

116TH CONGRESS
1ST SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice
and referred to the Committee on _____

A BILL

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.
- Sec. 2. Definitions.

TITLE I—ENDING SURPRISE MEDICAL BILLS

- Sec. 101. Protecting patients against out-of-network deductibles in emergencies.
- Sec. 102. Protection against surprise bills.

Subtitle A—Option 1

- Sec. 103. In-network guarantee.

2

- Sec. 104. Coverage of out-of-network emergency services.
- Sec. 105. Report.

Subtitle B—Option 2

- Sec. 103. Independent Dispute Resolution.

Subtitle C—Option 3

- Sec. 103. Benchmark for payment.

Subtitle D—Air Ambulance

- Sec. 106. Simplifying emergency air ambulance billing.

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.

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.

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 State 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.

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 **SEC. 2. DEFINITIONS.**

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

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

6 Section 2719A(b) of the Public Health Service Act
7 (42 U.S.C. 300gg–19a) is amended—

8 (1) in paragraph (1)—

9 (A) in the matter preceding subparagraph

10 (A), by inserting “or a freestanding emergency
11 room” after “hospital”; and

12 (B) in subparagraph (C)—

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

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

19 (2) in paragraph (2)(B)—

20 (A) in clause (i)—

- 1 (i) by inserting “or freestanding emer-
2 gency room” after “hospital”; and
3 (ii) by inserting “or emergency room”
4 after “emergency department”; and
5 (B) in clause (ii), by inserting “or emer-
6 gency room” after “hospital”.

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

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

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

13 “(1) IN GENERAL [*Option 1, with ‘subtitle A’*
14 *option*].—Subject to subsection (h), in the case of
15 an enrollee in a group health plan or group or indi-
16 vidual health insurance coverage who receives out-of-
17 network non-emergency services at an in-network fa-
18 cility—

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

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

5 “(2) IN GENERAL **【Option 2/Option 3, with**
6 *‘subtitle B’ or ‘subtitle C’ option***】**.—Subject to sub-
7 section (h), in the case of an enrollee in a group
8 health plan or group or individual health insurance
9 coverage who receives out-of-network, ancillary, non-
10 emergency services at an in-network facility, includ-
11 ing any referrals for diagnostic services—

12 “(A) the cost-sharing requirement (ex-
13 pressed as a copayment amount, coinsurance
14 rate, or deductible) with respect to such services
15 shall be the same requirement that would apply
16 if such services were provided by an in-network
17 practitioner; and

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

22 “(3) DEFINITION.—For purposes of this sub-
23 section, the term ‘facility’ has the meaning given the
24 term ‘health care facility’ in section 2729A(c).

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

3 “(1) NOTICE AND CONSENT.—Subject to sub-
4 section (h), in the case of an enrollee in a group
5 health plan or group or individual health insurance
6 coverage who is admitted to a hospital after receiv-
7 ing emergency services, or maternal care for a
8 woman in labor, in the emergency department of
9 such hospital and being stabilized (within the mean-
10 ing of subsection (b)(2)(C)), the cost-sharing re-
11 quirement (expressed as a copayment amount, coin-
12 surance rate, or deductible) with respect to any out-
13 of-network services is the same requirement that
14 would apply if such services were provided by a par-
15 ticipating provider, unless the enrollee, once stable
16 and in a condition, including having sufficient men-
17 tal capacity, to receive the information described in
18 this subsection —

19 “(A) has been provided by the hospital,
20 prior to the provision of any post-stabilization,
21 out-of-network service at such hospital, with—

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

1 plicable, and the option to affirmatively
2 consent to receiving services from such
3 practitioner or hospital;

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

8 “(iii) the estimated amount that such
9 provider will charge the participant, bene-
10 ficiary, or enrollee for such items and serv-
11 ices involved; and

12 “(B) 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 hospital, 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) is printed in the enrollee’s primary
13 language.

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

16 “(1) IN GENERAL.—A health care facility or
17 practitioner furnishing—

18 “(A) emergency services, as defined in sub-
19 section (b)(2), regardless of the state in which
20 the patient resides;

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

23 “(C) out-of-network services furnished
24 after the enrollee has been stabilized (within the
25 meaning of subsection (b)(2)(C)), where the no-

1 tice and option for referral required under sub-
2 section (f)(1) have not been provided to the en-
3 rollee and the assumption of responsibility for
4 out-of-pockets costs under subsection (f)(2) has
5 not been obtained,
6 may not bill an enrollee in a group health plan or
7 group or individual health insurance coverage for
8 amounts beyond the cost-sharing amount that would
9 apply under subsection (b)(1)(C)(ii)(II), (e), or (f),
10 as applicable.

11 “(2) ENFORCEMENT.—

12 “(A) IN GENERAL.—Subject to subpara-
13 graph (B), a health care facility or practitioner
14 that violates a requirement under paragraph (1)
15 shall be subject to a civil monetary penalty of
16 not more than \$10,000 for each act consti-
17 tuting such violation.

18 “(B) PROCEDURE.—The provisions of sec-
19 tion 1128A of the Social Security Act, other
20 than subsections (a) and (b) and the first sen-
21 tence of subsection (c)(1) of such section, shall
22 apply to civil money penalties under this sub-
23 section in the same manner as such provisions
24 apply to a penalty or proceeding under section
25 1128A of the Social Security Act.

1 “(C) SAFE HARBOR.—The Secretary may
2 waive the penalties described under subpara-
3 graph (A) with respect to a facility or practi-
4 tioner who unknowingly violates paragraph (1)
5 with respect to an enrollee, if such facility or
6 practitioner, within 30 days of the violation,
7 withdraws the bill that was in violation of para-
8 graph (1), and, as applicable, reimburses the
9 group health plan, health insurance issuer, or
10 enrollee, as applicable, in an amount equal to
11 the amount billed in violation of paragraph (1),
12 plus interest, at an interest rate determined by
13 the Secretary.

14 “(h) MAINTAINING STATE SURPRISE BILLING PRO-
15 TECTIONS.—

16 “(1) IN GENERAL.—Notwithstanding section
17 514 of the Employee Retirement Income Security
18 Act of 1974, except with respect to self-insured
19 group health plans, nothing in this section shall pre-
20 vent a State from establishing or continuing in effect
21 an alternate method under State law for determining
22 the appropriate compensation for services described
23 in subsection (b), (e), or (f).

24 “(2) ADDITIONAL APPLICATION.—In the case of
25 group health plans or health insurance coverage in

1 the individual or group market offered in a State
2 that has not enacted an alternate method described
3 in paragraph (1), such as arbitration or a bench-
4 mark, or for services described in subsection (b), (e),
5 or (f) that are not covered by such State’s alternate
6 method described in paragraph (1), the provisions of
7 this section shall apply.

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

12 (b) EFFECTIVE DATE.—The amendment made by
13 subsection (a) shall take effect beginning in the second
14 plan year that begins after the date of enactment of this
15 Act.

16 **Subtitle A—Option 1**

17 **SEC. 103. IN-NETWORK GUARANTEE.**

18 (a) IN GENERAL.—Subpart II of part A of title
19 XXVII of the Public Health Service Act (42 U.S.C.
20 300gg–11 et seq.) is amended by adding at the end the
21 following:

22 **“SEC. 2729A. IN-NETWORK GUARANTEE.**

23 “(a) IN GENERAL.—

24 “(1) CONTRACTS.—A group health plan and a
25 health insurance issuer offering group or individual

1 health insurance coverage may not contract (or enter
2 into a similar arrangement) with a health care facil-
3 ity with respect to such plan or coverage unless the
4 health care facility guarantees in the contract (or ar-
5 rangement) that—

6 “(A) each health care practitioner who pro-
7 vides services in the facility will be under con-
8 tract as a participating health care practitioner
9 with respect to the plan or coverage with re-
10 spect to all services provided at such facility;
11 and

12 “(B) all laboratory or diagnostic services—

13 “(i) provided in such facility, are in-
14 cluded in the network contract between
15 such facility and the group health plan or
16 health insurance issuer with respect to
17 such coverage; and

18 “(ii) referred by health care practi-
19 tioners at such facility, are referred only to
20 providers included in the network contract
21 between such facility and the group health
22 plan or health insurance issuer with re-
23 spect to such coverage.

24 “(2) SEPARATE CONTRACTS.—Contracts be-
25 tween the group health plan or health insurance

1 issuer and applicable health care practitioners may
2 be separate contracts from the contracts between the
3 group health plan or health insurance issuer and the
4 health care facility.

5 “(b) PROVIDER CHOICE.—A practitioner may elect to
6 be considered in-network for purposes of subsection (a)
7 if the practitioner agrees to have his or her reimbursement
8 from a group health plan or health insurance issuer in-
9 cluded as part of the group health plan or health insurance
10 issuer’s payment to the facility in which the practitioner
11 provides the services, and the practitioner agrees to not
12 separately bill the group health plan or health insurance
13 issuer or an enrollee in the group health plan or health
14 insurance coverage offered by such health insurance
15 issuer.

16 “(c) FACILITY.—For purposes of this section, the
17 term ‘health care facility’ includes hospitals, hospital out-
18 patient departments, critical access hospitals, ambulatory
19 surgery centers, laboratories, radiology clinics, and any
20 other facility that provides services that are covered under
21 a group health plan or health insurance coverage.

22 “(d) FAILURE TO COMPLY.—In the case of a health
23 care practitioner who does not establish a network con-
24 tract with a group health plan or health insurance issuer
25 that has a network contract with a facility in which the

1 practitioner provides services, as described in subsection
2 (a), the group health plan or health insurance issuer shall
3 not reimburse the health care practitioner for any services
4 provided to enrollees in the plan or coverage.”.

5 (b) EFFECTIVE DATE.—The amendment made by
6 subsection (a) shall take effect beginning in the second
7 plan year that begins after the date of enactment of this
8 Act.

9 **SEC. 104. COVERAGE OF OUT-OF-NETWORK EMERGENCY**
10 **SERVICES.**

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

15 **“SEC. 2729B. COVERAGE OF OUT-OF-NETWORK, EMER-**
16 **GENCY SERVICES.**

17 “(a) IN GENERAL.—In the case of an enrollee in a
18 group health plan or group or individual health insurance
19 coverage offered by a health insurance issuer who receives
20 emergency services (as defined in section 2719A(b)(2))
21 that are covered by such plan or coverage at an out-of-
22 network hospital, the group health plan or health insur-
23 ance coverage and facility and practitioner shall deter-
24 mine, within 30 business days of the service, the appro-
25 priate reimbursement for such services.

1 “(b) DEFAULT RATE.—If, after the 30-business-day
2 period described in subsection (a), the group health plan
3 or health insurance issuer offering group or individual
4 health insurance coverage and the facility and practitioner
5 do not reach an agreement under subsection (a), the group
6 health plan or health insurance issuer shall reimburse the
7 hospital and any out-of-network practitioners providing
8 such services in an amount that is equal to the median
9 contracted rate, using a methodology determined under
10 subsection (c), for the same or similar services offered by
11 the group health plan or group or individual health insur-
12 ance coverage in that geographic region.

13 “(c) MEDIAN CONTRACTED RATE.—

14 “(1) IN GENERAL.—For purposes of this sec-
15 tion, the term ‘median contracted rate’ means, with
16 respect to health care services covered by a group
17 health plan or health insurance coverage, the median
18 negotiated rate under the applicable plan or cov-
19 erage recognized under the plan or coverage as the
20 total maximum payment for the service, minus the
21 in-network cost-sharing for such service under the
22 plan or coverage, for the same or a similar service
23 that is provided by a provider in the same or similar
24 specialty, and in the geographic region in which the
25 service is furnished.

1 “(2) RULEMAKING.—Not later than 1 year
2 after the date of enactment, the Secretary shall,
3 through rulemaking, determine the methodology a
4 group health plan or health insurance issuer is re-
5 quired to use to determine the median contracted
6 rate described in paragraph (1), the information the
7 plan or issuer shall share with the non-participating
8 provider involved when making such a determination
9 , and the geographic regions applied for purposes of
10 this subparagraph.

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

1 health care providers for relevant services provided
2 in the applicable geographic region, and that such
3 plan or issuer will use that database to determine a
4 median contracted rate. The group health plan or
5 health insurance issuer shall cover the cost of ac-
6 cessing the database.

7 “(4) RULE OF CONSTRUCTION.—Nothing in
8 this subsection shall prevent a group health plan or
9 health insurance issuer from establishing separate
10 calculations of a median contracted rate under para-
11 graph (1) for services delivered in non-hospital facili-
12 ties, including freestanding emergency rooms.

13 “(d) MAINTAINING STATE SURPRISE BILLING PRO-
14 TECTIONS.—Notwithstanding section 514 of the Employee
15 Retirement Income Security Act of 1974, except with re-
16 spect to self-insured group health plans, nothing in this
17 section shall prevent a State from establishing or con-
18 tinuing in effect a requirement with respect to payments
19 described in subsection (a).”.

20 (b) EFFECTIVE DATE.—Section 2729B of the Public
21 Health Service Act, as added by subsection (a), shall take
22 effect beginning in the second plan year that begins after
23 the date of enactment of this Act.

1 **SEC. 105. REPORT.**

2 Not later than 1 year after the effective date de-
3 scribed in section 2(b), and annually for the following 4
4 years, the Secretary, in consultation with the Federal
5 Trade Commission and the Attorney General, shall—

6 (1) conduct a study on—

7 (A) the effects of the amendments made by
8 sections 102, 103, and 104, including any pat-
9 terns of vertical or horizontal integration of
10 health care facilities, providers, or insurers;

11 (B) the effects of the amendments made
12 by section 102, 103, and 104 on overall health
13 care costs; and

14 (C) recommendations for enforcement ac-
15 tion of sections 2729A and 2729B of the Public
16 Health Service Act, as added by sections 103
17 and 104, respectively, including potential chal-
18 lenges to addressing anti-competitive consolida-
19 tion by health care facilities, providers, or in-
20 surers; and

21 (2) submit a report on such study to the Com-
22 mittee on Health, Education, Labor, and Pensions,
23 the Committee on Commerce, Science, and Trans-
24 portation, the Committee on Finance, and the Com-
25 mittee on the Judiciary of the Senate and the Com-
26 mittee on Education and Labor, the Committee on

1 Energy and Commerce, the Committee on Ways and
2 Means, and the Committee on the Judiciary of the
3 House of Representatives.

