

116TH CONGRESS
1ST SESSION

S. 1895

To lower health care costs.

IN THE SENATE OF THE UNITED STATES

JUNE 19, 2019

Mr. ALEXANDER (for himself and Mrs. MURRAY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To lower health care costs.

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Lower Health Care Costs Act”.

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

Sec. 1. Short title; table of contents.

TITLE I—ENDING SURPRISE MEDICAL BILLS

Sec. 101. Protecting patients against out-of-network deductibles in emergencies.

Sec. 102. Protection against surprise bills.

Sec. 103. Benchmark for payment.

Sec. 104. Effective date.

Sec. 105. Ending surprise air ambulance bills.

Sec. 106. Report.

TITLE II—REDUCING THE PRICES OF PRESCRIPTION DRUGS

- Sec. 201. Biological product patent transparency.
- Sec. 202. Orange book modernization.
- Sec. 203. Ensuring timely access to generics.
- Sec. 204. Protecting access to biological products.
- Sec. 205. Preventing blocking of generic drugs.
- Sec. 206. Education on biological products.
- Sec. 207. Biological product innovation.
- Sec. 208. Clarifying the meaning of new chemical entity.
- Sec. 209. Streamlining the transition of biological products.
- Sec. 210. Orphan drug clarification.
- Sec. 211. Prompt approval of drugs related to safety information.
- Sec. 212. Conditions of use for biosimilar biological products.
- Sec. 213. Modernizing the labeling of certain generic drugs.

TITLE III—IMPROVING TRANSPARENCY IN HEALTH CARE

- Sec. 301. Increasing transparency by removing gag clauses on price and quality information.
- Sec. 302. Banning anticompetitive terms in facility and insurance contracts that limit access to higher quality, lower cost care.
- Sec. 303. Designation of a nongovernmental, nonprofit transparency organization to lower Americans' health care costs.
- Sec. 304. Protecting patients and improving the accuracy of provider directory information.
- Sec. 305. Timely bills for patients.
- Sec. 306. Health plan oversight of pharmacy benefit manager services.
- Sec. 307. Government Accountability Office study on profit- and revenue-sharing in health care.
- 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.
- Sec. 309. Ensuring enrollee access to cost-sharing information.
- Sec. 310. Strengthening parity in mental health and substance use disorder benefits.
- Sec. 311. Technical amendments.
- Sec. 312. Third-party administrators.

TITLE IV—IMPROVING PUBLIC HEALTH

- Sec. 401. Improving awareness of disease prevention.
- Sec. 402. Grants to address vaccine-preventable diseases.
- Sec. 403. Guide on evidence-based strategies for public health department obesity prevention programs.
- Sec. 404. Expanding capacity for health outcomes.
- Sec. 405. Public health data system modernization.
- Sec. 406. Innovation for maternal health.
- Sec. 407. Training for health care providers.
- Sec. 408. Study on training to reduce and prevent discrimination.
- Sec. 409. Perinatal quality collaboratives.
- Sec. 410. Integrated services for pregnant and postpartum women.

- Sec. 411. Extension for community health centers, the National Health Service Corps, and teaching health centers that operate GME programs.
- Sec. 412. Other programs.

TITLE V—IMPROVING THE EXCHANGE OF HEALTH
INFORMATION

- Sec. 501. Requirement to provide health claims, network, and cost information.
- Sec. 502. Recognition of security practices.
- 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.
- Sec. 504. Technical corrections.

1 **TITLE I—ENDING SURPRISE**
2 **MEDICAL BILLS**

3 **SEC. 101. PROTECTING PATIENTS AGAINST OUT-OF-NET-**
4 **WORK DEDUCTIBLES IN EMERGENCIES.**

5 Section 2719A(b) of the Public Health Service Act
6 (42 U.S.C. 300gg–19a) is amended—

7 (1) in paragraph (1)—

8 (A) in the matter preceding subparagraph
9 (A), by inserting “or a freestanding emergency
10 room” after “hospital”; and

11 (B) in subparagraph (C)—

12 (i) in clause (ii)(I), by inserting “or
13 emergency room” after “emergency depart-
14 ment”; and

15 (ii) in subparagraph (C)(ii)(II), by
16 adding, “a deductible,” after “(expressed
17 as”; and

18 (2) in paragraph (2)(B)—

1 (A) in clause (i)—

2 (i) by inserting “or freestanding emer-
3 gency room” after “hospital”; and

4 (ii) by inserting “or emergency room”
5 after “emergency department”; and

6 (B) in clause (ii), by inserting “or emer-
7 gency room” after “hospital”.

8 **SEC. 102. PROTECTION AGAINST SURPRISE BILLS.**

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

12 “(e) COVERAGE OF CERTAIN OUT-OF-NETWORK
13 SERVICES.—

14 “(1) IN GENERAL.—Subject to subsection (h),
15 in the case of an enrollee in a group health plan or
16 group or individual health insurance coverage who
17 receives out-of-network, ancillary, non-emergency
18 services at an in-network facility, including any re-
19 ferrals for diagnostic services—

20 “(A) the cost-sharing requirement (ex-
21 pressed as a copayment amount, coinsurance
22 rate, or deductible) with respect to such services
23 shall be the same requirement that would apply
24 if such services were provided by an in-network

1 practitioner, and any coinsurance or deductible
2 shall be based on in-network rates; and

3 “(B) such cost-sharing amounts shall be
4 counted towards the in-network deductible and
5 in-network out-of-pocket maximum amount
6 under the plan or coverage for the plan year.

7 “(2) DEFINITION.—For purposes of this sub-
8 section, the term ‘facility’ has the meaning given the
9 term ‘health care facility’ in section 2729A(c).

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

12 “(1) NOTICE AND CONSENT.—Subject to sub-
13 section (h), in the case of an enrollee in a group
14 health plan or group or individual health insurance
15 coverage who receives emergency services, or mater-
16 nal care for a woman in labor, in the emergency de-
17 partment of an out-of-network facility and has been
18 stabilized (within the meaning of subsection
19 (b)(2)(C)), if the patient is subsequently admitted to
20 the out-of-network facility for care, the cost-sharing
21 requirement (expressed as a copayment amount, co-
22 insurance rate, or deductible) with respect to any
23 out-of-network services is the same requirement that
24 would apply if such services were provided by a par-
25 ticipating provider, unless the enrollee, once stable

1 and in a condition to receive such information, in-
2 cluding having sufficient mental capacity—

3 “(A) has been provided by the facility,
4 prior to the provision of any post-stabilization,
5 out-of-network service at such facility, with—

6 “(i) paper and electronic notification
7 that the practitioner or facility is an out-
8 of-network health care provider and the
9 out-of-network rate of the provider, as ap-
10 plicable, and the option to affirmatively
11 consent to receiving services from such
12 practitioner or facility; and

13 “(ii) the estimated amount that such
14 provider may charge the participant, bene-
15 ficiary, or enrollee for such items and serv-
16 ices involved;

17 “(B) has been provided by the plan or cov-
18 erage, prior to the provision of any post-sta-
19 bilization, out-of-network service at such facil-
20 ity, with—

21 “(i) paper and electronic notification
22 that the practitioner or facility is an out-
23 of-network health care provider and the
24 out-of-network rate of the provider, as ap-
25 plicable, and the option to affirmatively

1 consent to receiving services from such
2 practitioner or facility;

3 “(ii) a list of in-network practitioners
4 or facilities that could provide the same
5 services, and an option for a referral to
6 such providers; and

7 “(iii) information about whether prior
8 authorization or other care management
9 limitations may be required in advance of
10 receiving in-network care at the facility;
11 and

12 “(C) has acknowledged that the out-of-net-
13 work treatment may not be covered or may be
14 covered at an out-of-network cost-sharing
15 amount, requiring higher cost-sharing obliga-
16 tions of the enrollee than if the service were
17 provided at an in-network facility, and has as-
18 sumed, in writing, full responsibility of out-of-
19 pocket costs associated with services furnished
20 after the enrollee has been stabilized, from the
21 out-of-network practitioner or facility, as appli-
22 cable.

23 “(2) REQUIREMENTS OF NOTICE.—The notice
24 under paragraph (1) shall be in a format determined
25 by the Secretary to give a reasonable layperson clear

1 comprehension of the terms of the agreement, in-
2 cluding all possible financial responsibilities, includ-
3 ing the requirements that the notice—

4 “(A) does not exceed one page in length;

5 “(B) is readily identifiable for its purpose
6 and as a contract of consent;

7 “(C) clearly states that consent is optional;

8 “(D) includes an estimate of the amount
9 that such provider will charge the participant,
10 beneficiary, or enrollee for such items and serv-
11 ices involved; and

12 “(E) be available in the 15 most common
13 languages in the facility’s geographic area, with
14 the facility making a good faith effort to pro-
15 vide oral notice in the enrollee’s primary lan-
16 guage if it is not one of such 15 languages.

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

19 “(1) IN GENERAL.—A facility or practitioner
20 furnishing—

21 “(A) emergency services, as defined in sub-
22 section (b)(2), regardless of the State in which
23 the patient resides;

24 “(B) services at an in-network facility de-
25 scribed in subsection (e); or

1 “(C) out-of-network services furnished
2 after the enrollee has been stabilized (within the
3 meaning of subsection (b)(2)(C)), where the no-
4 tice and option for referral required under sub-
5 section (f)(1) have not been provided to the en-
6 rollee and the assumption of responsibility for
7 out-of-pocket costs under subsection (f)(2) has
8 not been obtained,
9 may not bill an enrollee in a group health plan or
10 group or individual health insurance coverage for
11 amounts beyond the cost-sharing amount that would
12 apply under subsection (b)(1)(C)(ii)(II), (e), or (f),
13 as applicable.

14 “(2) NOTICE.—A facility furnishing services de-
15 scribed in paragraph (1) shall provide enrollees in a
16 group health plan or group or individual health in-
17 surance coverage with a one-page notice, in 16-point
18 font, upon intake at the emergency room or being
19 admitted at the facility of the prohibition on balance
20 billing under paragraph (1) and who to contact for
21 recourse if they are sent a balance bill in violation
22 of such paragraph. The facility shall be responsible
23 for obtaining the signature from the enrollee on such
24 notice. The Secretary shall issue regulations within
25 6 months of the date of enactment of the Lower

1 Health Care Costs Act on the requirements for the
2 notice under this paragraph.

3 “(3) ENFORCEMENT.—

4 “(A) IN GENERAL.—Subject to subpara-
5 graph (B), a facility or practitioner that vio-
6 lates a requirement under paragraph (1) shall
7 be subject to a civil monetary penalty of not
8 more than \$10,000 for each act constituting
9 such violation.

10 “(B) PROCEDURE.—The provisions of sec-
11 tion 1128A of the Social Security Act, other
12 than subsections (a) and (b) and the first sen-
13 tence of subsection (c)(1) of such section, shall
14 apply to civil money penalties under this sub-
15 section in the same manner as such provisions
16 apply to a penalty or proceeding under section
17 1128A of the Social Security Act.

18 “(C) SAFE HARBOR.—The Secretary shall
19 waive the penalties described under subpara-
20 graph (A) with respect to a facility or, practi-
21 tioner who unknowingly violates paragraph (1)
22 with respect to an enrollee, if such facility or
23 practitioner, within 30 days of the violation,
24 withdraws the bill that was in violation of para-
25 graph (1), and, as applicable, reimburses the

1 group health plan, health insurance issuer, or
2 enrollee, as applicable, in an amount equal to
3 the amount billed in violation of paragraph (1),
4 plus interest, at an interest rate determined by
5 the Secretary.

6 “(h) MAINTAINING STATE SURPRISE BILLING PRO-
7 TECTIONS.—

8 “(1) IN GENERAL.—Notwithstanding section
9 514 of the Employee Retirement Income Security
10 Act of 1974, except with respect to self-insured
11 group health plans, nothing in this section shall pre-
12 vent a State from establishing or continuing in effect
13 an alternate method under State law for determining
14 the appropriate compensation for services described
15 in subsection (b), (e), or (f).

16 “(2) ADDITIONAL APPLICATION.—In the case of
17 group health plans or health insurance coverage in
18 the individual or group market offered in a State
19 that has not enacted an alternate method described
20 in paragraph (1), such as arbitration or a bench-
21 mark, or for services described in subsection (b), (e),
22 or (f) that are not covered by such State’s alternate
23 method described in paragraph (1), the provisions of
24 this section shall apply.

1 “(3) SELF-INSURED PLANS.—Subsections (b),
2 (e), and (f) shall apply to a self-insured group health
3 plan that is not subject to State insurance regula-
4 tion.”.

5 (b) COVERAGE UNDER FEDERAL EMPLOYEES
6 HEALTH BENEFITS PROGRAM.—Section 8904 of title 5,
7 United States Code, is amended by adding at the end the
8 following:

9 “(c) Any health benefits plan offered under this chap-
10 ter shall be treated as a group health plan or group or
11 individual health insurance coverage for purposes of sub-
12 sections (e) through (g) of section 2719A of the Public
13 Health Service Act (42 U.S.C. 300gg–19a) (except for
14 paragraph (3) of such subsection (g)).”.

15 **SEC. 103. BENCHMARK FOR PAYMENT.**

16 (a) IN GENERAL.—Subpart II of part A of title
17 XXVII of the Public Health Service Act (42 U.S.C.
18 300gg–11 et seq.) is amended by adding at the end the
19 following:

20 **“SEC. 2729A. BENCHMARK FOR PAYMENT.**

21 “(a) ESTABLISHMENT OF BENCHMARK.—A group
22 health plan or health insurance issuer offering group or
23 individual health insurance coverage shall pay facilities or
24 practitioners furnishing services for which such facilities
25 and practitioners are prohibited from billing enrollees

1 under section 2719A(g), the median in-network rate,
2 using a methodology determined under subsection (b) for
3 the same or similar services offered by the group health
4 plan or health insurance issuer in that geographic region.

5 “(b) MEDIAN IN-NETWORK RATE.—

6 “(1) IN GENERAL.—For purposes of this sec-
7 tion, the term ‘median in-network rate’ means, with
8 respect to health care services covered by a group
9 health plan or group or individual health insurance
10 coverage, the median negotiated rate under the ap-
11 plicable plan or coverage recognized under the plan
12 or coverage as the total maximum payment for the
13 service minus the in-network cost-sharing for such
14 service under the plan or coverage, for the same or
15 a similar service that is provided by a provider in
16 the same or similar specialty and in the geographic
17 region in which the service is furnished.

18 “(2) RULEMAKING.—Not later than 1 year
19 after the date of enactment of the Lower Health
20 Care Costs Act, the Secretary shall, through rule-
21 making, determine the methodology a group health
22 plan or health insurance issuer is required to use to
23 determine the median in-network rate described in
24 paragraph (1), differentiating by business line, the
25 information the plan or issuer shall share with the

1 nonparticipating provider involved when making
2 such a determination, and the geographic regions
3 applied for purposes of this subparagraph. Such
4 rulemaking shall take into account payments that
5 are made by health insurance issuers that are not on
6 a fee-for-service basis.

7 “(3) CERTAIN INSURERS.—If a group health
8 plan or health insurance issuer offering group or in-
9 dividual health insurance coverage does not have
10 sufficient information to calculate a median in-net-
11 work rate for this service or provider type, or
12 amount of, claims for services (as determined by the
13 applicable State authority, in the case of health in-
14 surance coverage, or by the Secretary of Labor, in
15 the case of a self-insured group health plan) covered
16 under the list of out-of-network services set by the
17 State authority or Secretary of Labor, as applicable,
18 in a particular geographic area, such plan or issuer
19 shall demonstrate that it will use a database free of
20 conflicts of interest that has sufficient information
21 reflecting allowed amounts paid to individual health
22 care providers for relevant services provided in the
23 applicable geographic region, and that such plan or
24 issuer will use that database to determine a median
25 in-network rate. The group health plan or health in-

1 surance issuer shall cover the cost of accessing the
2 database.

3 “(4) **RULE OF CONSTRUCTION.**—Nothing in
4 this subsection shall prevent a group health plan or
5 health insurance issuer from establishing separate
6 calculations of a median in-network rate under para-
7 graph (1) for services delivered in nonhospital facili-
8 ties, including freestanding emergency rooms.

9 “(c) **FACILITY.**—For purposes of this section, the
10 term ‘health care facility’ includes hospitals, hospital out-
11 patient departments, critical access hospitals, ambulatory
12 surgery centers, laboratories, radiology clinics, and any
13 other facility that provides services that are covered under
14 a group health plan or health insurance coverage, includ-
15 ing settings of care subject to section 2719A(b).”.

16 (b) **NON-FEDERAL GOVERNMENTAL PLANS.**—Sec-
17 tion 2722(a)(2)(E) of the Public Health Service Act (42
18 U.S.C. 300gg–21(a)(2)(E)) is amended by inserting “, ex-
19 cept that such election shall be available with respect to
20 section 2729A” before the period.

21 **SEC. 104. EFFECTIVE DATE.**

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

1 **SEC. 105. ENDING SURPRISE AIR AMBULANCE BILLS.**

2 (a) IN GENERAL.—Part A of title XXVII of the Pub-
3 lic Health Service Act is amended by inserting after sec-
4 tion 2719A (42 U.S.C. 300gg–19a) the following:

5 **“SEC. 2719B. ENDING SURPRISE AIR AMBULANCE BILLS.**

6 “(a) IN GENERAL.—In the case of an enrollee in a
7 group health plan or group or individual health insurance
8 coverage who receives air ambulance services from an out-
9 of-network provider—

10 “(1) the cost-sharing requirement (expressed as
11 a copayment amount, coinsurance rate, or deduct-
12 ible) with respect to such services shall be the same
13 requirement that would apply if such services were
14 provided by an in-network practitioner, and any co-
15 insurance or deductible shall be based on in-network
16 rates; and

17 “(2) such cost-sharing amounts shall be count-
18 ed towards the in-network deductible and in-network
19 out-of-pocket maximum amount under the plan or
20 coverage for the plan year.

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

25 “(c) MEDIAN IN-NETWORK RATE.—

1 “(1) IN GENERAL.—For purposes of this sec-
2 tion, the term ‘median in-network rate’ means, with
3 respect to air ambulance services covered by a group
4 health plan or group or individual health insurance
5 coverage, the median negotiated rate under the ap-
6 plicable plan or coverage recognized under the plan
7 or coverage as the total maximum payment for the
8 service, minus the in-network cost-sharing for such
9 service under the plan or coverage, for the same or
10 a similar service that is provided by a provider in
11 the same or similar specialty, and in the geographic
12 region in which the service is furnished.

13 “(2) RULEMAKING.—Not later than 6 months
14 after the date of enactment of the Lower Health
15 Care Costs Act, the Secretary shall, through rule-
16 making, determine the methodology a group health
17 plan or health insurance issuer is required to use to
18 determine the median in-network rate described in
19 paragraph (1), the information the plan or issuer
20 shall share with the non-participating provider in-
21 volved when making such a determination, and the
22 geographic regions applied for purposes of this sub-
23 section. Such rulemaking shall take into account
24 payments that are made by issuers that are not on
25 a fee-for-service basis.

1 “(3) CERTAIN INSURERS.—If a group health
2 plan or health insurance issuer offering group or in-
3 dividual health insurance coverage does not have
4 sufficient information to calculate a median in-net-
5 work rate for this service or provider type, or
6 amount of, claims for services (as determined by the
7 applicable State authority, in the case of health in-
8 surance coverage, or by the Secretary of Labor, in
9 the case of a self-insured group health plan) covered
10 under the list of out-of-network services set by the
11 State authority or Secretary of Labor, as applicable,
12 in a particular geographic area, such plan or issuer
13 shall demonstrate that it will use a database free of
14 conflicts of interest that has sufficient information
15 reflecting allowed amounts paid to individual health
16 care providers for relevant services provided in the
17 applicable geographic region, and that such plan or
18 issuer will use that database to determine a median
19 in-network rate. The group health plan or health in-
20 surance issuer shall cover the cost of accessing the
21 database.

22 “(4) CLARIFICATION.—For purposes of this
23 subsection, the Secretary may define geographic re-
24 gions that are different from the geographic regions
25 identified for purposes of section 2729A(b) to ensure

1 that an adequate number of air ambulance services
2 are in-network in each geographic region so that a
3 median in-network rate for air ambulance services
4 may be calculated for each such region.

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

10 “(e) ENFORCEMENT.—

11 “(1) IN GENERAL.—Subject to paragraph (2),
12 an air ambulance service provider that violates sub-
13 section (d) shall be subject to a civil monetary pen-
14 alty of not more than \$10,000 for each act consti-
15 tuting such violation.

16 “(2) PROCEDURE.—The provisions of section
17 1128A of the Social Security Act, other than sub-
18 sections (a) and (b) and the first sentence of sub-
19 section (c)(1) of such section, shall apply to civil
20 money penalties under this subsection in the same
21 manner as such provisions apply to a penalty or pro-
22 ceeding under section 1128A of the Social Security
23 Act.

24 “(3) SAFE HARBOR.—The Secretary shall waive
25 the penalties described under paragraph (1) with re-

1 spect to an air ambulance service provider who un-
2 knowingly violates subsection (d) with respect to an
3 enrollee, if such air ambulance service provider with-
4 in 30 days of the violation, withdraws the bill that
5 was in violation of subsection (d), and, as applicable,
6 reimburses the group health plan, health insurance
7 issuer, or enrollee, as applicable, in an amount equal
8 to the amount billed in violation of subsection (d),
9 plus interest, at an interest rate determined by the
10 Secretary.”.

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

15 **SEC. 106. REPORT.**

16 Not later than 1 year after the effective date de-
17 scribed in section 104, and annually for the following 4
18 years, the Secretary of Health and Human Services, in
19 consultation with the Federal Trade Commission and the
20 Attorney General, shall—

21 (1) conduct a study on—

22 (A) the effects of the amendments made by
23 sections 101, 102, and 103, including any pat-
24 terns of vertical or horizontal integration of

1 health care facilities, providers, group health
2 plans, or health insurance issuers;

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

6 (C) recommendations for effective enforce-
7 ment of 2729A as added by section 103, includ-
8 ing potential challenges to addressing anti-com-
9 petitive consolidation by health care facilities,
10 providers, group health plans, or health insur-
11 ance issuers; and

12 (2) submit a report on such study to the Com-
13 mittee on Health, Education, Labor, and Pensions,
14 the Committee on Commerce, Science, and Trans-
15 portation, the Committee on Finance, and the Com-
16 mittee on the Judiciary of the Senate and the Com-
17 mittee on Education and Labor, the Committee on
18 Energy and Commerce, the Committee on Ways and
19 Means, and the Committee on the Judiciary of the
20 House of Representatives.

1 **TITLE II—REDUCING THE**
2 **PRICES OF PRESCRIPTION**
3 **DRUGS**

4 **SEC. 201. BIOLOGICAL PRODUCT PATENT TRANSPARENCY.**

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

8 “(o) ADDITIONAL REQUIREMENTS WITH RESPECT
9 TO PATENTS.—

10 “(1) APPROVED APPLICATION HOLDER LISTING
11 REQUIREMENTS.—

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

19 “(B) PREVIOUSLY APPROVED OR LI-
20 CENSED BIOLOGICAL PRODUCTS.—

21 “(i) PRODUCTS LICENSED UNDER
22 SECTION 351 OF THE PHSA.—Not later
23 than 30 days after the date of enactment
24 of the Lower Health Care Costs Act, the
25 holder of a biological product license that

1 was approved under subsection (a) or (k)
2 before the date of enactment of such Act
3 shall submit to the Secretary a list of each
4 patent required to be disclosed (as de-
5 scribed in paragraph (3)).

