AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—116th Cong., 1st Sess.

S. 1895

To lower health care costs.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Lower Health Care Costs Act''.

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

TITLE I—ENDING SURPRISE MEDICAL BILLS

SEC. 101. PROTECTING PATIENTS AGAINST OUT-OF-NETWORK DEDUCTIBLES IN EMERGENCIES.

Section 2719A(b) of the Public Health Service Act (42 U.S.C. 300gg–19a) is amended—

(1) in paragraph (1)—

(A) in the matter preceding subparagraph (A), by inserting ''or a freestanding emergency room'' after ''hospital''; and

(B) in subparagraph (C)—

(i) in clause (ii)(I), by inserting ''or freestanding emergency room'' after ''emergency department''; and

(ii) in subparagraph (C)(ii)(II), by adding, ''a deductible,'' after ''(expressed as''; and

(2) in paragraph (2)(B)—

(A) in clause (i)—

(i) by inserting ''or freestanding emergency room'' after ''hospital''; and

(ii) by inserting ''or freestanding emergency room'' after ''emergency department''; and

(B) in clause (ii), by inserting ''or freestanding emergency room'' after ''hospital''.

SEC. 102. PROTECTION AGAINST SURPRISE BILLS.

(a) PHSA.—Section 2719A of the Public Health Service Act (42 U.S.C. 300gg–19a) is amended by adding at the end the following:

''(e) OUT-OF-NETWORK ANCILLARY SERVICES.—

''(1) COVERAGE OF SERVICES.—Subject to subsection (h), in the case of an enrollee in a group health plan or group or individual health insurance coverage who receives out-of-network ancillary services at an in-network facility, including any referrals for diagnostic services, and such services would be covered under such plan or coverage if provided in-network—

''(A) the cost-sharing requirement (expressed as a copayment amount, coinsurance rate, or deductible) with respect to such services shall be the same requirement that would apply

if such services were provided by an in-network practitioner, and any coinsurance or deductible shall be based on in-network rates; and

"(B) amounts paid toward such cost-sharing shall be counted towards the in-network deductible and in-network out-of-pocket maximum amount, as applicable, under the plan or coverage for the plan year.

"(2) NOTICE BEFORE PROVIDING NON-EMERGENCY SERVICES.—Subject to subsection (h), in the case of an enrollee in a group health plan or group or individual health insurance coverage who receives out-of-network, non-emergency services that are not ancillary services, from an out-of-network provider at an in-network facility, and such services would be covered under such plan or coverage if provided in-network, the cost-sharing requirement (expressed as a copayment amount, coinsurance rate, or deductible) with respect to such services shall be the same requirement that would apply if such services were provided by an in-network practitioner, and any coinsurance or deductible shall be based on in-network rates, unless, as soon as practicable, and in no case later than 48 hours prior to providing non-emergency services that are not ancillary services—

"(A) the in-network facility provides to the enrollee who is scheduled to receive such services notice that—

"(i) is provided in paper or electronic form (and including electronic notification whenever practicable);

"(ii) states that such service will be provided out-of-network;

"(iii) includes the estimated amount that such practitioner or facility may charge the enrollee for such services; and

"(iv) provides the option to affirmatively consent to receiving such services from such practitioner or facility;

"(B) such enrollee signs such notice consenting to receive such services from an out-of-network provider at an in-network facility, and acknowledging that the out-of-network services may be covered at an out-of-network cost-sharing amount, requiring higher cost-sharing obligations of the enrollee than if the service were provided by an in-network practitioner or facility; and

"(C) such facility maintains documentation of the enrollee's signature or confirmation of re-

ceipt of such information under subparagraph (B) in the enrollee's patient record for 2 years after the date of services.

''(3) DEFINITION.—For purposes of this subsection, the term 'facility' has the meaning given the term 'health care facility' in section 2729A(c).

''(f) COVERAGE OF OUT-OF-NETWORK SERVICES FOR ENROLLEES ADMITTED AFTER EMERGENCY SERVICES.—

''(1) PROTECTION FOR ENROLLEES ADMITTED TO THE HOSPITAL FOR EMERGENCY SERVICES PRIOR TO STABILIZATION.—In the case of an enrollee in a group health plan or group or individual health insurance coverage who receives emergency services, or maternal care for a woman in labor, in the emergency department of an out-of-network facility and has not been stabilized (within the meaning of subsection (b)(2)(C)), if the patient is subsequently admitted to the out-of-network facility for care, the cost-sharing requirement (expressed as a copayment amount, coinsurance rate, or deductible) with respect to any out-of-network services provided to the enrollee prior to being stable and in a condition to receive information under (2), is the same requirement that would apply as under subsection (b)(2)(C)(ii)(II).

"(2) NOTICE AND CONSENT.—

"(A) IN GENERAL.—Subject to subsection (h), in the case of an enrollee in a group health plan or group or individual health insurance coverage who receives emergency services, or maternal care for a woman in labor, in the emergency department of an out-of-network facility and has been stabilized (within the meaning of subsection (b)(2)(C)), if the patient is subsequently admitted to the out-of-network facility for care, the cost-sharing requirement (expressed as a copayment amount, coinsurance rate, or deductible) with respect to any out-of-network services is the same requirement that would apply if such services were provided by an in-network provider, unless the enrollee, once stable and in a condition to receive such information, including having sufficient mental capacity—

"(i) has been provided by the facility, prior to the provision of any post-stabilization, out-of-network service at such facility, with—

"(I) paper or electronic notification that the practitioner or facility is

an out-of-network health care provider and the out-of-network rate of the provider, as applicable, and the option to affirmatively consent to receiving services from such practitioner or facility; and

''(II) the estimated amount that such provider may charge the participant, beneficiary, or enrollee for such services involved;

''(ii) has been provided by the plan or coverage, prior to the provision of any post-stabilization, out-of-network service at such facility, with—

''(I) paper or electronic notification (and including electronic notification whenever practicable) that the practitioner or facility is an out-of-network health care provider, and the option to affirmatively consent to receiving services from such practitioner or facility;

''(II) a list of in-network practitioners or facilities in the relevant geographic area that could provide the

same services, and an option for a referral to such providers; and

''(III) information about whether prior authorization or other care management limitations may be required in advance of receiving in-network services at the facility;

''(iii) has acknowledged, in writing, that the out-of-network services provided after the individual has been stabilized may not be covered or may be covered at an out-of-network cost-sharing amount, requiring higher cost-sharing obligations of the enrollee than if the service were provided at an in-network facility.

''(B) REQUIREMENTS OF NOTICE.—The notice under subparagraph (A) shall be in a format determined by the Secretary to give a reasonable layperson clear comprehension of the terms of the agreement, including all possible financial responsibilities, including the requirements that the notice—

''(i) does not exceed one page in length;

"(ii) is readily identifiable for its purpose and as a contract of consent;

"(iii) clearly states that consent to potential out-of-network charges is optional and that the enrollee has the choice to transfer to an in-network facility;

"(iv) includes an estimate of the amount that such provider will charge the participant, beneficiary, or enrollee for such services involved; and

"(v) be available in the 15 most common languages in the facility's geographic area, with the facility making a good faith effort to provide oral notice in the enrollee's primary language if it is not one of such 15 languages.

"(C) MAINTENANCE OF RECORDS.—A facility shall maintain documentation of notice given to an enrollee pursuant to this subsection and the enrollee's confirmation of receipt of such information in the enrollee's patient record for 2 years after the date of services.

"(3) RULEMAKING.—Not later than 6 months after the date of enactment of the Lower Health Care Costs Act, the Secretary shall issue regulations

to carry out this subsection, which shall include clarification on how to determine whether an individual is stabilized and the timing of the notice required under this paragraph.

"(g) PROHIBITION ON BILLING MORE THAN AN IN-NETWORK RATE UNDER CERTAIN CIRCUMSTANCES.—

"(1) IN GENERAL.—A facility or practitioner furnishing—

"(A) emergency services, as defined in subsection (b)(2), regardless of the State in which the patient resides;

"(B) out-of-network services at an in-network facility described in subsection (e)(1);

"(C) out-of-network services at an in-network facility described in subsection (e)(2), where the notice and consent for receiving such services out-of-network did not meet the requirement of such subsection;

"(D) services furnished by an out-of-network provider after an enrollee has been admitted to the hospital for emergency services but prior to stabilization, as described in subsection (f)(1); or

"(E) out-of-network services furnished after the enrollee has been stabilized (within the

meaning of subsection (b)(2)(C)), where the notice and option for receiving care at an alternate facility required under subsection (f)(2) have not been provided to the enrollee and the enrollee did not give consent under subsection (f)(3),

may not bill an enrollee in a group health plan or group or individual health insurance coverage for amounts beyond the cost-sharing amount that would apply under subsection (b)(1)(C)(ii)(II), (e)(1), (e)(2), or (f), as applicable.

''(2) NOTICE.—A facility furnishing services described in paragraph (1) shall provide enrollees in a group health plan or group or individual health insurance coverage with a one-page notice, in 16-point font, upon intake at the emergency room or being admitted at the facility of the prohibition on balance billing under paragraph (1) and who to contact for recourse if they are sent a balance bill in violation of such paragraph. The facility shall be responsible for obtaining the signature from the enrollee on such notice. The Secretary shall issue regulations within 6 months of the date of enactment of the Lower Health Care Costs Act on the requirements for the notice under this paragraph.

''(h) MAINTAINING STATE SURPRISE BILLING PROTECTIONS.—

''(1) IN GENERAL.—Nothing in this section shall prevent a State from establishing or continuing in effect, with respect to health insurance issuers, facilities, or practitioners, an alternate method under State law for determining the appropriate compensation for services described in subsection (b), (e), or (f).

''(2) ADDITIONAL APPLICATION.—In the case of group health plans or group or individual health insurance coverage offered in a State that has not established an alternate method described in paragraph (1), such as arbitration or a benchmark, or for services described in subsection (b), (e), or (f) that are not covered by such State's alternate method described in paragraph (1), the provisions of this section shall apply.

''(3) SELF-INSURED PLANS.—Subsections (b), (e), and (f) shall apply to a self-insured group health plan that is not subject to State insurance regulation.

''(i) DEFINITIONS.—In this section:

''(1) IN-NETWORK.—The term 'in-network', with respect to a group health plan or health insur-

ance coverage means a provider that has a contractual relationship with the plan.

''(2) ENROLLEE.—The term 'enrollee', with respect to health insurance coverage or a group health plan, includes a participant, dependent, or beneficiary.

''(3) ANCILLARY SERVICES.—The term 'ancillary services' means non-emergency care that is—

''(A) provided by anesthesiologists, pathologists, emergency medicine providers, intensivists, radiologists, neonatologists, hospitalists, and assistant surgeons, whether the care is provided by a physician or non-physician practitioner;

''(B) a diagnostic service (including radiology and lab services); or

''(C) provided by such other specialty practitioner not typically selected by the patients receiving the care, which the Secretary may add periodically to such definition through rulemaking.''.

(b) ENFORCEMENT OF BALANCE BILLING PROHIBITIONS.—Part C of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–91 et seq.) is amended by adding at the end the following:

"SEC. 2795. ENFORCEMENT OF BALANCE BILLING PROHIBITIONS.

''(a) IN GENERAL.—Subject to subsection (b), a facility or practitioner that violates a requirement under section 2719A(g)(1) or fails to provide notice or obtain consent as required under subsection (e)(2) or (f)(2) shall be subject to a civil monetary penalty of not more than $10,000 for each act constituting such violation.

''(b) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsections (a) and (b) and the first sentence of subsection (c)(1) of such section, shall apply to civil money penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

''(c) SAFE HARBOR.—

''(1) IN GENERAL.—The Secretary shall waive the penalties described under subsection (a) with respect to a facility or, practitioner who does not knowingly violate, and should not have reasonably known it violated, section 2719A(g)(1) with respect to an enrollee, if such facility or practitioner, within 30 days of the violation, withdraws the bill that was in violation of section 2719A(g)(1), and, as applicable, reimburses the group health plan, health insurance issuer, or enrollee, in an amount equal to the

difference between the amount billed and the amount allowed to be billed under section 2719A(g)(1), plus interest, at an interest rate determined by the Secretary.

''(2) HARDSHIP EXEMPTION.—The Secretary may establish a hardship exemption to the penalties under this section.

''(3) STATE ENFORCEMENT.—The Secretary shall waive penalties under this section with respect to a facility or practitioner that has already been subject to enforcement action under State law for a violation described in subsection (a).''.

(c) APPLICATION TO GRANDFATHERED PLANS.—Section 1251(a) of the Patient Protection and Affordable Care Act (42 U.S.C. 18011(a)) is amended by adding at the end the following:

''(5) APPLICATION OF ADDITIONAL PROVISIONS.—Subsections (b) through (h) of section 2719A of the Public Health Service Act (42 U.S.C. 300gg–19a) shall apply to grandfathered health plans for plan years beginning with the second plan year that begins after the date of enactment of the Lower Health Care Costs Act.''.

(d) COVERAGE UNDER FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM.—Section 8904 of title 5,

United States Code, is amended by adding at the end the following:

''(c) Any health benefits plan offered under this chapter shall be treated as a group health plan or group or individual health insurance coverage for purposes of subsections (e) through (g) of section 2719A of the Public Health Service Act (42 U.S.C. 300gg–19a) (except for paragraph (3) of such subsection (g)).''.

SEC. 103. BENCHMARK FOR PAYMENT.

(a) IN GENERAL.—Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–11 et seq.) is amended by adding at the end the following:

''SEC. 2729A. BENCHMARK FOR PAYMENT.

''(a) ESTABLISHMENT OF BENCHMARK.—A group health plan or health insurance issuer offering group or individual health insurance coverage shall pay providers, including facilities and practitioners, furnishing services for which such facilities and practitioners are prohibited under section 2719A(g) from billing enrollees for amounts beyond the cost-sharing amount that would apply under subsection (b)(1)(C)(ii)(II), (e), or (f) of section 2719A,the median in-network rate for such services provided to enrollees, using a methodology determined under subsection (b) for the same or similar services offered by

the group health plan or health insurance issuer in that geographic region. Such payment shall be made in a timely fashion in order to ensure compliance with sections 399V–7 and 2729D.

''(b) MEDIAN IN-NETWORK RATE.—

''(1) IN GENERAL.—For purposes of this section, the term 'median in-network rate' means, with respect to health care services covered by a group health plan or group or individual health insurance coverage, the median contracted rate under the applicable plan or coverage recognized under the plan or coverage as the total maximum payment for the service minus the in-network cost-sharing for such service under the plan or coverage, for the same or a similar service that is provided by a provider in the same or similar specialty and in the geographic region in which the service is furnished.

''(2) RULEMAKING.—

''(A) IN GENERAL.—Not later than 1 year after the date of enactment of the Lower Health Care Costs Act, the Secretary shall, through rulemaking, determine the methodology a group health plan or health insurance issuer is required to use to determine the median in-network rate described in paragraph (1), dif-

ferentiating by business line, the information the plan or issuer shall share with the out-of-network provider involved when making such a determination, and the geographic regions applied for purposes of this subsection. Such rulemaking shall take into account payments that are made by health insurance issuers that are not on a fee-for-service basis.

''(B) GEOGRAPHIC REGIONS.—In establishing geographic regions under subparagraph (A), the Secretary shall consider adequate access to services in rural areas and health professional shortage areas, as defined in section 332. The Secretary shall consult with the National Association of Insurance Commissioners in establishing the geographic regions. The Secretary shall update the geographic regions periodically, as appropriate, taking into account the findings of the report under section 106 of the Lower Health Care Costs Act.

''(3) CERTAIN INSURERS.—If a group health plan or health insurance issuer offering group or individual health insurance coverage does not have sufficient information to calculate a median in-network rate for this service or provider type, or

amount of, claims for services (as determined by the applicable State authority, in the case of health insurance coverage, or by the Secretary of Labor, in the case of a self-insured group health plan) covered under the list of out-of-network services set by the State authority or Secretary of Labor, as applicable, in a particular geographic area, such plan or issuer shall demonstrate that it will use a database free of conflicts of interest that has sufficient information reflecting allowed amounts paid to individual health care providers for relevant services provided in the applicable geographic region, and that such plan or issuer will use that database to determine a median in-network rate. The group health plan or health insurance issuer shall cover the cost of accessing the database.

''(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall prevent a group health plan or health insurance issuer from establishing separate calculations of a median in-network rate under paragraph (1) for services delivered in nonhospital facilities, including freestanding emergency rooms.

''(c) FACILITY.—For purposes of this section, the term 'health care facility' or 'facility' includes hospitals, hospital outpatient departments, critical access hospitals,

ambulatory surgery centers, laboratories, radiology clinics, freestanding emergency rooms, and any other facility that provides services that are covered under a group health plan or health insurance coverage, including settings of care subject to section 2719A(b).''.

(b) NON-FEDERAL GOVERNMENTAL PLANS.—Section 2722(a)(2)(E) of the Public Health Service Act (42 U.S.C. 300gg–21(a)(2)(E)) is amended by inserting '', except that such election shall be available with respect to section 2729A'' before the period.

SEC. 104. EFFECTIVE DATE.

The amendments made by sections 101, 102, and 103 shall take effect beginning in the second plan year that begins after the date of enactment of this Act.

SEC. 105. ENDING SURPRISE AIR AMBULANCE BILLS.

(a) IN GENERAL.—Part A of title XXVII of the Public Health Service Act is amended by inserting after section 2719A (42 U.S.C. 300gg–19a) the following:

''SEC. 2719B. ENDING SURPRISE AIR AMBULANCE BILLS.

''(a) IN GENERAL.—In the case of an enrollee in a group health plan or group or individual health insurance coverage who receives air ambulance services from an out-of-network provider, if such services would be covered if provided by an in-network provider—

''(1) the cost-sharing requirement (expressed as a copayment amount, coinsurance rate, or deductible) with respect to such services shall be the same requirement that would apply if such services were provided by an in-network practitioner, and any coinsurance or deductible shall be based on in-network rates; and

''(2) such cost-sharing amounts shall be counted towards the in-network deductible and in-network out-of-pocket maximum amount under the plan or coverage for the plan year.

''(b) PAYMENT RATE.—A group health plan or health insurance issuer shall pay for air ambulance services for purposes of subsection (a) at the median in-network as defined in subsection (c).

''(c) MEDIAN IN-NETWORK RATE.—

''(1) IN GENERAL.—For purposes of this section, the term 'median in-network rate' means, with respect to air ambulance services covered by a group health plan or group or individual health insurance coverage, the median contracted rate under the applicable plan or coverage recognized under the plan or coverage as the total maximum payment for the service, minus the in-network cost-sharing for such service under the plan or coverage, for the same or

a similar service that is provided by a provider in the same or similar specialty, and in the geographic region in which the service is furnished.

''(2) RULEMAKING.—

''(A) IN GENERAL.—Not later than 6 months after the date of enactment of the Lower Health Care Costs Act, the Secretary shall, through rulemaking, determine the methodology a group health plan or health insurance issuer is required to use to determine the median in-network rate described in paragraph (1), the information the plan or issuer shall share with the out-of-network provider involved when making such a determination, and the geographic regions applied for purposes of this subsection. Such rulemaking shall take into account payments that are made by issuers that are not on a fee-for-service basis.

''(B) GEOGRAPHIC REGIONS.—In establishing geographic regions as described in subparagraph (A), the Secretary shall consider adequate access to services in rural areas. The Secretary shall consult with the National Association of Insurance Commissioners in establishing the geographic regions. The Secretary

shall update the geographic regions periodically, as appropriate, taking into account the findings of the report under section 106 of the Lower Health Care Costs Act.

''(3) CERTAIN INSURERS.—If a group health plan or health insurance issuer offering group or individual health insurance coverage does not have sufficient information to calculate a median in-network rate for this service or provider type, or amount of, claims for services (as determined by the applicable State authority, in the case of health insurance coverage, or by the Secretary of Labor, in the case of a self-insured group health plan) covered under the list of out-of-network services set by the State authority or Secretary of Labor, as applicable, in a particular geographic area, such plan or issuer shall demonstrate that it will use a database free of conflicts of interest that has sufficient information reflecting allowed amounts paid to individual health care providers for relevant services provided in the applicable geographic region, and that such plan or issuer will use that database to determine a median in-network rate. The group health plan or health insurance issuer shall cover the cost of accessing the database.

''(4) CLARIFICATION.—For purposes of this subsection, the Secretary may define geographic regions that are different from the geographic regions identified for purposes of section 2729A(b) to ensure that an adequate number of air ambulance services are in-network in each geographic region so that a median in-network rate for air ambulance services may be calculated for each such region.

''(d) COST-SHARING LIMITATION.—An air ambulance service provider may not bill an enrollee in a group health plan or group or individual health insurance coverage for amounts beyond the cost-sharing amount that applies under subsection (a).

''(e) ENFORCEMENT.—

''(1) IN GENERAL.—Subject to paragraph (2), an air ambulance service provider that violates subsection (d) shall be subject to a civil monetary penalty of not more than $10,000 for each act constituting such violation.

''(2) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsections (a) and (b) and the first sentence of subsection (c)(1) of such section, shall apply to civil money penalties under this subsection in the same manner as such provisions apply to a penalty or pro-

ceeding under section 1128A of the Social Security Act.

''(3) SAFE HARBOR.—The Secretary shall waive the penalties described under paragraph (1) with respect to a air ambulance service provider who unknowingly violates subsection (d) with respect to an enrollee, if such air ambulance service provider within 30 days of the violation, withdraws the bill that was in violation of subsection (d), and, as applicable, reimburses the group health plan, health insurance issuer, or enrollee, as applicable, in an amount equal to the amount billed in violation of subsection (d), plus interest, at an interest rate determined by the Secretary.''.

(b) EFFECTIVE DATE.—Section 2719B of the Public Health Service Act, as added by subsection (a), shall take effect on the date that is 1 year after the date of enactment of this Act.

SEC. 106. REPORT.

Not later than 1 year after the effective date described in section 104, and annually for the following 4 years, the Secretary of Health and Human Services, in consultation with the Federal Trade Commission and the Attorney General, shall—

(1) conduct a study on—

(A) the effects of the amendments made by sections 101, 102, 103, and 105, including any patterns of vertical or horizontal integration of health care facilities, providers, group health plans, or health insurance issuers;

(B) the effects of the amendments made by sections 101, 102, 103, and 105 on overall health care costs;

(C) the effects of the amendments made by sections 101, 102, 103, and 105 on access to services, including specialty services, in rural areas and health professional shortage areas as defined in section 332; and

(D) recommendations, made in consultation with the Secretary of Labor and the Secretary of the Treasury, for effective enforcement of 2729A of the Public Health Service Act, as added by section 103, including potential challenges to addressing anti-competitive consolidation by health care facilities, providers, group health plans, or health insurance issuers; and

(2) submit a report on such study to the Committee on Health, Education, Labor, and Pensions, the Committee on Commerce, Science, and Trans-

portation, the Committee on Finance, and the Committee on the Judiciary of the Senate and the Committee on Education and Labor, the Committee on Energy and Commerce, the Committee on Ways and Means, and the Committee on the Judiciary of the House of Representatives.

TITLE II—REDUCING THE PRICES OF PRESCRIPTION DRUGS

SEC. 201. BIOLOGICAL PRODUCT PATENT TRANSPARENCY.