4 **Subtitle B—Option 2**

5 **SEC. 103. INDEPENDENT DISPUTE RESOLUTION.**

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

9 **“SEC. 2729A. INDEPENDENT DISPUTE RESOLUTION.**

10 “(a) ESTABLISHMENT.—The Secretary, in consulta-
11 tion with the Secretary of Labor, shall establish an inde-
12 pendent dispute resolution process (referred to in this sec-
13 tion as the ‘IDR process’) for resolving payment disputes
14 between group health plans or health insurance issuers of-
15 fering group or individual health insurance coverage, and
16 facilities or practitioners furnishing services subject to sec-
17 tion 2719A(g).

18 “(b) CERTIFICATION OF ENTITIES.—An entity may
19 conduct the IDR process under this section only after re-
20 ceiving certification as an independent dispute resolution
21 entity from the Secretary. An entity wishing to receive
22 such certification shall submit an application to the Sec-
23 retary. The Secretary, in consultation with the Secretary
24 of Labor, shall determine eligibility of applicant entities,
25 taking into consideration whether each applicant entity is

1 unbiased and unaffiliated with health plans and health in-
2 surance issuers and providers and free of conflicts of inter-
3 est, in accordance with the Secretary’s rulemaking on de-
4 termining criteria for conflicts of interest. For purposes
5 of this section, an entity certified under this subsection
6 is a ‘certified IDR entity’.

7 “(c) CLAIMS.—

8 “(1) APPLICABLE CLAIMS.—

9 “(A) IN GENERAL.—The IDR process
10 under this section may be used by a group
11 health plan or health insurance issuer offering
12 group or individual health insurance coverage,
13 or by a facility or practitioner, for the resolu-
14 tion of claims for services described in sub-
15 section (a) that exceed \$750.

16 “(B) ADJUSTMENT.—The Secretary, in
17 consultation with the Secretary of Labor, shall
18 annually adjust the dollar amount in this sub-
19 section in accordance with the rate of inflation.

20 “(2) NONAPPLICABLE CLAIMS.—In the case of
21 a claim for services described in subsection (a) that
22 are equal to or less than the dollar amount described
23 in paragraph (1)(A), as adjusted under paragraph
24 (1)(B), as applicable, a group health plan or health
25 insurance issuer shall pay the facility or practitioner

1 the median contracted rate, using a methodology de-
2 termined under subsection (e) for the same or simi-
3 lar services offered by the group health plan or
4 health insurance issuer in that geographic region

5 “(d) IDR PROCESS.—

6 “(1) TIMING.—A certified IDR entity that re-
7 ceives a request from a group health plan, health in-
8 surance issuer, facility, or practitioner under this
9 section shall, not later than 30 days after receiving
10 such request, determine the amount the group
11 health plan or health insurance issuer is required to
12 pay the facility or practitioner for services described
13 in subsection (a). Such amount shall be—

14 “(A) the amount determined by the parties
15 through a settlement under paragraph (2); or

16 “(B) the amount a certified IDR entity de-
17 termines reasonable in accordance with para-
18 graph (3).

19 “(2) SETTLEMENT.—

20 “(A) IN GENERAL.—If a certified IDR en-
21 tity determines, based on the amounts indicated
22 in the request under this section, that a settle-
23 ment between the group health plan or health
24 insurance issuer, and the facility or practitioner
25 is likely, the entity may direct the parties to at-

1 tempt, for a period not to exceed 10 days, a
2 good faith negotiation for a settlement.

3 “(B) TIMING.—The period for a settlement
4 described in subparagraph (A) shall accrue to-
5 wards the 30-day period required under para-
6 graph (1).

7 “(3) DETERMINATION OF AMOUNT.—

8 “(A) FINAL OFFERS.—In the absence of a
9 settlement under paragraph (2), the group
10 health plan or health insurance issuer, and fa-
11 cility or practitioner shall each submit to the
12 certified IDR entity their final offer. Such enti-
13 ty shall determine which of the 2 amounts is
14 more reasonable based on the factors described
15 in subparagraph (C).

16 “(B) FINAL DECISIONS.—The amount that
17 is determined to be the more reasonable amount
18 under subparagraph (A) shall be the final deci-
19 sion of the certified IDR entity as to the
20 amount the group health plan or health insur-
21 ance issuer is required to pay the facility or
22 practitioner.

23 “(C) FACTORS.—In determining which
24 final offer to select as the more reasonable
25 amount under subparagraph (A), the certified

1 IDR entity shall consider relevant factors in-
2 cluding the median contracted rate, using a
3 methodology determined under subsection (e)
4 for the same or similar services offered by the
5 group health plan or health insurance issuer in
6 that geographic region.

7 “(D) EFFECT OF DECISION.—A final deci-
8 sion of a certified IDR entity under subpara-
9 graph (B)—

10 “(i) shall be binding; and

11 “(ii) shall not be subject to judicial re-
12 view, except in cases comparable to those
13 described in section 10(a) of title 9, United
14 States Code, as determined by the Sec-
15 retary in consultation with the Secretary of
16 Labor, and cases in which information sub-
17 mitted by 1 party was determined to be
18 fraudulent.

19 “(4) PRIVACY LAWS.—A certified IDR entity
20 shall, in conducting an IDR process under this sec-
21 tion, comply with all applicable Federal and State
22 privacy laws.

23 “(5) COSTS OF INDEPENDENT DISPUTE RESO-
24 LUTION PROCESS.—The party whose final offer is
25 not chosen under paragraph (3) shall be responsible

1 for paying all fees charged by the certified IDR enti-
2 ty. If the parties reach a settlement prior to comple-
3 tion of the IDR process, the costs of such process
4 shall be divided equally between the parties.

5 “(6) PAYMENT.—Plans shall pay directly to the
6 health care facility or practitioner amounts deter-
7 mined by the certified IDR entity within 30 days of
8 the amount being determined.

9 “(e) MEDIAN CONTRACTED RATE.—

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

22 “(2) RULEMAKING.—Not later than 1 year
23 after the date of enactment, the Secretary shall,
24 through rulemaking, determine the methodology a
25 group health plan or health insurance issuer is re-

1 quired to use to determine the median contracted
2 rate described in paragraph (1), the information the
3 plan or issuer shall share with the nonparticipating
4 provider involved when making such a determina-
5 tion, and the geographic regions applied for pur-
6 poses of this subparagraph.

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 rates paid to noncontracting individual
22 health care providers for relevant services provided
23 in the applicable geographic region, and that such
24 plan or issuer will use that database to determine a
25 median contracted rate. The group health plan or

1 health insurance issuer shall cover the cost of ac-
2 cessing the 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 contracted rate under para-
7 graph (1) for services delivered in nonhospital facili-
8 ties, including freestanding emergency rooms.

9 “(f) 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 **Subtitle C—Option 3**

17 **SEC. 103. BENCHMARK FOR PAYMENT.**

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

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

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

1 and practitioners are prohibited from billing enrollees
2 under section 2719A(g), the median contracted rate, using
3 a methodology determined under subsection (b) for the
4 same or similar services offered by the group health plan
5 or health insurance issuer in that geographic region.

6 “(b) MEDIAN CONTRACTED RATE.—

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

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

1 shall share with the nonparticipating provider in-
2 volved when making such a determination, and the
3 geographic regions applied for purposes of this sub-
4 paragraph.

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

1 (2) the cost of emergency medical services and
2 supplies.

3 (b) RULEMAKING.—Not later than 1 year after the
4 date of enactment of this Act, the Secretary shall deter-
5 mine the form and manner for submitting the description
6 of charges in subsection (a) through notice and comment
7 rulemaking.

8 (c) CIVIL MONETARY PENALTIES.—

9 (1) IN GENERAL.—A provider of emergency air
10 medical services who violates the requirements of
11 subsection (a) shall be subject to a civil monetary
12 penalty of not more than \$10,000 for each act con-
13 stituting such violation.

14 (2) PROCEDURE.—The provisions of section
15 1128A of the Social Security Act (42 U.S.C. 1320a-
16 7a), other than subsections (a) and (b) and the first
17 sentence of subsection (c)(1) of such section, shall
18 apply to civil money penalties under this subsection
19 in the same manner as such provisions apply to a
20 penalty or proceeding under section 1128A of the
21 Social Security Act.

22 (d) DEFINITIONS.—In this section—

23 (1) the terms “group health plan”, “health in-
24 surance coverage”, and “health insurance issuer”
25 have the meanings given such terms in section 2791

1 of the Public Health Service Act (42 U.S.C. 300gg–
2 91); and

3 (2) the term “Secretary” means the Secretary
4 of Health and Human Services.

5 (e) EFFECTIVE DATE.—The requirement under sub-
6 section (a) shall take effect 6 months after the rules de-
7 scribed in subsection (b) are finalized.

8 **TITLE II—REDUCING THE**
9 **PRICES OF PRESCRIPTION**
10 **DRUGS**

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

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

15 “(o) ADDITIONAL REQUIREMENTS WITH RESPECT
16 TO PATENTS.—

17 “(1) APPROVED APPLICATION HOLDER LISTING
18 REQUIREMENTS.—

19 “(A) IN GENERAL.—Beginning on the date
20 of enactment of the Biologic Patent Trans-
21 parency Act, within 60 days of approval of an
22 application under subsection (a) or (k), the
23 holder of such approved application shall sub-
24 mit to the Secretary a list of each patent re-

1 required to be disclosed (as described in para-
2 graph (3)).

3 “(B) PREVIOUSLY APPROVED OR LI-
4 CENSED BIOLOGICAL PRODUCTS.—

5 “(i) PRODUCTS LICENSED UNDER
6 SECTION 351 OF THE PHSA.—Not later
7 than 30 days after the date of enactment
8 of the Biologic Patent Transparency Act,
9 the holder of a biological product license
10 that was approved under subsection (a) or
11 (k) before the date of enactment of such
12 Act shall submit to the Secretary a list of
13 each patent required to be disclosed (as de-
14 scribed in paragraph (3)).

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

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

5 “(i) any patent not previously re-
6 quired to be disclosed (as described in
7 paragraph (3)) under subparagraph (A) or
8 (B), as applicable, within 30 days of the
9 earlier of—

10 “(I) the date of issuance of such
11 patent by the United States Patent
12 and Trademark Office; or

13 “(II) the date of approval of a
14 supplemental application for the bio-
15 logical product; and

16 “(ii) any patent, or any claim with re-
17 spect to a patent, included on the list pur-
18 suant to this paragraph, that the Patent
19 Trial and Appeal Board of the United
20 States Patent and Trademark Office deter-
21 mines in a decision to be invalid or unen-
22 forceable, within 30 days of such decision.

23 “(2) PUBLICATION OF INFORMATION.—

24 “(A) IN GENERAL.—Within 1 year of the
25 date of enactment of the Biologic Patent Trans-

1 parenity Act, the Secretary shall publish and
2 make available to the public a single, easily
3 searchable, list that includes—

4 “(i) the official and proprietary name
5 of each biological product licensed under
6 subsection (a) or (k), and of each biological
7 product application approved under section
8 505 of the Federal Food, Drug, and Cos-
9 metic Act and deemed to be a license for
10 the biological product under this section on
11 March 23, 2020;

12 “(ii) with respect to each biological
13 product described in clause (i), each patent
14 submitted in accordance with paragraph
15 (1);

16 “(iii) the date of licensure and appli-
17 cation number for each such biological
18 product;

19 “(iv) the marketing status, dosage
20 form, route of administration, strength,
21 and, if applicable, reference product, for
22 each such biological product;

23 “(v) the licensure status for each such
24 biological product, including whether the li-

1 cense at the time of listing is approved,
2 withdrawn, or revoked;

3 “(vi) with respect to each such bio-
4 logical product, any period of any exclu-
5 sivity under paragraph (6), (7)(A), or
6 (7)(B) of subsection (k) of this section or
7 section 527 of the Federal Food, Drug,
8 and Cosmetic Act, and any extension of
9 such period in accordance with subsection
10 (m) of this section, for which the Secretary
11 has determined such biological product to
12 be eligible, and the date on which such ex-
13 clusivity expires;

14 “(vii) information regarding any de-
15 termination of biosimilarity or interchange-
16 ability for each such biological product;
17 and

18 “(viii) information regarding approved
19 indications for each such biological prod-
20 uct, in such manner as the Secretary de-
21 termines appropriate.

22 “(B) UPDATES.—Every 30 days after the
23 publication of the first list under subparagraph
24 (A), the Secretary shall revise the list to in-
25 clude—

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

4 “(II) with respect to each biological
5 product described in subclause (I), the in-
6 formation described in clauses (i) through
7 (viii) of subparagraph (A); and

8 “(ii) any updates to information pre-
9 viously published in accordance with sub-
10 paragraph (A).

11 “(C) NONCOMPLIANCE.—Beginning 18
12 months after the date of enactment of the Bio-
13 logic Patent Transparency Act, the Secretary,
14 in consultation with the Director of the United
15 States Patent and Trademark Office, shall pub-
16 lish and make available to the public a list of
17 any holders of biological product licenses, and
18 the corresponding biological product or prod-
19 ucts, that failed to submit information as re-
20 quired under paragraph (1), including any up-
21 dates required under paragraph (1)(C), in such
22 manner and format as the Secretary determines
23 appropriate. If information required under
24 paragraph (1) is submitted following publica-
25 tion of such list, the Secretary shall remove

1 such holders of such biological product licenses
2 from the public list in a reasonable period of
3 time.

4 “(3) PATENTS REQUIRED TO BE DISCLOSED.—

5 In this section, a ‘patent required to be disclosed’ is
6 any patent for which the holder of a biological prod-
7 uct license approved under subsection (a) or (k), or
8 a biological product application approved under sec-
9 tion 505 of the Federal Food, Drug, and Cosmetic
10 Act and deemed to be a license for a biological prod-
11 uct under this section on March 23, 2020, believes
12 a claim of patent infringement could reasonably be
13 asserted by the holder, or by a patent owner that
14 has granted an exclusive license to the holder with
15 respect to the biological product that is the subject
16 of such license, if a person not licensed by the holder
17 engaged in the making, using, offering to sell, sell-
18 ing, or importing into the United States of the bio-
19 logical product that is the subject of such license.”.

20 (b) DISCLOSURE OF PATENTS.—Section
21 351(l)(3)(A)(i) of the Public Health Service Act (42
22 U.S.C. 262(l)(3)(A)(i)) is amended by inserting “included
23 in the list provided by the reference product sponsor under
24 subsection (o)(1)” after “a list of patents”.