6 “(ii) PRODUCTS APPROVED UNDER
7 SECTION 505 OF THE FFDCA.—Not later
8 than 30 days after March 23, 2020, the
9 holder of an approved application for a bio-
10 logical product under section 505 of the
11 Federal Food, Drug, and Cosmetic Act
12 that is deemed to be a license for the bio-
13 logical product under this section on
14 March 23, 2020, shall submit to the Sec-
15 retary a list of each patent required to be
16 disclosed (as described in paragraph (3)).

17 “(C) UPDATES.—The holder of a biological
18 product license that is the subject of an applica-
19 tion under subsection (a) or (k) shall submit to
20 the Secretary a list that includes—

21 “(i) any patent not previously re-
22 quired to be disclosed (as described in
23 paragraph (3)) under subparagraph (A) or
24 (B), as applicable, within 30 days of the
25 earlier of—

1 “(I) the date of issuance of such
2 patent by the United States Patent
3 and Trademark Office; or

4 “(II) the date of approval of a
5 supplemental application for the bio-
6 logical product; and

7 “(ii) any patent, or any claim with re-
8 spect to a patent, included on the list pur-
9 suant to this paragraph, that the Patent
10 Trial and Appeal Board of the United
11 States Patent and Trademark Office deter-
12 mines in a decision to be invalid or unen-
13 forceable, within 30 days of such decision.

14 “(2) PUBLICATION OF INFORMATION.—

15 “(A) IN GENERAL.—Within 1 year of the
16 date of enactment of the Lower Health Care
17 Costs Act, the Secretary shall publish and make
18 available to the public a single, easily search-
19 able, list that includes—

20 “(i) the official and proprietary name
21 of each biological product licensed under
22 subsection (a) or (k), and of each biological
23 product application approved under section
24 505 of the Federal Food, Drug, and Cos-
25 metic Act and deemed to be a license for

1 the biological product under this section on
2 March 23, 2020;

3 “(ii) with respect to each biological
4 product described in clause (i), each patent
5 submitted in accordance with paragraph
6 (1);

7 “(iii) the date of approval and appli-
8 cation number for each such biological
9 product;

10 “(iv) the marketing status, dosage
11 form, route of administration, strength,
12 and, if applicable, reference product, for
13 each such biological product;

14 “(v) the licensure status for each such
15 biological product, including whether the li-
16 cense at the time of listing is approved,
17 withdrawn, or revoked;

18 “(vi) with respect to each such bio-
19 logical product, any period of any exclu-
20 sivity under paragraph (6), (7)(A), or
21 (7)(B) of subsection (k) of this section or
22 section 527 of the Federal Food, Drug,
23 and Cosmetic Act, and any extension of
24 such period in accordance with subsection
25 (m) of this section, for which the Secretary

1 has determined such biological product to
2 be eligible, and the date on which such ex-
3 clusivity expires;

4 “(vii) information regarding any de-
5 termination of biosimilarity or interchange-
6 ability for each such biological product;
7 and

8 “(viii) information regarding approved
9 indications for each such biological prod-
10 uct, in such manner as the Secretary de-
11 termines appropriate.

12 “(B) UPDATES.—Every 30 days after the
13 publication of the first list under subparagraph
14 (A), the Secretary shall revise the list to in-
15 clude—

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

19 “(II) with respect to each biological
20 product described in subclause (I), the in-
21 formation described in clauses (i) through
22 (viii) of subparagraph (A); and

23 “(ii) any updates to information pre-
24 viously published in accordance with sub-
25 paragraph (A).

1 “(C) NONCOMPLIANCE.—Beginning 18
2 months after the date of enactment of the
3 Lower Health Care Costs Act, the Secretary, in
4 consultation with the Director of the United
5 States Patent and Trademark Office, shall pub-
6 lish and make available to the public a list of
7 any holders of biological product licenses, and
8 the corresponding biological product or prod-
9 ucts, that failed to submit information as re-
10 quired under paragraph (1), including any up-
11 dates required under paragraph (1)(C), in such
12 manner and format as the Secretary determines
13 appropriate. If information required under
14 paragraph (1) is submitted following publica-
15 tion of such list, the Secretary shall remove
16 such holders of such biological product licenses
17 from the public list in a reasonable period of
18 time.

19 “(3) PATENTS REQUIRED TO BE DISCLOSED.—
20 In this section, a ‘patent required to be disclosed’ is
21 any patent for which the holder of a biological prod-
22 uct license approved under subsection (a) or (k), or
23 a biological product application approved under sec-
24 tion 505 of the Federal Food, Drug, and Cosmetic
25 Act and deemed to be a license for a biological prod-

1 uct under this section on March 23, 2020, believes
2 a claim of patent infringement could reasonably be
3 asserted by the holder, or by a patent owner that
4 has granted an exclusive license to the holder with
5 respect to the biological product that is the subject
6 of such license, if a person not licensed by the holder
7 engaged in the making, using, offering to sell, sell-
8 ing, or importing into the United States of the bio-
9 logical product that is the subject of such license.”.

10 (b) DISCLOSURE OF PATENTS.—Section
11 351(l)(3)(A)(i) of the Public Health Service Act (42
12 U.S.C. 262(l)(3)(A)(i)) is amended by inserting “included
13 in the list provided by the reference product sponsor under
14 subsection (o)(1)” after “a list of patents”.

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

18 (1) solicit public comments regarding appro-
19 priate remedies, in addition to the publication of the
20 list under subsection (o)(2)(C) of section 351 of the
21 Public Health Service Act (42 U.S.C. 262), as added
22 by subsection (a), with respect to holders of biologi-
23 cal product licenses who fail to timely submit infor-
24 mation as required under subsection (o)(1) of such

1 section 351, including any updates required under
2 subparagraph (C) of such subsection (o)(1); and

3 (2) submit to Congress an evaluation of com-
4 ments received under paragraph (1) and the rec-
5 ommendations of the Secretary concerning appro-
6 priate remedies.

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

11 (e) RULE OF CONSTRUCTION.—Nothing in this Act,
12 including an amendment made by this Act, shall be con-
13 strued to require or allow the Secretary of Health and
14 Human Services to delay the licensing of a biological prod-
15 uct under section 351 of the Public Health Service Act
16 (42 U.S.C. 262).

17 **SEC. 202. ORANGE BOOK MODERNIZATION.**

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

20 (1) IN GENERAL.—Paragraph (1) of section
21 505(b) of the Federal Food, Drug, and Cosmetic Act
22 (21 U.S.C. 355(b)) is amended to read as follows:

23 “(b)(1)(A) Any person may file with the Secretary
24 an application with respect to any drug subject to the pro-

1 visions of subsection (a). Such persons shall submit to the
2 Secretary as part of the application—

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

6 “(ii) a full list of the articles used as compo-
7 nents of such drug;

8 “(iii) a full statement of the composition of
9 such drug;

10 “(iv) a full description of the methods used in,
11 and the facilities and controls used for, the manufac-
12 ture, processing, and packing of such drug;

13 “(v) such samples of such drug and of the arti-
14 cles used as components thereof as the Secretary
15 may require;

16 “(vi) specimens of the labeling proposed to be
17 used for such drug;

18 “(vii) any assessments required under section
19 505B; and

20 “(viii) the patent number and expiration date,
21 of each patent for which a claim of patent infringe-
22 ment could reasonably be asserted if a person not li-
23 censed by the owner engaged in the manufacture,
24 use, or sale of the drug, and that—

1 “(I) claims the drug for which the appli-
2 cant submitted the application and is a drug
3 substance patent or a drug product patent; or

4 “(II) claims the method of using the drug
5 for which approval is sought or has been grant-
6 ed in the application.

7 “(B) If an application is filed under this subsection
8 for a drug, and a patent of the type described in subpara-
9 graph (A)(viii) that claims such drug or a method of using
10 such drug is issued after the filing date but before ap-
11 proval of the application, the applicant shall amend the
12 application to include such patent information.

13 “(C) Upon approval of the application, the Secretary
14 shall publish the information submitted under subpara-
15 graph (A)(viii).”.

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

1 (b) CONFORMING CHANGES TO REQUIREMENTS FOR
2 SUBSEQUENT SUBMISSION OF PATENT INFORMATION.—
3 Section 505(c)(2) of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 355(j)(7)) is amended—

5 (1) by inserting before the first sentence the
6 following: “Not later than 30 days after the date of
7 approval of an application under subsection (b), the
8 holder of the approved application shall file with the
9 Secretary the patent number and the expiration date
10 of any patent described in subclause (I) or (II) of
11 subsection (b)(1)(A)(viii), except that a patent that
12 claims a method of using such drug shall be filed
13 only if approval for such use has been granted in the
14 application. The holder of the approved application
15 shall file with the Secretary the patent number and
16 the expiration date of any patent described in sub-
17 clause (I) or (II) of subsection (b)(1)(A)(viii) that is
18 issued after the date of approval of the application,
19 not later than 30 days of the date of issuance of the
20 patent, except that a patent that claims a method of
21 using such drug shall be filed only if approval for
22 such use has been granted in the application.”;

23 (2) by inserting after “the patent number and
24 the expiration date of any patent which” the fol-
25 lowing: “fulfills the criteria in subsection (b) and”;

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

6 (4) by inserting after “could not file patent in-
7 formation under subsection (b) because no patent”
8 the following: “of the type required to be submitted
9 in subsection (b)”.

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

14 “(iv) For each drug included on the list, the Sec-
15 retary shall specify any exclusivity period that is applica-
16 ble, for which the Secretary has determined the expiration
17 date, and for which such period has not yet expired
18 under—

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

21 “(II) clause (iv) or (v) of paragraph (5)(B) of
22 this subsection;

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

25 “(IV) section 505A;

1 “(V) section 505E;
2 “(VI) section 527(a); or
3 “(VII) section 505(u)”.

4 (d) ORANGE BOOK UPDATES WITH RESPECT TO IN-
5 VALIDATED PATENTS.—

6 (1) IN GENERAL.—

7 (A) AMENDMENTS.—Section 505(j)(7)(A)
8 of the Federal Food, Drug, and Cosmetic Act
9 (21 U.S.C. 355(j)(7)(A)), as amended by sub-
10 section (c), is further amended by adding at the
11 end the following:

12 “(v) In the case of a listed drug for which the
13 list under clause (i) includes a patent or patent
14 claim for the drug, or a patent or a patent claim for
15 the use of such drug, and where the Under Sec-
16 retary of Commerce for Intellectual Property and
17 Director of the United States Patent and Trade-
18 mark Office has canceled any claim of the patent re-
19 lating to such drug or such use pursuant to a deci-
20 sion by the Patent Trial and Appeal Board in an
21 inter partes review conducted under chapter 31 of
22 title 35, United States Code, or a post-grant review
23 conducted under chapter 32 of that title, and from
24 which no appeal has been taken, or can be taken,
25 the holder of the applicable approved application

1 shall notify the Secretary, in writing, within 14 days
2 of such cancellation, and, if the patent has been
3 deemed wholly inoperative or invalid, or if a patent
4 claim has been canceled, the revisions required
5 under clause (iii) shall include striking the patent or
6 information regarding such patent claim from the
7 list with respect to such drug.”.

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

13 (2) NO EFFECT ON FIRST APPLICANT EXCLU-
14 SIVITY PERIOD.—Section 505(j)(5)(B)(iv)(I) is
15 amended by adding at the end the following: “This
16 subclause shall apply even if a patent is stricken
17 from the list under paragraph (7)(A), pursuant to
18 paragraph (7)(A)(v), provided that, at the time that
19 the first applicant submitted an application under
20 this subsection containing a certification described in
21 paragraph (2)(A)(vii)(IV), the patent that was the
22 subject of such certification was included in such list
23 with respect to the listed drug.”.

1 **SEC. 203. ENSURING TIMELY ACCESS TO GENERICS.**

2 Section 505(q) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 355(q)(1)) is amended—

4 (1) in paragraph (1)—

5 (A) in subparagraph (A)(i), by inserting “,
6 10.31,” after “10.30”;

7 (B) in subparagraph (E)—

8 (i) by striking “application and” and
9 inserting “application or”;

10 (ii) by striking “If the Secretary” and
11 inserting the following:

12 “(i) IN GENERAL.—If the Secretary”;

13 and

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

16 “(ii) PRIMARY PURPOSE OF DELAY-
17 ING.—

18 “(I) IN GENERAL.—For purposes
19 of this subparagraph, a petition or
20 supplement to a petition may be con-
21 sidered to be submitted with the pri-
22 mary purpose of delaying an applica-
23 tion under subsection (b)(2) or (j) of
24 this section or section 351(k) of the
25 Public Health Service Act, if the peti-
26 tioner has the purpose of setting

1 aside, delaying, rescinding, with-
2 drawing, or preventing submission, re-
3 view, or the approval of such an appli-
4 cation.

5 “(II) FACTORS.—In determining
6 whether a petition was submitted with
7 the primary purpose of delaying an
8 application, the Secretary may con-
9 sider the following factors:

10 “(aa) Whether the petition
11 was submitted in accordance with
12 paragraph (2)(B), based on when
13 the petitioner knew or reasonably
14 should have known the relevant
15 information relied upon to form
16 the basis of such petition.

17 “(bb) Whether the petitioner
18 has submitted multiple or serial
19 petitions raising issues that rea-
20 sonably could have been known
21 to the petitioner at the time of
22 submission of the earlier petition
23 or petitions.

24 “(cc) Whether the petition
25 was submitted close in time to a

1 known, first date upon which an
2 application under subsection
3 (b)(2) or (j) of this section or
4 section 351(k) of the Public
5 Health Service Act could be ap-
6 proved.

7 “(dd) Whether the petition
8 was submitted without any rel-
9 evant data or information in sup-
10 port of the scientific positions
11 forming the basis of such peti-
12 tion.

13 “(ee) Whether the petition
14 raises the same or substantially
15 similar issues as a prior petition
16 to which the Secretary has re-
17 sponded substantively already, in-
18 cluding if the subsequent submis-
19 sion follows such response from
20 the Secretary closely in time.

21 “(ff) Whether the petition
22 requests changing the applicable
23 standards that other applicants
24 are required to meet, including
25 requesting testing, data, or label-

1 ing standards that are more on-
2 erous or rigorous than the stand-
3 ards applicable to the listed drug,
4 reference product, or petitioner's
5 version of the same drug.

6 “(gg) The petitioner’s record
7 of submitting petitions to the
8 Food and Drug Administration
9 that have been determined by the
10 Secretary to have been submitted
11 with the primary purpose of
12 delay.

13 “(hh) Other relevant and
14 appropriate factors, which the
15 Secretary shall describe in guid-
16 ance.

17 “(III) GUIDANCE.—The Sec-
18 retary may issue or update guidance,
19 as appropriate, to describe factors the
20 Secretary considers in accordance
21 with subclause (II).”;

22 (C) by adding at the end the following:

23 “(iii) REFERRAL TO THE FEDERAL
24 TRADE COMMISSION.—The Secretary shall
25 establish procedures for referring to the

1 Federal Trade Commission any petition or
2 supplement to a petition that the Secretary
3 determines was submitted with the primary
4 purpose of delaying approval of an applica-
5 tion. Such procedures shall include notifi-
6 cation to the petitioner and an opportunity
7 for judicial review after the issuance of an
8 order by the Federal Trade Commission.”;
9 (D) by striking subparagraph (F);
10 (E) by redesignating subparagraphs (G)
11 through (I) as subparagraphs (F) through (H),
12 respectively; and
13 (F) in subparagraph (H), as so redesign-
14 ated, by striking “submission of this petition”
15 and inserting “submission of this document”;
16 (2) in paragraph (2)—
17 (A) by redesignating subparagraphs (A)
18 through (C) as subparagraphs (C) through (E),
19 respectively;
20 (B) by inserting before subparagraph (C),
21 as so redesignated, the following:
22 “(A) IN GENERAL.—A person shall submit
23 a petition to the Secretary under paragraph (1)
24 before filing a civil action in which the person
25 seeks to set aside, delay, rescind, withdraw, or

1 prevent submission, review, or approval of an
2 application submitted under subsection (b)(2)
3 or (j) of this section or section 351(k) of the
4 Public Health Service Act. Such petition and
5 any supplement to such a petition shall describe
6 all information and arguments that form the
7 basis of the relief requested in any civil action
8 described in the previous sentence.

9 “(B) TIMELY SUBMISSION OF CITIZEN PE-
10 TITION.—A petition and any supplement to a
11 petition shall be submitted within 60 days after
12 the person knew, or reasonably should have
13 known, the information that forms the basis of
14 the request made in the petition or supple-
15 ment.”;

16 (C) in subparagraph (C), as so redesign-
17 nated, by—

18 (i) in the heading, striking “WITHIN
19 150 DAYS”;

20 (ii) in clause (i), striking “during the
21 150-day period referred to in paragraph
22 (1)(F),”; and

23 (iii) amending clause (ii) to read as
24 follows:

1 “(ii) on or after the date that is 151
2 days after the date of submission of the
3 petition, the Secretary approves or has ap-
4 proved the application that is the subject
5 of the petition without having made such a
6 final decision.”;

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

9 “(D) DISMISSAL OF CERTAIN CIVIL AC-
10 TIONS.—

11 “(i) PETITION.—If a person files a
12 civil action against the Secretary in which
13 a person seeks to set aside, delay, rescind,
14 withdraw, or prevent submission, review, or
15 approval of an application submitted under
16 subsection (b)(2) or (j) of this section or
17 section 351(k) of the Public Health Service
18 Act without complying with the require-
19 ments of subparagraph (A), the court shall
20 dismiss without prejudice the action for
21 failure to exhaust administrative remedies.

22 “(ii) TIMELINESS.—If a person files a
23 civil action against the Secretary in which
24 a person seeks to set aside, delay, rescind,
25 withdraw, or prevent submission, review, or

1 approval of an application submitted under
2 subsection (b)(2) or (j) of this section or
3 section 351(k) of the Public Health Service
4 Act without complying with the require-
5 ments of subparagraph (B), the court shall
6 dismiss with prejudice the action for fail-
7 ure to timely file a petition.

8 “(iii) FINAL RESPONSE.—If a civil ac-
9 tion is filed against the Secretary with re-
10 spect to any issue raised in a petition time-
11 ly filed under paragraph (1) in which the
12 petitioner requests that the Secretary take
13 any form of action that could, if taken, set
14 aside, delay, rescind, withdraw, or prevent
15 submission, review, or approval of an appli-
16 cation submitted under subsection (b)(2)
17 or (j) of this section or section 351(k) of
18 the Public Health Service Act before the
19 Secretary has issued a final response to
20 any such petition submitted, the court
21 shall dismiss without prejudice the action
22 for failure to exhaust administrative rem-
23 edies.”; and

24 (E) in subparagraph (E), as so redesign-
25 nated—

1 (i) in clause (ii), by striking “, if
2 issued”; and

3 (ii) in clause (iii), by striking “final
4 agency action as defined under subpara-
5 graph (2)(A)” and inserting “the final re-
6 sponse to the petitioner”; and

7 (3) in paragraph (4)—

8 (A) by striking “EXCEPTIONS” and all that
9 follows through “This subsection does” and in-
10 sserting “EXCEPTIONS—This subsection does”;

11 (B) by striking subparagraph (B); and

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

15 **SEC. 204. PROTECTING ACCESS TO BIOLOGICAL PRODUCTS.**

16 Section 351(k)(7) of the Public Health Service Act
17 (42 U.S.C. 262(k)(7)) is amended by adding at the end
18 the following:

19 “(D) DEEMED LICENSES.—

20 “(i) NO ADDITIONAL EXCLUSIVITY
21 THROUGH DEEMING.—An approved appli-
22 cation that is deemed to be a license for a
23 biological product under this section pursu-
24 ant to section 7002(e)(4) of the Biologics
25 Price Competition and Innovation Act of

1 2009 shall not be treated as having been
2 first licensed under subsection (a) for pur-
3 poses of subparagraphs (A) and (B).

4 “(ii) LIMITATION ON EXCLUSIVITY.—
5 Subparagraph (C) shall apply to any ref-
6 erence product, without regard to wheth-
7 er—

8 “(I) such product was first li-
9 censed under subsection (a); or

10 “(II) the approved application for
11 such product was deemed to be a li-
12 cense for a biological product as de-
13 scribed in clause (i).

14 “(iii) APPLICABILITY.—Any unexpired
15 period of exclusivity under section 527 or
16 section 505A(c)(1)(A)(ii) of the Federal
17 Food, Drug, and Cosmetic Act with re-
18 spect to a biological product shall continue
19 to apply to such biological product after an
20 approved application for the biological
21 product is deemed to be a license for the
22 biological product as described in clause
23 (i).”.

1 **SEC. 205. PREVENTING BLOCKING OF GENERIC DRUGS.**

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

5 (1) by striking “180 days after the date” and
6 inserting “180 days after the earlier of the fol-
7 lowing:

8 “(aa) The date”; and

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

10 “(bb) The date on which all of the fol-
11 lowing conditions are first met:

12 “(AA) An application for the
13 drug submitted by an applicant other
14 than a first applicant could receive
15 approval, if no first applicant were eli-
16 gible for 180-day exclusivity under
17 this clause.

18 “(BB) Thirty-three months have
19 passed since the date of submission of
20 an application for the drug by one
21 first applicant, if there is only one
22 first applicant, or, in the case of more
23 than one first applicant, 33 months
24 have passed since the date of submis-
25 sion of all such applications.

1 “(CC) Approval of an application
2 for the drug submitted by at least one
3 first applicant would not be precluded
4 under clause (iii).

5 “(DD) No application for the
6 drug submitted by any first applicant
7 is approved at the time the conditions
8 under subitems (AA), (BB), and (CC)
9 are all met, regardless of whether
10 such an application is subsequently
11 approved.”.

12 **SEC. 206. EDUCATION ON BIOLOGICAL PRODUCTS.**

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

16 **“SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.**

17 “(a) INTERNET WEBSITE.—

18 “(1) IN GENERAL.—The Secretary may estab-
19 lish, maintain, and operate an internet website to
20 provide educational materials for health care pro-
21 viders, patients, and caregivers, regarding the mean-
22 ing of the terms, and the standards for review and
23 licensing of, biological products, including biosimilar
24 biological products and interchangeable biosimilar
25 biological products.

1 “(2) CONTENT.—Educational materials pro-
2 vided under paragraph (1) may include explanations
3 of—

4 “(A) key statutory and regulatory terms,
5 including ‘biosimilar’ and ‘interchangeable’, and
6 clarification regarding the appropriate use of
7 interchangeable biosimilar biological products;

8 “(B) information related to development
9 programs for biological products, including bio-
10 similar biological products and interchangeable
11 biosimilar biological products and relevant clin-
12 ical considerations for prescribers, which may
13 include, as appropriate and applicable, informa-
14 tion related to the comparability of such biologi-
15 cal products;

16 “(C) the process for reporting adverse
17 events for biological products, including bio-
18 similar biological products and interchangeable
19 biosimilar biological products; and

20 “(D) the relationship between biosimilar
21 biological products and interchangeable bio-
22 similar biological products licensed under sec-
23 tion 351(k) and reference products (as defined
24 in section 351(i)), including the standards for

1 review and licensing of each such type of bio-
2 logical product.

3 “(3) FORMAT.—The educational materials pro-
4 vided under paragraph (1) may be—

5 “(A) in formats such as webinars, con-
6 tinuing medical education modules, videos, fact
7 sheets, infographics, stakeholder toolkits, or
8 other formats as appropriate and applicable;
9 and

10 “(B) tailored for the unique needs of
11 health care providers, patients, caregivers, and
12 other audiences, as the Secretary determines
13 appropriate.

14 “(4) OTHER INFORMATION.—In addition to the
15 information described in paragraph (2), the internet
16 website established under paragraph (1) shall in-
17 clude the following information, as a single, search-
18 able database:

19 “(A) The action package of each biological
20 product licensed under subsection (a) or (k),
21 within 30 days of licensure, or, in the case of
22 a biological product licensed before the date of
23 enactment of the Lower Health Care Costs Act,
24 not later than 1 year after such date of enact-
25 ment.

