

116TH CONGRESS  
1ST SESSION

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

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

## 14           **Subtitle D—Air Ambulance**

### 15           **SEC. 106. SIMPLIFYING EMERGENCY AIR AMBULANCE BILL-** 16           **ING.**

17           (a) **IN GENERAL.**—Providers of emergency air med-  
18 ical services shall submit to a group health plan or health  
19 insurance issuer offering group or individual health insur-  
20 ance coverage, together with an electronic claims trans-  
21 action with respect to an enrollee in such plan or coverage,  
22 a description of charges for such services that are sepa-  
23 rated by—

24           (1) the cost of air travel; and

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           parenthood 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 nated, 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           fusal 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).