1 (c) REVIEW AND REPORT ON NONCOMPLIANCE.—

2 Not later than 30 months after the date of enactment of
3 this Act, the Secretary shall—

4 (1) solicit public comments regarding appro-
5 priate remedies, in addition to the publication of the
6 list under subsection (o)(2)(C) of section 351 of the
7 Public Health Service Act (42 U.S.C. 262), as added
8 by subsection (a), with respect to holders of biologi-
9 cal product licenses who fail to timely submit infor-
10 mation as required under subsection (o)(1) of such
11 section 351, including any updates required under
12 subparagraph (C) of such subsection (o)(1); and

13 (2) submit to Congress an evaluation of com-
14 ments received under paragraph (1) and the rec-
15 ommendations of the Secretary concerning appro-
16 priate remedies.

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

21 (e) RULE OF CONSTRUCTION.—Nothing in this Act,
22 including an amendment made by this Act, shall be con-
23 strued to require or allow the Secretary of Health and
24 Human Services to delay the licensing of a biological prod-

1 act under section 351 of the Public Health Service Act
2 (42 U.S.C. 262).

3 **SEC. 202. ORANGE BOOK MODERNIZATION.**

4 (a) SUBMISSION OF PATENT INFORMATION FOR
5 BRAND NAME DRUGS.—Paragraph (1) of section 505(b)
6 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 355(b)) is amended to read as follows:

8 “(b)(1)(A) Any person may file with the Secretary
9 an application with respect to any drug subject to the pro-
10 visions of subsection (a). Such persons shall submit to the
11 Secretary as part of the application—

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

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

17 “(iii) a full statement of the composition of
18 such drug;

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

22 “(v) such samples of such drug and of the arti-
23 cles used as components thereof as the Secretary
24 may require;

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

3 “(vii) any assessments required under section
4 505B; and

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

10 “(I) claims the drug for which the appli-
11 cant submitted the application and is a drug
12 substance patent or a drug product patent; or

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

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

22 “(C) Upon approval of the application, the Secretary
23 shall publish the information submitted under subpara-
24 graph (A)(viii).

1 “(D) The Secretary shall, in consultation with the Di-
2 rector of the National Institutes of Health and with rep-
3 resentatives of the drug manufacturing industry, review
4 and develop guidance, as appropriate, on the inclusion of
5 women and minorities in clinical trials required by sub-
6 paragraph (A)(i).”.

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

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

1 patent, except that a patent that claims a method of
2 using such drug shall be filed only if approval for
3 such use has been granted in the application.”;

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

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

12 (4) by inserting after “could not file patent in-
13 formation under subsection (b) because no patent”
14 the following: “of the type required to be submitted
15 in subsection (b)”.

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

20 “(iv) For each drug included on the list, the Sec-
21 retary shall specify any exclusivity period that is applica-
22 ble, for which the Secretary has determined the expiration
23 date, and for which such period has not yet expired
24 under—

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

3 “(II) clause (iv) or (v) of paragraph (5)(B) of
4 this subsection;

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

7 “(IV) section 505A;

8 “(V) section 505E;

9 “(VI) section 527(a); or

10 “(VII) section 505(u)”.

11 (d) ORANGE BOOK UPDATES WITH RESPECT TO IN-
12 VALIDATED PATENTS.—

13 (1) IN GENERAL.—

14 (A) AMENDMENTS.—Section 505(j)(7)(A)
15 of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 355(j)(7)(A)), as amended by sub-
17 section (c), is further amended by adding at the
18 end the following:

19 “(v) In the case of a listed drug for which the
20 list under clause (i) includes a patent or patent
21 claim for the drug, or a patent or a patent claim for
22 the use of such drug, and where the Under Sec-
23 retary of Commerce for Intellectual Property and
24 Director of the United States Patent and Trade-
25 mark Office has cancelled any claim of the patent

1 relating to such drug or such use pursuant to a deci-
2 sion by the Patent Trial and Appeal Board in an
3 inter partes review conducted under chapter 31 of
4 title 35, United States Code, or a post-grant review
5 conducted under chapter 32 of that title, and from
6 which no appeal has been taken, or can be taken,
7 the holder of the applicable approved application
8 shall notify the Secretary, in writing, within 14 days
9 of such cancellation, and, if the patent has been
10 deemed wholly inoperative or invalid, or if a patent
11 claim has been cancelled, the revisions required
12 under clause (iii) shall include striking the patent or
13 information regarding such patent claim from the
14 list with respect to such drug.”.

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

20 (2) NO EFFECT ON FIRST APPLICANT EXCLU-
21 SIVITY PERIOD.—Section 505(j)(5)(B)(iv)(I) is
22 amended by adding at the end the following: “This
23 subclause shall apply even if a patent is stricken
24 from the list under paragraph (7)(A), pursuant to
25 paragraph (7)(A)(v), provided that, at the time that

1 the first applicant submitted an application under
2 this subsection containing a certification described in
3 paragraph (2)(A)(vii)(IV), the patent that was the
4 subject of such certification was included in such list
5 with respect to the listed drug.”.

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

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

9 (1) in paragraph (1)—

10 (A) in subparagraph (A)(i), by inserting “,
11 10.31,” after “10.30”;

12 (B) in subparagraph (E)—

13 (i) by striking “application and” and
14 inserting “application or”;

15 (ii) by striking “If the Secretary” and
16 inserting the following:

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

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

20 “(ii) PRIMARY PURPOSE OF DELAY-
21 ING.—

22 “(I) IN GENERAL.—For purposes
23 of this subparagraph, a petition or
24 supplement to a petition may be con-
25 sidered to be submitted with the pri-

1 mary purpose of delaying an applica-
2 tion under subsection (b)(2) or (j) of
3 this section or section 351(k) of the
4 Public Health Service Act, if the peti-
5 tioner has the purpose of setting
6 aside, delaying, rescinding, with-
7 drawing, or preventing submission, re-
8 view, or the approval of such an appli-
9 cation.

10 “(II) FACTORS.—In determining
11 whether a petition was submitted with
12 the primary purpose of delaying an
13 application, the Secretary may con-
14 sider the following factors:

15 “(aa) Whether the petition
16 was submitted in accordance with
17 paragraph (2)(B), based on when
18 the petitioner knew or reasonably
19 should have known the relevant
20 information relied upon to form
21 the basis of such petition.

22 “(bb) Whether the petitioner
23 has submitted multiple or serial
24 petitions raising issues that rea-
25 sonably could have been known

1 to the petitioner at the time of
2 submission of the earlier petition
3 or petitions.

4 “(cc) Whether the petition
5 was submitted close in time to a
6 known, first date upon which an
7 application under subsection
8 (b)(2) or (j) of this section or
9 section 351(k) of the Public
10 Health Service Act could be ap-
11 proved.

12 “(dd) Whether the petition
13 was submitted without any rel-
14 evant data or information in sup-
15 port of the scientific positions
16 forming the basis of such peti-
17 tion.

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

1 “(ff) Whether the petition
2 requests changing the applicable
3 standards that other applicants
4 are required to meet, including
5 requesting testing, data, or label-
6 ing standards that are more on-
7 erous or rigorous than the stand-
8 ards applicable to the listed drug,
9 reference product, or petitioner’s
10 version of the same drug.

11 “(gg) The petitioner’s record
12 of submitting petitions to the
13 Food and Drug Administration
14 that have been determined by the
15 Secretary to have been submitted
16 with the primary purpose of
17 delay.

18 “(hh) Other relevant and
19 appropriate factors, which the
20 Secretary shall describe in guid-
21 ance.

22 “(III) GUIDANCE.—The Sec-
23 retary may issue or update guidance,
24 as appropriate, to describe factors the

1 Secretary considers in accordance
2 with subclause (II).”;

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

4 “(iii) REFERRAL TO THE FEDERAL
5 TRADE COMMISSION.—The Secretary shall
6 establish procedures for referring to the
7 Federal Trade Commission any petition or
8 supplement to a petition that the Secretary
9 determines was submitted with the primary
10 purpose of delaying approval of an applica-
11 tion. Such procedures shall include notifi-
12 cation to the petitioner and an opportunity
13 for judicial review after the issuance of an
14 order by the Federal Trade Commission.”;

15 (D) by striking subparagraph (F);

16 (E) by redesignating subparagraphs (G)
17 through (I) as subparagraphs (F) through (H),
18 respectively;

19 (F) in subparagraph (H), as so redesign-
20 ated, by striking “submission of this petition”
21 and inserting “submission of this document”;

22 (2) in paragraph (2)—

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

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

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

15 “(B) TIMELY SUBMISSION OF CITIZEN PE-
16 TITION.—A petition and any supplement to a
17 petition shall be submitted within 60 days after
18 the person knew, or reasonably should have
19 known, the information that forms the basis of
20 the request of the petition or supplement.”;

21 (C) in subparagraph (C), as so redesign-
22 nated, by—

23 (i) in the heading, by striking “WITH-
24 IN 150 DAYS”;

1 (ii) in clause (i), by striking “during
2 the 150-day period referred to in para-
3 graph (1)(F),”; and

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

6 “(ii) on or after the date that is 151
7 days after the date of submission of the
8 petition, the Secretary approves or has ap-
9 proved the application that is the subject
10 of the petition without having made such a
11 final decision.”;

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

14 “(D) DISMISSAL OF CERTAIN CIVIL AC-
15 TIONS.—

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

1 dismiss without prejudice the action for
2 failure to exhaust administrative remedies.

3 “(ii) TIMELINESS.—If a person files a
4 civil action against the Secretary in which
5 a person seeks to set aside, delay, rescind,
6 withdraw, or prevent submission, review, or
7 approval of an application submitted under
8 subsection (b)(2) or (j) of this section or
9 section 351(k) of the Public Health Service
10 Act without complying with the require-
11 ments of subparagraph (B), the court shall
12 dismiss with prejudice the action for fail-
13 ure to timely file a petition.

14 “(iii) FINAL RESPONSE.—If a civil ac-
15 tion is filed against the Secretary with re-
16 spect to any issue raised in a petition time-
17 ly filed under paragraph (1) in which the
18 petitioner requests that the Secretary take
19 any form of action that could, if taken, set
20 aside, delay, rescind, withdraw, or prevent
21 submission, review, or approval of an appli-
22 cation submitted under subsection (b)(2)
23 or (j) of this section or section 351(k) of
24 the Public Health Service Act before the
25 Secretary has issued a final response to

1 any such petition submitted, the court
2 shall dismiss without prejudice the action
3 for failure to exhaust administrative rem-
4 edies.”; and

5 (E) in subparagraph (E), as so redesign-
6 nated—

7 (i) in clause (ii), by striking “, if
8 issued”; and

9 (ii) in clause (iii), by striking “final
10 agency action as defined under subpara-
11 graph (2)(A)” and inserting “the final re-
12 sponse to the petitioner”; and

13 (3) in paragraph (4)—

14 (A) by striking “EXCEPTIONS” and all that
15 follows through “This subsection does” and in-
16 serting “EXCEPTIONS—This subsection does”;

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

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

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

22 Section 351(k)(7) of the Public Health Service Act
23 (42 U.S.C. 262(k)(7)) is amended by adding at the end
24 the following:

25 “(D) DEEMED LICENSES.—

1 “(i) NO ADDITIONAL EXCLUSIVITY
2 THROUGH DEEMING.—An approved appli-
3 cation that is deemed to be a license for a
4 biological product under this section pursu-
5 ant to section 7002(e)(4) of the Biologics
6 Price Competition and Innovation Act of
7 2009 shall not be treated as having been
8 first licensed under subsection (a) for pur-
9 poses of subparagraphs (A) and (B).

10 “(ii) LIMITATION ON EXCLUSIVITY.—
11 Subparagraph (C) shall apply to any ref-
12 erence product, without regard to wheth-
13 er—

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

16 “(II) the approved application for
17 such product was deemed to be a li-
18 cense for a biological product as de-
19 scribed in clause (i).

20 “(iii) APPLICABILITY.—Any unexpired
21 period of exclusivity under section 527 or
22 section 505A(c)(1)(A)(ii) of the Federal
23 Food, Drug, and Cosmetic Act with re-
24 spect to a biological product shall continue
25 to apply to such biological product after an

1 approved application for the biological
2 product is deemed to be a license for the
3 biological product as described in clause
4 (i).”.

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

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

9 (1) by striking “180 days after the date” and
10 inserting “180 days after the earlier of the fol-
11 lowing:

12 “(aa) The date”; and

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

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

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

22 “(BB) Thirty months have
23 passed since the date of submission of
24 an application for the drug by at least
25 one first applicant.

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, biosimilar biological products and inter-
24 changeable 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 the develop-
9 ment program for biosimilar biological products
10 and relevant clinical considerations for pre-
11 scribers;

12 “(C) the process for reporting adverse
13 events for biological products, including bio-
14 similar and interchangeable biological products;
15 and

16 “(D) the relationship between biosimilar
17 biological products licensed under section
18 351(k) and the applicable reference products
19 (as defined in section 351(i));

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

22 “(A) in formats such as webinars, con-
23 tinuing medical education modules, videos, fact
24 sheets, infographics, stakeholder toolkits, or

1 other formats as appropriate and applicable;
2 and

3 “(B) tailored for the unique needs of
4 health care providers, patients, caregivers, and
5 other audiences, as the Secretary determines
6 appropriate.

7 “(4) OTHER INFORMATION.—In addition to the
8 information described in paragraph (2), the internet
9 website established under paragraph (1) shall in-
10 clude the following information, as a single, search-
11 able database:

12 “(A) The action package of each biological
13 product licensed under subsection (a) or (k),
14 within 30 days of licensure, or, in the case of
15 a biological product licensed before the date of
16 enactment of the Lower Health Care Costs Act,
17 not later than 1 year after such date of enact-
18 ment.

19 “(B) The summary review of each biologi-
20 cal product licensed under subsection (a) or (k),
21 within 7 days of licensure, except where such
22 materials require redaction by the Secretary, or,
23 in the case of a biological product licensed be-
24 fore the date of enactment of the Lower Health

1 Care Costs Act, not later than 1 year after such
2 date of enactment.

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

8 “(b) CONTINUING MEDICAL EDUCATION.—The Sec-
9 retary shall advance education and awareness among
10 health care providers regarding biosimilar biological prod-
11 ucts, as appropriate, including by developing or improving
12 continuing medical education programs that advance the
13 education of such providers on the prescribing of, and rel-
14 evant clinical considerations with respect to, biosimilar bi-
15 ological products.”.