1 “(B) The summary review of each biological
2 product licensed under subsection (a) or (k),
3 within 7 days of licensure, except where such
4 materials require redaction by the Secretary, or,
5 in the case of a biological product licensed be-
6 fore the date of enactment of the Lower Health
7 Care Costs Act, not later than 1 year after such
8 date of enactment.

9 “(5) CONFIDENTIAL AND TRADE SECRET IN-
10 FORMATION.—This subsection does not authorize
11 the disclosure of any trade secret, confidential com-
12 mercial or financial information, or other matter de-
13 scribed in section 552(b) of title 5.

14 “(b) CONTINUING MEDICAL EDUCATION.—The Sec-
15 retary shall advance education and awareness among
16 health care providers regarding biological products, includ-
17 ing biosimilar biological products and interchangeable bio-
18 similar biological products, as appropriate, including by
19 developing or improving continuing medical education pro-
20 grams that advance the education of such providers on the
21 prescribing of, and relevant clinical considerations with re-
22 spect to biological products, including biosimilar biological
23 products and interchangeable biosimilar biological prod-
24 ucts.”.

1 **SEC. 207. BIOLOGICAL PRODUCT INNOVATION.**

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

4 (1) by striking “except that a product” and in-
5 serting “except that—

6 “(1) a product”;

7 (2) by striking “Act.” and inserting “Act; and”;

8 and

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

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

16 **SEC. 208. CLARIFYING THE MEANING OF NEW CHEMICAL**
17 **ENTITY.**

18 Chapter V of the Federal Food, Drug, and Cosmetic
19 Act is amended—

20 (1) in section 505 (21 U.S.C. 355)—

21 (A) in subsection (c)(3)(E)—

22 (i) in clause (ii), by striking “active
23 ingredient (including any ester or salt of
24 the active ingredient)” and inserting “ac-
25 tive moiety (as defined by the Secretary in
26 section 314.3 of title 21, Code of Federal

1 Regulations (or any successor regula-
2 tions))”; and

3 (ii) in clause (iii), by striking “active
4 ingredient (including any ester or salt of
5 the active ingredient)” and inserting “ac-
6 tive moiety (as defined by the Secretary in
7 section 314.3 of title 21, Code of Federal
8 Regulations (or any successor regula-
9 tions))”;

10 (B) in subsection (j)(5)(F)—

11 (i) in clause (ii), by striking “active
12 ingredient (including any ester or salt of
13 the active ingredient)” and inserting “ac-
14 tive moiety (as defined by the Secretary in
15 section 314.3 of title 21, Code of Federal
16 Regulations (or any successor regula-
17 tions))”;

18 (ii) in clause (iii), by striking “active
19 ingredient (including any ester or salt of
20 the active ingredient)” and inserting “ac-
21 tive moiety (as defined by the Secretary in
22 section 314.3 of title 21, Code of Federal
23 Regulations (or any successor regula-
24 tions))”;

1 (C) in subsection (l)(2)(A)(i), by striking
2 “active ingredient (including any ester or salt of
3 the active ingredient)” and inserting “active
4 moiety (as defined by the Secretary in section
5 314.3 of title 21, Code of Federal Regulations
6 (or any successor regulations))”;

7 (D) in subsection (s), in the matter pre-
8 ceding paragraph (1), by striking “active ingre-
9 dient (including any ester or salt of the active
10 ingredient)” and inserting “active moiety (as
11 defined by the Secretary in section 314.3 of
12 title 21, Code of Federal Regulations (or any
13 successor regulations))”; and

14 (E) in subsection (u)(1), in the matter pre-
15 ceding subparagraph (A)—

16 (i) by striking “active ingredient (in-
17 cluding any ester or salt of the active in-
18 gredient)” and inserting “active moiety (as
19 defined by the Secretary in section 314.3
20 of title 21, Code of Federal Regulations (or
21 any successor regulations))”; and

22 (ii) by striking “same active ingre-
23 dient” and inserting “same active moiety”;

24 (2) in section 512(c)(2)(F) (21 U.S.C.
25 360b(c)(2)(F))—

1 (A) in clause (i), by striking “active ingre-
2 dient (including any ester or salt of the active
3 ingredient)” and inserting “active moiety (as
4 defined by the Secretary in section 314.3 of
5 title 21, Code of Federal Regulations (or any
6 successor regulations))”;

7 (B) in clause (ii), by striking “active ingre-
8 dient (including any ester or salt of the active
9 ingredient)” and inserting “active moiety (as
10 defined by the Secretary in section 314.3 of
11 title 21, Code of Federal Regulations (or any
12 successor regulations))”; and

13 (C) in clause (v), by striking “active ingre-
14 dient (including any ester or salt of the active
15 ingredient)” and inserting “active moiety (as
16 defined by the Secretary in section 314.3 of
17 title 21, Code of Federal Regulations (or any
18 successor regulations))”;

19 (3) in section 524(a)(4)(C) (21 U.S.C.
20 360n(a)(4)(C)), by striking “active ingredient (in-
21 cluding any ester or salt of the active ingredient)”
22 and inserting “active moiety (as defined by the Sec-
23 retary in section 314.3 of title 21, Code of Federal
24 Regulations (or any successor regulations))”;

1 (4) in section 529(a)(4)(A)(ii) (21 U.S.C.
2 360ff(a)(4)(A)(ii)), by striking “active ingredient
3 (including any ester or salt of the active ingredient)”
4 and inserting “active moiety (as defined by the Sec-
5 retary in section 314.3 of title 21, Code of Federal
6 Regulations (or any successor regulations))”; and

7 (5) in section 565A(a)(4)(D) (21 U.S.C.
8 360bbb–4a(a)(4)(D)), by striking “active ingredient
9 (including any ester or salt of the active ingredient)”
10 and inserting “active moiety (as defined by the Sec-
11 retary in section 314.3 of title 21, Code of Federal
12 Regulations (or any successor regulations))”.

13 **SEC. 209. STREAMLINING THE TRANSITION OF BIOLOGICAL**
14 **PRODUCTS.**

15 Section 7002(e)(4) of the Biologics Price Competition
16 and Innovation Act of 2009 (Public Law 111–148) is
17 amended by adding at the end the following: “With respect
18 to an application for a biological product under section
19 505 of the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 355) with a filing date that is not later than Sep-
21 tember 23, 2019, the Secretary shall continue to review
22 and approve such application under section 505 of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355),
24 even if such review and approval process continues after
25 March 23, 2020. Effective on the later of March 23, 2020,

1 or the date of approval of such application under such sec-
2 tion 505, such approved application shall be deemed to
3 be a license for the biological product under section 351
4 of the Public Health Service Act.”.

5 **SEC. 210. ORPHAN DRUG CLARIFICATION.**

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

9 “(3) **APPLICABILITY.**—This subsection applies
10 to any drug designated under section 526 that was
11 approved under section 505 of this Act or licensed
12 under section 351 of the Public Health Service Act
13 after the date of enactment of the FDA Reauthor-
14 ization Act of 2017, regardless of the date of on
15 which such drug was designated under section
16 526.”.

17 **SEC. 211. PROMPT APPROVAL OF DRUGS RELATED TO**
18 **SAFETY INFORMATION.**

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

22 “(z) **PROMPT APPROVAL OF DRUGS WHEN SAFETY**
23 **INFORMATION IS ADDED TO LABELING.**—

24 “(1) **GENERAL RULE.**—A drug for which an ap-
25 plication has been submitted or approved under sub-

1 section (b)(2) or (j) shall not be considered ineligible
2 for approval under this section or misbranded under
3 section 502 on the basis that the labeling of the
4 drug omits safety information, including contra-
5 indications, warnings, precautions, dosing, adminis-
6 tration, or other information pertaining to safety,
7 when the omitted safety information is protected by
8 exclusivity under clause (iii) or (iv) of subsection
9 (j)(5)(F), clause (iii) or (iv) of subsection (c)(3)(E),
10 or section 527(a), or by an extension of such exclu-
11 sivity under section 505A or 505E.

12 “(2) LABELING.—Notwithstanding clauses (iii)
13 and (iv) of subsection (j)(5)(F), clauses (iii) and (iv)
14 of subsection (c)(3)(E), or section 527, the Sec-
15 retary shall require that the labeling of a drug ap-
16 proved pursuant to an application submitted under
17 subsection (b)(2) or (j) that omits safety information
18 described in paragraph (1) include a statement of
19 any appropriate safety information that the Sec-
20 retary considers necessary to assure safe use.

21 “(3) AVAILABILITY AND SCOPE OF EXCLU-
22 SIVITY.—This subsection does not affect—

23 “(A) the availability or scope of exclusivity
24 or an extension of exclusivity described in sub-
25 paragraph (A) or (B) of section 505A(o)(3);

1 “(B) the question of the eligibility for ap-
 2 proval under this section of any application de-
 3 scribed in subsection (b)(2) or (j) that omits
 4 any other aspect of labeling protected by exclu-
 5 sivity under—

6 “(i) clause (iii) or (iv) of subsection
 7 (j)(5)(F);

8 “(ii) clause (iii) or (iv) of subsection
 9 (c)(3)(E); or

10 “(iii) section 527(a); or

11 “(C) except as expressly provided in para-
 12 graphs (1) and (2), the operation of this section
 13 or section 527.”.

14 **SEC. 212. CONDITIONS OF USE FOR BIOSIMILAR BIOLOGI-**
 15 **CAL PRODUCTS.**

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

18 (1) in subclause (I), by striking “; and” and in-
 19 serting a semicolon;

20 (2) in subclause (II), by striking the period and
 21 inserting “; and”; and

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

23 “(III) may include information to
 24 show that the conditions of use pre-
 25 scribed, recommended, or suggested in

1 the labeling proposed for the biological
2 product have been previously approved
3 for the reference product.”.

4 **SEC. 213. MODERNIZING THE LABELING OF CERTAIN GE-**
5 **NERIC DRUGS.**

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

9 **“SEC. 503D. PROCESS TO UPDATE LABELING FOR CERTAIN**
10 **DRUGS.**

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

12 “(1) The term ‘covered drug’ means a drug ap-
13 proved under section 505(c)—

14 “(A) for which there are no unexpired pat-
15 ents included in the list under section 505(j)(7)
16 and no unexpired period of market exclusivity;

17 “(B) for which the approval of the applica-
18 tion has been withdrawn for reasons other than
19 safety or effectiveness; and

20 “(C) for which, with respect to the label-
21 ing—

22 “(i) new scientific evidence is available
23 regarding the conditions of use of the
24 drug;

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

4 “(iii) the labeling of such drug does
5 not reflect current legal and regulatory re-
6 quirements.

7 “(2) The term ‘period of market exclusivity’,
8 with respect to a drug approved under section
9 505(c), means any period of market exclusivity
10 under clause (ii), (iii), or (iv) of section
11 505(c)(3)(E), clause (ii), (iii), or (iv) of section
12 505(j)(5)(F), or section 505A, 505E, or 527.

13 “(3) The term ‘generic version’ means a drug
14 approved under section 505(j) whose reference drug
15 is a covered drug.

16 “(4) The term ‘relevant accepted use’ means a
17 use for a drug in clinical practice that is supported
18 by scientific evidence that appears to the Secretary
19 to meet the standards for approval under section
20 505.

21 “(5) The term ‘selected drug’ means a covered
22 drug for which the Secretary has determined
23 through the process under subsection (c) that the la-
24 beling should be changed.

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

6 “(1) Enter into cooperative agreements or con-
7 tracts with public or private entities to review the
8 available scientific evidence concerning such drugs.

9 “(2) Seek public input concerning such drugs,
10 including input on whether there is a relevant ac-
11 cepted use in clinical practice that is not reflected in
12 the approved labeling of such drugs or whether new
13 scientific evidence is available regarding the condi-
14 tions of use for such drug, by—

15 “(A) holding one or more public meetings;

16 “(B) opening a public docket for the sub-
17 mission of public comments; or

18 “(C) other means, as the Secretary deter-
19 mines appropriate.

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

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

3 “(d) INITIATION OF THE PROCESS OF UPDATING.—

4 If the Secretary determines that labeling changes are ap-
5 propriate for a selected drug pursuant to subsection (c),
6 the Secretary shall provide notice to the holders of ap-
7 proved applications for a generic version of such drug
8 that—

9 “(1) summarizes the findings supporting the
10 determination of the Secretary that the available sci-
11 entific evidence meets the standards under section
12 505 for adding or modifying information or pro-
13 viding supplemental information to the labeling of
14 the covered drug pursuant to subsection (c);

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

21 “(3) states whether the statement under para-
22 graph (2) applies to the selected drug as a class of
23 covered drugs or only as to a specific drug product.

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

1 ant to subsection (d), the holder of an approved applica-
2 tion for a generic version of the selected drug shall—

3 “(1) agree to change the approved labeling to
4 reflect the additional, modified, or supplemental in-
5 formation the Secretary has determined to be appro-
6 priate; or

7 “(2) notify the Secretary that the holder of the
8 approved application does not believe that the re-
9 quested labeling changes are warranted and submit
10 a statement detailing the reasons why such changes
11 are not warranted.

12 “(f) REVIEW OF APPLICATION HOLDER’S RE-
13 SPONSE.—

14 “(1) IN GENERAL.—Upon receipt of the appli-
15 cation holder’s response, the Secretary shall prompt-
16 ly review each statement received under subsection
17 (e)(2) and determine which labeling changes pursu-
18 ant to the Secretary’s notice under subsection (d)
19 are appropriate, if any. If the Secretary disagrees
20 with the reasons why such labeling changes are not
21 warranted, the Secretary shall provide opportunity
22 for discussions with the application holders to reach
23 agreement on whether the labeling for the covered
24 drug should be updated to reflect current scientific

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

3 “(2) CHANGES TO LABELING.—After consid-
4 ering all responses from the holder of an approved
5 application under paragraph (1) or (2) of subsection
6 (e), and any discussion under paragraph (1), the
7 Secretary may order such holder to make the label-
8 ing changes the Secretary determines are appro-
9 priate. Such holder of an approved application
10 shall—

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

13 “(B) update any electronic labeling for the
14 drug within 30 days; and

15 “(C) submit the revised labeling through
16 the form, ‘Supplement—Changes Being Ef-
17 fected’.

18 “(g) VIOLATION.—If the holder of an approved appli-
19 cation for the generic version of the selected drug does
20 not comply with the requirements of subsection (f)(2),
21 such generic version of the selected drug shall be deemed
22 to be misbranded under section 502.

23 “(h) LIMITATIONS; GENERIC DRUGS.—

24 “(1) IN GENERAL.—With respect to any label-
25 ing change required under this section, the generic

1 version shall be deemed to have the same conditions
2 of use and the same labeling as a reference drug for
3 purposes of clauses (i) and (v) of section
4 505(j)(2)(A). Any labeling change so required shall
5 not have any legal effect for the applicant that is
6 different than the legal effect that would have re-
7 sulted if a supplemental application had been sub-
8 mitted and approved to conform the labeling of the
9 generic version to a change in the labeling of the ref-
10 erence drug.

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

15 “(i) DRUG PRODUCT CLASSES.—In the case of a se-
16 lected drug for which the labeling changes ordered by the
17 Secretary under subsection (d)(2) are required for a class
18 of covered drugs, such labeling changes shall be made for
19 generic versions of such drug in that class.

20 “(j) RULES OF CONSTRUCTION.—

21 “(1) APPROVAL STANDARDS.—This section
22 shall not be construed as altering the applicability of
23 the standards for approval of an application under
24 section 505. No order shall be issued under this sub-
25 section unless the evidence supporting the changed

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

3 “(2) REMOVAL OF INFORMATION.—Nothing in
4 this section shall be construed to give the Secretary
5 additional authority to remove approved indications
6 for drugs, other than the authority to remove certain
7 indications from the labels of certain covered drugs,
8 as described in this section.

9 “(k) REPORTS.—Not later than 4 years after the
10 date of the enactment of the Lower Health Care Costs
11 Act and every 4 years thereafter, the Secretary shall pre-
12 pare and submit to the Committee on Health, Education,
13 Labor, and Pensions of the Senate and the Committee on
14 Energy and Commerce of the House of Representatives,
15 a report that—

16 “(1) describes the actions of the Secretary
17 under this section, including—

18 “(A) the number of covered drugs and de-
19 scription of the types of drugs the Secretary
20 has selected for labeling changes and the ra-
21 tionale for such recommended changes; and

22 “(B) the number of times the Secretary
23 entered into discussions concerning a disagree-
24 ment with an application holder or holders and

1 a summary of the decision regarding a labeling
 2 change, if any; and

3 “(2) includes any recommendations of the Sec-
 4 retary for modifying the program under this sec-
 5 tion.”.

6 **TITLE III—IMPROVING TRANSPARENCY IN HEALTH CARE**

8 **SEC. 301. INCREASING TRANSPARENCY BY REMOVING GAG** 9 **CLAUSES ON PRICE AND QUALITY INFORMA-** 10 **TION.**

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

15 **“SEC. 2729B. INCREASING TRANSPARENCY BY REMOVING** 16 **GAG CLAUSES ON PRICE AND QUALITY IN-** 17 **FORMATION.**

18 “(a) INCREASING PRICE AND QUALITY TRANS-
 19 PARENCY FOR PLAN SPONSORS AND CONSUMERS.—

20 “(1) GROUP HEALTH PLANS.—A group health
 21 plan or a health insurance issuer offering group
 22 health insurance coverage may not enter into an
 23 agreement with a health care provider, network or
 24 association of providers, third-party administrator,
 25 or other service provider offering access to a network

1 of providers that would directly or indirectly restrict
2 a group health plan or health insurance issuer
3 from—

4 “(A) providing provider-specific cost or
5 quality of care information, through a consumer
6 engagement tool or any other means, to refer-
7 ring providers, the plan sponsor, enrollees, or
8 eligible enrollees of the plan or coverage;

9 “(B) electronically accessing de-identified
10 claims and encounter data for each enrollee in
11 the plan or coverage, upon request and con-
12 sistent with the privacy regulations promul-
13 gated pursuant to section 264(c) of the Health
14 Insurance Portability and Accountability Act,
15 the amendments to this Act made by the Ge-
16 netic Information Nondiscrimination Act of
17 2008, and the Americans with Disabilities Act
18 of 1990, with respect to the applicable health
19 plan or health insurance coverage, including, on
20 a per claim basis—

21 “(i) financial information, such as the
22 allowed amount, or any other claim-related
23 financial obligations included in the pro-
24 vider contract;

1 “(ii) provider information, including
2 name and clinical designation;

3 “(iii) service codes; or

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

7 “(C) sharing data described in subpara-
8 graph (A) or (B) with a business associate as
9 defined in section 160.103 of title 45, Code of
10 Federal Regulations (or successor regulations),
11 consistent with the privacy regulations promul-
12 gated pursuant to section 264(c) of the Health
13 Insurance Portability and Accountability Act,
14 the amendments to this Act made by the Ge-
15 netic Information Nondiscrimination Act of
16 2008, and the Americans with Disabilities Act
17 of 1990.

18 “(2) INDIVIDUAL HEALTH INSURANCE COV-
19 ERAGE.—A health insurance issuer offering indi-
20 vidual health insurance coverage may not enter into
21 an agreement with a health care provider, network
22 or association of providers, or other service provider
23 offering access to a network of providers that would,
24 directly or indirectly restrict the health insurance
25 issuer from—

1 “(A) providing provider-specific price or
2 quality of care information, through a consumer
3 engagement tool or any other means, to refer-
4 ring providers or the plan sponsor, enrollees, or
5 eligible enrollees of the plan or coverage; or

6 “(B) sharing data described in subpara-
7 graph (A) with a business associate as defined
8 in section 160.103 of title 45, Code of Federal
9 Regulations (or successor regulations), con-
10 sistent with the privacy regulations promul-
11 gated pursuant to section 264(c) of the Health
12 Insurance Portability and Accountability Act,
13 the amendments to this Act made by the Ge-
14 netic Information Nondiscrimination Act of
15 2008, and the Americans with Disabilities Act
16 of 1990, for plan design, plan administration,
17 and plan, financial, legal, and quality improve-
18 ment activities.

19 “(3) CLARIFICATION REGARDING PUBLIC DIS-
20 CLOSURE OF INFORMATION.—Nothing in paragraph
21 (1)(A) or (2)(A) prevents a health care provider,
22 network or association of providers, or other service
23 provider from placing reasonable restrictions on the
24 public disclosure of the information described in
25 such paragraphs (1) and (2).

1 “(1) IN GENERAL.—A group health plan or a
2 health insurance issuer offering group or individual
3 health insurance coverage shall not enter into an
4 agreement with a provider, network or association of
5 providers, or other service provider offering access to
6 a network of service providers if such agreement, di-
7 rectly or indirectly—

8 “(A) restricts the group health plan or
9 health insurance issuer from—

10 “(i) directing or steering enrollees to
11 other health care providers; or

12 “(ii) offering incentives to encourage
13 enrollees to utilize specific health care pro-
14 viders;

15 “(B) requires the group health plan or
16 health insurance issuer to enter into any addi-
17 tional contract with an affiliate of the provider
18 as a condition of entering into a contract with
19 such provider;

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

24 “(D) restricts other group health plans or
25 health insurance issuers not party to the con-

1 tract, from paying a lower rate for items or
2 services than the contracting plan or issuer
3 pays for such items or services.

4 “(2) ADDITIONAL REQUIREMENT FOR SELF-IN-
5 SURED PLANS.—A self-insured group health plan
6 shall not enter into an agreement with a provider,
7 network or association of providers, third-party ad-
8 ministrator, or other service provider offering access
9 to a network of providers if such agreement, directly
10 or indirectly requires the group health plan to cer-
11 tify, attest, or otherwise confirm in writing that the
12 group health plan is bound by the terms of the con-
13 tract between the service provider and a third-party
14 administrator that the group health plan is not
15 party to and is not allowed to review.

16 “(3) EXCEPTION FOR CERTAIN GROUP MODEL
17 ISSUERS.—Paragraph (1)(A) shall not apply to a
18 group health plan or a health insurance issuer offer-
19 ing group or individual health insurance coverage
20 with respect to a health maintenance organization
21 (as defined in section 2791(b)(3)) if such health
22 maintenance organization operates primarily through
23 exclusive contracts with multi-specialty physician
24 groups, nor to any arrangement between such a
25 health maintenance organization and its affiliates.

1 “(4) ATTESTATION.—A group health plan or a
2 health insurance issuer offering group or individual
3 health insurance coverage shall annually submit to,
4 as applicable, the applicable authority described in
5 section 2723 or the Secretary of Labor, an attesta-
6 tion that such plan or issuer is in compliance with
7 the requirements of this subsection.

8 “(c) MAINTENANCE OF EXISTING HIPAA, GINA,
9 AND ADA PROTECTIONS.—Nothing in this section shall
10 modify, reduce, or eliminate the existing privacy protec-
11 tions and standards provided by reason of State and Fed-
12 eral law, including the requirements of parts 160 and 164
13 of title 45, Code of Federal Regulations (or any successor
14 regulations).

15 “(d) REGULATIONS.—The Secretary, in coordination
16 with the Secretary of Labor and the Secretary of the
17 Treasury, not later than 1 year after the date of enact-
18 ment of the Lower Health Care Costs Act, shall promul-
19 gate regulations to carry out this section.

20 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-
21 tion shall be construed to limit network design or cost or
22 quality initiatives by a group health plan or health insur-
23 ance issuer, including accountable care organizations, ex-
24 clusive provider organizations, networks that tier providers

1 by cost or quality or steer enrollees to centers of excel-
 2 lence, or other pay-for-performance programs.”.

