 mechanism or mechanisms of action
14 for the condition or conditions of use
15 prescribed, recommended, or sug-
16 gested in the proposed labeling, but
17 only to the extent the mechanism or
18 mechanisms of action are known for
19 the reference product;

20 “(III) the condition or conditions
21 of use prescribed, recommended, or
22 suggested in the labeling proposed for
23 the biological product have been pre-
24 viously approved for the reference
25 product;

1 “(IV) the route of administra-
2 tion, the dosage form, and the
3 strength of the biological product are
4 the same as those of the reference
5 product; and

6 “(V) the facility in which the bio-
7 logical product is manufactured, proc-
8 essed, packed, or held meets stand-
9 ards designed to assure that the bio-
10 logical product continues to be safe,
11 pure, and potent.

12 “(ii) DETERMINATION BY SEC-
13 RETARY.—The Secretary may determine,
14 in the Secretary’s discretion, that an ele-
15 ment described in clause (i)(I) is unneces-
16 sary in an application submitted under this
17 subsection.

18 “(iii) ADDITIONAL INFORMATION.—
19 An application submitted under this sub-
20 section—

21 “(I) shall include publicly avail-
22 able information regarding the Sec-
23 retary’s previous determination that
24 the reference product is safe, pure,
25 and potent; and

1 “(II) may include any additional
2 information in support of the applica-
3 tion, including publicly available infor-
4 mation with respect to the reference
5 product or another biological product.

6 “(B) INTERCHANGEABILITY.—An applica-
7 tion (or a supplement to an application) sub-
8 mitted under this subsection may include infor-
9 mation demonstrating that the biological prod-
10 uct meets the standards described in paragraph
11 (4).

12 “(3) EVALUATION BY SECRETARY.—Upon re-
13 view of an application (or a supplement to an appli-
14 cation) submitted under this subsection, the Sec-
15 retary shall license the biological product under this
16 subsection if—

17 “(A) the Secretary determines that the in-
18 formation submitted in the application (or the
19 supplement) is sufficient to show that the bio-
20 logical product—

21 “(i) is biosimilar to the reference
22 product; or

23 “(ii) meets the standards described in
24 paragraph (4), and therefore is inter-
25 changeable with the reference product; and

1 “(B) the applicant (or other appropriate
2 person) consents to the inspection of the facility
3 that is the subject of the application, in accord-
4 ance with subsection (c).

5 “(4) SAFETY STANDARDS FOR DETERMINING
6 INTERCHANGEABILITY.—Upon review of an applica-
7 tion submitted under this subsection or any supple-
8 ment to such application, the Secretary shall deter-
9 mine the biological product to be interchangeable
10 with the reference product if the Secretary deter-
11 mines that the information submitted in the applica-
12 tion (or a supplement to such application) is suffi-
13 cient to show that—

14 “(A) the biological product—

15 “(i) is biosimilar to the reference
16 product; and

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

20 “(B) for a biological product that is ad-
21 ministered more than once to an individual, the
22 risk in terms of safety or diminished efficacy of
23 alternating or switching between use of the bio-
24 logical product and the reference product is not

1 greater than the risk of using the reference
2 product without such alternation or switch.

3 “(5) GENERAL RULES.—

4 “(A) ONE REFERENCE PRODUCT PER AP-
5 PPLICATION.—A biological product, in an appli-
6 cation submitted under this subsection, may not
7 be evaluated against more than 1 reference
8 product.

9 “(B) REVIEW.—An application submitted
10 under this subsection shall be reviewed by the
11 division within the Food and Drug Administra-
12 tion that is responsible for the review and ap-
13 proval of the application under which the ref-
14 erence product is licensed.

15 “(C) RISK EVALUATION AND MITIGATION
16 STRATEGIES.—The authority of the Secretary
17 with respect to risk evaluation and mitigation
18 strategies under the Federal Food, Drug, and
19 Cosmetic Act shall apply to biological products
20 licensed under this subsection in the same man-
21 ner as such authority applies to biological prod-
22 ucts licensed under subsection (a).

23 “(D) RESTRICTIONS ON BIOLOGICAL PROD-
24 UCTS CONTAINING DANGEROUS INGREDI-
25 ENTS.—If information in an application sub-

1 mitted under this subsection, in a supplement
2 to such an application, or otherwise available to
3 the Secretary shows that a biological product—

4 “(i) is, bears, or contains a select
5 agent or toxin listed in section 73.3 or
6 73.4 of title 42, section 121.3 or 121.4 of
7 title 9, or section 331.3 of title 7, Code of
8 Federal Regulations (or any successor reg-
9 ulations); or

10 “(ii) is, bears, or contains a controlled
11 substance in schedule I or II of section
12 202 of the Controlled Substances Act, as
13 listed in part 1308 of title 21, Code of
14 Federal Regulations (or any successor reg-
15 ulations);

16 the Secretary shall not license the biological
17 product under this subsection unless the Sec-
18 retary determines, after consultation with ap-
19 propriate national security and drug enforce-
20 ment agencies, that there would be no increased
21 risk to the security or health of the public from
22 licensing such biological product under this sub-
23 section.

24 “(6) EXCLUSIVITY FOR FIRST INTERCHANGE-
25 ABLE BIOLOGICAL PRODUCT.—Upon review of an

1 application submitted under this subsection relying
2 on the same reference product for which a prior bio-
3 logical product has received a determination of inter-
4 changeability for any condition of use, the Secretary
5 shall not make a determination under paragraph (4)
6 that the second or subsequent biological product is
7 interchangeable for any condition of use until the
8 earlier of—

9 “(A) 1 year after the first commercial
10 marketing of the first interchangeable bio-
11 similar biological product to be approved as
12 interchangeable for that reference product;

13 “(B) 18 months after—

14 “(i) a final court decision on all pat-
15 ents in suit in an action instituted under
16 subsection (l)(5) against the applicant that
17 submitted the application for the first ap-
18 proved interchangeable biosimilar biological
19 product; or

20 “(ii) the dismissal with or without
21 prejudice of an action instituted under sub-
22 section (l)(5) against the applicant that
23 submitted the application for the first ap-
24 proved interchangeable biosimilar biological
25 product; or

1 “(C)(i) 42 months after approval of the
2 first interchangeable biosimilar biological prod-
3 uct if the applicant that submitted such appli-
4 cation has been sued under subsection (l)(5)
5 and such litigation is still ongoing within such
6 42-month period; or

7 “(ii) 18 months after approval of the first
8 interchangeable biosimilar biological product if
9 the applicant that submitted such application
10 has not been sued under subsection (l)(5).