16 **SEC. 207. BIOLOGICAL PRODUCT INNOVATION.**

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

19 (1) by striking “except that a product” and in-
20 sserting “except that—

21 “(1) a product”;

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

23 and

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

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

7 **SEC. 208. CLARIFYING THE MEANING OF NEW CHEMICAL**
8 **ENTITY.**

9 Chapter V of the Federal Food, Drug, and Cosmetic
10 Act is amended—

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

12 (A) in subsection (c)(3)(E)—

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

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

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

3 (B) in subsection (j)(5)(F)—

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

11 (ii) in clause (iii), 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 (C) in subsection (l)(2)(A)(i), by striking
19 “active ingredient (including any ester or salt of
20 the active ingredient)” and inserting “active
21 moiety (as defined by the Secretary in section
22 314.3 of title 21, Code of Federal Regulations
23 (or any successor regulations))”;

24 (D) in subsection (s), in the matter pre-
25 ceding paragraph (1), by striking “active ingre-

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

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

8 (i) by striking “active ingredient (in-
9 cluding any ester or salt of the active in-
10 gredient)” and inserting “active moiety (as
11 defined by the Secretary in section 314.3
12 of title 21, Code of Federal Regulations (or
13 any successor regulations))”; and

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

16 (2) in section 512(c)(2)(F) (21 U.S.C.
17 360b(c)(2)(F))—

18 (A) in clause (i), by striking “active ingre-
19 dient (including any ester or salt of the active
20 ingredient)” and inserting “active moiety (as
21 defined by the Secretary in section 314.3 of
22 title 21, Code of Federal Regulations (or any
23 successor regulations))”;

24 (B) in clause (ii), by striking “active ingre-
25 dient (including any ester or salt of the active

1 ingredient)” and inserting “active moiety (as
2 defined by the Secretary in section 314.3 of
3 title 21, Code of Federal Regulations (or any
4 successor regulations))”; and

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

11 (3) in section 524(a)(4)(C) (21 U.S.C.
12 360n(a)(4)(C)), by striking “active ingredient (in-
13 cluding any ester or salt of the active ingredient)”
14 and inserting “active moiety (as defined by the Sec-
15 retary in section 314.3 of title 21, Code of Federal
16 Regulations (or any successor regulations))”;

17 (4) in section 529(a)(4)(A)(ii) (21 U.S.C. 21
18 U.S.C. 360ff(a)(4)(A)(ii)), by striking “active ingre-
19 dient (including any ester or salt of the active ingre-
20 dient)” and inserting “active moiety (as defined by
21 the Secretary in section 314.3 of title 21, Code of
22 Federal Regulations (or any successor regula-
23 tions))”; and

24 (5) in section 565A(a)(4)(D) (21 U.S.C.
25 360bbb-4a(a)(4)(D)), by striking “active ingredient

1 (including any ester or salt of the active ingredient)”
2 and inserting “active moiety (as defined by the Sec-
3 retary in section 314.3 of title 21, Code of Federal
4 Regulations (or any successor regulations))”.

5 **SEC. 209. STREAMLINING THE TRANSITION OF BIOLOGICAL**
6 **PRODUCTS.**

7 Section 7002(e)(4) of the Biologics Price Competition
8 and Innovation Act of 2009 (Public Law 111–148) is
9 amended by adding at the end the following: “With respect
10 to an application for a biological product under section
11 505 of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 355) with a filing date that is not later than Sep-
13 tember 23, 2019, the Secretary shall continue to review
14 and approve such application under section 505 of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355),
16 even if such review and approval process continues after
17 March 23, 2020. Effective on the later of March 23, 2020,
18 or the date of approval of such application under such sec-
19 tion 505, such approved application shall be deemed to
20 be a license for the biological product under section 351
21 of the Public Health Service Act.”.

1 **TITLE III—IMPROVING TRANS-**
2 **PARENCY IN HEALTH CARE**

3 **SEC. 301. INCREASING TRANSPARENCY BY REMOVING GAG**
4 **CLAUSES ON PRICE AND QUALITY INFORMA-**
5 **TION.**

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

10 **“SEC. 2729B. INCREASING TRANSPARENCY BY REMOVING**
11 **GAG CLAUSES ON PRICE AND QUALITY IN-**
12 **FORMATION.**

13 **“(a) INCREASING PRICE AND QUALITY TRANS-**
14 **PARENCY FOR PLAN SPONSORS AND CONSUMERS.—**

15 **“(1) GROUP HEALTH PLANS.—**A group health
16 plan or a health insurance issuer offering group
17 health insurance coverage may not enter into an
18 agreement with a health care provider, network or
19 association of providers, or other service provider of-
20 fering access to a network of providers that would
21 directly or indirectly restrict a group health plan or
22 health insurance issuer from—

23 **“(A)** providing provider-specific cost or
24 quality of care information, through a consumer
25 engagement tool or any other means, to refer-

1 ring providers, the plan sponsor, enrollees, or
2 eligible enrollees of the plan or coverage;

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

15 “(i) financial information, such as the
16 allowed amount;

17 “(ii) provider information, including
18 name and clinical designation; or

19 “(iii) service codes; or

20 “(C) sharing data described in subpara-
21 graph (A) or (B) with a business associate as
22 defined in section 160.103 of title 45, Code of
23 Federal Regulations (or successor regulations),
24 consistent with the privacy regulations promul-
25 gated pursuant to section 264(c) of the Health

1 Insurance Portability and Accountability Act,
2 the amendments to this Act made by the Ge-
3 netic Information Nondiscrimination Act of
4 2008, and the Americans with Disabilities Act
5 of 1990.

6 “(2) INDIVIDUAL HEALTH INSURANCE COV-
7 ERAGE.—A health insurance issuer offering indi-
8 vidual health insurance coverage may not enter into
9 an agreement with a health care provider, network
10 or association of providers, or other service provider
11 offering access to a network of providers that would,
12 directly or indirectly restrict the health insurance
13 issuer from—

14 “(A) providing provider-specific price or
15 quality of care information, through a consumer
16 engagement tool or any other means, to refer-
17 ring providers or the plan sponsor, enrollees, or
18 eligible enrollees of the plan or coverage; or

19 “(B) sharing data described in subpara-
20 graph (A) with a business associate as defined
21 in section 160.103 of title 45, Code of Federal
22 Regulations (or successor regulations), con-
23 sistent with the privacy regulations promul-
24 gated pursuant to section 264(c) of the Health
25 Insurance Portability and Accountability Act,

1 the amendments to this Act made by the Ge-
2 netic Information Nondiscrimination Act of
3 2008, and the Americans with Disabilities Act
4 of 1990, for plan design, plan administration,
5 and plan, financial, legal, and quality improve-
6 ment activities.

7 “(3) CLARIFICATION REGARDING PUBLIC DIS-
8 CLOSURE OF INFORMATION.—Nothing in paragraph
9 (1)(A) or (2)(A) prevents a health care provider,
10 network or association of providers, or other service
11 provider from placing reasonable restrictions on the
12 public disclosure of the information described in
13 such paragraphs (1) and (2).”.

14 **SEC. 302. BANNING ANTICOMPETITIVE TERMS IN FACILITY**
15 **AND INSURANCE CONTRACTS THAT LIMIT AC-**
16 **CESS TO HIGHER QUALITY, LOWER COST**
17 **CARE.**

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

21 “(b) PROTECTING HEALTH PLANS NETWORK DE-
22 SIGN FLEXIBILITY.—

23 “(1) IN GENERAL.—A group health plan or a
24 health insurance issuer offering group or individual
25 health insurance coverage shall not enter into an

1 agreement with a provider, network or association of
2 providers, third-party administrator, or other service
3 provider if such agreement, directly or indirectly—

4 “(A) restricts the group health plan or
5 health insurance issuer from—

6 “(i) directing or steering enrollees to
7 other health care providers; or

8 “(ii) offering incentives to encourage
9 enrollees to utilize specific health care pro-
10 viders; or

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

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

20 “(D) restricts other group health plans or
21 health insurance issuers not party to the con-
22 tract, from paying a lower rate for items or
23 services than the contracting plan or issuer
24 pays for such items or services; and

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

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

20 “(d) REGULATIONS.—The Secretary, in coordination
21 with the Secretary of Labor and the Secretary of the
22 Treasury, not later than 1 year after the date of enact-
23 ment of the Lower Health Care Costs Act, shall promul-
24 gate regulations to carry out this section.”.

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

9 **SEC. 303. DESIGNATION OF A NONGOVERNMENTAL, NON-**
10 **PROFIT TRANSPARENCY ORGANIZATION TO**
11 **LOWER AMERICANS' HEALTH CARE COSTS.**

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

16 **“SEC. 735. DESIGNATION OF A NONGOVERNMENTAL, NON-**
17 **PROFIT TRANSPARENCY ORGANIZATION TO**
18 **LOWER AMERICANS' HEALTH CARE COSTS.**

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

1 and issues reports that are available to the public and au-
2 thorized users, and are submitted to the Department of
3 Labor.

4 “(b) REQUIREMENTS.—

5 “(1) IN GENERAL.—The database established
6 under subsection (a) shall—

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

9 “(i) inform patients about the cost
10 and quality of their care;

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

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

19 “(iv) enable purchasers, including em-
20 ployers, employee organizations, and health
21 plans, to develop value-based purchasing
22 models, improve quality, and reduce the
23 cost of health care and insurance coverage
24 for enrollees;

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

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

8 “(vii) promote competition based on
9 quality and cost;

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

14 “(C) be established in such a manner that
15 allows the data collected pursuant to subpara-
16 graph (B) to be shared with State all-payer
17 claims databases at cost, using a standardized
18 format, if such State databases also submit
19 claims data to the database established under
20 this section; and

21 “(D) be available to—

22 “(i) the Director of the Congressional
23 Budget Office, the Comptroller General of
24 the United States, the Executive Director
25 of the Medicare Payment Advisory Com-

1 mission, and the Executive Director of the
2 Medicaid and CHIP Payment Advisory
3 Commission, upon request, subject to the
4 privacy and security requirements of au-
5 thorized users under subsection (e)(2); and

6 “(ii) authorized users, including em-
7 ployers, employee organizations, research-
8 ers and policymakers, subject to subsection
9 (e).

10 “(2) PRIVACY AND SECURITY.—The entity re-
11 ceiving a contract under subsection (a) shall, in ac-
12 cordance with the regulations promulgated under
13 section 264(c) of the Health Insurance Portability
14 and Accountability Act of 1996—

15 “(A) ensure that the database under sub-
16 section (a) is capable of—

17 “(i) receiving data under subsection
18 (d);

19 “(ii) providing data access to author-
20 ized users; and

21 “(iii) storing data on secure servers in
22 a manner that is consistent with the pri-
23 vacy, security, and data breach regulations
24 promulgated under section 264(c) of the
25 Health Insurance Portability and Account-

1 ability Act of 1996 (or successor regula-
2 tions);

3 “(B) not disclose to the public any pro-
4 tected health information or proprietary finan-
5 cial information;

6 “(C) strictly limit staff access to the data
7 to staff with appropriate training, clearance,
8 and background checks;

9 “(D) maintain effective security standards
10 for transferring data or making data available
11 to authorized users;

12 “(E) develop a process for providing access
13 to data to authorized users, in a secure manner
14 that maintains privacy and confidentiality of
15 data;

16 “(F) adhere to current best security prac-
17 tices with respect to the management and use
18 of such data for health services research, in ac-
19 cordance with applicable Federal privacy law;
20 and

21 “(G) report on the security methods of the
22 entity to the Secretary, the Committee on
23 Health, Education, Labor, and Pensions of the
24 Senate, and the Committee on Education and
25 Labor of the House of Representatives

1 “(3) CONSULTATION.—

2 “(A) ADVISORY COMMITTEE.—Not later
3 than 180 days after the date of enactment of
4 the Lower Health Care Costs Act, the Secretary
5 shall convene an Advisory Committee (referred
6 to in this section as the ‘Committee’), con-
7 sisting of 11 members, to advise the Secretary,
8 the contracting entity, and Congress on the es-
9 tablishment, operations, and use of the data-
10 base established under this section.

11 “(B) MEMBERSHIP.—

12 “(i) APPOINTMENT.—The Secretary,
13 in consultation with the Secretary of
14 Health and Human Services, shall, not
15 later than 1 year after the date of enact-
16 ment of the Lower Health Care Costs Act,
17 appoint members to the Committee who
18 have distinguished themselves in the fields
19 of health services research, health econom-
20 ics, health informatics, or the governance
21 of State all-payer claims databases, or who
22 represent organizations likely to submit
23 data to or use the database, including pa-
24 tients, employers, or employee organiza-
25 tions that sponsor group health plans,

1 health care providers, health insurance
2 issuers, and third-party administrators of
3 group health plans. Such members shall
4 serve 3-year terms on a staggered basis.
5 Vacancies on the Committee shall be filled
6 by appointment consistent with this sub-
7 section not later than 3 months after the
8 vacancy arises.

9 “(ii) COMPOSITION.—The members
10 appointed to the Committee under clause
11 (i) shall include—

12 “(I) 1 member selected by the
13 Secretary, in coordination with the
14 Secretary of Health and Human Serv-
15 ices, to serve as the chair of the Com-
16 mittee;

17 “(II) the Assistant Secretary for
18 Planning and Evaluation of the De-
19 partment of Health and Human Serv-
20 ices;

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

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

4 “(V) 1 representative of the Of-
5 fice for Civil Rights of the Depart-
6 ment of Health and Human Services
7 with expertise in data privacy and se-
8 curity;

9 “(VI) 1 representative of the Na-
10 tional Center for Health Statistics;

11 “(VII) 1 representative of an em-
12 ployer that sponsors a group health
13 plan;

14 “(VIII) 1 representative of an
15 employee organization that sponsors a
16 group health plan;

17 “(IX) 1 academic researcher with
18 expertise in health economics or
19 health services research; and

20 “(X) 2 additional members.

21 “(C) DUTIES.—The Committee shall—

22 “(i) assist and advise the Secretary on
23 the management of the contract under sub-
24 section (a);

1 “(ii) assist and advise the entity re-
2 ceiving the contract under subsection (a) in
3 establishing—

4 “(I) the scope and format of the
5 data to be submitted under subsection
6 (d);

7 “(II) the appropriate uses of
8 data by authorized users, including
9 developing standards for the approval
10 of requests by organizations to access
11 and use the data; and

12 “(III) the appropriate formats
13 and methods for making reports and
14 analyses based on the database to the
15 public;

16 “(iii) make reports, as appropriate, to
17 the Secretary and Congress on the oper-
18 ation of the database and opportunities to
19 better achieve the objectives of this section;
20 and

21 “(iv) establish objectives for research
22 and public reporting.

23 “(4) STATE REQUIREMENTS.—A State may re-
24 quire health insurance issuers and other payers to
25 submit claims data to the database established

1 under this section, provided that such data is sub-
2 mitted in a form and manner established by the Sec-
3 retary, and pursuant to subsection (d)(4)(B).