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

11 **SEC. 303. DESIGNATION OF A NONGOVERNMENTAL, NON-**
 12 **PROFIT TRANSPARENCY ORGANIZATION TO**
 13 **LOWER AMERICANS’ HEALTH CARE COSTS.**

14 (a) IN GENERAL.—Subpart C of part 7 of subtitle
 15 B of title I of the Employee Retirement Income Security
 16 Act of 1974 (29 U.S.C. 1191 et seq.) is amended by add-
 17 ing at the end the following:

18 **“SEC. 735. DESIGNATION OF A NONGOVERNMENTAL, NON-**
 19 **PROFIT TRANSPARENCY ORGANIZATION TO**
 20 **LOWER AMERICANS’ HEALTH CARE COSTS.**

21 “(a) IN GENERAL.—The Secretary, in consultation
 22 with the Secretary of Health and Human Services, not
 23 later than 6 months after the date of enactment of the
 24 Lower Health Care Costs Act, shall have in effect a con-
 25 tract with a nonprofit entity to support the establishment

1 and maintenance of a database that receives and utilizes
2 health care claims information and related information
3 and issues reports that are available to the public and au-
4 thorized users, and are submitted to the Department of
5 Labor.

6 “(b) REQUIREMENTS.—

7 “(1) IN GENERAL.—The database established
8 under subsection (a) shall—

9 “(A) improve transparency by using de-
10 identified health care data to—

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

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

16 “(iii) enable providers, hospitals, and
17 communities to improve services and out-
18 comes for patients by benchmarking their
19 performance against that of other pro-
20 viders, hospitals, and communities;

21 “(iv) enable purchasers, including em-
22 ployers, employee organizations, and health
23 plans, to develop value-based purchasing
24 models, improve quality, and reduce the

1 cost of health care and insurance coverage
2 for enrollees;

3 “(v) enable employers and employee
4 organizations to evaluate network design
5 and construction, and the cost of care for
6 enrollees;

7 “(vi) facilitate State-led initiatives to
8 lower health care costs and improve qual-
9 ity; and

10 “(vii) promote competition based on
11 quality and cost;

12 “(B) collect medical claims, prescription
13 drug claims, and remittance data consistent
14 with the protections and requirements of sub-
15 section (d);

16 “(C) be established in such a manner that
17 allows the data collected pursuant to subpara-
18 graph (B) to be shared with any State all-payer
19 claims database or regional database operated
20 with authorization from States, at cost, using a
21 standardized format, if such State or regional
22 database also submits claims data to the data-
23 base established under this section; and

24 “(D) be available to—

1 “(i) the Director of the Congressional
2 Budget Office, the Comptroller General of
3 the United States, the Executive Director
4 of the Medicare Payment Advisory Com-
5 mission, and the Executive Director of the
6 Medicaid and CHIP Payment Advisory
7 Commission, upon request, subject to the
8 privacy and security requirements of au-
9 thorized users under subsection (e)(2); and

10 “(ii) authorized users, including em-
11 ployers, employee organizations, providers,
12 researchers, and policymakers, subject to
13 subsection (e).

14 “(2) PRIVACY AND SECURITY.—The entity re-
15 ceiving a contract under subsection (a) shall—

16 “(A) be subject to the breach notification
17 rule under subpart D of part 164 of title 45,
18 Code of Federal Regulations (or any successor
19 regulations), the security rule under part 160
20 and subparts A and C of part 164 of title 45,
21 Code of Federal Regulations (or any successor
22 regulations), and the privacy rule under part
23 160 and subparts A and E of part 164 of title
24 45, Code of Federal Regulations (or any suc-
25 cessor regulations); and

1 “(B) consistent with the requirements and
2 prohibitions in the regulations promulgated
3 under section 264(c) of the Health Insurance
4 Portability and Accountability Act of 1996—

5 “(i) ensure that the database under
6 subsection (a) is capable of—

7 “(I) receiving data under sub-
8 section (d);

9 “(II) providing data access to au-
10 thORIZED users; and

11 “(III) storing data on secure
12 servers in a manner that is consistent
13 with the privacy, security, and breach
14 notification requirements under sec-
15 tion 13402 of the HITECH Act and
16 under the regulations promulgated
17 under section 264(c) of the Health In-
18 surance Portability and Accountability
19 Act of 1996;

20 “(ii) not disclose to the public any in-
21 dividually identifiable health information or
22 proprietary financial information;

23 “(iii) strictly limit staff access to the
24 data to staff with appropriate training,

1 clearance, and background checks and re-
2 quire regular privacy and security training;

3 “(iv) maintain effective security
4 standards for transferring data or making
5 data available to authorized users;

6 “(v) develop a process for providing
7 access to data to authorized users, in a se-
8 cure manner that maintains privacy and
9 confidentiality of data;

10 “(vi) adhere to current best security
11 practices with respect to the management
12 and use of such data for health services re-
13 search, in accordance with applicable Fed-
14 eral privacy law; and

15 “(vii) report on the security methods
16 of the entity to the Secretary, the Com-
17 mittee on Health, Education, Labor, and
18 Pensions of the Senate, and the Committee
19 on Education and Labor of the House of
20 Representatives.

21 “(3) CONSULTATION.—

22 “(A) ADVISORY COMMITTEE.—Not later
23 than 180 days after the date of enactment of
24 the Lower Health Care Costs Act, the Secretary
25 shall convene an Advisory Committee (referred

1 to in this section as the ‘Committee’), con-
2 sisting of 11 members, to advise the Secretary,
3 the contracting entity, and Congress on the es-
4 tablishment, operations, and use of the data-
5 base established under this section.

6 “(B) MEMBERSHIP.—

7 “(i) APPOINTMENT.—In accordance
8 with clause (ii), the Secretary, in consulta-
9 tion with the Secretary of Health and
10 Human Services, and the Comptroller Gen-
11 eral of the United States shall, not later
12 than 1 year after the date of enactment of
13 the Lower Health Care Costs Act, appoint
14 members to the Committee who have dis-
15 tinguished themselves in the fields of
16 health services research, health economics,
17 health informatics, or the governance of
18 State all-payer claims databases, or who
19 represent organizations likely to submit
20 data to or use the database, including pa-
21 tients, employers, or employee organiza-
22 tions that sponsor group health plans,
23 health care providers, health insurance
24 issuers, and third-party administrators of
25 group health plans. Such members shall

1 serve 3-year terms on a staggered basis.
2 Vacancies on the Committee shall be filled
3 by appointment consistent with this sub-
4 section not later than 3 months after the
5 vacancy arises.

6 “(ii) COMPOSITION.—In accordance
7 with clause (i)—

8 “(I) the Secretary, in consulta-
9 tion with the Secretary of Health and
10 Human Services, shall appoint to the
11 Committee—

12 “(aa) 1 member selected by
13 the Secretary, in coordination
14 with the Secretary of Health and
15 Human Services, to serve as the
16 chair of the Committee;

17 “(bb) the Assistant Sec-
18 retary for Planning and Evalua-
19 tion of the Department of Health
20 and Human Services;

21 “(cc) 1 representative of the
22 Centers for Medicare & Medicaid
23 Services;

1 “(dd) 1 representative of the
2 Agency for Health Research and
3 Quality;

4 “(ee) 1 representative of the
5 Office for Civil Rights of the De-
6 partment of Health and Human
7 Services with expertise in data
8 privacy and security; and

9 “(ff) 1 representative of the
10 National Center for Health Sta-
11 tistics; and

12 “(II) the Comptroller General of
13 the United States shall appoint to the
14 Committee—

15 “(aa) 1 representative of an
16 employer that sponsors a group
17 health plan;

18 “(bb) 1 representative of an
19 employee organization that spon-
20 sors a group health plan;

21 “(cc) 1 academic researcher
22 with expertise in health econom-
23 ics or health services research;

24 “(dd) 1 patient advocate;
25 and

1 “(ee) 2 additional members.

2 “(C) DUTIES.—The Committee shall—

3 “(i) assist and advise the Secretary on
4 the management of the contract under sub-
5 section (a);

6 “(ii) assist and advise the entity re-
7 ceiving the contract under subsection (a) in
8 establishing—

9 “(I) the scope and format of the
10 data to be submitted under subsection
11 (d);

12 “(II) the appropriate uses of
13 data by authorized users, including
14 developing standards for the approval
15 of requests by organizations to access
16 and use the data; and

17 “(III) the appropriate formats
18 and methods for making reports and
19 analyses based on the database to the
20 public;

21 “(iii) conduct an annual review of
22 whether data was used according to the
23 appropriate uses as described in clause
24 (ii)(II), and advise the designated entity on
25 using the data for authorized purposes;

1 “(iv) report, as appropriate, to the
2 Secretary and Congress on the operation of
3 the database and opportunities to better
4 achieve the objectives of this section;

5 “(v) establish additional restrictions
6 on researchers who receive compensation
7 from entities described in subsection
8 (e)(2)(B)(ii), in order to protect propri-
9 etary financial information; and

10 “(vi) establish objectives for research
11 and public reporting.

12 “(4) STATE REQUIREMENTS.—A State may re-
13 quire health insurance issuers and other payers to
14 submit claims data to the database established
15 under this section, provided that such data is sub-
16 mitted in a form and manner established by the Sec-
17 retary, and pursuant to subsection (d)(4)(B).

18 “(5) SANCTIONS.—The Secretary shall take ap-
19 propriate action to sanction users who attempt to re-
20 identify data accessed pursuant to paragraph
21 (1)(D).

22 “(c) CONTRACT REQUIREMENTS.—

23 “(1) COMPETITIVE PROCEDURES.—The Sec-
24 retary shall enter into the contract under subsection

1 (a) using full and open competition procedures pur-
2 suant to chapter 33 of title 41, United States Code.

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

6 “(A) be a private nonprofit entity governed
7 by a board that includes representatives of the
8 academic research community and individuals
9 with expertise in employer-sponsored insurance,
10 research using health care claims data and ac-
11 tuarial analysis;

12 “(B) conduct its business in an open and
13 transparent manner that provides the oppor-
14 tunity for public comment on its activities; and

15 “(C) agree to maintain an active certifi-
16 cation as a qualified entity under section
17 1874(e) of the Social Security Act (or any suc-
18 cessor program) throughout the contract period.

19 “(3) CONSIDERATIONS.—In awarding the con-
20 tract under subsection (a), the Secretary shall con-
21 sider an entity’s experience in—

22 “(A) health care claims data collection, ag-
23 gregation, quality assurance, analysis, and secu-
24 rity;

1 “(B) supporting academic research on
2 health costs, spending, and utilization for and
3 by privately insured patients;

4 “(C) working with large health insurance
5 issuers and third-party administrators to as-
6 semble a national claims database;

7 “(D) effectively collaborating with and en-
8 gaging stakeholders to develop reports;

9 “(E) meeting budgets and timelines, in-
10 cluding in connection with report generation;
11 and

12 “(F) facilitating the creation of, or sup-
13 porting, State all-payer claims databases.

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

18 “(5) TRANSITION OF CONTRACT.—If the Sec-
19 retary, following a competitive process at the end of
20 the contract period, selects a new entity to maintain
21 the database, all data shall be transferred to the new
22 entity according to a schedule and process to be de-
23 termined by the Secretary. Upon termination of a
24 contract, no entity may keep data held by the data-
25 base or disclose such data to any entity other than

1 the entity so designated by the Secretary. The Sec-
2 retary shall include enforcement terms in any con-
3 tract with an organization chosen under this section,
4 to ensure the timely transfer of all data to a new en-
5 tity in the event of contract termination.

6 “(d) RECEIVING HEALTH INFORMATION.—

7 “(1) REQUIREMENTS.—

8 “(A) IN GENERAL.—An applicable self-in-
9 sured group health plan shall, through its
10 health insurance issuer, third-party adminis-
11 trator, pharmacy benefit manager, or other en-
12 tity designated by the group health plan, elec-
13 tronically submit all claims data with respect to
14 the plan, pursuant to subparagraph (B).

15 “(B) SCOPE OF INFORMATION AND FOR-
16 MAT OF SUBMISSION.—The entity awarded the
17 contract under subsection (a), in consultation
18 with the Committee described in subsection
19 (b)(3), and pursuant to the privacy and security
20 requirements of subsection (b)(2), shall—

21 “(i) specify the data elements required
22 to be submitted under subparagraph (A),
23 which shall include all data related to
24 transactions described in subparagraphs
25 (A) and (E) of section 1173(a)(2) of the

1 Social Security Act, including all data ele-
2 ments normally present in such trans-
3 actions when adjudicated, and enrollment
4 information;

5 “(ii) specify the form and manner for
6 such submissions, and the historical period
7 to be included in the initial submission;
8 and

9 “(iii) offer an automated submission
10 option to minimize administrative burdens
11 for entities required to submit data.

12 “(C) DE-IDENTIFICATION OF DATA.—The
13 entity awarded the contract under subsection
14 (a) shall—

15 “(i) establish a process under which
16 data is de-identified in accordance with
17 section 164.514(a) of title 45, Code of
18 Federal Regulations (or any successor reg-
19 ulations), while retaining the ability to link
20 data longitudinally for the purposes of re-
21 search on cost and quality, and the ability
22 to complete risk adjustment and geo-
23 graphic analysis;

24 “(ii) ensure that any third-party sub-
25 contractors who perform the de-identifica-

1 tion process described in clause (i) retain
2 the minimum necessary information to per-
3 form such a process, and adhere to effec-
4 tive security and encryption practices in
5 data storage and transmission;

6 “(iii) store claims and other data col-
7 lected under this subsection only in de-
8 identified form, in accordance with section
9 164.514(a) of title 45, Code of Federal
10 Regulations (or any successor regulations);
11 and

12 “(iv) ensure that data is encrypted, in
13 accordance with the regulations promul-
14 gated under section 264(e) of the Health
15 Insurance Portability and Accountability
16 Act of 1996.

17 “(2) APPLICABLE SELF-INSURED GROUP
18 HEALTH PLAN.—For purposes of paragraph (1), a
19 self-insured group health plan is an applicable self-
20 insured group health plan if such plan is self-admin-
21 istered, or is administered by a health insurance
22 issuer or third-party administrator that meets one or
23 both of the following criteria:

24 “(A) Administers health benefits for more
25 than 50,000 enrollees.

1 “(B) Is one of the 5 largest administrators
2 or issuers of self-insured group health plans in
3 a State in which such administrator operates,
4 as measured by the number of enrollees.

5 “(3) ISSUERS AND THIRD-PARTY ADMINISTRA-
6 TORS.—In the case of a health insurance issuer or
7 third-party administrator that is required under this
8 subsection to submit claims data with respect to an
9 applicable self-insured group health plan, such issuer
10 or administrator shall submit claims data with re-
11 spect to all self-insured group health plans that the
12 issuer or administrator administers, including such
13 plans that are not applicable self-insured group
14 health plans, as described in paragraph (2).

15 “(4) RECEIVING OTHER INFORMATION.—

16 “(A) MEDICARE DATA.—The entity award-
17 ed the contract under subsection (a) shall main-
18 tain active certification as a qualified entity
19 pursuant to section 1874(e) of the Social Secu-
20 rity Act for the term of the contract awarded
21 under subsection (a).

22 “(B) STATE DATA.—The entity awarded
23 the contract under subsection (a) shall collect
24 data from State all-payer claims databases that

1 seek access to the database established under
2 this section.

3 “(5) AVAILABILITY OF DATA.—An entity re-
4 quired to submit data under this subsection may not
5 place any restrictions on the use of such data by au-
6 thorized users.

7 “(e) USES OF INFORMATION.—

8 “(1) IN GENERAL.—The entity awarded the
9 contract under subsection (a) shall make the data-
10 base available to users who are authorized under
11 this subsection, at cost, and reports and analyses
12 based on the data available to the public with no
13 charge.

14 “(2) AUTHORIZATION OF USERS.—

15 “(A) IN GENERAL.—An entity may request
16 authorization by the entity awarded the con-
17 tract under subsection (a) for access to the
18 database in accordance with this paragraph.

19 “(B) APPLICATION.—An entity desiring
20 authorization under this paragraph shall submit
21 to the entity awarded the contract an applica-
22 tion for such access, which shall include—

23 “(i) in the case of an entity requesting
24 access for research purposes—

1 “(I) a description of the uses and
2 methodologies for evaluating health
3 system performance using such data;
4 and

5 “(II) documentation of approval
6 of the research by an institutional re-
7 view board, if applicable for a par-
8 ticular plan of research; or

9 “(ii) in the case of an entity such as
10 an employer, health insurance issuer,
11 third-party administrator, or health care
12 provider, requesting access for the purpose
13 of quality improvement or cost-contain-
14 ment, a description of the intended uses
15 for such data.

16 “(C) REQUIREMENTS.—

17 “(i) RESEARCH.—Upon approval of
18 an application for research purposes under
19 subparagraph (B)(i), the authorized user
20 shall enter into a data use and confiden-
21 tiality agreement with the entity awarded
22 the contract under subsection (a), which
23 shall include a prohibition on attempts to
24 reidentify and disclose protected health in-

1 formation and proprietary financial infor-
2 mation.

3 “(ii) QUALITY IMPROVEMENT AND
4 COST-CONTAINMENT.—In consultation with
5 the Committee described in subsection
6 (b)(3), the Secretary shall, through rule-
7 making, establish the form and manner in
8 which authorized users described in sub-
9 paragraph (B)(ii) may access data. Data
10 provided to such authorized users shall be
11 provided in a form and manner such that
12 users may not obtain individually identifi-
13 able price information with respect to di-
14 rect competitors. Upon approval, such au-
15 thorized user shall enter into a data use
16 and confidentiality agreement with the en-
17 tity.

18 “(iii) CUSTOMIZED REPORTS.—Em-
19 ployers and employer organizations may
20 request customized reports from the entity
21 awarded the contract under subsection (a),
22 at cost, subject to the requirements of this
23 section with respect to privacy, security,
24 and proprietary financial information.

1 “(iv) NON-CUSTOMIZED REPORTS.—

2 The entity awarded the contract under
3 subsection (a), in consultation with the
4 Committee, shall make available to all au-
5 thorized users aggregate data sets, free of
6 charge.

7 “(f) FUNDING.—

8 “(1) INITIAL FUNDING.—There are authorized
9 to be appropriated, and there are appropriated, out
10 of monies in the Treasury not otherwise appro-
11 priated, \$20,000,000 for fiscal year 2020, for the
12 implementation of the initial contract and establish-
13 ment of the database under this section.

14 “(2) ONGOING FUNDING.—There are author-
15 ized to be appropriated \$15,000,000 for each of fis-
16 cal years 2021 through 2025, for purposes of car-
17 rying out this section (other than the grant program
18 under subsection (h)).

19 “(g) ANNUAL REPORT.—

20 “(1) SUBMISSION.—Not later than March 1,
21 2021, and March 1 of each year thereafter, the enti-
22 ty receiving the contract under subsection (a) shall
23 submit to Congress, the Secretary of Labor, and the
24 Secretary of Health and Human Services, and pub-

1 lish online for access by the general public, a report
2 containing a description of—

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

7 “(B) limitations in the data set;

8 “(C) progress towards the objectives of
9 this section; and

10 “(D) the performance by the entity of the
11 duties required under such contract.

12 “(2) PUBLIC REPORTS AND RESEARCH.—The
13 entity receiving a contract under subsection (a)
14 shall, in coordination with authorized users, make
15 analyses and research available to the public on an
16 ongoing basis to promote the objectives of this sec-
17 tion.

18 “(h) GRANTS TO STATES.—

19 “(1) IN GENERAL.—The Secretary, in consulta-
20 tion with the Secretary of Health and Human Serv-
21 ices, may award grants to States for the purpose of
22 establishing and maintaining State all-payer claims
23 databases that improve transparency of data in
24 order to meet the goals of subsection (a)(1).

1 “(2) REQUIREMENT.—To be eligible to receive
2 the funding under paragraph (1), a State shall sub-
3 mit data to the database as described in subsection
4 (b)(1)(C), using the format described in subsection
5 (d)(1).

6 “(3) FUNDING.—There is authorized to be ap-
7 propriated \$100,000,000 for the period of fiscal
8 years 2020 through 2029 for the purpose of award-
9 ing grants to States under this subsection.

10 “(i) EXEMPTION FROM PUBLIC DISCLOSURE.—

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

15 “(2) RESTRICTIONS ON USES FOR CERTAIN
16 PROCEEDINGS.—Data disclosed to authorized users
17 shall not be subject to discovery or admission as
18 public information, or evidence in judicial or admin-
19 istrative proceedings without consent of the affected
20 parties.

21 “(j) DEFINITIONS.—

22 “(1) PROTECTED HEALTH INFORMATION.—The
23 term ‘protected health information’ has the meaning
24 given such term in section 160.103 of title 45, Code

1 of Federal Regulations (or any successor regula-
2 tions).

3 “(2) PROPRIETARY FINANCIAL INFORMATION.—

4 The term ‘proprietary financial information’ means
5 data that would disclose the terms of a specific con-
6 tract between an individual health care provider or
7 facility and a specific group health plan, Medicaid
8 managed care organization or other managed care
9 entity, or health insurance issuer offering group or
10 individual coverage.

11 “(k) RULE OF CONSTRUCTION.—Nothing in this sec-
12 tion shall be construed to affect or modify enforcement
13 of the privacy, security, or breach notification rules pro-
14 mulgated under section 264(c) of the Health Insurance
15 Portability and Accountability Act of 1996 (or successor
16 regulations).”.

17 (b) GAO REPORT.—

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

20 (A) the performance of the entity awarded
21 a contract under section 735(a) of the Em-
22 ployee Retirement Income Security Act of 1974,
23 as added by subsection (a), under such con-
24 tract;

1 (B) the privacy and security of the infor-
 2 mation reported to the entity; and

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

5 (2) REPORTS.—Not later than 2 years after the
 6 effective date of the first contract entered into under
 7 section 735(a) of the Employee Retirement Income
 8 Security Act of 1974, as added by subsection (a),
 9 and again not later than 4 years after such effective
 10 date, the Comptroller General of the United States
 11 shall submit to Congress a report containing the re-
 12 sults of the study conducted under paragraph (1),
 13 together with recommendations for such legislation
 14 and administrative action as the Comptroller Gen-
 15 eral determines appropriate.

16 (c) CLERICAL AMENDMENT.—The table of contents
 17 in section 1 of the Employee Retirement Income Security
 18 Act of 1974 is amended by inserting after the item relat-
 19 ing to section 734 the following new item:

“Sec. 735. Designation of a nongovernmental, nonprofit transparency organiza-
 tion to lower Americans’ health care costs.”.

20 **SEC. 304. PROTECTING PATIENTS AND IMPROVING THE AC-**
 21 **CURACY OF PROVIDER DIRECTORY INFOR-**
 22 **MATION.**

23 Subpart II of part A of title XXVII of the Public
 24 Health Service Act (42 U.S.C. 300gg–11 et seq.), as

1 amended by sections 301 and 302, is further amended by
2 adding at the end the following:

3 **“SEC. 2729C. PROTECTING PATIENTS AND IMPROVING THE**
4 **ACCURACY OF PROVIDER DIRECTORY INFOR-**
5 **MATION.**

6 “(a) NETWORK STATUS OF PROVIDERS.—

7 “(1) IN GENERAL.—Beginning on the date that
8 is one year after the date of enactment of this sec-
9 tion, a group health plan or a health insurance
10 issuer offering group or individual health insurance
11 coverage shall—

12 “(A) establish business processes to ensure
13 that all enrollees in such plan or coverage re-
14 ceive proof of a health care provider’s network
15 status—

16 “(i) through a written electronic com-
17 munication from the plan or issuer to the
18 enrollee, as soon as practicable and not
19 later than 1 business day after a telephone
20 inquiry is made by such enrollee for such
21 information; and

22 “(ii) in real-time through an online
23 health care provider directory search tool
24 maintained by the plan or issuer; and

1 “(B) include in any print directory a dis-
2 closure that the information included in the di-
3 rectory is accurate as of the date of the last
4 data update and that enrollees or prospective
5 enrollees should consult the group health plan
6 or issuer’s electronic provider directory on its
7 website or call a specified customer service tele-
8 phone number to obtain the most current pro-
9 vider directory information.

