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111TH CONGRESS
1ST 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.

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.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Medicare SGR Improvement and Reform Act of 2009''.

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

TITLE I—ENSURING CONTINUED ACCESS TO PHYSICIANS IN MEDICARE

SEC. 101. IMPROVING MEDICARE PHYSICIAN PAYMENTS.

Section 1848(d) of the Social Security Act (42 U.S.C. 1395w–4(d)) is amended by adding at the end the following new paragraphs:

''(10) 2 PERCENT ANNUAL UPDATE FOR YEARS 2010 THROUGH 2013.—

''(A) IN GENERAL.—Subject to paragraphs (7)(B), (8)(B), and (9)(B) and subparagraph (B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for each of 2010, 2011, 2012, and 2013, the update to the single conversion factor shall be 2 percent.

''(B) NO EFFECT ON COMPUTATION OF CONVERSION FACTOR FOR 2014 AND SUBSEQUENT YEARS.—The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2014 and subsequent years as if subparagraph (A) had never applied, subject to paragraph (11).

''(11) UPDATE FOR 2014 AND POSSIBLE SUBSEQUENT YEARS THROUGH 2019.—

"(A) IN GENERAL.—Subject to paragraphs (7)(B), (8)(B), and (9)(B) and subparagraph (B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2014 and, at the Secretary's discretion, for subsequent years ending not later than 2019, the update to the single conversion factor shall be such percentage for each such year as the Secretary determines will result in additional expenditures under this title in the aggregate for all such years of $26,400,000,000. Not later than October 1, 2013, the Secretary shall establish by regulation the method the Secretary will use in allocating the $26,400,000,000 under the previous sentence between 2014 and subsequent years. Such allocation shall be designed in a manner so that the single conversion factor for a year is not less than 79 percent of the conversion factor for the previous year.

"(B) LIMITED EFFECT ON COMPUTATION OF CONVERSION FACTOR FOR SUBSEQUENT YEARS.—The conversion factor under this subsection shall be computed under paragraph (1)(A) for subsequent years as if subparagraph

(A) had never applied, but taking into account the aggregate additional increase in expenditures permitted under such subparagraph.''.

SEC. 102. STATEMENT OF POLICY.

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

TITLE II—DEFICIT PROTECTION AND FISCAL RESPONSIBILITY

Subtitle A—Enacting Real Medical Liability Reform

SEC. 201. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.

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

(1) upon proof of fraud;

(2) intentional concealment; or

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

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

SEC. 202. COMPENSATING PATIENT INJURY.

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

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

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

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

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

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

SEC. 203. MAXIMIZING PATIENT RECOVERY.

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

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

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

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

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

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

SEC. 204. ADDITIONAL HEALTH BENEFITS.

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

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

SEC. 205. PUNITIVE DAMAGES.

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

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

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

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

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

(b) DETERMINING AMOUNT OF PUNITIVE DAMAGES.—

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

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

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

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

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

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

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

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

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

SEC. 206. AUTHORIZATION OF PAYMENT OF FUTURE DAMAGES TO CLAIMANTS IN HEALTH CARE LAWSUITS.

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

health care lawsuit, the court may be guided by the Uniform Periodic Payment of Judgments Act promulgated by the National Conference of Commissioners on Uniform State Laws.

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

SEC. 207. DEFINITIONS.

In this subtitle:

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

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

(3) COLLATERAL SOURCE BENEFITS.—The term ''collateral source benefits'' means any amount

paid or reasonably likely to be paid in the future to or on behalf of the claimant, or any service, product, or other benefit provided or reasonably likely to be provided in the future to or on behalf of the claimant, as a result of the injury or wrongful death, pursuant to—

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

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

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

(D) any other publicly or privately funded program.

(4) COMPENSATORY DAMAGES.—The term ''compensatory damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical ex-

penses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities, damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature. The term ''compensatory damages'' includes economic damages and noneconomic damages, as such terms are defined in this section.

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

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

loss of employment, and loss of business or employment opportunities.

(7) HEALTH CARE LAWSUIT.—The term ''health care lawsuit'' means any health care liability claim concerning the provision of health care goods or services or any medical product affecting interstate commerce, or any health care liability action concerning the provision of health care goods or services or any medical product affecting interstate commerce, brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider, a health care organization, or the manufacturer, distributor, supplier, marketer, promoter, or seller of a medical product, regardless of the theory of liability on which the claim is based, or the number of claimants, plaintiffs, defendants, or other parties, or the number of claims or causes of action, in which the claimant alleges a health care liability claim. Such term does not include a claim or action which is based on criminal liability; which seeks civil fines or penalties paid to Federal, State, or local government; or which is grounded in antitrust.

