

## Calendar No. 133

116TH CONGRESS  
1ST SESSION**S. 1895**

To lower health care costs.

## IN THE SENATE OF THE UNITED STATES

JUNE 19, 2019

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

JULY 8, 2019

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

**A BILL**

To lower health care costs.

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

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

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

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

See: 1. ~~Short title; table of contents.~~

## TITLE I—ENDING SURPRISE MEDICAL BILLS

- Sec. 101. Protecting patients against out-of-network deductibles in emergencies.
- Sec. 102. Protection against surprise bills.
- Sec. 103. Benchmark for payment.
- Sec. 104. Effective date.
- Sec. 105. Ending surprise air ambulance bills.
- Sec. 106. Report.

## TITLE II—REDUCING THE PRICES OF PRESCRIPTION DRUGS

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

## TITLE III—IMPROVING TRANSPARENCY IN HEALTH CARE

- Sec. 301. Increasing transparency by removing gag clauses on price and quality information.
- Sec. 302. Banning anticompetitive terms in facility and insurance contracts that limit access to higher quality, lower cost care.
- Sec. 303. Designation of a nongovernmental, nonprofit transparency organization to lower Americans' health care costs.
- Sec. 304. Protecting patients and improving the accuracy of provider directory information.
- Sec. 305. Timely bills for patients.
- Sec. 306. Health plan oversight of pharmacy benefit manager services.
- Sec. 307. Government Accountability Office study on profit- and revenue-sharing in health care.
- Sec. 308. Disclosure of direct and indirect compensation for brokers and consultants to employer-sponsored health plans and enrollees in plans on the individual market.
- Sec. 309. Ensuring enrollee access to cost-sharing information.
- Sec. 310. Strengthening parity in mental health and substance use disorder benefits.
- Sec. 311. Technical amendments.
- Sec. 312. Third-party administrators.

## TITLE IV—IMPROVING PUBLIC HEALTH

- Sec. 401. Improving awareness of disease prevention.
- Sec. 402. Grants to address vaccine-preventable diseases.
- Sec. 403. Guide on evidence-based strategies for public health department obesity prevention programs.
- Sec. 404. Expanding capacity for health outcomes.
- Sec. 405. Public health data system modernization.
- Sec. 406. Innovation for maternal health.

- Sec. 407. Training for health care providers.  
 Sec. 408. Study on training to reduce and prevent discrimination.  
 Sec. 409. Perinatal quality collaboratives.  
 Sec. 410. Integrated services for pregnant and postpartum women.  
 Sec. 411. Extension for community health centers, the National Health Service Corps, and teaching health centers that operate GME programs.  
 Sec. 412. Other programs.

TITLE V—IMPROVING THE EXCHANGE OF HEALTH  
 INFORMATION

- Sec. 501. Requirement to provide health claims, network, and cost information.  
 Sec. 502. Recognition of security practices.  
 Sec. 503. GAO study on the privacy and security risks of electronic transmission of individually identifiable health information to and from entities not covered by the Health Insurance Portability and Accountability Act.  
 Sec. 504. Technical corrections.

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

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

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

7                   (1) in paragraph (1)—

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

11                   (B) in subparagraph (C)—

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

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

1           (2) in paragraph (2)(B)—

2                   (A) in clause (i)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 ~~“(3) ENFORCEMENT.—~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 “(b) MEDIAN IN-NETWORK RATE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 ~~“(c) MEDIAN IN-NETWORK RATE.~~—

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

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

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

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

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

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

10 “(e) ENFORCEMENT.—

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

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

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

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

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

15      **SEC. 106. REPORT.**

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

21              (1) conduct a study on—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14                  “(2) PUBLICATION OF INFORMATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25                 “(IV) section 505A;

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

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

6           (1) IN GENERAL.—

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

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

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

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

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

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

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

4 (1) in paragraph (1)—

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

7 (B) in subparagraph (E)—

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

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

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

13 and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 ~~(3)~~ in paragraph (4)—

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

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

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

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

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

19 “(D) DEEMED LICENSES.—

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

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

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

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

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

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

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

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

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

8 “(aa) The date”; and

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

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

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

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

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

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

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

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

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

17                  “(a) INTERNET WEBSITE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 “(1) a product”;

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

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

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

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

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

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

21 (A) in subsection (c)(3)(E)—

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

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

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

10 (B) in subsection (j)(5)(F)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10                   “(iii) section 527(a); or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 “(h) LIMITATIONS; GENERIC DRUGS.—

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

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

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

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

20 “(j) RULES OF CONSTRUCTION.—

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

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

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

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

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

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

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

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

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

## 6 **TITLE III—IMPROVING TRANS-** 7 **PARENCY IN HEALTH CARE**

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

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

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

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

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

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

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

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

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

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

3           “(iii) service codes; or

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

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

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

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

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

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

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

8           “(5) RULE OF CONSTRUCTION.—Nothing in  
 9 this section shall be construed to otherwise limit  
 10 group health plan or plan sponsor access to data  
 11 currently permitted under the privacy regulations  
 12 promulgated pursuant to section 264(e) of the  
 13 Health Insurance Portability and Accountability Act,  
 14 the amendments to this Act made by the Genetic In-  
 15 formation Nondiscrimination Act of 2008, and the  
 16 Americans with Disabilities Act of 1990.”.

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

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

24           “(b) PROTECTING HEALTH PLANS NETWORK DE-  
 25 SIGN FLEXIBILITY.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 “(b) REQUIREMENTS.—

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

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

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

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

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

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

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

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

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

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

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

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

24 “(D) be available to—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 “(3) CONSULTATION.—

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

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

6 “(B) MEMBERSHIP.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24                   “(dd) 1 patient advocate;  
25 and

1                                   “(cc) 2 additional members.

2                                   “(C) DUTIES.—The Committee shall—

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

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

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

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

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

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

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

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

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

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

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

22          “(e) CONTRACT REQUIREMENTS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 “(d) RECEIVING HEALTH INFORMATION.—

7 “(1) REQUIREMENTS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15          “(4) RECEIVING OTHER INFORMATION.—

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

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

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

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

7           “(e) USES OF INFORMATION.—

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

14          “(2) AUTHORIZATION OF USERS.—

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

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

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

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

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

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

16                  “(C) REQUIREMENTS.—

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

1 formation and proprietary financial infor-  
2 mation.

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

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

1                   “(iv) NON-CUSTOMIZED REPORTS.—

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

7                   “(f) FUNDING.—

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

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

19                  “(g) ANNUAL REPORT.—

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

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

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

7               “(B) limitations in the data set;

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

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

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

18              “(h) GRANTS TO STATES.—

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

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

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

10          “(i) EXEMPTION FROM PUBLIC DISCLOSURE.—

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

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

21          “(j) DEFINITIONS.—

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

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

3 “(2) PROPRIETARY FINANCIAL INFORMATION.—

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

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

17 (b) GAO REPORT.—

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

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

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

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

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

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

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

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

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

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

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

6 “(a) NETWORK STATUS OF PROVIDERS.—

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

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

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

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

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

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

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

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

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

3           “(b) COST-SHARING LIMITATIONS.—

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

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

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

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

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

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

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

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

25 “(d) ENFORCEMENT.—

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

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

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

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

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

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

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

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

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

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

23           (a) IN GENERAL.—

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

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

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

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

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

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

23      “(c) EFFECT OF VIOLATION.—

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

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

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

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

11           and

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

16           “(2) CIVIL MONETARY PENALTIES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1           curred during the reporting pe-  
2           riod; or

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

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

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

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

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

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

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

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

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

1           ~~“(3) DISCLOSURE AND REDISCLOSURE.—~~

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

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

17           ~~“(c) LIMITATIONS ON SPREAD PRICING.—~~

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

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

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

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

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

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

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

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

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

1 entity providing pharmacy benefits management  
2 services; and

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

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

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

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

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

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

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

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

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

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

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

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

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

15           “(e) ENFORCEMENT.—

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

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

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

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

20 “(f) DEFINITIONS.—In this section—

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

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

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

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

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

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

16 (A) involve one or more—

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

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

24 (iii) surgical services;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3                   “(aa) the name of the covered plan;

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

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

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

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

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

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

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

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

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

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

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

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

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

24          (b) **APPLICABILITY OF EXISTING REGULATIONS.—**

25          Nothing in the amendments made by subsection (a) shall

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

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

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

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

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

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

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

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

7           “(e) 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 diselo-  
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 (e)) shall be subject to the requirements of  
 2 such section 408(b)(2)(B) or such section 2746, as appli-  
 3 eable.

4 (e) EFFECTIVE DATE.—The amendments made by  
 5 subsections (a) and (e) 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 H of part A of title  
 10 XXVII of the Public Health Service Act (42 U.S.C.  
 11 300gg–11 et seq.), as amended by section 306, is further  
 12 amended by adding at the end the following:

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

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

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

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

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

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

19 “(c) ENFORCEMENT.—

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



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

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

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

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

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

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

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

23 “(B) SECRETARY REQUEST PROCESS.—

24 “(i) SUBMISSION UPON COMPLAINT.—

25 The Secretary shall request that a group

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17           (2) in subsection (b)—

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

22               (B) by striking “(as so amended)”.

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

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

5           (2) in subsection (b)—

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

10                (B) by striking “(as so amended)”.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13           “(B) information on vaccinations for indi-  
14 viduals and communities, including individuals  
15 for whom vaccines are not recommended by the  
16 Advisory Committee for Immunization Prac-  
17 tices, and the effects of low vaccination rates  
18 within a community on such individuals;

19           “(C) information on diseases that may be  
20 prevented by vaccines; and

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

23           “(e) EVALUATION.—The Secretary shall—



1           “(E) planning, implementation, and evaluation  
2 of activities to address vaccine-preventable diseases,  
3 including activities to—

4           “(i) identify communities at high risk of  
5 outbreaks related to vaccine-preventable dis-  
6 eases, including through improved data collec-  
7 tion and analysis;

8           “(ii) pilot innovative approaches to improve  
9 vaccination rates in communities and among  
10 populations with low rates of vaccination;

11           “(iii) reduce barriers to accessing vaccines  
12 and evidence-based information about the  
13 health effects of vaccines;

14           “(iv) partner with community organiza-  
15 tions and health care providers to develop and  
16 deliver evidence-based interventions, including  
17 culturally and linguistically appropriate inter-  
18 ventions, to increase vaccination rates;

19           “(v) improve delivery of evidence-based  
20 vaccine-related information to parents and oth-  
21 ers; and

22           “(vi) improve the ability of State, local,  
23 tribal, and territorial public health departments  
24 to engage communities at high risk for out-

1           breaks related to vaccine-preventable diseases;  
 2           and  
 3           “(F) research related to strategies for improv-  
 4           ing awareness of scientific and evidence-based vac-  
 5           eine-related information, including for communities  
 6           with low rates of vaccination, in order to understand  
 7           barriers to vaccination, improve vaccination rates,  
 8           and assess the public health outcomes of such strate-  
 9           gies.”.

10 **SEC. 403. GUIDE ON EVIDENCE-BASED STRATEGIES FOR**  
 11                           **PUBLIC HEALTH DEPARTMENT OBESITY PRE-**  
 12                           **VENTION PROGRAMS.**

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

19                   (1) develop a guide on evidence-based strategies  
 20                   for State, territorial, and local health departments to  
 21                   use to build and maintain effective obesity preven-  
 22                   tion and reduction programs; and, in consultation  
 23                   with stakeholders that have expertise in Tribal  
 24                   health, a guide on such evidence-based strategies  
 25                   with respect to Indian Tribes and Tribal organiza-

1 tions for such Indian Tribes and Tribal organiza-  
2 tions to use for such purpose, both of which guides  
3 shall—

4 (A) describe an integrated program struc-  
5 ture for implementing interventions proven to  
6 be effective in preventing and reducing the inci-  
7 dence of obesity; and

8 (B) recommend—

9 (i) optimal resources, including staff-  
10 ing and infrastructure, for promoting nu-  
11 trition and obesity prevention and reduc-  
12 tion; and

13 (ii) strategies for effective obesity pre-  
14 vention programs for State and local  
15 health departments, Indian Tribes, and  
16 Tribal organizations, including strategies  
17 related to—

18 (I) the application of evidence-  
19 based and evidence-informed practices  
20 to prevent and reduce obesity rates;

21 (II) the development, implemen-  
22 tation, and evaluation of obesity pre-  
23 vention and reduction strategies for  
24 specific communities and populations;

1 (III) demonstrated knowledge of  
2 obesity prevention practices that re-  
3 duce associated preventable diseases,  
4 health conditions, death, and health  
5 care costs;

6 (IV) best practices for the coordi-  
7 nation of efforts to prevent and re-  
8 duce obesity and related chronic dis-  
9 eases;

10 (V) addressing the underlying  
11 risk factors and social determinants of  
12 health that impact obesity rates; and

13 (VI) interdisciplinary coordina-  
14 tion between relevant public health of-  
15 ficials specializing in fields such as  
16 nutrition, physical activity, epidemi-  
17 ology, communications, and policy im-  
18 plementation, and collaboration be-  
19 tween public health officials and com-  
20 munity-based organizations; and

21 (2) disseminate the guides and current re-  
22 search, evidence-based practices, tools, and edu-  
23 cational materials related to obesity prevention, con-  
24 sistent with the guide, to State and local health de-  
25 partments, Indian Tribes, and Tribal organizations.

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

7 (c) INDIAN TRIBES; TRIBAL ORGANIZATIONS.—The  
 8 terms “Indian Tribe” and “Tribal organization” have the  
 9 meanings given the terms “Indian tribe” and “tribal orga-  
 10 nization”, respectively, in section 4 of the Indian Self-De-  
 11 termination and Education Assistance Act (25 U.S.C.  
 12 5304).

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

14 Title III of the Public Health Service Act is amended  
 15 by inserting after section 330M (42 U.S.C. 254e–19) the  
 16 following:

17 **“SEC. 330N. EXPANDING CAPACITY FOR HEALTH OUT-  
 18 COMES.**

19 “(a) DEFINITIONS.—In this section:

20 “(1) ELIGIBLE ENTITY.—The term ‘eligible en-  
 21 tity’ means an entity providing health care services  
 22 in rural areas, frontier areas, health professional  
 23 shortage areas, or medically underserved areas, or to  
 24 medically underserved populations or Native Ameri-  
 25 cans, including Indian tribes or tribal organizations.

1           “(2) HEALTH PROFESSIONAL SHORTAGE  
2 AREA.—The term ‘health professional shortage area’  
3 means a health professional shortage area des-  
4 ignated under section 332.

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

9           “(4) MEDICALLY UNDERSERVED POPU-  
10 LATION.—The term ‘medically underserved popu-  
11 lation’ has the meaning given the term in section  
12 330(b)(3).

13           “(5) NATIVE AMERICANS.—The term ‘Native  
14 Americans’ has the meaning given such term in sec-  
15 tion 736 and includes Indian tribes and tribal orga-  
16 nizations.

17           “(6) TECHNOLOGY-ENABLED COLLABORATIVE  
18 LEARNING AND CAPACITY BUILDING MODEL.—The  
19 term ‘technology-enabled collaborative learning and  
20 capacity building model’ means a distance health  
21 education model that connects specialists with mul-  
22 tiple other health care professionals through simulta-  
23 neous interactive videoconferencing for the purpose  
24 of facilitating case-based learning; disseminating  
25 best practices; and evaluating outcomes.

1       “(b) PROGRAM ESTABLISHED.—The Secretary shall,  
2 as appropriate, award grants to evaluate, develop, and, as  
3 appropriate, expand the use of technology-enabled collabo-  
4 rative learning and capacity building models, to increase  
5 access to health care services, such as those to address  
6 chronic diseases and conditions, mental health, substance  
7 use disorders, prenatal and maternal health, pediatric  
8 care, pain management, palliative care, and other specialty  
9 care in medically underserved areas and for medically un-  
10 derserved populations.

11       “(c) USE OF FUNDS.—

12               “(1) IN GENERAL.—Grants awarded under sub-  
13 section (b) shall be used for—

14                       “(A) the development and acquisition of  
15 instructional programming; and the training of  
16 health care providers and other professionals  
17 that provide or assist in the provision of serv-  
18 ices through such models;

19                       “(B) information collection and evaluation  
20 activities to study the impact of such models on  
21 patient outcomes and health care providers, and  
22 to identify best practices for the expansion and  
23 use of such models; or

1           ~~“(C) other activities consistent with achiev-~~  
2           ~~ing the objectives of the grants awarded under~~  
3           ~~this section, as determined by the Secretary.~~

4           ~~“(2) OTHER USES.—In addition to any of the~~  
5           ~~uses under paragraph (1), grants awarded under~~  
6           ~~subsection (b) may be used for—~~

7           ~~“(A) equipment to support the use and ex-~~  
8           ~~pansion of technology-enabled collaborative~~  
9           ~~learning and capacity building models, including~~  
10          ~~for hardware and software that enables distance~~  
11          ~~learning, health care provider support, and the~~  
12          ~~secure exchange of electronic health informa-~~  
13          ~~tion; or~~

14          ~~“(B) support for health care providers and~~  
15          ~~other professionals that provide or assist in the~~  
16          ~~provision of services through such models.~~

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

19          ~~“(e) APPLICATION.—An eligible entity that seeks to~~  
20          ~~receive a grant under subsection (b) shall submit to the~~  
21          ~~Secretary an application, at such time, in such manner,~~  
22          ~~and containing such information as the Secretary may re-~~  
23          ~~quire. Such application criteria shall include an assess-~~  
24          ~~ment of the effect of technology-enabled collaborative~~

1 learning and capacity building models on patient outcomes  
2 and health care providers.

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

13       “(g) ~~REPORT BY SECRETARY.~~—Not later than 4  
14 years after the date of enactment of this section, the Sec-  
15 retary shall prepare and submit to the Committee on  
16 Health, Education, Labor, and Pensions of the Senate and  
17 the Committee on Energy and Commerce of the House  
18 of Representatives, and post on the internet website of the  
19 Department of Health and Human Services, a report in-  
20 cluding, at minimum—

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

24               “(2) an overview of—

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

3           “(B) technical assistance provided under  
4           subsection (f); and

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

10          “(h) AUTHORIZATION OF APPROPRIATIONS.—There  
11         is authorized to be appropriated to carry out this section,  
12         such sums as may be necessary for each of fiscal years  
13         2020 through 2024.”.

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

15                 Subtitle C of title XXVIII of the Public Health Serv-  
16         ice Act (42 U.S.C. 300hh–31 et seq.) is amended by add-  
17         ing at the end the following:

18         **“SEC. 2822. PUBLIC HEALTH DATA SYSTEM MODERNIZA-  
19                                 TION GRANTS.**

20                 “(a) IN GENERAL.—The Secretary, acting through  
21         the Director of the Centers for Disease Control and Pre-  
22         vention, shall—

23                 “(1) award grants to State, local, Tribal, and  
24         territorial public health departments for the expan-

1 sion and modernization of public health data sys-  
2 tems, to assist public health departments in—

3 “(A) assessing current data infrastructure  
4 capabilities and gaps to improve and increase  
5 consistency in data collection, storage, analysis,  
6 and, as appropriate, to improve dissemination  
7 of public health-related information;

8 “(B) improving secure public health data  
9 collection, transmission, exchange, maintenance,  
10 and analysis;

11 “(C) simplifying and supporting reporting  
12 by health care providers, as applicable, pursu-  
13 ant to State law, including through the use of  
14 health information technology, to State, local,  
15 Tribal, and territorial public health depart-  
16 ments, including public health officials in mul-  
17 tiple jurisdictions within such State, as appro-  
18 priate;

19 “(D) enhancing interoperability of public  
20 health data systems (including systems created  
21 or accessed by public health departments) with  
22 health information technology, including cer-  
23 tified health information technology;

24 “(E) supporting earlier disease and health  
25 condition detection, such as through near real-

1 time data monitoring; to support rapid public  
2 health responses; and

3 “(F) supporting activities within the appli-  
4 cable jurisdiction related to the expansion and  
5 modernization of electronic case reporting;

6 “(2) as appropriate, conduct activities related  
7 to the interoperability and improvement of applicable  
8 public health data systems used by the Centers for  
9 Disease Control and Prevention; and, in coordination  
10 with the Office of the National Coordinator for  
11 Health Information Technology, the designation of  
12 data and technology standards for health informa-  
13 tion systems of the public health infrastructure with  
14 deference given to standards published by standards  
15 development organizations and voluntary consensus-  
16 based standards bodies; and

17 “(3) develop and utilize public-private partner-  
18 ships for technical assistance and related implemen-  
19 tation support for State, local, Tribal, and territorial  
20 public health departments, and the Centers for Dis-  
21 ease Control and Prevention, on the expansion and  
22 modernization of electronic case reporting and public  
23 health data systems, as applicable.

24 “(b) REQUIREMENTS.—

1           “(1) IN GENERAL.—The Secretary may not  
2           award a grant under subsection (a)(1) unless the ap-  
3           plicant supports standards endorsed by the National  
4           Coordinator for Health Information Technology pur-  
5           suant to section 3001(e)(1) or adopted by the Sec-  
6           retary under section 3004.

7           “(2) WAIVER.—The Secretary may waive the  
8           requirement under paragraph (1) with respect to an  
9           applicant if the Secretary determines that the activi-  
10          ties under subsection (a) cannot otherwise be carried  
11          out within the applicable jurisdiction.

12          “(3) APPLICATION.—A State, local, Tribal, or  
13          territorial health department applying for a grant  
14          under this section shall submit an application to the  
15          Secretary at such time and in such manner as the  
16          Secretary may require. Such application shall in-  
17          clude information describing—

18                 “(A) the activities that will be supported  
19                 by the grant; and

20                 “(B) how the modernization of such public  
21                 health data systems will support or impact the  
22                 public health infrastructure of the health de-  
23                 partment, including a description of remaining  
24                 gaps, if any, and the actions needed to address  
25                 such gaps.

1       “(c) USE OF FUNDS.—An entity receiving a grant  
2 under this section may use amounts received under such  
3 grant for one or both of the following:

4           “(1) Carrying out activities described in sub-  
5 section (a)(1) to support public health data systems  
6 (including electronic case reporting); which may in-  
7 clude support for, and training of, professionals with  
8 expertise in contributing to and using such systems  
9 (including public health data scientists).

10          “(2) Developing and disseminating information  
11 related to the use and importance of public health  
12 data.

13       “(d) STRATEGY AND IMPLEMENTATION PLAN.—Not  
14 later than 180 days after the date of enactment of the  
15 Lower Health Care Costs Act, the Secretary, acting  
16 through the Director of the Centers for Disease Control  
17 and Prevention, shall submit to the Committee on Health,  
18 Education, Labor, and Pensions of the Senate and the  
19 Committee on Energy and Commerce of the House of  
20 Representatives, a coordinated strategy and an accom-  
21 panying implementation plan that identifies and dem-  
22 onstrates the steps the Secretary will carry out to—

23           “(1) update and improve applicable public  
24 health data systems used by the Centers for Disease  
25 Control and Prevention; and

1           “(2) carry out the activities described in this  
2           section to support the improvement of State, local,  
3           Tribal, and territorial public health data systems.

4           “(e) CONSULTATION.—The Secretary, acting through  
5           the Director of the Centers for Disease Control and Pre-  
6           vention, shall consult with State, local, Tribal, and terri-  
7           torial health departments, professional medical and public  
8           health associations, associations representing hospitals or  
9           other health care entities, health information technology  
10          experts, and other appropriate entities regarding the plan  
11          and grant program to modernize public health data sys-  
12          tems pursuant to this section. Such activities may include  
13          the provision of technical assistance related to the ex-  
14          change of information by such public health data systems  
15          used by relevant health care and public health entities at  
16          the local, State, Federal, Tribal, and territorial levels.

17          “(f) REPORT TO CONGRESS.—Not later than 1 year  
18          after the date of enactment of this section, the Secretary  
19          shall submit a report to the Committee on Health, Edu-  
20          cation, Labor, and Pensions of the Senate and the Com-  
21          mittee on Energy and Commerce of the House of Rep-  
22          resentatives that includes—

23                 “(1) a description of any barriers to—

1           “(A) public health authorities imple-  
2           menting electronic case reporting and interoper-  
3           able public health data systems; or

4           “(B) the exchange of information pursuant  
5           to electronic case reporting;

6           “(2) an assessment of the potential public  
7           health impact of implementing electronic case re-  
8           porting and interoperable public health data sys-  
9           tems; and

10          “(3) a description of the activities carried out  
11          pursuant to this section.

12          “(g) **ELECTRONIC CASE REPORTING.**—In this sec-  
13          tion, the term ‘electronic case reporting’ means the auto-  
14          mated identification, generation, and bilateral exchange of  
15          reports of health events among electronic health record or  
16          health information technology systems and public health  
17          authorities.

18          “(h) **AUTHORIZATION OF APPROPRIATIONS.**—For the  
19          purpose of carrying out this section, there are authorized  
20          to be appropriated such sums as may be necessary for fis-  
21          cal years 2020 through 2024.”.