10 “(2) GROUP HEALTH PLAN AND HEALTH IN-
11 SURANCE ISSUER BUSINESS PROCESSES.—Beginning
12 on the date that is one year after the date of enact-
13 ment of the Lower Health Care Costs Act, a group
14 health plan or a health insurance issuer offering
15 group or individual health insurance coverage shall
16 establish business processes to—

17 “(A) verify and update, at least once every
18 90 days, the provider directory information for
19 all providers included in the online health care
20 provider directory search tool described in para-
21 graph (1)(A)(ii); and

22 “(B) remove any provider from such online
23 directory search tool if such provider has not
24 verified the directory information within the
25 previous 6 months or the plan or issuer has

1 been unable to verify the provider’s network
2 participation.

3 “(b) COST-SHARING LIMITATIONS.—

4 “(1) IN GENERAL.—A group health plan or a
5 health insurance issuer offering group or individual
6 health insurance coverage shall not apply, and shall
7 ensure that no provider applies cost-sharing to an
8 enrollee for treatment or services provided by a
9 health care provider in excess of the normal cost-
10 sharing applied for in-network care (including any
11 balance bill issued by the health care provider in-
12 volved), if such enrollee, or health care provider re-
13 ferring such enrollee, demonstrates (based on the
14 electronic information described in subsection
15 (a)(1)(A)(i) or a copy of the online provider direc-
16 tory described in subsection (a)(1)(A)(ii) on the date
17 the enrollee attempted to obtain the provider’s net-
18 work status) that the enrollee relied on the informa-
19 tion described in subsection (a)(1), if the provider’s
20 network status or directory information on such di-
21 rectory was incorrect at the time the treatment or
22 services involved was provided.

23 “(2) REFUNDS TO ENROLLEES.—If a health
24 care provider submits a bill to an enrollee in viola-
25 tion of paragraph (1), and the enrollee pays such

1 bill, the provider shall reimburse the enrollee for the
2 full amount paid by the enrollee in excess of the in-
3 network cost-sharing amount for the treatment or
4 services involved, plus interest, at an interest rate
5 determined by the Secretary.

6 “(c) PROVIDER BUSINESS PROCESSES.—A health
7 care provider shall have in place business processes to en-
8 sure the timely provision of provider directory information
9 to a group health plan or a health insurance issuer offer-
10 ing group or individual health insurance coverage to sup-
11 port compliance by such plans or issuers with subsection
12 (a)(1). Such providers shall submit provider directory in-
13 formation to a plan or issuers, at a minimum—

14 “(1) when the provider begins a network agree-
15 ment with a plan or with an issuer with respect to
16 certain coverage;

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

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

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

25 “(d) ENFORCEMENT.—

1 “(1) IN GENERAL.—Subject to paragraph (2), a
2 health care provider that violates a requirement
3 under subsection (c) or takes actions that prevent a
4 group health plan or health insurance issuer from
5 complying with subsection (a)(1) or (b) shall be sub-
6 ject to a civil monetary penalty of not more than
7 \$10,000 for each act constituting such violation.

8 “(2) SAFE HARBOR.—The Secretary may waive
9 the penalty described under paragraph (1) with re-
10 spect to a health care provider that unknowingly vio-
11 lates subsection (b)(1) with respect to an enrollee if
12 such provider rescinds the bill involved and, if appli-
13 cable, reimburses the enrollee within 30 days of the
14 date on which the provider billed the enrollee in vio-
15 lation of such subsection.

16 “(3) PROCEDURE.—The provisions of section
17 1128A of the Social Security Act, other than sub-
18 sections (a) and (b) and the first sentence of sub-
19 section (c)(1) of such section, shall apply to civil
20 money penalties under this subsection in the same
21 manner as such provisions apply to a penalty or pro-
22 ceeding under section 1128A of the Social Security
23 Act.

24 “(e) SAVINGS CLAUSE.—Nothing in this section shall
25 prohibit a provider from requiring in the terms of a con-

1 tract, or contract termination, with a group health plan
2 or health insurance issuer—

3 “(1) that the plan or issuer remove, at the time
4 of termination of such contract, the provider from a
5 directory of the plan or issuer described in sub-
6 section (a)(1); or

7 “(2) that the plan or issuer bear financial re-
8 sponsibility, including under subsection (b), for pro-
9 viding inaccurate network status information to an
10 enrollee.

11 “(f) DEFINITION.—For purposes of this section, the
12 term ‘provider directory information’ includes the names,
13 addresses, specialty, and telephone numbers of individual
14 health care providers, and the names, addresses, and tele-
15 phone numbers of each medical group, clinic, or facility
16 contracted to participate in any of the networks of the
17 group health plan or health insurance coverage involved.

18 “(g) RULE OF CONSTRUCTION.—Nothing in this sec-
19 tion shall be construed to preempt any provision of State
20 law relating to health care provider directories or network
21 adequacy.”.

22 **SEC. 305. TIMELY BILLS FOR PATIENTS.**

23 (a) IN GENERAL.—

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

4 **“SEC. 399V-7. TIMELY BILLS FOR PATIENTS.**

5 “(a) IN GENERAL.—The Secretary shall require—

6 “(1) health care facilities, or in the case of
7 practitioners providing services outside of such a fa-
8 cility, practitioners, to provide to patients a list of
9 services rendered during the visit to such facility or
10 practitioner, and, in the case of a facility, the name
11 of the provider for each such service, upon discharge
12 or by postal or electronic communication as soon as
13 practicable and not later than 5 calendar days after
14 discharge; and

15 “(2) health care facilities and practitioners to
16 send all adjudicated bills to the patient as soon as
17 practicable, but not later than 45 calendar days
18 after discharge.

19 “(b) PAYMENT AFTER BILLING.—No patient may be
20 required to pay a bill for health care services any earlier
21 than 30 calendar days after receipt of a bill for such serv-
22 ices.

23 “(c) EFFECT OF VIOLATION.—

24 “(1) NOTIFICATION AND REFUND REQUIRE-
25 MENTS.—

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

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

10 “(i) report such bill to the Secretary;

11 and

12 “(ii) refund the patient for the full
13 amount paid in response to such bill with
14 interest, at a rate determined by the Sec-
15 retary.

16 “(2) CIVIL MONETARY PENALTIES.—

17 “(A) IN GENERAL.—The Secretary may
18 impose civil monetary penalties of up to
19 \$10,000 a day on any facility or practitioner
20 that—

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

1 “(ii) submits more than 10 bills out-
2 side of the period described in subsection
3 (a)(2), beginning on the date on which
4 such facility or practitioner sends the tenth
5 such bill;

6 “(iii) fails to report to the Secretary
7 any failure to provide lists as required
8 under paragraph (1)(A), beginning on the
9 date that is 45 calendar days after dis-
10 charge; or

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

15 “(B) PROCEDURE.—The provisions of sec-
16 tion 1128A of the Social Security Act, other
17 than subsections (a) and (b) and the first sen-
18 tence of subsection (c)(1) of such section, shall
19 apply to civil money penalties under this sub-
20 section in the same manner as such provisions
21 apply to a penalty or proceeding under section
22 1128A of the Social Security Act.

23 “(3) SAFE HARBOR.—The Secretary may ex-
24 empt a practitioner or facility from the penalties
25 under paragraph (2)(A) or extend the period of time

1 specified under subsection (a)(2) for compliance with
 2 such subsection if a practitioner or facility—

3 “(A) makes a good faith attempt to send
 4 a bill within 30 days but is unable to do so be-
 5 cause of an incorrect address; or

6 “(B) experiences extenuating circumstan-
 7 ces (as defined by the Secretary), such as a
 8 hurricane or cyberattack, that may reasonably
 9 delay delivery of a timely bill.”.

10 (2) RULEMAKING.—Not later than 1 year after
 11 the date of enactment of this Act, the Secretary
 12 shall promulgate final regulations to define the term
 13 “extenuating circumstance” for purposes of section
 14 399V–7(c)(3)(B) of the Public Health Service Act,
 15 as added by paragraph (1).

16 (b) GROUP HEALTH PLAN AND HEALTH INSURANCE
 17 ISSUER REQUIREMENTS.—Subpart II of part A of title
 18 XXVII of the Public Health Service Act (42 U.S.C.
 19 300gg–11), as amended by section 304, is further amend-
 20 ed by adding to the end the following:

21 **“SEC. 2729D. TIMELY BILLS FOR PATIENTS.**

22 “(a) IN GENERAL.—A group health plan or health
 23 insurance issuer offering group or individual health insur-
 24 ance coverage shall have in place business practices with
 25 respect to in-network facilities and practitioners to ensure

1 that claims are adjudicated in order to facilitate facility
 2 and practitioner compliance with the requirements under
 3 section 399V–7(a).

4 “(b) CLARIFICATION.—Nothing in subsection (a) pro-
 5 hibits a provider and a group health plan or health insur-
 6 ance issuer from establishing in a contract the timeline
 7 for submission by either party to the other party of billing
 8 information, adjudication, sending of remittance informa-
 9 tion, or any other coordination required between the pro-
 10 vider and the plan or issuer necessary for meeting the
 11 deadline described in section 399V–7(a)(2).”.

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

15 **SEC. 306. HEALTH PLAN OVERSIGHT OF PHARMACY BEN-**
 16 **EFIT MANAGER SERVICES.**

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

21 **“SEC. 2729E. HEALTH PLAN OVERSIGHT OF PHARMACY**
 22 **BENEFIT MANAGER SERVICES.**

23 “(a) IN GENERAL.—A group health plan or health
 24 insurance issuer offering group or individual health insur-
 25 ance coverage or an entity or subsidiary providing phar-

1 macy benefits management services shall not enter into
2 a contract with a drug manufacturer, distributor, whole-
3 saler, subcontractor, rebate aggregator, or any associated
4 third party that limits the disclosure of information to
5 plan sponsors in such a manner that prevents the plan
6 or coverage, or an entity or subsidiary providing pharmacy
7 benefits management services on behalf of a plan or cov-
8 erage from making the reports described in subsection (b).

9 “(b) REPORTS TO GROUP PLAN SPONSORS.—

10 “(1) IN GENERAL.—Beginning with the first
11 plan year that begins after the date of enactment of
12 the Lower Health Care Costs Act, not less fre-
13 quently than once per plan quarter, a health insur-
14 ance issuer offering group health insurance coverage
15 or an entity providing pharmacy benefits manage-
16 ment services on behalf of a group health plan shall
17 submit to the plan sponsor (as defined in section
18 3(16)(B) of the Employee Retirement Income Secu-
19 rity Act of 1974) of such group health plan or
20 health insurance coverage a report in accordance
21 with this subsection and make such report available
22 to the plan sponsor in a machine-readable format.
23 Each such report shall include, with respect to the
24 applicable group health plan or health insurance cov-
25 erage—

1 “(A) information collected from drug man-
2 ufacturers by such issuer or entity on the total
3 amount of copayment assistance dollars paid, or
4 copayment cards applied, that were funded by
5 the drug manufacturer with respect to the en-
6 rollees in such plan or coverage;

7 “(B) a list of each covered drug dispensed
8 during the reporting period, including, with re-
9 spect to each such drug during the reporting
10 period—

11 “(i) the brand name, chemical entity,
12 and National Drug Code;

13 “(ii) the number of enrollees for
14 whom the drug was filled during the plan
15 year, the total number of prescription fills
16 for the drug (including original prescrip-
17 tions and refills), and the total number of
18 dosage units of the drug dispensed across
19 the plan year, including whether the dis-
20 pensing channel was by retail, mail order,
21 or specialty pharmacy;

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

1 “(iv) the total out-of-pocket spending
2 by enrollees on such drug, including en-
3 rollee spending through copayments, coin-
4 surance, and deductibles; and

5 “(v) for any drug for which gross
6 spending of the group health plan or
7 health insurance coverage exceeded
8 \$10,000 during the reporting period—

9 “(I) a list of all other available
10 drugs in the same therapeutic cat-
11 egory or class, including brand name
12 drugs and biological products and ge-
13 neric drugs or biosimilar biological
14 products that are in the same thera-
15 peutic category or class; and

16 “(II) the rationale for preferred
17 formulary placement of a particular
18 drug or drugs in that therapeutic cat-
19 egory or class;

20 “(C) a list of each therapeutic category or
21 class of drugs that were dispensed under the
22 health plan or health insurance coverage during
23 the reporting period, and, with respect to each
24 such therapeutic category or class of drugs,
25 during the reporting period—

1 “(i) total gross spending by the plan,
2 before manufacturer rebates, fees, or other
3 manufacturer remuneration;

4 “(ii) the number of enrollees who
5 filled a prescription for a drug in that cat-
6 egory or class;

7 “(iii) if applicable to that category or
8 class, a description of the formulary tiers
9 and utilization mechanisms (such as prior
10 authorization or step therapy) employed
11 for drugs in that category or class;

12 “(iv) the total out-of-pocket spending
13 by enrollees, including enrollee spending
14 through copayments, coinsurance, and
15 deductibles; and

16 “(v) for each therapeutic category or
17 class under which three or more drugs are
18 marketed and available—

19 “(I) the amount received, or ex-
20 pected to be received, from drug man-
21 ufacturers in rebates, fees, alternative
22 discounts, or other remuneration—

23 “(aa) to be paid by drug
24 manufacturers for claims in-

1 curred during the reporting pe-
2 riod; or

3 “(bb) that is related to utili-
4 zation of drugs, in such thera-
5 peutic category or class;

6 “(II) the total net spending by
7 the health plan or health insurance
8 coverage on that category or class of
9 drugs; and

10 “(III) the net price per dosage
11 unit or course of treatment incurred
12 by the health plan or health insurance
13 coverage and its enrollees, after man-
14 ufacturer rebates, fees, and other re-
15 muneration for drugs dispensed within
16 such therapeutic category or class
17 during the reporting period;

18 “(D) total gross spending on prescription
19 drugs by the plan or coverage during the re-
20 porting period, before rebates and other manu-
21 facturer fees or remuneration;

22 “(E) total amount received, or expected to
23 be received, by the health plan or health insur-
24 ance coverage in drug manufacturer rebates,
25 fees, alternative discounts, and all other remu-

1 neration received from the manufacturer or any
2 third party related to utilization of drug or
3 drug spending under that health plan or health
4 insurance coverage during the reporting period;

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

8 “(G) amounts paid directly or indirectly in
9 rebates, fees, or any other type of remuneration
10 to brokers, consultants, advisors, or any other
11 individual or firm who referred the group health
12 plan’s or health insurance issuer’s business to
13 the pharmacy benefit manager.

14 “(2) PRIVACY REQUIREMENTS.—Health insur-
15 ance issuers offering group health insurance cov-
16 erage and entities providing pharmacy benefits man-
17 agement services on behalf of a group health plan
18 shall provide information under paragraph (1) in a
19 manner consistent with the privacy, security, and
20 breach notification regulations promulgated under
21 section 264(c) of the Health Insurance Portability
22 and Accountability Act of 1996 (or successor regula-
23 tions), and shall restrict the use and disclosure of
24 such information according to such privacy regula-
25 tions.

1 “(3) DISCLOSURE AND REDISCLOSURE.—

2 “(A) LIMITATION TO BUSINESS ASSOCI-
3 ATES.—A group health plan receiving a report
4 under paragraph (1) may disclose such informa-
5 tion only to business associates of such plan as
6 defined in section 160.103 of title 45, Code of
7 Federal Regulations (or successor regulations).

8 “(B) CLARIFICATION REGARDING PUBLIC
9 DISCLOSURE OF INFORMATION.—Nothing in
10 this section prevents a health insurance issuer
11 offering group health insurance coverage or an
12 entity providing pharmacy benefits management
13 services on behalf of a group health plan from
14 placing reasonable restrictions on the public dis-
15 closure of the information contained in a report
16 described in paragraph (1).

17 “(c) LIMITATIONS ON SPREAD PRICING.—

18 “(1) PRESCRIPTION DRUG TRANSACTIONS WITH
19 PHARMACIES INDEPENDENT OF THE ISSUER OR
20 PHARMACY BENEFITS MANAGER.—If the pharmacy
21 that dispenses a prescription drug to an enrollee in
22 a group health plan or group or individual health in-
23 surance coverage is not wholly or partially owned by
24 such plan, such issuer, or an entity providing phar-
25 macy benefit management services under such plan

1 or coverage, such plan, issuer, or entity shall not
2 charge the plan, issuer, or enrollee a price for such
3 prescription drug that exceeds the price paid to the
4 pharmacy, excluding penalties paid by pharmacies to
5 such plan, issuer, or entity.

6 “(2) INTRA-COMPANY PRESCRIPTION DRUG
7 TRANSACTIONS.—If the mail order, specialty, or re-
8 tail pharmacy that dispenses a prescription drug to
9 an enrollee in a group health plan or health insur-
10 ance coverage is wholly or partially owned by such
11 health insurance issuer or an entity providing phar-
12 macy benefit management services under a group
13 health plan or group or individual health insurance
14 coverage, the price charged for such drug by such
15 pharmacy to such group health plan or health insur-
16 ance issuer offering group or individual health insur-
17 ance coverage may not exceed the lesser of—

18 “(A) the wholesale acquisition cost of the
19 drug paid by the pharmacy, plus clearly docu-
20 mented dispensing costs, including pharmacy
21 profit; or

22 “(B) the median price charged to the
23 group health plan or health insurance issuer
24 when the same drug is dispensed to enrollees in
25 the plan or coverage by other similarly situated

1 pharmacies not wholly or partially owned by the
2 health insurance issuer or entity providing
3 pharmacy benefits management services, as de-
4 scribed in paragraph (1).

5 “(3) SUPPLEMENTARY REPORTING FOR INTRA-
6 COMPANY PRESCRIPTION DRUG TRANSACTIONS.—A
7 health insurance issuer of group health insurance
8 coverage or an entity providing pharmacy benefits
9 management services under a group health plan or
10 group health insurance coverage that conducts
11 transactions with a wholly or partially owned phar-
12 macy, as described in paragraph (2), shall submit,
13 together with the report under subsection (b), a sup-
14 plementary quarterly report to the plan sponsor that
15 includes—

16 “(A) an explanation of any benefit design
17 parameters that encourage enrollees in the plan
18 or coverage to fill prescriptions at mail order,
19 specialty, or retail pharmacies that are wholly
20 or partially owned by that issuer or entity;

21 “(B) the percentage of total prescriptions
22 charged to the plan, coverage, or enrollees in
23 the plan or coverage, that were dispensed by
24 mail order, specialty, or retail pharmacies that
25 are wholly or partially owned by the issuer or

1 entity providing pharmacy benefits management
2 services; and

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

8 “(i) the amount charged per dosage
9 unit or course of treatment with respect to
10 enrollees in the plan or coverage, including
11 amounts charged to the plan or coverage
12 and amounts charged to the enrollee;

13 “(ii) the median amount charged to
14 the plan or coverage, per dosage unit or
15 course of treatment, and including
16 amounts paid by the enrollee, when the
17 same drug is dispensed by other phar-
18 macies that are not wholly or partially
19 owned by the issuer or entity and that are
20 included in the pharmacy network of that
21 plan or coverage;

22 “(iii) the interquartile range of the
23 costs, per dosage unit or course of treat-
24 ment, and including amounts paid by the
25 enrollee, when the same drug is dispensed

1 by other pharmacies that are not wholly or
2 partially owned by the issuer or entity and
3 that are included in the pharmacy network
4 of that plan or coverage; and

5 “(iv) the lowest cost per dosage unit
6 or course of treatment, for such drug, in-
7 cluding amounts charged to the plan or
8 issuer and enrollee, that is available from
9 any pharmacy included in the network of
10 the plan or coverage.

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

12 “(1) IN GENERAL.—A pharmacy benefits man-
13 ager, a third-party administrator of a group health
14 plan, a health insurance issuer offering group health
15 insurance coverage, or an entity providing pharmacy
16 benefits management services under such health
17 plan or health insurance coverage shall remit 100
18 percent of rebates, fees, alternative discounts, and
19 all other remuneration received from a pharma-
20 ceutical manufacturer, distributor or any other third
21 party, that are related to utilization of drugs under
22 such health plan or health insurance coverage, to the
23 group health plan.

1 “(2) FORM AND MANNER OF REMITTANCE.—

2 Such rebates, fees, alternative discounts, and other
3 remuneration shall be—

4 “(A) remitted to the group health plan in
5 a timely fashion after the period for which such
6 rebates, fees, or other remuneration is cal-
7 culated, and in no case later than 90 days after
8 the end of such period;

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

12 “(C) available for audit by the plan spon-
13 sor, or a third-party designated by a plan spon-
14 sor no less than once per plan year.

15 “(e) ENFORCEMENT.—

16 “(1) FAILURE TO PROVIDE TIMELY INFORMA-
17 TION.—A health insurance issuer or an entity pro-
18 viding pharmacy benefit management services that
19 violates subsection (a), fails to provide information
20 required under subsection (b), engages in spread
21 pricing as defined in subsection (c), or fails to com-
22 ply with the requirements of subsection (d), or a
23 drug manufacturer that fails to provide information
24 under subsection (b)(1)(A), in a timely manner shall
25 be subject to a civil monetary penalty in the amount

1 of \$10,000 for each day during which such violation
2 continues or such information is not disclosed or re-
3 ported.

4 “(2) FALSE INFORMATION.—A health insurance
5 issuer, entity providing pharmacy benefit manage-
6 ment services, or drug manufacturer that knowingly
7 provides false information under this section shall be
8 subject to a civil money penalty in an amount not
9 to exceed \$100,000 for each item of false informa-
10 tion. Such civil money penalty shall be in addition to
11 other penalties as may be prescribed by law.

12 “(3) PROCEDURE.—The provisions of section
13 1128A of the Social Security Act, other than sub-
14 sections (a) and (b) and the first sentence of sub-
15 section (c)(1) of such section shall apply to civil
16 monetary penalties under this subsection in the
17 same manner as such provisions apply to a penalty
18 or proceeding under section 1128A of the Social Se-
19 curity Act.

20 “(f) DEFINITIONS.—In this section—

21 “(1) the term ‘similarly situated pharmacy’
22 means, with respect to a particular pharmacy, an-
23 other pharmacy that is approximately the same size
24 (as measured by the number of prescription drugs
25 dispensed), and that serves patients in the same geo-

1 graphical area, whether through physical locations or
2 mail order; and

3 “(2) the term ‘wholesale acquisition cost’ has
4 the meaning given such term in section
5 1847A(c)(6)(B) of the Social Security Act.”.

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

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

12 (1) describe what is known about profit- and
13 revenue-sharing relationships in the commercial
14 health care markets, including those relationships
15 that—

16 (A) involve one or more—

17 (i) physician groups that practice
18 within a hospital included in the profit- or
19 revenue-sharing relationship, or refer pa-
20 tients to such hospital;

21 (ii) laboratory, radiology, or pharmacy
22 services that are delivered to privately in-
23 sured patients of such hospital;

24 (iii) surgical services;

1 (iv) hospitals or group purchasing or-
2 ganizations; or

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

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

9 (2) describe Federal oversight of such relation-
10 ships, including authorities of the Department of
11 Health and Human Services and the Federal Trade
12 Commission to review such relationships and their
13 potential to increase costs for patients, and identify
14 limitations in such oversight; and

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

17 (b) REPORT.—Not later than 1 year after the date
18 of enactment of this Act, the Comptroller General of the
19 United States shall prepare and submit a report on the
20 study conducted under subsection (a) to the Committee
21 on Health, Education, Labor, and Pensions of the Senate
22 and the Committee on Education and Labor and the Com-
23 mittee on Energy and Commerce of the House of Rep-
24 resentatives.