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

tion brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider, a health care organization, or the manufacturer, distributor, supplier, marketer, promoter, or seller of a medical product, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action, in which the claimant alleges a health care liability claim.

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

(10) HEALTH CARE ORGANIZATION.—The term ''health care organization'' means any person or en-

tity which is obligated to provide or pay for health benefits under any health plan, including any person or entity acting under a contract or arrangement with a health care organization to provide or administer any health benefit.

(11) HEALTH CARE PROVIDER.—The term ''health care provider'' means any person or entity required by State or Federal laws or regulations to be licensed, registered, or certified to provide health care services, and being either so licensed, registered, or certified, or exempted from such requirement by other statute or regulation.

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

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

(14) MEDICAL PRODUCT.—The term ''medical product'' means a drug, device, or biological product intended for humans, and the terms ''drug'', ''device'', and ''biological product'' have the meanings given such terms in sections 201(g)(1) and 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(g)(1) and (h)) and section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), respectively, including any component or raw material used therein, but excluding health care services.

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

(16) PUNITIVE DAMAGES.—The term ''punitive damages'' means damages awarded, for the purpose of punishment or deterrence, and not solely for compensatory purposes, against a health care provider, health care organization, or a manufacturer, distributor, or supplier of a medical product. Punitive

damages are neither economic nor noneconomic damages.

(17) RECOVERY.—The term ''recovery'' means the net sum recovered after deducting any disbursements or costs incurred in connection with prosecution or settlement of the claim, including all costs paid or advanced by any person. Costs of health care incurred by the plaintiff and the attorneys' office overhead costs or charges for legal services are not deductible disbursements or costs for such purpose.

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

SEC. 208. EFFECT ON OTHER LAWS.

(a) VACCINE INJURY.—

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

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

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

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

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

SEC. 209. STATE FLEXIBILITY AND PROTECTION OF STATES' RIGHTS.

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

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

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

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

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

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

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

satory or punitive damages (or the total amount of damages) that may be awarded in a health care lawsuit, regardless of whether such monetary amount is greater or lesser than is provided for under this subtitle, notwithstanding section 202(a); or

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

SEC. 210. APPLICABILITY; EFFECTIVE DATE.

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

Subtitle B—Application of Medicare Improvement Fund

SEC. 211. APPLICATION OF MEDICARE IMPROVEMENT FUND.

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

Subtitle C—Pathway for Biosimilar Biological Products

SEC. 221. LICENSURE PATHWAY FOR BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—

(1) in subsection (a)(1)(A), by inserting ''under this subsection or subsection (k)'' after ''biologics license''; and

(2) by adding at the end the following:

''(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—

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

''(2) CONTENT.—

''(A) IN GENERAL.—

''(i) REQUIRED INFORMATION.—An application submitted under this subsection shall include information demonstrating that—

''(I) the biological product is biosimilar to a reference product based upon data derived from—

"(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

"(bb) animal studies (including the assessment of toxicity); and

"(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

"(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use

prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

''(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

''(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

''(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

''(ii) DETERMINATION BY SECRETARY.—The Secretary may determine, in the Secretary's discretion, that an ele-

ment described in clause (i)(I) is unnecessary in an application submitted under this subsection.

''(iii) ADDITIONAL INFORMATION.—An application submitted under this subsection—

''(I) shall include publicly available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

''(II) may include any additional information in support of the application, including publicly available information with respect to the reference product or another biological product.

''(B) INTERCHANGEABILITY.—An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

''(3) EVALUATION BY SECRETARY.—Upon review of an application (or a supplement to an application) submitted under this subsection, the Sec-

retary shall license the biological product under this subsection if—

"(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

"(i) is biosimilar to the reference product; or

"(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

"(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

"(4) SAFETY STANDARDS FOR DETERMINING INTERCHANGEABILITY.—Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

"(A) the biological product—

"(i) is biosimilar to the reference product; and

"(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

"(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

"(5) GENERAL RULES.—

"(A) ONE REFERENCE PRODUCT PER APPLICATION.—A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

"(B) REVIEW.—An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

"(C) RISK EVALUATION AND MITIGATION STRATEGIES.—The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

"(D) RESTRICTIONS ON BIOLOGICAL PRODUCTS CONTAINING DANGEROUS INGREDIENTS.—If information in an application submitted under this subsection, in a supplement to such an application, or otherwise available to the Secretary shows that a biological product—

"(i) is, bears, or contains a select agent or toxin listed in section 73.3 or 73.4 of title 42, section 121.3 or 121.4 of title 9, or section 331.3 of title 7, Code of Federal Regulations (or any successor regulations); or

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

Federal Regulations (or any successor regulations);

the Secretary shall not license the biological product under this subsection unless the Secretary determines, after consultation with appropriate national security and drug enforcement agencies, that there would be no increased risk to the security or health of the public from licensing such biological product under this subsection.