11 For purposes of this paragraph, the term ‘final court
12 decision’ means a final decision of a court from
13 which no appeal (other than a petition to the United
14 States Supreme Court for a writ of certiorari) has
15 been or can be taken.

16 “(7) EXCLUSIVITY FOR REFERENCE PROD-
17 UCT.—

18 “(A) EFFECTIVE DATE OF BIOSIMILAR AP-
19 PLICATION APPROVAL.—Approval of an applica-
20 tion under this subsection may not be made ef-
21 fective by the Secretary until the date that is
22 12 years after the date on which the reference
23 product was first licensed under subsection (a).

24 “(B) FILING PERIOD.—An application
25 under this subsection may not be submitted to

1 the Secretary until the date that is 4 years
2 after the date on which the reference product
3 was first licensed under subsection (a).

4 “(C) FIRST LICENSURE.—Subparagraphs
5 (A) and (B) shall not apply to a license for or
6 approval of—

7 “(i) a supplement for the biological
8 product that is the reference product; or

9 “(ii) a subsequent application filed by
10 the same sponsor or manufacturer of the
11 biological product that is the reference
12 product (or a licensor, predecessor in inter-
13 est, or other related entity) for—

14 “(I) a change (not including a
15 modification to the structure of the bi-
16 ological product) that results in a new
17 indication, route of administration,
18 dosing schedule, dosage form, delivery
19 system, delivery device, or strength; or

20 “(II) a modification to the struc-
21 ture of the biological product that
22 does not result in a change in safety,
23 purity, or potency.

24 “(8) PEDIATRIC STUDIES.—

1 “(A) EXCLUSIVITY.—If, before or after li-
2 censure of the reference product under sub-
3 section (a) of this section, the Secretary deter-
4 mines that information relating to the use of
5 such product in the pediatric population may
6 produce health benefits in that population, the
7 Secretary makes a written request for pediatric
8 studies (which shall include a timeframe for
9 completing such studies), the applicant or hold-
10 er of the approved application agrees to the re-
11 quest, such studies are completed using appro-
12 priate formulations for each age group for
13 which the study is requested within any such
14 timeframe, and the reports thereof are sub-
15 mitted and accepted in accordance with section
16 505A(d)(3) of the Federal Food, Drug, and
17 Cosmetic Act the period referred to in para-
18 graph (7)(A) of this subsection is deemed to be
19 12 years and 6 months rather than 12 years.

20 “(B) EXCEPTION.—The Secretary shall
21 not extend the period referred to in subpara-
22 graph (A) of this paragraph if the determina-
23 tion under section 505A(d)(3) of the Federal
24 Food, Drug, and Cosmetic Act is made later

1 than 9 months prior to the expiration of such
2 period.

3 “(C) APPLICATION OF CERTAIN PROVI-
4 SIONS.—The provisions of subsections (a), (d),
5 (e), (f), (h), (j), (k), and (l) of section 505A of
6 the Federal Food, Drug, and Cosmetic Act
7 shall apply with respect to the extension of a
8 period under subparagraph (A) of this para-
9 graph to the same extent and in the same man-
10 ner as such provisions apply with respect to the
11 extension of a period under subsection (b) or
12 (c) of section 505A of the Federal Food, Drug,
13 and Cosmetic Act.

14 “(9) GUIDANCE DOCUMENTS.—

15 “(A) IN GENERAL.—The Secretary may,
16 after opportunity for public comment, issue
17 guidance in accordance, except as provided in
18 subparagraph (B)(i), with section 701(h) of the
19 Federal Food, Drug, and Cosmetic Act with re-
20 spect to the licensure of a biological product
21 under this subsection. Any such guidance may
22 be general or specific.

23 “(B) PUBLIC COMMENT.—

24 “(i) IN GENERAL.—The Secretary
25 shall provide the public an opportunity to

1 comment on any proposed guidance issued
2 under subparagraph (A) before issuing
3 final guidance.

4 “(ii) INPUT REGARDING MOST VALU-
5 ABLE GUIDANCE.—The Secretary shall es-
6 tablish a process through which the public
7 may provide the Secretary with input re-
8 garding priorities for issuing guidance.

9 “(C) NO REQUIREMENT FOR APPLICATION
10 CONSIDERATION.—The issuance (or non-
11 issuance) of guidance under subparagraph (A)
12 shall not preclude the review of, or action on,
13 an application submitted under this subsection.

14 “(D) REQUIREMENT FOR PRODUCT CLASS-
15 SPECIFIC GUIDANCE.—If the Secretary issues
16 product class-specific guidance under subpara-
17 graph (A), such guidance shall include a de-
18 scription of—

19 “(i) the criteria that the Secretary will
20 use to determine whether a biological prod-
21 uct is highly similar to a reference product
22 in such product class; and

23 “(ii) the criteria, if available, that the
24 Secretary will use to determine whether a

1 biological product meets the standards de-
2 scribed in paragraph (4).

3 “(E) CERTAIN PRODUCT CLASSES.—

4 “(i) GUIDANCE.—The Secretary may
5 indicate in a guidance document that the
6 science and experience, as of the date of
7 such guidance, with respect to a product or
8 product class (not including any recom-
9 binant protein) does not allow approval of
10 an application for a license as provided
11 under this subsection for such product or
12 product class.