1 **SEC. 308. DISCLOSURE OF DIRECT AND INDIRECT COM-**
2 **PENSATION FOR BROKERS AND CONSULT-**
3 **ANTS TO EMPLOYER-SPONSORED HEALTH**
4 **PLANS AND ENROLLEES IN PLANS ON THE IN-**
5 **DIVIDUAL MARKET.**

6 (a) GROUP HEALTH PLANS.—Section 408(b)(2) of
7 the Employee Retirement Income Security Act of 1974
8 (29 U.S.C. 1108(b)(2)) is amended—

9 (1) by striking “(2) Contracting or making”
10 and inserting “(2)(A) Contracting or making”; and
11 (2) by adding at the end the following:

12 “(B)(i) No contract or arrangement for services
13 between a covered plan and a covered service pro-
14 vider, and no extension or renewal of such a contract
15 or arrangement, is reasonable within the meaning of
16 this paragraph unless the requirements of this
17 clause are met.

18 “(ii)(I) For purposes of this subparagraph:

19 “(aa) The term ‘covered plan’ means a
20 group health plan as defined section 733(a).

21 “(bb) The term ‘covered service provider’
22 means a service provider that enters into a con-
23 tract or arrangement with the covered plan and
24 reasonably expects \$1,000 (or such amount as
25 the Secretary may establish in regulations to
26 account for inflation since the date of enact-

1 ment of the Lower Health Care Costs Act, as
2 appropriate) or more in compensation, direct or
3 indirect, to be received in connection with pro-
4 viding one or more of the following services,
5 pursuant to the contract or arrangement, re-
6 gardless of whether such services will be per-
7 formed, or such compensation received, by the
8 covered service provider, an affiliate, or a sub-
9 contractor:

10 “(AA) Brokerage services, for which
11 the covered service provider, an affiliate, or
12 a subcontractor reasonably expects to re-
13 ceive indirect compensation or direct com-
14 pensation described in item (dd), provided
15 to a covered plan with respect to selection
16 of insurance products (including vision and
17 dental), recordkeeping services, medical
18 management vendor, benefits administra-
19 tion (including vision and dental), stop-loss
20 insurance, pharmacy benefit management
21 services, wellness services, transparency
22 tools and vendors, group purchasing orga-
23 nization preferred vendor panels, disease
24 management vendors and products, compli-
25 ance services, employee assistance pro-

1 grams, or third-party administration serv-
2 ices.

3 “(BB) Consulting, for which the cov-
4 ered service provider, an affiliate, or a sub-
5 contractor reasonably expects to receive in-
6 direct compensation or direct compensation
7 described in item (dd), related to the devel-
8 opment or implementation of plan design,
9 insurance or insurance product selection
10 (including vision and dental), record-
11 keeping, medical management, benefits ad-
12 ministration selection (including vision and
13 dental), stop-loss insurance, pharmacy ben-
14 efit management services, wellness design
15 and management services, transparency
16 tools, group purchasing organization agree-
17 ments and services, participation in and
18 services from preferred vendor panels, dis-
19 ease management, compliance services, em-
20 ployee assistance programs, or third-party
21 administration services.

22 “(cc) The term ‘affiliate’, with respect to a
23 covered service provider, means an entity that
24 directly or indirectly (through one or more
25 intermediaries) controls, is controlled by, or is

1 under common control with, such provider, or is
2 an officer, director, or employee of, or partner
3 in, such provider.

4 “(dd)(AA) The term ‘compensation’ means
5 anything of monetary value, but does not in-
6 clude non-monetary compensation valued at
7 \$250 (or such amount as the Secretary may es-
8 tablish in regulations to account for inflation
9 since the date of enactment of the Lower
10 Health Care Costs Act, as appropriate) or less,
11 in the aggregate, during the term of the con-
12 tract or arrangement.

13 “(BB) The term ‘direct compensation’
14 means compensation received directly from a
15 covered plan.

16 “(CC) The term ‘indirect compensation’
17 means compensation received from any source
18 other than the covered plan, the plan sponsor,
19 the covered service provider, or an affiliate.
20 Compensation received from a subcontractor is
21 indirect compensation, unless it is received in
22 connection with services performed under a con-
23 tract or arrangement with a subcontractor.

24 “(ee) The term ‘responsible plan fiduciary’
25 means a fiduciary with authority to cause the

1 covered plan to enter into, or extend or renew,
2 the contract or arrangement.

3 “(ff) The term ‘subcontractor’ means any
4 person or entity (or an affiliate of such person
5 or entity) that is not an affiliate of the covered
6 service provider and that, pursuant to a con-
7 tract or arrangement with the covered service
8 provider or an affiliate, reasonably expects to
9 receive \$1,000 (or such amount as the Sec-
10 retary may establish in regulations to account
11 for inflation since the date of enactment of the
12 Lower Health Care Costs Act, as appropriate)
13 or more in compensation for performing one or
14 more services described in item (bb) under a
15 contract or arrangement with the covered plan.

16 “(II) For purposes of this subparagraph, a de-
17 scription of compensation or cost may be expressed
18 as a monetary amount, formula, or a per capita
19 charge for each enrollee or, if the compensation or
20 cost cannot reasonably be expressed in such terms,
21 by any other reasonable method, including a dislo-
22 sure that additional compensation may be earned
23 but may not be calculated at the time of contract if
24 such a disclosure includes a description of the cir-
25 cumstances under which the additional compensation

1 may be earned and a reasonable and good faith esti-
2 mate if the covered service provider cannot otherwise
3 readily describe compensation or cost and explains
4 the methodology and assumptions used to prepare
5 such estimate. Any such description shall contain
6 sufficient information to permit evaluation of the
7 reasonableness of the compensation or cost.

8 “(III) No person or entity is a ‘covered service
9 provider’ within the meaning of subclause (I)(bb)
10 solely on the basis of providing services as an affil-
11 iate or a subcontractor that is performing one or
12 more of the services described in subitem (AA) or
13 (BB) of such subclause under the contract or ar-
14 rangement with the covered plan.

15 “(iii) A covered service provider shall disclose to
16 a responsible plan fiduciary, in writing, the fol-
17 lowing:

18 “(I) A description of the services to be pro-
19 vided to the covered plan pursuant to the con-
20 tract or arrangement.

21 “(II) If applicable, a statement that the
22 covered service provider, an affiliate, or a sub-
23 contractor will provide, or reasonably expects to
24 provide, services pursuant to the contract or ar-

1 rangement directly to the covered plan as a fi-
2 duciary (within the meaning of section 3(21)).

3 “(III) A description of all direct compensa-
4 tion, either in the aggregate or by service, that
5 the covered service provider, an affiliate, or a
6 subcontractor reasonably expects to receive in
7 connection with the services described in sub-
8 clause (I).

9 “(IV)(aa) A description of all indirect com-
10 pensation that the covered service provider, an
11 affiliate, or a subcontractor reasonably expects
12 to receive in connection with the services de-
13 scribed in subclause (I)—

14 “(AA) including compensation from a
15 vendor to a brokerage firm based on a
16 structure of incentives not solely related to
17 the contract with the covered plan; and

18 “(BB) not including compensation re-
19 ceived by an employee from an employer
20 on account of work performed by the em-
21 ployee.

22 “(bb) A description of the arrangement be-
23 tween the payer and the covered service pro-
24 vider, an affiliate, or a subcontractor, as appli-

1 cable, pursuant to which such indirect com-
2 pensation is paid.

3 “(cc) Identification of the services for
4 which the indirect compensation will be re-
5 ceived, if applicable.

6 “(dd) Identification of the payer of the in-
7 direct compensation.

8 “(V) A description of any compensation
9 that will be paid among the covered service pro-
10 vider, an affiliate, or a subcontractor, in con-
11 nection with the services described in subclause
12 (I) if such compensation is set on a transaction
13 basis (such as commissions, finder’s fees, or
14 other similar incentive compensation based on
15 business placed or retained), including identi-
16 fication of the services for which such com-
17 pensation will be paid and identification of the
18 payers and recipients of such compensation (in-
19 cluding the status of a payer or recipient as an
20 affiliate or a subcontractor), regardless of
21 whether such compensation also is disclosed
22 pursuant to subclause (III) or (IV).

23 “(VI) A description of any compensation
24 that the covered service provider, an affiliate, or
25 a subcontractor reasonably expects to receive in

1 connection with termination of the contract or
2 arrangement, and how any prepaid amounts
3 will be calculated and refunded upon such ter-
4 mination.

5 “(iv) A covered service provider shall disclose to
6 a responsible plan fiduciary, in writing a description
7 of the manner in which the compensation described
8 in clause (iii), as applicable, will be received.

9 “(v)(I) A covered service provider shall disclose
10 the information required under clauses (iii) and (iv)
11 to the responsible plan fiduciary not later than the
12 date that is reasonably in advance of the date on
13 which the contract or arrangement is entered into,
14 and extended or renewed.

15 “(II) A covered service provider shall disclose
16 any change to the information required under
17 clauses (iii) and (iv) as soon as practicable, but not
18 later than 60 days from the date on which the cov-
19 ered service provider is informed of such change, un-
20 less such disclosure is precluded due to extraor-
21 dinary circumstances beyond the covered service pro-
22 vider’s control, in which case the information shall
23 be disclosed as soon as practicable.

24 “(vi)(I) Upon the written request of the respon-
25 sible plan fiduciary or covered plan administrator, a

1 covered service provider shall furnish any other in-
2 formation relating to the compensation received in
3 connection with the contract or arrangement that is
4 required for the covered plan to comply with the re-
5 porting and disclosure requirements under this Act.

6 “(II) The covered service provider shall disclose
7 the information required under clause (iii)(I) reason-
8 ably in advance of the date upon which such respon-
9 sible plan fiduciary or covered plan administrator
10 states that it is required to comply with the applica-
11 ble reporting or disclosure requirement, unless such
12 disclosure is precluded due to extraordinary cir-
13 cumstances beyond the covered service provider’s
14 control, in which case the information shall be dis-
15 closed as soon as practicable.

16 “(vii) No contract or arrangement will fail to be
17 reasonable under this subparagraph solely because
18 the covered service provider, acting in good faith and
19 with reasonable diligence, makes an error or omis-
20 sion in disclosing the information required pursuant
21 to clause (iii) (or a change to such information dis-
22 closed pursuant to clause (v)(II)) or clause (vi), pro-
23 vided that the covered service provider discloses the
24 correct information to the responsible plan fiduciary
25 as soon as practicable, but not later than 30 days

1 from the date on which the covered service provider
2 knows of such error or omission.

3 “(viii)(I) Pursuant to subsection (a), subpara-
4 graphs (C) and (D) of section 406(a)(1) shall not
5 apply to a responsible plan fiduciary, notwithstand-
6 ing any failure by a covered service provider to dis-
7 close information required under clause (iii), if the
8 following conditions are met:

9 “(aa) The responsible plan fiduciary did
10 not know that the covered service provider
11 failed or would fail to make required disclosures
12 and reasonably believed that the covered service
13 provider disclosed the information required to
14 be disclosed.

15 “(bb) The responsible plan fiduciary, upon
16 discovering that the covered service provider
17 failed to disclose the required information, re-
18 quests in writing that the covered service pro-
19 vider furnish such information.

20 “(cc) If the covered service provider fails
21 to comply with a written request described in
22 subclause (II) within 90 days of the request,
23 the responsible plan fiduciary notifies the Sec-
24 retary of the covered service provider’s failure,
25 in accordance with subclauses (II) and (III).

1 “(II) A notice described in subclause (I)(cc)
2 shall contain—

3 “(aa) the name of the covered plan;

4 “(bb) the plan number used for the annual
5 report on the covered plan;

6 “(cc) the plan sponsor’s name, address,
7 and employer identification number;

8 “(dd) the name, address, and telephone
9 number of the responsible plan fiduciary;

10 “(ee) the name, address, phone number,
11 and, if known, employer identification number
12 of the covered service provider;

13 “(ff) a description of the services provided
14 to the covered plan;

15 “(gg) a description of the information that
16 the covered service provider failed to disclose;

17 “(hh) the date on which such information
18 was requested in writing from the covered serv-
19 ice provider; and

20 “(ii) a statement as to whether the covered
21 service provider continues to provide services to
22 the plan.

23 “(III) A notice described in subclause (I)(cc)
24 shall be filed with the Department not later than 30
25 days following the earlier of—

1 “(aa) the covered service provider’s refusal
2 to furnish the information requested by the
3 written request described in subclause (I)(bb);
4 or

5 “(bb) 90 days after the written request re-
6 ferred to in subclause (I)(cc) is made.

7 “(IV) If the covered service provider fails to
8 comply with the written request under subclause
9 (I)(bb) within 90 days of such request, the respon-
10 sible plan fiduciary shall determine whether to ter-
11 minate or continue the contract or arrangement
12 under section 404. If the requested information re-
13 lates to future services and is not disclosed promptly
14 after the end of the 90-day period, the responsible
15 plan fiduciary shall terminate the contract or ar-
16 rangement as expeditiously as possible, consistent
17 with such duty of prudence.

18 “(ix) Nothing in this subparagraph shall be
19 construed to supersede any provision of State law
20 that governs disclosures by parties that provide the
21 services described in this section, except to the ex-
22 tent that such law prevents the application of a re-
23 quirement of this section.”.

24 (b) APPLICABILITY OF EXISTING REGULATIONS.—
25 Nothing in the amendments made by subsection (a) shall

1 be construed to affect the applicability of section
2 2550.408b–2 of title 29, Code of Federal Regulations (or
3 any successor regulations), with respect to any applicable
4 entity other than a covered plan or a covered service pro-
5 vider (as defined in section 408(b)(2)(B)(ii) of the Em-
6 ployee Retirement Income Security Act of 1974, as
7 amended by subsection (a)).

8 (c) INDIVIDUAL MARKET COVERAGE.—Subpart 1 of
9 part B of title XVII of the Public Health Service Act (42
10 U.S.C. 300gg–41 et seq.) is amended by adding at the
11 end the following:

12 **“SEC. 2746. DISCLOSURE TO ENROLLEES OF INDIVIDUAL**
13 **MARKET COVERAGE.**

14 “(a) IN GENERAL.—A health insurance issuer offer-
15 ing individual health insurance coverage shall make dislo-
16 sures to enrollees in such coverage, as described in sub-
17 section (b), and reports to the Secretary, as described in
18 subsection (c), regarding direct or indirect compensation
19 provided to an agent or broker associated with enrolling
20 individuals in such coverage.

21 “(b) DISCLOSURE.—A health insurance issuer de-
22 scribed in subsection (a) shall disclose to an enrollee the
23 amount of direct or indirect compensation provided to an
24 agent or broker for services provided by such agent or

1 broker associated with plan selection and enrollment. Such
2 disclosure shall be—

3 “(1) made prior to the individual finalizing plan
4 selection; and

5 “(2) included on any documentation confirming
6 the individual’s enrollment.

7 “(c) REPORTING.—A health insurance issuer de-
8 scribed in subsection (a) shall report to the Secretary any
9 direct or indirect compensation provided to an agent or
10 broker associated with enrolling individuals in such cov-
11 erage.

12 “(d) RULEMAKING.—Not later than 1 year after the
13 date of enactment of the Lower Health Care Costs Act,
14 the Secretary shall finalize, through notice-and-comment
15 rulemaking, the form and manner in which issuers de-
16 scribed in subsection (a) are required to make the dislo-
17 sures described in subsection (b) and the reports described
18 in subsection (c).”.

19 (d) TRANSITION RULE.—No contract executed prior
20 to the effective date described in subsection (e) by a group
21 health plan subject to the requirements of section
22 408(b)(2)(B) of the Employee Retirement Income Secu-
23 rity Act of 1974 (as amended by subsection (a)) or by
24 a health insurance issuer subject to the requirements of
25 section 2746 of the Public Health Service Act (as added

1 by subsection (c)) shall be subject to the requirements of
 2 such section 408(b)(2)(B) or such section 2746, as appli-
 3 cable.

4 (e) EFFECTIVE DATE.—The amendments made by
 5 subsections (a) and (c) shall take effect 2 years after the
 6 date of enactment of this Act.

7 **SEC. 309. ENSURING ENROLLEE ACCESS TO COST-SHARING**
 8 **INFORMATION.**

9 (a) IN GENERAL.—Subpart II of part A of title
 10 XXVII of the Public Health Service Act (42 U.S.C.
 11 300gg–11 et seq.), as amended by section 306, is further
 12 amended by adding at the end the following:

13 **“SEC. 2729F. PROVISION OF COST-SHARING INFORMATION.**

14 “(a) PROVIDER DISCLOSURES.—A provider that is
 15 in-network with respect to a group health plan or a health
 16 insurance issuer offering group or individual health insur-
 17 ance coverage shall provide to an enrollee in the plan or
 18 coverage who submits a request for the information de-
 19 scribed in paragraph (1) or (2), together with accurate
 20 and complete information about the enrollee’s coverage
 21 under the applicable plan or coverage—

22 “(1) as soon as practicable and not later than
 23 2 business days after the enrollee requests such in-
 24 formation, a good faith estimate of the expected en-
 25 rollee cost-sharing for the provision of a particular

1 health care service (including any service that is rea-
2 sonably expected to be provided in conjunction with
3 such specific service); and

4 “(2) as soon as practicable and not later than
5 2 business days after an enrollee requests such in-
6 formation, the contact information for any ancillary
7 providers for a scheduled health care service.

8 “(b) INSURER DISCLOSURES.—A group health plan
9 or a health insurance issuer offering group or individual
10 health insurance coverage shall provide an enrollee in the
11 plan or coverage with a good faith estimate of the enroll-
12 ee’s cost-sharing (including deductibles, copayments, and
13 coinsurance) for which the enrollee would be responsible
14 for paying with respect to a specific health care service
15 (including any service that is reasonably expected to be
16 provided in conjunction with such specific service), as soon
17 as practicable and not later than 2 business days after
18 receiving a request for such information by an enrollee.

19 “(c) ENFORCEMENT.—

20 “(1) IN GENERAL.—Subject to paragraph (2), a
21 health care provider that violates a requirement
22 under subsection (a) shall be subject to a civil mone-
23 tary penalty of not more than \$10,000 for each act
24 constituting such violation.

1 stance use disorder benefits, the plan or cov-
2 erage shall perform comparative analyses about
3 the design and application of nonquantitative
4 treatment limitations (referred to in this para-
5 graph as the ‘NQTL’) in accordance with the
6 following process, and make available to the
7 Secretary upon request within 60 days begin-
8 ning January 1, 2020, and within 30 days be-
9 ginning January 1, 2021, the following infor-
10 mation:

11 “(i) The specific plan or coverage lan-
12 guage regarding the NQTL, that applies to
13 such plan or coverage, and a description of
14 all mental health or substance use disorder
15 and medical/surgical services to which it
16 applies in each respective benefits classi-
17 fication.

18 “(ii) The factors used to determine
19 that an NQTL will apply to mental health
20 or substance use disorder benefits and
21 medical/surgical benefits.

22 “(iii) The evidentiary standard (both
23 identified and deidentified) for the factors
24 identified in clause (ii) and any other evi-
25 dence relied upon to design and apply the

1 NQTL to mental health or substance use
2 disorder benefits and medical/surgical ben-
3 efits.

4 “(iv) The comparative analyses dem-
5 onstrating that the processes and strate-
6 gies used to design the NQTL, as written
7 and in operation, and the as written proc-
8 esses and strategies used to apply the
9 NQTL for mental health or substance use
10 disorder benefits are comparable to, and
11 are applied no more stringently than, the
12 processes and strategies used to design the
13 NQTL, as written and in operation, and
14 the as written processes and strategies
15 used to apply the NQTL to medical/sur-
16 gical benefits.

17 “(v) A disclosure of the specific find-
18 ings and conclusions reached by the plan
19 or coverage that the results of the analyses
20 described in this subparagraph indicate
21 that the plan or coverage is in compliance
22 with this section.

23 “(B) SECRETARY REQUEST PROCESS.—

24 “(i) SUBMISSION UPON COMPLAINT.—
25 The Secretary shall request that a group

1 health plan or a health insurance issuer of-
2 fering group or individual health insurance
3 coverage submit the comparative analyses
4 described in subparagraph (A) if the Sec-
5 retary has received any complaints from
6 plan participants or participating providers
7 about such a plan or coverage that involve
8 mental health or substance use disorder
9 benefits.

10 “(ii) RANDOM SUBMISSIONS.—The
11 Secretary shall request the comparative
12 analyses described in subparagraph (A)
13 from no fewer than 50 plans or coverages
14 selected at random, annually, and such
15 plans or coverages shall not—

16 “(I) be the same plans or cov-
17 erages for which the comparative
18 analyses are requested under clause
19 (i);

20 “(II) be the same plan or cov-
21 erage being investigated by the De-
22 partment regarding NQTLs or that
23 has been investigated by the Depart-
24 ment regarding NQTLs within the
25 last 5 years; and

1 “(III) be the same plan or cov-
2 erage that has been selected under
3 clause (i) or (ii) within the last 5
4 years.

5 “(iii) ADDITIONAL INFORMATION.—In
6 instances in which the Secretary has con-
7 cluded that the plan or coverage has not
8 submitted sufficient information for the
9 Secretary to review the comparative anal-
10 yses described in subparagraph (A), as re-
11 quested under clauses (i) and (ii), the Sec-
12 retary shall specify to the plan or coverage
13 the information the plan or coverage must
14 submit to be responsive to the request
15 under clauses (i) and (ii) for the Secretary
16 to review the comparative analyses de-
17 scribed in subparagraph (A) for compliance
18 with this section.

19 “(iv) REQUIRED ACTION.—In in-
20 stances in which the Secretary has re-
21 viewed the comparative analyses described
22 in subparagraph (A), as requested under
23 clauses (i) and (ii), and determined that
24 the plan or coverage is not in compliance
25 with this section, the Secretary shall speci-

1 fy to the plan or coverage the actions the
2 plan or coverage must take to be in compli-
3 ance with this section. Documents or com-
4 munications produced in connection with
5 the Secretary’s recommendations to the
6 plan or coverage shall not be subject to
7 disclosure pursuant to section 552 of title
8 5, United States Code.

9 “(v) REPORT.—Not later than 1 year
10 after the date of enactment of this para-
11 graph, and annually thereafter, the Sec-
12 retary shall submit to the Committee on
13 Education and Labor of the House of Rep-
14 resentatives and the Committee on Health,
15 Education, Labor, and Pensions of the
16 Senate a report that contains—

17 “(I) each of the comparative
18 analyses requested under clauses (i)
19 and (ii), except that the identity of
20 each plan or coverage and any con-
21 tracted entity of a plan or coverage
22 shall be redacted;

23 “(II) the Secretary’s conclusions
24 as to whether each plan or coverage
25 submitted sufficient information for

1 the Secretary to review the compara-
2 tive analyses requested under clauses
3 (i) and (ii) for compliance with this
4 section;

5 “(III) for each plan or coverage
6 that did submit sufficient information
7 for the Secretary to review the com-
8 parative analyses requested under
9 clause (i), the Secretary’s conclusions
10 as to whether and why the plan or
11 coverage is in compliance with this
12 section;

13 “(IV) the Secretary’s specifica-
14 tions described in clause (iii) for each
15 plan or coverage that the Secretary
16 determined did not submit sufficient
17 information for the Secretary to re-
18 view the comparative analyses re-
19 quested under clauses (i) and (ii) for
20 compliance with this section; and

21 “(V) the Secretary’s specifica-
22 tions described in clause (iv) of the
23 actions each plan or coverage that the
24 Secretary determined is not in compli-
25 ance with this section must take to be

1 in compliance with this section, in-
2 cluding the reason why the Secretary
3 determined the plan or coverage is not
4 in compliance.

5 “(C) COMPLIANCE PROGRAM GUIDANCE
6 DOCUMENT UPDATE PROCESS.—

7 “(i) IN GENERAL.—The Secretary
8 shall include select instances of noncompli-
9 ance that the Secretary discovers upon re-
10 viewing the comparative analyses requested
11 under clauses (i) and (ii) of subparagraph
12 (B) in the compliance program guidance
13 document described in section 2726(a)(6),
14 as it is updated every 2 years, except that
15 all instances shall be deidentified and such
16 instances shall not disclose any protected
17 health information or individually identifi-
18 able information.