4 “(c) CONTRACT REQUIREMENTS.—

5 “(1) COMPETITIVE PROCEDURES.—The Sec-
6 retary shall enter into the contract under subsection
7 (a) using full and open competition procedures pur-
8 suant to chapter 33 of title 41, United States Code.

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

12 “(A) be a private nonprofit entity governed
13 by a board that includes representatives of the
14 academic research community and individuals
15 with expertise in employer-sponsored insurance,
16 research using health care claims data and ac-
17 tuarial analysis;

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

21 “(C) hold an active certification as a quali-
22 fied entity under section 1874(e) of the Social
23 Security Act (or any successor program).

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

4 “(A) health care claims data collection, ag-
5 gregation, quality assurance, analysis, and secu-
6 rity;

7 “(B) supporting academic research on
8 health costs, spending, and utilization for and
9 by privately insured patients;

10 “(C) working with large health insurance
11 issuers and third-party administrators to as-
12 semble a national claims database;

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

15 “(E) meeting budgets and timelines, in-
16 cluding in connection with report generation;
17 and

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

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

24 “(5) TRANSITION OF CONTRACT.—If the Sec-
25 retary, following a competitive process at the end of

1 the contract period, selects a new entity to maintain
2 the database, all data shall be transferred to the new
3 entity according to a schedule and process to be de-
4 termined by the Secretary. Upon termination of a
5 contract, no entity may keep data held by the data-
6 base or disclose such data to any entity other than
7 the entity so designated by the Secretary. The Sec-
8 retary shall include enforcement terms in any con-
9 tract with an organization chosen under this section,
10 to ensure the timely transfer of all data to a new en-
11 tity in the event of contract termination.

12 “(d) RECEIVING HEALTH INFORMATION.—

13 “(1) REQUIREMENTS.—

14 “(A) IN GENERAL.—An applicable self-in-
15 sured group health plan shall, through its
16 health insurance issuer, third-party adminis-
17 trator, pharmacy benefit manager, or other en-
18 tity designated by the group health plan, elec-
19 tronically submit all claims data required pur-
20 suant to subparagraph (B) with respect to the
21 plan.

22 “(B) SCOPE OF INFORMATION AND FOR-
23 MAT OF SUBMISSION.—The entity awarded the
24 contract under subsection (a), in consultation
25 with the Committee described in subsection

1 (b)(3), and pursuant to the privacy and security
2 requirements of subsection (b)(2), shall speci-
3 fy—

4 “(i) the data elements required to be
5 submitted under subparagraph (A), which
6 shall include all data related to trans-
7 actions described in subparagraphs (A)
8 and (E) of section 1173(a)(2) of the Social
9 Security Act, including all data elements
10 normally present in such transactions when
11 adjudicated, and enrollment information;
12 and

13 “(ii) the form and manner for such
14 submissions, including the frequency of
15 such submissions.

16 “(C) DE-IDENTIFICATION OF DATA.—The
17 entity awarded the contract under subsection
18 (a) shall—

19 “(i) establish a process under which
20 data is de-identified in accordance with
21 section 164.514(a) of title 45, Code of
22 Federal Regulations (or any successor reg-
23 ulations), while retaining the ability to link
24 data longitudinally for the purposes of re-
25 search on cost and quality, and the ability

1 to complete risk adjustment and geo-
2 graphic analysis;

3 “(ii) ensure that any third-party sub-
4 contractors who perform the de-identifica-
5 tion process described in clause (i) retain
6 the minimum necessary information to per-
7 form such a process, and adhere to effec-
8 tive security and encryption practices in
9 data storage and transmission;

10 “(iii) store claims and other data col-
11 lected under this subsection only in de-
12 identified form, in accordance with section
13 164.514(a) of title 45, Code of Federal
14 Regulations (or any successor regulations);
15 and

16 “(iv) ensure that data is encrypted, in
17 accordance with the regulations promul-
18 gated under section 264(c) of the Health
19 Insurance Portability and Accountability
20 Act of 1996.

21 “(2) APPLICABLE SELF-INSURED GROUP
22 HEALTH PLAN.—For purposes of paragraph (1), a
23 self-insured group health plan is an applicable self-
24 insured group health plan if such plan is self-admin-
25 istered, or is administered by a health insurance

1 issuer or third-party administrator that meets 1 or
2 both of the following criteria:

3 “(A) Administers health benefits for more
4 than 50,000 enrollees.

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

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

19 “(4) RECEIVING OTHER INFORMATION.—

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

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

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

10 “(e) USES OF INFORMATION.—

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

17 “(2) AUTHORIZATION OF USERS.—

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

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

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

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

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

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

18 “(C) REQUIREMENTS.—

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

1 sure of protected health information and
2 proprietary financial information.

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.

25 “(f) FUNDING.—

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

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

12 “(g) ANNUAL REPORT.—

13 “(1) SUBMISSION.—Not later than March 1,
14 2021, and March 1 of each year thereafter, the enti-
15 ty receiving the contract under subsection (a) shall
16 submit to Congress, the Secretary of Labor, and the
17 Secretary of Health and Human Services, and pub-
18 lish online for access by the general public, a report
19 containing a description of—

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

24 “(B) progress towards the objectives of
25 this section; and

1 “(C) the performance by the entity of the
2 duties required under such contract.

3 “(2) PUBLIC REPORTS AND RESEARCH.—The
4 entity receiving a contract under subsection (a)
5 shall, in coordination with authorized users, make
6 analyses and research available to the public on an
7 ongoing basis to promote the objectives of this sec-
8 tion.

9 “(h) GRANTS TO STATES.—

10 “(1) IN GENERAL.—The Secretary, in consulta-
11 tion with the Secretary of Health and Human Serv-
12 ices, may award grants to States for the purpose of
13 establishing and maintaining State all-payer claims
14 databases that improve transparency of data in
15 order to meet the goals of subsection (a)(1).

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

21 “(3) FUNDING.—There is authorized to be ap-
22 propriated \$100,000,000 for the period of fiscal
23 years 2020 through 2029 for purposes of carrying
24 out the grant program under this subsection.

25 “(i) EXEMPTION FROM PUBLIC DISCLOSURE.—

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

5 “(2) RESTRICTIONS ON USES FOR CERTAIN
6 PROCEEDINGS.—Data disclosed to authorized users
7 shall not be subject to discovery or admission as
8 public information, or evidence in judicial or admin-
9 istrative proceedings without consent of the affected
10 parties.

11 “(j) DEFINITIONS.—

12 “(1) PROTECTED HEALTH INFORMATION.—The
13 term ‘protected health information’ has the meaning
14 given such term in section 160.103 of title 45, Code
15 of Federal Regulations (or any successor regula-
16 tions).

17 “(2) PROPRIETARY FINANCIAL INFORMATION.—
18 The term ‘proprietary financial information’ means
19 data that would disclose the terms of a specific con-
20 tract between an individual health care provider or
21 facility and a specific group health plan, Medicaid
22 managed care organization or other managed care
23 entity, or health insurance issuer offering group or
24 individual coverage.

1 “(k) RULE OF CONSTRUCTION.—Nothing in this sec-
2 tion shall be construed to affect or modify enforcement
3 of the privacy, security, or breach notification rules pro-
4 mulgated under section 264(c) of the Health Insurance
5 Portability and Accountability Act of 1996 (or successor
6 regulations).”.

7 (b) GAO REPORT.—

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

10 (A) the performance of the entity awarded
11 a contract under section 735(a) of the Em-
12 ployee Retirement Income Security Act of 1974,
13 as added by subsection (a), under such con-
14 tract;

15 (B) the privacy and security of the infor-
16 mation reported to the entity; and

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

19 (2) REPORTS.—Not later than 2 years after the
20 effective date of the first contract entered into under
21 section 735(a) of the Employee Retirement Income
22 Security Act of 1974, as added by subsection (a),
23 and again not later than 4 years after such effective
24 date, the Comptroller General of the United States
25 shall submit to Congress a report containing the re-

1 sults of the study conducted under paragraph (1),
 2 together with recommendations for such legislation
 3 and administrative action as the Comptroller Gen-
 4 eral determines appropriate.

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

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

9 **SEC. 304. PROTECTING PATIENTS AND IMPROVING THE AC-**
 10 **CURACY OF PROVIDER DIRECTORY INFOR-**
 11 **MATION.**

12 Subpart II of part A of title XXVII of the Public
 13 Health Service Act (42 U.S.C. 300gg-11 et seq.), as
 14 amended by sections 301 and 302, is further amended by
 15 adding at the end the following:

16 **“SEC. 2729C. PROTECTING PATIENTS AND IMPROVING THE**
 17 **ACCURACY OF PROVIDER DIRECTORY INFOR-**
 18 **MATION.**

19 “(a) PATIENT PROTECTIONS.—Beginning on the
 20 date that is one year after the date of enactment of this
 21 section, a group health plan or a health insurance issuer
 22 offering coverage in the individual or group market shall—

1 “(1) establish business processes to ensure that
2 all enrollees in such plan or coverage receive proof
3 of a health care provider’s network status—

4 “(A) through a written electronic commu-
5 nication from the plan or issuer to the enrollee,
6 not later than 24 hours after a telephone in-
7 quiry is made by such enrollee for such infor-
8 mation; and

9 “(B) in real-time through an online health
10 care provider directory search tool maintained
11 by the plan or issuer; and

12 “(2) not apply cost-sharing to an enrollee for
13 treatment or services provided by a health care pro-
14 vider in excess of the normal cost-sharing applied for
15 in-network care (including any balance bill issued by
16 the health care provider involved), if such enrollee,
17 or health care provider referring such enrollee, can
18 demonstrate (based on the electronic information de-
19 scribed in paragraph (1)(A) or a copy of the online
20 provider directory described in paragraph (1)(B) on
21 the date the enrollee attempted to obtain the pro-
22 vider’s network status) that the enrollee relied on
23 the information described in this subsection, regard-
24 less of whether the provider’s network status or di-

1 rectory information is incorrect, at the time the
2 treatment or services involved was provided.

3 “(b) REFUNDS TO ENROLLEES.—If a health care
4 provider submits a bill to an enrollee in violation of sub-
5 section (a)(2), and the enrollee pays such bill, the provider
6 shall reimburse the enrollee for the full amount paid by
7 the enrollee in excess of the in-network cost-sharing
8 amount for the treatment or services involved, plus inter-
9 est, at an interest rate determined by the Secretary.

10 “(c) ENFORCEMENT.—

11 “(1) IN GENERAL.—Subject to paragraph (2), a
12 health care provider that violates a requirement
13 under subsection (a) or (b) shall be subject to a civil
14 monetary penalty of not more than \$10,000 for each
15 act constituting such violation.

16 “(2) SAFE HARBOR.—The Secretary may waive
17 the penalty described under paragraph (1) with re-
18 spect to a health care provider that unknowingly vio-
19 lates subsection (a) with respect to an enrollee if
20 such provider rescinds the bill involved and, if appli-
21 cable, reimburses the enrollee within 30 days of the
22 date on which the provider billed the enrollee in vio-
23 lation of such subsection.

24 “(3) PROCEDURE.—The provisions of section
25 1128A of the Social Security Act, other than sub-

1 sections (a) and (b) and the first sentence of sub-
2 section (c)(1), shall apply to civil money penalties
3 under this subsection in the same manner as such
4 provisions apply to a penalty or proceeding under
5 section 1128A of the Social Security Act.

6 “(d) BUSINESS PROCESSES.—Beginning on the date
7 that is one year after the date of enactment of this section,
8 a group health plan or a health insurance issuer offering
9 coverage in the individual or group market shall establish
10 business processes to—

11 “(1) verify and update, at least once every 90
12 days, an online, core set of health care provider di-
13 rectory information (as defined in subsection (e)) for
14 all network providers; and

15 “(2) remove network providers from the online
16 directory described in paragraph (1) if such pro-
17 viders have not verified the directory information
18 within the previous 6 months.

19 “(e) PROVIDER DIRECTORY INFORMATION DE-
20 FINED.—For purposes of this section, the term ‘provider
21 directory information’ shall include the names, addresses,
22 specialty, and telephone numbers of individual health care
23 providers, and the names, addresses, and telephone num-
24 bers of each medical group, clinic, or facility contracted

1 to participate in any of the networks of the group health
2 plan or health insurance issuer involved.

3 “(f) **RULE OF CONSTRUCTION.**—Nothing in this sec-
4 tion shall be construed to preempt or limit any provision
5 of State law relating to health care provider directories
6 or network adequacy.”.

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

8 Part P of title III of the Public Health Service Act
9 (42 U.S.C. 280g et seq.) is amended by adding at the end
10 the following:

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

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

13 “(1) health care facilities and practitioners to
14 provide to patients a list of services rendered during
15 the visit to such facility or practitioner upon dis-
16 charge; and

17 “(2) health care facilities and practitioners to
18 send all bills to the patient within 30 business days.

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

23 “(c) **EFFECT OF VIOLATION.**—

24 “(1) **NOTIFICATION AND REFUND REQUIRE-**
25 **MENTS.**—If a facility or practitioner bills a patient

1 after the 30-business-day period described in sub-
2 section (a)(2), such facility or practitioner shall—

3 “(A) report such bill to the Secretary; and

4 “(B) refund the patient for the full
5 amount paid in response to such bill with inter-
6 est, at a rate determined by the Secretary.

7 “(2) CIVIL MONETARY PENALTIES.—

8 “(A) IN GENERAL.—The Secretary may
9 impose civil monetary penalties of up to
10 \$10,000 a day on any facility or practitioner
11 that submits more than 10 bills outside of the
12 period described in subsection (a)(2), beginning
13 on the date on which such facility or practi-
14 tioner sends the tenth such bill.

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.”.

1 **SEC. 306. HEALTH PLAN OVERSIGHT OF PHARMACY BEN-**
2 **EFIT MANAGER SERVICES.**

3 Subpart II of part A of title XXVII of the Public
4 Health Service Act (42 U.S.C. 300gg–11 et seq.), as
5 amended by section 304, is further amended by adding
6 at the end the following:

7 **“SEC. 2729D. HEALTH PLAN OVERSIGHT OF PHARMACY**
8 **BENEFIT MANAGER SERVICES.**

9 “(a) IN GENERAL.—A group health plan or health
10 insurance issuer offering group or individual health insur-
11 ance coverage or an entity or subsidiary providing phar-
12 macy benefits management services shall not enter into
13 a contract with a drug manufacturer, distributor, whole-
14 saler, subcontractor, rebate aggregator, or any associated
15 third party that limits the disclosure of information to
16 plan sponsors in such a manner that prevents the plan
17 or coverage, or an entity or subsidiary providing pharmacy
18 benefits management services on behalf of a plan or cov-
19 erage from making the reports described in subsection (b).