13 “(ii) MODIFICATION OR REVERSAL.—
14 The Secretary may issue a subsequent
15 guidance document under subparagraph
16 (A) to modify or reverse a guidance docu-
17 ment under clause (i).

18 “(iii) NO EFFECT ON ABILITY TO
19 DENY LICENSE.—Clause (i) shall not be
20 construed to require the Secretary to ap-
21 prove a product with respect to which the
22 Secretary has not indicated in a guidance
23 document that the science and experience,
24 as described in clause (i), does not allow
25 approval of such an application.

1 “(10) NAMING.—The Secretary shall ensure
2 that the labeling and packaging of each biological
3 product licensed under this subsection bears a name
4 that uniquely identifies the biological product and
5 distinguishes it from the reference product and any
6 other biological products licensed under this sub-
7 section following evaluation against such reference
8 product.

9 “(1) PATENT NOTICES; RELATIONSHIP TO FINAL AP-
10 PROVAL.—

11 “(1) DEFINITIONS.—For the purposes of this
12 subsection, the term—

13 “(A) ‘biosimilar product’ means the bio-
14 logical product that is the subject of the appli-
15 cation under subsection (k);

16 “(B) ‘relevant patent’ means a patent
17 that—

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

21 “(ii) could reasonably be asserted
22 against the applicant due to the unauthor-
23 ized making, use, sale, or offer for sale
24 within the United States, or the importa-
25 tion into the United States of the bio-

1 similar product, or materials used in the
2 manufacture of the biosimilar product, or
3 due to a use of the biosimilar product in
4 a method of treatment that is indicated in
5 the application;

6 “(C) ‘reference product sponsor’ means the
7 holder of an approved application or license for
8 the reference product; and

9 “(D) ‘interested third party’ means a per-
10 son other than the reference product sponsor
11 that owns a relevant patent, or has the right to
12 commence or participate in an action for in-
13 fringement of a relevant patent.

14 “(2) HANDLING OF CONFIDENTIAL INFORMA-
15 TION.—Any entity receiving confidential information
16 pursuant to this subsection shall designate one or
17 more individuals to receive such information. Each
18 individual so designated shall execute an agreement
19 in accordance with regulations promulgated by the
20 Secretary. The regulations shall require each such
21 individual to take reasonable steps to maintain the
22 confidentiality of information received pursuant to
23 this subsection and use the information solely for
24 purposes authorized by this subsection. The obliga-
25 tions imposed on an individual who has received con-

1 confidential information pursuant to this subsection
2 shall continue until the individual returns or de-
3 stroys the confidential information, a court imposes
4 a protective order that governs the use or handling
5 of the confidential information, or the party pro-
6 viding the confidential information agrees to other
7 terms or conditions regarding the handling or use of
8 the confidential information.

9 “(3) PUBLIC NOTICE BY SECRETARY.—Within
10 30 days of acceptance by the Secretary of an appli-
11 cation filed under subsection (k), the Secretary shall
12 publish a notice identifying—

13 “(A) the reference product identified in the
14 application; and

15 “(B) the name and address of an agent
16 designated by the applicant to receive notices
17 pursuant to paragraph (4)(B).

18 “(4) EXCHANGES CONCERNING PATENTS.—

19 “(A) EXCHANGES WITH REFERENCE
20 PRODUCT SPONSOR.—

21 “(i) Within 30 days of the date of ac-
22 ceptance of the application by the Sec-
23 retary, the applicant shall provide the ref-
24 erence product sponsor with a copy of the
25 application and information concerning the

1 biosimilar product and its production. This
2 information shall include a detailed de-
3 scription of the biosimilar product, its
4 method of manufacture, and the materials
5 used in the manufacture of the product.

6 “(ii) Within 60 days of the date of re-
7 ceipt of the information required to be pro-
8 vided under clause (i), the reference prod-
9 uct sponsor shall provide to the applicant
10 a list of relevant patents owned by the ref-
11 erence product sponsor, or in respect of
12 which the reference product sponsor has
13 the right to commence an action of in-
14 fringement or otherwise has an interest in
15 the patent as such patent concerns the bio-
16 similar product.

17 “(iii) If the reference product sponsor
18 is issued or acquires an interest in a rel-
19 evant patent after the date on which the
20 reference product sponsor provides the list
21 required by clause (ii) to the applicant, the
22 reference product sponsor shall identify
23 that patent to the applicant within 30 days
24 of the date of issue of the patent, or the

1 date of acquisition of the interest in the
2 patent, as applicable.

3 “(B) EXCHANGES WITH INTERESTED
4 THIRD PARTIES.—

5 “(i) At any time after the date on
6 which the Secretary publishes a notice for
7 an application under paragraph (3), any
8 interested third party may provide notice
9 to the designated agent of the applicant
10 that the interested third party owns or has
11 rights under 1 or more patents that may
12 be relevant patents. The notice shall iden-
13 tify at least 1 patent and shall designate
14 an individual who has executed an agree-
15 ment in accordance with paragraph (2) to
16 receive confidential information from the
17 applicant.

18 “(ii) Within 30 days of the date of re-
19 ceiving notice pursuant to clause (i), the
20 applicant shall send to the individual des-
21 ignated by the interested third party the
22 information specified in subparagraph
23 (A)(i), unless the applicant and interested
24 third party otherwise agree.

1 “(iii) Within 90 days of the date of
2 receiving information pursuant to clause
3 (ii), the interested third party shall provide
4 to the applicant a list of relevant patents
5 which the interested third party owns, or
6 in respect of which the interested third
7 party has the right to commence or partici-
8 pate in an action for infringement.

9 “(iv) If the interested third party is
10 issued or acquires an interest in a relevant
11 patent after the date on which the inter-
12 ested third party provides the list required
13 by clause (iii), the interested third party
14 shall identify that patent within 30 days of
15 the date of issue of the patent, or the date
16 of acquisition of the interest in the patent,
17 as applicable.