19 “(ii) GUIDANCE AND REGULATIONS.—
20 Not later than 18 months after the date of
21 enactment of this paragraph, the Secretary
22 shall finalize any draft or interim guidance
23 and regulations relating to mental health
24 parity under this section.

1 “(iii) STATE.—Any instances of non-
2 compliance the Secretary discovers upon
3 reviewing the comparative analyses re-
4 quested under clauses (i) and (ii) of sub-
5 paragraph (B) shall be shared with a State
6 for coverage offered by a health insurance
7 issuer in the group market, in accordance
8 with section 2726(a)(6)(B)(iii)(II).”.

9 **SEC. 311. TECHNICAL AMENDMENTS.**

10 (a) ERISA.—Section 715 of the Employee Retire-
11 ment Income Security Act of 1974 (29 U.S.C. 1185d) is
12 amended—

13 (1) in subsection (a)(1), by striking “(as
14 amended by the Patient Protection and Affordable
15 Care Act)” and inserting “(including any subsequent
16 amendments to such part)”; and

17 (2) in subsection (b)—

18 (A) by striking “(as amended by the Pa-
19 tient Protection and Affordable Care Act)” and
20 inserting “(including any subsequent amend-
21 ments to such part)”; and

22 (B) by striking “(as so amended)”.

23 (b) IRC.—Section 9815 of the Internal Revenue
24 Code of 1986 is amended—

1 (1) in subsection (a)(1), by striking “(as
2 amended by the Patient Protection and Affordable
3 Care Act)” and inserting “(including any subsequent
4 amendments to such part)”; and

5 (2) in subsection (b)—

6 (A) by striking “(as amended by the Pa-
7 tient Protection and Affordable Care Act)” and
8 inserting “(including any subsequent amend-
9 ments to such part)”; and

10 (B) by striking “(as so amended)”.

11 (c) **APPLICABILITY.**—The amendments made by sub-
12 sections (a) and (b) shall take effect as though included
13 in the enactment of the Patient Protection and Affordable
14 Care Act (Public Law 111–148).

15 **SEC. 312. THIRD-PARTY ADMINISTRATORS.**

16 Any obligation on a third-party administrator under
17 this Act (including the amendments made by this Act)
18 shall not affect any other direct or indirect requirement
19 under any other provision of Federal law that applies to
20 third-party administrators offering services to group
21 health plans.

1 **TITLE IV—IMPROVING PUBLIC**
2 **HEALTH**

3 **SEC. 401. IMPROVING AWARENESS OF DISEASE PREVEN-**
4 **TION.**

5 The Public Health Service Act is amended by striking
6 section 313 of such Act (42 U.S.C. 245) and inserting
7 the following:

8 **“SEC. 313. PUBLIC AWARENESS CAMPAIGN ON THE IMPOR-**
9 **TANCE OF VACCINATIONS.**

10 “(a) IN GENERAL.—The Secretary, acting through
11 the Director of the Centers for Disease Control and Pre-
12 vention and in coordination with other offices and agen-
13 cies, as appropriate, shall award competitive grants to one
14 or more public or private entities to carry out a national,
15 evidence-based campaign to increase awareness and
16 knowledge of the safety and effectiveness of vaccines for
17 the prevention and control of diseases, combat misin-
18 formation about vaccines, and disseminate scientific and
19 evidence-based vaccine-related information, with the goal
20 of increasing rates of vaccination across all ages, as appli-
21 cable, particularly in communities with low rates of vac-
22 cination, to reduce and eliminate vaccine-preventable dis-
23 eases.

24 “(b) CONSULTATION.—In carrying out the campaign
25 under this section, the Secretary shall consult with appro-

1 p r i a t e p u b l i c h e a l t h a n d m e d i c a l e x p e r t s , i n c l u d i n g t h e N a -
2 t i o n a l A c a d e m y o f M e d i c i n e a n d m e d i c a l a n d p u b l i c h e a l t h
3 a s s o c i a t i o n s a n d n o n p r o f i t o r g a n i z a t i o n s , i n t h e d e v e l o p -
4 m e n t , i m p l e m e n t a t i o n , a n d e v a l u a t i o n o f t h e e v i d e n c e -
5 b a s e d p u b l i c a w a r e n e s s c a m p a i g n .

6 “(c) REQUIREMENTS.—The campaign under this sec-
7 tion shall—

8 “(1) be a national, evidence-based initiative;

9 “(2) include the development of resources for
10 communities with low rates of vaccination, including
11 culturally and linguistically appropriate resources, as
12 applicable;

13 “(3) include the dissemination of vaccine infor-
14 mation and communication resources to public
15 health departments, health care providers, and
16 health care facilities, including such providers and
17 facilities that provide prenatal and pediatric care;

18 “(4) be complementary to, and coordinated
19 with, any other Federal, State, or local efforts, as
20 appropriate; and

21 “(5) assess the effectiveness of communication
22 strategies to increase rates of vaccination.

23 “(d) ADDITIONAL ACTIVITIES.—The campaign under
24 this section may—

1 “(1) include the use of television, radio, the
2 internet, and other media and telecommunications
3 technologies;

4 “(2) be focused to address specific needs of
5 communities and populations with low rates of vac-
6 cination; and

7 “(3) include the dissemination of scientific and
8 evidence-based vaccine-related information, such
9 as—

10 “(A) advancements in evidence-based re-
11 search related to diseases that may be pre-
12 vented by vaccines and vaccine development;

13 “(B) information on vaccinations for indi-
14 viduals and communities, including individuals
15 for whom vaccines are not recommended by the
16 Advisory Committee for Immunization Prac-
17 tices, and the effects of low vaccination rates
18 within a community on such individuals;

19 “(C) information on diseases that may be
20 prevented by vaccines; and

21 “(D) information on vaccine safety and the
22 systems in place to monitor vaccine safety.

23 “(e) EVALUATION.—The Secretary shall—

1 “(1) establish benchmarks and metrics to quan-
2 titatively measure and evaluate the awareness cam-
3 paign under this section;

4 “(2) conduct qualitative assessments regarding
5 the awareness campaign under this section; and

6 “(3) prepare and submit to the Committee on
7 Health, Education, Labor, and Pensions of the Sen-
8 ate and the Committee on Energy and Commerce of
9 the House of Representatives an evaluation of the
10 awareness campaign under this section.

11 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
12 are authorized to be appropriated to carry out this section
13 and section 317(k) such sums as may be necessary for
14 fiscal years 2020 through 2024.”.

15 **SEC. 402. GRANTS TO ADDRESS VACCINE-PREVENTABLE**
16 **DISEASES.**

17 Section 317(k)(1) of the Public Health Service Act
18 (42 U.S.C. 247b(k)(1)) is amended—

19 (1) in subparagraph (C), by striking “; and”
20 and inserting a semicolon;

21 (2) in subparagraph (D), by striking the period
22 and inserting a semicolon; and

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

1 “(E) planning, implementation, and evaluation
2 of activities to address vaccine-preventable diseases,
3 including activities to—

4 “(i) identify communities at high risk of
5 outbreaks related to vaccine-preventable dis-
6 eases, including through improved data collec-
7 tion and analysis;

8 “(ii) pilot innovative approaches to improve
9 vaccination rates in communities and among
10 populations with low rates of vaccination;

11 “(iii) reduce barriers to accessing vaccines
12 and evidence-based information about the
13 health effects of vaccines;

14 “(iv) partner with community organiza-
15 tions and health care providers to develop and
16 deliver evidence-based interventions, including
17 culturally and linguistically appropriate inter-
18 ventions, to increase vaccination rates;

19 “(v) improve delivery of evidence-based
20 vaccine-related information to parents and oth-
21 ers; and

22 “(vi) improve the ability of State, local,
23 tribal, and territorial public health departments
24 to engage communities at high risk for out-

1 breaks related to vaccine-preventable diseases;
2 and

3 “(F) research related to strategies for improv-
4 ing awareness of scientific and evidence-based vac-
5 cine-related information, including for communities
6 with low rates of vaccination, in order to understand
7 barriers to vaccination, improve vaccination rates,
8 and assess the public health outcomes of such strate-
9 gies.”.

10 **SEC. 403. GUIDE ON EVIDENCE-BASED STRATEGIES FOR**
11 **PUBLIC HEALTH DEPARTMENT OBESITY PRE-**
12 **VENTION PROGRAMS.**

13 (a) DEVELOPMENT AND DISSEMINATION OF AN EVI-
14 DENCE-BASED STRATEGIES GUIDE.—The Secretary of
15 Health and Human Services (referred to in this section
16 as the “Secretary”), acting through the Director of the
17 Centers for Disease Control and Prevention, not later than
18 2 years after the date of enactment of this Act, shall—

19 (1) develop a guide on evidence-based strategies
20 for State, territorial, and local health departments to
21 use to build and maintain effective obesity preven-
22 tion and reduction programs, and, in consultation
23 with stakeholders that have expertise in Tribal
24 health, a guide on such evidence-based strategies
25 with respect to Indian Tribes and Tribal organiza-

1 tions for such Indian Tribes and Tribal organiza-
2 tions to use for such purpose, both of which guides
3 shall—

4 (A) describe an integrated program struc-
5 ture for implementing interventions proven to
6 be effective in preventing and reducing the inci-
7 dence of obesity; and

8 (B) recommend—

9 (i) optimal resources, including staff-
10 ing and infrastructure, for promoting nu-
11 trition and obesity prevention and reduc-
12 tion; and

13 (ii) strategies for effective obesity pre-
14 vention programs for State and local
15 health departments, Indian Tribes, and
16 Tribal organizations, including strategies
17 related to—

18 (I) the application of evidence-
19 based and evidence-informed practices
20 to prevent and reduce obesity rates;

21 (II) the development, implemen-
22 tation, and evaluation of obesity pre-
23 vention and reduction strategies for
24 specific communities and populations;

1 (III) demonstrated knowledge of
2 obesity prevention practices that re-
3 duce associated preventable diseases,
4 health conditions, death, and health
5 care costs;

6 (IV) best practices for the coordi-
7 nation of efforts to prevent and re-
8 duce obesity and related chronic dis-
9 eases;

10 (V) addressing the underlying
11 risk factors and social determinants of
12 health that impact obesity rates; and

13 (VI) interdisciplinary coordina-
14 tion between relevant public health of-
15 ficials specializing in fields such as
16 nutrition, physical activity, epidemi-
17 ology, communications, and policy im-
18 plementation, and collaboration be-
19 tween public health officials and com-
20 munity-based organizations; and

21 (2) disseminate the guides and current re-
22 search, evidence-based practices, tools, and edu-
23 cational materials related to obesity prevention, con-
24 sistent with the guide, to State and local health de-
25 partments, Indian Tribes, and Tribal organizations.

1 (b) TECHNICAL ASSISTANCE.—The Secretary, acting
2 through the Director of the Centers for Disease Control
3 and Prevention, shall provide technical assistance to State
4 and local health departments, Indian Tribes, and Tribal
5 organizations to support such health departments in im-
6 plementing the guide developed under subsection (a)(1).

7 (c) INDIAN TRIBES; TRIBAL ORGANIZATIONS.—The
8 terms “Indian Tribe” and “Tribal organization” have the
9 meanings given the terms “Indian tribe” and “tribal orga-
10 nization”, respectively, in section 4 of the Indian Self-De-
11 termination and Education Assistance Act (25 U.S.C.
12 5304).

13 **SEC. 404. EXPANDING CAPACITY FOR HEALTH OUTCOMES.**

14 Title III of the Public Health Service Act is amended
15 by inserting after section 330M (42 U.S.C. 254c-19) the
16 following:

17 **“SEC. 330N. EXPANDING CAPACITY FOR HEALTH OUT-
18 COMES.**

19 “(a) DEFINITIONS.—In this section:

20 “(1) ELIGIBLE ENTITY.—The term ‘eligible en-
21 tity’ means an entity providing health care services
22 in rural areas, frontier areas, health professional
23 shortage areas, or medically underserved areas, or to
24 medically underserved populations or Native Ameri-
25 cans, including Indian tribes or tribal organizations.

1 “(2) HEALTH PROFESSIONAL SHORTAGE
2 AREA.—The term ‘health professional shortage area’
3 means a health professional shortage area des-
4 ignated under section 332.

5 “(3) INDIAN TRIBE.—The terms ‘Indian tribe’
6 and ‘tribal organization’ have the meanings given
7 such terms in section 4 of the Indian Self-Deter-
8 mination and Education Assistance Act.

9 “(4) MEDICALLY UNDERSERVED POPU-
10 LATION.—The term ‘medically underserved popu-
11 lation’ has the meaning given the term in section
12 330(b)(3).

13 “(5) NATIVE AMERICANS.—The term ‘Native
14 Americans’ has the meaning given such term in sec-
15 tion 736 and includes Indian tribes and tribal orga-
16 nizations.

17 “(6) TECHNOLOGY-ENABLED COLLABORATIVE
18 LEARNING AND CAPACITY BUILDING MODEL.—The
19 term ‘technology-enabled collaborative learning and
20 capacity building model’ means a distance health
21 education model that connects specialists with mul-
22 tiple other health care professionals through simulta-
23 neous interactive videoconferencing for the purpose
24 of facilitating case-based learning, disseminating
25 best practices, and evaluating outcomes.

1 “(b) PROGRAM ESTABLISHED.—The Secretary shall,
2 as appropriate, award grants to evaluate, develop, and, as
3 appropriate, expand the use of technology-enabled collabo-
4 rative learning and capacity building models, to increase
5 access to health care services, such as those to address
6 chronic diseases and conditions, mental health, substance
7 use disorders, prenatal and maternal health, pediatric
8 care, pain management, palliative care, and other specialty
9 care in medically underserved areas and for medically un-
10 derserved populations.

11 “(c) USE OF FUNDS.—

12 “(1) IN GENERAL.—Grants awarded under sub-
13 section (b) shall be used for—

14 “(A) the development and acquisition of
15 instructional programming, and the training of
16 health care providers and other professionals
17 that provide or assist in the provision of serv-
18 ices through such models;

19 “(B) information collection and evaluation
20 activities to study the impact of such models on
21 patient outcomes and health care providers, and
22 to identify best practices for the expansion and
23 use of such models; or

1 “(C) other activities consistent with achiev-
2 ing the objectives of the grants awarded under
3 this section, as determined by the Secretary.

4 “(2) OTHER USES.—In addition to any of the
5 uses under paragraph (1), grants awarded under
6 subsection (b) may be used for—

7 “(A) equipment to support the use and ex-
8 pansion of technology-enabled collaborative
9 learning and capacity building models, including
10 for hardware and software that enables distance
11 learning, health care provider support, and the
12 secure exchange of electronic health informa-
13 tion; or

14 “(B) support for health care providers and
15 other professionals that provide or assist in the
16 provision of services through such models.

17 “(d) LENGTH OF GRANTS.—Grants awarded under
18 subsection (b) shall be for a period of up to 5 years.

19 “(e) APPLICATION.—An eligible entity that seeks to
20 receive a grant under subsection (b) shall submit to the
21 Secretary an application, at such time, in such manner,
22 and containing such information as the Secretary may re-
23 quire. Such application criteria shall include an assess-
24 ment of the effect of technology-enabled collaborative

1 learning and capacity building models on patient outcomes
2 and health care providers.

3 “(f) TECHNICAL ASSISTANCE.—The Secretary shall
4 provide (either directly through the Department of Health
5 and Human Services or by contract) technical assistance
6 to eligible entities, including recipients of grants under
7 subsection (b), on the development, use, and evaluation
8 of technology-enabled collaborative learning and capacity
9 building models in order to expand access to health care
10 services provided by such entities, including for medically
11 underserved areas and to medically underserved popu-
12 lations.

13 “(g) REPORT BY SECRETARY.—Not later than 4
14 years after the date of enactment of this section, the Sec-
15 retary shall prepare and submit to the Committee on
16 Health, Education, Labor, and Pensions of the Senate and
17 the Committee on Energy and Commerce of the House
18 of Representatives, and post on the internet website of the
19 Department of Health and Human Services, a report in-
20 cluding, at minimum—

21 “(1) a description of any new and continuing
22 grants awarded to entities under subsection (b) and
23 the specific purpose and amounts of such grants;

24 “(2) an overview of—

1 sion and modernization of public health data sys-
2 tems, to assist public health departments in—

3 “(A) assessing current data infrastructure
4 capabilities and gaps to improve and increase
5 consistency in data collection, storage, analysis,
6 and, as appropriate, to improve dissemination
7 of public health-related information;

8 “(B) improving secure public health data
9 collection, transmission, exchange, maintenance,
10 and analysis;

11 “(C) simplifying and supporting reporting
12 by health care providers, as applicable, pursu-
13 ant to State law, including through the use of
14 health information technology, to State, local,
15 Tribal, and territorial public health depart-
16 ments, including public health officials in mul-
17 tiple jurisdictions within such State, as appro-
18 priate;

19 “(D) enhancing interoperability of public
20 health data systems (including systems created
21 or accessed by public health departments) with
22 health information technology, including cer-
23 tified health information technology;

24 “(E) supporting earlier disease and health
25 condition detection, such as through near real-

1 time data monitoring, to support rapid public
2 health responses; and

3 “(F) supporting activities within the appli-
4 cable jurisdiction related to the expansion and
5 modernization of electronic case reporting;

6 “(2) as appropriate, conduct activities related
7 to the interoperability and improvement of applicable
8 public health data systems used by the Centers for
9 Disease Control and Prevention, and, in coordination
10 with the Office of the National Coordinator for
11 Health Information Technology, the designation of
12 data and technology standards for health informa-
13 tion systems of the public health infrastructure with
14 deference given to standards published by standards
15 development organizations and voluntary consensus-
16 based standards bodies; and

17 “(3) develop and utilize public-private partner-
18 ships for technical assistance and related implemen-
19 tation support for State, local, Tribal, and territorial
20 public health departments, and the Centers for Dis-
21 ease Control and Prevention, on the expansion and
22 modernization of electronic case reporting and public
23 health data systems, as applicable.

24 “(b) REQUIREMENTS.—

1 “(1) IN GENERAL.—The Secretary may not
2 award a grant under subsection (a)(1) unless the ap-
3 plicant supports standards endorsed by the National
4 Coordinator for Health Information Technology pur-
5 suant to section 3001(c)(1) or adopted by the Sec-
6 retary under section 3004.

7 “(2) WAIVER.—The Secretary may waive the
8 requirement under paragraph (1) with respect to an
9 applicant if the Secretary determines that the activi-
10 ties under subsection (a) cannot otherwise be carried
11 out within the applicable jurisdiction.

12 “(3) APPLICATION.—A State, local, Tribal, or
13 territorial health department applying for a grant
14 under this section shall submit an application to the
15 Secretary at such time and in such manner as the
16 Secretary may require. Such application shall in-
17 clude information describing—

18 “(A) the activities that will be supported
19 by the grant; and

20 “(B) how the modernization of such public
21 health data systems will support or impact the
22 public health infrastructure of the health de-
23 partment, including a description of remaining
24 gaps, if any, and the actions needed to address
25 such gaps.

1 “(c) USE OF FUNDS.—An entity receiving a grant
2 under this section may use amounts received under such
3 grant for one or both of the following:

4 “(1) Carrying out activities described in sub-
5 section (a)(1) to support public health data systems
6 (including electronic case reporting), which may in-
7 clude support for, and training of, professionals with
8 expertise in contributing to and using such systems
9 (including public health data scientists).

10 “(2) Developing and disseminating information
11 related to the use and importance of public health
12 data.

13 “(d) STRATEGY AND IMPLEMENTATION PLAN.—Not
14 later than 180 days after the date of enactment of the
15 Lower Health Care Costs Act, the Secretary, acting
16 through the Director of the Centers for Disease Control
17 and Prevention, shall submit to the Committee on Health,
18 Education, Labor, and Pensions of the Senate and the
19 Committee on Energy and Commerce of the House of
20 Representatives, a coordinated strategy and an accom-
21 panying implementation plan that identifies and dem-
22 onstrates the steps the Secretary will carry out to—

23 “(1) update and improve applicable public
24 health data systems used by the Centers for Disease
25 Control and Prevention; and

1 “(2) carry out the activities described in this
2 section to support the improvement of State, local,
3 Tribal, and territorial public health data systems.

4 “(e) CONSULTATION.—The Secretary, acting through
5 the Director of the Centers for Disease Control and Pre-
6 vention, shall consult with State, local, Tribal, and terri-
7 torial health departments, professional medical and public
8 health associations, associations representing hospitals or
9 other health care entities, health information technology
10 experts, and other appropriate entities regarding the plan
11 and grant program to modernize public health data sys-
12 tems pursuant to this section. Such activities may include
13 the provision of technical assistance related to the ex-
14 change of information by such public health data systems
15 used by relevant health care and public health entities at
16 the local, State, Federal, Tribal, and territorial levels.

17 “(f) REPORT TO CONGRESS.—Not later than 1 year
18 after the date of enactment of this section, the Secretary
19 shall submit a report to the Committee on Health, Edu-
20 cation, Labor, and Pensions of the Senate and the Com-
21 mittee on Energy and Commerce of the House of Rep-
22 resentatives that includes—

23 “(1) a description of any barriers to—

1 “(A) public health authorities imple-
2 menting electronic case reporting and interoper-
3 able public health data systems; or

4 “(B) the exchange of information pursuant
5 to electronic case reporting;

6 “(2) an assessment of the potential public
7 health impact of implementing electronic case re-
8 porting and interoperable public health data sys-
9 tems; and

10 “(3) a description of the activities carried out
11 pursuant to this section.

12 “(g) ELECTRONIC CASE REPORTING.—In this sec-
13 tion, the term ‘electronic case reporting’ means the auto-
14 mated identification, generation, and bilateral exchange of
15 reports of health events among electronic health record or
16 health information technology systems and public health
17 authorities.

18 “(h) AUTHORIZATION OF APPROPRIATIONS.—For the
19 purpose of carrying out this section, there are authorized
20 to be appropriated such sums as may be necessary for fis-
21 cal years 2020 through 2024.”.

22 **SEC. 406. INNOVATION FOR MATERNAL HEALTH.**

23 (a) IN GENERAL.—The Secretary of Health and
24 Human Services (referred to in this section as the “Sec-
25 retary”), in consultation with experts representing a vari-

1 ety of clinical specialties, State, tribal, or local public
2 health officials, researchers, epidemiologists, statisticians,
3 and community organizations, shall establish a program
4 to award competitive grants to eligible entities for the pur-
5 pose of—

6 (1) identifying, developing, or disseminating
7 best practices to improve maternal health care qual-
8 ity and outcomes, eliminate preventable maternal
9 mortality and severe maternal morbidity, and im-
10 prove infant health outcomes, which may include—

11 (A) information on evidence-based prac-
12 tices to improve the quality and safety of ma-
13 ternal health care in hospitals and other health
14 care settings of a State or health care system,
15 including by addressing topics commonly associ-
16 ated with health complications or risks related
17 to prenatal care, labor care, birthing, and post-
18 partum care;

19 (B) best practices for improving maternal
20 health care based on data findings and reviews
21 conducted by a State maternal mortality review
22 committee that address topics of relevance to
23 common complications or health risks related to
24 prenatal care, labor care, birthing, and postpar-
25 tum care; and

1 (C) information on addressing deter-
2 minants of health that impact maternal health
3 outcomes for women before, during, and after
4 pregnancy;

5 (2) collaborating with State maternal mortality
6 review committees to identify issues for the develop-
7 ment and implementation of evidence-based practices
8 to improve maternal health outcomes and reduce
9 preventable maternal mortality and severe maternal
10 morbidity;

11 (3) providing technical assistance and sup-
12 porting the implementation of best practices identi-
13 fied in paragraph (1) to entities providing health
14 care services to pregnant and postpartum women;
15 and

16 (4) identifying, developing, and evaluating new
17 models of care that improve maternal and infant
18 health outcomes, which may include the integration
19 of community-based services and clinical care.