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

21 “(1) IN GENERAL.—Beginning with the first
22 plan year that begins after the date of enactment of
23 the Lower Health Care Costs Act, not less fre-
24 quently than once per plan quarter, a health insur-
25 ance issuer offering group health insurance coverage
26 or an entity providing pharmacy benefits manage-

1 ment services on behalf of a group health plan shall
2 submit to the plan sponsor (as defined in section
3 3(16)(B) of the Employee Retirement Income Secu-
4 rity Act of 1974) of such group health plan or
5 health insurance coverage a report in accordance
6 with this subsection, in a machine-readable format.
7 Each such report shall include, with respect to the
8 applicable group health plan or health insurance cov-
9 erage—

10 “(A) a description of all formulary tiers
11 and the utilization mechanisms (such as prior
12 authorization or step therapy) employed for
13 each therapeutic class within such tier; and

14 “(B) a list of each covered drug dispensed
15 during the reporting period, including, with re-
16 spect to each such drug during the reporting
17 period—

18 “(i) the brand name, chemical entity,
19 and National Drug Code;

20 “(ii) the number of enrollees for
21 whom the drug was filled during the plan
22 year, the total number of prescription fills
23 for the drug (including original prescrip-
24 tions and refills), and the total number of
25 dosage units of the drug dispensed across

1 the plan year, including whether the dis-
2 pensing channel was by retail, mail order,
3 or specialty pharmacy;

4 “(iii) cost and price information, list-
5 ed as cost per days supply and cost per
6 pill, or in the case of a drug in another
7 form, per dose, on the date of dispensing,
8 including—

9 “(I) the list unit price;

10 “(II) the usual and customary
11 cost; and

12 “(III) the net unit price (after all
13 discounts, rebates, and fees tied to the
14 list price or sales volume of the drug)
15 paid by the plan or coverage;

16 “(iv) amount received from drug man-
17 ufacturers in rebates due to be paid by
18 drug manufacturers for claims incurred
19 during the reporting period, fees, alter-
20 native discounts, and all other remunera-
21 tion received from any third party related
22 to utilization of that drug under such
23 health plan or health insurance coverage;

1 “(v) the total net spending by the
2 health plan or health insurance coverage
3 on the drug;

4 “(vi) total gross spending by the
5 health plan or health insurance coverage
6 on the drug, before rebates and fees;

7 “(vii) the total out-of-pocket spending
8 by enrollees, including copayments, coin-
9 surance, and deductibles that are pending;

10 “(viii) amount paid to the coverage in
11 rebates and fees;

12 “(ix) amounts paid directly or indi-
13 rectly in rebates, fees, or any other type of
14 remuneration to brokers, consultants, advi-
15 sors, or any other individual or firm who
16 referred the group health plan’s or health
17 insurance issuer’s business to the phar-
18 macy benefit manager; and

19 “(x) the total amount of copayment
20 assistance dollars paid, or copayment cards
21 applied, with respect to the drug that were
22 funded by the drug manufacturer or other
23 nongovernmental entities to reduce an en-
24 rollee’s cost-sharing amount with respect
25 to the drug;

1 “(C) for any drug on which the plan or
2 issuer, with respect to the applicable health in-
3 surance coverage, spent more than \$1,000 dur-
4 ing the reporting period—

5 “(i) a list of all other drugs, including
6 brand name drugs and biological products
7 and the generic drugs or biosimilar biologi-
8 cal products that are in the same thera-
9 peutic category or class of such brand
10 name drugs or biological products;

11 “(ii) the formulary tier and utilization
12 mechanism for each such potential sub-
13 stitute drug; and

14 “(iii) the list price on the date of dis-
15 pensing for each such potential substitute
16 drug, as reported in publically-available
17 databases; and

18 “(D) the total net spending on prescription
19 drugs by the health plan or health insurance
20 coverage;

21 “(E) the total gross spending on prescrip-
22 tion drugs, before rebates and fees, by the
23 health plan or health insurance coverage; and

24 “(F) for a therapeutic class with more
25 than one drug, the net spending and gross

1 spending, before rebates and fees, on drugs in
2 such class.

3 “(2) PRIVACY REQUIREMENTS.—Health insur-
4 ance issuers offering group health insurance cov-
5 erage and entities providing pharmacy benefits man-
6 agement services on behalf of a group health plan
7 shall provide information under paragraph (1) in a
8 manner consistent with the privacy, security, and
9 breach notification regulations promulgated under
10 section 264(c) of the Health Insurance Portability
11 and Accountability Act of 1996 (or successor regula-
12 tions), and shall restrict the use and disclosure of
13 such information according to such privacy regula-
14 tions.

15 “(3) DISCLOSURE AND REDISCLOSURE.—

16 “(A) LIMITATION TO BUSINESS ASSOCI-
17 ATES.—A group health plan receiving a report
18 under paragraph (1) may disclose such informa-
19 tion only to business associates of such plan as
20 defined in section 160.103 of title 45, Code of
21 Federal Regulations (or successor regulations).

22 “(B) CLARIFICATION REGARDING PUBLIC
23 DISCLOSURE OF INFORMATION.—Nothing in
24 this section prevents a health insurance issuer
25 offering group health insurance coverage or an

1 entity providing pharmacy benefits management
2 services on behalf of a group health plan from
3 placing reasonable restrictions on the public dis-
4 closure of the information contained in a report
5 described in paragraph (1).

6 “(c) LIMITATIONS ON SPREAD PRICING.—

7 “(1) IN GENERAL.—A group health plan, a
8 health insurance issuer offering group or individual
9 health insurance coverage, or an entity providing
10 pharmacy benefits management services under such
11 health plan or health insurance coverage may not
12 charge the group health plan, health insurance
13 issuer, or enrollee a price for a prescription drug dis-
14 pensed to an enrollee that exceeds the actual price
15 paid by the group health plan or health insurance
16 issuer to the pharmacy for the drug, including
17 amounts paid by such plan, coverage, or entity and
18 cost-sharing amounts paid directly by the enrollee,
19 and excluding penalties paid by pharmacies to such
20 plan, coverage, or entity.

21 “(2) LIMITATIONS ON SPREAD PRICING.—The
22 price charged to a group health plan or health insur-
23 ance issuer offering group or individual health insur-
24 ance coverage for a prescription drug that is dis-
25 pensed by a pharmacy that is wholly owned by the

1 group health plan, health insurance issuer, or the
2 prescription benefits manager or other pharmacy
3 benefits administrator of such plan or coverage, to
4 an enrollee in the plan or coverage may not exceed
5 the lesser of—

6 “(A) the wholesale acquisition cost of the
7 drug paid by the pharmacy, plus clearly docu-
8 mented dispensing costs, including pharmacy
9 profit; or

10 “(B) the price charged to the group health
11 plan or health insurance issuer when the same
12 drug is dispensed by another similarly-situated
13 pharmacy not wholly owned by the group health
14 plan, health insurance issuer, or the prescrip-
15 tion benefits manager or other pharmacy bene-
16 fits administrator of such plan or coverage.

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

18 “(1) IN GENERAL.—A pharmacy benefits man-
19 ager, a third-party administrator of a group health
20 plan, a health insurance issuer offering group health
21 insurance coverage, or an entity providing pharmacy
22 benefits management services under such health
23 plan or health insurance coverage shall remit 100
24 percent of rebates, fees, alternative discounts, and
25 all other remuneration received from a pharma-

1 ceutical manufacturer, distributor or any other third
2 party, that are related to utilization of drugs under
3 such health plan or health insurance coverage, to the
4 group health plan.

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

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

13 “(B) fully disclosed and enumerated to the
14 group health plan sponsor, as described in
15 (b)(2)(D); and

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

19 “(e) ENFORCEMENT.—

20 “(1) FAILURE TO PROVIDE TIMELY INFORMA-
21 TION.—A group health plan, a health insurance
22 issuer offering group health insurance coverage, or
23 an entity providing pharmacy benefit management
24 services that violates subsection (a), fails to provide
25 information required under subsection (b), engages

1 in spread pricing as defined in subsection (c), or
2 fails to comply with the requirements of subsection
3 (d) in a timely manner shall be subject to a civil
4 monetary penalty in the amount of \$10,000 for each
5 day during which such violation continues or such
6 information is not disclosed or reported.

7 “(2) FALSE INFORMATION.—An entity pro-
8 viding pharmacy benefit management services that
9 knowingly provides false information under this sec-
10 tion shall be subject to a civil money penalty in an
11 amount not to exceed \$100,000 for each item of
12 false information. Such civil money penalty shall be
13 in addition to other penalties as may be prescribed
14 by law.

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

23 “(f) DEFINITIONS.—In this section—

24 “(1) the term ‘similarly situated pharmacy’
25 means, with respect to a particular pharmacy, an-

1 other pharmacy that is approximately the same size
2 (as measured by the number of prescription drugs
3 dispensed), and that serves patients in the same geo-
4 graphical area, whether through physical locations or
5 mail order; and

6 “(2) the term ‘wholesale acquisition cost’ has
7 the meaning given such term in
8 section b1847A(c)(6)(B) of the Social Security Act.”.

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

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

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

19 (A) involve one or more—

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

1 (ii) laboratory, radiology, or pharmacy
2 services that are delivered to privately in-
3 sured patients of such hospital;

4 (iii) surgical services; or

5 (iv) rehabilitation or physical therapy
6 facilities or services; and

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

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

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

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

1 mittee on Energy and Commerce of the House of Rep-
2 resentatives.

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

8 (a) GROUP HEALTH PLANS.—Section 408(b)(2) of
9 the Employee Retirement Income Security Act of 1974
10 (29 U.S.C. 1108(b)(2)) is amended—

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

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

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

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

23 “(bb) The term ‘covered service provider’
24 means a service provider that enters into a con-
25 tract or arrangement with the covered plan and

1 reasonably expects \$1,000 (or such amount as
2 the Secretary may establish in regulations to
3 account for inflation since the date of enact-
4 ment of the Lower Health Care Costs Act, as
5 appropriate) or more in compensation, direct or
6 indirect, to be received in connection with pro-
7 viding one or more of the following services,
8 pursuant to the contract or arrangement, re-
9 gardless of whether such services will be per-
10 formed, or such compensation received, by the
11 covered service provider, an affiliate, or a sub-
12 contractor:

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

1 nization preferred vendor panels, disease
2 management vendors and products, compli-
3 ance services, employee assistance pro-
4 grams, or third party administration serv-
5 ices.

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

1 “(cc) The term ‘affiliate’, with respect to a
2 covered service provider, means an entity that
3 directly or indirectly (through one or more
4 intermediaries) controls, is controlled by, or is
5 under common control with, such provider, or is
6 an officer, director, or employee of, or partner
7 in, such provider.

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

17 “(BB) The term ‘direct compensation’
18 means compensation received directly from a
19 covered plan.

20 “(CC) The term ‘indirect compensation’
21 means compensation received from any source
22 other than the covered plan, the plan sponsor,
23 the covered service provider, or an affiliate.
24 Compensation received from a subcontractor is
25 indirect compensation, unless it is received in

1 connection with services performed under a con-
2 tract or arrangement with a subcontractor.

3 “(ee) The term ‘responsible plan fiduciary’
4 means a fiduciary with authority to cause the
5 covered plan to enter into, or extend or renew,
6 the contract or arrangement.

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

20 “(II) For purposes of this subparagraph, a de-
21 scription of compensation or cost may be expressed
22 as a monetary amount, formula, or a per capita
23 charge for each participant or beneficiary or, if the
24 compensation or cost cannot reasonably be expressed
25 in such terms, by any other reasonable method. The

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

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

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

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

22 “(II) If applicable, a statement that the
23 covered service provider, an affiliate, or a sub-
24 contractor will provide, or reasonably expects to
25 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 clause
17 (iii) and (iv) as soon as practicable, but not later
18 than 60 days from the date on which the covered
19 service provider is informed of such change, unless
20 such disclosure is precluded due to extraordinary cir-
21 cumstances beyond the covered service provider’s
22 control, in which case the information shall be dis-
23 closed 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, notwith-
6 standing any failure by a covered service provider to
7 disclose information required under clause (iii), if
8 the 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 re-
2 fusals to furnish the information requested by
3 the written request described in subclause
4 (I)(bb); 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/as in effect on the date of enact-
4 ment of this Act), with respect to any applicable entity
5 other than a covered plan or a covered service provider
6 (as defined in section 408(b)(2)(B)(ii) of the Employee
7 Retirement Income Security Act of 1974, as amended by
8 subsection (a)).

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

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

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

22 “(b) DISCLOSURE.—A health insurance issuer de-
23 scribed in subsection (a) shall disclose to an enrollee the
24 amount of direct or indirect compensation provided to an
25 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. 2729E. PROVISION OF COST-SHARING INFORMATION.**

14 “(a) PROVIDER DISCLOSURES.—A group health plan
15 or a health insurance issuer offering group or individual
16 health insurance coverage shall not contract with a pro-
17 vider with respect to the plan or coverage unless the pro-
18 vider agrees to provide, at the time of scheduling a service
19 or not later than 48 hours of the enrollee requesting such
20 information, an enrollee in the plan or coverage with the
21 expected enrollee cost-sharing for the provision of a par-
22 ticular health care service (including any service that is
23 reasonably expected to be provided in conjunction with
24 such specific service).

1 **“SEC. 313. PUBLIC AWARENESS CAMPAIGN ON THE IMPOR-**
2 **TANCE OF VACCINATIONS.**

3 “(a) IN GENERAL.—The Secretary, acting through
4 the Director of the Centers for Disease Control and Pre-
5 vention and in coordination with other offices and agen-
6 cies, as appropriate, shall award competitive grants to one
7 or more public or private entities to carry out a national,
8 evidence-based campaign to increase awareness of vaccines
9 for the prevention and control of diseases, combat misin-
10 formation about vaccines, and disseminate scientific and
11 evidence-based vaccine-related information, with the goal
12 of increasing rates of vaccination across all ages, as appli-
13 cable, particularly in communities with low rates of vac-
14 cination.

15 “(b) CONSULTATION.—In carrying out the campaign
16 under this section, the Secretary shall consult with appro-
17 priate public health and medical experts, including the Na-
18 tional Academy of Medicine and medical and public health
19 associations and nonprofit organizations, in the develop-
20 ment, implementation, and evaluation of the evidence-
21 based public awareness campaign.