22          **SEC. 406. INNOVATION FOR MATERNAL HEALTH.**

23          (a) **IN GENERAL.**—The Secretary of Health and  
24          Human Services (referred to in this section as the “Sec-  
25          retary”), in consultation with experts representing a vari-

1 ety of clinical specialties, State, tribal, or local public  
2 health officials, researchers, epidemiologists, statisticians,  
3 and community organizations, shall establish a program  
4 to award competitive grants to eligible entities for the pur-  
5 pose of—

6           (1) identifying, developing, or disseminating  
7           best practices to improve maternal health care qual-  
8           ity and outcomes, eliminate preventable maternal  
9           mortality and severe maternal morbidity, and im-  
10          prove infant health outcomes, which may include—

11                   (A) information on evidence-based prac-  
12                   tices to improve the quality and safety of ma-  
13                   ternal health care in hospitals and other health  
14                   care settings of a State or health care system,  
15                   including by addressing topics commonly associ-  
16                   ated with health complications or risks related  
17                   to prenatal care, labor care, birthing, and post-  
18                   partum care;

19                   (B) best practices for improving maternal  
20                   health care based on data findings and reviews  
21                   conducted by a State maternal mortality review  
22                   committee that address topics of relevance to  
23                   common complications or health risks related to  
24                   prenatal care, labor care, birthing, and postpar-  
25                   tum care; and

1           (C) information on addressing deter-  
2           minants of health that impact maternal health  
3           outcomes for women before, during, and after  
4           pregnancy;

5           (2) collaborating with State maternal mortality  
6           review committees to identify issues for the develop-  
7           ment and implementation of evidence-based practices  
8           to improve maternal health outcomes and reduce  
9           preventable maternal mortality and severe maternal  
10          morbidity;

11          (3) providing technical assistance and sup-  
12          porting the implementation of best practices identi-  
13          fied in paragraph (1) to entities providing health  
14          care services to pregnant and postpartum women;  
15          and

16          (4) identifying, developing, and evaluating new  
17          models of care that improve maternal and infant  
18          health outcomes, which may include the integration  
19          of community-based services and clinical care.

20          (b) ELIGIBLE ENTITIES.—To be eligible for a grant  
21          under subsection (a), an entity shall—

22                (1) submit to the Secretary an application at  
23                such time, in such manner, and containing such in-  
24                formation as the Secretary may require; and

1           (2) demonstrate in such application that the en-  
2           tity has a demonstrated expertise in data-driven ma-  
3           ternal safety and quality improvement initiatives in  
4           the areas of obstetrics and gynecology or maternal  
5           health.

6           (c) AUTHORIZATION OF APPROPRIATIONS.—To carry  
7           out this section, there is authorized to be appropriated  
8           such sums as may be necessary for each of fiscal years  
9           2020 through 2024.

10   **SEC. 407. TRAINING FOR HEALTH CARE PROVIDERS.**

11           Title VII of the Public Health Service Act is amended  
12           by striking section 763 (42 U.S.C. 294p) and inserting  
13           the following:

14   **“SEC. 763. TRAINING FOR HEALTH CARE PROVIDERS.**

15           “(a) GRANT PROGRAM.—The Secretary shall estab-  
16           lish a program to award grants to accredited schools of  
17           allopathic medicine, osteopathic medicine, and nursing,  
18           and other health professional training programs for the  
19           training of health care professionals to reduce and prevent  
20           discrimination (including training related to implicit bi-  
21           ases) in the provision of health care services related to  
22           prenatal care, labor care, birthing, and postpartum care.

23           “(b) ELIGIBILITY.—To be eligible for a grant under  
24           subsection (a), an entity described in such subsection shall  
25           submit to the Secretary an application at such time, in

1 such manner, and containing such information as the Sec-  
 2 retary may require.

3 “(c) REPORTING REQUIREMENT.—Each entity  
 4 awarded a grant under this section shall periodically sub-  
 5 mit to the Secretary a report on the status of activities  
 6 conducted using the grant, including a description of the  
 7 impact of such training on patient outcomes, as applicable.

8 “(d) BEST PRACTICES.—The Secretary may identify  
 9 and disseminate best practices for the training of health  
 10 care professionals to reduce and prevent discrimination  
 11 (including training related to implicit biases) in the provi-  
 12 sion of health care services related to prenatal care, labor  
 13 care, birthing, and postpartum care.

14 “(e) AUTHORIZATION OF APPROPRIATIONS.—To  
 15 carry out this section, there is authorized to be appro-  
 16 priated such sums as may be necessary for each of fiscal  
 17 years 2020 through 2024.”.

18 **SEC. 408. STUDY ON TRAINING TO REDUCE AND PREVENT**  
 19 **DISCRIMINATION.**

20 Not later than 2 years after date of enactment of this  
 21 Act, the Secretary of Health and Human Services (re-  
 22 ferred to in this section as the “Secretary”) shall, through  
 23 a contract with an independent research organization,  
 24 study and make recommendations for accredited schools  
 25 of allopathic medicine, osteopathic medicine, and nursing;

1 and other health professional training programs on best  
2 practices related to training to reduce and prevent dis-  
3 crimination, including training related to implicit biases,  
4 in the provision of health care services related to prenatal  
5 care, labor care, birthing, and postpartum care.

6 **SEC. 409. PERINATAL QUALITY COLLABORATIVES.**

7 Section 317K(a)(2) of the Public Health Service Act  
8 (42 U.S.C. 247b-12(a)(2)) is amended by adding at the  
9 end the following:

10 “(E)(i) The Secretary, acting through the  
11 Director of the Centers for Disease Control and  
12 Prevention and in coordination with other of-  
13 fices and agencies, as appropriate, shall estab-  
14 lish or continue a competitive grant program  
15 for the establishment or support of perinatal  
16 quality collaboratives to improve perinatal care  
17 and perinatal health outcomes for pregnant and  
18 postpartum women and their infants. A State  
19 or Indian Tribe may use funds received through  
20 such grant to—

21 “(I) support the use of evidence-based  
22 or evidence-informed practices to improve  
23 outcomes for maternal and infant health;

24 “(II) work with clinical teams; ex-  
25 perts; State, local, and, as appropriate,

1 tribal public health officials; and stake-  
2 holders, including patients and families, to  
3 identify, develop, or disseminate best prac-  
4 tices to improve perinatal care and out-  
5 comes; and

6 “(III) employ strategies that provide  
7 opportunities for health care professionals  
8 and clinical teams to collaborate across  
9 health care settings and disciplines, includ-  
10 ing primary care and mental health, as ap-  
11 propriate, to improve maternal and infant  
12 health outcomes, which may include the  
13 use of data to provide timely feedback  
14 across hospital and clinical teams to in-  
15 form responses, and to provide support  
16 and training to hospital and clinical teams  
17 for quality improvement, as appropriate.

18 “(ii) To be eligible for a grant under  
19 clause (i), an entity shall submit to the Sec-  
20 retary an application in such form and manner  
21 and containing such information as the Sec-  
22 retary may require.”

1 **SEC. 410. INTEGRATED SERVICES FOR PREGNANT AND**  
 2 **POSTPARTUM WOMEN.**

3 (a) GRANTS.—Title III of the Public Health Service  
 4 Act is amended by inserting after section 330N of such  
 5 Act, as added by section 404, the following:

6 **“SEC. 330O. INTEGRATED SERVICES FOR PREGNANT AND**  
 7 **POSTPARTUM WOMEN.**

8 “(a) IN GENERAL.—The Secretary may award grants  
 9 for the purpose of establishing or operating evidence-based  
 10 or innovative, evidence-informed programs to deliver inte-  
 11 grated health care services to pregnant and postpartum  
 12 women to optimize the health of women and their infants,  
 13 including to reduce adverse maternal health outcomes,  
 14 pregnancy-related deaths, and related health disparities  
 15 (including such disparities associated with racial and eth-  
 16 nic minority populations), and as appropriate, by address-  
 17 ing issues researched under subsection (b)(2) of section  
 18 317K.

19 “(b) INTEGRATED SERVICES FOR PREGNANT AND  
 20 POSTPARTUM WOMEN.—

21 “(1) ELIGIBILITY.—To be eligible to receive a  
 22 grant under subsection (a), a State or Indian Tribe  
 23 (as defined in section 4 of the Indian Self-Deter-  
 24 mination and Education Assistance Act) shall work  
 25 with relevant stakeholders that coordinate care (in-  
 26 cluding coordinating resources and referrals for

1 health care and social services) to develop and carry  
2 out the program, including—

3 “(A) State, tribal, and local agencies re-  
4 sponsible for Medicaid, public health, social  
5 services, mental health, and substance use dis-  
6 order treatment and services;

7 “(B) health care providers who serve preg-  
8 nant women; and

9 “(C) community-based health organiza-  
10 tions and health workers, including providers of  
11 home visiting services and individuals rep-  
12 resenting communities with disproportionately  
13 high rates of maternal mortality and severe ma-  
14 ternal morbidity, and including those rep-  
15 resenting racial and ethnicity minority popu-  
16 lations.

17 “(2) TERMS.—

18 “(A) LIMITATION.—The Secretary may  
19 award a grant under subsection (a) to up to 10  
20 States.

21 “(B) PERIOD.—A grant awarded under  
22 subsection (a) shall be made for a period of 5  
23 years.

24 “(C) PRIORITIZATION.—In awarding  
25 grants under subsection (a), the Secretary shall

1           prioritize applications from States or Indian  
2           Tribes with the highest rates of maternal mor-  
3           tality and severe maternal morbidity; and shall  
4           consider health disparities related to maternal  
5           mortality and severe maternal morbidity, in-  
6           cluding such disparities associated with racial  
7           and ethnic minority populations:

8                   “(D) EVALUATION.—The Secretary shall  
9           require grantees to evaluate the outcomes of the  
10          programs supported under the grant.

11          “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
12       are authorized to be appropriated to carry out this section  
13       such sums as may be necessary for each of fiscal years  
14       2020 through 2024.”.

15          (b) REPORT ON GRANT OUTCOMES AND DISSEMINA-  
16       TION OF BEST PRACTICES.—

17                   (1) REPORT.—Not later than April 1, 2025, the  
18       Secretary of Health and Human Services shall sub-  
19       mit to the Committee on Health, Education, Labor,  
20       and Pensions of the Senate and the Committee on  
21       Energy and Commerce of the House of Representa-  
22       tives a report that describes—

23                   (A) the outcomes of the activities sup-  
24       ported by the grants awarded under the amend-

1           ments made by this section on maternal and  
2           child health;

3           (B) best practices and models of care used  
4           by recipients of grants under such amendments;  
5           and

6           (C) obstacles identified by recipients of  
7           grants under such amendments, and strategies  
8           used by such recipients to deliver care, improve  
9           maternal and child health, and reduce health  
10          disparities.

11          (2) DISSEMINATION OF BEST PRACTICES.—Not  
12          later than October 1, 2025, the Secretary of Health  
13          and Human Services shall disseminate information  
14          on best practices and models of care used by recipi-  
15          ents of grants under the amendments made by this  
16          section (including best practices and models of care  
17          relating to the reduction of health disparities, includ-  
18          ing such disparities associated with racial and ethnic  
19          minority populations, in rates of maternal mortality  
20          and severe maternal morbidity) to relevant stake-  
21          holders, which may include health providers, medical  
22          schools, nursing schools, relevant State, tribal, and  
23          local agencies, and the general public.

1 **SEC. 411. EXTENSION FOR COMMUNITY HEALTH CENTERS,**  
2 **THE NATIONAL HEALTH SERVICE CORPS,**  
3 **AND TEACHING HEALTH CENTERS THAT OP-**  
4 **ERATE GME PROGRAMS.**

5 (a) **COMMUNITY HEALTH CENTERS FUNDING.**—Sec-  
6 tion ~~10503(b)(1)(F)~~ of the Patient Protection and Afford-  
7 able Care Act (~~42 U.S.C. 254b-2(b)(1)(F)~~) is amended  
8 by striking “fiscal year 2019” and inserting “each of fiscal  
9 years 2019 through 2024”.

10 (b) **NATIONAL HEALTH SERVICE CORPS.**—Section  
11 ~~10503(b)(2)(F)~~ of the Patient Protection and Affordable  
12 Care Act (~~42 U.S.C. 254b-2(b)(2)(F)~~) is amended by  
13 striking “and 2019” and inserting “through 2024”.

14 (c) **TEACHING HEALTH CENTERS THAT OPERATE**  
15 **GRADUATE MEDICAL EDUCATION PROGRAMS.**—Section  
16 ~~340H(g)(1)~~ of the Public Health Service Act (~~42 U.S.C.~~  
17 ~~256h(g)(1)~~) is amended by striking “and 2019” and in-  
18 serting “through 2024”.

19 (d) **APPLICATION OF PROVISIONS.**—Amounts appro-  
20 priated pursuant to this section for each of fiscal years  
21 2019 through 2024 shall be subject to the requirements  
22 contained in Public Law ~~115-245~~ for funds for programs  
23 authorized under sections ~~330~~ through ~~340~~ of the Public  
24 Health Service Act.

25 (e) **CONFORMING AMENDMENTS.**—Paragraph (4) of  
26 section ~~3014(h)~~ of title 18, United States Code, as amend-

1 ed by section 50901 of Public Law 115–123, is amended  
 2 by striking “and section 50901(e) of the Advancing  
 3 Chronic Care, Extenders, and Social Services Act” and in-  
 4 serting “, section 50901(e) of the Advancing Chronic  
 5 Care, Extenders, and Social Services Act, and section  
 6 411(d) of the Lower Health Care Costs Act”.

7 **SEC. 412. OTHER PROGRAMS.**

8 (a) TYPE I.—Section 330B(b)(2)(D) of the Public  
 9 Health Service Act (42 U.S.C. 254e–2(b)(2)(D)) is  
 10 amended by striking “and 2019” and inserting “through  
 11 2024”.

12 (b) INDIANS.—Subparagraph (D) of section  
 13 330C(c)(2) of the Public Health Service Act (42 U.S.C.  
 14 254e–3(c)(2)(D)) is amended by striking “and 2019” and  
 15 inserting “through 2024”.

16 **TITLE V—IMPROVING THE EX-**  
 17 **CHANGE OF HEALTH INFOR-**  
 18 **MATION**

19 **SEC. 501. REQUIREMENT TO PROVIDE HEALTH CLAIMS,**  
 20 **NETWORK, AND COST INFORMATION.**

21 (a) IN GENERAL.—Part A of title XXVII of the Pub-  
 22 lic Health Service Act (42 U.S.C. 300gg et seq.) is amend-  
 23 ed by inserting after section 2715A the following:

1 **“SEC. 2715B. REQUIREMENT TO PROVIDE HEALTH CLAIMS,**  
2 **NETWORK, AND COST INFORMATION.**

3 “(a) IN GENERAL.—A group health plan or a health  
4 insurance issuer offering group or individual health insur-  
5 ance coverage shall make available for access, exchange,  
6 or use without special effort, through application program-  
7 ming interfaces (or successor technology or standards),  
8 the information described in subsection (b), in the manner  
9 described in subsection (b) and otherwise consistent with  
10 this section.

11 “(b) INFORMATION.—The following information is re-  
12 quired to be made available, in such form and manner as  
13 the Secretary may specify, as described in subsection (a):

14 “(1) Historical claims, provider encounter, and  
15 payment data for each enrollee, which shall—

16 “(A) include adjudicated medical and pre-  
17 scription drug claims and equivalent encoun-  
18 ters, including all data elements contained in  
19 such transactions—

20 “(i) that were adjudicated by the  
21 group health plan or health insurance  
22 issuer during the previous 5 years or the  
23 enrollee’s entire period of enrollment in the  
24 applicable plan or coverage if such period  
25 is less than 5 years;

1           “(ii) that involve benefits managed by  
2           any third party, such as a pharmacy bene-  
3           fits manager or radiology benefits manager  
4           that manages benefits or adjudicates  
5           claims on behalf of the plan or coverage;  
6           and

7           “(iii) from any other health plan or  
8           health insurance coverage issued or admin-  
9           istered by the same insurance issuer, in  
10          which the same enrollee was enrolled dur-  
11          ing the previous 5 years; and

12          “(B) be available—

13               “(i) in a single, longitudinal format  
14               that is easy to understand and secure, and  
15               that may update automatically, including  
16               by using the standards adopted for imple-  
17               mentation of section 3001(e)(5)(D)(iv);

18               “(ii) as soon as practicable, and in no  
19               case later than the period of time deter-  
20               mined by the Secretary, after the claim is  
21               adjudicated or the data is received by the  
22               health plan or health insurance issuer; and

23               “(iii) to the enrollee, and any pro-  
24               viders or third-party applications or serv-  
25               ices authorized by the enrollee, for 5 years

1           after the end date of the enrollee's enroll-  
2           ment in the plan or in any coverage offered  
3           by the health insurance issuer.

4           ~~“(2) Identifying directory information for all in-~~  
5           network providers, including facilities and practi-  
6           tioners, that participate in the plan or coverage,  
7           which shall—

8           ~~“(A) include—~~

9           ~~“(i) the national provider identifier~~  
10          ~~for in-network facilities and practitioners;~~  
11          ~~and~~

12          ~~“(ii) the name, address, phone num-~~  
13          ~~ber, and specialty for each such facility~~  
14          ~~and practitioner, based on the most recent~~  
15          ~~interaction between the plan or coverage~~  
16          ~~and that facility or practitioner;~~

17          ~~“(B) be capable of returning a list of par-~~  
18          ~~ticipating in-network facilities and practitioners,~~  
19          ~~in a given specialty or at a particular facility~~  
20          ~~type, within a specified geographic radius; and~~

21          ~~“(C) be capable of returning the network~~  
22          ~~status, when presented with identifiers for a~~  
23          ~~given enrollee and facility or practitioner.~~

24          ~~“(3) Estimated patient out-of-pocket costs, in-~~  
25          ~~cluding costs expected to be incurred through a de-~~

1 ductible, copayment, coinsurance, or other form of  
2 cost-sharing, for—

3 “(A) a designated set of common services  
4 or episodes of care, to be established by the  
5 Secretary through rulemaking, including, at a  
6 minimum—

7 “(i) in the case of services provided by  
8 a hospital, the 100 most common diag-  
9 nosis-related groups, as used in the Medi-  
10 care Inpatient Prospective Patient System  
11 (or successor episode-based reimbursement  
12 methodology) at that hospital, based on  
13 claims data adjudicated by the group  
14 health plan or health insurance issuer;

15 “(ii) in the case of services provided  
16 in an outpatient setting, including radi-  
17 ology, lab tests, and outpatient surgical  
18 procedures, any service rendered by the fa-  
19 cility or practitioner, and reimbursed by  
20 the health plan or health insurance issuer;  
21 and

22 “(iii) in the case of post-acute care,  
23 including home health providers, skilled  
24 nursing facilities, inpatient rehabilitation  
25 facilities, and long-term care hospitals, the

1 patient out-of-pocket costs for an episode  
 2 of care, as the Secretary may determine,  
 3 which permits users to reasonably compare  
 4 costs across different facility and service  
 5 types; and

6 “(B) all prescription drugs currently in-  
 7 cluded on any tier of the formulary of the plan  
 8 or coverage.

9 “(e) AVAILABILITY AND ACCESS.—The application  
 10 programming interfaces, including all data required to be  
 11 made available through such interfaces, shall—

12 “(1) be made available by the applicable group  
 13 health plan or health insurance issuer, at no charge,  
 14 to—

15 “(A) enrollees in the group health plan or  
 16 health insurance coverage;

17 “(B) third parties authorized by the en-  
 18 rollee;

19 “(C) facilities and practitioners who are  
 20 under contract with the plan or coverage; and

21 “(D) business associates of such facilities  
 22 and practitioners, as defined in section 160.103  
 23 of title 45, Code of Federal Regulations (or any  
 24 successor regulations);

1           “(2) be available to enrollees in the group  
 2 health plan or health insurance coverage, and to  
 3 third-party applications or services facilitating such  
 4 access by enrollees, during the enrollment process  
 5 and for a minimum of 5 years after the end date of  
 6 the enrollee’s enrollment in the plan or in any cov-  
 7 erage offered by the health insurance issuer;

8           “(3) permit persistent access by third-party ap-  
 9 plications or services authorized by the enrollee, for  
 10 a reasonable period of time, consistent with current  
 11 security practices;

12           “(4) employ the applicable content, vocabulary,  
 13 and technical standards, including, as appropriate,  
 14 such standards adopted by the Secretary pursuant  
 15 to title ~~XXX~~; and

16           “(5) employ security and authentication stand-  
 17 ards, as the Secretary determines appropriate.

18           “(d) ~~RULE OF CONSTRUCTION REGARDING PRI-~~  
 19 ~~VACY.~~—Nothing in this section shall be construed to alter  
 20 existing obligations under the privacy, security, and  
 21 breach notification rules promulgated under section 264(e)  
 22 of the Health Insurance Portability and Accountability  
 23 Act (or successor regulations), under part 2 of title 42,  
 24 Code of Federal Regulations (or successor regulations),  
 25 under section 444 of the General Education Provisions

1 Act (20 U.S.C. 1232g) (commonly referred to as the  
 2 ‘Family Educational Rights and Privacy Act of 1974’),  
 3 under the amendments made by the Genetic Information  
 4 Nondiscrimination Act, or under State privacy law.”

5 (b) EFFECTIVE DATE.—Section 2715B of the Public  
 6 Health Service Act, as added by subsection (a), shall take  
 7 effect 1 year after the date of enactment of this Act.

8 **SEC. 502. RECOGNITION OF SECURITY PRACTICES.**

9 Part 1 of subtitle D of the Health Information Tech-  
 10 nology for Economic and Clinical Health Act (42 U.S.C.  
 11 17931 et seq.) is amended by adding at the end the fol-  
 12 lowing:

13 **“SEC. 13412. RECOGNITION OF SECURITY PRACTICES.**

14 “(a) IN GENERAL.—Consistent with the authority of  
 15 the Secretary under sections 1176 and 1177 of the Social  
 16 Security Act, when making determinations relating to  
 17 fines under section 13410, decreasing the length and ex-  
 18 tent of an audit under section 13411, or remedies other-  
 19 wise agreed to by the Secretary, the Secretary shall con-  
 20 sider whether the entity or business associate had, for not  
 21 less than the previous 12 months, recognized security  
 22 practices in place that may—

23 “(1) mitigate fines under section 13410;

24 “(2) result in the early, favorable termination  
 25 of an audit under section 13411; and

1           “(3) limit the remedies that would otherwise be  
2           agreed to in any agreement between the entity or  
3           business associate and the Department of Health  
4           and Human Services.

5           “(b) ADDITIONAL CONSIDERATION.—At the election  
6           of the entity or business associate, the Secretary may pro-  
7           vide further consideration to an entity or business asso-  
8           ciate that can adequately demonstrate that such recog-  
9           nized security practices were in place, as determined by  
10          the Secretary.

11          “(c) DEFINITION AND MISCELLANEOUS PROVI-  
12          SIONS.—

13           “(1) RECOGNIZED SECURITY PRACTICES.—The  
14          term ‘recognized security practices’ means the stand-  
15          ards, guidelines, best practices, methodologies, pro-  
16          cedures, and processes developed under section  
17          2(e)(15) of the National Institute of Standards and  
18          Technology Act, the approaches promulgated under  
19          section 405(d) of the Cybersecurity Information  
20          Sharing Act of 2015, and any other program or  
21          processes that are equivalent to such requirements  
22          as may be developed through regulations. Such prac-  
23          tices shall be determined by the entity or business  
24          associate, except where additional consideration is  
25          requested under subsection (b).

1           “(2) **LIMITATION.**—Nothing in this section  
2 shall be construed as providing the Secretary author-  
3 ity to—

4           “(A) increase fines under section 13410, or  
5 the length, extent or quantity of audits under  
6 section 13411, due to a lack of compliance with  
7 the recognized security practices; or

8           “(B) mandate, direct, or condition the  
9 award of any Federal grant, contract, or pur-  
10 chase, on compliance with such recognized secu-  
11 rity practices.

12           “(3) **NO LIABILITY FOR NONPARTICIPATION.**—  
13 Nothing in this section shall be construed to subject  
14 an entity or business associate to liability for elect-  
15 ing not to engage in the recognized security prac-  
16 tices defined by this section.

17           “(4) **RULE OF CONSTRUCTION.**—Nothing in  
18 this section shall be construed to limit the Sec-  
19 retary’s authority to enforce the HIPAA Security  
20 rule (part 160 of title 45, Code of Federal Regula-  
21 tions, and subparts A and C of part 164 of such  
22 title); or to supersede or conflict with an entity or  
23 business associate’s obligations under the HIPAA  
24 Security rule.”.

1 **SEC. 503. GAO STUDY ON THE PRIVACY AND SECURITY**  
2 **RISKS OF ELECTRONIC TRANSMISSION OF IN-**  
3 **DIVIDUALLY IDENTIFIABLE HEALTH INFOR-**  
4 **MATION TO AND FROM ENTITIES NOT COV-**  
5 **ERED BY THE HEALTH INSURANCE PORT-**  
6 **ABILITY AND ACCOUNTABILITY ACT.**

7 (a) **IN GENERAL.**—Not later than 1 year after the  
8 date of enactment of this Act, the Comptroller General  
9 of the United States shall conduct a study to—

10 (1) describe the roles of Federal agencies and  
11 the private sector with respect to protecting the pri-  
12 vacy and security of individually identifiable health  
13 information transmitted electronically to and from  
14 entities not covered by the regulations promulgated  
15 under section 264(e) 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 eally to or from entities, selected by an individual,  
 2 that are not subject to the regulations promulgated  
 3 under section 264(e) 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).

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) *SHORT TITLE.*—This Act may be cited as the  
5 “Lower Health Care Costs Act”.