(a) IN GENERAL.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(o) ADDITIONAL REQUIREMENTS WITH RESPECT TO PATENTS.—

''(1) APPROVED APPLICATION HOLDER LISTING REQUIREMENTS.—

''(A) IN GENERAL.—Beginning on the date of enactment of the Lower Health Care Costs Act, within 60 days of approval of an application under subsection (a) or (k), the holder of such approved application shall submit to the Secretary a list of each patent required to be disclosed (as described in paragraph (3)).

"(B) PREVIOUSLY APPROVED OR LICENSED BIOLOGICAL PRODUCTS.—

"(i) PRODUCTS LICENSED UNDER SECTION 351 OF THE PHSA.—Not later than 30 days after the date of enactment of the Lower Health Care Costs Act, the holder of a biological product license that was approved under subsection (a) or (k) before the date of enactment of such Act shall submit to the Secretary a list of each patent required to be disclosed (as described in paragraph (3)).

"(ii) PRODUCTS APPROVED UNDER SECTION 505 OF THE FFDCA.—Not later than 30 days after March 23, 2020, the holder of an approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act that is deemed to be a license for the biological product under this section on March 23, 2020, shall submit to the Secretary a list of each patent required to be disclosed (as described in paragraph (3)).

"(C) UPDATES.—The holder of a biological product license that is the subject of an applica-

tion under subsection (a) or (k) shall submit to the Secretary a list that includes—

"(i) any patent not previously required to be disclosed (as described in paragraph (3)) under subparagraph (A) or (B), as applicable, within 30 days of the earlier of—

"(I) the date of issuance of such patent by the United States Patent and Trademark Office; or

"(II) the date of approval of a supplemental application for the biological product; and

"(ii) any patent, or any claim with respect to a patent, included on the list pursuant to this paragraph, that the Patent Trial and Appeal Board of the United States Patent and Trademark Office determines in a written decision to cancel as unpatentable, within 30 days of such decision.

"(2) PUBLICATION OF INFORMATION.—

"(A) IN GENERAL.—Within 1 year of the date of enactment of the Lower Health Care Costs Act, the Secretary shall publish and make

available to the public a single, easily searchable list that includes—

"(i) the official and proprietary name of each biological product licensed, or deemed to be licensed, under subsection (a) or (k);

"(ii) with respect to each biological product described in clause (i), each patent submitted in accordance with paragraph (1);

"(iii) the date of licensure and application number for each such biological product;

"(iv) the marketing status, dosage form, route of administration, strength, and, if applicable, reference product, for each such biological product;

"(v) the licensure status for each such biological product, including whether the license at the time of listing is approved, withdrawn, or revoked;

"(vi) with respect to each such biological product, any period of exclusivity under paragraph (6), (7)(A), or (7)(B) of subsection (k) of this section or section

527 of the Federal Food, Drug, and Cosmetic Act, and any extension of such period in accordance with subsection (m) of this section, for which the Secretary has determined such biological product to be eligible, and the date on which such exclusivity expires;

''(vii) any determination of biosimilarity or interchangeability for each such biological product; and

''(viii) information regarding approved indications for each such biological product, in such manner as the Secretary determines appropriate.

''(B) UPDATES.—Every 30 days after the publication of the first list under subparagraph (A), the Secretary shall revise the list to include—

''(i)(I) each biological product licensed under subsection (a) or (k) during the 30-day period; and

''(II) with respect to each biological product described in subclause (I), the information described in clauses (i) through (viii) of subparagraph (A); and

"(ii) any updates to information previously published in accordance with subparagraph (A).

"(C) NONCOMPLIANCE.—Beginning 18 months after the date of enactment of the Lower Health Care Costs Act, the Secretary, in consultation with the Director of the United States Patent and Trademark Office, shall publish and make available to the public a list of any holders of biological product licenses, and the corresponding biological product or products, that failed to submit information as required under paragraph (1), including any updates required under paragraph (1)(C), in such manner and format as the Secretary determines appropriate. If information required under paragraph (1) is submitted following publication of such list, the Secretary shall remove such holders of such biological product licenses from the public list in a reasonable period of time.

"(3) PATENTS REQUIRED TO BE DISCLOSED.—In this section, a 'patent required to be disclosed' is any patent for which the holder of a biological product license approved under subsection (a) or (k), or

a biological product application approved under section 505 of the Federal Food, Drug, and Cosmetic Act and deemed to be a license for a biological product under this section on March 23, 2020, believes a claim of patent infringement could reasonably be asserted by the holder, or by a patent owner that has granted an exclusive license to the holder with respect to the biological product that is the subject of such license, if a person not licensed by the owner engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of such license.''.

(b) DISCLOSURE OF PATENTS.—Section 351(l)(3)(A)(i) of the Public Health Service Act (42 U.S.C. 262(l)(3)(A)(i)) is amended by inserting ''included in the list provided by the reference product sponsor under subsection (o)(1)'' after ''a list of patents''.

(c) REVIEW AND REPORT ON NONCOMPLIANCE.—Not later than 30 months after the date of enactment of this Act, the Secretary shall—

(1) solicit public comments regarding appropriate remedies, in addition to the publication of the list under subsection (o)(2)(C) of section 351 of the Public Health Service Act (42 U.S.C. 262), as added by subsection (a), with respect to holders of biologi-

cal product licenses who fail to timely submit information as required under subsection (o)(1) of such section 351, including any updates required under subparagraph (C) of such subsection (o)(1); and

(2) submit to Congress an evaluation of comments received under paragraph (1) and the recommendations of the Secretary concerning appropriate remedies.

(d) REGULATIONS.—The Secretary of Health and Human Services may promulgate regulations to carry out subsection (o) of section 351 of the Public Health Service Act (42 U.S.C. 262), as added by subsection (a).

(e) RULE OF CONSTRUCTION.—Nothing in this Act, including an amendment made by this Act, shall be construed to require or allow the Secretary of Health and Human Services to delay the licensing of a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262).

SEC. 202. ORANGE BOOK MODERNIZATION.

(a) SUBMISSION OF PATENT INFORMATION FOR BRAND NAME DRUGS.—

(1) IN GENERAL.—Paragraph (1) of section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended to read as follows:

"(b)(1)(A) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application—

"(i) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;

"(ii) a full list of the articles used as components of such drug;

"(iii) a full statement of the composition of such drug;

"(iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

"(v) such samples of such drug and of the articles used as components thereof as the Secretary may require;

"(vi) specimens of the labeling proposed to be used for such drug;

"(vii) any assessments required under section 505B; and

"(viii) the patent number and expiration date, of each patent for which a claim of patent infringement could reasonably be asserted if a person not li-

censed by the owner engaged in the manufacture, use, or sale of the drug, and that—

"(I) claims the drug for which the applicant submitted the application and is a drug substance patent or a drug product patent; or

"(II) claims the method of using the drug for which approval is sought or has been granted in the application.

"(B) If an application is filed under this subsection for a drug, and a patent of the type described in subparagraph (A)(viii) that claims such drug or a method of using such drug is issued after the filing date, the applicant shall amend the application to include such patent information.".

(2) GUIDANCE.—The Secretary of Health and Human Services shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required under subsection (b)(1)(A)(i) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by paragraph (1).

(b) CONFORMING CHANGES TO REQUIREMENTS FOR SUBSEQUENT SUBMISSION OF PATENT INFORMATION.—

Section 505(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(2)) is amended—

(1) by inserting before the first sentence the following: ''Not later than 30 days after the date of approval of an application under subsection (b), the holder of the approved application shall file with the Secretary the patent number and the expiration date of any patent described in subclause (I) or (II) of subsection (b)(1)(A)(viii), except that a patent that is identified as claiming a method of using such drug shall be filed only if the patent claims a method of use approved in the application. The holder of the approved application shall file with the Secretary the patent number and the expiration date of any patent described in subclause (I) or (II) of subsection (b)(1)(A)(viii) that is issued after the date of approval of the application, not later than 30 days after the date of issuance of the patent, except that a patent that claims a method of using such drug shall be filed only if approval for such use has been granted in the application.'';

(2) by inserting after ''the patent number and the expiration date of any patent which'' the following: ''fulfills the criteria in subsection (b) and'';

(3) by inserting after the third sentence (as amended by paragraph (1)) the following: ''Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph.''; and

(4) by inserting after ''could not file patent information under subsection (b) because no patent'' the following: ''of the type required to be submitted in subsection (b)(1)(A)(viii)''.

(c) LISTING OF EXCLUSIVITIES.—Subparagraph (A) of section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by adding at the end the following:

''(iv) For each drug included on the list, the Secretary shall specify any exclusivity period that is applicable, for which the Secretary has determined the expiration date, and for which such period has not yet expired under—

''(I) clause (ii), (iii), or (iv) of subsection (c)(3)(E) of this section;

''(II) clause (iv) or (v) of paragraph (5)(B) of this subsection;

''(III) clause (ii), (iii), or (iv) of paragraph (5)(F) of this subsection;

''(IV) section 505A;

''(V) section 505E;

''(VI) section 527(a); or

''(VII) subsection (u)''.

(d) ORANGE BOOK UPDATES WITH RESPECT TO INVALIDATED PATENTS.—

(1) IN GENERAL.—

(A) AMENDMENTS.—Section 505(j)(7)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)(A)), as amended by subsection (c), is further amended by adding at the end the following:

''(v) In the case of a listed drug for which the list under clause (i) includes a patent for such drug, and where the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office have cancelled any claim of the patent pursuant to a decision by the Patent Trial and Appeal Board in an inter partes review conducted under chapter 31 of title 35, United States Code, or a post-grant review conducted under chapter 32 of that title, and from which no appeal has been taken, or can be taken, the holder of the applicable approved application shall notify the Secretary, in writing, within 14 days of such cancellation, and, if the patent has been

deemed wholly inoperative or invalid, or if a patent claim has been cancelled, the revisions required under clause (iii) shall include striking the patent or information regarding such patent claim from the list with respect to such drug, as applicable, except that the Secretary shall not remove a patent from the list before the expiration of any 180-day exclusivity period under paragraph (5)(B)(iv) that relies on a certification described in paragraph (2)(A)(vii)(IV) with respect to such patent.''.

(B) APPLICATION.—The amendment made by subparagraph (A) shall not apply with respect to any determination with respect to a patent or patent claim that is made prior to the date of enactment of this Act.

(2) NO EFFECT ON FIRST APPLICANT EXCLUSIVITY PERIOD.—Section 505(j)(5)(B)(iv)(I) is amended by adding at the end the following: ''This subclause shall apply even if a patent is stricken from the list under paragraph (7)(A), pursuant to paragraph (7)(A)(v), provided that, at the time that the first applicant submitted an application under this subsection containing a certification described in paragraph (2)(A)(vii)(IV), the patent that was the

subject of such certification was included in such list with respect to the listed drug.''.

SEC. 203. ENSURING TIMELY ACCESS TO GENERICS.

Section 505(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(q)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A)(i), by inserting '', 10.31,'' after ''10.30'';

(B) in subparagraph (E)—

(i) by striking ''application and'' and inserting ''application or'';

(ii) by striking ''If the Secretary'' and inserting the following:

''(i) IN GENERAL.—If the Secretary''; and

(iii) by striking the second sentence and inserting the following:

''(ii) PRIMARY PURPOSE OF DELAYING.—

''(I) IN GENERAL.—In determining whether a petition was submitted with the primary purpose of delaying an application, the Secretary may consider the following factors:

"(aa) Whether the petition was submitted in accordance with paragraph (2)(B), based on when the petitioner knew or reasonably should have known the relevant information relied upon to form the basis of such petition.

"(bb) Whether the petitioner has submitted multiple or serial petitions or supplements to petitions raising issues that reasonably could have been known to the petitioner at the time of submission of the earlier petition or petitions.

"(cc) Whether the petition was submitted close in time to a known, first date upon which an application under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act could be approved.

"(dd) Whether the petition was submitted without relevant

data or information in support of the scientific positions forming the basis of such petition.

"(ee) Whether the petition raises the same or substantially similar issues as a prior petition to which the Secretary has responded substantively already, including if the subsequent submission follows such response from the Secretary closely in time.

"(ff) Whether the petition requests changing the applicable standards that other applicants are required to meet, including requesting testing, data, or labeling standards that are more onerous or rigorous than the standards the Secretary has determined to be applicable to the listed drug, reference product, or petitioner's version of the same drug.

"(gg) The petitioner's record of submitting petitions to the

Food and Drug Administration that have been determined by the Secretary to have been submitted with the primary purpose of delay.

''(hh) Other relevant and appropriate factors, which the Secretary shall describe in guidance.

''(II) GUIDANCE.—The Secretary may issue or update guidance, as appropriate, to describe factors the Secretary considers in accordance with subclause (II).'';

(C) by adding at the end the following:

''(iii) REFERRAL TO THE FEDERAL TRADE COMMISSION.—The Secretary shall establish procedures for referring to the Federal Trade Commission any petition or supplement to a petition that the Secretary determines was submitted with the primary purpose of delaying approval of an application. Such procedures shall include notification to the petitioner by the Secretary.'';

(D) by striking subparagraph (F);

(E) by redesignating subparagraphs (G) through (I) as subparagraphs (F) through (H), respectively; and

(F) in subparagraph (H), as so redesignated, by striking ''submission of this petition'' and inserting ''submission of this document'';

(2) in paragraph (2)—

(A) by redesignating subparagraphs (A) through (C) as subparagraphs (C) through (E), respectively;

(B) by inserting before subparagraph (C), as so redesignated, the following:

''(A) IN GENERAL.—A person shall submit a petition to the Secretary under paragraph (1) before filing a civil action in which the person seeks to set aside, delay, rescind, withdraw, or prevent submission, review, or approval of an application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act. Such petition and any supplement to such a petition shall describe all information and arguments that form the basis of the relief requested in any civil action described in the previous sentence.

"(B) TIMELY SUBMISSION OF CITIZEN PETITION.—A petition and any supplement to a petition shall be submitted within 60 days after the person knew, or reasonably should have known, the information that forms the basis of the request made in the petition or supplement.";

(C) in subparagraph (C), as so redesignated—

(i) in the heading, by striking "WITHIN 150 DAYS";

(ii) in clause (i), by striking "during the 150-day period referred to in paragraph (1)(F),"; and

(iii) by amending clause (ii) to read as follows:

"(ii) on or after the date that is 151 days after the date of submission of the petition, the Secretary approves or has approved the application that is the subject of the petition without having made such a final decision.";

(D) by amending subparagraph (D), as so redesignated, to read as follows:

"(D) DISMISSAL OF CERTAIN CIVIL ACTIONS.—

"(i) PETITION.—If a person files a civil action against the Secretary in which a person seeks to set aside, delay, rescind, withdraw, or prevent submission, review, or approval of an application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act without complying with the requirements of subparagraph (A), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies.

"(ii) TIMELINESS.—If a person files a civil action against the Secretary in which a person seeks to set aside, delay, rescind, withdraw, or prevent submission, review, or approval of an application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act without complying with the requirements of subparagraph (B), the court shall dismiss with prejudice the action for failure to timely file a petition.

''(iii) FINAL RESPONSE.—If a civil action is filed against the Secretary with respect to any issue raised in a petition timely filed under paragraph (1) in which the petitioner requests that the Secretary take any form of action that could, if taken, set aside, delay, rescind, withdraw, or prevent submission, review, or approval of an application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act before the Secretary has taken final agency action on the petition within the meaning of subparagraph (C), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies.''; and

(E) in clause (iii) of subparagraph (E), as so redesignated, by striking ''as defined under subparagraph (2)(A)'' and inserting ''within the meaning of subparagraph (C)''; and

(3) in paragraph (4)—

(A) by striking ''EXCEPTIONS'' and all that follows through ''This subsection does'' and inserting ''EXCEPTIONS.—This subsection does'';

(B) by striking subparagraph (B); and

(C) by redesignating clauses (i) and (ii) as subparagraphs (A) and (B), respectively, and adjusting the margins accordingly.

SEC. 204. PROTECTING ACCESS TO BIOLOGICAL PRODUCTS.

Section 351(k)(7) of the Public Health Service Act (42 U.S.C. 262(k)(7)) is amended by adding at the end the following:

''(D) DEEMED LICENSES.—

''(i) NO ADDITIONAL EXCLUSIVITY THROUGH DEEMING.—An approved application that is deemed to be a license for a biological product under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 shall not be treated as having been first licensed under subsection (a) for purposes of subparagraphs (A) and (B).

''(ii) APPLICATION OF LIMITATIONS ON EXCLUSIVITY.—Subparagraph (C) shall apply with respect to a reference product referred to in such subparagraph that was the subject of an approved application that was deemed to be a license pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

"(iii) APPLICABILITY.—The exclusivity periods described in section 527, section 505A(b)(1)(A)(ii), and section 505A(c)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act shall continue to apply to a biological product after an approved application for the biological product is deemed to be a license for the biological product under subsection (a) pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.".

SEC. 205. PREVENTING BLOCKING OF GENERIC DRUGS.

(a) IN GENERAL.—Section 505(j)(5)(B)(iv)(I) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)(I)) is amended—

(1) by striking "180 days after the date" and inserting "180 days after the earlier of the following:

"(aa) The date"; and

(2) by adding at the end the following:

"(bb) The date on which all of the following conditions are first met, provided no application submitted by any first applicant is approved on or before such date:

''(AA) An application for the drug submitted by an applicant other than a first applicant has received tentative approval and could receive approval, if no first applicant were eligible for 180-day exclusivity under this clause, and such applicant has not entered into an agreement that would prevent commercial marketing upon approval and has submitted a notification to the Secretary documenting that it has not entered into an agreement that would prevent commercial marketing.

''(BB) Thirty-three months have passed since the date of submission of an application for the drug by one first applicant, if there is only one first applicant, or, in the case of more than one first applicant, 33 months have passed since the date of submission of all such applications.

''(CC) Approval of an application for the drug submitted by at least one

first applicant would not be precluded under clause (iii).''.

(b) INFORMATION.—Not later than 60 days of the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall publish, as appropriate and available, information sufficient to allow applicants to assess whether the conditions described in subitems (AA) through (CC) of section 505(j)(5)(B)(iv)(I)(bb) of the Federal Food, Drug, and Cosmetic Act (as amended by subsection (a)) have been or will be satisfied for all applications where the exclusivity period under (iv)(I) of section 505(j)(5)(B) of the Federal Food, Drug, and Cosmetic Act (as so amended) has not expired, and shall provide updates to reflect the most recent information available to the Secretary.

SEC. 206. EDUCATION ON BIOLOGICAL PRODUCTS.

Subpart 1 of part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended by adding at the end the following:

''SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.

''(a) INTERNET WEBSITE.—

''(1) IN GENERAL.—The Secretary may maintain and operate an internet website to provide educational materials for health care providers, patients,

and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

''(2) CONTENT.—Educational materials provided under paragraph (1) may include—

''(A) explanations of key statutory and regulatory terms, including 'biosimilar' and 'interchangeable', and clarification regarding the use of interchangeable biosimilar biological products;

''(B) information related to development programs for biological products, including biosimilar biological products and interchangeable biosimilar biological products and relevant clinical considerations for prescribers, which may include, as appropriate and applicable, information related to the comparability of such biological products;

''(C) an explanation of the process for reporting adverse events for biological products, including biosimilar biological products and interchangeable biosimilar biological products; and

"(D) an explanation of the relationship between biosimilar biological products and interchangeable biosimilar biological products licensed under section 351(k) and reference products (as defined in section 351(i)), including the standards for review and licensing of each such type of biological product.

"(3) FORMAT.—The educational materials provided under paragraph (1) may be—

"(A) in formats such as webinars, continuing medical education modules, videos, fact sheets, infographics, stakeholder toolkits, or other formats as appropriate and applicable; and

"(B) tailored for the unique needs of health care providers, patients, caregivers, and other audiences, as the Secretary determines appropriate.

"(4) OTHER INFORMATION.—In addition to the information described in paragraph (2), the Secretary shall continue to publish the following information:

"(A) The action package of each biological product licensed under subsection (a) or (k).

''(B) The summary review of each biological product licensed under subsection (a) or (k).

''(5) CONFIDENTIAL AND TRADE SECRET INFORMATION.—This subsection does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter described in section 552(b) of title 5.

''(b) CONTINUING EDUCATION.—The Secretary shall advance education and awareness among health care providers regarding biological products, including biosimilar biological products and interchangeable biosimilar biological products, as appropriate, including by developing or improving continuing medical education programs that advance the education of such providers on the prescribing of, and relevant clinical considerations with respect to, biological products, including biosimilar biological products and interchangeable biosimilar biological products.''.

SEC. 207. BIOLOGICAL PRODUCT INNOVATION.

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

(1) by striking ''except that a product'' and inserting ''except that—

''(1) a product'';

(2) by striking ''Act.'' and inserting ''Act; and''; and

(3) by adding at the end the following:

''(2) no requirement under such Act regarding an official compendium (as defined in section 201(j) of such Act), or other reference in such Act to an official compendium (as so defined), shall apply with respect to a biological product subject to regulation under this section.''.

SEC. 208. CLARIFYING THE MEANING OF NEW CHEMICAL ENTITY.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 505 (21 U.S.C. 355)—

(A) in subsection (c)(3)(E), by striking ''active ingredient (including any ester or salt of the active ingredient)'' each place it appears and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(B) in subsection (j)(5)(F), by striking ''active ingredient (including any ester or salt of the active ingredient)'' each place it appears and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of

Federal Regulations (or any successor regulations))'';

(C) in subsection (l)(2)(A)—

(i) by amending clause (i) to read as follows:

''(i) not later than 30 days after the date of approval of such applications—

''(I) for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

''(II) for a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act; and''; and

(ii) in clause (ii), by inserting ″or biological product″ before the period;

(D) by amending subsection (s) to read as follows:

''(s) REFERRAL TO ADVISORY COMMITTEE.—The Secretary shall—

''(1) refer a drug or biological product to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee prior to the approval of such drug or biological if it is—

''(A) a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

''(B) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act; or

''(2) if the Secretary does not refer a drug or biological product described in paragraph (1) to a Food and Drug Administration advisory committee prior to such approval, provide in the action letter on the application for the drug or biological product a summary of the reasons why the Secretary did not refer the drug or biological product to an advisory committee prior to approval.''; and

(E) in subsection (u)(1), in the matter preceding subparagraph (A)—

(i) by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))''; and

(ii) by striking ''same active ingredient'' and inserting ''same active moiety'';

(2) in section 512(c)(2)(F) (21 U.S.C. 360b(c)(2)(F)), by striking ''active ingredient (including any ester or salt of the active ingredient)'' each place it appears and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(3) in section 524(a)(4) (21 U.S.C. 360n(a)(4)), by amending subparagraph (C) to read as follows:

''(C) is for—

''(i) a human drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under section 505(b)(1); or

"(ii) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act.";

(4) in section 529(a)(4) (21 U.S.C. 21 U.S.C. 360ff(a)(4)), by striking subparagraphs (A) and (B) and inserting the following:

"(A) is for a drug or biological product that is for the prevention or treatment of a rare pediatric disease;

"(B)(i) is for such a drug—

"(I) that contains no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been previously approved in any other application under subsection (b)(1), (b)(2), or (j) of section 505; and

"(II) that is the subject of an application submitted under section 505(b)(1); or

"(ii) or is for such a biological product—

"(I) that contains no active ingredient that has been previously approved in any other application under section 351(a) or

351(k) of the Public Health Service Act; and

"(II) that is the subject of an application submitted under section 351(a) of the Public Health Service Act;"; and

(5) in section 565A(a)(4) (21 U.S.C. 360bbb–4a(a)(4)), by amending subparagraph (D) to read as follows:

"(D) is for—

"(i) a human drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under section 505(b)(1); or

"(ii) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act.".