22 “(c) REQUIREMENTS.—The campaign under this sec-
23 tion—

24 “(1) shall be a national, evidence-based initia-
25 tive;

1 “(2) may include the use of television, radio,
2 the internet, and other telecommunications tech-
3 nologies;

4 “(3) may be focused to address specific needs
5 of communities with low rates of vaccination;

6 “(4) shall include the development of resources
7 for communities with low rates of vaccination, in-
8 cluding culturally- and linguistically-appropriate re-
9 sources, as applicable;

10 “(5) shall include the dissemination of vaccine
11 information and communication resources to health
12 care providers and health care facilities, including
13 such providers and facilities that provide prenatal
14 and pediatric care;

15 “(6) shall be complementary to, and coordi-
16 nated with, any other Federal efforts and State ef-
17 forts, as appropriate;

18 “(7) shall assess the effectiveness of commu-
19 nication strategies to increase rates of vaccination;
20 and

21 “(8) may include the dissemination of scientific
22 and evidence-based vaccine-related information, such
23 as—

1 “(A) advancements in evidence-based re-
2 search related to diseases that may be pre-
3 vented by vaccines and vaccine development;

4 “(B) information on vaccinations for indi-
5 viduals and communities, including individuals
6 for whom vaccines are not recommended by the
7 Advisory Committee for Immunization Prac-
8 tices, and the effects of low vaccination rates
9 within a community on such individuals;

10 “(C) information on diseases that may be
11 prevented by vaccines; and

12 “(D) information on vaccine safety and the
13 systems in place to monitor vaccine safety.

14 “(d) EVALUATION.—The Secretary shall—

15 “(1) establish benchmarks and metrics to quan-
16 titatively measure and evaluate the awareness cam-
17 paign under this section;

18 “(2) conduct qualitative assessments regarding
19 the awareness campaign under this section; and

20 “(3) prepare and submit to the Committee on
21 Health, Education, Labor, and Pensions of the Sen-
22 ate and Committee on Energy and Commerce of the
23 House of Representatives an evaluation of the
24 awareness campaign under this section.

1 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated to carry out this section
3 and section 317(k) such sums as may be necessary for
4 fiscal years 2020 through 2024.”.

5 **SEC. 402. GRANTS TO ADDRESS VACCINE-PREVENTABLE**
6 **DISEASES.**

7 Section 317(k)(1) of the Public Health Service Act
8 (42 U.S.C. 247b(k)(1)) is amended—

9 (1) in subparagraph (C), by striking “; and”
10 and inserting a semicolon;

11 (2) in subparagraph (D), by striking the period
12 and inserting a semicolon; and

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

14 “(E) planning, implementation, and evaluation
15 of activities to address vaccine-preventable diseases,
16 including activities to—

17 “(i) identify communities at high risk of
18 outbreaks related to vaccine-preventable dis-
19 eases;

20 “(ii) pilot innovative approaches to improve
21 vaccination rates in communities with low rates
22 of vaccination;

23 “(iii) reduce barriers to accessing vaccines
24 and evidence-based information about the
25 health effects of vaccines;

1 “(iv) partner with community organiza-
2 tions and health care providers to develop and
3 deliver evidence-based interventions to increase
4 vaccination rates; and

5 “(v) improve delivery of evidence-based
6 vaccine-related information to parents and oth-
7 ers; and

8 “(F) research related to strategies for improv-
9 ing awareness of scientific and evidence-based vac-
10 cine-related information, including for communities
11 with low rates of vaccination, in order to understand
12 barriers to vaccination, improve vaccination rates,
13 and assess the public health outcomes of such strate-
14 gies.”.

15 **SEC. 403. GUIDE ON EVIDENCE-BASED STRATEGIES FOR**
16 **STATE HEALTH DEPARTMENT OBESITY PRE-**
17 **VENTION PROGRAMS.**

18 (a) DEVELOPMENT AND DISSEMINATION OF AN EVI-
19 DENCE-BASED STRATEGIES GUIDE.—The Secretary of
20 Health and Human Services (referred to in this section
21 as the “Secretary”), acting through the Director of the
22 Centers for Disease Control and Prevention, not later than
23 2 years after the date of enactment of this Act, shall—

24 (1) develop a guide on evidence-based strategies
25 for State and local health departments, Indian

1 Tribes, and Tribal organizations to use to build and
2 maintain effective obesity prevention and control
3 programs, which shall—

4 (A) describe an integrated program struc-
5 ture for implementing interventions proven to
6 be effective in preventing, controlling, and re-
7 ducing obesity; and

8 (B) recommend—

9 (i) optimal resources, including staff-
10 ing and infrastructure, for promoting nu-
11 trition and obesity prevention, control and
12 reduction; 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 practices to prevent, control,
20 and reduce obesity rates;

21 (II) demonstrated knowledge of
22 obesity prevention practices that re-
23 duce associated preventable diseases,
24 health conditions, death, and health
25 care costs; and

1 (III) interdisciplinary coordina-
2 tion between relevant public health of-
3 ficials specializing in fields such as
4 nutrition, physical activity, epidemi-
5 ology, communications, and policy im-
6 plementation; and

7 (2) disseminate the guide and current research,
8 evidence-based practices, tools, and educational ma-
9 terials related to obesity prevention, consistent with
10 the guide, to State and local health departments, In-
11 dian Tribes, and Tribal organizations.

12 (b) TECHNICAL ASSISTANCE.—The Secretary, acting
13 through the Director of the Centers for Disease Control
14 and Prevention, shall provide technical assistance to State
15 and local health departments, Indian Tribes, and Tribal
16 organizations to support such health departments in im-
17 plementing the guide developed under subsection (a)(1).

18 (c) INDIAN TRIBES; TRIBAL ORGANIZATIONS.—The
19 terms “Indian Tribe” and “Tribal organization” have the
20 meanings given the terms “Indian tribe” and “tribal orga-
21 nization”, respectively, in section 4 of the Indian Self-De-
22 termination and Education Assistance Act (25 U.S.C.
23 5304).

1 **SEC. 404. EXPANDING CAPACITY FOR HEALTH OUTCOMES.**

2 Title III of the Public Health Service Act is amended
3 by inserting after section 330M (42 U.S.C. 254c-19) the
4 following:

5 **“SEC. 330N. EXPANDING CAPACITY FOR HEALTH OUT-**
6 **COMES.**

7 “(a) DEFINITIONS.—In this section:

8 “(1) ELIGIBLE ENTITY.—The term ‘eligible en-
9 tity’ means an entity providing health care services
10 in rural areas, frontier areas, health professional
11 shortage areas, or medically underserved areas, or to
12 medically underserved populations or Native Ameri-
13 cans, including Indian tribes or tribal organizations.

14 “(2) HEALTH PROFESSIONAL SHORTAGE
15 AREA.—The term ‘health professional shortage area’
16 means a health professional shortage area des-
17 ignated under section 332.

18 “(3) INDIAN TRIBE.—The terms ‘Indian tribe’
19 and ‘tribal organization’ have the meanings given
20 such terms in section 4 of the Indian Self-Deter-
21 mination and Education Assistance Act.

22 “(4) MEDICALLY UNDERSERVED POPU-
23 LATION.—The term ‘medically underserved popu-
24 lation’ has the meaning given the term in section
25 330(b)(3).

1 “(5) NATIVE AMERICANS.—The term ‘Native
2 Americans’ has the meaning given such term in sec-
3 tion 736 and includes Indian tribes and tribal orga-
4 nizations.

5 “(6) TECHNOLOGY-ENABLED COLLABORATIVE
6 LEARNING AND CAPACITY BUILDING MODEL.—The
7 term ‘technology-enabled collaborative learning and
8 capacity building model’ means a distance health
9 education model that connects specialists with mul-
10 tiple other health care professionals through simulta-
11 neous interactive videoconferencing for the purpose
12 of facilitating case-based learning, disseminating
13 best practices, and evaluating outcomes.

14 “(b) PROGRAM ESTABLISHED.—The Secretary shall,
15 as appropriate, award grants to evaluate, develop, and, as
16 appropriate, expand the use of technology-enabled collabo-
17 rative learning and capacity building models, to increase
18 access to health care services, such as those to address
19 chronic diseases and conditions, mental health, substance
20 use disorders, prenatal and maternal health, pediatric
21 care, pain management, palliative care, and other specialty
22 care in medically underserved areas and for medically un-
23 derserved populations.

24 “(c) USE OF FUNDS.—Grants awarded under sub-
25 section (b) shall, as appropriate, be used for—

1 “(1) equipment to support the use and expan-
2 sion of technology-enabled collaborative learning and
3 capacity building models, including for hardware and
4 software that enables distance learning, health care
5 provider support, and the secure exchange of elec-
6 tronic health information;

7 “(2) support for health care providers and other
8 professionals that provide or assist in the provision
9 of services through such models;

10 “(3) the development and acquisition of instruc-
11 tional programming, and the training of health care
12 providers and other professionals that provide or as-
13 sist in the provision of services through such models;

14 “(4) information collection and evaluation ac-
15 tivities to study the impact of such models on pa-
16 tient outcomes and health care providers, and to
17 identify best practices for the expansion and use of
18 such models; and

19 “(5) other activities consistent with achieving
20 the objectives of the grants awarded under this sec-
21 tion, as determined by the Secretary.

22 “(d) LENGTH OF GRANTS.—Grants awarded under
23 subsection (b) shall be for a period of up to 5 years.

24 “(e) APPLICATION.—An eligible entity that seeks to
25 receive a grant under subsection (b) shall submit to the

1 Secretary an application, at such time, in such manner,
2 and containing such information as the Secretary may re-
3 quire. Such application criteria shall include an evaluation
4 of patient outcomes and health care providers resulting
5 from technology-enabled collaborative learning and capac-
6 ity building models.

7 “(f) TECHNICAL ASSISTANCE.—The Secretary shall
8 provide (either directly through the Department of Health
9 and Human Services or by contract) technical assistance
10 to eligible entities, including recipients of grants under
11 subsection (b), on the development, use, and evaluation
12 of technology-enabled collaborative learning and capacity
13 building models in order to expand access to health care
14 services provided by such entities, including for medically
15 underserved areas and to medically underserved popu-
16 lations.

17 “(g) REPORT BY SECRETARY.—Not later than 4
18 years after the date of enactment of this section, the Sec-
19 retary shall prepare and submit to the Committee on
20 Health, Education, Labor, and Pensions of the Senate and
21 the Committee on Energy and Commerce of the House
22 of Representatives, and post on the Internet website of
23 the Department of Health and Human Services, a report
24 including, at minimum—

1 “(1) a description of any new and continuing
2 grants awarded to entities under subsection (b) and
3 the specific purpose and amounts of such grants;

4 “(2) an overview of—

5 “(A) the evaluations conducted under sub-
6 sections (b) or (f); and

7 “(B) technical assistance provided under
8 subsection (f); and

9 “(3) a description of any significant findings or
10 developments in patient outcomes and health care
11 providers and best practices for eligible entities ex-
12 panding, using, or evaluating technology-enabled col-
13 laborative learning and capacity building models.

14 “(h) AUTHORIZATION OF APPROPRIATIONS.—There
15 is authorized to be appropriated to carry out this section,
16 such sums as may be necessary for each of fiscal years
17 2020 through 2024.”.

18 **SEC. 405. PUBLIC HEALTH DATA SYSTEM MODERNIZATION.**

19 Subtitle C of title XXVIII of the Public Health Serv-
20 ice Act (42 U.S.C. 300hh–31 et seq.) is amended by add-
21 ing at the end the following:

1 **“SEC. 2822. PUBLIC HEALTH DATA SYSTEM MODERNIZA-**
2 **TION GRANTS.**

3 “(a) IN GENERAL.—The Secretary, acting through
4 the Director of the Centers for Disease Control and Pre-
5 vention, shall—

6 “(1) award grants to State, local, Tribal, and
7 territorial public health departments for the expan-
8 sion and modernization of public health data sys-
9 tems, to assist public health departments in—

10 “(A) improving secure public health data
11 collection, transmission, exchange, maintenance,
12 and analysis;

13 “(B) simplifying reporting by health care
14 providers, as applicable, pursuant to State law,
15 including through the use of health information
16 technology, to State, local, Tribal, and terri-
17 torial public health departments, including pub-
18 lic health officials in multiple jurisdictions with-
19 in such State, as appropriate;

20 “(C) enhancing interoperability of current
21 public health data systems with health informa-
22 tion technology, including certified health infor-
23 mation technology;

24 “(D) supporting earlier disease and health
25 condition detection for public health responses;
26 and

1 “(E) supporting activities within the appli-
2 cable jurisdiction related to the expansion and
3 modernization of electronic case reporting;

4 “(2) conduct activities related to the interoper-
5 ability and improvement of applicable public health
6 data systems used by the Centers for Disease Con-
7 trol and Prevention, as appropriate; and

8 “(3) develop and utilize public-private partner-
9 ships for technical assistance and related implemen-
10 tation support for State, local, Tribal, and territorial
11 public health departments, and the Centers for Dis-
12 ease Control and Prevention, on the expansion and
13 modernization of electronic case reporting and public
14 health data systems, as applicable.

15 “(b) REQUIREMENTS.—

16 “(1) IN GENERAL.—The Secretary may not
17 award a grant under subsection (a)(1) unless the ap-
18 plicant supports standards endorsed by the National
19 Coordinator for Health Information Technology pur-
20 suant to section 3001(c)(1) or adopted by the Sec-
21 retary under section 3004.

22 “(2) WAIVER.—The Secretary may waive the
23 requirement under paragraph (1) with respect to an
24 applicant if the Secretary determines that the activi-

1 ties under subsection (a) cannot otherwise be carried
2 out within the applicable jurisdiction.

3 “(c) USE OF FUNDS.—An entity receiving a grant
4 under this section may use amounts received under such
5 grant for one or both of the following:

6 “(1) Carrying out activities described in sub-
7 section (a)(1) to support public health data systems
8 (including electronic case reporting), which may in-
9 clude support for, and training of, professionals with
10 expertise in contributing to and using such systems.

11 “(2) Developing and disseminating information
12 related to the use and importance of public health
13 data.

14 “(d) STRATEGY AND IMPLEMENTATION PLAN.—Not
15 later than 180 days after the date of enactment of the
16 Lower Health Care Costs Act, the Secretary, acting
17 through the Director of the Centers for Disease Control
18 and Prevention, shall submit to the Committee on Health,
19 Education, Labor, and Pensions of the Senate and the
20 Committee on Energy and Commerce of the House of
21 Representatives, a coordinated strategy and an accom-
22 panying implementation plan that identifies and dem-
23 onstrates the steps the Secretary will carry out to—

1 “(1) update and improve applicable public
2 health data systems used by the Centers for Disease
3 Control and Prevention; and

4 “(2) carry out the activities described in this
5 section to support the improvement of State, local,
6 Tribal, and territorial public health data systems.