18 “(C) IDENTIFICATION OF BASIS FOR IN-
19 FRINGEMENT.—For any patent identified under
20 clause (ii) or (iii) of subparagraph (A) or under
21 clause (iii) or (iv) of subparagraph (B), the ref-
22 erence product sponsor or the interested third
23 party, as applicable—

24 “(i) shall explain in writing why the
25 sponsor or the interested third party be-

1 believes the relevant patent would be in-
2 fringed by the making, use, sale, or offer
3 for sale within the United States, or im-
4 portation into the United States, of the
5 biosimilar product or by a use of the bio-
6 similar product in treatment that is indi-
7 cated in the application;

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

10 “(iii) shall specify the number and
11 date of expiration of the relevant patent.

12 “(D) CERTIFICATION BY APPLICANT CON-
13 CERNING IDENTIFIED RELEVANT PATENTS.—
14 Not later than 45 days after the date on which
15 a patent is identified under clause (ii) or (iii) of
16 subparagraph (A) or under clause (iii) or (iv) of
17 subparagraph (B), the applicant shall send a
18 written statement regarding each identified pat-
19 ent to the party that identified the patent. Such
20 statement shall either—

21 “(i) state that the applicant will not
22 commence marketing of the biosimilar
23 product and has requested the Secretary to
24 not grant final approval of the application

1 before the date of expiration of the noticed
2 patent; or

3 “(ii) provide a detailed written expla-
4 nation setting forth the reasons why the
5 applicant believes—

6 “(I) the making, use, sale, or
7 offer for sale within the United
8 States, or the importation into the
9 United States, of the biosimilar prod-
10 uct, or the use of the biosimilar prod-
11 uct in a treatment indicated in the ap-
12 plication, would not infringe the pat-
13 ent; or

14 “(II) the patent is invalid or un-
15 enforceable.

16 “(5) ACTION FOR INFRINGEMENT INVOLVING
17 REFERENCE PRODUCT SPONSOR.—If an action for
18 infringement concerning a relevant patent identified
19 by the reference product sponsor under clause (ii) or
20 (iii) of paragraph (4)(A), or by an interested third
21 party under clause (iii) or (iv) of paragraph (4)(B),
22 is brought within 60 days of the date of receipt of
23 a statement under paragraph (4)(D)(ii), and the
24 court in which such action has been commenced de-
25 termines the patent is infringed prior to the date ap-

1 plicable under subsection (k)(7)(A) or (k)(8), the
2 Secretary shall make approval of the application ef-
3 fective on the day after the date of expiration of the
4 patent that has been found to be infringed. If more
5 than one such patent is found to be infringed by the
6 court, the approval of the application shall be made
7 effective on the day after the date that the last such
8 patent expires.

9 “(6) NOTIFICATION OF AGREEMENTS.—

10 “(A) REQUIREMENTS.—

11 “(i) AGREEMENT BETWEEN BIO-
12 SIMILAR PRODUCT APPLICANT AND REF-
13ERENCE PRODUCT SPONSOR.—If a bio-
14 similar product applicant under subsection
15 (k) and the reference product sponsor
16 enter into an agreement described in sub-
17 paragraph (B), the applicant and sponsor
18 shall each file the agreement in accordance
19 with subparagraph (C).

20 “(ii) AGREEMENT BETWEEN BIO-
21 SIMILAR PRODUCT APPLICANTS.—If 2 or
22 more biosimilar product applicants submit
23 an application under subsection (k) for bio-
24 similar products with the same reference
25 product and enter into an agreement de-

1 scribed in subparagraph (B), the appli-
2 cants shall each file the agreement in ac-
3 cordance with subparagraph (C).

4 “(B) SUBJECT MATTER OF AGREEMENT.—

5 An agreement described in this subparagraph—

6 “(i) is an agreement between the bio-
7 similar product applicant under subsection
8 (k) and the reference product sponsor or
9 between 2 or more biosimilar product ap-
10 plicants under subsection (k) regarding the
11 manufacture, marketing, or sale of—

12 “(I) the biosimilar product (or
13 biosimilar products) for which an ap-
14 plication was submitted; or

15 “(II) the reference product;

16 “(ii) includes any agreement between
17 the biosimilar product applicant under sub-
18 section (k) and the reference product spon-
19 sor or between 2 or more biosimilar prod-
20 uct applicants under subsection (k) that is
21 contingent upon, provides a contingent
22 condition for, or otherwise relates to an
23 agreement described in clause (i); and

24 “(iii) excludes any agreement that
25 solely concerns—

1 “(I) purchase orders for raw ma-
2 terial supplies;

3 “(II) equipment and facility con-
4 tracts;

5 “(III) employment or consulting
6 contracts; or

7 “(IV) packaging and labeling
8 contracts.

9 “(C) FILING.—

10 “(i) IN GENERAL.—The text of an
11 agreement required to be filed by subpara-
12 graph (A) shall be filed with the Assistant
13 Attorney General and the Federal Trade
14 Commission not later than—

15 “(I) 10 business days after the
16 date on which the agreement is exe-
17 cuted; and

18 “(II) prior to the date of the first
19 commercial marketing of, for agree-
20 ments described in subparagraph
21 (A)(i), the biosimilar product that is
22 the subject of the application or, for
23 agreements described in subparagraph
24 (A)(ii), any biosimilar product that is

1 the subject of an application described
2 in such subparagraph.

3 “(ii) IF AGREEMENT NOT REDUCED
4 TO TEXT.—If an agreement required to be
5 filed by subparagraph (A) has not been re-
6 duced to text, the persons required to file
7 the agreement shall each file written de-
8 scriptions of the agreement that are suffi-
9 cient to disclose all the terms and condi-
10 tions of the agreement.