(b) TECHNICAL CORRECTIONS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq) is amended—

(1) in section 505 (21 U.S.C. 355)—

(A) in subsection (c)(3)(E), by repealing clause (i); and

(B) in subsection (j)(5)(F), by repealing clause (i); and

(2) in section 505A(c)(1)(A)(i)(II) (21 U.S.C. 355a(c)(1)(A)(i)), by striking ''(c)(3)(D)'' and inserting ''(c)(3)(E)''.

SEC. 209. STREAMLINING THE TRANSITION OF BIOLOGICAL PRODUCTS.

Section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148) is amended by adding at the end the following: ''With respect to an application for a biological product submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) with a filing date that is not later than September 23, 2019, and that does not receive final approval on or before March 23, 2020, such application shall be deemed to be withdrawn and the Secretary shall refund the fee paid under section 736(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)(1)(B)). Notwithstanding any such withdrawal of the drug application, the Secretary shall consider any previously conducted scientific review and accelerate review of any such subsequent application with respect to such biological product under section 351 of the Public Health Service Act (42 U.S.C. 262). The Secretary shall provide

additional assistance to the sponsor or manufacturer of such application.''.

SEC. 210. ORPHAN DRUG CLARIFICATION.

Section 527(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(c)) is amended by adding at the end the following:

''(3) APPLICABILITY.—This subsection applies to any drug designated under section 526 for which an application was approved under section 505 of this Act or licensed under section 351 of the Public Health Service Act after the date of enactment of the FDA Reauthorization Act of 2017, regardless of the date of on which such drug was designated under section 526.''.

SEC. 211. PROMPT APPROVAL OF DRUGS RELATED TO SAFETY INFORMATION.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(z) PROMPT APPROVAL OF DRUGS WHEN SAFETY INFORMATION IS ADDED TO LABELING.—

''(1) GENERAL RULE.—A drug for which an application has been submitted or approved under subsection (b)(2) or (j) shall not be considered ineligible for approval under this section or misbranded under

section 502 on the basis that the labeling of the drug omits safety information, including contraindications, warnings, precautions, dosing, administration, or other information pertaining to safety, when the omitted safety information is protected by exclusivity under clause (iii) or (iv) of subsection (j)(5)(F), clause (iii) or (iv) of subsection (c)(3)(E), or section 527(a), or by an extension of such exclusivity under section 505A or 505E.

''(2) LABELING.—Notwithstanding clauses (iii) and (iv) of subsection (j)(5)(F), clauses (iii) and (iv) of subsection (c)(3)(E), or section 527, the Secretary shall require that the labeling of a drug approved pursuant to an application submitted under subsection (b)(2) or (j) that omits safety information described in paragraph (1) include a statement of any appropriate safety information that the Secretary considers necessary to assure safe use.

''(3) AVAILABILITY AND SCOPE OF EXCLUSIVITY.—This subsection does not affect—

''(A) the availability or scope of exclusivity or an extension of exclusivity described in subparagraph (A) or (B) of section 505A(o)(3);

''(B) the question of the eligibility for approval under this section of any application de-

scribed in subsection (b)(2) or (j) that omits any other aspect of labeling protected by exclusivity under—

"(i) clause (iii) or (iv) of subsection (j)(5)(F);

"(ii) clause (iii) or (iv) of subsection (c)(3)(E); or

"(iii) section 527(a); or

"(C) except as expressly provided in paragraphs (1) and (2), the operation of this section or section 527.".

SEC. 212. CONDITIONS OF USE FOR BIOSIMILAR BIOLOGICAL PRODUCTS.

Section 351(k)(2)(A)(iii) of the Public Health Service Act (42 U.S.C. 262(k)(2)(A)(iii) is amended—

(1) in subclause (I), by striking "; and" and inserting a semicolon;

(2) in subclause (II), by striking the period and inserting "; and"; and

(3) by adding at the end the following:

"(III) may include information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological

product have been previously approved for the reference product.''.

SEC. 213. MODERNIZING THE LABELING OF CERTAIN GENERIC DRUGS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503C the following:

''SEC. 503D. PROCESS TO UPDATE LABELING FOR CERTAIN DRUGS.

''(a) DEFINITIONS.—For purposes of this section:

''(1) The term 'covered drug' means a drug approved under section 505(c)—

''(A) for which there are no unexpired patents included in the list under section 505(j)(7) and no unexpired period of exclusivity;

''(B) for which the approval of the application has been withdrawn for reasons other than safety or effectiveness; and

''(C) for which, with respect to the labeling—

''(i) new scientific evidence is available regarding the conditions of use of the drug;

"(ii) there is a relevant accepted use in clinical practice that is not reflected in the approved labeling; or

"(iii) the labeling of such drug does not reflect current legal and regulatory requirements.

"(2) The term 'period of exclusivity', with respect to a drug approved under section 505(c), means any period of exclusivity under clause (ii), (iii), or (iv) of section 505(c)(3)(E), clause (ii), (iii), or (iv) of section 505(j)(5)(F), or section 505A, 505E, or 527.

"(3) The term 'generic version' means a drug approved under section 505(j) whose reference drug is a covered drug.

"(4) The term 'relevant accepted use' means a use for a drug in clinical practice that is supported by scientific evidence that appears to the Secretary to meet the standards for approval under section 505.

"(5) The term 'selected drug' means a covered drug for which the Secretary has determined through the process under subsection (c) that the labeling should be changed.

''(b) IDENTIFICATION OF COVERED DRUGS.—The Secretary may identify covered drugs for which labeling updates would provide a public health benefit. To assist in identifying covered drugs, the Secretary may do one or both of the following:

''(1) Enter into cooperative agreements or contracts with public or private entities to review the available scientific evidence concerning such drugs.

''(2) Seek public input concerning such drugs, including input on whether there is a relevant accepted use in clinical practice that is not reflected in the approved labeling of such drugs or whether new scientific evidence is available regarding the conditions of use for such drug, by—

''(A) holding one or more public meetings;

''(B) opening a public docket for the submission of public comments; or

''(C) other means, as the Secretary determines appropriate.

''(c) SELECTION OF DRUGS FOR UPDATING.—If the Secretary determines, with respect to a covered drug, that the available scientific evidence meets the standards under section 505 for adding or modifying information to the labeling or providing supplemental information to the la-

beling regarding the use of the covered drug, the Secretary may initiate the process under subsection (d).

''(d) INITIATION OF THE PROCESS OF UPDATING.—If the Secretary determines that labeling changes are appropriate for a selected drug pursuant to subsection (c), the Secretary shall provide notice to the holders of approved applications for a generic version of such drug that—

''(1) summarizes the findings supporting the determination of the Secretary that the available scientific evidence meets the standards under section 505 for adding or modifying information or providing supplemental information to the labeling of the covered drug pursuant to subsection (c);

''(2) provides a clear statement regarding the additional, modified, or supplemental information for such labeling, according to the determination by the Secretary (including, as applicable, modifications to add the relevant accepted use to the labeling of the drug as an additional indication for the drug); and

''(3) states whether the statement under paragraph (2) applies to the selected drug as a class of covered drugs or only to a specific drug product.

''(e) RESPONSE TO NOTIFICATION.—Within 30 days of receipt of notification provided by the Secretary pursu-

ant to subsection (d), the holder of an approved application for a generic version of the selected drug shall—

"(1) agree to change the approved labeling to reflect the additional, modified, or supplemental information the Secretary has determined to be appropriate; or

"(2) notify the Secretary that the holder of the approved application does not believe that the requested labeling changes are warranted and submit a statement detailing the reasons why such changes are not warranted.

"(f) REVIEW OF APPLICATION HOLDER'S RESPONSE.—

"(1) IN GENERAL.—Upon receipt of the application holder's response, the Secretary shall promptly review each statement received under subsection (e)(2) and determine which labeling changes pursuant to the Secretary's notice under subsection (d) are appropriate, if any. If the Secretary disagrees with the reasons why such labeling changes are not warranted, the Secretary shall provide opportunity for discussions with the application holders to reach agreement on whether the labeling for the covered drug should be updated to reflect current scientific

evidence, and if so, the content of such labeling changes.

''(2) CHANGES TO LABELING.—After considering all responses from the holder of an approved application under paragraph (1) or (2) of subsection (e), and any discussion under paragraph (1), the Secretary may order such holder to make the labeling changes the Secretary determines are appropriate. Such holder of an approved application shall—

''(A) update its paper labeling for the drug at the next printing of that labeling;

''(B) update any electronic labeling for the drug within 30 days; and

''(C) submit the revised labeling through the form, 'Supplement—Changes Being Effected'.

''(g) VIOLATION.—If the holder of an approved application for the generic version of the selected drug does not comply with the requirements of subsection (f)(2), such generic version of the selected drug shall be deemed to be misbranded under section 502.

''(h) LIMITATIONS; GENERIC DRUGS.—

''(1) IN GENERAL.—With respect to any labeling change required under this section, the generic

version shall be deemed to have the same conditions of use and the same labeling as a reference drug for purposes of clauses (i) and (v) of section 505(j)(2)(A). Any labeling change so required shall not have any legal effect for the applicant that is different than the legal effect that would have resulted if a supplemental application had been submitted and approved to conform the labeling of the generic version to a change in the labeling of the reference drug.

''(2) SUPPLEMENTAL APPLICATIONS.—Changes to labeling made in accordance with this paragraph shall not be eligible for an exclusivity period under this Act.

''(i) DRUG PRODUCT CLASSES.—In the case of a selected drug for which the labeling changes ordered by the Secretary under subsection (d)(2) are required for a class of covered drugs, such labeling changes shall be made for generic versions of such drug in that class.

''(j) RULES OF CONSTRUCTION.—

''(1) APPROVAL STANDARDS.—This section shall not be construed as altering the applicability of the standards for approval of an application under section 505. No order shall be issued under this subsection unless the evidence supporting the changed

labeling meets the standards for approval applicable to any change to labeling under section 505.

''(2) REMOVAL OF INFORMATION.—Nothing in this section shall be construed to give the Secretary additional authority to remove approved indications for drugs, other than the authority described in this section.

''(k) REPORTS.—Not later than 4 years after the date of the enactment of the Lower Health Care Costs Act and every 4 years thereafter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report that—

''(1) describes the actions of the Secretary under this section, including—

''(A) the number of covered drugs and description of the types of drugs the Secretary has selected for labeling changes and the rationale for such recommended changes; and

''(B) the number of times the Secretary entered into discussions concerning a disagreement with an application holder or holders and a summary of the decision regarding a labeling change, if any; and

''(2) includes any recommendations of the Secretary for modifying the program under this section.''.

SEC. 214. ACTIONS FOR DELAYS OF GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) DEFINITIONS.—In this section—

(1) the term ''commercially reasonable, market-based terms'' means—

(A) a nondiscriminatory price for the sale of the covered product at or below, but not greater than, the most recent wholesale acquisition cost for the drug, as defined in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B));

(B) a schedule for delivery that results in the transfer of the covered product to the eligible product developer consistent with the timing under subsection (b)(2)(A)(iv); and

(C) no additional conditions are imposed on the sale of the covered product;

(2) the term ''covered product''—

(A) means—

(i) any drug approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 355) or biological product licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262);

(ii) any combination of a drug or biological product described in clause (i); or

(iii) when reasonably necessary to support approval of an application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), or section 351 of the Public Health Service Act (42 U.S.C. 262), as applicable, or otherwise meet the requirements for approval under either such section, any product, including any device, that is marketed or intended for use with such a drug or biological product; and

(B) does not include any drug or biological product that appears on the drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e), unless—

(i) the drug or biological product has been on the drug shortage list in effect

under such section 506E continuously for more than 6 months; or

(ii) the Secretary determines that inclusion of the drug or biological product as a covered product is likely to contribute to alleviating or preventing a shortage.

(3) the term ''device'' has the meaning given the term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321);

(4) the term ''eligible product developer'' means a person that seeks to develop a product for approval pursuant to an application for approval under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or for licensing pursuant to an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k));

(5) the term ''license holder'' means the holder of an application approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or the holder of a license under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) for a covered product;

(6) the term ''REMS'' means a risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1);

(7) the term ''REMS with ETASU'' means a REMS that contains elements to assure safe use under section 505–1(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f));

(8) the term ''Secretary'' means the Secretary of Health and Human Services;

(9) the term ''single, shared system of elements to assure safe use'' means a single, shared system of elements to assure safe use under section 505–1(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f)); and

(10) the term ''sufficient quantities'' means an amount of a covered product that the eligible product developer determines allows it to—

(A) conduct testing to support an application under—

(i) subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); or

(ii) section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)); and

(B) fulfill any regulatory requirements relating to approval of such an application.

(b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFICIENT QUANTITIES OF A COVERED PRODUCT.—

(1) IN GENERAL.—An eligible product developer may bring a civil action against the license holder for a covered product seeking relief under this subsection in an appropriate district court of the United States alleging that the license holder has declined to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms.

(2) ELEMENTS.—

(A) IN GENERAL.—To prevail in a civil action brought under paragraph (1), an eligible product developer shall prove, by a preponderance of the evidence—

(i) that—

(I) the covered product is not subject to a REMS with ETASU; or

(II) if the covered product is subject to a REMS with ETASU—

(aa) the eligible product developer has obtained a covered product authorization from the Secretary in accordance with subparagraph (B); and

(bb) the eligible product developer has provided a copy of the covered product authorization to the license holder;

(ii) that, as of the date on which the civil action is filed, the product developer has not obtained sufficient quantities of the covered product on commercially reasonable, market-based terms;

(iii) that the eligible product developer has submitted a written request to purchase sufficient quantities of the covered product to the license holder, and such request—

(I) was sent to a named corporate officer of the license holder;

(II) was made by certified or registered mail with return receipt requested;

(III) specified an individual as the point of contact for the license holder to direct communications related to the sale of the covered product to the eligible product developer and a means for electronic and written communications with that individual; and

(IV) specified an address to which the covered product was to be shipped upon reaching an agreement to transfer the covered product; and

(iv) that the license holder has not delivered to the eligible product developer sufficient quantities of the covered product on commercially reasonable, market-based terms—

(I) for a covered product that is not subject to a REMS with ETASU, by the date that is 31 days after the date on which the license holder received the request for the covered product; and

(II) for a covered product that is subject to a REMS with ETASU, by 31 days after the later of—

(aa) the date on which the license holder received the request for the covered product; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with subparagraph (B).

(B) AUTHORIZATION FOR COVERED PRODUCT SUBJECT TO A REMS WITH ETASU.—

(i) REQUEST.—An eligible product developer may submit to the Secretary a written request for the eligible product developer to be authorized to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU.

(ii) AUTHORIZATION.—Not later than 120 days after the date on which a request under clause (i) is received, the Secretary shall, by written notice, authorize the eligible product developer to obtain sufficient quantities of an individual covered product

subject to a REMS with ETASU for purposes of—

(I) development and testing that does not involve human clinical trials, if the eligible product developer has agreed to comply with any conditions the Secretary determines necessary; or

(II) development and testing that involves human clinical trials, if the eligible product developer has—

(aa)(AA) submitted protocols, informed consent documents, and informational materials for testing that include protections that provide safety protections comparable to those provided by the REMS for the covered product; or

(BB) otherwise satisfied the Secretary that such protections will be provided; and

(bb) met any other requirements the Secretary may establish.

(iii) NOTICE.—A covered product authorization issued under this subparagraph shall state that the provision of the covered product by the license holder under the terms of the authorization will not be a violation of the REMS for the covered product.

(3) AFFIRMATIVE DEFENSE.—In a civil action brought under paragraph (1), it shall be an affirmative defense, on which the defendant has the burden of persuasion by a preponderance of the evidence—

(A) that, on the date on which the eligible product developer requested to purchase sufficient quantities of the covered product from the license holder—

(i) neither the license holder nor any of its agents, wholesalers, or distributors was engaged in the manufacturing or commercial marketing of the covered product; and

(ii) neither the license holder nor any of its agents, wholesalers, or distributors otherwise had access to inventory of the covered product to supply to the eligible

product developer on commercially reasonable, market-based terms;

(B) that—

(i) the license holder sells the covered product through agents, distributors, or wholesalers;

(ii) the license holder has placed no restrictions, explicit or implicit, on its agents, distributors, or wholesalers to sell covered products to eligible product developers; and

(iii) the covered product can be purchased by the eligible product developer in sufficient quantities on commercially reasonable, market-based terms from the agents, distributors, or wholesalers of the license holder; or

(C) that the license holder made an offer to the individual specified pursuant to paragraph (2)(A)(iii)(III), by a means of communication (electronic, written, or both) specified pursuant to such paragraph, to sell sufficient quantities of the covered product to the eligible product developer at commercially reasonable market-based terms—

(i) for a covered product that is not subject to a REMS with ETASU, by the date that is 14 days after the date on which the license holder received the request for the covered product, and the eligible product developer did not accept such offer by the date that is 7 days after the date on which the eligible product developer received such offer from the license holder; or

(ii) for a covered product that is subject to a REMS with ETASU, by the date that is 20 days after the date on which the license holder received the request for the covered product, and the eligible product developer did not accept such offer by the date that is 10 days after the date on which the eligible product developer received such offer from the license holder.

(4) REMEDIES.—

(A) IN GENERAL.—If an eligible product developer prevails in a civil action brought under paragraph (1), the court shall—

(i) order the license holder to provide to the eligible product developer without

delay sufficient quantities of the covered product on commercially reasonable, market-based terms;

(ii) award to the eligible product developer reasonable attorney's fees and costs of the civil action; and

(iii) award to the eligible product developer a monetary amount sufficient to deter the license holder from failing to provide eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms, if the court finds, by a preponderance of the evidence—

(I) that the license holder delayed providing sufficient quantities of the covered product to the eligible product developer without a legitimate business justification; or

(II) that the license holder failed to comply with an order issued under clause (i).

(B) MAXIMUM MONETARY AMOUNT.—A monetary amount awarded under subparagraph (A)(iii) shall not be greater than the revenue

that the license holder earned on the covered product during the period—

(i) beginning on—

(I) for a covered product that is not subject to a REMS with ETASU, the date that is 31 days after the date on which the license holder received the request; or

(II) for a covered product that is subject to a REMS with ETASU, the date that is 31 days after the later of—

(aa) the date on which the license holder received the request; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with paragraph (2)(B); and

(ii) ending on the date on which the eligible product developer received sufficient quantities of the covered product.

(C) AVOIDANCE OF DELAY.—The court may issue an order under subparagraph (A)(i) before conducting further proceedings that may be necessary to determine whether the eligible product developer is entitled to an award under clause (ii) or (iii) of subparagraph (A), or the amount of any such award.

(c) LIMITATION OF LIABILITY.—A license holder for a covered product shall not be liable for any claim under Federal, State, or local law arising out of the failure of an eligible product developer to follow adequate safeguards to assure safe use of the covered product during development or testing activities described in this section, including transportation, handling, use, or disposal of the covered product by the eligible product developer.

(d) NO VIOLATION OF REMS.—Section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) is amended by adding at the end the following new subsection:

''(l) PROVISION OF SAMPLES NOT A VIOLATION OF STRATEGY.—The provision of samples of a covered product to an eligible product developer (as those terms are defined in section 214(a) of the Lower Health Care Costs Act) shall not be considered a violation of the require-

ments of any risk evaluation and mitigation strategy that may be in place under this section for such drug.''.

(e) RULE OF CONSTRUCTION.—

(1) DEFINITION.—In this subsection, the term ''antitrust laws''—

(A) has the meaning given the term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12); and

(B) includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section applies to unfair methods of competition.

(2) ANTITRUST LAWS.—Nothing in this section shall be construed to limit the operation of any provision of the antitrust laws.

(f) REMS APPROVAL PROCESS FOR SUBSEQUENT FILERS.—Section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1), as amended by subsection (d), is further amended—

(1) in subsection (g)(4)(B)—

(A) in clause (i) by striking ''or'' after the semicolon;

(B) in clause (ii) by striking the period at the end and inserting ''; or''; and

(C) by adding at the end the following:

"(iii) accommodate different, comparable aspects of the elements to assure safe use for a drug that is the subject of an application under section 505(j), and the applicable listed drug.";

(2) in subsection (i)(1), by striking subparagraph (C) and inserting the following:

"(C)(i) Elements to assure safe use, if required under subsection (f) for the listed drug, which, subject to clause (ii), for a drug that is the subject of an application under section 505(j) may use—

"(I) a single, shared system with the listed drug under subsection (f); or

"(II) a different, comparable aspect of the elements to assure safe use under subsection (f).

"(ii) The Secretary may require a drug that is the subject of an application under section 505(j) and the listed drug to use a single, shared system under subsection (f), if the Secretary determines that no different, comparable aspect of the elements to assure safe use could satisfy the requirements of subsection (f).";

(3) in subsection (i), by adding at the end the following:

''(3) SHARED REMS.—If the Secretary approves, in accordance with paragraph (1)(C)(i)(II), a different, comparable aspect of the elements to assure safe use under subsection (f) for a drug that is the subject of an abbreviated new drug application under section 505(j), the Secretary may require that such different comparable aspect of the elements to assure safe use can be used with respect to any other drug that is the subject of an application under section 505(j) or 505(b) that references the same listed drug.''; and

(4) by adding at the end the following:

''(m) SEPARATE REMS.—When used in this section, the terms 'different, comparable aspect of the elements to assure safe use' or 'different, comparable approved risk evaluation and mitigation strategies' means a risk evaluation and mitigation strategy for a drug that is the subject of an application under section 505(j) that uses different methods or operational means than the strategy required under subsection (a) for the applicable listed drug, or other application under section 505(j) with the same such listed drug, but achieves the same level of safety as such strategy.''.

(g) RULE OF CONSTRUCTION.—Nothing in this section, the amendments made by this section, or in section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1), shall be construed as—

(1) prohibiting a license holder from providing an eligible product developer access to a covered product in the absence of an authorization under this section; or

(2) in any way negating the applicability of a REMS with ETASU, as otherwise required under such section 505–1, with respect to such covered product.

TITLE III—IMPROVING TRANSPARENCY IN HEALTH CARE

SEC. 301. INCREASING TRANSPARENCY BY REMOVING GAG CLAUSES ON PRICE AND QUALITY INFORMATION.

Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–11 et seq.), as amended by section 103, is amended by adding at the end the following:

"SEC. 2729B. INCREASING TRANSPARENCY BY REMOVING GAG CLAUSES ON PRICE AND QUALITY INFORMATION.

"(a) INCREASING PRICE AND QUALITY TRANSPARENCY FOR PLAN SPONSORS AND GROUP AND INDIVIDUAL MARKET AND CONSUMERS.—

"(1) GROUP HEALTH PLANS.—A group health plan or health insurance issuer offering group health insurance coverage may not enter into an agreement with a health care provider, network or association of providers, third-party administrator, or other service provider offering access to a network of providers that would directly or indirectly restrict a group health plan or health insurance issuer from—

"(A) providing provider-specific cost or quality of care information, through a consumer engagement tool or any other means, to referring providers, the plan sponsor, enrollees, or eligible enrollees of the plan or coverage;

"(B) electronically accessing de-identified claims and encounter data for each enrollee in the plan or coverage, upon request and consistent with the privacy regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act, the amendments to this Act made by the Ge-

netic Information Nondiscrimination Act of 2008, and the Americans with Disabilities Act of 1990, with respect to the applicable health plan or health insurance coverage, including, on a per claim basis—

''(i) financial information, such as the allowed amount, or any other claim-related financial obligations included in the provider contract;

''(ii) provider information, including name and clinical designation;

''(iii) service codes; or

''(iv) any other data element normally included in claim or encounter transactions when received by a plan or issuer; or

''(C) sharing data described in subparagraph (A) or (B) with a business associate as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations), consistent with the privacy regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act, the amendments to this Act made by the Genetic Information Nondiscrimination Act of

2008, and the Americans with Disabilities Act of 1990.