6 (b) *TABLE OF CONTENTS.*—The table of contents for  
7 this Act is as follows:

*Sec. 1. Short title; table of contents.*

*TITLE I—ENDING SURPRISE MEDICAL BILLS*

*Sec. 101. Protecting patients against out-of-network deductibles in emergencies.*

*Sec. 102. Protection against surprise bills.*

*Sec. 103. Benchmark for payment.*

*Sec. 104. Effective date.*

*Sec. 105. Ending surprise air ambulance bills.*

*Sec. 106. Report.*

*TITLE II—REDUCING THE PRICES OF PRESCRIPTION DRUGS*

*Sec. 201. Biological product patent transparency.*

*Sec. 202. Orange Book modernization.*

*Sec. 203. Ensuring timely access to generics.*

*Sec. 204. Protecting access to biological products.*

*Sec. 205. Preventing blocking of generic drugs.*

*Sec. 206. Education on biological products.*

*Sec. 207. Biological product innovation.*

*Sec. 208. Clarifying the meaning of new chemical entity.*

*Sec. 209. Streamlining the transition of biological products.*

*Sec. 210. Orphan drug clarification.*

*Sec. 211. Prompt approval of drugs related to safety information.*

*Sec. 212. Conditions of use for biosimilar biological products.*

*Sec. 213. Modernizing the labeling of certain generic drugs.*

*Sec. 214. Actions for delays of generic drugs and biosimilar biological products.*

*Sec. 215. Reducing the price of prescription drugs.*

*TITLE III—IMPROVING TRANSPARENCY IN HEALTH CARE*

*Sec. 301. Increasing transparency by removing gag clauses on price and quality information.*

*Sec. 302. Banning anticompetitive terms in facility and insurance contracts that limit access to higher quality, lower cost care.*

*Sec. 303. Designation of a nongovernmental, nonprofit transparency organization to lower Americans’ health care costs.*

*Sec. 304. Protecting patients and improving the accuracy of provider directory information.*

*Sec. 305. Timely bills for patients.*

*Sec. 306. Health plan oversight of pharmacy benefit manager services.*

- Sec. 307. Government Accountability Office study on profit- and revenue-sharing in health care.*
- Sec. 308. Disclosure of direct and indirect compensation for brokers and consultants to employer-sponsored health plans and enrollees in plans on the individual market.*
- Sec. 309. Ensuring enrollee access to cost-sharing information.*
- Sec. 310. Strengthening parity in mental health and substance use disorder benefits.*
- Sec. 311. Technical amendments.*
- Sec. 312. Third-party administrators.*
- Sec. 313. Group health plan reporting requirements.*
- Sec. 314. Study by Comptroller General of United States.*

#### **TITLE IV—IMPROVING PUBLIC HEALTH**

- Sec. 401. Improving awareness of disease prevention.*
- Sec. 402. Grants to address vaccine-preventable diseases.*
- Sec. 403. Guide on evidence-based strategies for public health department obesity prevention programs.*
- Sec. 404. Expanding capacity for health outcomes.*
- Sec. 405. Public health data system modernization.*
- Sec. 406. Innovation for maternal health.*
- Sec. 407. Training for health care providers.*
- Sec. 408. Study on training to reduce and prevent discrimination.*
- Sec. 409. Perinatal quality collaboratives.*
- Sec. 410. Integrated services for pregnant and postpartum women.*
- Sec. 411. Extension for community health centers, the national health service corps, and teaching health centers that operate GME programs.*
- Sec. 412. Other programs.*
- Sec. 413. Native American suicide prevention.*
- Sec. 414. Minimum age of sale of tobacco products.*
- Sec. 415. Sale of tobacco products to individuals under the age of 21.*

#### **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.*
- Sec. 505. Public meeting.*

1           **TITLE I—ENDING SURPRISE**

2                           **MEDICAL BILLS**

3   **SEC. 101. PROTECTING PATIENTS AGAINST OUT-OF-NET-**

4                           **WORK DEDUCTIBLES IN EMERGENCIES.**

5           *Section 2719A(b) of the Public Health Service Act (42*

6 *U.S.C. 300gg–19a) is amended—*

1 (1) in paragraph (1)—

2 (A) in the matter preceding subparagraph  
3 (A), by inserting “or a freestanding emergency  
4 room” after “hospital”; and

5 (B) in subparagraph (C)—

6 (i) in clause (i)(I), by inserting “or  
7 freestanding emergency room” after “emer-  
8 gency department”; and

9 (ii) in subparagraph (C)(ii)(II), by  
10 adding, “a deductible,” after “(expressed  
11 as”; and

12 (2) in paragraph (2)(B)—

13 (A) in clause (i)—

14 (i) by inserting “or freestanding emer-  
15 gency room” after “hospital”; and

16 (ii) by inserting “or freestanding emer-  
17 gency room” after “emergency department”;  
18 and

19 (B) in clause (ii), by inserting “or free-  
20 standing emergency room” after “hospital”.

21 **SEC. 102. PROTECTION AGAINST SURPRISE BILLS.**

22 (a) PHSA.—Section 2719A of the Public Health Serv-  
23 ice Act (42 U.S.C. 300gg–19a) is amended by adding at  
24 the end the following:

25 “(e) OUT-OF-NETWORK ANCILLARY SERVICES.—

1           “(1) *COVERAGE OF SERVICES.*—Subject to sub-  
2           section (h), in the case of an enrollee in a group  
3           health plan or group or individual health insurance  
4           coverage who receives out-of-network ancillary services  
5           at an in-network facility, including any referrals for  
6           diagnostic services, and such services would be covered  
7           under such plan or coverage if provided in-network—

8                   “(A) the cost-sharing requirement (expressed  
9                   as a copayment amount, coinsurance rate, or de-  
10                  ductible) with respect to such services shall be the  
11                  same requirement that would apply if such serv-  
12                  ices were provided by an in-network practi-  
13                  tioner, and any coinsurance or deductible shall  
14                  be based on in-network rates; and

15                  “(B) amounts paid toward such cost-shar-  
16                  ing shall be counted towards the in-network de-  
17                  ductible and in-network out-of-pocket maximum  
18                  amount, as applicable, under the plan or cov-  
19                  erage for the plan year.

20           “(2) *NOTICE BEFORE PROVIDING NON-EMER-*  
21           *GENCY SERVICES.*—Subject to subsection (h), in the  
22           case of an enrollee in a group health plan or group  
23           or individual health insurance coverage who receives  
24           out-of-network, non-emergency services that are not  
25           ancillary services, from an out-of-network provider at

1        *an in-network facility, and such services would be*  
2        *covered under such plan or coverage if provided in-*  
3        *network, the cost-sharing requirement (expressed as a*  
4        *copayment amount, coinsurance rate, or deductible)*  
5        *with respect to such services shall be the same require-*  
6        *ment that would apply if such services were provided*  
7        *by an in-network practitioner, and any coinsurance*  
8        *or deductible shall be based on in-network rates, un-*  
9        *less, as soon as practicable, and in no case later than*  
10       *48 hours prior to providing non-emergency services*  
11       *that are not ancillary services—*

12                *“(A) the in-network facility provides to the*  
13                *enrollee who is scheduled to receive such services*  
14                *notice that—*

15                        *“(i) is provided in paper or electronic*  
16                        *form (and including electronic notification*  
17                        *whenever practicable);*

18                        *“(ii) states that such service will be*  
19                        *provided out-of-network;*

20                        *“(iii) includes the estimated amount*  
21                        *that such practitioner or facility may*  
22                        *charge the enrollee for such services; and*

23                        *“(iv) provides the option to affirma-*  
24                        *tively consent to receiving such services*  
25                        *from such practitioner or facility;*

1           “(B) such enrollee signs such notice con-  
 2           senting to receive such services from an out-of-  
 3           network provider at an in-network facility, and  
 4           acknowledging that the out-of-network services  
 5           may be covered at an out-of-network cost-sharing  
 6           amount, requiring higher cost-sharing obliga-  
 7           tions of the enrollee than if the service were pro-  
 8           vided by an in-network practitioner or facility;  
 9           and

10           “(C) such facility maintains documentation  
 11           of the enrollee’s signature or confirmation of re-  
 12           ceipt of such information under subparagraph  
 13           (B) in the enrollee’s patient record for 2 years  
 14           after the date of services.

15           “(3) DEFINITION.—For purposes of this sub-  
 16           section, the term ‘facility’ has the meaning given the  
 17           term ‘health care facility’ in section 2729A(c).

18           “(f) COVERAGE OF OUT-OF-NETWORK SERVICES FOR  
 19           ENROLLEES ADMITTED AFTER EMERGENCY SERVICES.—

20           “(1) PROTECTION FOR ENROLLEES ADMITTED TO  
 21           THE HOSPITAL FOR EMERGENCY SERVICES PRIOR TO  
 22           STABILIZATION.—In the case of an enrollee in a  
 23           group health plan or group or individual health in-  
 24           surance coverage who receives emergency services, or  
 25           maternal care for a woman in labor, in the emer-

1        *gency department of an out-of-network facility and*  
2        *has not been stabilized (within the meaning of sub-*  
3        *section (b)(2)(C)), if the patient is subsequently ad-*  
4        *mitted to the out-of-network facility for care, the cost-*  
5        *sharing requirement (expressed as a copayment*  
6        *amount, coinsurance rate, or deductible) with respect*  
7        *to any out-of-network services provided to the enrollee*  
8        *prior to being stable and in a condition to receive in-*  
9        *formation under (2), is the same requirement that*  
10       *would apply as under subsection (b)(2)(C)(ii)(II).*

11            *“(2) NOTICE AND CONSENT.—*

12                    *“(A) IN GENERAL.—Subject to subsection*  
13                    *(h), in the case of an enrollee in a group health*  
14                    *plan or group or individual health insurance*  
15                    *coverage who receives emergency services, or ma-*  
16                    *ternal care for a woman in labor, in the emer-*  
17                    *gency department of an out-of-network facility*  
18                    *and has been stabilized (within the meaning of*  
19                    *subsection (b)(2)(C)), if the patient is subse-*  
20                    *quently admitted to the out-of-network facility*  
21                    *for care, the cost-sharing requirement (expressed*  
22                    *as a copayment amount, coinsurance rate, or de-*  
23                    *ductible) with respect to any out-of-network serv-*  
24                    *ices is the same requirement that would apply if*  
25                    *such services were provided by an in-network*

1            *provider, unless the enrollee, once stable and in*  
2            *a condition to receive such information, includ-*  
3            *ing having sufficient mental capacity—*

4            *“(i) has been provided by the facility,*  
5            *prior to the provision of any post-stabiliza-*  
6            *tion, out-of-network service at such facility,*  
7            *with—*

8            *“(I) paper or electronic notifica-*  
9            *tion that the practitioner or facility is*  
10           *an out-of-network health care provider*  
11           *and the out-of-network rate of the pro-*  
12           *vider, as applicable, and the option to*  
13           *affirmatively consent to receiving serv-*  
14           *ices from such practitioner or facility;*  
15           *and*

16           *“(II) the estimated amount that*  
17           *such provider may charge the partici-*  
18           *part, beneficiary, or enrollee for such*  
19           *services involved;*

20           *“(ii) has been provided by the plan or*  
21           *coverage, prior to the provision of any post-*  
22           *stabilization, out-of-network service at such*  
23           *facility, with—*

24           *“(I) paper or electronic notifica-*  
25           *tion (and including electronic notifica-*

1                    *tion whenever practicable) that the*  
2                    *practitioner or facility is an out-of-net-*  
3                    *work health care provider, and the op-*  
4                    *tion to affirmatively consent to receiv-*  
5                    *ing services from such practitioner or*  
6                    *facility;*

7                    *“(II) a list of in-network practi-*  
8                    *tioners or facilities in the relevant geo-*  
9                    *graphic area that could provide the*  
10                   *same services, and an option for a re-*  
11                   *ferral to such providers; and*

12                   *“(III) information about whether*  
13                   *prior authorization or other care man-*  
14                   *agement limitations may be required*  
15                   *in advance of receiving in-network*  
16                   *services at the facility;*

17                   *“(iii) has acknowledged, in writing,*  
18                   *that the out-of-network services provided*  
19                   *after the individual has been stabilized may*  
20                   *not be covered or may be covered at an out-*  
21                   *of-network cost-sharing amount, requiring*  
22                   *higher cost-sharing obligations of the en-*  
23                   *rollee than if the service were provided at*  
24                   *an in-network facility.*

1           “(B) *REQUIREMENTS OF NOTICE.*—*The no-*  
2           *tice under subparagraph (A) shall be in a format*  
3           *determined by the Secretary to give a reasonable*  
4           *layperson clear comprehension of the terms of the*  
5           *agreement, including all possible financial re-*  
6           *sponsibilities, including the requirements that*  
7           *the notice—*

8                     “(i) *does not exceed one page in length;*

9                     “(ii) *is readily identifiable for its pur-*  
10            *pose and as a contract of consent;*

11                    “(iii) *clearly states that consent to po-*  
12            *tential out-of-network charges is optional*  
13            *and that the enrollee has the choice to trans-*  
14            *fer to an in-network facility;*

15                    “(iv) *includes an estimate of the*  
16            *amount that such provider will charge the*  
17            *participant, beneficiary, or enrollee for such*  
18            *services involved; and*

19                    “(v) *be available in the 15 most com-*  
20            *mon languages in the facility’s geographic*  
21            *area, with the facility making a good faith*  
22            *effort to provide oral notice in the enrollee’s*  
23            *primary language if it is not one of such 15*  
24            *languages.*

1           “(C) *MAINTENANCE OF RECORDS.*—A facil-  
2           ity shall maintain documentation of notice given  
3           to an enrollee pursuant to this subsection and  
4           the enrollee’s confirmation of receipt of such in-  
5           formation in the enrollee’s patient record for 2  
6           years after the date of services.

7           “(3) *RULEMAKING.*—Not later than 6 months  
8           after the date of enactment of the Lower Health Care  
9           Costs Act, the Secretary shall issue regulations to  
10          carry out this subsection, which shall include clari-  
11          fication on how to determine whether an individual  
12          is stabilized and the timing of the notice required  
13          under this paragraph.

14          “(g) *PROHIBITION ON BILLING MORE THAN AN IN-*  
15 *NETWORK RATE UNDER CERTAIN CIRCUMSTANCES.*—

16           “(1) *IN GENERAL.*—A facility or practitioner  
17          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) *out-of-network services at an in-net-*  
22          *work facility described in subsection (e)(1);*

23           “(C) *out-of-network services at an in-net-*  
24          *work facility described in subsection (e)(2),*  
25          *where the notice and consent for receiving such*

1           *services out-of-network did not meet the require-*  
2           *ment of such subsection;*

3           “(D) *services furnished by an out-of-network*  
4           *provider after an enrollee has been admitted to*  
5           *the hospital for emergency services but prior to*  
6           *stabilization, as described in subsection (f)(1); or*

7           “(E) *out-of-network services furnished after*  
8           *the enrollee has been stabilized (within the mean-*  
9           *ing of subsection (b)(2)(C)), where the notice and*  
10          *option for receiving care at an alternate facility*  
11          *required under subsection (f)(2) have not been*  
12          *provided to the enrollee and the enrollee did not*  
13          *give consent under subsection (f)(3),*  
14          *may not bill an enrollee in a group health plan or*  
15          *group or individual health insurance coverage for*  
16          *amounts beyond the cost-sharing amount that would*  
17          *apply under subsection (b)(1)(C)(ii)(II), (e)(1), (e)(2),*  
18          *or (f), as applicable.*

19          “(2) *NOTICE.—A facility furnishing services de-*  
20          *scribed in paragraph (1) shall provide enrollees in a*  
21          *group health plan or group or individual health in-*  
22          *surance coverage with a one-page notice, in 16-point*  
23          *font, upon intake at the emergency room or being ad-*  
24          *mitted at the facility of the prohibition on balance*  
25          *billing under paragraph (1) and who to contact for*

1 *recourse if they are sent a balance bill in violation of*  
2 *such paragraph. The facility shall be responsible for*  
3 *obtaining the signature from the enrollee on such no-*  
4 *tice. The Secretary shall issue regulations within 6*  
5 *months of the date of enactment of the Lower Health*  
6 *Care Costs Act on the requirements for the notice*  
7 *under this paragraph.*

8 *“(h) MAINTAINING STATE SURPRISE BILLING PRO-*  
9 *TECTIONS.—*

10 *“(1) IN GENERAL.—Nothing in this section shall*  
11 *prevent a State from establishing or continuing in ef-*  
12 *fect, with respect to health insurance issuers, facili-*  
13 *ties, or practitioners, an alternate method under State*  
14 *law for determining the appropriate compensation for*  
15 *services described in subsection (b), (e), or (f).*

16 *“(2) ADDITIONAL APPLICATION.—In the case of*  
17 *group health plans or group or individual health in-*  
18 *surance coverage offered in a State that has not estab-*  
19 *lished an alternate method described in paragraph*  
20 *(1), such as arbitration or a benchmark, or for serv-*  
21 *ices described in subsection (b), (e), or (f) that are not*  
22 *covered by such State’s alternate method described in*  
23 *paragraph (1), the provisions of this section shall*  
24 *apply.*

1           “(3) *SELF-INSURED PLANS*.—Subsections (b), (e),  
2           and (f) shall apply to a self-insured group health  
3           plan that is not subject to State insurance regulation.

4           “(i) *DEFINITIONS*.—In this section:

5           “(1) *IN-NETWORK*.—The term ‘in-network’, with  
6           respect to a group health plan or health insurance  
7           coverage means a provider that has a contractual re-  
8           lationship with the plan.

9           “(2) *ENROLLEE*.—The term ‘enrollee’, with re-  
10          spect to health insurance coverage or a group health  
11          plan, includes a participant, dependent, or bene-  
12          ficiary.

13          “(3) *ANCILLARY SERVICES*.—The term ‘ancillary  
14          services’ means non-emergency care that is—

15               “(A) provided by anesthesiologists, patholo-  
16               gists, emergency medicine providers, intensivists,  
17               radiologists, neonatologists, hospitalists, and as-  
18               sistant surgeons, whether the care is provided by  
19               a physician or non-physician practitioner;

20               “(B) a diagnostic service (including radi-  
21               ology and lab services); or

22               “(C) provided by such other specialty prac-  
23               titioner not typically selected by the patients re-  
24               ceiving the care, which the Secretary may add

1           *periodically to such definition through rule-*  
 2           *making.”.*

3           **(b) ENFORCEMENT OF BALANCE BILLING PROHIBI-**  
 4           **TIONS.**—*Part C of title XXVII of the Public Health Service*  
 5           *Act (42 U.S.C. 300gg–91 et seq.) is amended by adding at*  
 6           *the end the following:*

7           **“SEC. 2795. ENFORCEMENT OF BALANCE BILLING PROHIBI-**  
 8           **TIONS.**

9           **“(a) IN GENERAL.**—*Subject to subsection (b), a facil-*  
 10           *ity or practitioner that violates a requirement under section*  
 11           *2719A(g)(1) or fails to provide notice or obtain consent as*  
 12           *required under subsection (e)(2) or (f)(2) shall be subject*  
 13           *to a civil monetary penalty of not more than \$10,000 for*  
 14           *each act constituting such violation.*

15           **“(b) PROCEDURE.**—*The provisions of section 1128A of*  
 16           *the Social Security Act, other than subsections (a) and (b)*  
 17           *and the first sentence of subsection (c)(1) of such section,*  
 18           *shall apply to civil money penalties under this subsection*  
 19           *in the same manner as such provisions apply to a penalty*  
 20           *or proceeding under section 1128A of the Social Security*  
 21           *Act.*

22           **“(c) SAFE HARBOR.**—

23           **“(1) IN GENERAL.**—*The Secretary shall waive*  
 24           *the penalties described under subsection (a) with re-*  
 25           *spect to a facility or, practitioner who does not know-*

1 *ingly violate, and should not have reasonably known*  
2 *it violated, section 2719A(g)(1) with respect to an en-*  
3 *rollee, if such facility or practitioner, within 30 days*  
4 *of the violation, withdraws the bill that was in viola-*  
5 *tion of section 2719A(g)(1), and, as applicable, reim-*  
6 *burses the group health plan, health insurance issuer,*  
7 *or enrollee, in an amount equal to the difference be-*  
8 *tween the amount billed and the amount allowed to*  
9 *be billed under section 2719A(g)(1), plus interest, at*  
10 *an interest rate determined by the Secretary.*

11 *“(2) HARDSHIP EXEMPTION.—The Secretary*  
12 *may establish a hardship exemption to the penalties*  
13 *under this section.*

14 *“(3) STATE ENFORCEMENT.—The Secretary shall*  
15 *wave penalties under this section with respect to a*  
16 *facility or practitioner that has already been subject*  
17 *to enforcement action under State law for a violation*  
18 *described in subsection (a).”.*

19 *(c) APPLICATION TO GRANDFATHERED PLANS.—Sec-*  
20 *tion 1251(a) of the Patient Protection and Affordable Care*  
21 *Act (42 U.S.C. 18011(a)) is amended by adding at the end*  
22 *the following:*

23 *“(5) APPLICATION OF ADDITIONAL PROVI-*  
24 *SIONS.—Subsections (b) through (h) of section 2719A*  
25 *of the Public Health Service Act (42 U.S.C. 300gg—*

1       19a) shall apply to grandfathered health plans for  
 2       plan years beginning with the second plan year that  
 3       begins after the date of enactment of the Lower Health  
 4       Care Costs Act.”.

5       (d) *COVERAGE UNDER FEDERAL EMPLOYEES HEALTH*  
 6 *BENEFITS PROGRAM.*—Section 8904 of title 5, United  
 7 States Code, is amended by adding at the end the following:  
 8       “(c) Any health benefits plan offered under this chapter  
 9 shall be treated as a group health plan or group or indi-  
 10 vidual health insurance coverage for purposes of subsections  
 11 (e) through (g) of section 2719A of the Public Health Service  
 12 Act (42 U.S.C. 300gg–19a) (except for paragraph (3) of  
 13 such subsection (g)).”.

14 **SEC. 103. BENCHMARK FOR PAYMENT.**

15       (a) *IN GENERAL.*—Subpart II of part A of title XXVII  
 16 of the Public Health Service Act (42 U.S.C. 300gg–11 et  
 17 seq.) is amended by adding at the end the following:

18 **“SEC. 2729A. BENCHMARK FOR PAYMENT.**

19       “(a) *ESTABLISHMENT OF BENCHMARK.*—A group  
 20 health plan or health insurance issuer offering group or in-  
 21 dividual health insurance coverage shall pay providers, in-  
 22 cluding facilities and practitioners, furnishing services for  
 23 which such facilities and practitioners are prohibited under  
 24 section 2719A(g) from billing enrollees for amounts beyond  
 25 the cost-sharing amount that would apply under subsection

1 *(b)(1)(C)(ii)(II), (e), or (f) of section 2719A, the median in-*  
 2 *network rate for such services provided to enrollees, using*  
 3 *a methodology determined under subsection (b) for the same*  
 4 *or similar services offered by the group health plan or health*  
 5 *insurance issuer in that geographic region. Such payment*  
 6 *shall be made in a timely fashion in order to ensure compli-*  
 7 *ance with sections 399V-7 and 2729D.*

8 *“(b) MEDIAN IN-NETWORK RATE.—*

9 *“(1) IN GENERAL.—For purposes of this section,*  
 10 *the term ‘median in-network rate’ means, with respect*  
 11 *to health care services covered by a group health plan*  
 12 *or group or individual health insurance coverage, the*  
 13 *median contracted rate under the applicable plan or*  
 14 *coverage recognized under the plan or coverage as the*  
 15 *total maximum payment for the service minus the in-*  
 16 *network cost-sharing for such service under the plan*  
 17 *or coverage, for the same or a similar service that is*  
 18 *provided by a provider in the same or similar spe-*  
 19 *cialty and in the geographic region in which the serv-*  
 20 *ice is furnished.*

21 *“(2) RULEMAKING.—*

22 *“(A) IN GENERAL.—Not later than 1 year*  
 23 *after the date of enactment of the Lower Health*  
 24 *Care Costs Act, the Secretary shall, through rule-*  
 25 *making, determine the methodology a group*

1 health plan or health insurance issuer is re-  
2 quired to use to determine the median in-net-  
3 work rate described in paragraph (1), differen-  
4 tiating by business line, the information the plan  
5 or issuer shall share with the out-of-network pro-  
6 vider involved when making such a determina-  
7 tion, and the geographic regions applied for pur-  
8 poses of this subsection. Such rulemaking shall  
9 take into account payments that are made by  
10 health insurance issuers that are not on a fee-for-  
11 service basis.

12 “(B) GEOGRAPHIC REGIONS.—In estab-  
13 lishing geographic regions under subparagraph  
14 (A), the Secretary shall consider adequate access  
15 to services in rural areas and health professional  
16 shortage areas, as defined in section 332. The  
17 Secretary shall consult with the National Asso-  
18 ciation of Insurance Commissioners in estab-  
19 lishing the geographic regions. The Secretary  
20 shall update the geographic regions periodically,  
21 as appropriate, taking into account the findings  
22 of the report under section 106 of the Lower  
23 Health Care Costs Act.