''(6) EXCLUSIVITY FOR FIRST INTERCHANGEABLE BIOLOGICAL PRODUCT.—Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

''(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

''(B) 18 months after—

"(i) a final court decision on all patents in suit in an action instituted under subsection (l)(5) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

"(ii) the dismissal with or without prejudice of an action instituted under subsection (l)(5) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

"(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (l)(5) and such litigation is still ongoing within such 42-month period; or

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

For purposes of this paragraph, the term 'final court decision' means a final decision of a court from which no appeal (other than a petition to the United

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

''(7) EXCLUSIVITY FOR REFERENCE PRODUCT.—

''(A) EFFECTIVE DATE OF BIOSIMILAR APPLICATION APPROVAL.—Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

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

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

''(i) a supplement for the biological product that is the reference product; or

''(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

"(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

"(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

"(8) PEDIATRIC STUDIES.—

"(A) EXCLUSIVITY.—If, before or after licensure of the reference product under subsection (a) of this section, the Secretary determines that information relating to the use of such product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant or holder of the approved application agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are sub-

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

''(B) EXCEPTION.—The Secretary shall not extend the period referred to in subparagraph (A) of this paragraph if the determination under section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act is made later than 9 months prior to the expiration of such period.

''(C) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subsections (a), (d), (e), (f), (h), (j), (k), and (l) of section 505A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the extension of a period under subparagraph (A) of this paragraph to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act.

''(9) GUIDANCE DOCUMENTS.—

"(A) IN GENERAL.—The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

"(B) PUBLIC COMMENT.—

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

"(ii) INPUT REGARDING MOST VALUABLE GUIDANCE.—The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

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

''(D) REQUIREMENT FOR PRODUCT CLASS-SPECIFIC GUIDANCE.—If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

''(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

''(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

''(E) CERTAIN PRODUCT CLASSES.—

''(i) GUIDANCE.—The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

''(ii) MODIFICATION OR REVERSAL.—The Secretary may issue a subsequent

guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

''(iii) NO EFFECT ON ABILITY TO DENY LICENSE.—Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

''(10) NAMING.—The Secretary shall ensure that the labeling and packaging of each biological product licensed under this subsection bears a name that uniquely identifies the biological product and distinguishes it from the reference product and any other biological products licensed under this subsection following evaluation against such reference product.

''(l) PATENT NOTICES; RELATIONSHIP TO FINAL APPROVAL.—

''(1) DEFINITIONS.—For the purposes of this subsection, the term—

"(A) 'biosimilar product' means the biological product that is the subject of the application under subsection (k);

"(B) 'relevant patent' means a patent that—

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

"(ii) could reasonably be asserted against the applicant due to the unauthorized making, use, sale, or offer for sale within the United States, or the importation into the United States of the biosimilar product, or materials used in the manufacture of the biosimilar product, or due to a use of the biosimilar product in a method of treatment that is indicated in the application;

"(C) 'reference product sponsor' means the holder of an approved application or license for the reference product; and

"(D) 'interested third party' means a person other than the reference product sponsor that owns a relevant patent, or has the right to

commence or participate in an action for infringement of a relevant patent.

''(2) HANDLING OF CONFIDENTIAL INFORMATION.—Any entity receiving confidential information pursuant to this subsection shall designate one or more individuals to receive such information. Each individual so designated shall execute an agreement in accordance with regulations promulgated by the Secretary. The regulations shall require each such individual to take reasonable steps to maintain the confidentiality of information received pursuant to this subsection and use the information solely for purposes authorized by this subsection. The obligations imposed on an individual who has received confidential information pursuant to this subsection shall continue until the individual returns or destroys the confidential information, a court imposes a protective order that governs the use or handling of the confidential information, or the party providing the confidential information agrees to other terms or conditions regarding the handling or use of the confidential information.