11 “(iii) CERTIFICATION.—The chief ex-
12 ecutive officer or the company official re-
13 sponsible for negotiating any agreement re-
14 quired to be filed by subparagraph (A)
15 shall include in any filing under this para-
16 graph a certification as follows: ‘I declare
17 under penalty of perjury that the following
18 is true and correct: The materials filed
19 with the Federal Trade Commission and
20 the Department of Justice under section
21 351(l)(6) of the Public Health Service Act,
22 with respect to the agreement referenced in
23 this certification: (1) represent the com-
24 plete, final, and exclusive agreement be-
25 tween the parties; (2) include any ancillary

1 agreements that are contingent upon, pro-
2 vide a contingent condition for, or are oth-
3 erwise related to, the referenced agree-
4 ment; and (3) include written descriptions
5 of any oral agreements, representations,
6 commitments, or promises between the
7 parties that are responsive to such section
8 and have not been reduced to writing.’.

9 “(D) DISCLOSURE EXEMPTION.—Any in-
10 formation or documentary material filed with
11 the Assistant Attorney General or the Federal
12 Trade Commission pursuant to this paragraph
13 shall be exempt from disclosure under section
14 552 of title 5, United States Code, and no such
15 information or documentary material may be
16 made public, except as may be relevant to any
17 administrative or judicial action or proceeding.
18 Nothing in this subparagraph prevents dislo-
19 sure of information or documentary material to
20 either body of the Congress or to any duly au-
21 thorized committee or subcommittee of the Con-
22 gress.

23 “(E) ENFORCEMENT.—

24 “(i) CIVIL PENALTY.—Any person
25 that violates a provision of this paragraph

1 shall be liable for a civil penalty of not
2 more than \$11,000 for each day on which
3 the violation occurs. Such penalty may be
4 recovered in a civil action—

5 “(I) brought by the United
6 States; or

7 “(II) brought by the Federal
8 Trade Commission in accordance with
9 the procedures established in section
10 16(a)(1) of the Federal Trade Com-
11 mission Act.

12 “(ii) COMPLIANCE AND EQUITABLE
13 RELIEF.—If any person violates any provi-
14 sion of this paragraph, the United States
15 district court may order compliance, and
16 may grant such other equitable relief as
17 the court in its discretion determines nec-
18 essary or appropriate, upon application of
19 the Assistant Attorney General or the Fed-
20 eral Trade Commission.

21 “(F) RULEMAKING.—The Federal Trade
22 Commission, with the concurrence of the Assist-
23 ant Attorney General and by rule in accordance
24 with section 553 of title 5, United States Code,

1 consistent with the purposes of this para-
2 graph—

3 “(i) may define the terms used in this
4 paragraph;

5 “(ii) may exempt classes of persons or
6 agreements from the requirements of this
7 paragraph; and

8 “(iii) may prescribe such other rules
9 as may be necessary and appropriate to
10 carry out the purposes of this paragraph.

11 “(G) SAVINGS CLAUSE.—Any action taken
12 by the Assistant Attorney General or the Fed-
13 eral Trade Commission, or any failure of the
14 Assistant Attorney General or the Commission
15 to take action, under this paragraph shall not
16 at any time bar any proceeding or any action
17 with respect to any agreement between a bio-
18 similar product applicant under subsection (k)
19 and the reference product sponsor, or any
20 agreement between biosimilar product appli-
21 cants under subsection (k), under any other
22 provision of law, nor shall any filing under this
23 paragraph constitute or create a presumption of
24 any violation of any competition laws.”.

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

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

5 “In this section:

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

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

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

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

14 “(A) that the biological product is highly
15 similar to the reference product notwith-
16 standing minor differences in clinically inactive
17 components; and

18 “(B) there are no clinically meaningful dif-
19 ferences between the biological product and the
20 reference product in terms of the safety, purity,
21 and potency of the product.

22 “(3) The term ‘interchangeable’ or ‘inter-
23 changeability’, in reference to a biological product
24 that is shown to meet the standards described in
25 subsection (k)(4), means that the biological product

1 may be substituted for the reference product without
2 the intervention of the health care provider who pre-
3 scribed the reference product.

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

8 (c) PRODUCTS PREVIOUSLY APPROVED UNDER SEC-
9 TION 505.—

10 (1) REQUIREMENT TO FOLLOW SECTION 351.—

11 Except as provided in paragraph (2), an application
12 for a biological product shall be submitted under
13 section 351 of the Public Health Service Act (42
14 U.S.C. 262) (as amended by this Act).

15 (2) EXCEPTION.—An application for a biologi-
16 cal product may be submitted under section 505 of
17 the Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 355) if—

19 (A) such biological product is in a product
20 class for which a biological product in such
21 product class is the subject of an application
22 approved under such section 505 not later than
23 the date of enactment of this Act; and

24 (B) such application—

1 (i) has been submitted to the Sec-
2 retary of Health and Human Services (re-
3 ferred to in this Act as the “Secretary”)
4 before the date of enactment of this Act;
5 or

6 (ii) is submitted to the Secretary not
7 later than the date that is 10 years after
8 the date of enactment of this Act.

9 (3) LIMITATION.—Notwithstanding paragraph
10 (2), an application for a biological product may not
11 be submitted under section 505 of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 355) if there is
13 another biological product approved under sub-
14 section (a) of section 351 of the Public Health Serv-
15 ice Act that could be a reference product with re-
16 spect to such application (within the meaning of
17 such section 351) if such application were submitted
18 under subsection (k) of such section 351.

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

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

6 **SEC. 222. FEES RELATING TO BIOSIMILAR BIOLOGICAL**
7 **PRODUCTS.**

8 Subparagraph (B) of section 735(1) of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)) is
10 amended by inserting “, including licensure of a biological
11 product under section 351(k) of such Act” before the pe-
12 riod at the end.

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

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

16 (1) in subparagraph (A), by striking “or” after
17 “patent,”;

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

20 (3) by inserting the following after subpara-
21 graph (B):

22 “(C) a statement under section
23 351(l)(4)(D)(ii) of the Public Health Service
24 Act,”; and

1 (4) in the matter following subparagraph (C)
2 (as added by paragraph (3)), by inserting before the
3 period the following: “, or if the statement described
4 in subparagraph (C) is provided in connection with
5 an application to obtain a license to engage in the
6 commercial manufacture, use, or sale of a biological
7 product claimed in a patent or the use of which is
8 claimed in a patent before the expiration of such
9 patent”.