24 “(3) CERTAIN INSURERS.—If a group health  
25 plan or health insurance issuer offering group or in-

1        *dividual health insurance coverage does not have suf-*  
2        *ficient information to calculate a median in-network*  
3        *rate for this service or provider type, or amount of,*  
4        *claims for services (as determined by the applicable*  
5        *State authority, in the case of health insurance cov-*  
6        *erage, or by the Secretary of Labor, in the case of a*  
7        *self-insured group health plan) covered under the list*  
8        *of out-of-network services set by the State authority or*  
9        *Secretary of Labor, as applicable, in a particular geo-*  
10       *graphic area, such plan or issuer shall demonstrate*  
11       *that it will use a database free of conflicts of interest*  
12       *that has sufficient information reflecting allowed*  
13       *amounts paid to individual health care providers for*  
14       *relevant services provided in the applicable geo-*  
15       *graphic region, and that such plan or issuer will use*  
16       *that database to determine a median in-network rate.*  
17       *The group health plan or health insurance issuer shall*  
18       *cover the cost of accessing the database.*

19                *“(4) RULE OF CONSTRUCTION.—Nothing in this*  
20        *subsection shall prevent a group health plan or health*  
21        *insurance issuer from establishing separate calcula-*  
22        *tions of a median in-network rate under paragraph*  
23        *(1) for services delivered in nonhospital facilities, in-*  
24        *cluding freestanding emergency rooms.*

1           “(c) *FACILITY*.—For purposes of this section, the term  
 2 *‘health care facility’* or *‘facility’* includes hospitals, hospital  
 3 *outpatient departments, critical access hospitals, ambula-*  
 4 *tory surgery centers, laboratories, radiology clinics, free-*  
 5 *standing emergency rooms, and any other facility that pro-*  
 6 *vides services that are covered under a group health plan*  
 7 *or health insurance coverage, including settings of care sub-*  
 8 *ject to section 2719A(b).”.*

9           (b) *NON-FEDERAL GOVERNMENTAL PLANS*.—Section  
 10 *2722(a)(2)(E) of the Public Health Service Act (42 U.S.C.*  
 11 *300gg–21(a)(2)(E)) is amended by inserting “, except that*  
 12 *such election shall be available with respect to section*  
 13 *2729A” before the period.*

14 **SEC. 104. EFFECTIVE DATE.**

15           *The amendments made by sections 101, 102, and 103*  
 16 *shall take effect beginning in the second plan year that be-*  
 17 *gins after the date of enactment of this Act.*

18 **SEC. 105. ENDING SURPRISE AIR AMBULANCE BILLS.**

19           (a) *IN GENERAL*.—Part A of title XXVII of the Public  
 20 *Health Service Act is amended by inserting after section*  
 21 *2719A (42 U.S.C. 300gg–19a) the following:*

22 **“SEC. 2719B. ENDING SURPRISE AIR AMBULANCE BILLS.**

23           “(a) *IN GENERAL*.—In the case of an enrollee in a  
 24 *group health plan or group or individual health insurance*  
 25 *coverage who receives air ambulance services from an out-*

1 *of-network provider, if such services would be covered if pro-*  
 2 *vided by an in-network provider—*

3           “(1) *the cost-sharing requirement (expressed as a*  
 4 *copayment amount, coinsurance rate, or deductible)*  
 5 *with respect to such services shall be the same require-*  
 6 *ment that would apply if such services were provided*  
 7 *by an in-network practitioner, and any coinsurance*  
 8 *or deductible shall be based on in-network rates; and*

9           “(2) *such cost-sharing amounts shall be counted*  
 10 *towards the in-network deductible and in-network*  
 11 *out-of-pocket maximum amount under the plan or*  
 12 *coverage for the plan year.*

13           “(b) *PAYMENT RATE.—A group health plan or health*  
 14 *insurance issuer shall pay for air ambulance services for*  
 15 *purposes of subsection (a) at the median in-network as de-*  
 16 *finied in subsection (c).*

17           “(c) *MEDIAN IN-NETWORK RATE.—*

18           “(1) *IN GENERAL.—For purposes of this section,*  
 19 *the term ‘median in-network rate’ means, with respect*  
 20 *to air ambulance services covered by a group health*  
 21 *plan or group or individual health insurance cov-*  
 22 *erage, the median contracted rate under the applica-*  
 23 *ble plan or coverage recognized under the plan or cov-*  
 24 *erage as the total maximum payment for the service,*  
 25 *minus the in-network cost-sharing for such service*

1       under the plan or coverage, for the same or a similar  
2       service that is provided by a provider in the same or  
3       similar specialty, and in the geographic region in  
4       which the service is furnished.

5               “(2) RULEMAKING.—

6               “(A) IN GENERAL.—Not later than 6  
7       months after the date of enactment of the Lower  
8       Health Care Costs Act, the Secretary shall,  
9       through rulemaking, determine the methodology  
10      a group health plan or health insurance issuer is  
11      required to use to determine the median in-net-  
12      work rate described in paragraph (1), the infor-  
13      mation the plan or issuer shall share with the  
14      out-of-network provider involved when making  
15      such a determination, and the geographic regions  
16      applied for purposes of this subsection. Such  
17      rulemaking shall take into account payments  
18      that are made by issuers that are not on a fee-  
19      for-service basis.

20              “(B) GEOGRAPHIC REGIONS.—In estab-  
21      lishing geographic regions as described in sub-  
22      paragraph (A), the Secretary shall consider ade-  
23      quate access to services in rural areas. The Sec-  
24      retary shall consult with the National Associa-  
25      tion of Insurance Commissioners in establishing

1           *the geographic regions. The Secretary shall up-*  
2           *date the geographic regions periodically, as ap-*  
3           *propriate, taking into account the findings of the*  
4           *report under section 106 of the Lower Health*  
5           *Care Costs Act.*

6           “(3) *CERTAIN INSURERS.—If a group health*  
7           *plan or health insurance issuer offering group or in-*  
8           *dividual health insurance coverage does not have suf-*  
9           *ficient information to calculate a median in-network*  
10          *rate for this service or provider type, or amount of,*  
11          *claims for services (as determined by the applicable*  
12          *State authority, in the case of health insurance cov-*  
13          *erage, or by the Secretary of Labor, in the case of a*  
14          *self-insured group health plan) covered under the list*  
15          *of out-of-network services set by the State authority or*  
16          *Secretary of Labor, as applicable, in a particular geo-*  
17          *graphic area, such plan or issuer shall demonstrate*  
18          *that it will use a database free of conflicts of interest*  
19          *that has sufficient information reflecting allowed*  
20          *amounts paid to individual health care providers for*  
21          *relevant services provided in the applicable geo-*  
22          *graphic region, and that such plan or issuer will use*  
23          *that database to determine a median in-network rate.*  
24          *The group health plan or health insurance issuer shall*  
25          *cover the cost of accessing the database.*

1           “(4) *CLARIFICATION.*—*For purposes of this sub-*  
2           *section, the Secretary may define geographic regions*  
3           *that are different from the geographic regions identi-*  
4           *fied for purposes of section 2729A(b) to ensure that*  
5           *an adequate number of air ambulance services are in-*  
6           *network in each geographic region so that a median*  
7           *in-network rate for air ambulance services may be*  
8           *calculated for each such region.*

9           “(d) *COST-SHARING LIMITATION.*—*An air ambulance*  
10          *service provider may not bill an enrollee in a group health*  
11          *plan or group or individual health insurance coverage for*  
12          *amounts beyond the cost-sharing amount that applies under*  
13          *subsection (a).*

14          “(e) *ENFORCEMENT.*—

15                 “(1) *IN GENERAL.*—*Subject to paragraph (2), an*  
16                 *air ambulance service provider that violates sub-*  
17                 *section (d) shall be subject to a civil monetary penalty*  
18                 *of not more than \$10,000 for each act constituting*  
19                 *such violation.*

20                 “(2) *PROCEDURE.*—*The provisions of section*  
21                 *1128A of the Social Security Act, other than sub-*  
22                 *sections (a) and (b) and the first sentence of sub-*  
23                 *section (c)(1) of such section, shall apply to civil*  
24                 *money penalties under this subsection in the same*  
25                 *manner as such provisions apply to a penalty or pro-*

1        *ceeding under section 1128A of the Social Security*  
2        *Act.*

3            “(3) *SAFE HARBOR.*—*The Secretary shall waive*  
4        *the penalties described under paragraph (1) with re-*  
5        *spect to a air ambulance service provider who un-*  
6        *knowingly violates subsection (d) with respect to an*  
7        *enrollee, if such air ambulance service provider with-*  
8        *in 30 days of the violation, withdraws the bill that*  
9        *was in violation of subsection (d), and, as applicable,*  
10       *reimburses the group health plan, health insurance*  
11       *issuer, or enrollee, as applicable, in an amount equal*  
12       *to the amount billed in violation of subsection (d),*  
13       *plus interest, at an interest rate determined by the*  
14       *Secretary.”.*

15        (b) *EFFECTIVE DATE.*—*Section 2719B of the Public*  
16       *Health Service Act, as added by subsection (a), shall take*  
17       *effect on the date that is 1 year after the date of enactment*  
18       *of this Act.*

19        **SEC. 106. REPORT.**

20        *Not later than 1 year after the effective date described*  
21       *in section 104, and annually for the following 4 years, the*  
22       *Secretary of Health and Human Services, in consultation*  
23       *with the Federal Trade Commission and the Attorney Gen-*  
24       *eral, shall—*

25            (1) *conduct a study on—*

1           (A) the effects of the amendments made by  
2 sections 101, 102, 103, and 105, including any  
3 patterns of vertical or horizontal integration of  
4 health care facilities, providers, group health  
5 plans, or health insurance issuers;

6           (B) the effects of the amendments made by  
7 sections 101, 102, 103, and 105 on overall health  
8 care costs;

9           (C) the effects of the amendments made by  
10 sections 101, 102, 103, and 105 on access to serv-  
11 ices, including specialty services, in rural areas  
12 and health professional shortage areas as defined  
13 in section 332; and

14           (D) recommendations, made in consultation  
15 with the Secretary of Labor and the Secretary of  
16 the Treasury, for effective enforcement of 2729A  
17 of the Public Health Service Act, as added by  
18 section 103, including potential challenges to ad-  
19 dressing anti-competitive consolidation by health  
20 care facilities, providers, group health plans, or  
21 health insurance issuers; and

22           (2) submit a report on such study to the Com-  
23 mittee on Health, Education, Labor, and Pensions,  
24 the Committee on Commerce, Science, and Transpor-  
25 tation, the Committee on Finance, and the Committee

1        *on the Judiciary of the Senate and the Committee on*  
 2        *Education and Labor, the Committee on Energy and*  
 3        *Commerce, the Committee on Ways and Means, and*  
 4        *the Committee on the Judiciary of the House of Rep-*  
 5        *resentatives.*

6        **TITLE            II—REDUCING            THE**  
 7        **PRICES    OF    PRESCRIPTION**  
 8        **DRUGS**

9        **SEC. 201. BIOLOGICAL PRODUCT PATENT TRANSPARENCY.**

10        *(a) IN GENERAL.—Section 351 of the Public Health*  
 11        *Service Act (42 U.S.C. 262) is amended by adding at the*  
 12        *end the following:*

13        *“(o) ADDITIONAL REQUIREMENTS WITH RESPECT TO*  
 14        *PATENTS.—*

15                *“(1) APPROVED APPLICATION HOLDER LISTING*  
 16        *REQUIREMENTS.—*

17                        *“(A) IN GENERAL.—Beginning on the date*  
 18        *of enactment of the Lower Health Care Costs Act,*  
 19        *within 60 days of approval of an application*  
 20        *under subsection (a) or (k), the holder of such*  
 21        *approved application shall submit to the Sec-*  
 22        *retary a list of each patent required to be dis-*  
 23        *closed (as described in paragraph (3)).*

24                        *“(B) PREVIOUSLY APPROVED OR LICENSED*  
 25        *BIOLOGICAL PRODUCTS.—*

1                   “(i) *PRODUCTS LICENSED UNDER SEC-*  
2                   *TION 351 OF THE PHSA.—Not later than 30*  
3                   *days after the date of enactment of the*  
4                   *Lower Health Care Costs Act, the holder of*  
5                   *a biological product license that was ap-*  
6                   *proved under subsection (a) or (k) before the*  
7                   *date of enactment of such Act shall submit*  
8                   *to the Secretary a list of each patent re-*  
9                   *quired to be disclosed (as described in para-*  
10                   *graph (3)).*

11                   “(ii) *PRODUCTS APPROVED UNDER*  
12                   *SECTION 505 OF THE FFDCA.—Not later*  
13                   *than 30 days after March 23, 2020, the*  
14                   *holder of an approved application for a bio-*  
15                   *logical product under section 505 of the*  
16                   *Federal Food, Drug, and Cosmetic Act that*  
17                   *is deemed to be a license for the biological*  
18                   *product under this section on March 23,*  
19                   *2020, shall submit to the Secretary a list of*  
20                   *each patent required to be disclosed (as de-*  
21                   *scribed in paragraph (3)).*

22                   “(C) *UPDATES.—The holder of a biological*  
23                   *product license that is the subject of an applica-*  
24                   *tion under subsection (a) or (k) shall submit to*  
25                   *the Secretary a list that includes—*

1           “(i) any patent not previously required  
2           to be disclosed (as described in paragraph  
3           (3)) under subparagraph (A) or (B), as ap-  
4           plicable, within 30 days of the earlier of—

5                   “(I) the date of issuance of such  
6                   patent by the United States Patent  
7                   and Trademark Office; or

8                   “(II) the date of approval of a  
9                   supplemental application for the bio-  
10                  logical product; and

11           “(ii) any patent, or any claim with re-  
12           spect to a patent, included on the list pur-  
13           suant to this paragraph, that the Patent  
14           Trial and Appeal Board of the United  
15           States Patent and Trademark Office deter-  
16           mines in a written decision to cancel as  
17           unpatentable, within 30 days of such deci-  
18           sion.

19           “(2) PUBLICATION OF INFORMATION.—

20                   “(A) IN GENERAL.—Within 1 year of the  
21                   date of enactment of the Lower Health Care  
22                   Costs Act, the Secretary shall publish and make  
23                   available to the public a single, easily searchable  
24                   list that includes—

1           “(i) the official and proprietary name  
2 of each biological product licensed, or  
3 deemed to be licensed, under subsection (a)  
4 or (k);

5           “(ii) with respect to each biological  
6 product described in clause (i), each patent  
7 submitted in accordance with paragraph  
8 (1);

9           “(iii) the date of licensure and appli-  
10 cation number for each such biological prod-  
11 uct;

12           “(iv) the marketing status, dosage  
13 form, route of administration, strength,  
14 and, if applicable, reference product, for  
15 each such biological product;

16           “(v) the licensure status for each such  
17 biological product, including whether the li-  
18 cense at the time of listing is approved,  
19 withdrawn, or revoked;

20           “(vi) with respect to each such biologi-  
21 cal product, any period of exclusivity under  
22 paragraph (6), (7)(A), or (7)(B) of sub-  
23 section (k) of this section or section 527 of  
24 the Federal Food, Drug, and Cosmetic Act,  
25 and any extension of such period in accord-

1            *ance with subsection (m) of this section, for*  
2            *which the Secretary has determined such bi-*  
3            *ological product to be eligible, and the date*  
4            *on which such exclusivity expires;*

5            *“(vii) any determination of biosimi-*  
6            *larity or interchangeability for each such*  
7            *biological product; and*

8            *“(viii) information regarding approved*  
9            *indications for each such biological product,*  
10           *in such manner as the Secretary determines*  
11           *appropriate.*

12           *“(B) UPDATES.—Every 30 days after the*  
13           *publication of the first list under subparagraph*  
14           *(A), the Secretary shall revise the list to in-*  
15           *clude—*

16           *“(i)(I) each biological product licensed*  
17           *under subsection (a) or (k) during the 30-*  
18           *day period; and*

19           *“(II) with respect to each biological*  
20           *product described in subclause (I), the infor-*  
21           *mation described in clauses (i) through*  
22           *(viii) of subparagraph (A); and*

23           *“(ii) any updates to information pre-*  
24           *viously published in accordance with sub-*  
25           *paragraph (A).*

1           “(C) *NONCOMPLIANCE.*—Beginning 18  
2           *months after the date of enactment of the Lower*  
3           *Health Care Costs Act, the Secretary, in con-*  
4           *sultation with the Director of the United States*  
5           *Patent and Trademark Office, shall publish and*  
6           *make available to the public a list of any holders*  
7           *of biological product licenses, and the cor-*  
8           *responding biological product or products, that*  
9           *failed to submit information as required under*  
10           *paragraph (1), including any updates required*  
11           *under paragraph (1)(C), in such manner and*  
12           *format as the Secretary determines appropriate.*  
13           *If information required under paragraph (1) is*  
14           *submitted following publication of such list, the*  
15           *Secretary shall remove such holders of such bio-*  
16           *logical product licenses from the public list in a*  
17           *reasonable period of time.*

18           “(3) *PATENTS REQUIRED TO BE DISCLOSED.*—*In*  
19           *this section, a ‘patent required to be disclosed’ is any*  
20           *patent for which the holder of a biological product li-*  
21           *cence approved under subsection (a) or (k), or a bio-*  
22           *logical product application approved under section*  
23           *505 of the Federal Food, Drug, and Cosmetic Act and*  
24           *deemed to be a license for a biological product under*  
25           *this section on March 23, 2020, believes a claim of*

1        *patent infringement could reasonably be asserted by*  
2        *the holder, or by a patent owner that has granted an*  
3        *exclusive license to the holder with respect to the bio-*  
4        *logical product that is the subject of such license, if*  
5        *a person not licensed by the owner engaged in the*  
6        *making, using, offering to sell, selling, or importing*  
7        *into the United States of the biological product that*  
8        *is the subject of such license.”.*

9        (b)        *DISCLOSURE        OF        PATENTS.—Section*  
10        *351(l)(3)(A)(i) of the Public Health Service Act (42 U.S.C.*  
11        *262(l)(3)(A)(i)) is amended by inserting “included in the*  
12        *list provided by the reference product sponsor under sub-*  
13        *section (o)(1)” after “a list of patents”.*

14        (c) *REVIEW AND REPORT ON NONCOMPLIANCE.—Not*  
15        *later than 30 months after the date of enactment of this*  
16        *Act, the Secretary shall—*

17                (1) *solicit public comments regarding appro-*  
18        *priate remedies, in addition to the publication of the*  
19        *list under subsection (o)(2)(C) of section 351 of the*  
20        *Public Health Service Act (42 U.S.C. 262), as added*  
21        *by subsection (a), with respect to holders of biological*  
22        *product licenses who fail to timely submit informa-*  
23        *tion as required under subsection (o)(1) of such sec-*  
24        *tion 351, including any updates required under sub-*  
25        *paragraph (C) of such subsection (o)(1); and*

1           (2) *submit to Congress an evaluation of com-*  
2           *ments received under paragraph (1) and the rec-*  
3           *ommendations of the Secretary concerning appro-*  
4           *priate remedies.*

5           (d) *REGULATIONS.—The Secretary of Health and*  
6           *Human Services may promulgate regulations to carry out*  
7           *subsection (o) of section 351 of the Public Health Service*  
8           *Act (42 U.S.C. 262), as added by subsection (a).*

9           (e) *RULE OF CONSTRUCTION.—Nothing in this Act, in-*  
10          *cluding an amendment made by this Act, shall be construed*  
11          *to require or allow the Secretary of Health and Human*  
12          *Services to delay the licensing of a biological product under*  
13          *section 351 of the Public Health Service Act (42 U.S.C.*  
14          *262).*

15   **SEC. 202. ORANGE BOOK MODERNIZATION.**

16          (a) *SUBMISSION OF PATENT INFORMATION FOR BRAND*  
17          *NAME DRUGS.—*

18               (1) *IN GENERAL.—Paragraph (1) of section*  
19               *505(b) of the Federal Food, Drug, and Cosmetic Act*  
20               *(21 U.S.C. 355(b)) is amended to read as follows:*

21               “*(b)(1)(A) Any person may file with the Secretary an*  
22               *application with respect to any drug subject to the provi-*  
23               *sions of subsection (a). Such persons shall submit to the*  
24               *Secretary as part of the application—*

1           “(i) full reports of investigations which have  
2           been made to show whether or not such drug is safe  
3           for use and whether such drug is effective in use;

4           “(ii) a full list of the articles used as components  
5           of such drug;

6           “(iii) a full statement of the composition of such  
7           drug;

8           “(iv) a full description of the methods used in,  
9           and the facilities and controls used for, the manufac-  
10          ture, processing, and packing of such drug;

11          “(v) such samples of such drug and of the arti-  
12          cles used as components thereof as the Secretary may  
13          require;

14          “(vi) specimens of the labeling proposed to be  
15          used for such drug;

16          “(vii) any assessments required under section  
17          505B; and

18          “(viii) the patent number and expiration date, of  
19          each patent for which a claim of patent infringement  
20          could reasonably be asserted if a person not licensed  
21          by the owner engaged in the manufacture, use, or sale  
22          of the drug, and that—

23                 “(I) claims the drug for which the applicant  
24                 submitted the application and is a drug sub-  
25                 stance patent or a drug product patent; or

1                   “(II) claims the method of using the drug  
2                   for which approval is sought or has been granted  
3                   in the application.

4                   “(B) If an application is filed under this subsection  
5 for a drug, and a patent of the type described in subpara-  
6 graph (A)(viii) that claims such drug or a method of using  
7 such drug is issued after the filing date, the applicant shall  
8 amend the application to include such patent informa-  
9 tion.”.

10                   (2) *GUIDANCE.*—The Secretary of Health and  
11                   Human Services shall, in consultation with the Direc-  
12                   tor of the National Institutes of Health and with rep-  
13                   resentatives of the drug manufacturing industry, re-  
14                   view and develop guidance, as appropriate, on the in-  
15                   clusion of women and minorities in clinical trials re-  
16                   quired under subsection (b)(1)(A)(i) of section 505 of  
17                   the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
18                   355), as amended by paragraph (1).

19                   (b) *CONFORMING CHANGES TO REQUIREMENTS FOR*  
20 *SUBSEQUENT SUBMISSION OF PATENT INFORMATION.*—  
21 Section 505(c)(2) of the Federal Food, Drug, and Cosmetic  
22 Act (21 U.S.C. 355(c)(2)) is amended—

23                   (1) by inserting before the first sentence the fol-  
24                   lowing: “Not later than 30 days after the date of ap-  
25                   proval of an application under subsection (b), the

1 holder of the approved application shall file with the  
2 Secretary the patent number and the expiration date  
3 of any patent described in subclause (I) or (II) of sub-  
4 section (b)(1)(A)(viii), except that a patent that is  
5 identified as claiming a method of using such drug  
6 shall be filed only if the patent claims a method of  
7 use approved in the application. The holder of the ap-  
8 proved application shall file with the Secretary the  
9 patent number and the expiration date of any patent  
10 described in subclause (I) or (II) of subsection  
11 (b)(1)(A)(viii) that is issued after the date of ap-  
12 proval of the application, not later than 30 days after  
13 the date of issuance of the patent, except that a patent  
14 that claims a method of using such drug shall be filed  
15 only if approval for such use has been granted in the  
16 application.”;

17 (2) by inserting after “the patent number and  
18 the expiration date of any patent which” the fol-  
19 lowing: “fulfills the criteria in subsection (b) and”;

20 (3) by inserting after the third sentence (as  
21 amended by paragraph (1)) the following: “Patent in-  
22 formation that is not the type of patent information  
23 required by subsection (b)(1)(A)(viii) shall not be sub-  
24 mitted under this paragraph.”; and

1           (4) by inserting after “could not file patent in-  
2           formation under subsection (b) because no patent” the  
3           following: “of the type required to be submitted in  
4           subsection (b)(1)(A)(viii)”.

5           (c) *LISTING OF EXCLUSIVITIES*.—Subparagraph (A) of  
6           section 505(j)(7) of the Federal Food, Drug, and Cosmetic  
7           Act (21 U.S.C. 355(j)(7)) is amended by adding at the end  
8           the following:

9           “(iv) For each drug included on the list, the Secretary  
10          shall specify any exclusivity period that is applicable, for  
11          which the Secretary has determined the expiration date,  
12          and for which such period has not yet expired under—

13               “(I) clause (ii), (iii), or (iv) of subsection  
14               (c)(3)(E) of this section;

15               “(II) clause (iv) or (v) of paragraph (5)(B) of  
16               this subsection;

17               “(III) clause (ii), (iii), or (iv) of paragraph  
18               (5)(F) of this subsection;

19               “(IV) section 505A;

20               “(V) section 505E;

21               “(VI) section 527(a); or

22               “(VII) subsection (u)”.