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

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

"(A) the reference product identified in the application; and

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

"(4) EXCHANGES CONCERNING PATENTS.—

"(A) EXCHANGES WITH REFERENCE PRODUCT SPONSOR.—

"(i) Within 30 days of the date of acceptance of the application by the Secretary, the applicant shall provide the reference product sponsor with a copy of the application and information concerning the biosimilar product and its production. This information shall include a detailed description of the biosimilar product, its method of manufacture, and the materials used in the manufacture of the product.

"(ii) Within 60 days of the date of receipt of the information required to be provided under clause (i), the reference product sponsor shall provide to the applicant a list of relevant patents owned by the ref-

erence product sponsor, or in respect of which the reference product sponsor has the right to commence an action of infringement or otherwise has an interest in the patent as such patent concerns the biosimilar product.

''(iii) If the reference product sponsor is issued or acquires an interest in a relevant patent after the date on which the reference product sponsor provides the list required by clause (ii) to the applicant, the reference product sponsor shall identify that patent to the applicant within 30 days of the date of issue of the patent, or the date of acquisition of the interest in the patent, as applicable.

''(B) EXCHANGES WITH INTERESTED THIRD PARTIES.—

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

be relevant patents. The notice shall identify at least 1 patent and shall designate an individual who has executed an agreement in accordance with paragraph (2) to receive confidential information from the applicant.

''(ii) Within 30 days of the date of receiving notice pursuant to clause (i), the applicant shall send to the individual designated by the interested third party the information specified in subparagraph (A)(i), unless the applicant and interested third party otherwise agree.

''(iii) Within 90 days of the date of receiving information pursuant to clause (ii), the interested third party shall provide to the applicant a list of relevant patents which the interested third party owns, or in respect of which the interested third party has the right to commence or participate in an action for infringement.

''(iv) If the interested third party is issued or acquires an interest in a relevant patent after the date on which the interested third party provides the list required

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

''(C) IDENTIFICATION OF BASIS FOR INFRINGEMENT.—For any patent identified under clause (ii) or (iii) of subparagraph (A) or under clause (iii) or (iv) of subparagraph (B), the reference product sponsor or the interested third party, as applicable—

''(i) shall explain in writing why the sponsor or the interested third party believes the relevant patent would be infringed by the making, use, sale, or offer for sale within the United States, or importation into the United States, of the biosimilar product or by a use of the biosimilar product in treatment that is indicated in the application;

''(ii) may specify whether the relevant patent is available for licensing; and

''(iii) shall specify the number and date of expiration of the relevant patent.

''(D) CERTIFICATION BY APPLICANT CONCERNING IDENTIFIED RELEVANT PATENTS.—Not later than 45 days after the date on which a patent is identified under clause (ii) or (iii) of subparagraph (A) or under clause (iii) or (iv) of subparagraph (B), the applicant shall send a written statement regarding each identified patent to the party that identified the patent. Such statement shall either—

''(i) state that the applicant will not commence marketing of the biosimilar product and has requested the Secretary to not grant final approval of the application before the date of expiration of the noticed patent; or

''(ii) provide a detailed written explanation setting forth the reasons why the applicant believes—

''(I) the making, use, sale, or offer for sale within the United States, or the importation into the United States, of the biosimilar product, or the use of the biosimilar product in a treatment indicated in the ap-

plication, would not infringe the patent; or

"(II) the patent is invalid or unenforceable.

"(5) ACTION FOR INFRINGEMENT INVOLVING REFERENCE PRODUCT SPONSOR.—If an action for infringement concerning a relevant patent identified by the reference product sponsor under clause (ii) or (iii) of paragraph (4)(A), or by an interested third party under clause (iii) or (iv) of paragraph (4)(B), is brought within 60 days of the date of receipt of a statement under paragraph (4)(D)(ii), and the court in which such action has been commenced determines the patent is infringed prior to the date applicable under subsection (k)(7)(A) or (k)(8), the Secretary shall make approval of the application effective on the day after the date of expiration of the patent that has been found to be infringed. If more than one such patent is found to be infringed by the court, the approval of the application shall be made effective on the day after the date that the last such patent expires.

"(6) NOTIFICATION OF AGREEMENTS.—

"(A) REQUIREMENTS.—

''(i) AGREEMENT BETWEEN BIOSIMILAR PRODUCT APPLICANT AND REFERENCE PRODUCT SPONSOR.—If a biosimilar product applicant under subsection (k) and the reference product sponsor enter into an agreement described in subparagraph (B), the applicant and sponsor shall each file the agreement in accordance with subparagraph (C).