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

13 **Subtitle D—Administrative** 14 **Simplification**

15 **SEC. 231. ADMINISTRATIVE SIMPLIFICATION.**

16 (a) OPERATING RULES FOR HEALTH INFORMATION
17 TRANSACTIONS.—

18 (1) DEFINITION OF OPERATING RULES.—Sec-
19 tion 1171 of the Social Security Act (42 U.S.C.
20 1320d) is amended by adding at the end the fol-
21 lowing:

22 “(9) OPERATING RULES.—The term ‘operating
23 rules’ means the necessary business rules and guide-
24 lines for the electronic exchange of information that

1 are not defined by a standard or its implementation
2 specifications as adopted for purposes of this part.”.

3 (2) OPERATING RULES AND COMPLIANCE.—

4 Section 1173 of the Social Security Act (42 U.S.C.
5 1320d–2) is amended—

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

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

9 (B) by adding at the end the following new
10 subsections:

11 “(g) OPERATING RULES.—

12 “(1) IN GENERAL.—The Secretary shall adopt
13 a single set of operating rules for each transaction
14 described in subsection (a)(2) with the goal of cre-
15 ating as much uniformity in the implementation of
16 the electronic standards as possible. Such operating
17 rules shall be consensus-based and reflect the nec-
18 essary business rules affecting health plans and
19 health care providers and the manner in which they
20 operate pursuant to standards issued under Health
21 Insurance Portability and Accountability Act of
22 1996.

23 “(2) OPERATING RULES DEVELOPMENT.—In
24 adopting operating rules under this subsection, the
25 Secretary shall rely on recommendations for oper-

1 ating rules developed by a qualified nonprofit entity,
2 as selected by the Secretary, that meets the fol-
3 lowing requirements:

4 “(A) The entity focuses its mission on ad-
5 ministrative simplification.

6 “(B) The entity demonstrates an estab-
7 lished multi-stakeholder and consensus-based
8 process for development of operating rules, in-
9 cluding representation by or participation from
10 health plans, health care providers, vendors, rel-
11 evant Federal agencies, and other standard de-
12 velopment organizations.

13 “(C) The entity has established a public
14 set of guiding principles that ensure the oper-
15 ating rules and process are open and trans-
16 parent.

17 “(D) The entity coordinates its activities
18 with the HIT Policy Committee and the HIT
19 Standards Committee (as established under
20 title XXX of the Public Health Service Act)
21 and complements the efforts of the Office of the
22 National Healthcare Coordinator and its related
23 health information exchange goals.

24 “(E) The entity incorporates national
25 standards, including the transaction standards

1 issued under Health Insurance Portability and
2 Accountability Act of 1996.

3 “(F) The entity supports nondiscrimina-
4 tion and conflict of interest policies that dem-
5 onstrate a commitment to open, fair, and non-
6 discriminatory practices.

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

9 “(3) REVIEW AND RECOMMENDATIONS.—The
10 National Committee on Vital and Health Statistics
11 shall—

12 “(A) review the operating rules developed
13 by a nonprofit entity described under paragraph
14 (2);

15 “(B) determine whether such rules rep-
16 resent a consensus view of the health care in-
17 dustry and are consistent with and do not alter
18 current standards;

19 “(C) evaluate whether such rules are con-
20 sistent with electronic standards adopted for
21 health information technology; and

22 “(D) submit to the Secretary a rec-
23 ommendation as to whether the Secretary
24 should adopt such rules.

25 “(4) IMPLEMENTATION.—

1 “(A) IN GENERAL.—The Secretary shall
2 adopt operating rules under this subsection, by
3 regulation in accordance with subparagraph
4 (C), following consideration of the rules devel-
5 oped by the non-profit entity described in para-
6 graph (2) and the recommendation submitted
7 by the National Committee on Vital and Health
8 Statistics under paragraph (3)(D) and having
9 ensured consultation with providers.

10 “(B) ADOPTION REQUIREMENTS; EFFEC-
11 TIVE DATES.—

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

22 “(ii) ELECTRONIC FUNDS TRANSFERS
23 AND HEALTH CARE PAYMENT AND REMIT-
24 TANCE ADVICE.—The set of operating
25 rules for electronic funds transfers and

1 health care payment and remittance advice
2 shall be adopted not later than July 1,
3 2012, in a manner ensuring that such
4 rules are effective not later than January
5 1, 2014.

6 “(iii) OTHER COMPLETED TRANS-
7 ACTIONS.—The set of operating rules for
8 the remainder of the completed trans-
9 actions described in subsection (a)(2), in-
10 cluding health claims or equivalent encoun-
11 ter information, enrollment and
12 disenrollment in a health plan, health plan
13 premium payments, and referral certifi-
14 cation and authorization, shall be adopted
15 not later than July 1, 2014, in a manner
16 ensuring that such rules are effective not
17 later than January 1, 2016.

18 “(C) EXPEDITED RULEMAKING.—The Sec-
19 retary shall promulgate an interim final rule
20 applying any standard or operating rule rec-
21 ommended by the National Committee on Vital
22 and Health Statistics pursuant to paragraph
23 (3). The Secretary shall accept public comments
24 on any interim final rule published under this

1 subparagraph for 60 days after the date of such
2 publication.

3 “(h) COMPLIANCE.—

4 “(1) HEALTH PLAN CERTIFICATION.—

5 “(A) ELIGIBILITY FOR A HEALTH PLAN,
6 HEALTH CLAIM STATUS, ELECTRONIC FUNDS
7 TRANSFERS, HEALTH CARE PAYMENT AND RE-
8 MITTANCE ADVICE.—Not later than December
9 31, 2013, a health plan shall file a statement
10 with the Secretary, in such form as the Sec-
11 retary may require, certifying that the data and
12 information systems for such plan are in com-
13 pliance with any applicable standards (as de-
14 scribed under paragraph (7) of section 1171)
15 and operating rules (as described under para-
16 graph (9) of such section) for electronic funds
17 transfers, eligibility for a health plan, health
18 claim status, and health care payment and re-
19 mittance advice, respectively.