20 (b) ELIGIBLE ENTITIES.—To be eligible for a grant
21 under subsection (a), an entity shall—

22 (1) submit to the Secretary an application at
23 such time, in such manner, and containing such in-
24 formation as the Secretary may require; and

1 (2) demonstrate in such application that the en-
2 tity has a demonstrated expertise in data-driven ma-
3 ternal safety and quality improvement initiatives in
4 the areas of obstetrics and gynecology or maternal
5 health.

6 (c) AUTHORIZATION OF APPROPRIATIONS.—To carry
7 out this section, there is authorized to be appropriated
8 such sums as may be necessary for each of fiscal years
9 2020 through 2024.

10 **SEC. 407. TRAINING FOR HEALTH CARE PROVIDERS.**

11 Title VII of the Public Health Service Act is amended
12 by striking section 763 (42 U.S.C. 294p) and inserting
13 the following:

14 **“SEC. 763. TRAINING FOR HEALTH CARE PROVIDERS.**

15 “(a) GRANT PROGRAM.—The Secretary shall estab-
16 lish a program to award grants to accredited schools of
17 allopathic medicine, osteopathic medicine, and nursing,
18 and other health professional training programs for the
19 training of health care professionals to reduce and prevent
20 discrimination (including training related to implicit bi-
21 ases) in the provision of health care services related to
22 prenatal care, labor care, birthing, and postpartum care.

23 “(b) ELIGIBILITY.—To be eligible for a grant under
24 subsection (a), an entity described in such subsection shall
25 submit to the Secretary an application at such time, in

1 such manner, and containing such information as the Sec-
2 retary may require.

3 “(c) REPORTING REQUIREMENT.—Each entity
4 awarded a grant under this section shall periodically sub-
5 mit to the Secretary a report on the status of activities
6 conducted using the grant, including a description of the
7 impact of such training on patient outcomes, as applicable.

8 “(d) BEST PRACTICES.—The Secretary may identify
9 and disseminate best practices for the training of health
10 care professionals to reduce and prevent discrimination
11 (including training related to implicit biases) in the provi-
12 sion of health care services related to prenatal care, labor
13 care, birthing, and postpartum care.

14 “(e) AUTHORIZATION OF APPROPRIATIONS.—To
15 carry out this section, there is authorized to be appro-
16 priated such sums as may be necessary for each of fiscal
17 years 2020 through 2024.”.

18 **SEC. 408. STUDY ON TRAINING TO REDUCE AND PREVENT**
19 **DISCRIMINATION.**

20 Not later than 2 years after date of enactment of this
21 Act, the Secretary of Health and Human Services (re-
22 ferred to in this section as the “Secretary”) shall, through
23 a contract with an independent research organization,
24 study and make recommendations for accredited schools
25 of allopathic medicine, osteopathic medicine, and nursing,

1 and other health professional training programs on best
2 practices related to training to reduce and prevent dis-
3 crimination, including training related to implicit biases,
4 in the provision of health care services related to prenatal
5 care, labor care, birthing, and postpartum care.

6 **SEC. 409. PERINATAL QUALITY COLLABORATIVES.**

7 Section 317K(a)(2) of the Public Health Service Act
8 (42 U.S.C. 247b–12(a)(2)) is amended by adding at the
9 end the following:

10 “(E)(i) The Secretary, acting through the
11 Director of the Centers for Disease Control and
12 Prevention and in coordination with other of-
13 fices and agencies, as appropriate, shall estab-
14 lish or continue a competitive grant program
15 for the establishment or support of perinatal
16 quality collaboratives to improve perinatal care
17 and perinatal health outcomes for pregnant and
18 postpartum women and their infants. A State
19 or Indian Tribe may use funds received through
20 such grant to—

21 “(I) support the use of evidence-based
22 or evidence-informed practices to improve
23 outcomes for maternal and infant health;

24 “(II) work with clinical teams; ex-
25 perts; State, local, and, as appropriate,

1 tribal public health officials; and stake-
2 holders, including patients and families, to
3 identify, develop, or disseminate best prac-
4 tices to improve perinatal care and out-
5 comes; and

6 “(III) employ strategies that provide
7 opportunities for health care professionals
8 and clinical teams to collaborate across
9 health care settings and disciplines, includ-
10 ing primary care and mental health, as ap-
11 propriate, to improve maternal and infant
12 health outcomes, which may include the
13 use of data to provide timely feedback
14 across hospital and clinical teams to in-
15 form responses, and to provide support
16 and training to hospital and clinical teams
17 for quality improvement, as appropriate.

18 “(ii) To be eligible for a grant under
19 clause (i), an entity shall submit to the Sec-
20 retary an application in such form and manner
21 and containing such information as the Sec-
22 retary may require.”.

1 **SEC. 410. INTEGRATED SERVICES FOR PREGNANT AND**
2 **POSTPARTUM WOMEN.**

3 (a) GRANTS.—Title III of the Public Health Service
4 Act is amended by inserting after section 330N of such
5 Act, as added by section 404, the following:

6 **“SEC. 3300. INTEGRATED SERVICES FOR PREGNANT AND**
7 **POSTPARTUM WOMEN.**

8 “(a) IN GENERAL.—The Secretary may award grants
9 for the purpose of establishing or operating evidence-based
10 or innovative, evidence-informed programs to deliver inte-
11 grated health care services to pregnant and postpartum
12 women to optimize the health of women and their infants,
13 including to reduce adverse maternal health outcomes,
14 pregnancy-related deaths, and related health disparities
15 (including such disparities associated with racial and eth-
16 nic minority populations), and as appropriate, by address-
17 ing issues researched under subsection (b)(2) of section
18 317K.

19 “(b) INTEGRATED SERVICES FOR PREGNANT AND
20 POSTPARTUM WOMEN.—

21 “(1) ELIGIBILITY.—To be eligible to receive a
22 grant under subsection (a), a State or Indian Tribe
23 (as defined in section 4 of the Indian Self-Deter-
24 mination and Education Assistance Act) shall work
25 with relevant stakeholders that coordinate care (in-
26 cluding coordinating resources and referrals for

1 health care and social services) to develop and carry
2 out the program, including—

3 “(A) State, tribal, and local agencies re-
4 sponsible for Medicaid, public health, social
5 services, mental health, and substance use dis-
6 order treatment and services;

7 “(B) health care providers who serve preg-
8 nant women; and

9 “(C) community-based health organiza-
10 tions and health workers, including providers of
11 home visiting services and individuals rep-
12 resenting communities with disproportionately
13 high rates of maternal mortality and severe ma-
14 ternal morbidity, and including those rep-
15 resenting racial and ethnicity minority popu-
16 lations.

17 “(2) TERMS.—

18 “(A) LIMITATION.—The Secretary may
19 award a grant under subsection (a) to up to 10
20 States.

21 “(B) PERIOD.—A grant awarded under
22 subsection (a) shall be made for a period of 5
23 years.

24 “(C) PRIORITIZATION.—In awarding
25 grants under subsection (a), the Secretary shall

1 prioritize applications from States or Indian
2 Tribes with the highest rates of maternal mor-
3 tality and severe maternal morbidity, and shall
4 consider health disparities related to maternal
5 mortality and severe maternal morbidity, in-
6 cluding such disparities associated with racial
7 and ethnic minority populations.

8 “(D) EVALUATION.—The Secretary shall
9 require grantees to evaluate the outcomes of the
10 programs supported under the grant.

11 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
12 are authorized to be appropriated to carry out this section
13 such sums as may be necessary for each of fiscal years
14 2020 through 2024.”.

15 (b) REPORT ON GRANT OUTCOMES AND DISSEMINA-
16 TION OF BEST PRACTICES.—

17 (1) REPORT.—Not later than April 1, 2025, the
18 Secretary of Health and Human Services shall sub-
19 mit to the Committee on Health, Education, Labor,
20 and Pensions of the Senate and the Committee on
21 Energy and Commerce of the House of Representa-
22 tives a report that describes—

23 (A) the outcomes of the activities sup-
24 ported by the grants awarded under the amend-

1 ments made by this section on maternal and
2 child health;

3 (B) best practices and models of care used
4 by recipients of grants under such amendments;
5 and

6 (C) obstacles identified by recipients of
7 grants under such amendments, and strategies
8 used by such recipients to deliver care, improve
9 maternal and child health, and reduce health
10 disparities.

11 (2) DISSEMINATION OF BEST PRACTICES.—Not
12 later than October 1, 2025, the Secretary of Health
13 and Human Services shall disseminate information
14 on best practices and models of care used by recipi-
15 ents of grants under the amendments made by this
16 section (including best practices and models of care
17 relating to the reduction of health disparities, includ-
18 ing such disparities associated with racial and ethnic
19 minority populations, in rates of maternal mortality
20 and severe maternal morbidity) to relevant stake-
21 holders, which may include health providers, medical
22 schools, nursing schools, relevant State, tribal, and
23 local agencies, and the general public.

1 **SEC. 411. EXTENSION FOR COMMUNITY HEALTH CENTERS,**
2 **THE NATIONAL HEALTH SERVICE CORPS,**
3 **AND TEACHING HEALTH CENTERS THAT OP-**
4 **ERATE GME PROGRAMS.**

5 (a) **COMMUNITY HEALTH CENTERS FUNDING.**—Sec-
6 tion 10503(b)(1)(F) of the Patient Protection and Afford-
7 able Care Act (42 U.S.C. 254b–2(b)(1)(F)) is amended
8 by striking “fiscal year 2019” and inserting “each of fiscal
9 years 2019 through 2024”.

10 (b) **NATIONAL HEALTH SERVICE CORPS.**—Section
11 10503(b)(2)(F) of the Patient Protection and Affordable
12 Care Act (42 U.S.C. 254b–2(b)(2)(F)) is amended by
13 striking “and 2019” and inserting “through 2024”.

14 (c) **TEACHING HEALTH CENTERS THAT OPERATE**
15 **GRADUATE MEDICAL EDUCATION PROGRAMS.**—Section
16 340H(g)(1) of the Public Health Service Act (42 U.S.C.
17 256h(g)(1)) is amended by striking “and 2019” and in-
18 serting “through 2024”.

19 (d) **APPLICATION OF PROVISIONS.**—Amounts appro-
20 priated pursuant to this section for each of fiscal years
21 2019 through 2024 shall be subject to the requirements
22 contained in Public Law 115–245 for funds for programs
23 authorized under sections 330 through 340 of the Public
24 Health Service Act.

25 (e) **CONFORMING AMENDMENTS.**—Paragraph (4) of
26 section 3014(h) of title 18, United States Code, as amend-

1 ed by section 50901 of Public Law 115–123, is amended
 2 by striking “and section 50901(e) of the Advancing
 3 Chronic Care, Extenders, and Social Services Act” and in-
 4 serting “, section 50901(e) of the Advancing Chronic
 5 Care, Extenders, and Social Services Act, and section
 6 411(d) of the Lower Health Care Costs Act”.

7 **SEC. 412. OTHER PROGRAMS.**

8 (a) TYPE I.—Section 330B(b)(2)(D) of the Public
 9 Health Service Act (42 U.S.C. 254c–2(b)(2)(D)) is
 10 amended by striking “and 2019” and inserting “through
 11 2024”.

12 (b) INDIANS.—Subparagraph (D) of section
 13 330C(c)(2) of the Public Health Service Act (42 U.S.C.
 14 254c–3(c)(2)(D)) is amended by striking “and 2019” and
 15 inserting “through 2024”.

16 **TITLE V—IMPROVING THE EX-**
 17 **CHANGE OF HEALTH INFOR-**
 18 **MATION**

19 **SEC. 501. REQUIREMENT TO PROVIDE HEALTH CLAIMS,**
 20 **NETWORK, AND COST INFORMATION.**

21 (a) IN GENERAL.—Part A of title XXVII of the Pub-
 22 lic Health Service Act (42 U.S.C. 300gg et seq.) is amend-
 23 ed by inserting after section 2715A the following:

1 **“SEC. 2715B. REQUIREMENT TO PROVIDE HEALTH CLAIMS,**
2 **NETWORK, AND COST INFORMATION.**

3 “(a) IN GENERAL.—A group health plan or a health
4 insurance issuer offering group or individual health insur-
5 ance coverage shall make available for access, exchange,
6 or use without special effort, through application program-
7 ming interfaces (or successor technology or standards),
8 the information described in subsection (b), in the manner
9 described in subsection (b) and otherwise consistent with
10 this section.

11 “(b) INFORMATION.—The following information is re-
12 quired to be made available, in such form and manner as
13 the Secretary may specify, as described in subsection (a):

14 “(1) Historical claims, provider encounter, and
15 payment data for each enrollee, which shall—

16 “(A) include adjudicated medical and pre-
17 scription drug claims and equivalent encoun-
18 ters, including all data elements contained in
19 such transactions—

20 “(i) that were adjudicated by the
21 group health plan or health insurance
22 issuer during the previous 5 years or the
23 enrollee’s entire period of enrollment in the
24 applicable plan or coverage if such period
25 is less than 5 years;

1 “(ii) that involve benefits managed by
2 any third party, such as a pharmacy bene-
3 fits manager or radiology benefits manager
4 that manages benefits or adjudicates
5 claims on behalf of the plan or coverage;
6 and

7 “(iii) from any other health plan or
8 health insurance coverage issued or admin-
9 istered by the same insurance issuer, in
10 which the same enrollee was enrolled dur-
11 ing the previous 5 years; and

12 “(B) be available—

13 “(i) in a single, longitudinal format
14 that is easy to understand and secure, and
15 that may update automatically, including
16 by using the standards adopted for imple-
17 mentation of section 3001(c)(5)(D)(iv);

18 “(ii) as soon as practicable, and in no
19 case later than the period of time deter-
20 mined by the Secretary, after the claim is
21 adjudicated or the data is received by the
22 health plan or health insurance issuer; and

23 “(iii) to the enrollee, and any pro-
24 viders or third-party applications or serv-
25 ices authorized by the enrollee, for 5 years

1 after the end date of the enrollee’s enroll-
2 ment in the plan or in any coverage offered
3 by the health insurance issuer.

4 “(2) Identifying directory information for all in-
5 network providers, including facilities and practi-
6 tioners, that participate in the plan or coverage,
7 which shall—

8 “(A) include—

9 “(i) the national provider identifier
10 for in-network facilities and practitioners;
11 and

12 “(ii) the name, address, phone num-
13 ber, and specialty for each such facility
14 and practitioner, based on the most recent
15 interaction between the plan or coverage
16 and that facility or practitioner;

17 “(B) be capable of returning a list of par-
18 ticipating in-network facilities and practitioners,
19 in a given specialty or at a particular facility
20 type, within a specified geographic radius; and

21 “(C) be capable of returning the network
22 status, when presented with identifiers for a
23 given enrollee and facility or practitioner.

24 “(3) Estimated patient out-of-pocket costs, in-
25 cluding costs expected to be incurred through a de-

1 ductible, copayment, coinsurance, or other form of
2 cost-sharing, for—

3 “(A) a designated set of common services
4 or episodes of care, to be established by the
5 Secretary through rulemaking, including, at a
6 minimum—

7 “(i) in the case of services provided by
8 a hospital, the 100 most common diag-
9 nosis-related groups, as used in the Medi-
10 care Inpatient Prospective Patient System
11 (or successor episode-based reimbursement
12 methodology) at that hospital, based on
13 claims data adjudicated by the group
14 health plan or health insurance issuer;

15 “(ii) in the case of services provided
16 in an outpatient setting, including radi-
17 ology, lab tests, and outpatient surgical
18 procedures, any service rendered by the fa-
19 cility or practitioner, and reimbursed by
20 the health plan or health insurance issuer;
21 and

22 “(iii) in the case of post-acute care,
23 including home health providers, skilled
24 nursing facilities, inpatient rehabilitation
25 facilities, and long-term care hospitals, the

1 patient out-of-pocket costs for an episode
2 of care, as the Secretary may determine,
3 which permits users to reasonably compare
4 costs across different facility and service
5 types; and

6 “(B) all prescription drugs currently in-
7 cluded on any tier of the formulary of the plan
8 or coverage.

9 “(c) AVAILABILITY AND ACCESS.—The application
10 programming interfaces, including all data required to be
11 made available through such interfaces, shall—

12 “(1) be made available by the applicable group
13 health plan or health insurance issuer, at no charge,
14 to—

15 “(A) enrollees in the group health plan or
16 health insurance coverage;

17 “(B) third parties authorized by the en-
18 rollee;

19 “(C) facilities and practitioners who are
20 under contract with the plan or coverage; and

21 “(D) business associates of such facilities
22 and practitioners, as defined in section 160.103
23 of title 45, Code of Federal Regulations (or any
24 successor regulations);

1 “(2) be available to enrollees in the group
2 health plan or health insurance coverage, and to
3 third-party applications or services facilitating such
4 access by enrollees, during the enrollment process
5 and for a minimum of 5 years after the end date of
6 the enrollee’s enrollment in the plan or in any cov-
7 erage offered by the health insurance issuer;

8 “(3) permit persistent access by third-party ap-
9 plications or services authorized by the enrollee, for
10 a reasonable period of time, consistent with current
11 security practices;

12 “(4) employ the applicable content, vocabulary,
13 and technical standards, including, as appropriate,
14 such standards adopted by the Secretary pursuant
15 to title XXX; and

16 “(5) employ security and authentication stand-
17 ards, as the Secretary determines appropriate.

18 “(d) RULE OF CONSTRUCTION REGARDING PRI-
19 VACY.—Nothing in this section shall be construed to alter
20 existing obligations under the privacy, security, and
21 breach notification rules promulgated under section 264(c)
22 of the Health Insurance Portability and Accountability
23 Act (or successor regulations), under part 2 of title 42,
24 Code of Federal Regulations (or successor regulations),
25 under section 444 of the General Education Provisions

1 Act (20 U.S.C. 1232g) (commonly referred to as the
2 ‘Family Educational Rights and Privacy Act of 1974’),
3 under the amendments made by the Genetic Information
4 Nondiscrimination Act, or under State privacy law.”.

5 (b) EFFECTIVE DATE.—Section 2715B of the Public
6 Health Service Act, as added by subsection (a), shall take
7 effect 1 year after the date of enactment of this Act.

8 **SEC. 502. RECOGNITION OF SECURITY PRACTICES.**

9 Part 1 of subtitle D of the Health Information Tech-
10 nology for Economic and Clinical Health Act (42 U.S.C.
11 17931 et seq.) is amended by adding at the end the fol-
12 lowing:

13 **“SEC. 13412. RECOGNITION OF SECURITY PRACTICES.**

14 “(a) IN GENERAL.—Consistent with the authority of
15 the Secretary under sections 1176 and 1177 of the Social
16 Security Act, when making determinations relating to
17 fines under section 13410, decreasing the length and ex-
18 tent of an audit under section 13411, or remedies other-
19 wise agreed to by the Secretary, the Secretary shall con-
20 sider whether the entity or business associate had, for not
21 less than the previous 12 months, recognized security
22 practices in place that may—

23 “(1) mitigate fines under section 13410;

24 “(2) result in the early, favorable termination
25 of an audit under section 13411; and

1 “(3) limit the remedies that would otherwise be
2 agreed to in any agreement between the entity or
3 business associate and the Department of Health
4 and Human Services.

5 “(b) ADDITIONAL CONSIDERATION.—At the election
6 of the entity or business associate, the Secretary may pro-
7 vide further consideration to an entity or business asso-
8 ciate that can adequately demonstrate that such recog-
9 nized security practices were in place, as determined by
10 the Secretary.

11 “(c) DEFINITION AND MISCELLANEOUS PROVI-
12 SIONS.—

13 “(1) RECOGNIZED SECURITY PRACTICES.—The
14 term ‘recognized security practices’ means the stand-
15 ards, guidelines, best practices, methodologies, pro-
16 cedures, and processes developed under section
17 2(c)(15) of the National Institute of Standards and
18 Technology Act, the approaches promulgated under
19 section 405(d) of the Cybersecurity Information
20 Sharing Act of 2015, and any other program or
21 processes that are equivalent to such requirements
22 as may be developed through regulations. Such prac-
23 tices shall be determined by the entity or business
24 associate, except where additional consideration is
25 requested under subsection (b).

1 “(2) LIMITATION.—Nothing in this section
2 shall be construed as providing the Secretary author-
3 ity to—

4 “(A) increase fines under section 13410, or
5 the length, extent or quantity of audits under
6 section 13411, due to a lack of compliance with
7 the recognized security practices; or

8 “(B) mandate, direct, or condition the
9 award of any Federal grant, contract, or pur-
10 chase, on compliance with such recognized secu-
11 rity practices.

12 “(3) NO LIABILITY FOR NONPARTICIPATION.—
13 Nothing in this section shall be construed to subject
14 an entity or business associate to liability for elect-
15 ing not to engage in the recognized security prac-
16 tices defined by this section.

17 “(4) RULE OF CONSTRUCTION.—Nothing in
18 this section shall be construed to limit the Sec-
19 retary’s authority to enforce the HIPAA Security
20 rule (part 160 of title 45, Code of Federal Regula-
21 tions, and subparts A and C of part 164 of such
22 title), or to supersede or conflict with an entity or
23 business associate’s obligations under the HIPAA
24 Security rule.”.

1 **SEC. 503. GAO STUDY ON THE PRIVACY AND SECURITY**
2 **RISKS OF ELECTRONIC TRANSMISSION OF IN-**
3 **DIVIDUALLY IDENTIFIABLE HEALTH INFOR-**
4 **MATION TO AND FROM ENTITIES NOT COV-**
5 **ERED BY THE HEALTH INSURANCE PORT-**
6 **ABILITY AND ACCOUNTABILITY ACT.**

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

10 (1) describe the roles of Federal agencies and
11 the private sector with respect to protecting the pri-
12 vacy and security of individually identifiable health
13 information transmitted electronically to and from
14 entities not covered by the regulations promulgated
15 under section 264(c) of the Health Insurance Port-
16 ability and Accountability Act of 1996 (42 U.S.C.
17 1320d–2 note);

18 (2) identify recent developments regarding the
19 use of application programming interfaces to access
20 individually identifiable health information, and im-
21 plications for the privacy and security of such infor-
22 mation;

23 (3) identify practices in the private sector, such
24 as terms and conditions for use, relating to the pri-
25 vacy, disclosure, and secondary uses of individually
26 identifiable health information transmitted electroni-

1 cally to or from entities, selected by an individual,
2 that are not subject to the regulations promulgated
3 under section 264(c) of the Health Insurance Port-
4 ability and Accountability Act of 1996; and

5 (4) identify steps the public and private sectors
6 can take to improve the private and secure access to
7 and availability of individually identifiable health in-
8 formation.

9 (b) REPORT.—Not later than 1 year after the date
10 of enactment of this Act, the Comptroller General of the
11 United States shall submit to Congress a report con-
12 cerning the findings of the study conducted under sub-
13 section (a).

14 **SEC. 504. TECHNICAL CORRECTIONS.**

15 (a) IN GENERAL.—Section 3022(b) of the Public
16 Health Service Act (42 U.S.C. 300jj–52(b)) is amended
17 by adding at the end the following new paragraph:

18 “(4) APPLICATION OF AUTHORITIES UNDER IN-
19 SPECTOR GENERAL ACT OF 1978.—In carrying out
20 this subsection, the Inspector General shall have the
21 same authorities as provided under section 6 of the
22 Inspector General Act of 1978 (5 U.S.C. App.).”.

23 (b) EFFECTIVE DATE.—The amendment made by
24 subsection (a) shall take effect as if included in the enact-

1 ment of the 21st Century Cures Act (Public Law 114–
2 255).

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