23           (d) *ORANGE BOOK UPDATES WITH RESPECT TO IN-*  
24           *VALIDATED PATENTS*.—

25               (1) *IN GENERAL*.—

1           (A) *AMENDMENTS.*—Section 505(j)(7)(A) of  
2           the Federal Food, Drug, and Cosmetic Act (21  
3           U.S.C. 355(j)(7)(A)), as amended by subsection  
4           (c), is further amended by adding at the end the  
5           following:

6           “(v) In the case of a listed drug for which the  
7           list under clause (i) includes a patent for such drug,  
8           and where the Under Secretary of Commerce for In-  
9           tellectual Property and Director of the United States  
10          Patent and Trademark Office have cancelled any  
11          claim of the patent pursuant to a decision by the Pat-  
12          ent Trial and Appeal Board in an inter partes review  
13          conducted under chapter 31 of title 35, United States  
14          Code, or a post-grant review conducted under chapter  
15          32 of that title, and from which no appeal has been  
16          taken, or can be taken, the holder of the applicable  
17          approved application shall notify the Secretary, in  
18          writing, within 14 days of such cancellation, and, if  
19          the patent has been deemed wholly inoperative or in-  
20          valid, or if a patent claim has been cancelled, the re-  
21          visions required under clause (iii) shall include strik-  
22          ing the patent or information regarding such patent  
23          claim from the list with respect to such drug, as ap-  
24          plicable, except that the Secretary shall not remove a  
25          patent from the list before the expiration of any 180-

1 *day exclusivity period under paragraph (5)(B)(iv)*  
 2 *that relies on a certification described in paragraph*  
 3 *(2)(A)(vii)(IV) with respect to such patent.”.*

4 (B) *APPLICATION.—The amendment made*  
 5 *by subparagraph (A) shall not apply with re-*  
 6 *spect to any determination with respect to a pat-*  
 7 *ent or patent claim that is made prior to the*  
 8 *date of enactment of this Act.*

9 (2) *NO EFFECT ON FIRST APPLICANT EXCLU-*  
 10 *SIVITY PERIOD.—Section 505(j)(5)(B)(iv)(I), as*  
 11 *amended by section 205, is amended by adding at the*  
 12 *end the following: “This subclause shall apply even if*  
 13 *a patent is stricken from the list under paragraph*  
 14 *(7)(A), pursuant to paragraph (7)(A)(v), provided*  
 15 *that, at the time that the first applicant submitted an*  
 16 *application under this subsection containing a certifi-*  
 17 *cation described in paragraph (2)(A)(vii)(IV), the*  
 18 *patent that was the subject of such certification was*  
 19 *included in such list with respect to the listed drug.”.*

20 **SEC. 203. ENSURING TIMELY ACCESS TO GENERICS.**

21 *Section 505(q) of the Federal Food, Drug, and Cos-*  
 22 *metic Act (21 U.S.C. 355(q)) is amended—*

23 (1) *in paragraph (1)—*

24 (A) *in subparagraph (A)(i), by inserting “,*  
 25 *10.31,” after “10.30”;*

1                   (B) in subparagraph (E)—

2                   (i) by striking “application and” and  
3                   inserting “application or”;

4                   (ii) by striking “If the Secretary” and  
5                   inserting the following:

6                   “(i) *IN GENERAL.—If the Secretary*”;

7                   and

8                   (iii) by striking the second sentence  
9                   and inserting the following:

10                   “(i) *PRIMARY PURPOSE OF DELAY-*  
11                   *ING.—*

12                   “(I) *IN GENERAL.—In deter-*  
13                   *mining whether a petition was sub-*  
14                   *mitted with the primary purpose of de-*  
15                   *laying an application, the Secretary*  
16                   *may consider the following factors:*

17                   “(aa) *Whether the petition*  
18                   *was submitted in accordance with*  
19                   *paragraph (2)(B), based on when*  
20                   *the petitioner knew or reasonably*  
21                   *should have known the relevant*  
22                   *information relied upon to form*  
23                   *the basis of such petition.*

24                   “(bb) *Whether the petitioner*  
25                   *has submitted multiple or serial*

1            *petitions or supplements to peti-*  
2            *tions raising issues that reason-*  
3            *ably could have been known to the*  
4            *petitioner at the time of submis-*  
5            *sion of the earlier petition or peti-*  
6            *tions.*

7            *“(cc) Whether the petition*  
8            *was submitted close in time to a*  
9            *known, first date upon which an*  
10           *application under subsection*  
11           *(b)(2) or (j) of this section or sec-*  
12           *tion 351(k) of the Public Health*  
13           *Service Act could be approved.*

14           *“(dd) Whether the petition*  
15           *was submitted without relevant*  
16           *data or information in support of*  
17           *the scientific positions forming the*  
18           *basis of such petition.*

19           *“(ee) Whether the petition*  
20           *raises the same or substantially*  
21           *similar issues as a prior petition*  
22           *to which the Secretary has re-*  
23           *sponded substantively already, in-*  
24           *cluding if the subsequent submis-*

1            *sion follows such response from*  
2            *the Secretary closely in time.*

3            *“(ff) Whether the petition re-*  
4            *quests changing the applicable*  
5            *standards that other applicants*  
6            *are required to meet, including re-*  
7            *questing testing, data, or labeling*  
8            *standards that are more onerous*  
9            *or rigorous than the standards the*  
10           *Secretary has determined to be*  
11           *applicable to the listed drug, ref-*  
12           *erence product, or petitioner’s*  
13           *version of the same drug.*

14           *“(gg) The petitioner’s record*  
15           *of submitting petitions to the*  
16           *Food and Drug Administration*  
17           *that have been determined by the*  
18           *Secretary to have been submitted*  
19           *with the primary purpose of*  
20           *delay.*

21           *“(hh) Other relevant and ap-*  
22           *propriate factors, which the Sec-*  
23           *retary shall describe in guidance.*

24           *“(II) GUIDANCE.—The Secretary*  
25           *may issue or update guidance, as ap-*

1                   *appropriate, to describe factors the Sec-*  
2                   *retary considers in accordance with*  
3                   *subclause (II).”;*

4                   *(C) by adding at the end the following:*

5                   *“(iii) REFERRAL TO THE FEDERAL*  
6                   *TRADE COMMISSION.—The Secretary shall*  
7                   *establish procedures for referring to the Fed-*  
8                   *eral Trade Commission any petition or sup-*  
9                   *plement to a petition that the Secretary de-*  
10                   *termines was submitted with the primary*  
11                   *purpose of delaying approval of an applica-*  
12                   *tion. Such procedures shall include notifica-*  
13                   *tion to the petitioner by the Secretary.”;*

14                   *(D) by striking subparagraph (F);*

15                   *(E) by redesignating subparagraphs (G)*  
16                   *through (I) as subparagraphs (F) through (H),*  
17                   *respectively; and*

18                   *(F) in subparagraph (H), as so redesign-*  
19                   *ated, by striking “submission of this petition”*  
20                   *and inserting “submission of this document”;*

21                   *(2) in paragraph (2)—*

22                   *(A) by redesignating subparagraphs (A)*  
23                   *through (C) as subparagraphs (C) through (E),*  
24                   *respectively;*

1           (B) by inserting before subparagraph (C),  
2 as so redesignated, the following:

3           “(A) *IN GENERAL.*—A person shall submit a  
4 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) or  
9 (j) of this section or section 351(k) of the Public  
10 Health Service Act. Such petition and any sup-  
11 plement to such a petition shall describe all in-  
12 formation and arguments that form the basis of  
13 the relief requested in any civil action described  
14 in the previous sentence.

15           “(B) *TIMELY SUBMISSION OF CITIZEN PETI-*  
16 *TION.*—A petition and any supplement to a peti-  
17 tion shall be submitted within 60 days after the  
18 person knew, or reasonably should have known,  
19 the information that forms the basis of the re-  
20 quest made in the petition or supplement.”;

21           (C) in subparagraph (C), as so redesign-  
22 ated—

23           (i) in the heading, by striking “*WITHIN*  
24           *150 DAYS*”;

1           (ii) in clause (i), by striking “during  
2           the 150-day period referred to in paragraph  
3           (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 peti-  
8           tion, the Secretary approves or has ap-  
9           proved the application that is the subject of  
10          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 sec-  
22               tion 351(k) of the Public Health Service Act  
23               without complying with the requirements of  
24               subparagraph (A), the court shall dismiss

1           *without prejudice the action for failure to*  
2           *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 sec-*  
9           *tion 351(k) of the Public Health Service Act*  
10           *without complying with the requirements of*  
11           *subparagraph (B), the court shall dismiss*  
12           *with prejudice the action for failure to time-*  
13           *ly 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) or*  
23           *(j) of this section or section 351(k) of the*  
24           *Public Health Service Act before the Sec-*  
25           *retary has taken final agency action on the*

1            *petition within the meaning of subpara-*  
 2            *graph (C), the court shall dismiss without*  
 3            *prejudice the action for failure to exhaust*  
 4            *administrative remedies.”; and*

5            *(E) in clause (iii) of subparagraph (E), as*  
 6            *so redesignated, by striking “as defined under*  
 7            *subparagraph (2)(A)” and inserting “within the*  
 8            *meaning of subparagraph (C)”;* and  
 9            *(3) in paragraph (4)—*

10            *(A) by striking “EXCEPTIONS” and all that*  
 11            *follows through “This subsection does” and in-*  
 12            *serting “EXCEPTIONS.—This subsection does”;*

13            *(B) by striking subparagraph (B); and*

14            *(C) by redesignating clauses (i) and (ii) as*  
 15            *subparagraphs (A) and (B), respectively, and*  
 16            *adjusting the margins accordingly.*

17 **SEC. 204. PROTECTING ACCESS TO BIOLOGICAL PRODUCTS.**

18            *Section 351(k)(7) of the Public Health Service Act (42*  
 19            *U.S.C. 262(k)(7)) is amended by adding at the end the fol-*  
 20            *lowing:*

21            *“(D) DEEMED LICENSES.—*

22            *“(i) NO ADDITIONAL EXCLUSIVITY*  
 23            *THROUGH DEEMING.—An approved appli-*  
 24            *cation that is deemed to be a license for a*  
 25            *biological product under this section pursu-*

1            *ant to section 7002(e)(4) of the Biologics*  
2            *Price Competition and Innovation Act of*  
3            *2009 shall not be treated as having been*  
4            *first licensed under subsection (a) for pur-*  
5            *poses of subparagraphs (A) and (B).*

6            *“(ii) APPLICATION OF LIMITATIONS ON*  
7            *EXCLUSIVITY.—Subparagraph (C) shall*  
8            *apply with respect to a reference product re-*  
9            *ferred to in such subparagraph that was the*  
10           *subject of an approved application that was*  
11           *deemed to be a license pursuant to section*  
12           *7002(e)(4) of the Biologics Price Competi-*  
13           *tion and Innovation Act of 2009.*

14           *“(iii) APPLICABILITY.—The exclusivity*  
15           *periods described in section 527, section*  
16           *505A(b)(1)(A)(ii), and section*  
17           *505A(c)(1)(A)(ii) of the Federal Food,*  
18           *Drug, and Cosmetic Act shall continue to*  
19           *apply to a biological product after an ap-*  
20           *proved application for the biological prod-*  
21           *uct is deemed to be a license for the biologi-*  
22           *cal product under subsection (a) pursuant*  
23           *to section 7002(e)(4) of the Biologics Price*  
24           *Competition and Innovation Act of 2009.”.*

1 **SEC. 205. PREVENTING BLOCKING OF GENERIC DRUGS.**

2 (a) *IN GENERAL.*—Section 505(j)(5)(B)(iv)(I) of the  
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
4 355(j)(5)(B)(iv)(I)) is amended—

5 (1) by striking “180 days after the date” and in-  
6 serting “180 days after the earlier of the following:

7 “(aa) The date”; and

8 (2) by adding at the end the following:

9 “(bb) The date on which all of the fol-  
10 lowing conditions are first met, provided no  
11 application submitted by any first appli-  
12 cant is approved on or before such date:

13 “(AA) An application for the drug  
14 submitted by an applicant other than  
15 a first applicant has received tentative  
16 approval and could receive approval, if  
17 no first applicant were eligible for 180-  
18 day exclusivity under this clause, and  
19 such applicant has not entered into an  
20 agreement that would prevent commer-  
21 cial marketing upon approval and has  
22 submitted a notification to the Sec-  
23 retary documenting that it has not en-  
24 tered into an agreement that would  
25 prevent commercial marketing.

1                   “(BB) *Thirty-three months have*  
2                   *passed since the date of submission of*  
3                   *an application for the drug by one*  
4                   *first applicant, if there is only one*  
5                   *first applicant, or, in the case of more*  
6                   *than one first applicant, 33 months*  
7                   *have passed since the date of submis-*  
8                   *sion of all such applications.*

9                   “(CC) *Approval of an application*  
10                  *for the drug submitted by at least one*  
11                  *first applicant would not be precluded*  
12                  *under clause (iii).”.*

13           (b) *INFORMATION.—Not later than 60 days of the date*  
14           *of enactment of this Act, the Secretary of Health and*  
15           *Human Services (referred to in this subsection as the “Sec-*  
16           *retary”)* shall publish, as appropriate and available, infor-  
17           *mation sufficient to allow applicants to assess whether the*  
18           *conditions described in subitems (AA) through (CC) of sec-*  
19           *tion 505(j)(5)(B)(iv)(I)(bb) of the Federal Food, Drug, and*  
20           *Cosmetic Act (as amended by subsection (a)) have been or*  
21           *will be satisfied for all applications where the exclusivity*  
22           *period under (iv)(I) of section 505(j)(5)(B) of the Federal*  
23           *Food, Drug, and Cosmetic Act (as so amended) has not ex-*  
24           *pired, and shall provide updates to reflect the most recent*  
25           *information available to the Secretary.*

1 **SEC. 206. EDUCATION ON BIOLOGICAL PRODUCTS.**

2 *Subpart 1 of part F of title III of the Public Health*  
3 *Service Act (42 U.S.C. 262 et seq.) is amended by adding*  
4 *at the end the following:*

5 **“SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.**

6 *“(a) INTERNET WEBSITE.—*

7 *“(1) IN GENERAL.—The Secretary may main-*  
8 *tain and operate an internet website to provide edu-*  
9 *cational materials for health care providers, patients,*  
10 *and caregivers, regarding the meaning of the terms,*  
11 *and the standards for review and licensing of, biologi-*  
12 *cal products, including biosimilar biological products*  
13 *and interchangeable biosimilar biological products.*

14 *“(2) CONTENT.—Educational materials provided*  
15 *under paragraph (1) may include—*

16 *“(A) explanations of key statutory and reg-*  
17 *ulatory terms, including ‘biosimilar’ and ‘inter-*  
18 *changeable’, and clarification regarding the use*  
19 *of interchangeable biosimilar biological products;*

20 *“(B) information related to development*  
21 *programs for biological products, including bio-*  
22 *similar biological products and interchangeable*  
23 *biosimilar biological products and relevant clin-*  
24 *ical considerations for prescribers, which may*  
25 *include, as appropriate and applicable, informa-*

1            *tion related to the comparability of such biological*  
2            *products;*

3            *“(C) an explanation of the process for re-*  
4            *porting adverse events for biological products, in-*  
5            *cluding biosimilar biological products and inter-*  
6            *changeable biosimilar biological products; and*

7            *“(D) an explanation of the relationship be-*  
8            *tween biosimilar biological products and inter-*  
9            *changeable biosimilar biological products li-*  
10           *icensed under section 351(k) and reference prod-*  
11           *ucts (as defined in section 351(i)), including the*  
12           *standards for review and licensing of each such*  
13           *type of biological product.*

14           *“(3) FORMAT.—The educational materials pro-*  
15           *vided under paragraph (1) may be—*

16           *“(A) in formats such as webinars, con-*  
17           *tinuing medical education modules, videos, fact*  
18           *sheets, infographics, stakeholder toolkits, or other*  
19           *formats as appropriate and applicable; and*

20           *“(B) tailored for the unique needs of health*  
21           *care providers, patients, caregivers, and other*  
22           *audiences, as the Secretary determines appro-*  
23           *priate.*

1           “(4) *OTHER INFORMATION.*—*In addition to the*  
2           *information described in paragraph (2), the Secretary*  
3           *shall continue to publish the following information:*

4                     “(A) *The action package of each biological*  
5                     *product licensed under subsection (a) or (k).*

6                     “(B) *The summary review of each biological*  
7                     *product licensed under subsection (a) or (k).*

8           “(5) *CONFIDENTIAL AND TRADE SECRET INFOR-*  
9           *MATION.*—*This subsection does not authorize the dis-*  
10           *closure of any trade secret, confidential commercial or*  
11           *financial information, or other matter described in*  
12           *section 552(b) of title 5.*

13           “(b) *CONTINUING EDUCATION.*—*The Secretary shall*  
14           *advance education and awareness among health care pro-*  
15           *viders regarding biological products, including biosimilar*  
16           *biological products and interchangeable biosimilar biologi-*  
17           *cal products, as appropriate, including by developing or*  
18           *improving continuing medical education programs that ad-*  
19           *vance the education of such providers on the prescribing of,*  
20           *and relevant clinical considerations with respect to, biologi-*  
21           *cal products, including biosimilar biological products and*  
22           *interchangeable biosimilar biological products.”.*

23   **SEC. 207. BIOLOGICAL PRODUCT INNOVATION.**

24           *Section 351(j) of the Public Health Service Act (42*  
25           *U.S.C. 262(j)) is amended—*

1           (1) *by striking “except that a product” and in-*  
2 *serting “except that—*  
3 *“(1) a product”;*  
4           (2) *by striking “Act.” and inserting “Act; and”;*  
5 *and*  
6           (3) *by adding at the end the following:*  
7           *“(2) no requirement under such Act regarding*  
8 *an official compendium (as defined in section 201(j)*  
9 *of such Act), or other reference in such Act to an offi-*  
10 *cial compendium (as so defined), shall apply with re-*  
11 *spect to a biological product subject to regulation*  
12 *under this section.”.*

13 **SEC. 208. CLARIFYING THE MEANING OF NEW CHEMICAL**  
14 **ENTITY.**

15           (a) *IN GENERAL.—Chapter V of the Federal Food,*  
16 *Drug, and Cosmetic Act is amended—*

17           (1) *in section 505 (21 U.S.C. 355)—*

18           (A) *in subsection (c)(3)(E), by striking “ac-*  
19 *tive ingredient (including any ester or salt of the*  
20 *active ingredient)” each place it appears and in-*  
21 *serting “active moiety (as defined by the Sec-*  
22 *retary in section 314.3 of title 21, Code of Fed-*  
23 *eral Regulations (or any successor regula-*  
24 *tions))”;*

1           (B) in subsection (j)(5)(F), by striking “ac-  
2           tive ingredient (including any ester or salt of the  
3           active ingredient)” each place it appears and in-  
4           serting “active moiety (as defined by the Sec-  
5           retary in section 314.3 of title 21, Code of Fed-  
6           eral Regulations (or any successor regula-  
7           tions))”;

8           (C) in subsection (l)(2)(A)—

9           (i) by amending clause (i) to read as  
10          follows:

11          “(i) not later than 30 days after the date of  
12          approval of such applications—

13               “(I) for a drug, no active moiety (as  
14               defined by the Secretary in section 314.3 of  
15               title 21, Code of Federal Regulations (or  
16               any successor regulations)) of which has  
17               been approved in any other application  
18               under this section; or

19               “(II) for a biological product, no active  
20               ingredient of which has been approved in  
21               any other application under section 351 of  
22               the Public Health Service Act; and”;

23               (ii) in clause (ii), by inserting “or bio-  
24               logical product” before the period;

1                   (D) by amending subsection (s) to read as  
2                   follows:

3                   “(s) *REFERRAL TO ADVISORY COMMITTEE.*—The Sec-  
4                   retary shall—

5                   “(1) refer a drug or biological product to a Food  
6                   and Drug Administration advisory committee for re-  
7                   view at a meeting of such advisory committee prior  
8                   to the approval of such drug or biological if it is—

9                   “(A) a drug, no active moiety (as defined  
10                  by the Secretary in section 314.3 of title 21,  
11                  Code of Federal Regulations (or any successor  
12                  regulations)) of which has been approved in any  
13                  other application under this section; or

14                  “(B) a biological product, no active ingre-  
15                  dient of which has been approved in any other  
16                  application under section 351 of the Public  
17                  Health Service Act; or

18                  “(2) if the Secretary does not refer a drug or bio-  
19                  logical product described in paragraph (1) to a Food  
20                  and Drug Administration advisory committee prior  
21                  to such approval, provide in the action letter on the  
22                  application for the drug or biological product a sum-  
23                  mary of the reasons why the Secretary did not refer  
24                  the drug or biological product to an advisory com-  
25                  mittee prior to approval.”; and

1           (E) in subsection (u)(1), in the matter pre-  
2           ceding subparagraph (A)—

3           (i) by striking “active ingredient (in-  
4           cluding any ester or salt of the active ingre-  
5           dient)” and inserting “active moiety (as de-  
6           fined by the Secretary in section 314.3 of  
7           title 21, Code of Federal Regulations (or  
8           any successor regulations))”; and

9           (ii) by striking “same active ingre-  
10          dient” and inserting “same active moiety”;

11          (2) in section 512(c)(2)(F) (21 U.S.C.  
12          360b(c)(2)(F)), by striking “active ingredient (includ-  
13          ing any ester or salt of the active ingredient)” each  
14          place it appears and inserting “active moiety (as de-  
15          fined by the Secretary in section 314.3 of title 21,  
16          Code of Federal Regulations (or any successor regula-  
17          tions))”;

18          (3) in section 524(a)(4) (21 U.S.C. 360n(a)(4)),  
19          by amending subparagraph (C) to read as follows:

20               “(C) is for—

21               “(i) a human drug, no active moiety  
22               (as defined by the Secretary in section  
23               314.3 of title 21, Code of Federal Regula-  
24               tions (or any successor regulations)) of

1           *which has been approved in any other ap-*  
2           *plication under section 505(b)(1); or*

3           *“(ii) a biological product, no active in-*  
4           *redient of which has been approved in any*  
5           *other application under section 351 of the*  
6           *Public Health Service Act.”;*

7           *(4) in section 529(a)(4) (21 U.S.C. 21 U.S.C.*  
8           *360ff(a)(4)), by striking subparagraphs (A) and (B)*  
9           *and inserting the following:*

10           *“(A) is for a drug or biological product that*  
11           *is for the prevention or treatment of a rare pedi-*  
12           *atric disease;*

13           *“(B)(i) is for such a drug—*

14           *“(I) that contains no active moiety (as*  
15           *defined by the Secretary in section 314.3 of*  
16           *title 21, Code of Federal Regulations (or*  
17           *any successor regulations)) that has been*  
18           *previously approved in any other applica-*  
19           *tion under subsection (b)(1), (b)(2), or (j) of*  
20           *section 505; and*

21           *“(II) that is the subject of an applica-*  
22           *tion submitted under section 505(b)(1); or*

23           *“(ii) or is for such a biological product—*

24           *“(I) that contains no active ingredient*  
25           *that has been previously approved in any*

1            *other application under section 351(a) or*  
2            *351(k) of the Public Health Service Act;*  
3            *and*

4            *“(II) that is the subject of an applica-*  
5            *tion submitted under section 351(a) of the*  
6            *Public Health Service Act;”*; and

7            (5) *in section 565A(a)(4) (21 U.S.C. 360bbb-*  
8            *4a(a)(4)), by amending subparagraph (D) to read as*  
9            *follows:*

10            *“(D) is for—*

11            *“(i) a human drug, no active moiety*  
12            *(as defined by the Secretary in section*  
13            *314.3 of title 21, Code of Federal Regula-*  
14            *tions (or any successor regulations)) of*  
15            *which has been approved in any other ap-*  
16            *plication under section 505(b)(1); or*

17            *“(ii) a biological product, no active in-*  
18            *redient of which has been approved in any*  
19            *other application under section 351 of the*  
20            *Public Health Service Act.”.*

21            (b) *TECHNICAL CORRECTIONS.—Chapter V of the Fed-*  
22            *eral Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq)*  
23            *is amended—*

24            (1) *in section 505 (21 U.S.C. 355)—*

1           (A) in subsection (c)(3)(E), by repealing  
2           clause (i); and

3           (B) in subsection (j)(5)(F), by repealing  
4           clause (i); and

5           (2) in section 505A(c)(1)(A)(i)(II) (21 U.S.C.  
6           355a(c)(1)(A)(i)), by striking “(c)(3)(D)” and insert-  
7           ing “(c)(3)(E)”.

8   **SEC. 209. STREAMLINING THE TRANSITION OF BIOLOGICAL**  
9           **PRODUCTS.**

10        Section 7002(e)(4) of the *Biologics Price Competition*  
11        and *Innovation Act of 2009* (Public Law 111–148) is  
12        amended by adding at the end the following: “With respect  
13        to an application for a biological product submitted under  
14        section 505(b) of the *Federal Food, Drug, and Cosmetic Act*  
15        (21 U.S.C. 355(b)) with a filing date that is not later than  
16        September 23, 2019, and that does not receive final ap-  
17        proval on or before March 23, 2020, such application shall  
18        be deemed to be withdrawn and the Secretary shall refund  
19        the fee paid under section 736(a)(1)(B) of the *Federal Food,*  
20        *Drug, and Cosmetic Act* (21 U.S.C. 379h(a)(1)(B)). Not-  
21        withstanding any such withdrawal of the drug application,  
22        the Secretary shall consider any previously conducted sci-  
23        entific review and accelerate review of any such subsequent  
24        application with respect to such biological product under  
25        section 351 of the *Public Health Service Act* (42 U.S.C.