''(2) INDIVIDUAL HEALTH INSURANCE COVERAGE.—A health insurance issuer offering individual health insurance coverage may not enter into an agreement with a health care provider, network or association of providers, or other service provider offering access to a network of providers that would directly or indirectly restrict the health insurance issuer from—

''(A) providing provider-specific price or quality of care information, through a consumer engagement tool or any other means, to referring providers, enrollees, or eligible enrollees of the plan or coverage; or

''(B) sharing, for plan design, plan administration, and plan, financial, legal, and quality improvement activities, data described in subparagraph (A) with a business associate as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations), consistent with the privacy regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act, the amendments to this Act made by the Ge-

netic Information Nondiscrimination Act of 2008, and the Americans with Disabilities Act of 1990.

''(3) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in paragraph (1)(A) or (2)(A) prevents a health care provider, network or association of providers, or other service provider from placing reasonable restrictions on the public disclosure of the information described in such paragraphs (1) and (2).

''(4) ATTESTATION.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall annually submit to, as applicable, the applicable authority described in section 2723 or the Secretary of Labor, an attestation that such plan or issuer is in compliance with the requirements of this subsection.

''(5) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to otherwise limit group health plan, plan sponsor, or health insurance issuer access to data currently permitted under the privacy regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act, the amendments to this Act made by the Genetic Information Nondiscrimination Act of

2008, and the Americans with Disabilities Act of 1990.''.

SEC. 302. BANNING ANTICOMPETITIVE TERMS IN FACILITY AND INSURANCE CONTRACTS THAT LIMIT ACCESS TO HIGHER QUALITY, LOWER COST CARE.

(a) IN GENERAL.—Section 2729B of the Public Health Service Act, as added by section 301, is amended by adding at the end the following:

''(b) PROTECTING HEALTH PLANS NETWORK DESIGN FLEXIBILITY.—

''(1) IN GENERAL.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall not enter into an agreement with a provider, network or association of providers, or other service provider offering access to a network of service providers if such agreement, directly or indirectly—

''(A) restricts the group health plan or health insurance issuer from—

''(i) directing or steering enrollees to other health care providers; or

''(ii) offering incentives to encourage enrollees to utilize specific health care providers; or

''(B) requires the group health plan or health insurance issuer to enter into any additional contract with an affiliate of the provider, such as an affiliate of the provider, as a condition of entering into a contract with such provider;

''(C) requires the group health plan or health insurance issuer to agree to payment rates or other terms for any affiliate not party to the contract of the provider involved; or

''(D) restricts other group health plans or health insurance issuers not party to the contract from paying a lower rate for items or services than the contracting plan or issuer pays for such items or services.

''(2) ADDITIONAL REQUIREMENT FOR SELF-INSURED PLANS.—A self-insured group health plan shall not enter into an agreement with a provider, network or association of providers, third-party administrator, or other service provider offering access to a network of providers if such agreement directly or indirectly requires the group health plan to certify, attest, or otherwise confirm in writing that the group health plan is bound by restrictive contracting terms between the service provider and a third-party

administrator that the group health plan is not party to, without a disclosure that such terms exist.

''(3) EXCEPTION FOR CERTAIN GROUP MODEL ISSUERS.—Paragraph (1)(A) shall not apply to a group health plan or health insurance issuer offering group or individual health insurance coverage with respect to—

''(A) a health maintenance organization (as defined in section 2791(b)(3)), if such health maintenance organization operates primarily through exclusive contracts with multi-specialty physician groups, nor to any arrangement between such a health maintenance organization and its affiliates; or

''(B) a value-based network arrangement, such as an exclusive provider network, accountable care organization, center of excellence, a provider sponsored health insurance issuer that operates primarily through aligned multi-specialty physician group practices or integrated health systems, or such other similar network arrangements as determined by the Secretary through rulemaking.

''(4) ATTESTATION.—A group health plan or health insurance issuer offering group or individual

health insurance coverage shall annually submit to, as applicable, the applicable authority described in section 2723 or the Secretary of Labor, an attestation that such plan or issuer is in compliance with the requirements of this subsection.

''(c) MAINTENANCE OF EXISTING HIPAA, GINA, AND ADA PROTECTIONS.—Nothing in this section shall modify, reduce, or eliminate the existing privacy protections and standards provided by reason of State and Federal law, including the requirements of parts 160 and 164 of title 45, Code of Federal Regulations (or any successor regulations).

''(d) REGULATIONS.—The Secretary, not later than 1 year after the date of enactment of the Lower Health Care Costs Act, shall promulgate regulations to carry out this section.

''(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit network design or cost or quality initiatives by a group health plan or health insurance issuer, including accountable care organizations, exclusive provider organizations, networks that tier providers by cost or quality or steer enrollees to centers of excellence, or other pay-for-performance programs.

''(f) CLARIFICATION WITH RESPECT TO ANTITRUST LAWS.—Compliance with this section does not constitute

compliance with the antitrust laws, as defined in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)).''.

(b) EFFECTIVE DATE.—Section 2729B of the Public Health Service Act (as added by section 301 and amended by subsection (a)) shall apply with respect to any contract entered into on or after the date that is 18 months after the date of enactment of this Act. With respect to an applicable contract that is in effect on the date of enactment of this Act, such section 2729B shall apply on the earlier of the date of renewal of such contract or 3 years after such date of enactment.

SEC. 303. DESIGNATION OF A NONGOVERNMENTAL, NONPROFIT TRANSPARENCY ORGANIZATION TO LOWER AMERICANS' HEALTH CARE COSTS.

(a) IN GENERAL.—Subpart C of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–91 et seq.), as amended by section 102, is further amended by adding at the end the following:

''SEC. 2796. DESIGNATION OF A NONGOVERNMENTAL, NONPROFIT TRANSPARENCY ORGANIZATION TO LOWER AMERICANS' HEALTH CARE COSTS.

''(a) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor, not later than 1 year after the date of enactment of the Lower Health Care Costs

Act, shall enter into a contract with a nonprofit entity to support the establishment and maintenance of a database that receives and utilizes health care claims information and related information and issues reports that are available to the public and authorized users, and are submitted to the Department of Health and Human Services.

''(b) REQUIREMENTS.—

''(1) IN GENERAL.—The database established under subsection (a) shall—

''(A) improve transparency by using de-identified health care data to—

''(i) inform patients about the cost, quality, and value of their care;

''(ii) assist providers and hospitals, as they work with patients, to make informed choices about care;

''(iii) enable providers, hospitals, and communities to improve services and outcomes for patients by benchmarking their performance against that of other providers, hospitals, and communities;

''(iv) enable purchasers, including employers, employee organizations, and health plans, to develop value-based purchasing models, improve quality, and reduce the

cost of health care and insurance coverage for enrollees;

''(v) enable employers and employee organizations to evaluate network design and construction, and the cost of care for enrollees;

''(vi) facilitate State-led initiatives to lower health care costs and improve quality; and

''(vii) promote competition based on quality and cost;

''(B) collect medical claims, prescription drug claims, and remittance data consistent with the protections and requirements of subsection (d);

''(C) be established in such a manner that allows the data collected pursuant to subparagraph (B) to be shared with any State all-payer claims database or regional database operated with authorization from States, at cost, using a standardized format, if such State or regional database also submits claims data to the database established under this section; and

''(D) be available to—

''(i) the Director of the Congressional Budget Office, the Comptroller General of the United States, the Executive Director of the Medicare Payment Advisory Commission, and the Executive Director of the Medicaid and CHIP Payment Advisory Commission, upon request, subject to the privacy and security requirements of authorized users under subsection (e)(2); and

''(ii) authorized users, including employers, employee organizations, providers, researchers, and policymakers, subject to subsection (e).

''(2) PRIVACY AND SECURITY; BREACH NOTIFICATIONS.—

''(A) REGULATIONS.—

''(i) IN GENERAL.—The Secretary shall issue regulations prescribing the extent to which, and the manner in which, the following rules (and any successors of such rules) shall apply to the activities under this section of an entity receiving a contract under subsection (a):

''(I) The Privacy Rule under part 160 and subparts A and E of part

164 of title 45, Code of Federal Regulations (or any successor regulations).

"(II) The Security Rule under part 160 and subparts A and C of part 164 of such title 45 (or any successor regulations).

"(III) The Breach Notification Rule under part 160 and subparts A and D of part 164 of such title 45 (or any successor regulations).

"(ii) SUPPLEMENTAL REGULATIONS.—In order to ensure data privacy and security and the notification of breaches, the Secretary may issue such supplemental regulations on the subjects of the rules listed under clause (i) as the Secretary determines appropriate to address differences between the activities described by this section and the activities covered by such rules.

"(B) ENFORCEMENT.—Section 1176 of Social Security Act shall apply with respect to a violation of this paragraph in the same manner such section 1176 applies to a violation of part C of title XI of the Social Security Act,

and the Secretary may include in the regulations promulgated under this section provisions to apply such section to this paragraph.

"(C) PROCEDURE.—

"(i) TIMING.—The Secretary shall issue the initial set of regulations under this paragraph not later than 1 year after the date of enactment of the Lower Health Care Costs Act.

"(ii) AUTHORITY TO USE INTERIM FINAL PROCEDURES.—The Secretary may make such initial set of regulations effective and final immediately upon issuance, on an interim basis, and provide for a period of public comment on such initial set of regulations after the date of publication.

"(D) REQUIREMENTS OF ENTITY.—The entity receiving the contract under this section shall—

"(i) not disclose to the public any individually identifiable health information or proprietary financial information;

"(ii) strictly limit staff access to the data to staff with appropriate training,

clearance, and background checks and require regular privacy and security training;

"(iii) maintain effective security standards for transferring data or making data available to authorized users;

"(iv) develop a process for providing access to data to authorized users, in a secure manner that maintains privacy and confidentiality of data; and

"(v) adhere to current best security practices with respect to the management and use of such data for health services research, in accordance with applicable Federal privacy law

"(3) CONSULTATION.—

"(A) ADVISORY COMMITTEE.—Not later than 180 days after the date of enactment of the Lower Health Care Costs Act, the Secretary shall convene an Advisory Committee (referred to in this section as the 'Committee'), consisting of 13 members, to advise the Secretary, the contracting entity, and Congress on the establishment, operations, and use of the database established under this section.

"(B) MEMBERSHIP.—

"(i) APPOINTMENT.—In accordance with clause (ii), the Secretary, in consultation with the Secretary of Labor and the Comptroller General of the United States shall, not later than 180 days after the date of enactment of the Lower Health Care Costs Act, appoint members to the Committee who have distinguished themselves in the fields of health services research, health economics, health informatics, or the governance of State all-payer claims databases, or who represent organizations likely to submit data to or use the database, including patients, employers, or employee organizations that sponsor group health plans, health care providers, health insurance issuers, or third-party administrators of group health plans. Such members shall serve 3-year terms on a staggered basis. Vacancies on the Committee shall be filled by appointment consistent with this subsection not later than 3 months after the vacancy arises.

"(ii) COMPOSITION.—In accordance with clause (i)—

"(I) the Secretary, in consultation with the Secretary of Labor, shall appoint to the Committee—

"(aa) 1 member selected by the Secretary, in coordination with the Secretary of Labor, to serve as the chair of the Committee;

"(bb) the Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services, or a designee of such Assistant Secretary;

"(cc) 1 representative of the Centers for Medicare & Medicaid Services;

"(dd) 1 representative of the Agency for Health Research and Quality;

"(ee) 1 representative of the Office for Civil Rights of the Department of Health and Human

Services with expertise in data privacy and security;

''(ff) 1 representative of the National Center for Health Statistics; and

''(gg) 1 representative of the Employee Benefits and Security Administration of the Department of Labor; and

''(II) the Comptroller General of the United States shall appoint to the Committee—

''(aa) 1 representative of an employer that sponsors a group health plan;

''(bb) 1 representative of an employee organization that sponsors a group health plan;

''(cc) 1 academic researcher with expertise in health economics or health services research;

''(dd) 1 consumer advocate; and

''(ee) 2 additional members.

''(C) DUTIES.—The Committee shall—

"(i) advise the Secretary on the management of the contract under subsection (a);

"(ii) assist and advise the entity receiving the contract under subsection (a) in establishing—

"(I) the scope and format of the data to be submitted under subsection (d);

"(II) best practices with respect to de-identification of data, as appropriate;

"(III) the appropriate uses of data by authorized users, including developing standards for the approval of requests by organizations to access and use the data; and

"(IV) the appropriate formats and methods for making reports and analyses based on the database to the public;

"(iii) conduct an annual review of whether data was used according to the appropriate uses as described in clause

(ii)(II), and advise the designated entity on using the data for authorized purposes;

''(iv) report, as appropriate, to the Secretary and Congress on the operation of the database and opportunities to better achieve the objectives of this section;

''(v) establish additional restrictions on researchers who receive compensation from entities described in subsection (e)(2)(B)(ii), in order to protect proprietary financial information; and

''(vi) establish objectives for research and public reporting.

''(4) STATE REQUIREMENTS.—A State may require health insurance issuers and other payers to submit claims data to the database established under this section, provided that such data is submitted to the entity awarded the contract under this section in a form and manner established by the Secretary, and pursuant to subsection (d)(4)(B).

''(5) SANCTIONS.—The Secretary shall take appropriate action to sanction users who attempt to reidentify data accessed pursuant to paragraph (1)(D).

''(e) CONTRACT REQUIREMENTS.—

''(1) COMPETITIVE PROCEDURES.—The Secretary shall enter into the contract under subsection (a) using full and open competition procedures pursuant to chapter 33 of title 41, United States Code.

''(2) ELIGIBLE ENTITIES.—To be eligible to enter into a contract described in subsection (a), an entity shall—

''(A) be a private nonprofit entity governed by a board that includes representatives of the academic research community and individuals with expertise in employer-sponsored insurance, research using health care claims data and actuarial analysis;

''(B) conduct its business in an open and transparent manner that provides the opportunity for public comment on its activities; and

''(C) agree to comply with any requirements imposed under the rulemaking described in subsection (d)(4)(A).

''(3) CONSIDERATIONS.—In awarding the contract under subsection (a), the Secretary shall consider an entity's experience in—

''(A) health care claims data collection, aggregation, quality assurance, analysis, and security;

''(B) supporting academic research on health costs, spending, and utilization for and by privately insured patients;

''(C) working with large health insurance issuers and third-party administrators to assemble a national claims database;

''(D) effectively collaborating with and engaging stakeholders to develop reports;

''(E) meeting budgets and timelines, including in connection with report generation; and

''(F) facilitating the creation of, or supporting, State all-payer claims databases.

''(4) CONTRACT TERM.—A contract awarded under this section shall be for a period of 5 years, and may be renewed after a subsequent competitive bidding process under this section.

''(5) TRANSITION OF CONTRACT.—If the Secretary, following a competitive process at the end of the contract period, selects a new entity to maintain the database, all data shall be transferred to the new entity according to a schedule and process to be determined by the Secretary. Upon termination of a contract, no entity may keep data held by the database or disclose such data to any entity other than

the entity so designated by the Secretary. The Secretary shall include enforcement terms in any contract with an organization chosen under this section, to ensure the timely transfer of all data, and any associated code or algorithms, to a new entity in the event of contract termination.

''(d) RECEIVING HEALTH INFORMATION.—

''(1) REQUIREMENTS.—

''(A) IN GENERAL.—The Secretary of Labor shall ensure that the applicable self-insured group health plan, through its third-party administrator, pharmacy benefit manager, or other entity designated by the group health plan, as applicable, electronically submits all claims data with respect to the plan, pursuant to subparagraph (B).

''(B) SCOPE OF INFORMATION AND FORMAT OF SUBMISSION.—The entity awarded the contract under subsection (a), in consultation with the Committee described in subsection (b)(3), and pursuant to the privacy and security requirements of subsection (b)(2), shall—

''(i) specify the data elements required to be submitted under subparagraph (A), which shall include all data related to

transactions described in subparagraphs (A) and (E) of section 1173(a)(2) of the Social Security Act, including all data elements normally present in such transactions when adjudicated, and enrollment information;

''(ii) specify the form and manner for such submissions, and the historical period to be included in the initial submission; and

''(iii) offer an automated submission option to minimize administrative burdens for entities required to submit data.

''(C) DE-IDENTIFICATION OF DATA.—The entity awarded the contract under subsection (a) shall—

''(i) establish a process under which data is de-identified consistent with the de-identification requirements under section 164.514 of title 45, Code of Federal Regulations (or any successor regulations), while retaining the ability to link data longitudinally for the purposes of research on cost and quality, and the ability to com-

plete risk adjustment and geographic analysis;

"(ii) ensure that any third-party subcontractors who perform the de-identification process described in clause (i) retain only the minimum necessary information to perform such a process, and adhere to effective security and encryption practices in data storage and transmission;

"(iii) store claims and other data collected under this subsection only in de-identified form, in accordance with section 164.514 of title 45, Code of Federal Regulations (or any successor regulations); and

"(iv) ensure that individually identifiable data is encrypted, in accordance with guidance issued by the Secretary under section 13402(h)(2) of the HITECH Act.

"(2) APPLICABLE SELF-INSURED GROUP HEALTH PLAN.—For purposes of paragraph (1), a self-insured group health plan is an applicable self-insured group health plan if such plan is self-administered, or is administered by a third-party plan administrator that meets 1 or both of the following criteria:

"(A) Administers health, medical, or pharmacy benefits for more than 50,000 enrollees.

"(B) Is one of the 5 largest administrators or issuers of self-insured group health plans in a State in which such administrator operates, as measured by the aggregate number of enrollees in plans administered by such administrator in such State, as determined by the Secretary.

"(3) THIRD-PARTY ADMINISTRATORS.—In the case of a third-party administrator that is required under this subsection to submit claims data with respect to an applicable self-insured group health plan, such administrator shall submit claims data with respect to all self-insured group health plans that the administrator administers, including such plans that are not applicable self-insured group health plans, as described in paragraph (2).

"(4) RECEIVING OTHER INFORMATION.—

"(A) MEDICARE DATA.—The Secretary, through rulemaking, shall ensure that the data made available to such entity is available to qualified entities under section 1874(e) of the Social Security Act is made available to the entity awarded a contract under subsection (a).

''(B) STATE DATA.—The entity awarded the contract under subsection (a) shall collect data from State all payer claims databases that seek access to the database established under this section.

''(5) AVAILABILITY OF DATA.—An entity required to submit data under this subsection may not place any restrictions on the use of such data by authorized users.

''(e) USES OF INFORMATION.—

''(1) IN GENERAL.—The entity awarded the contract under subsection (a) shall make the database available to users who are authorized under this subsection, at cost, and reports and analyses based on the data available to the public with no charge.

''(2) AUTHORIZATION OF USERS.—

''(A) IN GENERAL.—An entity may request authorization by the entity awarded the contract under subsection (a) for access to the database in accordance with this paragraph.

''(B) APPLICATION.—An entity desiring authorization under this paragraph shall submit to the entity awarded the contract an application for such access, which shall include—

"(i) in the case of an entity requesting access for research purposes—

"(I) a description of the uses and methodologies for evaluating health system performance using such data; and

"(II) documentation of approval of the research by an institutional review board, if applicable for a particular plan of research; or

"(ii) in the case of an entity such as an employer, health insurance issuer, third-party administrator, or health care provider, requesting access for the purpose of quality improvement or cost-containment, a description of the intended uses for such data.

"(C) REQUIREMENTS.—

"(i) RESEARCH.—Upon approval of an application for research purposes under subparagraph (B)(i), the authorized user shall enter into a data use and confidentiality agreement with the entity awarded the contract under subsection (a), which shall include a prohibition on attempts to

reidentify and disclose individually identifiable health information and proprietary financial information.

"(ii) QUALITY IMPROVEMENT AND COST-CONTAINMENT.—In consultation with the Committee described in subsection (b)(3), the Secretary shall, through rulemaking, establish the form and manner in which authorized users described in subparagraph (B)(ii) may access data. Data provided to such authorized users shall be provided in a form and manner such that users may not obtain individually identifiable price information with respect to direct competitors. Upon approval, such authorized user shall enter into a data use and confidentiality agreement with the entity.

"(iii) CUSTOMIZED REPORTS.—Employers and employer organizations may request customized reports from the entity awarded the contract under subsection (a), at cost, subject to the requirements of this section with respect to privacy, security, and proprietary financial information.

''(iv) NON-CUSTOMIZED REPORTS.—The entity awarded the contract under subsection (a), in consultation with the Committee, shall make available to all authorized users aggregate data sets, free of charge.

''(f) FUNDING.—

''(1) INITIAL FUNDING.—There are authorized to be appropriated, and there are appropriated, out of monies in the Treasury not otherwise appropriated, $20,000,000 for fiscal year 2020, for the implementation of the initial contract and establishment of the database under this section.

''(2) ONGOING FUNDING.—There are authorized to be appropriated $15,000,000 for each of fiscal years 2021 through 2025, for purposes of carrying out this section (other than the grant program under subsection (h)).

''(g) ANNUAL REPORT.—

''(1) SUBMISSION.—On each of the dates described in paragraph (2), the entity receiving the contract under subsection (a) shall submit to Congress, the Secretary of Health and Human Services, and the Secretary of Labor and publish online for

access by the general public, a report containing a description of—

"(A) trends in the price, utilization, and total spending on health care services, including a geographic analysis of differences in such trends;

"(B) limitations in the data set;

"(C) progress towards the objectives of this section; and

"(D) the performance by the entity of the duties required under such contract.

"(2) DATES DESCRIBED.—The reports described in paragraph (1) shall be submitted—

"(A) not later than 3 years after the date of enactment of the Lower Health Care Costs Act;

"(B) the later of 1 year after the date that is 3 years after such date of enactment or March 1 of the year after the date that is 3 years after such date of enactment; and

"(C) March 1 of each year thereafter.

"(3) PUBLIC REPORTS AND RESEARCH.—The entity receiving a contract under subsection (a) shall, in coordination with authorized users, make analyses and research available to the public on an

ongoing basis to promote the objectives of this section.

''(h) GRANTS TO STATES.—

''(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor, may award grants to States for the purpose of establishing and maintaining State all-payer claims databases that improve transparency of data in order to meet the goals of subsection (a)(1).

''(2) REQUIREMENT.—To be eligible to receive the funding under paragraph (1), a State shall submit data to the database as described in subsection (b)(1)(C), using the format described in subsection (d)(1).

''(3) FUNDING.—There is authorized to be appropriated $100,000,000 for the period of fiscal years 2020 through 2029 for the purpose of awarding grants to States under this subsection.

''(i) EXEMPTION FROM PUBLIC DISCLOSURE.—

''(1) IN GENERAL.—Claims data provided to the database, and the database itself shall not be considered public records and shall be exempt from public disclosure requirements.