''(ii) AGREEMENT BETWEEN BIOSIMILAR PRODUCT APPLICANTS.—If 2 or more biosimilar product applicants submit an application under subsection (k) for biosimilar products with the same reference product and enter into an agreement described in subparagraph (B), the applicants shall each file the agreement in accordance with subparagraph (C).

''(B) SUBJECT MATTER OF AGREEMENT.—An agreement described in this subparagraph—

''(i) is an agreement between the biosimilar product applicant under subsection (k) and the reference product sponsor or between 2 or more biosimilar product ap-

plicants under subsection (k) regarding the manufacture, marketing, or sale of—

"(I) the biosimilar product (or biosimilar products) for which an application was submitted; or

"(II) the reference product;

"(ii) includes any agreement between the biosimilar product applicant under subsection (k) and the reference product sponsor or between 2 or more biosimilar product applicants under subsection (k) that is contingent upon, provides a contingent condition for, or otherwise relates to an agreement described in clause (i); and

"(iii) excludes any agreement that solely concerns—

"(I) purchase orders for raw material supplies;

"(II) equipment and facility contracts;

"(III) employment or consulting contracts; or

"(IV) packaging and labeling contracts.

"(C) FILING.—

"(i) IN GENERAL.—The text of an agreement required to be filed by subparagraph (A) shall be filed with the Assistant Attorney General and the Federal Trade Commission not later than—

"(I) 10 business days after the date on which the agreement is executed; and

"(II) prior to the date of the first commercial marketing of, for agreements described in subparagraph (A)(i), the biosimilar product that is the subject of the application or, for agreements described in subparagraph (A)(ii), any biosimilar product that is the subject of an application described in such subparagraph.

"(ii) IF AGREEMENT NOT REDUCED TO TEXT.—If an agreement required to be filed by subparagraph (A) has not been reduced to text, the persons required to file the agreement shall each file written descriptions of the agreement that are sufficient to disclose all the terms and conditions of the agreement.

''(iii) CERTIFICATION.—The chief executive officer or the company official responsible for negotiating any agreement required to be filed by subparagraph (A) shall include in any filing under this paragraph a certification as follows: 'I declare under penalty of perjury that the following is true and correct: The materials filed with the Federal Trade Commission and the Department of Justice under section 351(l)(6) of the Public Health Service Act, with respect to the agreement referenced in this certification: (1) represent the complete, final, and exclusive agreement between the parties; (2) include any ancillary agreements that are contingent upon, provide a contingent condition for, or are otherwise related to, the referenced agreement; and (3) include written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to such section and have not been reduced to writing.'.

''(D) DISCLOSURE EXEMPTION.—Any information or documentary material filed with

the Assistant Attorney General or the Federal Trade Commission pursuant to this paragraph shall be exempt from disclosure under section 552 of title 5, United States Code, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this subparagraph prevents disclosure of information or documentary material to either body of the Congress or to any duly authorized committee or subcommittee of the Congress.

''(E) ENFORCEMENT.—

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

''(I) brought by the United States; or

''(II) brought by the Federal Trade Commission in accordance with the procedures established in section

16(a)(1) of the Federal Trade Commission Act.

''(ii) COMPLIANCE AND EQUITABLE RELIEF.—If any person violates any provision of this paragraph, the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion determines necessary or appropriate, upon application of the Assistant Attorney General or the Federal Trade Commission.

''(F) RULEMAKING.—The Federal Trade Commission, with the concurrence of the Assistant Attorney General and by rule in accordance with section 553 of title 5, United States Code, consistent with the purposes of this paragraph—

''(i) may define the terms used in this paragraph;

''(ii) may exempt classes of persons or agreements from the requirements of this paragraph; and

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

''(G) SAVINGS CLAUSE.—Any action taken by the Assistant Attorney General or the Federal Trade Commission, or any failure of the Assistant Attorney General or the Commission to take action, under this paragraph shall not at any time bar any proceeding or any action with respect to any agreement between a biosimilar product applicant under subsection (k) and the reference product sponsor, or any agreement between biosimilar product applicants under subsection (k), under any other provision of law, nor shall any filing under this paragraph constitute or create a presumption of any violation of any competition laws.''.

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

(1) by striking ''In this section, the term 'biological product' means'' and inserting the following: ''In this section:

''(1) The term 'biological product' means'';

(2) in paragraph (1), as so designated, by inserting ''protein (except any chemically synthesized polypeptide),'' after ''allergenic product,''; and

(3) by adding at the end the following:

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

''(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

''(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

''(3) The term 'interchangeable' or 'interchangeability', in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

''(4) The term 'reference product' means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).''.