1 262). *The Secretary shall provide additional assistance to*  
2 *the sponsor or manufacturer of such application.”.*

3 **SEC. 210. ORPHAN DRUG CLARIFICATION.**

4 *Section 527(c) of the Federal Food, Drug, and Cos-*  
5 *metic Act (21 U.S.C. 360cc(c)) is amended by adding at*  
6 *the end the following:*

7 *“(3) APPLICABILITY.—This subsection applies to*  
8 *any drug designated under section 526 for which an*  
9 *application was approved under section 505 of this*  
10 *Act or licensed under section 351 of the Public Health*  
11 *Service Act after the date of enactment of the FDA*  
12 *Reauthorization Act of 2017, regardless of the date of*  
13 *on which such drug was designated under section*  
14 *526.”.*

15 **SEC. 211. PROMPT APPROVAL OF DRUGS RELATED TO SAFE-**  
16 **TY INFORMATION.**

17 *Section 505 of the Federal Food, Drug, and Cosmetic*  
18 *Act (21 U.S.C. 355) is amended by adding at the end the*  
19 *following:*

20 *“(z) PROMPT APPROVAL OF DRUGS WHEN SAFETY IN-*  
21 *FORMATION IS ADDED TO LABELING.—*

22 *“(1) GENERAL RULE.—A drug for which an ap-*  
23 *plication has been submitted or approved under sub-*  
24 *section (b)(2) or (j) shall not be considered ineligible*  
25 *for approval under this section or misbranded under*

1        *section 502 on the basis that the labeling of the drug*  
2        *omits safety information, including contraindica-*  
3        *tions, warnings, precautions, dosing, administration,*  
4        *or other information pertaining to safety, when the*  
5        *omitted safety information is protected by exclusivity*  
6        *under clause (iii) or (iv) of subsection (j)(5)(F),*  
7        *clause (iii) or (iv) of subsection (c)(3)(E), or section*  
8        *527(a), or by an extension of such exclusivity under*  
9        *section 505A or 505E.*

10            *“(2) LABELING.—Notwithstanding clauses (iii)*  
11            *and (iv) of subsection (j)(5)(F), clauses (iii) and (iv)*  
12            *of subsection (c)(3)(E), or section 527, the Secretary*  
13            *shall require that the labeling of a drug approved*  
14            *pursuant to an application submitted under sub-*  
15            *section (b)(2) or (j) that omits safety information de-*  
16            *scribed in paragraph (1) include a statement of any*  
17            *appropriate safety information that the Secretary*  
18            *considers necessary to assure safe use.*

19            *“(3) AVAILABILITY AND SCOPE OF EXCLU-*  
20            *SIVITY.—This subsection does not affect—*

21                    *“(A) the availability or scope of exclusivity*  
22                    *or an extension of exclusivity described in sub-*  
23                    *paragraph (A) or (B) of section 505A(o)(3);*

24                    *“(B) the question of the eligibility for ap-*  
25                    *proval under this section of any application de-*

1           *scribed in subsection (b)(2) or (j) that omits any*  
 2           *other aspect of labeling protected by exclusivity*  
 3           *under—*

4                   *“(i) clause (iii) or (iv) of subsection*  
 5                   *(j)(5)(F);*

6                   *“(ii) clause (iii) or (iv) of subsection*  
 7                   *(c)(3)(E); or*

8                   *“(iii) section 527(a); or*

9                   *“(C) except as expressly provided in para-*  
 10                  *graphs (1) and (2), the operation of this section*  
 11                  *or section 527.”.*

12 **SEC. 212. CONDITIONS OF USE FOR BIOSIMILAR BIOLOGI-**  
 13                   **CAL PRODUCTS.**

14           *Section 351(k)(2)(A)(iii) of the Public Health Service*  
 15 *Act (42 U.S.C. 262(k)(2)(A)(iii) is amended—*

16                   *(1) in subclause (I), by striking “; and” and in-*  
 17                   *serting a semicolon;*

18                   *(2) in subclause (II), by striking the period and*  
 19                   *inserting “; and”; and*

20                   *(3) by adding at the end the following:*

21                           *“(III) may include information to*  
 22                           *show that the conditions of use pre-*  
 23                           *scribed, recommended, or suggested in*  
 24                           *the labeling proposed for the biological*

1                    *product have been previously approved*  
 2                    *for the reference product.”.*

3 **SEC. 213. MODERNIZING THE LABELING OF CERTAIN GE-**  
 4                    **NERIC DRUGS.**

5                    *Chapter V of the Federal Food, Drug, and Cosmetic*  
 6 *Act (21 U.S.C. 351 et seq.) is amended by inserting after*  
 7 *section 503C the following:*

8 **“SEC. 503D. PROCESS TO UPDATE LABELING FOR CERTAIN**  
 9                    **DRUGS.**

10                    *“(a) DEFINITIONS.—For purposes of this section:*

11                    *“(1) The term ‘covered drug’ means a drug ap-*  
 12 *proved under section 505(c)—*

13                    *“(A) for which there are no unexpired pat-*  
 14 *ents included in the list under section 505(j)(7)*  
 15 *and no unexpired period of exclusivity;*

16                    *“(B) for which the approval of the applica-*  
 17 *tion has been withdrawn for reasons other than*  
 18 *safety or effectiveness; and*

19                    *“(C) for which, with respect to the label-*  
 20 *ing—*

21                    *“(i) new scientific evidence is available*  
 22 *regarding the conditions of use of the drug;*

23                    *“(ii) there is a relevant accepted use in*  
 24 *clinical practice that is not reflected in the*  
 25 *approved labeling; or*

1                   “(iii) the labeling of such drug does not  
2                   reflect current legal and regulatory require-  
3                   ments.

4                   “(2) The term ‘period of exclusivity’, with respect  
5                   to a drug approved under section 505(c), means any  
6                   period of exclusivity under clause (ii), (iii), or (iv) of  
7                   section 505(c)(3)(E), clause (ii), (iii), or (iv) of sec-  
8                   tion 505(j)(5)(F), or section 505A, 505E, or 527.

9                   “(3) The term ‘generic version’ means a drug ap-  
10                  proved under section 505(j) whose reference drug is a  
11                  covered drug.

12                  “(4) The term ‘relevant accepted use’ means a  
13                  use for a drug in clinical practice that is supported  
14                  by scientific evidence that appears to the Secretary to  
15                  meet the standards for approval under section 505.

16                  “(5) The term ‘selected drug’ means a covered  
17                  drug for which the Secretary has determined through  
18                  the process under subsection (c) that the labeling  
19                  should be changed.

20                  “(b) IDENTIFICATION OF COVERED DRUGS.—The Sec-  
21                  retary may identify covered drugs for which labeling up-  
22                  dates would provide a public health benefit. To assist in  
23                  identifying covered drugs, the Secretary may do one or both  
24                  of the following:

1           “(1) *Enter into cooperative agreements or con-*  
2           *tracts with public or private entities to review the*  
3           *available scientific evidence concerning such drugs.*

4           “(2) *Seek public input concerning such drugs,*  
5           *including input on whether there is a relevant accept-*  
6           *ed use in clinical practice that is not reflected in the*  
7           *approved labeling of such drugs or whether new sci-*  
8           *entific evidence is available regarding the conditions*  
9           *of use for such drug, by—*

10                   “(A) *holding one or more public meetings;*

11                   “(B) *opening a public docket for the sub-*  
12                   *mission of public comments; or*

13                   “(C) *other means, as the Secretary deter-*  
14                   *mines appropriate.*

15           “(c) *SELECTION OF DRUGS FOR UPDATING.—If the*  
16           *Secretary determines, with respect to a covered drug, that*  
17           *the available scientific evidence meets the standards under*  
18           *section 505 for adding or modifying information to the la-*  
19           *beling or providing supplemental information to the label-*  
20           *ing regarding the use of the covered drug, the Secretary may*  
21           *initiate the process under subsection (d).*

22           “(d) *INITIATION OF THE PROCESS OF UPDATING.—If*  
23           *the Secretary determines that labeling changes are appro-*  
24           *priate for a selected drug pursuant to subsection (c), the*

1 *Secretary shall provide notice to the holders of approved*  
2 *applications for a generic version of such drug that—*

3           “(1) *summarizes the findings supporting the de-*  
4 *termination of the Secretary that the available sci-*  
5 *entific evidence meets the standards under section 505*  
6 *for adding or modifying information or providing*  
7 *supplemental information to the labeling of the cov-*  
8 *ered drug pursuant to subsection (c);*

9           “(2) *provides a clear statement regarding the ad-*  
10 *ditional, modified, or supplemental information for*  
11 *such labeling, according to the determination by the*  
12 *Secretary (including, as applicable, modifications to*  
13 *add the relevant accepted use to the labeling of the*  
14 *drug as an additional indication for the drug); and*

15           “(3) *states whether the statement under para-*  
16 *graph (2) applies to the selected drug as a class of*  
17 *covered drugs or only to a specific drug product.*

18           “(e) *RESPONSE TO NOTIFICATION.—Within 30 days of*  
19 *receipt of notification provided by the Secretary pursuant*  
20 *to subsection (d), the holder of an approved application for*  
21 *a generic version of the selected drug shall—*

22           “(1) *agree to change the approved labeling to re-*  
23 *flect the additional, modified, or supplemental infor-*  
24 *mation the Secretary has determined to be appro-*  
25 *priate; or*

1           “(2) *notify the Secretary that the holder of the*  
2           *approved application does not believe that the re-*  
3           *quested labeling changes are warranted and submit a*  
4           *statement detailing the reasons why such changes are*  
5           *not warranted.*

6           “(f) *REVIEW OF APPLICATION HOLDER’S RE-*  
7           *SPONSE.—*

8           “(1) *IN GENERAL.—Upon receipt of the applica-*  
9           *tion holder’s response, the Secretary shall promptly*  
10           *review each statement received under subsection (e)(2)*  
11           *and determine which labeling changes pursuant to the*  
12           *Secretary’s notice under subsection (d) are appro-*  
13           *priate, if any. If the Secretary disagrees with the rea-*  
14           *sons why such labeling changes are not warranted, the*  
15           *Secretary shall provide opportunity for discussions*  
16           *with the application holders to reach agreement on*  
17           *whether the labeling for the covered drug should be*  
18           *updated to reflect current scientific evidence, and if*  
19           *so, the content of such labeling changes.*

20           “(2) *CHANGES TO LABELING.—After considering*  
21           *all responses from the holder of an approved applica-*  
22           *tion under paragraph (1) or (2) of subsection (e), and*  
23           *any discussion under paragraph (1), the Secretary*  
24           *may order such holder to make the labeling changes*

1       *the Secretary determines are appropriate. Such holder*  
2       *of an approved application shall—*

3               “(A) *update its paper labeling for the drug*  
4               *at the next printing of that labeling;*

5               “(B) *update any electronic labeling for the*  
6               *drug within 30 days; and*

7               “(C) *submit the revised labeling through the*  
8               *form, ‘Supplement—Changes Being Effected’.*

9       “(g) *VIOLATION.—If the holder of an approved appli-*  
10       *cation for the generic version of the selected drug does not*  
11       *comply with the requirements of subsection (f)(2), such ge-*  
12       *neric version of the selected drug shall be deemed to be mis-*  
13       *branded under section 502.*

14       “(h) *LIMITATIONS; GENERIC DRUGS.—*

15               “(1) *IN GENERAL.—With respect to any labeling*  
16               *change required under this section, the generic version*  
17               *shall be deemed to have the same conditions of use*  
18               *and the same labeling as a reference drug for pur-*  
19               *poses of clauses (i) and (v) of section 505(j)(2)(A).*  
20               *Any labeling change so required shall not have any*  
21               *legal effect for the applicant that is different than the*  
22               *legal effect that would have resulted if a supplemental*  
23               *application had been submitted and approved to con-*  
24               *form the labeling of the generic version to a change*  
25               *in the labeling of the reference drug.*

1           “(2) *SUPPLEMENTAL APPLICATIONS.*—Changes to  
2           *labeling made in accordance with this paragraph*  
3           *shall not be eligible for an exclusivity period under*  
4           *this Act.*

5           “(i) *DRUG PRODUCT CLASSES.*—In the case of a se-  
6           *lected drug for which the labeling changes ordered by the*  
7           *Secretary under subsection (d)(2) are required for a class*  
8           *of covered drugs, such labeling changes shall be made for*  
9           *generic versions of such drug in that class.*

10          “(j) *RULES OF CONSTRUCTION.*—

11           “(1) *APPROVAL STANDARDS.*—This section shall  
12           *not be construed as altering the applicability of the*  
13           *standards for approval of an application under sec-*  
14           *tion 505. No order shall be issued under this sub-*  
15           *section unless the evidence supporting the changed la-*  
16           *beling meets the standards for approval applicable to*  
17           *any change to labeling under section 505.*

18           “(2) *REMOVAL OF INFORMATION.*—Nothing in  
19           *this section shall be construed to give the Secretary*  
20           *additional authority to remove approved indications*  
21           *for drugs, other than the authority described in this*  
22           *section.*

23           “(k) *REPORTS.*—Not later than 4 years after the date  
24           *of the enactment of the Lower Health Care Costs Act and*  
25           *every 4 years thereafter, the Secretary shall prepare and*

1 *submit to the Committee on Health, Education, Labor, and*  
 2 *Pensions of the Senate and the Committee on Energy and*  
 3 *Commerce of the House of Representatives, a report that—*

4           “(1) *describes the actions of the Secretary under*  
 5 *this section, including—*

6                   “(A) *the number of covered drugs and de-*  
 7 *scription of the types of drugs the Secretary has*  
 8 *selected for labeling changes and the rationale for*  
 9 *such recommended changes; and*

10                   “(B) *the number of times the Secretary en-*  
 11 *tered into discussions concerning a disagreement*  
 12 *with an application holder or holders and a*  
 13 *summary of the decision regarding a labeling*  
 14 *change, if any; and*

15           “(2) *includes any recommendations of the Sec-*  
 16 *retary for modifying the program under this sec-*  
 17 *tion.*”.

18 **SEC. 214. ACTIONS FOR DELAYS OF GENERIC DRUGS AND**

19                   **BIOSIMILAR BIOLOGICAL PRODUCTS.**

20           (a) *DEFINITIONS.—In this section—*

21                   (1) *the term “commercially reasonable, market-*  
 22 *based terms” means—*

23                           (A) *a nondiscriminatory price for the sale*  
 24 *of the covered product at or below, but not great-*  
 25 *er than, the most recent wholesale acquisition*

1           *cost for the drug, as defined in section*  
2           *1847A(c)(6)(B) of the Social Security Act (42*  
3           *U.S.C. 1395w-3a(c)(6)(B));*

4           *(B) a schedule for delivery that results in*  
5           *the transfer of the covered product to the eligible*  
6           *product developer consistent with the timing*  
7           *under subsection (b)(2)(A)(iv); and*

8           *(C) no additional conditions are imposed*  
9           *on the sale of the covered product;*

10          (2) *the term “covered product”—*

11           *(A) means—*

12           *(i) any drug approved under sub-*  
13           *section (c) or (j) of section 505 of the Fed-*  
14           *eral Food, Drug, and Cosmetic Act (21*  
15           *U.S.C. 355) or biological product licensed*  
16           *under subsection (a) or (k) of section 351 of*  
17           *the Public Health Service Act (42 U.S.C.*  
18           *262);*

19           *(ii) any combination of a drug or bio-*  
20           *logical product described in clause (i); or*

21           *(iii) when reasonably necessary to sup-*  
22           *port approval of an application under sec-*  
23           *tion 505 of the Federal Food, Drug, and*  
24           *Cosmetic Act (21 U.S.C. 355), or section*  
25           *351 of the Public Health Service Act (42*

1           *U.S.C. 262), as applicable, or otherwise*  
2           *meet the requirements for approval under*  
3           *either such section, any product, including*  
4           *any device, that is marketed or intended for*  
5           *use with such a drug or biological product;*  
6           *and*

7           *(B) does not include any drug or biological*  
8           *product that appears on the drug shortage list in*  
9           *effect under section 506E of the Federal Food,*  
10          *Drug, and Cosmetic Act (21 U.S.C. 356e), un-*  
11          *less—*

12                 *(i) the drug or biological product has*  
13                 *been on the drug shortage list in effect*  
14                 *under such section 506E continuously for*  
15                 *more than 6 months; or*

16                 *(ii) the Secretary determines that in-*  
17                 *clusion of the drug or biological product as*  
18                 *a covered product is likely to contribute to*  
19                 *alleviating or preventing a shortage.*

20           *(3) the term “device” has the meaning given the*  
21           *term in section 201 of the Federal Food, Drug, and*  
22           *Cosmetic Act (21 U.S.C. 321);*

23           *(4) the term “eligible product developer” means*  
24           *a person that seeks to develop a product for approval*  
25           *pursuant to an application for approval under sub-*

1        *section (b)(2) or (j) of section 505 of the Federal*  
2        *Food, Drug, and Cosmetic Act (21 U.S.C. 355) or for*  
3        *licensing pursuant to an application under section*  
4        *351(k) of the Public Health Service Act (42 U.S.C.*  
5        *262(k));*

6                *(5) the term “license holder” means the holder of*  
7        *an application approved under subsection (c) or (j) of*  
8        *section 505 of the Federal Food, Drug, and Cosmetic*  
9        *Act (21 U.S.C. 355) or the holder of a license under*  
10        *subsection (a) or (k) of section 351 of the Public*  
11        *Health Service Act (42 U.S.C. 262) for a covered*  
12        *product;*

13                *(6) the term “REMS” means a risk evaluation*  
14        *and mitigation strategy under section 505–1 of the*  
15        *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*  
16        *355–1);*

17                *(7) the term “REMS with ETASU” means a*  
18        *REMS that contains elements to assure safe use under*  
19        *section 505–1(f) of the Federal Food, Drug, and Cos-*  
20        *metic Act (21 U.S.C. 355–1(f));*

21                *(8) the term “Secretary” means the Secretary of*  
22        *Health and Human Services;*

23                *(9) the term “single, shared system of elements to*  
24        *assure safe use” means a single, shared system of ele-*  
25        *ments to assure safe use under section 505–1(f) of the*

1 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*  
 2 *355–1(f)); and*

3 *(10) the term “sufficient quantities” means an*  
 4 *amount of a covered product that the eligible product*  
 5 *developer determines allows it to—*

6 *(A) conduct testing to support an applica-*  
 7 *tion under—*

8 *(i) subsection (b)(2) or (j) of section*  
 9 *505 of the Federal Food, Drug, and Cos-*  
 10 *metic Act (21 U.S.C. 355); or*

11 *(ii) section 351(k) of the Public Health*  
 12 *Service Act (42 U.S.C. 262(k)); and*

13 *(B) fulfill any regulatory requirements re-*  
 14 *lating to approval of such an application.*

15 *(b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFI-*  
 16 *CIENT QUANTITIES OF A COVERED PRODUCT.—*

17 *(1) IN GENERAL.—An eligible product developer*  
 18 *may bring a civil action against the license holder for*  
 19 *a covered product seeking relief under this subsection*  
 20 *in an appropriate district court of the United States*  
 21 *alleging that the license holder has declined to provide*  
 22 *sufficient quantities of the covered product to the eli-*  
 23 *gible product developer on commercially reasonable,*  
 24 *market-based terms.*

25 *(2) ELEMENTS.—*

1           (A) *IN GENERAL.*—*To prevail in a civil ac-*  
2           *tion brought under paragraph (1), an eligible*  
3           *product developer shall prove, by a preponder-*  
4           *ance of the evidence—*

5                   (i) *that—*

6                           (I) *the covered product is not sub-*  
7                           *ject to a REMS with ETASU; or*

8                           (II) *if the covered product is sub-*  
9                           *ject to a REMS with ETASU—*

10                                   (aa) *the eligible product de-*  
11                                   *veloper has obtained a covered*  
12                                   *product authorization from the*  
13                                   *Secretary in accordance with sub-*  
14                                   *paragraph (B); and*

15                                   (bb) *the eligible product de-*  
16                                   *veloper has provided a copy of the*  
17                                   *covered product authorization to*  
18                                   *the license holder;*

19                           (ii) *that, as of the date on which the*  
20                           *civil action is filed, the product developer*  
21                           *has not obtained sufficient quantities of the*  
22                           *covered product on commercially reasonable,*  
23                           *market-based terms;*

24                           (iii) *that the eligible product developer*  
25                           *has submitted a written request to purchase*

1           *sufficient quantities of the covered product*  
2           *to the license holder, and such request—*

3                     *(I) was sent to a named corporate*  
4                     *officer of the license holder;*

5                     *(II) was made by certified or reg-*  
6                     *istered mail with return receipt re-*  
7                     *quested;*

8                     *(III) specified an individual as*  
9                     *the point of contact for the license*  
10                    *holder to direct communications re-*  
11                    *lated to the sale of the covered product*  
12                    *to the eligible product developer and a*  
13                    *means for electronic and written com-*  
14                    *munications with that individual; and*

15                    *(IV) specified an address to which*  
16                    *the covered product was to be shipped*  
17                    *upon reaching an agreement to trans-*  
18                    *fer the covered product; and*

19                    *(iv) that the license holder has not de-*  
20                    *livered to the eligible product developer suf-*  
21                    *ficient quantities of the covered product on*  
22                    *commercially reasonable, market-based*  
23                    *terms—*

24                    *(I) for a covered product that is*  
25                    *not subject to a REMS with ETASU,*

1                   by the date that is 31 days after the  
2                   date on which the license holder re-  
3                   ceived the request for the covered prod-  
4                   uct; and

5                   (II) for a covered product that is  
6                   subject to a REMS with ETASU, by  
7                   31 days after the later of—

8                   (aa) the date on which the li-  
9                   cense holder received the request  
10                  for the covered product; or

11                  (bb) the date on which the li-  
12                  cense holder received a copy of the  
13                  covered product authorization  
14                  issued by the Secretary in accord-  
15                  ance with subparagraph (B).

16                  (B) AUTHORIZATION FOR COVERED PROD-  
17                  UCT SUBJECT TO A REMS WITH ETASU.—

18                  (i) REQUEST.—An eligible product de-  
19                  veloper may submit to the Secretary a writ-  
20                  ten request for the eligible product developer  
21                  to be authorized to obtain sufficient quan-  
22                  tities of an individual covered product sub-  
23                  ject to a REMS with ETASU.

24                  (ii) AUTHORIZATION.—Not later than  
25                  120 days after the date on which a request

1           under clause (i) is received, the Secretary  
2           shall, by written notice, authorize the eligi-  
3           ble product developer to obtain sufficient  
4           quantities of an individual covered product  
5           subject to a REMS with ETASU for pur-  
6           poses of—

7                       (I) development and testing that  
8                       does not involve human clinical trials,  
9                       if the eligible product developer has  
10                      agreed to comply with any conditions  
11                      the Secretary determines necessary; or

12                     (II) development and testing that  
13                     involves human clinical trials, if the  
14                     eligible product developer has—

15                               (aa)(AA) submitted protocols,  
16                               informed consent documents, and  
17                               informational materials for test-  
18                               ing that include protections that  
19                               provide safety protections com-  
20                               parable to those provided by the  
21                               REMS for the covered product; or

22                               (BB) otherwise satisfied the  
23                               Secretary that such protections  
24                               will be provided; and

1                   (bb) met any other require-  
2                   ments the Secretary may estab-  
3                   lish.

4                   (iii) NOTICE.—A covered product au-  
5                   thorization issued under this subparagraph  
6                   shall state that the provision of the covered  
7                   product by the license holder under the  
8                   terms of the authorization will not be a vio-  
9                   lation of the REMS for the covered product.

10                  (3) AFFIRMATIVE DEFENSE.—In a civil action  
11                  brought under paragraph (1), it shall be an affirma-  
12                  tive defense, on which the defendant has the burden  
13                  of persuasion by a preponderance of the evidence—

14                         (A) that, on the date on which the eligible  
15                         product developer requested to purchase sufficient  
16                         quantities of the covered product from the license  
17                         holder—

18                                 (i) neither the license holder nor any of  
19                                 its agents, wholesalers, or distributors was  
20                                 engaged in the manufacturing or commer-  
21                                 cial marketing of the covered product; and

22                                 (ii) neither the license holder nor any  
23                                 of its agents, wholesalers, or distributors  
24                                 otherwise had access to inventory of the cov-  
25                                 ered product to supply to the eligible prod-

1            *uct developer on commercially reasonable,*  
2            *market-based terms;*

3            *(B) that—*

4                    *(i) the license holder sells the covered*  
5                    *product through agents, distributors, or*  
6                    *wholesalers;*

7                    *(ii) the license holder has placed no re-*  
8                    *strictions, explicit or implicit, on its agents,*  
9                    *distributors, or wholesalers to sell covered*  
10                   *products to eligible product developers; and*

11                   *(iii) the covered product can be pur-*  
12                   *chased by the eligible product developer in*  
13                   *sufficient quantities on commercially rea-*  
14                   *sonable, market-based terms from the*  
15                   *agents, distributors, or wholesalers of the li-*  
16                   *cence holder; or*

17                   *(C) that the license holder made an offer to*  
18                   *the individual specified pursuant to paragraph*  
19                   *(2)(A)(iii)(III), by a means of communication*  
20                   *(electronic, written, or both) specified pursuant*  
21                   *to such paragraph, to sell sufficient quantities of*  
22                   *the covered product to the eligible product devel-*  
23                   *oper at commercially reasonable market-based*  
24                   *terms—*

1           (i) for a covered product that is not  
2           subject to a REMS with ETASU, by the  
3           date that is 14 days after the date on which  
4           the license holder received the request for the  
5           covered product, and the eligible product de-  
6           veloper did not accept such offer by the date  
7           that is 7 days after the date on which the  
8           eligible product developer received such offer  
9           from the license holder; or

10           (ii) for a covered product that is sub-  
11           ject to a REMS with ETASU, by the date  
12           that is 20 days after the date on which the  
13           license holder received the request for the  
14           covered product, and the eligible product de-  
15           veloper did not accept such offer by the date  
16           that is 10 days after the date on which the  
17           eligible product developer received such offer  
18           from the license holder.