''(2) RESTRICTIONS ON USES FOR CERTAIN PROCEEDINGS.—Data disclosed to authorized users

shall not be subject to discovery or admission as public information, or evidence in judicial or administrative proceedings without consent of the affected parties.

''(j) DEFINITIONS.—

''(1) INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION.—The term 'individually identifiable health information' has the meaning given such term in section 1171(6) of the Social Security Act.

''(2) PROPRIETARY FINANCIAL INFORMATION.—The term 'proprietary financial information' means data that would disclose the terms of a specific contract between an individual health care provider or facility and a specific group health plan, Medicaid managed care organization or other managed care entity, or health insurance issuer offering group or individual coverage.

''(k) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect or modify enforcement of the privacy, security, or breach notification rules promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (or successor regulations).''.

(b) GAO REPORT.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study on—

(A) the performance of the entity awarded a contract under section 2795(a) of the Public Health Service Act, as added by subsection (a), under such contract;

(B) the privacy and security of the information reported to the entity; and

(C) the costs incurred by such entity in performing such duties.

(2) REPORTS.—Not later than 2 years after the effective date of the first contract entered into under section 2795(a) of the Public Health Service Act, as added by subsection (a), and again not later than 4 years after such effective date, the Comptroller General of the United States shall submit to Congress a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

SEC. 304. PROTECTING PATIENTS AND IMPROVING THE ACCURACY OF PROVIDER DIRECTORY INFORMATION.

(a) IN GENERAL.—Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–11 et seq.), as amended by sections 301 and 302, is further amended by adding at the end the following:

"SEC. 2729C. PROTECTING PATIENTS AND IMPROVING THE ACCURACY OF PROVIDER DIRECTORY INFORMATION.

"(a) NETWORK STATUS OF PROVIDERS.—

"(1) IN GENERAL.—Beginning on the date that is one year after the date of enactment of this section, a group health plan or a health insurance issuer offering group or individual health insurance coverage shall—

"(A) establish business processes to ensure that all enrollees in such plan or coverage receive proof of a health care provider's network status, based on what a plan or issuer knows or could reasonably know—

"(i) through a written electronic communication from the plan or issuer to the enrollee, as soon as practicable and not later than 1 business day after a telephone

inquiry is made by such enrollee for such information;

"(ii) through an oral confirmation, documented by such issuer or coverage, and kept in the enrollee's file for a minimum of 2 years; and

"(iii) in real-time through an online health care provider directory search tool maintained by the plan or issuer; and

"(B) include in any print directory a disclosure that the information included in the directory is accurate as of the date of the last data update and that enrollees or prospective enrollees should consult the group health plan or issuer's electronic provider directory on its website or call a specified customer service telephone number to obtain the most current provider directory information.

"(2) GROUP HEALTH PLAN AND HEALTH INSURANCE ISSUER BUSINESS PROCESSES.—Beginning on the date that is one year after the date of enactment of the Lower Health Care Costs Act, a group health plan or a health insurance issuer offering group or individual health insurance coverage shall establish business processes to—

"(A) verify and update, at least once every 90 days, the provider directory information for all providers included in the online health care provider directory search tool described in paragraph (1)(A)(iii); and

"(B) remove any provider from such online directory search tool if such provider has not verified the directory information within the previous 6 months or the plan or issuer has been unable to verify the provider's network participation.

"(b) COST-SHARING LIMITATIONS.—

"(1) IN GENERAL.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall not apply, and shall ensure that no provider applies cost-sharing to an enrollee for treatment or services provided by a health care provider in excess of the normal cost-sharing applied for in-network care (including any balance bill issued by the health care provider involved), if such enrollee, or health care provider referring such enrollee, demonstrates (based on the electronic, written information described in subsection (a)(1)(A)(i), the oral confirmation described in subsection (a)(1)(A)(ii), or a copy of the online

provider directory described in subsection (a)(1)(A)(iii) on the date the enrollee attempted to obtain the provider's network status) that the enrollee relied on the information described in subsection (a)(1), if the provider's network status or directory information on such directory was incorrect at the time the treatment or services involved was provided.

"(2) REFUNDS TO ENROLLEES.—If a health care provider submits a bill to an enrollee in violation of paragraph (1), and the enrollee pays such bill, the provider shall reimburse the enrollee for the full amount paid by the enrollee in excess of the in-network cost-sharing amount for the treatment or services involved, plus interest, at an interest rate determined by the Secretary.

"(c) PROVIDER BUSINESS PROCESSES.—A health care provider shall have in place business processes to ensure the timely provision of provider directory information to a group health plan or a health insurance issuer offering group or individual health insurance coverage to support compliance by such plans or issuers with subsection (a)(1). Such providers shall submit provider directory information to a plan or issuers, at a minimum—

''(1) when the provider begins a network agreement with a plan or with an issuer with respect to certain coverage;

''(2) when the provider terminates a network agreement with a plan or with an issuer with respect to certain coverage;

''(3) when there are material changes to the content of provider directory information described in subsection (a)(1); and

''(4) every 90 days throughout the duration of the network agreement with a plan or issuer.

''(d) ENFORCEMENT.—

''(1) IN GENERAL.—Subject to paragraph (2), a health care provider that violates a requirement under subsection (c) or takes actions that prevent a group health plan or health insurance issuer from complying with subsection (a)(1) or (b) shall be subject to a civil monetary penalty of not more than $10,000 for each act constituting such violation.

''(2) SAFE HARBOR.—The Secretary may waive the penalty described under paragraph (1) with respect to a health care provider that unknowingly violates subsection (b)(1) with respect to an enrollee if such provider rescinds the bill involved and, if applicable, reimburses the enrollee within 30 days of the

date on which the provider billed the enrollee in violation of such subsection.

''(3) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsections (a) and (b) and the first sentence of subsection (c)(1) of such section, shall apply to civil money penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

''(e) SAVINGS CLAUSE.—Nothing in this section shall prohibit a provider from requiring in the terms of a contract, or contract termination, with a group health plan or health insurance issuer—

''(1) that the plan or issuer remove, at the time of termination of such contract, the provider from a directory of the plan or issuer described in subsection (a)(1); or

''(2) that the plan or issuer bear financial responsibility, including under subsection (b), for providing inaccurate network status information to an enrollee.

''(f) DEFINITION.—For purposes of this section, the term 'provider directory information' includes the names, addresses, specialty, and telephone numbers of individual

health care providers, and the names, addresses, and telephone numbers of each medical group, clinic, or facility contracted to participate in any of the networks of the group health plan or health insurance coverage involved.

''(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to preempt any provision of State law relating to health care provider directories or network adequacy.''.

(b) EFFECTIVE DATE.—Section 2729C of the Public Health Service Act, as added by subsection (a), shall take effect with respect to plan years beginning on or after the date that is 18 months after the date of enactment of this Act.

SEC. 305. TIMELY BILLS FOR PATIENTS.

(a) IN GENERAL.—

(1) AMENDMENT.—Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

''SEC. 399V–7. TIMELY BILLS FOR PATIENTS.

''(a) IN GENERAL.—The Secretary shall require—

''(1) health care facilities, or in the case of practitioners providing services outside of such a facility, practitioners, to provide to patients a list of services rendered during the visit to such facility or practitioner, and, in the case of a facility, the name

of the provider for each such service, upon discharge or end of the visit or by postal or electronic communication as soon as practicable and not later than 5 calendar days after discharge or date of visit; and

''(2) health care facilities and practitioners to furnish all adjudicated bills to the patient as soon as practicable, but not later than 45 calendar days after discharge or date of visit.

''(b) PAYMENT AFTER BILLING.—No patient may be required to pay a bill for health care services any earlier than 35 days after the postmark date of a bill for such services.

''(c) EFFECT OF VIOLATION.—

''(1) NOTIFICATION AND REFUND REQUIREMENTS.—

''(A) PROVIDER LISTS.—If a facility or practitioner fails to provide a patient a list as required under subsection (a)(1), such facility or practitioner shall report such failure to the Secretary.

''(B) BILLING.—If a facility or practitioner bills a patient after the 45-calendar-day period described in subsection (a)(2), such facility or practitioner shall—

''(i) report such bill to the Secretary; and

''(ii) refund the patient for the full amount paid in response to such bill with interest, at a rate determined by the Secretary.

''(2) CIVIL MONETARY PENALTIES.—

''(A) IN GENERAL.—The Secretary may impose civil monetary penalties of up to $10,000 a day on any facility or practitioner that—

''(i) fails to provide a list required under subsection (a)(1) more than 10 times, beginning on the date of such tenth failure;

''(ii) submits more than 10 bills outside of the period described in subsection (a)(2), beginning on the date on which such facility or practitioner sends the tenth such bill;

''(iii) fails to report to the Secretary any failure to provide lists as required under paragraph (1)(A), beginning on the date that is 45 calendar days after discharge or visit; or

"(iv) fails to send any bill as required under subsection (a)(2), beginning on the date that is 45 calendar days after the date of discharge or visit, as applicable.

"(B) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsections (a) and (b) and the first sentence of subsection (c)(1) of such section, shall apply to civil money penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

"(3) SAFE HARBOR.—The Secretary may exempt a practitioner or facility from the penalties under paragraph (2)(A) or extend the period of time specified under subsection (a)(2) for compliance with such subsection if a practitioner or facility—

"(A) makes a good-faith attempt to send a bill within 30 days but is unable to do so because of an incorrect address; or

"(B) experiences extenuating circumstances (as defined by the Secretary), such as a hurricane or cyberattack, that may reasonably delay delivery of a timely bill.".

(2) RULEMAKING.—Not later than 1 year after the date of enactment of this Act, the Secretary shall promulgate final regulations to define the term ''extenuating circumstance'' for purposes of section 399V–7(c)(3)(B) of the Public Health Service Act, as added by paragraph (1).

(b) GROUP HEALTH PLAN AND HEALTH INSURANCE ISSUER REQUIREMENTS.—Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–11), as amended by section 304, is further amended by adding at the end the following:

''SEC. 2729D. TIMELY BILLS FOR PATIENTS.

''(a) IN GENERAL.—A group health plan or health insurance issuer offering group or individual health insurance coverage shall have in place business practices with respect to in-network facilities and practitioners to ensure that claims are adjudicated in order to facilitate facility and practitioner compliance with the requirements under section 399V–7(a).

''(b) CLARIFICATION.—Nothing in subsection (a) prohibits a provider and a group health plan or health insurance issuer from establishing in a contract the timeline for submission by either party to the other party of billing information, adjudication, sending of remittance information, or any other coordination required between the pro-

vider and the plan or issuer necessary for meeting the deadline described in section 399V–7(a)(2).''.

(c) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) shall take effect 6 months after the date of enactment of this Act.

SEC. 306. HEALTH PLAN OVERSIGHT OF PHARMACY BENEFIT MANAGER SERVICES.

Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–11 et seq.), as amended by section 305(b), is further amended by adding at the end the following:

''SEC. 2729E. HEALTH PLAN OVERSIGHT OF PHARMACY BENEFIT MANAGER SERVICES.

''(a) IN GENERAL.—A group health plan or health insurance issuer offering group health insurance coverage or an entity or subsidiary providing pharmacy benefits management services shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of information to plan sponsors in such a manner that prevents the plan or coverage, or an entity or subsidiary providing pharmacy benefits management services on behalf of a plan or coverage from making the reports described in subsection (b).

''(b) REPORTS TO GROUP PLAN SPONSORS.—

"(1) IN GENERAL.—Beginning with the first plan year that begins after the date of enactment of the Lower Health Care Costs Act, not less frequently than once every 6 months, a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan shall submit to the plan sponsor (as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974) of such group health plan or health insurance coverage a report in accordance with this subsection and make such report available to the plan sponsor in a machine-readable format. Each such report shall include, with respect to the applicable group health plan or health insurance coverage—

"(A) information collected from drug manufacturers by such issuer or entity on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer with respect to the enrollees in such plan or coverage;

"(B) a list of each covered drug dispensed during the reporting period, including, with re-

spect to each such drug during the reporting period—

"(i) the brand name, chemical entity, and National Drug Code;

"(ii) the number of enrollees for whom the drug was filled during the plan year, the total number of prescription fills for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, including whether the dispensing channel was by retail, mail order, or specialty pharmacy;

"(iii) the wholesale acquisition cost, listed as cost per days supply and cost per pill, or in the case of a drug in another form, per dose;

"(iv) the total out-of-pocket spending by enrollees on such drug, including enrollee spending through copayments, coinsurance, and deductibles;

"(v) for any drug for which gross spending of the group health plan or health insurance coverage exceeded $10,000 during the reporting period—

''(I) a list of all other available drugs in the same therapeutic category or class, including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic category or class; and

''(II) the rationale for preferred formulary placement of a particular drug or drugs in that therapeutic category or class;

''(C) a list of each therapeutic category or class of drugs that were dispensed under the health plan or health insurance coverage during the reporting period, and, with respect to each such therapeutic category or class of drugs, during the reporting period—

''(i) total gross spending by the plan, before manufacturer rebates, fees, or other manufacturer remuneration;

''(ii) the number of enrollees who filled a prescription for a drug in that category or class;

''(iii) if applicable to that category or class, a description of the formulary tiers

and utilization mechanisms (such as prior authorization or step therapy) employed for drugs in that category or class;

"(iv) the total out-of-pocket spending by enrollees, including enrollee spending through copayments, coinsurance, and deductibles; and

"(v) for each therapeutic category or class under which 3 or more drugs are included on the formulary of such plan or coverage—

"(I) the amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration—

"(aa) to be paid by drug manufacturers for claims incurred during the reporting period; or

"(bb) that is related to utilization of drugs, in such therapeutic category or class;

"(II) the total net spending, after deducting rebates, price concessions, alternative discounts or other remu-

neration from drug manufacturers, by the health plan or health insurance coverage on that category or class of drugs; and

''(III) the net price per course of treatment or 30-day supply incurred by the health plan or health insurance coverage and its enrollees, after manufacturer rebates, fees, and other remuneration for drugs dispensed within such therapeutic category or class during the reporting period;

''(D) total gross spending on prescription drugs by the plan or coverage during the reporting period, before rebates and other manufacturer fees or remuneration;

''(E) total amount received, or expected to be received, by the health plan or health insurance coverage in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party, other than the plan sponsor, related to utilization of drug or drug spending under that health plan or health insurance coverage during the reporting period;

"(F) the total net spending on prescription drugs by the health plan or health insurance coverage during the reporting period; and

"(G) amounts paid directly or indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm who referred the group health plan's or health insurance issuer's business to the pharmacy benefit manager.

"(2) PRIVACY REQUIREMENTS.—Health insurance issuers offering group health insurance coverage and entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (or successor regulations), and shall restrict the use and disclosure of such information according to such privacy regulations.

"(3) DISCLOSURE AND REDISCLOSURE.—

"(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such informa-

tion only to business associates of such plan as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations).

''(B) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section prevents a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such issuer or entity may not restrict disclosure of such report to governmental agencies pursuant to an investigation or enforcement action.

''(C) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1) required of plan sponsors who are drug manufacturers, drug wholesalers, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

''(c) LIMITATIONS ON SPREAD PRICING.—

''(1) PRESCRIPTION DRUG TRANSACTIONS WITH PHARMACIES INDEPENDENT OF THE ISSUER OR

PHARMACY BENEFITS MANAGER.—If the pharmacy that dispenses a prescription drug to an enrollee in a group health plan or group or individual health insurance coverage is not wholly or partially-owned by such plan, such issuer, or an entity providing pharmacy benefit management services under such plan or coverage, such plan, issuer, or entity shall not charge the plan, issuer, or enrollee a price for such prescription drug that exceeds the price paid to the pharmacy, excluding penalties paid by pharmacies to such plan, issuer, or entity.

''(2) INTRA-COMPANY PRESCRIPTION DRUG TRANSACTIONS.—If the mail order, specialty, or retail pharmacy that dispenses a prescription drug to an enrollee in a group health plan or health insurance coverage is wholly or partially owned by, and submits claims to, such health insurance issuer or an entity providing pharmacy benefit management services under a group health plan or group or individual health insurance coverage, the price charged for such drug by such pharmacy to such group health plan or health insurance issuer offering group or individual health insurance coverage may not exceed the lesser of—

"(A) the amount paid to the pharmacy for acquisition of the drug; or

"(B) the median price charged to the group health plan or health insurance issuer when the same drug is dispensed to enrollees in the plan or coverage by other similarly-situated pharmacies not wholly or partially owned by the health insurance issuer or entity providing pharmacy benefits management services, as described in paragraph (1).

"(3) SUPPLEMENTARY REPORTING FOR INTRA-COMPANY PRESCRIPTION DRUG TRANSACTIONS.—A health insurance issuer of group health insurance coverage or an entity providing pharmacy benefits management services under a group health plan or group health insurance coverage that conducts transactions with a wholly or partially-owned pharmacy, as described in paragraph (2), shall submit, together with the report under subsection (b), a supplementary report every 6 months to the plan sponsor that includes—

"(A) an explanation of any benefit design parameters that encourage enrollees in the plan or coverage to fill prescriptions at mail order,

specialty, or retail pharmacies that are wholly or partially-owned by that issuer or entity;

"(B) the percentage of total prescriptions charged to the plan, coverage, or enrollees in the plan or coverage, that were dispensed by mail order, specialty, or retail pharmacies that are wholly or partially-owned by the issuer or entity providing pharmacy benefits management services; and

"(C) a list of all drugs dispensed by such wholly or partially-owned pharmacy and charged to the plan or coverage, or enrollees of the plan or coverage, during the applicable quarter, and, with respect to each drug—

"(i) the amount charged per course of treatment or 30-day supply with respect to enrollees in the plan or coverage, including amounts charged to the plan or coverage and amounts charged to the enrollee;

"(ii) the median amount charged to the plan or coverage, per course of treatment or 30-day supply, including amounts paid by the enrollee, when the same drug is dispensed by other pharmacies that are not wholly or partially-owned by the issuer

or entity and that are included in the pharmacy network of that plan or coverage;

''(iii) the interquartile range of the costs, per course of treatment or 30-day supply, including amounts paid by the enrollee, when the same drug is dispensed by other pharmacies that are not wholly or partially-owned by the issuer or entity and that are included in the pharmacy network of that plan or coverage;

''(iv) the lowest cost per course of treatment or 30-day supply, for such drug, including amounts charged to the plan or issuer and enrollee, that is available from any pharmacy included in the network of the plan or coverage.

''(d) FULL REBATE PASS-THROUGH TO PLAN.—

''(1) IN GENERAL.—A pharmacy benefits manager, a third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefits management services under such health plan or health insurance coverage shall remit 100 percent of rebates, fees, alternative discounts, and

all other remuneration received from a pharmaceutical manufacturer, distributor or any other third party, that are related to utilization of drugs under such health plan or health insurance coverage, to the group health plan.

''(2) FORM AND MANNER OF REMITTANCE.—Such rebates, fees, alternative discounts, and other remuneration shall be—

''(A) remitted to the group health plan in a timely fashion after the period for which such rebates, fees, or other remuneration is calculated, and in no case later than 90 days after the end of such period;

''(B) fully disclosed and enumerated to the group health plan sponsor, as described in (b)(1);

''(C) available for audit by the plan sponsor, or a third-party designated by a plan sponsor no less than once per plan year; and

''(D) returned to the issuer or entity providing pharmaceutical benefit management services by the group health plan if audits by such issuer or entity indicate that the amounts received are incorrect after such amounts have been paid to the group health plan.

''(3) AUDIT OF REBATE CONTRACTS.—A pharmacy benefits manager, a third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefits management services under such health plan or health insurance coverage shall make rebate contracts with drug manufacturers available for audit by such plan sponsor or designated third-party, subject to confidentiality agreements to prevent re-disclosure of such contracts.

''(e) ENFORCEMENT.—

''(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor and the Secretary of the Treasury, shall enforce this section.

''(2) FAILURE TO PROVIDE TIMELY INFORMATION.—A health insurance issuer or an entity providing pharmacy benefit management services that violates subsection (a), fails to provide information required under subsection (b), engages in spread pricing as defined in subsection (c), or fails to comply with the requirements of subsection (d), or a drug manufacturer that fails to provide information under subsection (b)(1)(A), in a timely manner shall be subject to a civil monetary penalty in the amount of $10,000 for each day during which such violation

continues or such information is not disclosed or reported.

''(3) FALSE INFORMATION.—A health insurance issuer, entity providing pharmacy benefit management services, or drug manufacturer that knowingly provides false information under this section shall be subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalty shall be in addition to other penalties as may be prescribed by law.

''(4) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsection (a) and (b) and the first sentence of subsection (c)(1) of such section shall apply to civil monetary penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

''(5) SAFE HARBOR.—The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this section, for an entity in violation of this section that has made a good-faith effort to comply with this section.

''(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit payments to entities offering pharmacy benefits management services for bona fide services using a fee structure not contemplated by this section, provided that such fees are transparent to group health plans and health insurance issuers.

''(g) DEFINITIONS.—In this section—

''(1) the term 'similarly situated pharmacy' means, with respect to a particular pharmacy, another pharmacy that is approximately the same size (as measured by the number of prescription drugs dispensed), and that serves patients in the same geographical area, whether through physical locations or mail order; and

''(2) the term 'wholesale acquisition cost' has the meaning given such term in sectionb1847A(c)(6)(B) of the Social Security Act.''.

SEC. 307. GOVERNMENT ACCOUNTABILITY OFFICE STUDY ON PROFIT- AND REVENUE-SHARING IN HEALTH CARE.

(a) STUDY.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study to—

(1) describe what is known about profit- and revenue-sharing relationships in the commercial

health care markets, including those relationships that—

(A) involve one or more—

(i) physician groups that practice within a hospital included in the profit- or revenue-sharing relationship, or refer patients to such hospital;

(ii) laboratory, radiology, or pharmacy services that are delivered to privately insured patients of such hospital;

(iii) surgical services;

(iv) hospitals or group purchasing organizations; or

(v) rehabilitation or physical therapy facilities or services; and

(B) include revenue- or profit-sharing whether through a joint venture, management or professional services agreement, or other form of gain-sharing contract;

(2) describe Federal oversight of such relationships, including authorities of the Department of Health and Human Services and the Federal Trade Commission to review such relationships and their potential to increase costs for patients, and identify limitations in such oversight; and

(3) as appropriate, make recommendations to improve Federal oversight of such relationships.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall prepare and submit a report on the study conducted under subsection (a) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Education and Labor and Committee on Energy and Commerce of the House of Representatives.

SEC. 308. DISCLOSURE OF DIRECT AND INDIRECT COMPENSATION FOR BROKERS AND CONSULTANTS TO EMPLOYER-SPONSORED HEALTH PLANS AND ENROLLEES IN PLANS ON THE INDIVIDUAL MARKET.

(a) GROUP HEALTH PLANS.—Section 408(b)(2) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1108(b)(2)) is amended—

(1) by striking ''(2) Contracting or making'' and inserting ''(2)(A) Contracting or making''; and

(2) by adding at the end the following:

''(B)(i) No contract or arrangement for services between a covered plan and a covered service provider, and no extension or renewal of such a contract or arrangement, is reasonable within the meaning of

this paragraph unless the requirements of this clause are met.

"(ii)(I) For purposes of this subparagraph:

"(aa) The term 'covered plan' means a group health plan as defined section 733(a).