(c) PRODUCTS PREVIOUSLY APPROVED UNDER SECTION 505.—

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

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

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

(B) such application—

(i) has been submitted to the Secretary of Health and Human Services (referred to in this Act as the ''Secretary'') before the date of enactment of this Act; or

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

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

be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if there is another biological product approved under subsection (a) of section 351 of the Public Health Service Act that could be a reference product with respect to such application (within the meaning of such section 351) if such application were submitted under subsection (k) of such section 351.

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

(5) DEFINITIONS.—For purposes of this subsection, the term ''biological product'' has the meaning given such term under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

SEC. 222. FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS.

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

product under section 351(k) of such Act'' before the period at the end.

SEC. 223. AMENDMENTS TO CERTAIN PATENT PROVISIONS.

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

(1) in subparagraph (A), by striking ''or'' after ''patent,'';

(2) in subparagraph (B), by adding ''or'' after the comma at the end;

(3) by inserting the following after subparagraph (B):

''(C) a statement under section 351(l)(4)(D)(ii) of the Public Health Service Act,''; and

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

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

Subtitle D—Administrative Simplification

SEC. 231. ADMINISTRATIVE SIMPLIFICATION.

(a) OPERATING RULES FOR HEALTH INFORMATION TRANSACTIONS.—

(1) DEFINITION OF OPERATING RULES.—Section 1171 of the Social Security Act (42 U.S.C. 1320d) is amended by adding at the end the following:

''(9) OPERATING RULES.—The term 'operating rules' means the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications as adopted for purposes of this part.''.

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

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

''(J) Electronic funds transfers.''; and

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

''(g) OPERATING RULES.—

''(1) IN GENERAL.—The Secretary shall adopt a single set of operating rules for each transaction described in subsection (a)(2) with the goal of creating as much uniformity in the implementation of the electronic standards as possible. Such operating rules shall be consensus-based and reflect the necessary business rules affecting health plans and health care providers and the manner in which they operate pursuant to standards issued under Health Insurance Portability and Accountability Act of 1996.

''(2) OPERATING RULES DEVELOPMENT.—In adopting operating rules under this subsection, the Secretary shall rely on recommendations for operating rules developed by a qualified nonprofit entity, as selected by the Secretary, that meets the following requirements:

''(A) The entity focuses its mission on administrative simplification.

''(B) The entity demonstrates an established multi-stakeholder and consensus-based process for development of operating rules, including representation by or participation from health plans, health care providers, vendors, rel-

evant Federal agencies, and other standard development organizations.

''(C) The entity has established a public set of guiding principles that ensure the operating rules and process are open and transparent.

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

''(E) The entity incorporates national standards, including the transaction standards issued under Health Insurance Portability and Accountability Act of 1996.

''(F) The entity supports nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory practices.

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

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

''(A) review the operating rules developed by a nonprofit entity described under paragraph (2);

''(B) determine whether such rules represent a consensus view of the health care industry and are consistent with and do not alter current standards;

''(C) evaluate whether such rules are consistent with electronic standards adopted for health information technology; and

''(D) submit to the Secretary a recommendation as to whether the Secretary should adopt such rules.

''(4) IMPLEMENTATION.—

''(A) IN GENERAL.—The Secretary shall adopt operating rules under this subsection, by regulation in accordance with subparagraph (C), following consideration of the rules developed by the non-profit entity described in paragraph (2) and the recommendation submitted by the National Committee on Vital and Health

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

''(B) ADOPTION REQUIREMENTS; EFFECTIVE DATES.—

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

''(ii) ELECTRONIC FUNDS TRANSFERS AND HEALTH CARE PAYMENT AND REMITTANCE ADVICE.—The set of operating rules for electronic funds transfers and health care payment and remittance advice shall be adopted not later than July 1, 2012, in a manner ensuring that such rules are effective not later than January 1, 2014.

''(iii) OTHER COMPLETED TRANSACTIONS.—The set of operating rules for

the remainder of the completed transactions described in subsection (a)(2), including health claims or equivalent encounter information, enrollment and disenrollment in a health plan, health plan premium payments, and referral certification and authorization, shall be adopted not later than July 1, 2014, in a manner ensuring that such rules are effective not later than January 1, 2016.