19           (4) *REMEDIES.*—

20           (A) *IN GENERAL.*—If an eligible product de-  
21           veloper prevails in a civil action brought under  
22           paragraph (1), the court shall—

23           (i) order the license holder to provide  
24           to the eligible product developer without  
25           delay sufficient quantities of the covered

1           *product on commercially reasonable, mar-*  
2           *ket-based terms;*

3                   *(ii) award to the eligible product devel-*  
4           *oper reasonable attorney's fees and costs of*  
5           *the civil action; and*

6                   *(iii) award to the eligible product de-*  
7           *veloper a monetary amount sufficient to*  
8           *deter the license holder from failing to pro-*  
9           *vide eligible product developers with suffi-*  
10          *cient quantities of a covered product on*  
11          *commercially reasonable, market-based*  
12          *terms, if the court finds, by a preponder-*  
13          *ance of the evidence—*

14                   *(I) that the license holder delayed*  
15          *providing sufficient quantities of the*  
16          *covered product to the eligible product*  
17          *developer without a legitimate business*  
18          *justification; or*

19                   *(II) that the license holder failed*  
20          *to comply with an order issued under*  
21          *clause (i).*

22                   *(B) MAXIMUM MONETARY AMOUNT.—A*  
23          *monetary amount awarded under subparagraph*  
24          *(A)(iii) shall not be greater than the revenue that*

1           *the license holder earned on the covered product*  
2           *during the period—*

3                   *(i) beginning on—*

4                           *(I) for a covered product that is*  
5                           *not subject to a REMS with ETASU,*  
6                           *the date that is 31 days after the date*  
7                           *on which the license holder received the*  
8                           *request; or*

9                           *(II) for a covered product that is*  
10                           *subject to a REMS with ETASU, the*  
11                           *date that is 31 days after the later of—*

12                                   *(aa) the date on which the li-*  
13                                   *cence holder received the request;*  
14                                   *or*

15                                   *(bb) the date on which the li-*  
16                                   *cence holder received a copy of the*  
17                                   *covered product authorization*  
18                                   *issued by the Secretary in accord-*  
19                                   *ance with paragraph (2)(B); and*

20                           *(ii) ending on the date on which the el-*  
21                           *igible product developer received sufficient*  
22                           *quantities of the covered product.*

23                   *(C) AVOIDANCE OF DELAY.—The court may*  
24                   *issue an order under subparagraph (A)(i) before*  
25                   *conducting further proceedings that may be nec-*

1            *essary to determine whether the eligible product*  
2            *developer is entitled to an award under clause*  
3            *(ii) or (iii) of subparagraph (A), or the amount*  
4            *of any such award.*

5            *(c) LIMITATION OF LIABILITY.—A license holder for a*  
6            *covered product shall not be liable for any claim under Fed-*  
7            *eral, State, or local law arising out of the failure of an*  
8            *eligible product developer to follow adequate safeguards to*  
9            *assure safe use of the covered product during development*  
10           *or testing activities described in this section, including*  
11           *transportation, handling, use, or disposal of the covered*  
12           *product by the eligible product developer.*

13           *(d) NO VIOLATION OF REMS.—Section 505–1 of the*  
14           *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1)*  
15           *is amended by adding at the end the following new sub-*  
16           *section:*

17           *“(l) PROVISION OF SAMPLES NOT A VIOLATION OF*  
18           *STRATEGY.—The provision of samples of a covered product*  
19           *to an eligible product developer (as those terms are defined*  
20           *in section 214(a) of the Lower Health Care Costs Act) shall*  
21           *not be considered a violation of the requirements of any risk*  
22           *evaluation and mitigation strategy that may be in place*  
23           *under this section for such drug.”.*

24           *(e) RULE OF CONSTRUCTION.—*

1           (1) *DEFINITION.*—*In this subsection, the term*  
2           “*antitrust laws*”—

3                   (A) *has the meaning given the term in sub-*  
4                   *section (a) of the first section of the Clayton Act*  
5                   *(15 U.S.C. 12); and*

6                   (B) *includes section 5 of the Federal Trade*  
7                   *Commission Act (15 U.S.C. 45) to the extent that*  
8                   *such section applies to unfair methods of com-*  
9                   *petition.*

10           (2) *ANTITRUST LAWS.*—*Nothing in this section*  
11           *shall be construed to limit the operation of any provi-*  
12           *sion of the antitrust laws.*

13           (f) *REMS APPROVAL PROCESS FOR SUBSEQUENT FIL-*  
14           *ERS.*—*Section 505–1 of the Federal Food, Drug, and Cos-*  
15           *metic Act (21 U.S.C. 355–1), as amended by subsection (d),*  
16           *is further amended—*

17                   (1) *in subsection (g)(4)(B)—*

18                           (A) *in clause (i) by striking “or” after the*  
19                           *semicolon;*

20                           (B) *in clause (ii) by striking the period at*  
21                           *the end and inserting “; or”; and*

22                           (C) *by adding at the end the following:*

23                                   “*(iii) accommodate different, com-*  
24                                   *parable aspects of the elements to assure*  
25                                   *safe use for a drug that is the subject of an*

1 application under section 505(j), and the  
2 applicable listed drug.”;

3 (2) in subsection (i)(1), by striking subpara-  
4 graph (C) and inserting the following:

5 “(C)(i) Elements to assure safe use, if re-  
6 quired under subsection (f) for the listed drug,  
7 which, subject to clause (ii), for a drug that is  
8 the subject of an application under section 505(j)  
9 may use—

10 “(I) a single, shared system with the  
11 listed drug under subsection (f); or

12 “(II) a different, comparable aspect of  
13 the elements to assure safe use under sub-  
14 section (f).

15 “(ii) The Secretary may require a drug that  
16 is the subject of an application under section  
17 505(j) and the listed drug to use a single, shared  
18 system under subsection (f), if the Secretary de-  
19 termines that no different, comparable aspect of  
20 the elements to assure safe use could satisfy the  
21 requirements of subsection (f).”;

22 (3) in subsection (i), by adding at the end the  
23 following:

24 “(3) SHARED REMS.—If the Secretary approves,  
25 in accordance with paragraph (1)(C)(i)(II), a dif-

1        *ferent, comparable aspect of the elements to assure*  
2        *safe use under subsection (f) for a drug that is the*  
3        *subject of an abbreviated new drug application under*  
4        *section 505(j), the Secretary may require that such*  
5        *different comparable aspect of the elements to assure*  
6        *safe use can be used with respect to any other drug*  
7        *that is the subject of an application under section*  
8        *505(j) or 505(b) that references the same listed drug.”;*  
9        *and*

10                *(4) by adding at the end the following:*

11                *“(m) SEPARATE REMS.—When used in this section,*  
12        *the terms ‘different, comparable aspect of the elements to*  
13        *assure safe use’ or ‘different, comparable approved risk eval-*  
14        *uation and mitigation strategies’ means a risk evaluation*  
15        *and mitigation strategy for a drug that is the subject of*  
16        *an application under section 505(j) that uses different*  
17        *methods or operational means than the strategy required*  
18        *under subsection (a) for the applicable listed drug, or other*  
19        *application under section 505(j) with the same such listed*  
20        *drug, but achieves the same level of safety as such strategy.”.*

21                *(g) RULE OF CONSTRUCTION.—Nothing in this section,*  
22        *the amendments made by this section, or in section 505–*  
23        *1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*  
24        *355–1), shall be construed as—*

1           (1) *prohibiting a license holder from providing*  
 2           *an eligible product developer access to a covered prod-*  
 3           *uct in the absence of an authorization under this sec-*  
 4           *tion; or*

5           (2) *in any way negating the applicability of a*  
 6           *REMS with ETASU, as otherwise required under*  
 7           *such section 505–1, with respect to such covered prod-*  
 8           *uct.*

9 **SEC. 215. REDUCING THE PRICE OF PRESCRIPTION DRUGS.**

10           *Title III of the Public Health Service Act (42 U.S.C.*  
 11 *241 et seq.) is amended by adding at the end the following:*

12 **“PART W—DRUG PRICE REPORTING; DRUG VALUE**  
 13 **FUND**

14 **“SEC. 3990O. REPORTING ON JUSTIFICATION FOR DRUG**  
 15 **PRICE INCREASES.**

16           “(a) *DEFINITIONS.—In this section:*

17                   “(1) *MANUFACTURER.—The term ‘manufacturer’*  
 18                   *means the person—*

19                           “(A) *that holds the application for a drug*  
 20                           *approved under section 505 of the Federal Food,*  
 21                           *Drug, and Cosmetic Act or the license issued*  
 22                           *under section 351 of this Act; or*

23                           “(B) *who is responsible for setting the price*  
 24                           *for the drug.*

1           “(2) *QUALIFYING DRUG.*—*The term ‘qualifying*  
2 *drug’ means any drug that is approved under sub-*  
3 *section (c) or (j) of section 505 of the Federal Food,*  
4 *Drug, and Cosmetic Act or licensed under subsection*  
5 *(a) or (k) of section 351 of this Act—*

6           “(A) *that has a wholesale acquisition cost of*  
7 *\$100 or more per month supply, or per a course*  
8 *of treatment that lasts less than a month, and*  
9 *is—*

10           “(i)(I) *subject to section 503(b)(1) of*  
11 *the Federal Food, Drug, and Cosmetic Act;*

12           *or*

13           “(II) *commonly administered by hos-*  
14 *pitals (as determined by the Secretary); and*

15           “(ii) *not designated by the Secretary*  
16 *as a vaccine; and*

17           “(B) *for which, during the previous cal-*  
18 *endar year, at least 1 dollar of the total amount*  
19 *of sales were for individuals enrolled under the*  
20 *Medicare program under title XVIII of the So-*  
21 *cial Security Act (42 U.S.C. 1395 et seq.) or*  
22 *under a State Medicaid plan under title XIX of*  
23 *such Act (42 U.S.C. 1396 et seq.) or under a*  
24 *waiver of such plan.*

1           “(3) *WHOLESALE ACQUISITION COST.*—*The term*  
2           *‘wholesale acquisition cost’ has the meaning given*  
3           *that term in section 1847A(c)(6)(B) of the Social Se-*  
4           *curity Act (42 U.S.C. 1395w-3a(c)(6)(B)).*

5           “(b) *REPORT.*—

6           “(1) *REPORT REQUIRED.*—*The manufacturer of*  
7           *a qualifying drug shall submit a report to the Sec-*  
8           *retary for each price increase of a qualifying drug*  
9           *that will result in an increase in the wholesale acqui-*  
10           *sition cost of that drug that is equal to—*

11                   “(A) *10 percent or more over a 12-month*  
12                   *period; or*

13                   “(B) *25 percent or more over a 36-month*  
14                   *period.*

15           “(2) *REPORT DEADLINE.*—*Each report described*  
16           *in paragraph (1) shall be submitted to the Secretary*  
17           *not later than 30 days prior to the planned effective*  
18           *date of such price increase.*

19           “(c) *CONTENTS.*—*A report under subsection (b) shall,*  
20           *at a minimum, include—*

21                   “(1) *with respect to the qualifying drug—*

22                           “(A) *the percentage by which the manufac-*  
23                           *turer will raise the wholesale acquisition cost of*  
24                           *the drug on the planned effective date of such*  
25                           *price increase;*

1           “(B) a justification for, and description of,  
2 each manufacturer’s price increase that will  
3 occur during the 12-month period described in  
4 subsection (b)(1)(A) or the 36-month period de-  
5 scribed in subsection (b)(1)(B), as applicable;

6           “(C) the identity of the initial developer of  
7 the drug;

8           “(D) a description of the history of the  
9 manufacturer’s price increases for the drug since  
10 the approval of the application for the drug  
11 under section 505 of the Federal Food, Drug,  
12 and Cosmetic Act or the issuance of the license  
13 for the drug under section 351, or since the man-  
14 ufacturer acquired such approved application or  
15 license;

16           “(E) the current list price of the drug;

17           “(F) the total expenditures of the manufac-  
18 turer on—

19                 “(i) materials and manufacturing for  
20 such drug; and

21                 “(ii) acquiring patents and licensing  
22 for such drug;

23           “(G) the percentage of total expenditures of  
24 the manufacturer on research and development

1       *for such drug that was derived from Federal*  
2       *funds;*

3               “(H) *the total expenditures of the manufac-*  
4       *turer on research and development for such drug*  
5       *that is used for—*

6                       “(i) *basic and preclinical research;*

7                       “(ii) *clinical research;*

8                       “(iii) *new drug development;*

9                       “(iv) *pursuing new or expanded indi-*  
10       *cations for such drug through supplemental*  
11       *applications under section 505 of the Fed-*  
12       *eral Food, Drug, and Cosmetic Act or sec-*  
13       *tion 351 of this Act; and*

14                       “(v) *carrying out postmarket require-*  
15       *ments related to such drug, including those*  
16       *under section 505(o)(3) of the Federal Food,*  
17       *Drug, and Cosmetic Act;*

18               “(I) *the total revenue and the net profit*  
19       *generated from the qualifying drug for each cal-*  
20       *endar year since the approval of the application*  
21       *for the drug under section 505 of the Federal*  
22       *Food, Drug, and Cosmetic Act or the issuance of*  
23       *the license for the drug under section 351, or*  
24       *since the manufacturer acquired such approved*  
25       *application or license; and*

1           “(J) the total costs associated with mar-  
2           keting and advertising for the qualifying drug;

3           “(2) with respect to the manufacturer—

4           “(A) the total revenue and the net profit of  
5           the manufacturer—

6           “(i) for the 12-month period preceding  
7           the date of the report, in the case of a report  
8           based on an increase described in subsection  
9           (b)(1)(A); or

10          “(ii) for the 36-month period preceding  
11          the date of the report, in the case of a report  
12          based on an increase described in subsection  
13          (b)(1)(B);

14          “(B) all stock-based performance metrics  
15          used by the manufacturer to determine executive  
16          compensation—

17          “(i) for the 12-month period preceding  
18          the date of the report, in the case of a report  
19          based on an increase described in subsection  
20          (b)(1)(A); or

21          “(ii) for the 36-month period preceding  
22          the date of the report, in the case of a report  
23          based on an increase described in subsection  
24          (b)(1)(B); and

1           “(C) *any additional information the manu-*  
2           *facturer chooses to provide related to drug pric-*  
3           *ing decisions, such as total expenditures on—*

4                     “(i) *drug research and development; or*

5                     “(ii) *clinical trials on drugs that failed*  
6           *to receive approval by the Food and Drug*  
7           *Administration; and*

8           “(3) *such other related information as the Sec-*  
9           *retary considers appropriate, as specified through no-*  
10          *tice and comment rulemaking.*

11          “(d) *CIVIL PENALTY.—Any manufacturer of a quali-*  
12          *fying drug that fails to submit a report for the drug as*  
13          *required by this section shall be subject to a civil penalty*  
14          *of \$100,000 for each day on which the violation continues.*

15          “(e) *PUBLIC POSTING.—*

16                     “(1) *IN GENERAL.—Subject to paragraph (3),*  
17                     *not later than 30 days after the submission of a re-*  
18                     *port under subsection (b), the Secretary shall post the*  
19                     *report on the public website of the Department of*  
20                     *Health and Human Services.*

21                     “(2) *FORMAT.—In developing the format of such*  
22                     *report for public posting, the Secretary shall consult*  
23                     *stakeholders, including beneficiary groups, and shall*  
24                     *seek feedback on the content and format from con-*  
25                     *sumer advocates and readability experts to ensure*

1        *such public reports are user-friendly to the public and*  
2        *are written in plain language that consumers can*  
3        *readily understand.*

4                *“(3) TRADE SECRETS AND CONFIDENTIAL INFOR-*  
5        *MATION.—In carrying out this section the Secretary*  
6        *shall enforce current law concerning the protection of*  
7        *confidential commercial information and trade se-*  
8        *crets.”.*

9        **“SEC. 39900-1. USE OF CIVIL PENALTY AMOUNTS.**

10        *“The Secretary shall, without further appropriation,*  
11        *collect civil penalties under section 39900 and use the*  
12        *funds derived from such civil penalties, in addition to any*  
13        *other amounts available to the Secretary, to carry out ac-*  
14        *tivities described in this part and to improve consumer and*  
15        *provider information about drug value and drug price*  
16        *transparency.*

17        **“SEC. 39900-2. ANNUAL REPORT TO CONGRESS.**

18        *“(a) IN GENERAL.—Subject to subsection (b), the Sec-*  
19        *retary shall submit to Congress, and post on the public*  
20        *website of the Department of Health and Human Services*  
21        *in a way that is easy to find, use, and understand, an an-*  
22        *nual report—*

23                *“(1) summarizing the information reported pur-*  
24        *suant to section 39900; and*

1           “(2) including copies of the reports and sup-  
2           porting detailed economic analyses submitted pursu-  
3           ant to such section.

4           “(b) *TRADE SECRETS AND CONFIDENTIAL INFORMA-*  
5           *TION.—In carrying out this section the Secretary shall en-*  
6           *force current law concerning the protection of confidential*  
7           *commercial information and trade secrets.”.*

8           **TITLE III—IMPROVING TRANSPARENCY IN HEALTH CARE**  
9

10          **SEC. 301. INCREASING TRANSPARENCY BY REMOVING GAG**

11                           **CLAUSES ON PRICE AND QUALITY INFORMA-**  
12                           **TION.**

13           Subpart II of part A of title XXVII of the Public  
14          Health Service Act (42 U.S.C. 300gg–11 et seq.), as amend-  
15          ed by section 103, is amended by adding at the end the  
16          following:

17          **“SEC. 2729B. INCREASING TRANSPARENCY BY REMOVING**

18                           **GAG CLAUSES ON PRICE AND QUALITY IN-**  
19                           **FORMATION.**

20           “(a) *INCREASING PRICE AND QUALITY TRANSPARENCY*  
21          *FOR PLAN SPONSORS AND GROUP AND INDIVIDUAL MAR-*  
22          *KET AND CONSUMERS.—*

23                           “(1) *GROUP HEALTH PLANS.—A group health*  
24          *plan or health insurance issuer offering group health*  
25          *insurance coverage may not enter into an agreement*

1       with a health care provider, network or association of  
2       providers, third-party administrator, or other service  
3       provider offering access to a network of providers that  
4       would directly or indirectly restrict a group health  
5       plan or health insurance issuer from—

6               “(A) providing provider-specific cost or  
7               quality of care information, through a consumer  
8               engagement tool or any other means, to referring  
9               providers, the plan sponsor, enrollees, or eligible  
10              enrollees of the plan or coverage;

11             “(B) electronically accessing de-identified  
12             claims and encounter data for each enrollee in  
13             the plan or coverage, upon request and consistent  
14             with the privacy regulations promulgated pursu-  
15             ant to section 264(c) of the Health Insurance  
16             Portability and Accountability Act, the amend-  
17             ments to this Act made by the Genetic Informa-  
18             tion Nondiscrimination Act of 2008, and the  
19             Americans with Disabilities Act of 1990, with  
20             respect to the applicable health plan or health  
21             insurance coverage, including, on a per claim  
22             basis—

23                   “(i) financial information, such as the  
24                   allowed amount, or any other claim-related

1           *financial obligations included in the pro-*  
2           *vider contract;*

3           “(ii) *provider information, including*  
4           *name and clinical designation;*

5           “(iii) *service codes; or*

6           “(iv) *any other data element normally*  
7           *included in claim or encounter transactions*  
8           *when received by a plan or issuer; or*

9           “(C) *sharing data described in subpara-*  
10          *graph (A) or (B) with a business associate as de-*  
11          *fined in section 160.103 of title 45, Code of Fed-*  
12          *eral Regulations (or successor regulations), con-*  
13          *sistent with the privacy regulations promulgated*  
14          *pursuant to section 264(e) of the Health Insur-*  
15          *ance Portability and Accountability Act, the*  
16          *amendments to this Act made by the Genetic In-*  
17          *formation Nondiscrimination Act of 2008, and*  
18          *the Americans with Disabilities Act of 1990.*

19          “(2) *INDIVIDUAL HEALTH INSURANCE COV-*  
20          *ERAGE.—A health insurance issuer offering indi-*  
21          *vidual health insurance coverage may not enter into*  
22          *an agreement with a health care provider, network or*  
23          *association of providers, or other service provider of-*  
24          *fering access to a network of providers that would di-*

1 *rectly or indirectly restrict the health insurance issuer*  
2 *from—*

3 *“(A) providing provider-specific price or*  
4 *quality of care information, through a consumer*  
5 *engagement tool or any other means, to referring*  
6 *providers, enrollees, or eligible enrollees of the*  
7 *plan or coverage; or*

8 *“(B) sharing, for plan design, plan admin-*  
9 *istration, and plan, financial, legal, and quality*  
10 *improvement activities, data described in sub-*  
11 *paragraph (A) with a business associate as de-*  
12 *finied in section 160.103 of title 45, Code of Fed-*  
13 *eral Regulations (or successor regulations), con-*  
14 *sistent with the privacy regulations promulgated*  
15 *pursuant to section 264(c) of the Health Insur-*  
16 *ance Portability and Accountability Act, the*  
17 *amendments to this Act made by the Genetic In-*  
18 *formation Nondiscrimination Act of 2008, and*  
19 *the Americans with Disabilities Act of 1990.*

20 *“(3) CLARIFICATION REGARDING PUBLIC DISCLO-*  
21 *SURE OF INFORMATION.—Nothing in paragraph*  
22 *(1)(A) or (2)(A) prevents a health care provider, net-*  
23 *work or association of providers, or other service pro-*  
24 *vider from placing reasonable restrictions on the pub-*

1        *lic disclosure of the information described in such*  
 2        *paragraphs (1) and (2).*

3            “(4) *ATTESTATION.*—*A group health plan or a*  
 4        *health insurance issuer offering group or individual*  
 5        *health insurance coverage shall annually submit to,*  
 6        *as applicable, the applicable authority described in*  
 7        *section 2723 or the Secretary of Labor, an attestation*  
 8        *that such plan or issuer is in compliance with the re-*  
 9        *quirements of this subsection.*

10           “(5) *RULE OF CONSTRUCTION.*—*Nothing in this*  
 11        *section shall be construed to otherwise limit group*  
 12        *health plan, plan sponsor, or health insurance issuer*  
 13        *access to data currently permitted under the privacy*  
 14        *regulations promulgated pursuant to section 264(c) of*  
 15        *the Health Insurance Portability and Accountability*  
 16        *Act, the amendments to this Act made by the Genetic*  
 17        *Information Nondiscrimination Act of 2008, and the*  
 18        *Americans with Disabilities Act of 1990.”*

19    **SEC. 302. BANNING ANTICOMPETITIVE TERMS IN FACILITY**  
 20                                    **AND INSURANCE CONTRACTS THAT LIMIT AC-**  
 21                                    **CESS TO HIGHER QUALITY, LOWER COST**  
 22                                    **CARE.**

23            (a) *IN GENERAL.*—*Section 2729B of the Public Health*  
 24        *Service Act, as added by section 301, is amended by adding*  
 25        *at the end the following:*

1       “(b) *PROTECTING HEALTH PLANS NETWORK DESIGN*  
2 *FLEXIBILITY.*—

3               “(1) *IN GENERAL.*—*A group health plan or a*  
4 *health insurance issuer offering group or individual*  
5 *health insurance coverage shall not enter into an*  
6 *agreement with a provider, network or association of*  
7 *providers, or other service provider offering access to*  
8 *a network of service providers if such agreement, di-*  
9 *rectly or indirectly—*

10               “(A) *restricts the group health plan or*  
11 *health insurance issuer from—*

12                       “(i) *directing or steering enrollees to*  
13 *other health care providers; or*

14                       “(ii) *offering incentives to encourage*  
15 *enrollees to utilize specific health care pro-*  
16 *viders; or*

17               “(B) *requires the group health plan or*  
18 *health insurance issuer to enter into any addi-*  
19 *tional contract with an affiliate of the provider,*  
20 *such as an affiliate of the provider, as a condi-*  
21 *tion of entering into a contract with such pro-*  
22 *vider;*

23               “(C) *requires the group health plan or*  
24 *health insurance issuer to agree to payment rates*

1           *or other terms for any affiliate not party to the*  
2           *contract of the provider involved; or*

3           “(D) *restricts other group health plans or*  
4           *health insurance issuers not party to the contract*  
5           *from paying a lower rate for items or services*  
6           *than the contracting plan or issuer pays for such*  
7           *items or services.*

8           “(2) *ADDITIONAL REQUIREMENT FOR SELF-IN-*  
9           *SURED PLANS.—A self-insured group health plan*  
10          *shall not enter into an agreement with a provider,*  
11          *network or association of providers, third-party ad-*  
12          *ministrator, or other service provider offering access*  
13          *to a network of providers if such agreement directly*  
14          *or indirectly requires the group health plan to certify,*  
15          *attest, or otherwise confirm in writing that the group*  
16          *health plan is bound by restrictive contracting terms*  
17          *between the service provider and a third-party ad-*  
18          *ministrator that the group health plan is not party*  
19          *to, without a disclosure that such terms exist.*

20          “(3) *EXCEPTION FOR CERTAIN GROUP MODEL*  
21          *ISSUERS.—Paragraph (1)(A) shall not apply to a*  
22          *group health plan or health insurance issuer offering*  
23          *group or individual health insurance coverage with*  
24          *respect to—*

1           “(A) a health maintenance organization (as  
2           defined in section 2791(b)(3)), if such health  
3           maintenance organization operates primarily  
4           through exclusive contracts with multi-specialty  
5           physician groups, nor to any arrangement be-  
6           tween such a health maintenance organization  
7           and its affiliates; or

8           “(B) a value-based network arrangement,  
9           such as an exclusive provider network, account-  
10          able care organization, center of excellence, a  
11          provider sponsored health insurance issuer that  
12          operates primarily through aligned multi-spe-  
13          cialty physician group practices or integrated  
14          health systems, or such other similar network ar-  
15          rangements as determined by the Secretary  
16          through rulemaking.

17          “(4) ATTESTATION.—A group health plan or  
18          health insurance issuer offering group or individual  
19          health insurance coverage shall annually submit to,  
20          as applicable, the applicable authority described in  
21          section 2723 or the Secretary of Labor, an attestation  
22          that such plan or issuer is in compliance with the re-  
23          quirements of this subsection.