"(bb) The term 'covered service provider' means a service provider that enters into a contract or arrangement with the covered plan and reasonably expects $1,000 (or such amount as the Secretary may establish in regulations to account for inflation since the date of enactment of the Lower Health Care Costs Act, as appropriate) or more in compensation, direct or indirect, to be received in connection with providing one or more of the following services, pursuant to the contract or arrangement, regardless of whether such services will be performed, or such compensation received, by the covered service provider, an affiliate, or a subcontractor:

"(AA) Brokerage services, for which the covered service provider, an affiliate, or a subcontractor reasonably expects to receive indirect compensation or direct compensation described in item (dd), provided

to a covered plan with respect to selection of insurance products (including vision and dental), recordkeeping services, medical management vendor, benefits administration (including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness services, transparency tools and vendors, group purchasing organization preferred vendor panels, disease management vendors and products, compliance services, employee assistance programs, or third party administration services.

''(BB) Consulting, for which the covered service provider, an affiliate, or a subcontractor reasonably expects to receive indirect compensation or direct compensation described in item (dd), related to the development or implementation of plan design, insurance or insurance product selection (including vision and dental), recordkeeping, medical management, benefits administration selection (including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness design

and management services, transparency tools, group purchasing organization agreements and services, participation in and services from preferred vendor panels, disease management, compliance services, employee assistance programs, or third party administration services.

''(cc) The term 'affiliate', with respect to a covered service provider, means an entity that directly or indirectly (through one or more intermediaries) controls, is controlled by, or is under common control with, such provider, or is an officer, director, or employee of, or partner in, such provider.

''(dd)(AA) The term 'compensation' means anything of monetary value, but does not include non-monetary compensation valued at $250 (or such amount as the Secretary may establish in regulations to account for inflation since the date of enactment of the Lower Health Care Costs Act, as appropriate) or less, in the aggregate, during the term of the contract or arrangement.

"(BB) The term 'direct compensation' means compensation received directly from a covered plan.

"(CC) The term 'indirect compensation' means compensation received from any source other than the covered plan, the plan sponsor, the covered service provider, or an affiliate. Compensation received from a subcontractor is indirect compensation, unless it is received in connection with services performed under a contract or arrangement with a subcontractor.

"(ee) The term 'responsible plan fiduciary' means a fiduciary with authority to cause the covered plan to enter into, or extend or renew, the contract or arrangement.

"(ff) The term 'subcontractor' means any person or entity (or an affiliate of such person or entity) that is not an affiliate of the covered service provider and that, pursuant to a contract or arrangement with the covered service provider or an affiliate, reasonably expects to receive $1,000 (or such amount as the Secretary may establish in regulations to account for inflation since the date of enactment of the Lower Health Care Costs Act, as appropriate)

or more in compensation for performing one or more services described in item (bb) under a contract or arrangement with the covered plan.

''(II) For purposes of this subparagraph, a description of compensation or cost may be expressed as a monetary amount, formula, or a per capita charge for each enrollee or, if the compensation or cost cannot reasonably be expressed in such terms, by any other reasonable method, including a disclosure that additional compensation may be earned but may not be calculated at the time of contract if such a disclosure includes a description of the circumstances under which the additional compensation may be earned and a reasonable and good faith estimate if the covered service provider cannot otherwise readily describe compensation or cost and explains the methodology and assumptions used to prepare such estimate. Any such description shall contain sufficient information to permit evaluation of the reasonableness of the compensation or cost.

''(III) No person or entity is a 'covered service provider' within the meaning of subclause (I)(bb) solely on the basis of providing services as an affiliate or a subcontractor that is performing one or more of the services described in subitem (AA) or

(BB) of such subclause under the contract or arrangement with the covered plan.

''(iii) A covered service provider shall disclose to a responsible plan fiduciary, in writing, the following:

''(I) A description of the services to be provided to the covered plan pursuant to the contract or arrangement.

''(II) If applicable, a statement that the covered service provider, an affiliate, or a subcontractor will provide, or reasonably expects to provide, services pursuant to the contract or arrangement directly to the covered plan as a fiduciary (within the meaning of section 3(21)).

''(III) A description of all direct compensation, either in the aggregate or by service, that the covered service provider, an affiliate, or a subcontractor reasonably expects to receive in connection with the services described in subclause (I).

''(IV)(aa) A description of all indirect compensation that the covered service provider, an affiliate, or a subcontractor reasonably expects to receive in connection with the services described in subclause (I)—

"(AA) including compensation from a vendor to a brokerage firm based on a structure of incentives not solely related to the contract with the covered plan; and

"(BB) not including compensation received by an employee from an employer on account of work performed by the employee.

"(bb) A description of the arrangement between the payer and the covered service provider, an affiliate, or a subcontractor, as applicable, pursuant to which such indirect compensation is paid.

"(cc) Identification of the services for which the indirect compensation will be received, if applicable.

"(dd) Identification of the payer of the indirect compensation.

"(V) A description of any compensation that will be paid among the covered service provider, an affiliate, or a subcontractor, in connection with the services described in subclause (I) if such compensation is set on a transaction basis (such as commissions, finder's fees, or other similar incentive compensation based on

business placed or retained), including identification of the services for which such compensation will be paid and identification of the payers and recipients of such compensation (including the status of a payer or recipient as an affiliate or a subcontractor), regardless of whether such compensation also is disclosed pursuant to subclause (III) or (IV).

''(VI) A description of any compensation that the covered service provider, an affiliate, or a subcontractor reasonably expects to receive in connection with termination of the contract or arrangement, and how any prepaid amounts will be calculated and refunded upon such termination.

''(iv) A covered service provider shall disclose to a responsible plan fiduciary, in writing a description of the manner in which the compensation described in clause (iii), as applicable, will be received.

''(v)(I) A covered service provider shall disclose the information required under clauses (iii) and (iv) to the responsible plan fiduciary not later than the date that is reasonably in advance of the date on which the contract or arrangement is entered into, and extended or renewed.

''(II) A covered service provider shall disclose any change to the information required under clause (iii) and (iv) as soon as practicable, but not later than 60 days from the date on which the covered service provider is informed of such change, unless such disclosure is precluded due to extraordinary circumstances beyond the covered service provider's control, in which case the information shall be disclosed as soon as practicable.

''(vi)(I) Upon the written request of the responsible plan fiduciary or covered plan administrator, a covered service provider shall furnish any other information relating to the compensation received in connection with the contract or arrangement that is required for the covered plan to comply with the reporting and disclosure requirements under this Act.

''(II) The covered service provider shall disclose the information required under clause (iii)(I) reasonably in advance of the date upon which such responsible plan fiduciary or covered plan administrator states that it is required to comply with the applicable reporting or disclosure requirement, unless such disclosure is precluded due to extraordinary circumstances beyond the covered service provider's

control, in which case the information shall be disclosed as soon as practicable.

''(vii) No contract or arrangement will fail to be reasonable under this subparagraph solely because the covered service provider, acting in good faith and with reasonable diligence, makes an error or omission in disclosing the information required pursuant to clause (iii) (or a change to such information disclosed pursuant to clause (v)(II)) or clause (vi), provided that the covered service provider discloses the correct information to the responsible plan fiduciary as soon as practicable, but not later than 30 days from the date on which the covered service provider knows of such error or omission.

''(viii)(I) Pursuant to subsection (a), subparagraphs (C) and (D) of section 406(a)(1) shall not apply to a responsible plan fiduciary, notwithstanding any failure by a covered service provider to disclose information required under clause (iii), if the following conditions are met:

''(aa) The responsible plan fiduciary did not know that the covered service provider failed or would fail to make required disclosures and reasonably believed that the covered service

provider disclosed the information required to be disclosed.

''(bb) The responsible plan fiduciary, upon discovering that the covered service provider failed to disclose the required information, requests in writing that the covered service provider furnish such information.

''(cc) If the covered service provider fails to comply with a written request described in subclause (II) within 90 days of the request, the responsible plan fiduciary notifies the Secretary of the covered service provider's failure, in accordance with subclauses (II) and (III).

''(II) A notice described in subclause (I)(cc) shall contain—

''(aa) the name of the covered plan;

''(bb) the plan number used for the annual report on the covered plan;

''(cc) the plan sponsor's name, address, and employer identification number;

''(dd) the name, address, and telephone number of the responsible plan fiduciary;

''(ee) the name, address, phone number, and, if known, employer identification number of the covered service provider;

"(ff) a description of the services provided to the covered plan;

"(gg) a description of the information that the covered service provider failed to disclose;

"(hh) the date on which such information was requested in writing from the covered service provider; and

"(ii) a statement as to whether the covered service provider continues to provide services to the plan.

"(III) A notice described in subclause (I)(cc) shall be filed with the Department not later than 30 days following the earlier of—

"(aa) The covered service provider's refusal to furnish the information requested by the written request described in subclause (I)(bb); or

"(bb) 90 days after the written request referred to in subclause (I)(cc) is made.

"(IV) If the covered service provider fails to comply with the written request under subclause (I)(bb) within 90 days of such request, the responsible plan fiduciary shall determine whether to terminate or continue the contract or arrangement under section 404. If the requested information re-

lates to future services and is not disclosed promptly after the end of the 90-day period, the responsible plan fiduciary shall terminate the contract or arrangement as expeditiously as possible, consistent with such duty of prudence.

''(ix) Nothing in this subparagraph shall be construed to supersede any provision of State law that governs disclosures by parties that provide the services described in this section, except to the extent that such law prevents the application of a requirement of this section.''.

(b) APPLICABILITY OF EXISTING REGULATIONS.—Nothing in the amendments made by subsection (a) shall be construed to affect the applicability of section 2550.408b–2 of title 29, Code of Federal Regulations (or any successor regulations), with respect to any applicable entity other than a covered plan or a covered service provider (as defined in section 408(b)(2)(B)(ii) of the Employee Retirement Income Security Act of 1974, as amended by subsection (a)).

(c) INDIVIDUAL MARKET COVERAGE.—Subpart 1 of part B of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–41 et seq.) is amended by adding at the end the following:

"SEC. 2746. DISCLOSURE TO ENROLLEES OF INDIVIDUAL MARKET COVERAGE.

"(a) IN GENERAL.—A health insurance issuer offering individual health insurance coverage shall make disclosures to enrollees in such coverage, as described in subsection (b), and reports to the Secretary, as described in subsection (c), regarding direct or indirect compensation provided to an agent or broker associated with enrolling individuals in such coverage.

"(b) DISCLOSURE.—A health insurance issuer described in subsection (a) shall disclose to an enrollee the amount of direct or indirect compensation provided to an agent or broker for services provided by such agent or broker associated with plan selection and enrollment. Such disclosure shall be—

"(1) made prior to the individual finalizing plan selection; and

"(2) included on any documentation confirming the individual's enrollment.

"(c) REPORTING.—A health insurance issuer described in subsection (a) shall annually report to the Secretary, prior to the beginning of open enrollment, any direct or indirect compensation provided to an agent or broker associated with enrolling individuals in such coverage.

''(d) RULEMAKING.—Not later than 1 year after the date of enactment of the Lower Health Care Costs Act, the Secretary shall finalize, through notice-and-comment rulemaking, the form and manner in which issuers described in subsection (a) are required to make the disclosures described in subsection (b) and the reports described in subsection (c).''.

(d) TRANSITION RULE.—No contract executed prior to the effective date described in subsection (e) by a group health plan subject to the requirements of section 408(b)(2)(B) of the Employee Retirement Income Security Act of 1974 (as amended by subsection (a)) or by a health insurance issuer subject to the requirements of section 2746 of the Public Health Service Act (as added by subsection (c)) shall be subject to the requirements of such section 408(b)(2)(B) or such section 2746, as applicable.

(e) EFFECTIVE DATE.—The amendments made by subsections (a) and (c) shall take effect 2 years after the date of enactment of this Act.

SEC. 309. ENSURING ENROLLEE ACCESS TO COST-SHARING INFORMATION.

(a) IN GENERAL.—Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C.

300gg–11 et seq.), as amended by section 306, is further amended by adding at the end the following:

"SEC. 2729F. PROVISION OF COST-SHARING INFORMATION.

"(a) PROVIDER DISCLOSURES.—A provider that is in-network with respect to a group health plan or a health insurance issuer offering group or individual health insurance coverage shall provide to an enrollee in the plan or coverage who submits a request for the information described in paragraph (1) or (2), together with accurate and complete information about the enrollee's coverage under the applicable plan or coverage—

"(1) as soon as practicable and not later than 2 business days after the enrollee requests such information, a good faith estimate of the expected enrollee cost-sharing for the provision of a particular health care service (including any service that is reasonably expected to be provided in conjunction with such specific service); and

"(2) as soon as practicable and not later than 2 business days after an enrollee requests such information, the contact information for any ancillary providers for a scheduled health care service.

"(b) INSURER DISCLOSURES.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall provide an enrollee in the

plan or coverage with a good faith estimate of the enrollee's cost-sharing (including deductibles, copayments, and coinsurance) for which the enrollee would be responsible for paying with respect to a specific health care service (including any service that is reasonably expected to be provided in conjunction with such specific service), as soon as practicable and not later than 2 business days after a request for such information by an enrollee.

''(c) ENFORCEMENT.—

''(1) IN GENERAL.—Subject to paragraph (2), a health care provider that violates a requirement under subsection (a) shall be subject to a civil monetary penalty of not more than $10,000 for each act constituting such violation.

''(2) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsections (a) and (b) and the first sentence of subsection (c)(1) of such section, shall apply to civil money penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.''.

(b) EFFECTIVE DATE.—Section 2729G of the Public Health Service Act, as added by subsection (a), shall apply

with respect to plan years beginning on or after the date that is 18 months after the date of enactment of this Act.

SEC. 310. STRENGTHENING PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS.

Section 2726 of the Public Health Service Act (42 U.S.C. 300gg–26) is amended—

(1) in subsection (a), by adding at the end the following:

''(8) COMPLIANCE REQUIREMENTS.—

''(A) NONQUANTITATIVE TREATMENT LIMITATION (NQTL) REQUIREMENTS.—In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits and that imposes nonquantitative treatment limitations (referred to in this section as 'NQTL') on mental health or substance use disorder benefits, the plan or issuer offering health insurance coverage in connection with such a plan, shall perform comparative analyses of the design and application of NQTLs in accordance with the following process, and make available to the applicable State authority (or, as applicable, to the Sec-

retary of Labor with respect to group health plans or the Secretary of Health and Human Services with respect to health insurance coverage), upon request within 60 days beginning 6 months after the date of enactment of the Lower Health Care Costs Act, the following information:

''(i) The specific plan or coverage terms regarding the NQTL, that applies to such plan or coverage, and a description of all mental health or substance use disorder and medical or surgical benefits to which it applies in each respective benefits classification.

''(ii) The factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

''(iii) The evidentiary standards used for the factors identified in clause (ii), when applicable, provided that every factor shall be defined and any other source or evidence relied upon to design and apply the NQTL to mental health or substance

use disorder benefits and medical or surgical benefits.

''(iv) The comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to design the NQTL, as written, and the operation processes and strategies as written and in operation that are used to apply the NQTL for mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to design the NQTL, as written, and the operation processes and strategies as written and in operation that are used to apply the NQTL to medical or surgical benefits.

''(v) A disclosure of the specific findings and conclusions reached by the plan or coverage that the results of the analyses described in this subparagraph indicate that the plan or coverage is in compliance with this section.

''(B) SECRETARY REQUEST PROCESS.—

"(i) SUBMISSION UPON REQUEST.—With respect to group health plans or health insurance coverage for which the Secretary is enforcing this section in accordance with section 2723, the Secretary, in consultation with the Secretary of Labor and the Secretary of Treasury, shall request that a group health plan or a health insurance issuer offering group or individual health insurance coverage submit the comparative analyses described in subparagraph (A) for plans that involve potential violations of this section concerning NQTLs and any other instances in which the Secretary determines appropriate. The Secretary shall request not fewer than 20 such analyses per year.

"(ii) ADDITIONAL INFORMATION.—In instances in which the Secretary has concluded that the plan or coverage has not submitted sufficient information for the Secretary to review the comparative analyses described in subparagraph (A), as requested under clause (i), the Secretary shall specify to the plan or coverage the in-

formation the plan or coverage must submit to be responsive to the request under clause (i) for the Secretary to review the comparative analyses described in subparagraph(A) for compliance with this section. Nothing in this paragraph shall require the Secretary to conclude that a plan is in compliance with this section solely based upon the inspection of the comparative analyses described in subparagraph (A), as requested under clause (i).

''(iii) REQUIRED ACTION.—In instances in which the Secretary has reviewed the comparative analyses described in subparagraph (A), as requested under clause (i), and determined that the plan or coverage is not in compliance with this section, the plan or coverage shall specify to the Secretary the actions the plan or coverage will take to be in compliance with this section. Documents or communications produced in connection with the Secretary's recommendations to the plan or coverage shall not be subject to disclosure

pursuant to section 552 of title 5, United States Code.

''(iv) REPORT.—Not later than 1 year after the date of enactment of this paragraph, and annually thereafter, the Secretary shall submit to the Committee on Education and Labor of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report that contains—

''(I) a summary of the comparative analyses requested under clause (i), except that the identity of each plan or coverage and any contracted entity of a plan or coverage shall be redacted;

''(II) the Secretary's conclusions as to whether each plan or coverage submitted sufficient information for the Secretary to review the comparative analyses requested under clause (i) for compliance with this section;

''(III) for each plan or coverage that did submit sufficient information for the Secretary to review the com-

parative analyses requested under clause (i), the Secretary's conclusions as to whether and why the plan or coverage is in compliance with the disclosure requirements under this section;

"(IV) the Secretary's specifications described in clause (ii) for each plan or coverage that the Secretary determined did not submit sufficient information for the Secretary to review the comparative analyses requested under clause (i) for compliance with this section; and

"(V) the Secretary's specifications described in clause (iii) of the actions each plan or coverage that the Secretary determined is not in compliance with this section must take to be in compliance with this section, including the reason why the Secretary determined the plan or coverage is not in compliance.

"(C) COMPLIANCE PROGRAM GUIDANCE DOCUMENT UPDATE PROCESS.—

"(i) IN GENERAL.—The Secretary shall include select instances of noncompliance that the Secretary discovers upon reviewing the comparative analyses requested under subparagraph (B)(i) in the compliance program guidance document described in section 2726(a)(6), as it is updated every 2 years, except that all instances shall be deidentified and such instances shall not disclose any protected health information or individually identifiable information.

"(ii) GUIDANCE AND REGULATIONS.—Not later than 18 months after the date of enactment of this paragraph, the Secretary shall finalize any draft or interim guidance and regulations relating to mental health parity under this section.

"(iii) STATE.—The Secretary shall share information on findings of compliance and noncompliance discovered upon reviewing the comparative analyses requested under subparagraph (B)(i) shall be shared with the State where the group health plan is located or the State where

the health insurance issuer is licensed to do business for coverage offered by a health insurance issuer in the group market, in accordance with section 2726(a)(6)(B)(iii)(II).''.

SEC. 311. TECHNICAL AMENDMENTS.

(a) ERISA.—Section 715 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185d) is amended—

(1) in subsection (a)(1), by striking ''(as amended by the Patient Protection and Affordable Care Act)'' and inserting ''(including any subsequent amendments to such part)''; and

(2) in subsection (b)—

(A) by striking ''(as amended by the Patient Protection and Affordable Care Act)'' and inserting ''(including any subsequent amendments to such part)''; and

(B) by striking ''(as so amended)''.

(b) IRC.—Section 9815 of the Internal Revenue Code of 1986 is amended—

(1) in subsection (a)(1), by striking ''(as amended by the Patient Protection and Affordable Care Act)'' and inserting ''(including any subsequent amendments to such part)''; and

(2) in subsection (b)—

(A) by striking ''(as amended by the Patient Protection and Affordable Care Act)'' and inserting ''(including any subsequent amendments to such part)''; and

(B) by striking ''(as so amended)''.

(c) APPLICABILITY.—The amendments made by subsections (a) and (b) shall take effect as though included in the enactment of the Patient Protection and Affordable Care Act (Public Law 111–148).

SEC. 312. THIRD-PARTY ADMINISTRATORS.

Any obligation on a third-party administrator under this Act (including the amendments made by this Act) shall not affect any other direct or indirect requirement under any other provision Federal law that applies to third-party administrators offering services to group health plans.

SEC. 313. GROUP HEALTH PLAN REPORTING REQUIREMENTS.

Part C of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–91 et seq.), as amended by section 303, is further amended by adding at the end the following:

"SEC. 2797. GROUP HEALTH PLAN REPORTING.

"(a) IN GENERAL.—A group health plan or health insurance issuer offering group or individual health insurance coverage shall submit to the Secretary, not later than March 1 of each year, the following information with respect to the health plan in the previous plan year:

"(1) The beginning and end dates of the plan year.

"(2) The number of enrollees.

"(3) Each State in which the plan is offered.

"(4) The 50 brand prescription drugs most frequently dispensed by pharmacies for claims paid by the issuer, and the total number of paid claims for each such drug.

"(5) The 50 most costly prescription drugs with respect to the plan by total annual spending, and the annual amount spent by the plan for each such drug.

"(6) The 50 prescription drugs with the greatest increase in plan expenditures over the plan year preceding the plan year that is the subject of the report, and, for each such drug, the change in amounts expended by the plan in each such plan year.

"(7) Total spending on health care services by such group health plan, broken down by—

"(A) the type of costs, including—

"(i) hospital costs;

"(ii) health care provider and clinical service costs;

"(iii) costs for prescription drugs; and

"(iv) other medical costs; and

"(B) spending on prescription drugs by—

"(i) the health plan; and

"(ii) the enrollees.

"(8) The average monthly premium—

"(A) paid by employers on behalf of enrollees; and

"(B) paid by enrollees.

"(9) Any impact on premiums by rebates, fees, and any other remuneration paid by drug manufacturers to the plan or its administrators or service providers, with respect to prescription drugs prescribed to enrollees in the plan, including—

"(A) the amounts so paid for each therapeutic class of drugs; and

"(B) the amounts so paid for each of the 25 drugs that yielded the highest amount of rebates and other remuneration under the plan from drug manufacturers during the plan year.

''(10) Any reduction in premiums and out-of-pocket costs associated with rebates, fees, or other remuneration described in paragraph (9).

''(b) REPORT.—Not later than 18 months after the date on which the first report is required under subsection (a) and biannually thereafter, the Secretary, acting through the Assistant Secretary of Planning and Evaluation and in coordination with the Inspector General of the Department of Health and Human Services, shall make available on the internet website of the Department of Health and Human Services a report on prescription drug reimbursements under group health plans, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under such plans, aggregated in such a way as no drug or plan specific information will be made public.

''(c) PRIVACY PROTECTIONS.—No confidential or trade secret information submitted to the Secretary under subsection (a) shall be included in the report under subsection (b).''.

SEC. 314. STUDY BY COMPTROLLER GENERAL OF UNITED STATES.

(a) IN GENERAL.—The Comptroller General of the United States (referred to in this section as the ''Comptroller General'') shall, in consultation with appropriate

stakeholders, conduct a study on the role of pharmacy benefit managers.

(b) PERMISSIBLE EXAMINATION.—In conducting the study required under subsection (a), the Comptroller General may examine various qualitative and quantitative aspects of the role of pharmacy benefit managers, such as the following:

(1) The role that pharmacy benefit managers play in the pharmaceutical supply chain.

(2) The state of competition among pharmacy benefit managers, including the market share for the Nation's largest pharmacy benefit managers.