''(C) EXPEDITED RULEMAKING.—The Secretary shall promulgate an interim final rule applying any standard or operating rule recommended by the National Committee on Vital and Health Statistics pursuant to paragraph (3). The Secretary shall accept public comments on any interim final rule published under this subparagraph for 60 days after the date of such publication.

''(h) COMPLIANCE.—

''(1) HEALTH PLAN CERTIFICATION.—

''(A) ELIGIBILITY FOR A HEALTH PLAN, HEALTH CLAIM STATUS, ELECTRONIC FUNDS TRANSFERS, HEALTH CARE PAYMENT AND REMITTANCE ADVICE.—Not later than December

31, 2013, a health plan shall file a statement with the Secretary, in such form as the Secretary may require, certifying that the data and information systems for such plan are in compliance with any applicable standards (as described under paragraph (7) of section 1171) and operating rules (as described under paragraph (9) of such section) for electronic funds transfers, eligibility for a health plan, health claim status, and health care payment and remittance advice, respectively.

''(B) OTHER COMPLETED TRANSACTIONS.—Not later than December 31, 2015, a health plan shall file a statement with the Secretary, in such form as the Secretary may require, certifying that the data and information systems for such plan are in compliance with any applicable standards and operating rules for the remainder of the completed transactions described in subsection (a)(2), including health claims or equivalent encounter information, enrollment and disenrollment in a health plan, health plan premium payments, and referral certification and authorization, respectively. A health plan shall provide the same level of

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

''(2) DOCUMENTATION OF COMPLIANCE.—A health plan shall provide the Secretary, in such form as the Secretary may require, with adequate documentation of compliance with the standards and operating rules described under paragraph (1). A health plan shall not be considered to have provided adequate documentation and shall not be certified as being in compliance with such standards, unless the health plan—

''(A) demonstrates to the Secretary that the plan conducts the electronic transactions specified in paragraph (1) in a manner that fully complies with the regulations of the Secretary; and

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

''(3) SERVICE CONTRACTS.—A health plan shall be required to comply with any applicable certification and compliance requirements (and provide the

Secretary with adequate documentation of such compliance) under this subsection for any entities that provide services pursuant to a contract with such health plan.

''(4) CERTIFICATION BY OUTSIDE ENTITY.—The Secretary may contract with an independent, outside entity to certify that a health plan has complied with the requirements under this subsection, provided that the certification standards employed by such entities are in accordance with any standards or rules issued by the Secretary.

''(5) COMPLIANCE WITH REVISED STANDARDS AND RULES.—A health plan (including entities described under paragraph (3)) shall comply with the certification and documentation requirements under this subsection for any interim final rule promulgated by the Secretary under subsection (i) that amends any standard or operating rule described under paragraph (1) of this subsection. A health plan shall comply with such requirements not later than the effective date of the applicable interim final rule.

''(6) AUDITS OF HEALTH PLANS.—The Secretary shall conduct periodic audits to ensure that health plans (including entities described under

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

''(i) REVIEW AND AMENDMENT OF STANDARDS AND RULES.—

''(1) ESTABLISHMENT.—Not later than January 1, 2014, the Secretary shall establish a review committee (as described under paragraph (4)).

''(2) EVALUATIONS AND REPORTS.—

''(A) HEARINGS.—Not later than April 1, 2014, and not less than biennially thereafter, the Secretary, acting through the review committee, shall conduct hearings to evaluate and review the existing standards and operating rules established under this section.

''(B) REPORT.—Not later than July 1, 2014, and not less than biennially thereafter, the review committee shall provide recommendations for updating and improving such standards and rules. The review committee shall recommend a single set of operating rules per transaction standard and maintain the goal of creating as much uniformity as possible in the implementation of the electronic standards.

''(3) INTERIM FINAL RULEMAKING.—

''(A) IN GENERAL.—Any recommendations to amend existing standards and operating rules that have been approved by the review committee and reported to the Secretary under paragraph (2)(B) shall be adopted by the Secretary through promulgation of an interim final rule not later than 90 days after receipt of the committee's report.

''(B) PUBLIC COMMENT.—

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

''(ii) EFFECTIVE DATE.—The effective date of any amendment to existing standards or operating rules that is adopted through an interim final rule published under this paragraph shall be 25 months following the close of such public comment period.

''(4) REVIEW COMMITTEE.—

''(A) DEFINITION.—For the purposes of this subsection, the term 'review committee' means a committee within the Department of

Health and Human services that has been designated by the Secretary to carry out this subsection, including—

"(i) the National Committee on Vital and Health Statistics; or

"(ii) any appropriate committee as determined by the Secretary.