20 “(B) OTHER COMPLETED TRANS-
21 ACTIONS.—Not later than December 31, 2015,
22 a health plan shall file a statement with the
23 Secretary, in such form as the Secretary may
24 require, certifying that the data and informa-
25 tion systems for such plan are in compliance

1 with any applicable standards and operating
2 rules for the remainder of the completed trans-
3 actions described in subsection (a)(2), including
4 health claims or equivalent encounter informa-
5 tion, enrollment and disenrollment in a health
6 plan, health plan premium payments, and refer-
7 ral certification and authorization, respectively.
8 A health plan shall provide the same level of
9 documentation to certify compliance with such
10 transactions as is required to certify compliance
11 with the transactions specified in subparagraph
12 (A).

13 “(2) DOCUMENTATION OF COMPLIANCE.—A
14 health plan shall provide the Secretary, in such form
15 as the Secretary may require, with adequate docu-
16 mentation of compliance with the standards and op-
17 erating rules described under paragraph (1). A
18 health plan shall not be considered to have provided
19 adequate documentation and shall not be certified as
20 being in compliance with such standards, unless the
21 health plan—

22 “(A) demonstrates to the Secretary that
23 the plan conducts the electronic transactions
24 specified in paragraph (1) in a manner that

1 fully complies with the regulations of the Sec-
2 retary; and

3 “(B) provides documentation showing that
4 the plan has completed end-to-end testing for
5 such transactions with their partners, such as
6 hospitals and physicians.

7 “(3) SERVICE CONTRACTS.—A health plan shall
8 be required to comply with any applicable certifi-
9 cation and compliance requirements (and provide the
10 Secretary with adequate documentation of such com-
11 pliance) under this subsection for any entities that
12 provide services pursuant to a contract with such
13 health plan.

14 “(4) CERTIFICATION BY OUTSIDE ENTITY.—
15 The Secretary may contract with an independent,
16 outside entity to certify that a health plan has com-
17 plied with the requirements under this subsection,
18 provided that the certification standards employed
19 by such entities are in accordance with any stand-
20 ards or rules issued by the Secretary.

21 “(5) COMPLIANCE WITH REVISED STANDARDS
22 AND RULES.—A health plan (including entities de-
23 scribed under paragraph (3)) shall comply with the
24 certification and documentation requirements under
25 this subsection for any interim final rule promul-

1 gated by the Secretary under subsection (i) that
2 amends any standard or operating rule described
3 under paragraph (1) of this subsection. A health
4 plan shall comply with such requirements not later
5 than the effective date of the applicable interim final
6 rule.

7 “(6) AUDITS OF HEALTH PLANS.—The Sec-
8 retary shall conduct periodic audits to ensure that
9 health plans (including entities described under
10 paragraph (3)) are in compliance with any standards
11 and operating rules that are described under para-
12 graph (1).

13 “(i) REVIEW AND AMENDMENT OF STANDARDS AND
14 RULES.—

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

18 “(2) EVALUATIONS AND REPORTS.—

19 “(A) HEARINGS.—Not later than April 1,
20 2014, and not less than biennially thereafter,
21 the Secretary, acting through the review com-
22 mittee, shall conduct hearings to evaluate and
23 review the existing standards and operating
24 rules established under this section.

1 “(B) REPORT.—Not later than July 1,
2 2014, and not less than biennially thereafter,
3 the review committee shall provide rec-
4 ommendations for updating and improving such
5 standards and rules. The review committee
6 shall recommend a single set of operating rules
7 per transaction standard and maintain the goal
8 of creating as much uniformity as possible in
9 the implementation of the electronic standards.

10 “(3) INTERIM FINAL RULEMAKING.—

11 “(A) IN GENERAL.—Any recommendations
12 to amend existing standards and operating
13 rules that have been approved by the review
14 committee and reported to the Secretary under
15 paragraph (2)(B) shall be adopted by the Sec-
16 retary through promulgation of an interim final
17 rule not later than 90 days after receipt of the
18 committee’s report.

19 “(B) PUBLIC COMMENT.—

20 “(i) PUBLIC COMMENT PERIOD.—The
21 Secretary shall accept public comments on
22 any interim final rule published under this
23 paragraph for 60 days after the date of
24 such publication.

1 “(ii) EFFECTIVE DATE.—The effective
2 date of any amendment to existing stand-
3 ards or operating rules that is adopted
4 through an interim final rule published
5 under this paragraph shall be 25 months
6 following the close of such public comment
7 period.

8 “(4) REVIEW COMMITTEE.—

9 “(A) DEFINITION.—For the purposes of
10 this subsection, the term ‘review committee’
11 means a committee within the Department of
12 Health and Human services that has been des-
13 ignated by the Secretary to carry out this sub-
14 section, including—

15 “(i) the National Committee on Vital
16 and Health Statistics; or

17 “(ii) any appropriate committee as de-
18 termined by the Secretary.

19 “(B) COORDINATION OF HIT STAND-
20 ARDS.—In developing recommendations under
21 this subsection, the review committee shall con-
22 sider the standards approved by the Office of
23 the National Coordinator for Health Informa-
24 tion Technology.

25 “(j) PENALTIES.—

1 “(1) PENALTY FEE.—

2 “(A) IN GENERAL.—Not later than April
3 1, 2014, and annually thereafter, the Secretary
4 shall assess a penalty fee (as determined under
5 subparagraph (B)) against a health plan that
6 has failed to meet the requirements under sub-
7 section (h) with respect to certification and docu-
8 mentation of compliance with the standards
9 (and their operating rules) as described under
10 paragraph (1) of such subsection.