(3) The use of rebates and fees by pharmacy benefit managers, including—

(A) the extent to which rebates are passed on to health plans and whether such rebates are passed on to individuals enrolled in such plans;

(B) the extent to which rebates are kept by such pharmacy benefit managers; and

(C) the role of any fees charged by such pharmacy benefit managers.

(4) Whether pharmacy benefit managers structure their formularies in favor of high-rebate prescription drugs over lower-cost, lower-rebate alternatives.

(5) The average prior authorization approval time for pharmacy benefit managers.

(6) Factors affecting the use of step therapy by pharmacy benefit managers.

(c) REPORT.—Not later than 3 years after the date of enactment of this Act, the Comptroller General shall submit to the Secretary of Health and Human Services, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report containing the results of the study conducted under subsection (a), including policy recommendations.

TITLE IV—IMPROVING PUBLIC HEALTH

SEC. 401. IMPROVING AWARENESS OF DISEASE PREVENTION.

The Public Health Service Act is amended by striking section 313 of such Act (42 U.S.C. 245) and inserting the following:

"SEC. 313. PUBLIC AWARENESS CAMPAIGN ON THE IMPORTANCE OF VACCINATIONS.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other offices and agencies, as appropriate, shall award competitive grants to one

or more public or private entities to carry out a national, evidence-based campaign to increase awareness and knowledge of the safety and effectiveness of vaccines for the prevention and control of diseases, combat misinformation about vaccines, and disseminate scientific and evidence-based vaccine-related information, with the goal of increasing rates of vaccination across all ages, as applicable, particularly in communities with low rates of vaccination, to reduce and eliminate vaccine-preventable diseases.

''(b) CONSULTATION.—In carrying out the campaign under this section, the Secretary shall consult with appropriate public health and medical experts, including the National Academy of Medicine and medical and public health associations and nonprofit organizations, in the development, implementation, and evaluation of the evidence-based public awareness campaign.

''(c) REQUIREMENTS.—The campaign under this section shall—

''(1) be a national, evidence-based initiative;

''(2) include the development of resources for communities with low rates of vaccination, including culturally- and linguistically-appropriate resources, as applicable;

''(3) include the dissemination of vaccine information and communication resources to public health departments, health care providers, and health care facilities, including such providers and facilities that provide prenatal and pediatric care;

''(4) be complementary to, and coordinated with, any other Federal, State, local, or Tribal efforts, as appropriate; and

''(5) assess the effectiveness of communication strategies to increase rates of vaccination.

''(d) ADDITIONAL ACTIVITIES.—The campaign under this section may—

''(1) include the use of television, radio, the internet, and other media and telecommunications technologies;

''(2) be focused to address specific needs of communities and populations with low rates of vaccination; and

''(3) include the dissemination of scientific and evidence-based vaccine-related information, such as—

''(A) advancements in evidence-based research related to diseases that may be prevented by vaccines and vaccine development;

"(B) information on vaccinations for individuals and communities, including individuals for whom vaccines are not recommended by the Advisory Committee for Immunization Practices, and the effects of low vaccination rates within a community on such individuals;

"(C) information on diseases that may be prevented by vaccines; and

"(D) information on vaccine safety and the systems in place to monitor vaccine safety.

"(e) EVALUATION.—The Secretary shall—

"(1) establish benchmarks and metrics to quantitatively measure and evaluate the awareness campaign under this section;

"(2) conduct qualitative assessments regarding the awareness campaign under this section; and

"(3) prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and Committee on Energy and Commerce of the House of Representatives an evaluation of the awareness campaign under this section.

"(f) SUPPLEMENT NOT SUPPLANT.—Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities described in this section.

''(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section and section 317(k) such sums as may be necessary for fiscal years 2020 through 2024.''.

SEC. 402. GRANTS TO ADDRESS VACCINE-PREVENTABLE DISEASES.

(a) IN GENERAL.—Section 317(k)(1) of the Public Health Service Act (42 U.S.C. 247b(k)(1)) is amended—

(1) in subparagraph (C), by striking ''; and'' and inserting a semicolon;

(2) in subparagraph (D), by striking the period and inserting a semicolon; and

(3) by adding at the end the following:

''(E) planning, implementation, and evaluation of activities to address vaccine-preventable diseases, including activities to—

''(i) identify communities at high risk of outbreaks related to vaccine-preventable diseases, including through improved data collection and analysis;

''(ii) pilot innovative approaches to improve vaccination rates in communities and among populations with low rates of vaccination;

''(iii) reduce barriers to accessing vaccines and evidence-based information about the health effects of vaccines;

''(iv) partner with community organizations and health care providers to develop and deliver evidence-based interventions, including culturally- and linguistically-appropriate interventions, to increase vaccination rates;

''(v) improve delivery of evidence-based vaccine-related information to parents and others; and

''(vi) improve the ability of State, local, tribal, and territorial public health departments to engage communities at high risk for outbreaks related to vaccine-preventable diseases; and

''(F) research related to strategies for improving awareness of scientific and evidence-based vaccine-related information, including for communities with low rates of vaccination, in order to understand barriers to vaccination, improve vaccination rates, and assess the public health outcomes of such strategies.''.

(b) SUPPLEMENTAL GRANT FUNDS.—Section 330(d)(1) of the Public Health Service Act (42 U.S.C. 254b) is amended—

(1) in subparagraph (F), by striking ''and'' at the end;

(2) in subparagraph (G), by striking the period and and inserting ''; and''; and

(3) by adding at the end the following:

''(H) improving access to recommended immunizations.''.

SEC. 403. GUIDE ON EVIDENCE-BASED STRATEGIES FOR PUBLIC HEALTH DEPARTMENT OBESITY PREVENTION PROGRAMS.

(a) DEVELOPMENT AND DISSEMINATION OF AN EVIDENCE-BASED STRATEGIES GUIDE.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Director of the Centers for Disease Control and Prevention, not later than 2 years after the date of enactment of this Act, shall—

(1) develop a guide on evidence-based strategies for State, territorial, and local health departments to use to build and maintain effective obesity prevention and reduction programs, and, in consultation with Indian Tribes and Tribal organizations, a guide on such evidence-based strategies with respect to In-

dian Tribes and Tribal organizations for such Indian Tribes and Tribal organizations to use for such purpose, both of which guides shall—

(A) describe an integrated program structure for implementing interventions proven to be effective in preventing and reducing the incidence of obesity; and

(B) recommend—

(i) optimal resources, including staffing and infrastructure, for promoting nutrition and obesity prevention and reduction; and

(ii) strategies for effective obesity prevention programs for State, territorial, and local health departments, Indian Tribes, and Tribal organizations, including strategies related to—

(I) the application of evidence-based and evidence-informed practices to prevent and reduce obesity rates;

(II) the development, implementation, and evaluation of obesity prevention and reduction strategies for specific communities and populations;

(III) demonstrated knowledge of obesity prevention practices that reduce associated preventable diseases, health conditions, death, and health care costs;

(IV) best practices for the coordination of efforts to prevent and reduce obesity and related chronic diseases;

(V) addressing the underlying risk factors and social determinants of health that impact obesity rates; and

(VI) interdisciplinary coordination between relevant public health officials specializing in fields such as nutrition, physical activity, epidemiology, communications, and policy implementation, and collaboration between public health officials, community-based organizations, and others, as appropriate; and

(2) disseminate the guides and current research, evidence-based practices, tools, and educational materials related to obesity prevention, consistent with the guide, to State, territorial, and local

health departments, Indian Tribes, and Tribal organizations.

(b) TECHNICAL ASSISTANCE.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall provide technical assistance to State, territorial, and local health departments, Indian Tribes, and Tribal organizations to support such health departments in implementing the guide developed under subsection (a)(1).

(c) INDIAN TRIBES; TRIBAL ORGANIZATIONS.—The terms ''Indian Tribe'' and ''Tribal organization'' have the meanings given the terms ''Indian tribe'' and ''tribal organization'', respectively, in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

SEC. 404. EXPANDING CAPACITY FOR HEALTH OUTCOMES.

Title III of the Public Health Service Act is amended by inserting after section 330M (42 U.S.C. 254c–19) the following:

''SEC. 330N. EXPANDING CAPACITY FOR HEALTH OUTCOMES.

''(a) DEFINITIONS.—In this section:

''(1) ELIGIBLE ENTITY.—The term 'eligible entity' means an entity providing health care services in rural areas, frontier areas, health professional

shortage areas, or medically underserved areas, or to medically underserved populations or Native Americans, including Indian tribes or tribal organizations.

''(2) HEALTH PROFESSIONAL SHORTAGE AREA.—The term 'health professional shortage area' means a health professional shortage area designated under section 332.

''(3) INDIAN TRIBE.—The terms 'Indian tribe' and 'tribal organization' have the meanings given such terms in section 4 of the Indian Self-Determination and Education Assistance Act.

''(4) MEDICALLY UNDERSERVED POPULATION.—The term 'medically underserved population' has the meaning given the term in section 330(b)(3).

''(5) NATIVE AMERICANS.—The term 'Native Americans' has the meaning given such term in section 736 and includes Indian tribes and tribal organizations.

''(6) TECHNOLOGY-ENABLED COLLABORATIVE LEARNING AND CAPACITY BUILDING MODEL.—The term 'technology-enabled collaborative learning and capacity building model' means a distance health education model that connects health care professionals, and particularly specialists, with multiple

other health care professionals through simultaneous interactive videoconferencing for the purpose of facilitating case-based learning, disseminating best practices, and evaluating outcomes.

''(b) PROGRAM ESTABLISHED.—The Secretary shall, as appropriate, award grants to evaluate, develop, and, as appropriate, expand the use of technology-enabled collaborative learning and capacity building models, to increase access to health care services, such as those to address chronic diseases and conditions, mental health, substance use disorders, prenatal and maternal health, pediatric care, pain management, palliative care, and other specialty care in rural areas, frontier areas, health professional shortage areas, or medically underserved areas and for medically underserved populations or Native Americans, including Indian Tribes and Tribal organizations.

''(c) USE OF FUNDS.—

''(1) IN GENERAL.—Grants awarded under subsection (b) shall be used for—

''(A) the development and acquisition of instructional programming, and the training of health care providers and other professionals that provide or assist in the provision of services through such models;

"(B) information collection and evaluation activities to study the impact of such models on patient outcomes and health care providers, and to identify best practices for the expansion and use of such models; or

"(C) other activities consistent with achieving the objectives of the grants awarded under this section, as determined by the Secretary.

"(2) OTHER USES.—In addition to any of the uses under paragraph (1), grants awarded under subsection (b) may be used for—

"(A) equipment to support the use and expansion of technology-enabled collaborative learning and capacity building models, including for hardware and software that enables distance learning, health care provider support, and the secure exchange of electronic health information; or

"(B) support for health care providers and other professionals that provide or assist in the provision of services through such models.

"(d) LENGTH OF GRANTS.—Grants awarded under subsection (b) shall be for a period of up to 5 years.

"(e) APPLICATION.—An eligible entity that seeks to receive a grant under subsection (b) shall submit to the

Secretary an application, at such time, in such manner, and containing such information as the Secretary may require. Such application criteria shall include an assessment of the effect of technology-enabled collaborative learning and capacity building models on patient outcomes and health care providers.

''(f) ACCESS TO BROADBAND.—In administering grants under this section, the Secretary may coordinate with other agencies to ensure that funding opportunities are available to support access to reliable, high-speed internet for grantees.

''(g) TECHNICAL ASSISTANCE.—The Secretary shall provide (either directly through the Department of Health and Human Services or by contract) technical assistance to eligible entities, including recipients of grants under subsection (b), on the development, use, and evaluation of technology-enabled collaborative learning and capacity building models in order to expand access to health care services provided by such entities, including for medically underserved areas and to medically underserved populations or Native Americans, including Indian tribes and Tribal organizations.

''(h) RESEARCH AND EVALUATION.—The Secretary, in consultation with stakeholders with appropriate expertise in such models, shall develop a strategic plan to re-

search and evaluate the evidence for such models. The Secretary shall use such plan to inform the activities carried out under this section.

''(i) REPORT BY SECRETARY.—Not later than 4 years after the date of enactment of this section, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and post on the Internet website of the Department of Health and Human Services, a report including, at minimum—

''(1) a description of any new and continuing grants awarded to entities under subsection (b) and the specific purpose and amounts of such grants;

''(2) an overview of—

''(A) the evaluations conducted under subsections (b) or (f); and

''(B) technical assistance provided under subsection (g); and

''(3) a description of any significant findings or developments in patient outcomes and health care providers and best practices for eligible entities expanding, using, or evaluating technology-enabled collaborative learning and capacity building models, in-

cluding through the activities described in subsection (g).

''(j) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, such sums as may be necessary for each of fiscal years 2020 through 2024.''.

SEC. 405. PUBLIC HEALTH DATA SYSTEM MODERNIZATION.

Subtitle C of title XXVIII of the Public Health Service Act (42 U.S.C. 300hh–31 et seq.) is amended by adding at the end the following:

''SEC. 2822. PUBLIC HEALTH DATA SYSTEM MODERNIZATION GRANTS.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

''(1) award grants to State, local, Tribal, and territorial public health departments for the expansion and modernization of public health data systems, to assist public health departments in—

''(A) assessing current data infrastructure capabilities and gaps to improve and increase consistency in data collection, storage, analysis, and, as appropriate, to improve dissemination of public health-related information;

"(B) improving secure public health data collection, transmission, exchange, maintenance, and analysis;

"(C) simplifying and supporting reporting by health care providers, as applicable, pursuant to State law, including through the use of health information technology, to State, local, Tribal, and territorial public health departments, including public health officials in multiple jurisdictions within such State, as appropriate;

"(D) enhancing interoperability of public health data systems (including systems created or accessed by public health departments) with health information technology, including health information technology certified under section 3001(c)(5);

"(E) supporting earlier disease and health condition detection, such as through near real-time data monitoring, to support rapid public health responses; and

"(F) supporting activities within the applicable jurisdiction related to the expansion and modernization of electronic case reporting;

''(2) as appropriate, conduct activities related to the interoperability and improvement of applicable public health data systems used by the Centers for Disease Control and Prevention, and, in coordination with the Office of the National Coordinator for Health Information Technology, the designation of data and technology standards for health information systems of the public health infrastructure with deference given to standards published by standards development organizations and voluntary consensus-based standards bodies; and

''(3) develop and utilize public-private partnerships for technical assistance and related implementation support for State, local, Tribal, and territorial public health departments, and the Centers for Disease Control and Prevention, on the expansion and modernization of electronic case reporting and public health data systems, as applicable.

''(b) REQUIREMENTS.—

''(1) IN GENERAL.—The Secretary may not award a grant under subsection (a)(1) unless the applicant uses or agrees to use standards recognized by the National Coordinator for Health Information Technology pursuant to section 3001(c)(1) or adopted by the Secretary under section 3004.

''(2) WAIVER.—The Secretary may waive the requirement under paragraph (1) with respect to an applicant if the Secretary determines that the activities under subsection (a) cannot otherwise be carried out within the applicable jurisdiction.

''(3) APPLICATION.—A State, local, Tribal, or territorial health department applying for a grant under this section shall submit an application to the Secretary at such time and in such manner as the Secretary may require. Such application shall include information describing—

''(A) the activities that will be supported by the grant; and

''(B) how the modernization of such public health data systems will support or impact the public health infrastructure of the health department, including a description of remaining gaps, if any, and the actions needed to address such gaps.

''(c) USE OF FUNDS.—An entity receiving a grant under this section may use amounts received under such grant for one or both of the following:

''(1) Carrying out activities described in subsection (a)(1) to support public health data systems (including electronic case reporting), which may in-

clude support for, and training of, professionals with expertise in contributing to and using such systems (including public health data scientists).

''(2) Developing and disseminating information related to the use and importance of public health data.

''(d) STRATEGY AND IMPLEMENTATION PLAN.—Not later than 180 days after the date of enactment of the Lower Health Care Costs Act, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a coordinated strategy and an accompanying implementation plan that identifies and demonstrates the steps the Secretary will carry out to—

''(1) update and improve applicable public health data systems used by the Centers for Disease Control and Prevention; and

''(2) carry out the activities described in this section to support the improvement of State, local, Tribal, and territorial public health data systems.

''(e) CONSULTATION.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall consult with State, local, Tribal, and terri-

torial health departments, professional medical and public health associations, associations representing hospitals or other health care entities, health information technology experts, and other appropriate entities regarding the plan and grant program to modernize public health data systems pursuant to this section. Such activities may include the provision of technical assistance related to the exchange of information by such public health data systems used by relevant health care and public health entities at the local, State, Federal, Tribal, and territorial levels.

''(f) REPORT TO CONGRESS.—Not later than 1 year after the date of enactment of this section, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that includes—

''(1) a description of any barriers to—

''(A) public health authorities implementing interoperable public health data systems and electronic case reporting;

''(B) the exchange of information pursuant to electronic case reporting; or

''(C) reporting by health care providers using such public health data systems, as appropriate, and pursuant to State law;

''(2) an assessment of the potential public health impact of implementing electronic case reporting and interoperable public health data systems; and

''(3) a description of the activities carried out pursuant to this section.

''(g) ELECTRONIC CASE REPORTING.—In this section, the term 'electronic case reporting' means the automated identification, generation, and bilateral exchange of reports of health events among electronic health record or health information technology systems and public health authorities.

''(h) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2020 through 2024.''.

SEC. 406. INNOVATION FOR MATERNAL HEALTH.

Title III of the Public Health Service Act is amended by inserting after section 330N of such Act, as added by section 404, the following:

''SEC. 330O. INNOVATION FOR MATERNAL HEALTH.

''(a) IN GENERAL.—The Secretary, in consultation with experts representing a variety of clinical specialties, State, tribal, or local public health officials, researchers, epidemiologists, statisticians, and community organiza-

tions, shall establish or continue a program to award competitive grants to eligible entities for the purpose of—

"(1) identifying, developing, or disseminating best practices to improve maternal health care quality and outcomes, eliminate preventable maternal mortality and severe maternal morbidity, and improve infant health outcomes, which may include—

"(A) information on evidence-based practices to improve the quality and safety of maternal health care in hospitals and other health care settings of a State or health care system, including by addressing topics commonly associated with health complications or risks related to prenatal care, labor care, birthing, and postpartum care;

"(B) best practices for improving maternal health care based on data findings and reviews conducted by a State maternal mortality review committee that address topics of relevance to common complications or health risks related to prenatal care, labor care, birthing, and postpartum care; and

"(C) information on addressing determinants of health that impact maternal health

outcomes for women before, during, and after pregnancy;

''(2) collaborating with State maternal mortality review committees to identify issues for the development and implementation of evidence-based practices to improve maternal health outcomes and reduce preventable maternal mortality and severe maternal morbidity;

''(3) providing technical assistance and supporting the implementation of best practices identified in paragraph (1) to entities providing health care services to pregnant and postpartum women; and

''(4) identifying, developing, and evaluating new models of care that improve maternal and infant health outcomes, which may include the integration of community-based services and clinical care.

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

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

''(2) demonstrate in such application that the entity is capable of carrying out data-driven maternal safety and quality improvement initiatives in the

areas of obstetrics and gynecology or maternal health.

''(c) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated such sums as may be necessary for each of fiscal years 2020 through 2024.''.

SEC. 407. TRAINING FOR HEALTH CARE PROVIDERS.

Title VII of the Public Health Service Act is amended by striking section 763 (42 U.S.C. 294p) and inserting the following:

''SEC. 763. TRAINING FOR HEALTH CARE PROVIDERS.

''(a) GRANT PROGRAM.—The Secretary shall establish a program to award grants to accredited schools of allopathic medicine, osteopathic medicine, and nursing, and other health professional training programs for the training of health care professionals to reduce and prevent discrimination (including training related to implicit biases) in the provision of health care services related to prenatal care, labor care, birthing, and postpartum care.

''(b) ELIGIBILITY.—To be eligible for a grant under subsection (a), an entity described in such subsection shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''(c) REPORTING REQUIREMENT.—Each entity awarded a grant under this section shall periodically submit to the Secretary a report on the status of activities conducted using the grant, including a description of the impact of such training on patient outcomes, as applicable.

''(d) BEST PRACTICES.—The Secretary may identify and disseminate best practices for the training of health care professionals to reduce and prevent discrimination (including training related to implicit biases) in the provision of health care services related to prenatal care, labor care, birthing, and postpartum care.

''(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated such sums as may be necessary for each of fiscal years 2020 through 2024.''.

SEC. 408. STUDY ON TRAINING TO REDUCE AND PREVENT DISCRIMINATION.

Not later than 2 years after date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall, through a contract with an independent research organization, conduct a study and make recommendations for accredited schools of allopathic medicine, osteopathic medicine, and nursing, and other health professional training programs on best practices related to training to reduce and prevent

discrimination, including training related to implicit biases, in the provision of health care services related to prenatal care, labor care, birthing, and postpartum care.

SEC. 409. PERINATAL QUALITY COLLABORATIVES.

Section 317K(a)(2) of the Public Health Service Act (42 U.S.C. 247b–12(a)(2)) is amended by adding at the end the following:

"(E)(i) The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other offices and agencies, as appropriate, shall establish or continue a competitive grant program for the establishment or support of perinatal quality collaboratives to improve perinatal care and perinatal health outcomes for pregnant and postpartum women and their infants. A State, Indian Tribe, or Tribal organization may use funds received through such grant to—

"(I) support the use of evidence-based or evidence-informed practices to improve outcomes for maternal and infant health;

"(II) work with clinical teams; experts; State, local, and, as appropriate, tribal public health officials; and stakeholders, including patients and families, to

identify, develop, or disseminate best practices to improve perinatal care and outcomes; and

''(III) employ strategies that provide opportunities for health care professionals and clinical teams to collaborate across health care settings and disciplines, including primary care and mental health, as appropriate, to improve maternal and infant health outcomes, which may include the use of data to provide timely feedback across hospital and clinical teams to inform responses, and to provide support and training to hospital and clinical teams for quality improvement, as appropriate.

''(ii) To be eligible for a grant under clause (i), an entity shall submit to the Secretary an application in such form and manner and containing such information as the Secretary may require.''.

SEC. 410. INTEGRATED SERVICES FOR PREGNANT AND POSTPARTUM WOMEN.

(a) GRANTS.—Title III of the Public Health Service Act is amended by inserting after section 330O of such Act, as added by section 406, the following:

"SEC. 330P. INTEGRATED SERVICES FOR PREGNANT AND POSTPARTUM WOMEN.

''(a) IN GENERAL.—The Secretary may award grants for the purpose of establishing or operating evidence-based or innovative, evidence-informed programs to deliver integrated health care services to pregnant and postpartum women to optimize the health of women and their infants, including to reduce adverse maternal health outcomes, pregnancy-related deaths, and related health disparities (including such disparities associated with racial and ethnic minority populations), and, as appropriate, by addressing issues researched under subsection (b)(2) of section 317K.

''(b) INTEGRATED SERVICES FOR PREGNANT AND POSTPARTUM WOMEN.—

''(1) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), a State, Indian Tribe, or Tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act) shall work with relevant stakeholders that coordinate care (including coordinating resources and referrals for health care and social services) to develop and carry out the program, including—

''(A) State, Tribal, and local agencies responsible for Medicaid, public health, social

services, mental health, and substance use disorder treatment and services;

''(B) health care providers who serve pregnant and postpartum women; and

''(C) community-based health organizations and health workers, including providers of home visiting services and individuals representing communities with disproportionately high rates of maternal mortality and severe maternal morbidity, and including those representing racial and ethnicity minority populations.