"(B) COORDINATION OF HIT STANDARDS.—In developing recommendations under this subsection, the review committee shall consider the standards approved by the Office of the National Coordinator for Health Information Technology.

"(j) PENALTIES.—

"(1) PENALTY FEE.—

"(A) IN GENERAL.—Not later than April 1, 2014, and annually thereafter, the Secretary shall assess a penalty fee (as determined under subparagraph (B)) against a health plan that has failed to meet the requirements under subsection (h) with respect to certification and documentation of compliance with the standards (and their operating rules) as described under paragraph (1) of such subsection.

"(B) FEE AMOUNT.—Subject to subparagraphs (C), (D), and (E), the Secretary shall assess a penalty fee against a health plan in the amount of $1 per covered life until certification is complete. The penalty shall be assessed per person covered by the plan for which its data systems for major medical policies are not in compliance and shall be imposed against the health plan for each day that the plan is not in compliance with the requirements under subsection (h).

"(C) ADDITIONAL PENALTY FOR MISREPRESENTATION.—A health plan that knowingly provides inaccurate or incomplete information in a statement of certification or documentation of compliance under subsection (h) shall be subject to a penalty fee that is double the amount that would otherwise be imposed under this subsection.

"(D) ANNUAL FEE INCREASE.—The amount of the penalty fee imposed under this subsection shall be increased on an annual basis by the annual percentage increase in total national health care expenditures, as determined by the Secretary.

"(E) PENALTY LIMIT.—A penalty fee assessed against a health plan under this subsection shall not exceed, on an annual basis—

"(i) an amount equal to $20 per covered life under such plan; or

"(ii) an amount equal to $40 per covered life under the plan if such plan has knowingly provided inaccurate or incomplete information (as described under subparagraph (C)).

"(F) DETERMINATION OF COVERED INDIVIDUALS.—The Secretary shall determine the number of covered lives under a health plan based upon the most recent statements and filings that have been submitted by such plan to the Securities and Exchange Commission.

"(2) NOTICE AND DISPUTE PROCEDURE.—The Secretary shall establish a procedure for assessment of penalty fees under this subsection that provides a health plan with reasonable notice and a dispute resolution procedure prior to provision of a notice of assessment by the Secretary of the Treasury (as described under paragraph (4)(B)).

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

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

''(4) COLLECTION OF PENALTY FEE.—

''(A) IN GENERAL.—The Secretary of the Treasury, acting through the Financial Management Service, shall administer the collection of penalty fees from health plans that have been identified by the Secretary in the penalty fee report provided under paragraph (3).

''(B) NOTICE.—Not later than August 1, 2014, and annually thereafter, the Secretary of the Treasury shall provide notice to each health plan that has been assessed a penalty fee by the Secretary under this subsection. Such notice shall include the amount of the penalty fee assessed by the Secretary and the due date for payment of such fee to the Secretary of the Treasury (as described in subparagraph (C)).

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

''(D) UNPAID PENALTY FEES.—Any amount of a penalty fee assessed against a health plan under this subsection for which payment has not been made by the due date provided under subparagraph (C) shall be—

''(i) increased by the interest accrued on such amount, as determined pursuant to the underpayment rate established under section 6601 of the Internal Revenue Code of 1986; and

''(ii) treated as a past-due, legally enforceable debt owed to a Federal agency for purposes of section 6402(d) of the Internal Revenue Code of 1986.

''(E) ADMINISTRATIVE FEES.—Any fee charged or allocated for collection activities conducted by the Financial Management Service will be passed on to a health plan on a pro-rata basis and added to any penalty fee collected from the plan.''.

(b) PROMULGATION OF RULES.—

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

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

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

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

(1) in paragraph (23), by striking the ''or'' at the end;

(2) in paragraph (24), by striking the period and inserting ''; or''; and

(3) by inserting after paragraph (24) the following new paragraph:

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

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

(d) MEDICARE AND MEDICAID COMPLIANCE REPORTS.—Not later than July 1, 2013, the Secretary of Health and Human Services shall submit a report to the Chairs and Ranking Members of the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives and the Chairs and Ranking Members of the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate on the extent to which the Medicare program and providers that serve beneficiaries under that program, and State Medicaid programs and providers that serve beneficiaries under those programs, transact electronically in accordance with transaction standards issued under the Health Insurance Portability and Accountability Act of 1996, part C of title XI of the Social Security Act, and regulations promulgated under such Acts.

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