11 “(B) FEE AMOUNT.—Subject to subpara-
12 graphs (C), (D), and (E), the Secretary shall
13 assess a penalty fee against a health plan in the
14 amount of \$1 per covered life until certification
15 is complete. The penalty shall be assessed per
16 person covered by the plan for which its data
17 systems for major medical policies are not in
18 compliance and shall be imposed against the
19 health plan for each day that the plan is not in
20 compliance with the requirements under sub-
21 section (h).

22 “(C) ADDITIONAL PENALTY FOR MIS-
23 REPRESENTATION.—A health plan that know-
24 ingly provides inaccurate or incomplete informa-
25 tion in a statement of certification or docu-

1 mentation of compliance under subsection (h)
2 shall be subject to a penalty fee that is double
3 the amount that would otherwise be imposed
4 under this subsection.

5 “(D) ANNUAL FEE INCREASE.—The
6 amount of the penalty fee imposed under this
7 subsection shall be increased on an annual basis
8 by the annual percentage increase in total na-
9 tional health care expenditures, as determined
10 by the Secretary.

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

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

16 “(ii) an amount equal to \$40 per cov-
17 ered life under the plan if such plan has
18 knowingly provided inaccurate or incom-
19 plete information (as described under sub-
20 paragraph (C)).

21 “(F) DETERMINATION OF COVERED INDI-
22 VIDUALS.—The Secretary shall determine the
23 number of covered lives under a health plan
24 based upon the most recent statements and fil-

1 ings that have been submitted by such plan to
2 the Securities and Exchange Commission.

3 “(2) NOTICE AND DISPUTE PROCEDURE.—The
4 Secretary shall establish a procedure for assessment
5 of penalty fees under this subsection that provides a
6 health plan with reasonable notice and a dispute res-
7 olution procedure prior to provision of a notice of as-
8 sessment by the Secretary of the Treasury (as de-
9 scribed under paragraph (4)(B)).

10 “(3) PENALTY FEE REPORT.—Not later than
11 May 1, 2014, and annually thereafter, the Secretary
12 shall provide the Secretary of the Treasury with a
13 report identifying those health plans that have been
14 assessed a penalty fee under this subsection.

15 “(4) COLLECTION OF PENALTY FEE.—

16 “(A) IN GENERAL.—The Secretary of the
17 Treasury, acting through the Financial Man-
18 agement Service, shall administer the collection
19 of penalty fees from health plans that have been
20 identified by the Secretary in the penalty fee re-
21 port provided under paragraph (3).

22 “(B) NOTICE.—Not later than August 1,
23 2014, and annually thereafter, the Secretary of
24 the Treasury shall provide notice to each health
25 plan that has been assessed a penalty fee by the

1 Secretary under this subsection. Such notice
2 shall include the amount of the penalty fee as-
3 sessed by the Secretary and the due date for
4 payment of such fee to the Secretary of the
5 Treasury (as described in subparagraph (C)).

6 “(C) PAYMENT DUE DATE.—Payment by a
7 health plan for a penalty fee assessed under
8 this subsection shall be made to the Secretary
9 of the Treasury not later than November 1,
10 2014, and annually thereafter.

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

16 “(i) increased by the interest accrued
17 on such amount, as determined pursuant
18 to the underpayment rate established
19 under section 6601 of the Internal Rev-
20 enue Code of 1986; and

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

1 “(E) ADMINISTRATIVE FEES.—Any fee
2 charged or allocated for collection activities con-
3 ducted by the Financial Management Service
4 will be passed on to a health plan on a pro-rata
5 basis and added to any penalty fee collected
6 from the plan.”.

7 (b) PROMULGATION OF RULES.—

8 (1) UNIQUE HEALTH PLAN IDENTIFIER.—The
9 Secretary shall promulgate a final rule to establish
10 a unique health plan identifier (as described in sec-
11 tion 1173(b) of the Social Security Act (42 U.S.C.
12 1320d-2(b))) based on the input of the National
13 Committee of Vital and Health Statistics. The Sec-
14 retary may do so on an interim final basis and such
15 rule shall be effective not later than October 1,
16 2012.

17 (2) ELECTRONIC FUNDS TRANSFER.—The Sec-
18 retary shall promulgate a final rule to establish a
19 standard for electronic funds transfers (as described
20 in section 1173(a)(2)(J) of the Social Security Act,
21 as added by subsection (a)(2)(A)). The Secretary
22 may do so on an interim final basis and shall adopt
23 such standard not later than January 1, 2012, in a
24 manner ensuring that such standard is effective not
25 later than January 1, 2014.

1 (c) EXPANSION OF ELECTRONIC TRANSACTIONS IN
2 MEDICARE.—Section 1862(a) of the Social Security Act
3 (42 U.S.C. 1395y(a)) is amended—

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

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

8 (3) by inserting after paragraph (24) the fol-
9 lowing new paragraph:

10 “(25) not later than January 1, 2014, for
11 which the payment is other than by electronic funds
12 transfer (EFT) or an electronic remittance in a form
13 as specified in ASC X12 835 Health Care Payment
14 and Remittance Advice or subsequent standard.”.

15 (d) MEDICARE AND MEDICAID COMPLIANCE RE-
16 PORTS.—Not later than July 1, 2013, the Secretary of
17 Health and Human Services shall submit a report to the
18 Chairs and Ranking Members of the Committee on Ways
19 and Means and the Committee on Energy and Commerce
20 of the House of Representatives and the Chairs and Rank-
21 ing Members of the Committee on Health, Education,
22 Labor, and Pensions and the Committee on Finance of
23 the Senate on the extent to which the Medicare program
24 and providers that serve beneficiaries under that program,
25 and State Medicaid programs and providers that serve

1 beneficiaries under those programs, transact electronically
2 in accordance with transaction standards issued under the
3 Health Insurance Portability and Accountability Act of
4 1996, part C of title XI of the Social Security Act, and
5 regulations promulgated under such Acts.