''(2) TERMS.—

''(A) PERIOD.—A grant awarded under subsection (a) shall be made for a period of 5 years. Any supplemental award made to a grantee under subsection (a) may be made for a period of less than 5 years.

''(B) PREFERENCE.—In awarding grants under subsection (a), the Secretary shall—

''(i) give preference to States, Indian Tribes, and Tribal organizations that have the highest rates of maternal mortality and severe maternal morbidity relative to other

such States, Indian Tribes, or Tribal organizations, respectively; and

''(ii) shall consider health disparities related to maternal mortality and severe maternal morbidity, including such disparities associated with racial and ethnic minority populations.

''(C) PRIORITY.—In awarding grants under subsection (a), the Secretary shall give priority to applications from up to 15 entities described in subparagraph (B)(i).

''(D) EVALUATION.—The Secretary shall require grantees to evaluate the outcomes of the programs supported under the grant.

''(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2020 through 2024.''.

(b) REPORT ON GRANT OUTCOMES AND DISSEMINATION OF BEST PRACTICES.—

(1) REPORT.—Not later than February 1, 2026, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the

Committee on Energy and Commerce of the House of Representatives a report that describes—

(A) the outcomes of the activities supported by the grants awarded under the amendments made by this section on maternal and child health;

(B) best practices and models of care used by recipients of grants under such amendments; and

(C) obstacles identified by recipients of grants under such amendments, and strategies used by such recipients to deliver care, improve maternal and child health, and reduce health disparities.

(2) DISSEMINATION OF BEST PRACTICES.—Not later than August 1, 2026, the Secretary of Health and Human Services shall disseminate information on best practices and models of care used by recipients of grants under the amendments made by this section (including best practices and models of care relating to the reduction of health disparities, including such disparities associated with racial and ethnic minority populations, in rates of maternal mortality and severe maternal morbidity) to relevant stakeholders, which may include health providers, medical

schools, nursing schools, relevant State, tribal, and local agencies, and the general public.

SEC. 411. EXTENSION FOR COMMUNITY HEALTH CENTERS, THE NATIONAL HEALTH SERVICE CORPS, AND TEACHING HEALTH CENTERS THAT OPERATE GME PROGRAMS.

(a) COMMUNITY HEALTH CENTERS.—Section 10503(b)(1)(F) of the Patient Protection and Affordable Care Act (42 U.S.C. 254b–2(b)(1)(F)) is amended by striking ''fiscal year 2019'' and inserting ''each of fiscal years 2019 through 2024''.

(b) NATIONAL HEALTH SERVICE CORPS.—Section 10503(b)(2)(F) of the Patient Protection and Affordable Care Act (42 U.S.C. 254b–2(b)(2)(F)) is amended by striking ''and 2019'' and inserting ''through 2024''.

(c) TEACHING HEALTH CENTERS THAT OPERATE GRADUATE MEDICAL EDUCATION PROGRAMS.—Section 340H(g)(1) of the Public Health Service Act (42 U.S.C. 256h(g)(1)) is amended by striking ''and 2019'' and inserting ''through 2024''.

(d) APPLICATION OF PROVISIONS.—Amounts appropriated pursuant to this section for each of fiscal years 2019 through 2024 shall be subject to the requirements contained in Public Law 115–245 for funds for programs

authorized under sections 330 through 340 of the Public Health Service Act.

(e) CONFORMING AMENDMENTS.—Paragraph (4) of section 3014(h) of title 18, United States Code, as amended by section 50901 of Public Law 115–123, is amended by striking ''and section 50901(e) of the Advancing Chronic Care, Extenders, and Social Services Act'' and inserting '', section 50901(e) of the Advancing Chronic Care, Extenders, and Social Services Act, and section 411(d) of the Lower Health Care Costs Act''.

SEC. 412. OTHER PROGRAMS.

(a) TYPE I.—Section 330B(b)(2)(D) of the Public Health Service Act (42 U.S.C. 254c–2(b)(2)(D)) is amended by striking ''and 2019'' and inserting ''through 2024''.

(b) INDIANS.—Subparagraph (D) of section 330C(c)(2) of the Public Health Service Act (42 U.S.C. 254c–3(c)(2)(D)) is amended by striking ''and 2019'' and inserting ''through 2024''.

SEC. 413. NATIVE AMERICAN SUICIDE PREVENTION.

Section 520E(b) of the Public Health Service Act (42 U.S.C. 290bb–36(b) is amended by inserting after paragraph (3) the following:

''(4) CONSULTATION.—A State applying for a grant or cooperative agreement under this section

shall, in the development and implementation of a statewide early intervention strategy, consult or confer with entities described in paragraph (1)(C) in such State.''.

SEC. 414. MINIMUM AGE OF SALE OF TOBACCO PRODUCTS.

(a) IN GENERAL.—Section 906(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)) is amended—

(1) in paragraph (3)(A)(ii), by striking ''18 years'' and inserting ''21 years''; and

(2) by adding at the end the following:

''(5) MINIMUM AGE OF SALE.—It shall be unlawful for any retailer to sell a tobacco product to any person younger than 21 years of age.''.

(b) REGULATIONS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall publish in the Federal Register a final rule to update the regulations issued under chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387 et seq.) as appropriate, only to carry out the amendments made by subsection (a), including updating the relevant age verification requirements under part 1140 of title 21, Code of Federal Regulations to require age verification for individuals under the age of 30. Such final rule shall—

(1) take full effect not later than 90 days after the date on which such final rule is published; and

(2) be deemed to be in compliance with all applicable provisions of chapter 5 of title 5, United States Code and all other provisions of law relating to rulemaking procedures.

(c) NOTIFICATION.—Not later than 90 days after the date of enactment of this Act, the Secretary shall provide written notification to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding the progress of the Department of Health and Human Services towards promulgating the final rule under subsection (b). If, 180 days after the date of enactment of this Act, such rule has not been promulgated in accordance with subsection (b), the Secretary shall provide a written notification and a justification for the delay in rulemaking to such committees.

(d) PENALTIES FOR VIOLATIONS.—

(1) IN GENERAL.—Section 103(q)(2) of the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31) is amended—

(A) in subparagraph (A), in the matter preceding clause (i), by inserting ''section 906(d)(5) or of'' after ''violations of''; and

(B) in subparagraph (C), by inserting ''section 906(d)(5) or of'' after ''a retailer of''.

(2) REPEATED VIOLATIONS.—Section 303(f)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(8)) is amended by inserting ''section 906(d)(5) or of'' after ''repeated violations of''.

(3) MISBRANDED PRODUCTS.—Section 903(a)(7)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387c) is amended by inserting ''section 906(d)(5) or of'' after ''violation of''.

SEC. 415. SALE OF TOBACCO PRODUCTS TO INDIVIDUALS UNDER THE AGE OF 21.

(a) IN GENERAL.—Section 1926 of the Public Health Service Act (42 U.S.C. 300x–26) is amended—

(1) in the heading—

(A) by striking ''**STATE LAW REGARDING**''; and

(B) by striking ''**18**'' and inserting ''**21**'';

(2) by striking subsections (a) and (d);

(3) by redesignating subsections (b) and (c) as subsections (a) and (b), respectively;

(4) by amending subsection (a), as so redesignated, to read as follows:

''(a) IN GENERAL.—A funding agreement for a grant under section 1921 is that the State involved will—

''(1) annually conduct random, unannounced inspections to ensure that retailers do not sell tobacco products to individuals under the age of 21; and

''(2) annually submit to the Secretary a report describing—

''(A) the activities carried out by the State to ensure that retailers do not sell tobacco products to individuals under the age of 21;

''(B) the extent of success the State has achieved in ensuring that retailers do not sell tobacco products to individuals under the age of 21; and

''(C) the strategies to be utilized by the State to ensure that retailers do not sell tobacco products to individuals under the age of 21 during the fiscal year for which the grant is sought.'';

(5) in subsection (b), as so redesignated—

(A) by striking paragraphs (1), (2), (3), and (4);

(B) by striking ''Before making'' and inserting the following:

''(1) IN GENERAL.—Before making'';

(C) by striking ''for the first applicable fiscal year or any subsequent fiscal year'';

(D) by striking ''subsections (a) and (b)'' and inserting ''subsection (a)'';

(E) by striking ''equal to—'' and inserting ''up to 10 percent of the amount determined under section 1933 for the State for the applicable fiscal year.''; and

(F) by adding at the end the following:

''(2) LIMITATION.—

''(A) IN GENERAL.—A State shall not have funds withheld pursuant to paragraph (1) if such State for which the Secretary has made a determination of noncompliance under such paragraph—

''(i) certifies to the Secretary by May 1 of the fiscal year for which the funds are appropriated, consistent with subparagraph (B), that the State will commit additional State funds, in accordance with paragraph (1), to ensure that retailers do not sell tobacco products to individuals under 21 years of age;

''(ii) agrees to comply with a negotiated agreement for a corrective action plan that is approved by the Secretary and

carried out in accordance with guidelines issued by the Secretary; or

''(iii) is a territory that receives less than $1,000,000 for a fiscal year under section 1921.

''(B) CERTIFICATION.—

''(i) IN GENERAL.—The amount of funds to be committed by a State pursuant to subparagraph (A)(i) shall be equal to 1 percent of such State's substance abuse allocation determined under section 1933 for each percentage point by which the State misses the retailer compliance rate goal established by the Secretary.

''(ii) STATE EXPENDITURES.—For a fiscal year in which a State commits funds as described in clause (i), such State shall maintain State expenditures for tobacco prevention programs and for compliance activities at a level that is not less than the level of such expenditures maintained by the State for the preceding fiscal year, plus the additional funds for tobacco compliance activities required under clause (i). The State shall submit a report to the Sec-

retary on all State obligations of funds for such fiscal year and all State expenditures for the preceding fiscal year for tobacco prevention and compliance activities by program activity by July 31 of such fiscal year.

''(iii) DISCRETION.—The Secretary shall exercise discretion in enforcing the timing of the State obligation of the additional funds required by the certification described in subparagraph (A)(i) as late as July 31 of such fiscal year.

''(C) FAILURE TO CERTIFY.—If a State described in subparagraph (A) fails to certify to the Secretary pursuant to subparagraph (A)(i) or enter into, or comply with, a negotiated agreement under subparagraph (A)(ii), the Secretary may take action pursuant to paragraph (1).''; and

(6) by adding at the end the following:

''(c) IMPLEMENTATION OF REPORTING REQUIREMENTS.—

''(1) TRANSITION PERIOD.—The Secretary shall—

"(A) not withhold amounts under subsection (b) for the 3-year period immediately following the date of enactment of the Lower Health Care Costs Act; and

"(B) use discretion in exercising its authority under subsection (b) during the 2-year period immediately following the 3-year period described in subparagraph (A), to allow for a transition period for implementation of the reporting requirements under subsection (a)(2).

"(2) REGULATIONS OR GUIDANCE.—Not later than 180 days after the date of enactment of the Lower Health Care Costs Act the Secretary shall update regulations under part 96 of title 45, Code of Federal Regulations or guidance on the retailer compliance rate goal under subsection (b), the use of funds provided under section 1921 for purposes of meeting the requirements of this section, and reporting requirements under subsection (a)(2).

"(3) COORDINATION.—The Secretary shall ensure the Assistant Secretary for Mental Health and Substance Use coordinates, as appropriate, with the Commissioner of Food and Drugs in providing technical assistance under this section to States, related to ensuring retailers do not sell tobacco products to

individuals under the age of 21, that is consistent with applicable regulations issued by the Food and Drug Administration.

''(d) TRANSITIONAL GRANTS.—

''(1) IN GENERAL.—The Secretary shall award grants under this subsection to each State that receives funding under section 1921 to ensure compliance of each such State with this section.

''(2) USE OF FUNDS.—A State receiving a grant under this subsection—

''(A) shall use amounts received under such grant for activities to plan for or ensure compliance in the States that ensure compliance in the State with subsection (a); and

''(B) in the case of a State for which the Secretary has made a determination under subsection (b) that the State is prepared to meet, or has met, the requirements of subsection (a), may use such funds for tobacco cessation activities, strategies to prevent the use of tobacco products by individuals under the age of 21, or allowable uses under section 1921.

''(3) SUPPLEMENT NOT SUPPLANT.—Grants under this subsection shall be used to supplement and not supplant other Federal, State, and local

public funds provided for activities under this section.

''(4) AUTHORIZATION OF APPROPRIATIONS.—To carry out this subsection, there are authorized to be appropriated $18,580,790 for each of fiscal years 2020 through 2024.

''(5) SUNSET.—This subsection shall have no force or effect after September 30, 2024.

''(e) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to States related to the activities required under this section.''.

(b) REPORT TO CONGRESS.—Not later than 3 years after the date of enactment of this Act, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the status of implementing the requirements of section 1926 of the Public Health Service Act (42 U.S.C. 300x–26), as amended by subsection (a), and a description of any technical assistance provided under subsection (e) of such section, including the number of meetings held and requested related to technical assistance.

(c) CONFORMING AMENDMENT.—Section 212 of division D of the Consolidated Appropriations Act, 2010 (Public Law 111–117) is repealed.

TITLE V—IMPROVING THE EXCHANGE OF HEALTH INFORMATION

SEC. 501. REQUIREMENT TO PROVIDE HEALTH CLAIMS, NETWORK, AND COST INFORMATION.

(a) IN GENERAL.—Part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.) is amended by inserting after section 2715A the following:

"SEC. 2715B. REQUIREMENT TO PROVIDE HEALTH CLAIMS, NETWORK, AND COST INFORMATION.

''(a) IN GENERAL.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall make available for access, exchange, and use without special effort, through application programming interfaces (or successor technology or standards), the information described in subsection (b), in the manner described in subsection (b) and otherwise consistent with this section.

''(b) INFORMATION.—The following information is required to be made available, as the Secretary may specify:

''(1) Historical claims, provider encounter, and payment data for each enrollee, which shall—

''(A) include adjudicated medical and prescription drug claims and equivalent encoun-

ters, including all data elements contained in such transactions—

"(i) that were adjudicated by the group health plan or health insurance issuer during the previous 5 years or the enrollee's entire period of enrollment in the applicable plan or coverage if such period is less than the previous 5 years;

"(ii) that involve benefits managed by any third party, such as a pharmacy benefits manager or radiology benefits manager that manages benefits or adjudicates claims on behalf of the plan or coverage; and

"(iii) from any other health plan or health insurance coverage offered by the same insurance issuer, in which the same enrollee was enrolled during the previous 5 years; and

"(B) be available to an enrollee or former enrollee, the enrollee's providers, and any third-party applications or services authorized by the enrollee—

"(i) through the application programming interfaces (or successor technology or

standards) as required by this paragraph, in a single, longitudinal format that is easy to understand, secure, and that may update automatically;

''(ii) as soon as practicable, and in no case later than the period of time determined by the Secretary, after the claim is adjudicated or the data is received by the health plan or health insurance issuer; and

''(iii) to the enrollee, former enrollee, and any providers or third-party applications or services authorized by the enrollee, for 5 years after the end date of the enrollee's enrollment in the plan or in any coverage offered by the health insurance issuer.

''(2) Identifying directory information for all in-network providers, including facilities and practitioners, that participate in the plan or coverage, which shall—

''(A) include—

''(i) the national provider identifier for in-network facilities and practitioners; and

"(ii) the name, address, phone number, and specialty for each such facility and practitioner, based on the most recent interaction between the plan or coverage and that facility or practitioner;

"(B) be capable of returning the information necessary to establish a list of participating in-network facilities and practitioners, in a given specialty or at a particular facility type, within a specified geographic radius; and

"(C) be capable of returning the network status, when presented with identifiers for a given enrollee and facility or practitioner.

"(3) Estimated enrollee out-of-pocket costs, including costs expected to be incurred through a deductible, co-payment, coinsurance, or other form of cost-sharing, for—

"(A) a designated set of common services or episodes of care, to be established by the Secretary through rulemaking, including, at a minimum—

"(i) in the case of services provided by a hospital, the 100 most common diagnosis-related groups, as used in the Medicare Inpatient Prospective Patient System

(or successor episode-based reimbursement methodology) at that hospital, based on claims data adjudicated by the group health plan or health insurance issuer;

''(ii) in the case of services provided in an out-patient setting, including radiology, lab tests, and out-patient surgical procedures, any service rendered by the facility or practitioner, and reimbursed by the health plan or health insurance issuer; and

''(iii) in the case of post-acute care, including home health providers, skilled nursing facilities, inpatient rehabilitation facilities, and long-term care hospitals, the patient out-of-pocket costs for an episode of care, as the Secretary may determine, which permits users to reasonably compare costs across different facility and service types; and

''(B) all prescription drugs currently included on any tier of the formulary of the plan or coverage.

''(c) AVAILABILITY AND ACCESS.—Subject to all applicable Federal and State privacy, security, and breach

notification laws, the application programming interfaces, including all data required to be made available through such interfaces, shall—

''(1) be made available by the applicable group health plan or health insurance issuer, at no charge, to—

''(A) enrollees and prospective enrollees in the group health plan or health insurance coverage;

''(B) third parties authorized by the enrollee;

''(C) facilities and practitioners who are under contract with the plan or coverage; and

''(D) business associates of such facilities and practitioners, as defined in section 160.103 of title 45, Code of Federal Regulations (or any successor regulations);

''(2) be available to enrollees in the group health plan or health insurance coverage, and to third-party applications or services facilitating such access by enrollees, during the enrollment process and for a minimum of 5 years after the end date of the enrollee's enrollment in the plan or in any coverage offered by the health insurance issuer;

''(3) permit persistent access by third party applications or services authorized by the enrollee, for a reasonable period of time, consistent with the requirements of the HIPAA Security rule (part 160 of title 45 Code of Federal Regulations and subparts A and C of part 164 of such title);

''(4) employ the applicable content, vocabulary, and technical standards, as determined by the Secretary pursuant to title XXX; and

''(5) employ security and authentication standards, as the Secretary determines appropriate.

''(d) RULE OF CONSTRUCTION REGARDING PRIVACY.—Nothing in this section shall be construed to alter existing obligations of a covered entity or business associate under the privacy, security, and breach notification rules promulgated under section 264(c) of the Health Insurance Portability and Accountability Act or section 13402 of the HITECH Act, or to alter the Secretary's existing authority to modify such rules, under part 2 of title 42, Code of Federal Regulations (or successor regulations), under section 444 of the General Education Provisions Act (20 U.S.C. 1232g) (commonly referred to as the 'Family Educational Rights and Privacy Act of 1974'), under the amendments made by the Genetic Information Nondiscrimination Act, or under State privacy law.''.

(b) EFFECTIVE DATE.—Section 2715B of the Public Health Service Act, as added by subsection (a), shall take effect 18 months after the date of enactment of this Act.

SEC. 502. RECOGNITION OF SECURITY PRACTICES.

Part 1 of subtitle D of the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. 17931 et seq.) is amended by adding at the end the following:

"SEC. 13412. RECOGNITION OF SECURITY PRACTICES.

''(a) IN GENERAL.—Consistent with the authority of the Secretary under sections 1176 and 1177 of the Social Security Act, when making determinations relating to fines under section 13410, decreasing the length and extent of an audit under section 13411, or remedies otherwise agreed to by the Secretary, the Secretary shall consider whether the covered entity or business associate has adequately demonstrated that it had, for not less than the previous 12 months, recognized security practices in place that may—

''(1) mitigate fines under section 13410;

''(2) result in the early, favorable termination of an audit under section 13411; and

''(3) mitigate the remedies that would otherwise be agreed to in any agreement with respect to resolving potential violations of the HIPAA Security

rule (part 160 of title 45 Code of Federal Regulations and subparts A and C of part 164 of such title) between the covered entity or business associate and the Department of Health and Human Services.

''(b) DEFINITION AND MISCELLANEOUS PROVISIONS.—

''(1) RECOGNIZED SECURITY PRACTICES.—The term 'recognized security practices' means the standards, guidelines, best practices, methodologies, procedures, and processes developed under section 2(c)(15) of the National Institute of Standards and Technology Act, the approaches promulgated under section 405(d) of the Cybersecurity Act of 2015, and other programs and processes that address cybersecurity and that are developed, recognized, or promulgated through regulations under other statutory authorities. Such practices shall be determined by the covered entity or business associate.

''(2) LIMITATION.—Nothing in this section shall be construed as providing the Secretary authority to increase fines under section 13410, or the length, extent or quantity of audits under section 13411, due to a lack of compliance with the recognized security practices.

''(3) NO LIABILITY FOR NONPARTICIPATION.—Subject to paragraph (4), nothing in this section shall be construed to subject a covered entity or business associate to liability for electing not to engage in the recognized security practices defined by this section.

''(4) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the Secretary's authority to enforce the HIPAA Security rule (part 160 of title 45 Code of Federal Regulations and subparts A and C of part 164 of such title), or to supersede or conflict with an entity or business associate's obligations under the HIPAA Security rule.''.

SEC. 503. GAO STUDY ON THE PRIVACY AND SECURITY RISKS OF ELECTRONIC TRANSMISSION OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION TO AND FROM ENTITIES NOT COVERED BY THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study to—

(1) describe the roles of Federal agencies and the private sector with respect to protecting the pri-

vacy and security of individually identifiable health information transmitted electronically to and from entities not covered by the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note);

(2) identify recent developments regarding the use of application programming interfaces to access individually identifiable health information, and implications for the privacy and security of such information;

(3) identify practices in the private sector, such as terms and conditions for use, relating to the privacy, disclosure, and secondary uses of individually identifiable health information transmitted electronically to or from entities, selected by an individual, that are not subject to the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996; and

(4) identify steps the public and private sectors can take to improve the private and secure access to and availability of individually identifiable health information.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the

United States shall submit to Congress a report concerning the findings of the study conducted under subsection (a).

SEC. 504. TECHNICAL CORRECTIONS.

(a) IN GENERAL.—Section 3022(b) of the Public Health Service Act (42 U.S.C. 300jj–52(b)) is amended by adding at the end the following new paragraph:

''(4) APPLICATION OF AUTHORITIES UNDER INSPECTOR GENERAL ACT OF 1978.—In carrying out this subsection, the Inspector General shall have the same authorities as provided under section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect as if included in the enactment of the 21st Century Cures Act (Public Law 114–255).

SEC. 505. PUBLIC MEETING.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall convene a public meeting for purposes of discussing and providing input on patient-matching metrics for the purpose of enabling interoperability and the exchange of health information across health care organizations.

(b) EXPERTS.—The public meeting under this section may include—

(1) representatives of relevant Federal agencies (including representatives from the Office of the National Coordinator for Health Information Technology);

(2) State, local, Tribal, and territorial public health officials;

(3) stakeholders with expertise in health information exchange;

(4) stakeholders with expertise in capabilities relevant to patient matching, such as experts in informatics and data analytics;

(5) stakeholders affected by record-matching (including patients, hospitals, health systems, payers, health information exchanges, and prescription drug monitoring programs); and

(6) other representatives, as the Secretary determines appropriate.

(c) TOPICS.—Such public meeting shall include a discussion of—

(1) standards and processes for assessing the accuracy of patient-matching algorithms;

(2) performance metrics for health care providers purchasing patient-matching technology and algorithm developers;

(3) the development of benchmarks for the accuracy of patient-matching algorithms;

(4) considerations for State, local, Tribal, and territorial capabilities and infrastructure related to data exchange, interoperability, and matching patient records;

(5) opportunities for the incorporation of innovative technologies to improve patient matching; and

(6) privacy and security protections.