7 “(e) CONSULTATION.—The Secretary, acting through
8 the Director of the Centers for Disease Control and Pre-
9 vention, shall consult with State, local, Tribal, and terri-
10 torial health departments, professional medical and public
11 health associations, health information technology experts,
12 and other appropriate entities regarding the plan and
13 grant program to modernize public health data systems
14 pursuant to this section. Such activities may include the
15 provision of technical assistance related to the exchange
16 of information by such public health data systems used
17 by relevant health care and public health entities at the
18 local, State, Federal, Tribal, and territorial levels.

19 “(f) REPORT TO CONGRESS.—Not later than 1 year
20 after the date of enactment of this section, the Secretary
21 shall submit a report to the Committee on Health, Edu-
22 cation, Labor, and Pensions of the Senate and the Com-
23 mittee on Energy and Commerce of the House of Rep-
24 resentatives that includes—

25 “(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 eliminate preventable maternal mortality and
9 severe maternal morbidity, which may include—

10 (A) information on evidence-based prac-
11 tices to improve the quality and safety of ma-
12 ternity care in hospitals and other health care
13 settings of a State or health care system, in-
14 cluding by addressing topics commonly associ-
15 ated with health complications or risks related
16 to prenatal care, labor care, birthing, and
17 postpartum care;

18 (B) best practices for improving maternity
19 care based on data findings and reviews con-
20 ducted by a State maternal mortality review
21 committee that address topics of relevance to
22 common complications or health risks related to
23 prenatal care, labor care, birthing, and
24 postpartum care;

1 (2) collaborating with State maternal mortality
2 review committees to identify issues for the develop-
3 ment and implementation of evidence-based practices
4 to improve maternal health outcomes and reduce
5 preventable maternal mortality and severe maternal
6 morbidity; and

7 (3) providing technical assistance and sup-
8 porting the implementation of best practices identi-
9 fied in paragraph (1) to entities providing health
10 care services to pregnant and postpartum women.

11 (b) ELIGIBLE ENTITIES.—To be eligible for a grant
12 under subsection (a), an entity shall—

13 (1) submit to the Secretary an application at
14 such time, in such manner, and containing such in-
15 formation as the Secretary may require; and

16 (2) demonstrate in such application that the en-
17 tity has a demonstrated expertise in data-driven ma-
18 ternal safety and quality improvement initiatives in
19 the areas of obstetrics and gynecology or maternal
20 health.

21 (c) AUTHORIZATION OF APPROPRIATIONS.—To carry
22 out this section, there is authorized to be appropriated
23 such sums as may be necessary for each of fiscal years
24 2020 through 2024.

1 **SEC. 407. TRAINING FOR HEALTH CARE PROVIDERS.**

2 Title VII of the Public Health Service Act is amended
3 by striking section 763 (42 U.S.C. 294p) and inserting
4 the following:

5 **“SEC. 763. TRAINING FOR HEALTH CARE PROVIDERS.**

6 “(a) GRANT PROGRAM.—The Secretary shall estab-
7 lish a program to award grants to accredited schools of
8 allopathic medicine, osteopathic medicine, and nursing,
9 and other health professional training programs for the
10 training of health care professionals to reduce and prevent
11 discrimination (including training related to implicit bi-
12 ases) in the provision of health care services related to
13 prenatal care, labor care, birthing, and postpartum care.

14 “(b) ELIGIBILITY.—To be eligible for a grant under
15 subsection (a), an entity described in such subsection shall
16 submit to the Secretary an application at such time, in
17 such manner, and containing such information as the Sec-
18 retary may require.

19 “(c) AUTHORIZATION OF APPROPRIATIONS.—To
20 carry out this section, there is authorized to be appro-
21 priated such sums as may be necessary for each of fiscal
22 years 2020 through 2024.”.

23 **SEC. 408. STUDY ON TRAINING TO REDUCE AND PREVENT**
24 **DISCRIMINATION.**

25 Not later than 2 years after date of enactment of this
26 Act, the Secretary of Health and Human Services (re-

1 ferred to in this section as the “Secretary”) shall, through
2 a contract with an independent research organization,
3 study and make recommendations for accredited schools
4 of allopathic medicine, osteopathic medicine, and nursing,
5 and other health professional training programs on best
6 practices related to training to reduce and prevent dis-
7 crimination, including training related to implicit biases,
8 in the provision of health care services related to prenatal
9 care, labor care, birthing, and postpartum care.

10 **SEC. 409. PERINATAL QUALITY COLLABORATIVES.**

11 Section 317K(a)(2) of the Public Health Service Act
12 (42 U.S.C. 247b–12(a)(2)) is amended by adding at the
13 end the following:

14 “(E)(i) The Secretary, acting through the
15 Director of the Centers for Disease Control and
16 Prevention and in coordination with other of-
17 fices and agencies, as appropriate, shall estab-
18 lish or continue a competitive grant program
19 for the establishment or support of perinatal
20 quality collaboratives to improve perinatal care
21 and perinatal health outcomes for pregnant and
22 postpartum women and their infants. A State
23 may use funds received through such grant
24 to—

1 “(I) support the use of evidence-based
2 or evidence-informed practices to improve
3 outcomes for maternal and infant health;

4 “(II) work with hospital-based or out-
5 patient facility-based clinical teams, ex-
6 perts, and stakeholders, including patients
7 and families, to identify, develop, or dis-
8 seminate best practices to improve
9 perinatal care and outcomes; and

10 “(III) employ strategies that provide
11 opportunities for health care professionals
12 and clinical teams to collaborate across
13 health care settings to improve maternal
14 and infant health outcomes, which may in-
15 clude the use of data to provide timely
16 feedback across hospital and clinical teams
17 to inform responses, and to provide sup-
18 port and training to hospital and clinical
19 teams for quality improvement, as appro-
20 priate.

21 “(ii) To be eligible for a grant under
22 clause (i), an entity shall submit to the Sec-
23 retary an application in such form and manner
24 and containing such information as the Sec-
25 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 to States for the purpose of establishing or operating evi-
10 dence-based or innovative, evidence-informed programs to
11 deliver integrated health care services to pregnant and
12 postpartum women, including, as appropriate, by address-
13 ing issues researched under subsection (b)(2) of section
14 317K, and to reduce adverse maternal health outcomes,
15 pregnancy-related deaths, and related health disparities,
16 including such disparities associated with racial and ethnic
17 minority populations.

18 “(b) INTEGRATED SERVICES FOR PREGNANT AND
19 POSTPARTUM WOMEN.—

20 “(1) ELIGIBILITY.—To be eligible to receive a
21 grant under subsection (a), a State shall work with
22 relevant stakeholders that coordinate care (including
23 coordinating resources and referrals for health care
24 and social services) to develop and carry out the pro-
25 gram, including—

1 “(A) State, tribal, and local agencies re-
2 sponsible for Medicaid, public health, social
3 services, mental health, and substance use dis-
4 order treatment and services;

5 “(B) health care providers who serve preg-
6 nant women; and

7 “(C) community-based health organiza-
8 tions and health workers, including individuals
9 representing communities with disproportion-
10 ately high rates of maternal mortality and se-
11 vere maternal morbidity, and including those
12 representing racial and ethnicity minority popu-
13 lations.

14 “(2) TERMS.—

15 “(A) LIMITATION.—The Secretary may
16 award a grant under subsection (a) to up to 10
17 States.

18 “(B) PERIOD.—A grant awarded under
19 subsection (a) shall be made for a period of 5
20 years.

21 “(C) PRIORITIZATION.—In awarding
22 grants under subsection (a), the Secretary shall
23 prioritize applications from States with the
24 highest rates of maternal mortality and severe
25 maternal morbidity, and shall consider health

1 disparities related to maternal mortality and se-
2 vere maternal morbidity, including such dispari-
3 ties associated with racial and ethnic minority
4 populations.

5 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
6 are authorized to be appropriated to carry out this section
7 such sums as may be necessary for each of fiscal years
8 2020 through 2024.”.

9 (b) REPORT ON GRANT OUTCOMES AND DISSEMINA-
10 TION OF BEST PRACTICES.—

11 (1) REPORT.—Not later than April 1, 2025, the
12 Secretary of Health and Human Services shall sub-
13 mit to the Committee on Health, Education, Labor,
14 and Pensions of the Senate and the Committee on
15 Energy and Commerce of the House of Representa-
16 tives a report that describes—

17 (A) the outcomes of the activities sup-
18 ported by the grants awarded under the amend-
19 ments made by this section on maternal and
20 child health;

21 (B) best practices and models of care used
22 by recipients of grants under such amendments;
23 and

24 (C) obstacles identified by recipients of
25 grants under such amendments, and strategies

1 used by such recipients to deliver care, improve
2 maternal and child health, and reduce health
3 disparities.

4 (2) DISSEMINATION OF BEST PRACTICES.—Not
5 later than October 1, 2025, the Secretary of Health
6 and Human Services shall disseminate information
7 on best practices and models of care used by recipi-
8 ents of grants under the amendments made by this
9 section (including best practices and models of care
10 relating to the reduction of health disparities, includ-
11 ing such disparities associated with racial and ethnic
12 minority populations, in rates of maternal mortality
13 and severe maternal morbidity) to relevant stake-
14 holders, which may include health providers, medical
15 schools, nursing schools, relevant State, tribal, and
16 local agencies, and the general public.

17 **TITLE V—IMPROVING THE EX-**
18 **CHANGE OF HEALTH INFOR-**
19 **MATION**

20 **SEC. 501. REQUIREMENT TO PROVIDE HEALTH CLAIMS,**
21 **NETWORK, AND COST INFORMATION.**

22 (a) IN GENERAL.—Part A of title XXVII of the Pub-
23 lic Health Service Act (42 U.S.C. 300gg et seq.) is amend-
24 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) not later than 3 days after the
19 claim is adjudicated or the data is received
20 by the health plan or health insurance
21 issuer; and

22 “(iii) to the enrollee, and any pro-
23 viders or third-party applications or serv-
24 ices authorized by the enrollee, for 5 years
25 after the end date of the enrollee’s enroll-

1 ment in the plan or in any coverage offered
2 by the health insurance issuer.

3 “(2) Identifying directory information for all in-
4 network providers, including facilities and practi-
5 tioners, that participate in the plan or coverage,
6 which shall—

7 “(A) include—

8 “(i) the national provider identifier
9 for in-network facilities and practitioners;
10 and

11 “(ii) the name, address, phone num-
12 ber, and specialty for each such facility
13 and practitioner, based on the most recent
14 interaction between the plan or coverage
15 and that facility or practitioner;

16 “(B) be capable of returning a list of par-
17 ticipating in-network facilities and practitioners,
18 in a given specialty or at a particular facility
19 type, within a specified geographic radius; and

20 “(C) be capable of returning the network
21 status, when presented with identifiers for a
22 given enrollee and facility or practitioner.

23 “(3) Estimated patient out-of-pocket costs, in-
24 cluding costs expected to be incurred through a de-

1 ductible, co-payment, 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 out-patient setting, including radi-
17 ology, lab tests, and out-patient 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 authenticated
9 third party applications or services for a reasonable
10 period of time, consistent with current security prac-
11 tices;

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), or under State privacy
24 law.”.

1 (b) EFFECTIVE DATE.—Section 2715B of the Public
2 Health Service Act, as added by subsection (a), shall take
3 effect 1 year after the date of enactment of this Act.

4 **SEC. 502. RECOGNITION OF SECURITY PRACTICES.**

5 Part 1 of subtitle D of the Health Information Tech-
6 nology for Economic and Clinical Health Act (42 U.S.C.
7 17931 et seq.) is amended by adding at the end the fol-
8 lowing:

9 **“SEC. 13412. RECOGNITION OF SECURITY PRACTICES.**

10 “(a) IN GENERAL.—Consistent with the authority of
11 the Secretary under sections 1176 and 1177 of the Social
12 Security Act, when making determinations relating to
13 fines under section 13410, decreasing the length and ex-
14 tent of an audit under section 13411, or remedies other-
15 wise agreed to by the Secretary, the Secretary shall con-
16 sider whether the entity or business associate had, for not
17 less than the previous 12 months, recognized security
18 practices in place that may—

19 “(1) mitigate fines under section 13410;

20 “(2) result in the early, favorable termination
21 of an audit under section 13411; and

22 “(3) limit the remedies that would otherwise be
23 agreed to in any agreement between the entity or
24 business associate and the Department of Health
25 and Human Services.

1 “(b) ADDITIONAL CONSIDERATION.—At the election
2 of the entity or business associate, the Secretary may pro-
3 vide further consideration to an entity or business asso-
4 ciate that can adequately demonstrate that such recog-
5 nized security practices were in place, as determined by
6 the Secretary.

7 “(c) DEFINITION AND MISCELLANEOUS PROVI-
8 SIONS.—

9 “(1) RECOGNIZED SECURITY PRACTICES.—The
10 term ‘recognized security practices’ means the stand-
11 ards, guidelines, best practices, methodologies, pro-
12 cedures, and processes developed under section
13 2(c)(15) of the National Institute of Standards and
14 Technology Act, the approaches promulgated under
15 section 405(d) of the Cybersecurity Information
16 Sharing Act of 2015, and any other program or
17 processes that are equivalent to such requirements
18 as may be developed through regulations. Such prac-
19 tices shall be determined by the entity or business
20 associate, except where additional consideration is
21 requested under subsection (b).

22 “(2) LIMITATION.—Nothing in this section
23 shall be construed as providing the Secretary author-
24 ity to—

1 “(A) increase fines under section 13410, or
2 the length, extent or quantity of audits under
3 section 13411, due to a lack of compliance with
4 the recognized security practices; or

5 “(B) mandate, direct, or condition the
6 award of any Federal grant, contract, or pur-
7 chase, on compliance with such recognized secu-
8 rity practices.

9 “(3) NO LIABILITY FOR NONPARTICIPATION.—
10 Nothing in this section shall be construed to subject
11 an entity or business associate to liability for elect-
12 ing not to engage in the recognized security prac-
13 tices defined by this section.

14 “(4) RULE OF CONSTRUCTION.—Nothing in
15 this section shall be construed to limit the Sec-
16 retary’s authority to enforce the HIPAA Security
17 rule (part 160 of title 45 Code of Federal Regula-
18 tions and subparts A and C of part 164 of such
19 title), or to supersede or conflict with an entity or
20 business associate’s obligations under the HIPAA
21 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).