24          “(c) MAINTENANCE OF EXISTING HIPAA, GINA, AND  
25          ADA PROTECTIONS.—Nothing in this section shall modify,

1 *reduce, or eliminate the existing privacy protections and*  
2 *standards provided by reason of State and Federal law, in-*  
3 *cluding the requirements of parts 160 and 164 of title 45,*  
4 *Code of Federal Regulations (or any successor regulations).*

5       “(d) *REGULATIONS.*—*The Secretary, not later than 1*  
6 *year after the date of enactment of the Lower Health Care*  
7 *Costs Act, shall promulgate regulations to carry out this*  
8 *section.*

9       “(e) *RULE OF CONSTRUCTION.*—*Nothing in this sec-*  
10 *tion shall be construed to limit network design or cost or*  
11 *quality initiatives by a group health plan or health insur-*  
12 *ance issuer, including accountable care organizations, ex-*  
13 *clusive provider organizations, networks that tier providers*  
14 *by cost or quality or steer enrollees to centers of excellence,*  
15 *or other pay-for-performance programs.*

16       “(f) *CLARIFICATION WITH RESPECT TO ANTITRUST*  
17 *LAWS.*—*Compliance with this section does not constitute*  
18 *compliance with the antitrust laws, as defined in subsection*  
19 *(a) of the first section of the Clayton Act (15 U.S.C.*  
20 *12(a)).”.*

21       “(b) *EFFECTIVE DATE.*—*Section 2729B of the Public*  
22 *Health Service Act (as added by section 301 and amended*  
23 *by subsection (a)) shall apply with respect to any contract*  
24 *entered into on or after the date that is 18 months after*  
25 *the date of enactment of this Act. With respect to an appli-*

1 *cable contract that is in effect on the date of enactment of*  
 2 *this Act, such section 2729B shall apply on the earlier of*  
 3 *the date of renewal of such contract or 3 years after such*  
 4 *date of enactment.*

5 **SEC. 303. DESIGNATION OF A NONGOVERNMENTAL, NON-**  
 6 **PROFIT TRANSPARENCY ORGANIZATION TO**  
 7 **LOWER AMERICANS' HEALTH CARE COSTS.**

8 *(a) IN GENERAL.—Subpart C of title XXVII of the*  
 9 *Public Health Service Act (42 U.S.C. 300gg–91 et seq.), as*  
 10 *amended by section 102, is further amended by adding at*  
 11 *the end the following:*

12 **“SEC. 2796. DESIGNATION OF A NONGOVERNMENTAL, NON-**  
 13 **PROFIT TRANSPARENCY ORGANIZATION TO**  
 14 **LOWER AMERICANS' HEALTH CARE COSTS.**

15 *“(a) IN GENERAL.—The Secretary, in consultation*  
 16 *with the Secretary of Labor, not later than 1 year after*  
 17 *the date of enactment of the Lower Health Care Costs Act,*  
 18 *shall enter into a contract with a nonprofit entity to sup-*  
 19 *port the establishment and maintenance of a database that*  
 20 *receives and utilizes health care claims information and re-*  
 21 *lated information and issues reports that are available to*  
 22 *the public and authorized users, and are submitted to the*  
 23 *Department of Health and Human Services.*

24 *“(b) REQUIREMENTS.—*

1           “(1) *IN GENERAL.*—*The database established*  
2           *under subsection (a) shall—*

3                   “(A) *improve transparency by using de-*  
4                   *identified health care data to—*

5                           “(i) *inform patients about the cost,*  
6                           *quality, and value of their care;*

7                           “(ii) *assist providers and hospitals, as*  
8                           *they work with patients, to make informed*  
9                           *choices about care;*

10                           “(iii) *enable providers, hospitals, and*  
11                           *communities to improve services and out-*  
12                           *comes for patients by benchmarking their*  
13                           *performance against that of other providers,*  
14                           *hospitals, and communities;*

15                           “(iv) *enable purchasers, including em-*  
16                           *ployers, employee organizations, and health*  
17                           *plans, to develop value-based purchasing*  
18                           *models, improve quality, and reduce the cost*  
19                           *of health care and insurance coverage for*  
20                           *enrollees;*

21                           “(v) *enable employers and employee or-*  
22                           *ganizations to evaluate network design and*  
23                           *construction, and the cost of care for enroll-*  
24                           *ees;*

1           “(vi) facilitate State-led initiatives to  
2           lower health care costs and improve quality;  
3           and

4           “(vii) promote competition based on  
5           quality and cost;

6           “(B) collect medical claims, prescription  
7           drug claims, and remittance data consistent with  
8           the protections and requirements of subsection  
9           (d);

10           “(C) be established in such a manner that  
11           allows the data collected pursuant to subpara-  
12           graph (B) to be shared with any State all-payer  
13           claims database or regional database operated  
14           with authorization from States, at cost, using a  
15           standardized format, if such State or regional  
16           database also submits claims data to the data-  
17           base established under this section; and

18           “(D) be available to—

19           “(i) the Director of the Congressional  
20           Budget Office, the Comptroller General of  
21           the United States, the Executive Director of  
22           the Medicare Payment Advisory Commis-  
23           sion, and the Executive Director of the Med-  
24           icaid and CHIP Payment Advisory Com-  
25           mission, upon request, subject to the privacy

1           *and security requirements of authorized*  
2           *users under subsection (e)(2); and*

3           “(ii) *authorized users, including em-*  
4           *ployers, employee organizations, providers,*  
5           *researchers, and policymakers, subject to*  
6           *subsection (e).*

7           “(2) *PRIVACY AND SECURITY; BREACH NOTIFICA-*  
8           *TIONS.—*

9           “(A) *REGULATIONS.—*

10           “(i) *IN GENERAL.—The Secretary shall*  
11           *issue regulations prescribing the extent to*  
12           *which, and the manner in which, the fol-*  
13           *lowing rules (and any successors of such*  
14           *rules) shall apply to the activities under*  
15           *this section of an entity receiving a contract*  
16           *under subsection (a):*

17           “(I) *The Privacy Rule under part*  
18           *160 and subparts A and E of part 164*  
19           *of title 45, Code of Federal Regulations*  
20           *(or any successor regulations).*

21           “(II) *The Security Rule under*  
22           *part 160 and subparts A and C of part*  
23           *164 of such title 45 (or any successor*  
24           *regulations).*

1                   “(III) *The Breach Notification*  
2                   *Rule under part 160 and subparts A*  
3                   *and D of part 164 of such title 45 (or*  
4                   *any successor regulations).*

5                   “(ii) *SUPPLEMENTAL REGULATIONS.—*  
6                   *In order to ensure data privacy and secu-*  
7                   *rity and the notification of breaches, the*  
8                   *Secretary may issue such supplemental reg-*  
9                   *ulations on the subjects of the rules listed*  
10                   *under clause (i) as the Secretary determines*  
11                   *appropriate to address differences between*  
12                   *the activities described by this section and*  
13                   *the activities covered by such rules.*

14                   “(B) *ENFORCEMENT.—Section 1176 of So-*  
15                   *cial Security Act shall apply with respect to a*  
16                   *violation of this paragraph in the same manner*  
17                   *such section 1176 applies to a violation of part*  
18                   *C of title XI of the Social Security Act, and the*  
19                   *Secretary may include in the regulations pro-*  
20                   *mulgated under this section provisions to apply*  
21                   *such section to this paragraph.*

22                   “(C) *PROCEDURE.—*

23                   “(i) *TIMING.—The Secretary shall*  
24                   *issue the initial set of regulations under this*  
25                   *paragraph not later than 1 year after the*

1           *date of enactment of the Lower Health Care*  
2           *Costs Act.*

3           “(ii) *AUTHORITY TO USE INTERIM*  
4           *FINAL PROCEDURES.—The Secretary may*  
5           *make such initial set of regulations effective*  
6           *and final immediately upon issuance, on an*  
7           *interim basis, and provide for a period of*  
8           *public comment on such initial set of regu-*  
9           *lations after the date of publication.*

10          “(D) *REQUIREMENTS OF ENTITY.—The en-*  
11          *tity receiving the contract under this section*  
12          *shall—*

13                 “(i) *not disclose to the public any indi-*  
14                 *vidually identifiable health information or*  
15                 *proprietary financial information;*

16                 “(ii) *strictly limit staff access to the*  
17                 *data to staff with appropriate training,*  
18                 *clearance, and background checks and re-*  
19                 *quire regular privacy and security training;*

20                 “(iii) *maintain effective security*  
21                 *standards for transferring data or making*  
22                 *data available to authorized users;*

23                 “(iv) *develop a process for providing*  
24                 *access to data to authorized users, in a se-*

1           *cure manner that maintains privacy and*  
2           *confidentiality of data; and*

3           “(v) *adhere to current best security*  
4           *practices with respect to the management*  
5           *and use of such data for health services re-*  
6           *search, in accordance with applicable Fed-*  
7           *eral privacy law*

8           “(3) *CONSULTATION.—*

9           “(A) *ADVISORY COMMITTEE.—Not later*  
10          *than 180 days after the date of enactment of the*  
11          *Lower Health Care Costs Act, the Secretary shall*  
12          *convene an Advisory Committee (referred to in*  
13          *this section as the ‘Committee’), consisting of 13*  
14          *members, to advise the Secretary, the contracting*  
15          *entity, and Congress on the establishment, oper-*  
16          *ations, and use of the database established under*  
17          *this section.*

18          “(B) *MEMBERSHIP.—*

19          “(i) *APPOINTMENT.—In accordance*  
20          *with clause (ii), the Secretary, in consulta-*  
21          *tion with the Secretary of Labor and the*  
22          *Comptroller General of the United States*  
23          *shall, not later than 180 days after the date*  
24          *of enactment of the Lower Health Care*  
25          *Costs Act, appoint members to the Com-*

1            *mittee who have distinguished themselves in*  
2            *the fields of health services research, health*  
3            *economics, health informatics, or the gov-*  
4            *ernance of State all-payer claims databases,*  
5            *or who represent organizations likely to sub-*  
6            *mit data to or use the database, including*  
7            *patients, employers, or employee organiza-*  
8            *tions that sponsor group health plans,*  
9            *health care providers, health insurance*  
10           *issuers, or third-party administrators of*  
11           *group health plans. Such members shall*  
12           *serve 3-year terms on a staggered basis. Va-*  
13           *cancies on the Committee shall be filled by*  
14           *appointment consistent with this subsection*  
15           *not later than 3 months after the vacancy*  
16           *arises.*

17           *“(ii) COMPOSITION.—In accordance*  
18           *with clause (i)—*

19           *“(I) the Secretary, in consultation*  
20           *with the Secretary of Labor, shall ap-*  
21           *point to the Committee—*

22           *“(aa) 1 member selected by*  
23           *the Secretary, in coordination*  
24           *with the Secretary of Labor, to*

1                   *serve as the chair of the Com-*  
2                   *mittee;*

3                   *“(bb) the Assistant Secretary*  
4                   *for Planning and Evaluation of*  
5                   *the Department of Health and*  
6                   *Human Services, or a designee of*  
7                   *such Assistant Secretary;*

8                   *“(cc) 1 representative of the*  
9                   *Centers for Medicare & Medicaid*  
10                  *Services;*

11                  *“(dd) 1 representative of the*  
12                  *Agency for Health Research and*  
13                  *Quality;*

14                  *“(ee) 1 representative of the*  
15                  *Office for Civil Rights of the De-*  
16                  *partment of Health and Human*  
17                  *Services with expertise in data*  
18                  *privacy and security;*

19                  *“(ff) 1 representative of the*  
20                  *National Center for Health Statis-*  
21                  *tics; and*

22                  *“(gg) 1 representative of the*  
23                  *Employee Benefits and Security*  
24                  *Administration of the Department*  
25                  *of Labor; and*

1                   “(II) the Comptroller General of  
2 the United States shall appoint to the  
3 Committee—

4                   “(aa) 1 representative of an  
5 employer that sponsors a group  
6 health plan;

7                   “(bb) 1 representative of an  
8 employee organization that spon-  
9 sors a group health plan;

10                  “(cc) 1 academic researcher  
11 with expertise in health economics  
12 or health services research;

13                  “(dd) 1 consumer advocate;  
14 and

15                  “(ee) 2 additional members.

16                  “(C) DUTIES.—The Committee shall—

17                  “(i) advise the Secretary on the man-  
18 agement of the contract under subsection  
19 (a);

20                  “(ii) assist and advise the entity re-  
21 ceiving the contract under subsection (a) in  
22 establishing—

23                  “(I) the scope and format of the  
24 data to be submitted under subsection  
25 (d);

1                   “(II) best practices with respect to  
2                   de-identification of data, as appro-  
3                   priate;

4                   “(III) the appropriate uses of  
5                   data by authorized users, including de-  
6                   veloping standards for the approval of  
7                   requests by organizations to access and  
8                   use the data; and

9                   “(IV) the appropriate formats and  
10                  methods for making reports and anal-  
11                  yses based on the database to the pub-  
12                  lic;

13                  “(iii) conduct an annual review of  
14                  whether data was used according to the ap-  
15                  propriate uses as described in clause  
16                  (ii)(II), and advise the designated entity on  
17                  using the data for authorized purposes;

18                  “(iv) report, as appropriate, to the  
19                  Secretary and Congress on the operation of  
20                  the database and opportunities to better  
21                  achieve the objectives of this section;

22                  “(v) establish additional restrictions on  
23                  researchers who receive compensation from  
24                  entities described in subsection (e)(2)(B)(i),

1                   *in order to protect proprietary financial in-*  
2                   *formation; and*

3                   “*(vi) establish objectives for research*  
4                   *and public reporting.*”

5                   “(4) *STATE REQUIREMENTS.—A State may re-*  
6                   *quire health insurance issuers and other payers to*  
7                   *submit claims data to the database established under*  
8                   *this section, provided that such data is submitted to*  
9                   *the entity awarded the contract under this section in*  
10                  *a form and manner established by the Secretary, and*  
11                  *pursuant to subsection (d)(4)(B).*”

12                  “(5) *SANCTIONS.—The Secretary shall take ap-*  
13                  *propriate action to sanction users who attempt to re-*  
14                  *identify data accessed pursuant to paragraph (1)(D).*”

15                  “(c) *CONTRACT REQUIREMENTS.—*

16                  “(1) *COMPETITIVE PROCEDURES.—The Secretary*  
17                  *shall enter into the contract under subsection (a)*  
18                  *using full and open competition procedures pursuant*  
19                  *to chapter 33 of title 41, United States Code.*”

20                  “(2) *ELIGIBLE ENTITIES.—To be eligible to enter*  
21                  *into a contract described in subsection (a), an entity*  
22                  *shall—*

23                         “(A) *be a private nonprofit entity governed*  
24                         *by a board that includes representatives of the*  
25                         *academic research community and individuals*

1           *with expertise in employer-sponsored insurance,*  
2           *research using health care claims data and actu-*  
3           *arial analysis;*

4           “(B) *conduct its business in an open and*  
5           *transparent manner that provides the oppor-*  
6           *tunity for public comment on its activities; and*

7           “(C) *agree to comply with any requirements*  
8           *imposed under the rulemaking described in sub-*  
9           *section (d)(4)(A).*

10          “(3) *CONSIDERATIONS.—In awarding the con-*  
11          *tract under subsection (a), the Secretary shall con-*  
12          *sider an entity’s experience in—*

13                 “(A) *health care claims data collection, ag-*  
14                 *gregation, quality assurance, analysis, and secu-*  
15                 *rity;*

16                 “(B) *supporting academic research on*  
17                 *health costs, spending, and utilization for and by*  
18                 *privately insured patients;*

19                 “(C) *working with large health insurance*  
20                 *issuers and third-party administrators to assem-*  
21                 *ble a national claims database;*

22                 “(D) *effectively collaborating with and en-*  
23                 *gaging stakeholders to develop reports;*

24                 “(E) *meeting budgets and timelines, includ-*  
25                 *ing in connection with report generation; and*

1           “(F) *facilitating the creation of, or sup-*  
2           *porting, State all-payer claims databases.*

3           “(4) *CONTRACT TERM.*—*A contract awarded*  
4           *under this section shall be for a period of 5 years, and*  
5           *may be renewed after a subsequent competitive bid-*  
6           *ding process under this section.*

7           “(5) *TRANSITION OF CONTRACT.*—*If the Sec-*  
8           *retary, following a competitive process at the end of*  
9           *the contract period, selects a new entity to maintain*  
10          *the database, all data shall be transferred to the new*  
11          *entity according to a schedule and process to be deter-*  
12          *mined by the Secretary. Upon termination of a con-*  
13          *tract, no entity may keep data held by the database*  
14          *or disclose such data to any entity other than the en-*  
15          *tity so designated by the Secretary. The Secretary*  
16          *shall include enforcement terms in any contract with*  
17          *an organization chosen under this section, to ensure*  
18          *the timely transfer of all data, and any associated*  
19          *code or algorithms, to a new entity in the event of*  
20          *contract termination.*

21          “(d) *RECEIVING HEALTH INFORMATION.*—

22                  “(1) *REQUIREMENTS.*—

23                          “(A) *IN GENERAL.*—*The Secretary of Labor*  
24                          *shall ensure that the applicable self-insured*  
25                          *group health plan, through its third-party ad-*

1           *administrator, pharmacy benefit manager, or other*  
2           *entity designated by the group health plan, as*  
3           *applicable, electronically submits all claims data*  
4           *with respect to the plan, pursuant to subpara-*  
5           *graph (B).*

6           “(B) *SCOPE OF INFORMATION AND FORMAT*  
7           *OF SUBMISSION.—The entity awarded the con-*  
8           *tract under subsection (a), in consultation with*  
9           *the Committee described in subsection (b)(3), and*  
10           *pursuant to the privacy and security require-*  
11           *ments of subsection (b)(2), shall—*

12           “(i) *specify the data elements required*  
13           *to be submitted under subparagraph (A),*  
14           *which shall include all data related to*  
15           *transactions described in subparagraphs (A)*  
16           *and (E) of section 1173(a)(2) of the Social*  
17           *Security Act, including all data elements*  
18           *normally present in such transactions when*  
19           *adjudicated, and enrollment information;*

20           “(ii) *specify the form and manner for*  
21           *such submissions, and the historical period*  
22           *to be included in the initial submission;*  
23           *and*

1           “(iii) offer an automated submission  
2           option to minimize administrative burdens  
3           for entities required to submit data.

4           “(C) *DE-IDENTIFICATION OF DATA.*—The  
5           entity awarded the contract under subsection (a)  
6           shall—

7           “(i) establish a process under which  
8           data is de-identified consistent with the de-  
9           identification requirements under section  
10          164.514 of title 45, Code of Federal Regula-  
11          tions (or any successor regulations), while  
12          retaining the ability to link data longitu-  
13          dinally for the purposes of research on cost  
14          and quality, and the ability to complete  
15          risk adjustment and geographic analysis;

16          “(ii) ensure that any third-party sub-  
17          contractors who perform the de-identifica-  
18          tion process described in clause (i) retain  
19          only the minimum necessary information to  
20          perform such a process, and adhere to effec-  
21          tive security and encryption practices in  
22          data storage and transmission;

23          “(iii) store claims and other data col-  
24          lected under this subsection only in de-iden-  
25          tified form, in accordance with section

1           164.514 of title 45, Code of Federal Regula-  
2           tions (or any successor regulations); and

3           “(iv) ensure that individually identifi-  
4           able data is encrypted, in accordance with  
5           guidance issued by the Secretary under sec-  
6           tion 13402(h)(2) of the HITECH Act.

7           “(2) *APPLICABLE SELF-INSURED GROUP HEALTH*  
8           *PLAN.*—For purposes of paragraph (1), a self-insured  
9           group health plan is an applicable self-insured group  
10          health plan if such plan is self-administered, or is ad-  
11          ministered by a third-party plan administrator that  
12          meets 1 or both of the following criteria:

13           “(A) Administers health, medical, or phar-  
14           macy benefits for more than 50,000 enrollees.

15           “(B) Is one of the 5 largest administrators  
16           or issuers of self-insured group health plans in a  
17           State in which such administrator operates, as  
18           measured by the aggregate number of enrollees in  
19           plans administered by such administrator in  
20           such State, as determined by the Secretary.

21           “(3) *THIRD-PARTY ADMINISTRATORS.*—In the  
22           case of a third-party administrator that is required  
23           under this subsection to submit claims data with re-  
24           spect to an applicable self-insured group health plan,  
25           such administrator shall submit claims data with re-

1 *spect to all self-insured group health plans that the*  
2 *administrator administers, including such plans that*  
3 *are not applicable self-insured group health plans, as*  
4 *described in paragraph (2).*

5 *“(4) RECEIVING OTHER INFORMATION.—*

6 *“(A) MEDICARE DATA.—The Secretary,*  
7 *through rulemaking, shall ensure that the data*  
8 *made available to such entity is available to*  
9 *qualified entities under section 1874(e) of the So-*  
10 *cial Security Act is made available to the entity*  
11 *awarded a contract under subsection (a).*

12 *“(B) STATE DATA.—The entity awarded the*  
13 *contract under subsection (a) shall collect data*  
14 *from State all payer claims databases that seek*  
15 *access to the database established under this sec-*  
16 *tion.*

17 *“(5) AVAILABILITY OF DATA.—An entity re-*  
18 *quired to submit data under this subsection may not*  
19 *place any restrictions on the use of such data by au-*  
20 *thorized users.*

21 *“(e) USES OF INFORMATION.—*

22 *“(1) IN GENERAL.—The entity awarded the con-*  
23 *tract under subsection (a) shall make the database*  
24 *available to users who are authorized under this sub-*

1        *section, at cost, and reports and analyses based on the*  
2        *data available to the public with no charge.*

3            *“(2) AUTHORIZATION OF USERS.—*

4            *“(A) IN GENERAL.—An entity may request*  
5            *authorization by the entity awarded the contract*  
6            *under subsection (a) for access to the database in*  
7            *accordance with this paragraph.*

8            *“(B) APPLICATION.—An entity desiring au-*  
9            *thorization under this paragraph shall submit to*  
10           *the entity awarded the contract an application*  
11           *for such access, which shall include—*

12           *“(i) in the case of an entity requesting*  
13           *access for research purposes—*

14           *“(I) a description of the uses and*  
15           *methodologies for evaluating health*  
16           *system performance using such data;*  
17           *and*

18           *“(II) documentation of approval*  
19           *of the research by an institutional re-*  
20           *view board, if applicable for a par-*  
21           *ticular plan of research; or*

22           *“(ii) in the case of an entity such as*  
23           *an employer, health insurance issuer, third-*  
24           *party administrator, or health care pro-*  
25           *vider, requesting access for the purpose of*

1           *quality improvement or cost-containment, a*  
2           *description of the intended uses for such*  
3           *data.*

4           “(C) *REQUIREMENTS.*—

5                 “(i) *RESEARCH.*—*Upon approval of an*  
6                 *application for research purposes under*  
7                 *subparagraph (B)(i), the authorized user*  
8                 *shall enter into a data use and confiden-*  
9                 *tiality agreement with the entity awarded*  
10                *the contract under subsection (a), which*  
11                *shall include a prohibition on attempts to*  
12                *reidentify and disclose individually identifi-*  
13                *able health information and proprietary fi-*  
14                *nancial information.*

15               “(ii) *QUALITY IMPROVEMENT AND*  
16                *COST-CONTAINMENT.*—*In consultation with*  
17                *the Committee described in subsection*  
18                *(b)(3), the Secretary shall, through rule-*  
19                *making, establish the form and manner in*  
20                *which authorized users described in sub-*  
21                *paragraph (B)(i) may access data. Data*  
22                *provided to such authorized users shall be*  
23                *provided in a form and manner such that*  
24                *users may not obtain individually identifi-*  
25                *able price information with respect to direct*

1            *competitors. Upon approval, such author-*  
2            *ized user shall enter into a data use and*  
3            *confidentiality agreement with the entity.*

4            *“(iii) CUSTOMIZED REPORTS.—Em-*  
5            *ployers and employer organizations may re-*  
6            *quest customized reports from the entity*  
7            *awarded the contract under subsection (a),*  
8            *at cost, subject to the requirements of this*  
9            *section with respect to privacy, security,*  
10           *and proprietary financial information.*

11           *“(iv) NON-CUSTOMIZED REPORTS.—*  
12           *The entity awarded the contract under sub-*  
13           *section (a), in consultation with the Com-*  
14           *mittee, shall make available to all author-*  
15           *ized users aggregate data sets, free of charge.*

16           *“(f) FUNDING.—*

17           *“(1) INITIAL FUNDING.—There are authorized to*  
18           *be appropriated, and there are appropriated, out of*  
19           *monies in the Treasury not otherwise appropriated,*  
20           *\$20,000,000 for fiscal year 2020, for the implementa-*  
21           *tion of the initial contract and establishment of the*  
22           *database under this section.*

23           *“(2) ONGOING FUNDING.—There are authorized*  
24           *to be appropriated \$15,000,000 for each of fiscal*  
25           *years 2021 through 2025, for purposes of carrying out*

1        *this section (other than the grant program under sub-*  
2        *section (h)).*

3        “(g) *ANNUAL REPORT.*—

4                “(1) *SUBMISSION.*—*On each of the dates de-*  
5        *scribed in paragraph (2), the entity receiving the con-*  
6        *tract under subsection (a) shall submit to Congress,*  
7        *the Secretary of Health and Human Services, and the*  
8        *Secretary of Labor and publish online for access by*  
9        *the general public, a report containing a description*  
10       *of—*

11                “(A) *trends in the price, utilization, and*  
12        *total spending on health care services, including*  
13        *a geographic analysis of differences in such*  
14        *trends;*

15                “(B) *limitations in the data set;*

16                “(C) *progress towards the objectives of this*  
17        *section; and*

18                “(D) *the performance by the entity of the*  
19        *duties required under such contract.*

20                “(2) *DATES DESCRIBED.*—*The reports described*  
21        *in paragraph (1) shall be submitted—*

22                “(A) *not later than 3 years after the date*  
23        *of enactment of the Lower Health Care Costs Act;*

24                “(B) *the later of 1 year after the date that*  
25        *is 3 years after such date of enactment or March*

1           *1 of the year after the date that is 3 years after*  
2           *such date of enactment; and*

3           “(C) *March 1 of each year thereafter.*

4           “(3) *PUBLIC REPORTS AND RESEARCH.—The en-*  
5           *tity receiving a contract under subsection (a) shall, in*  
6           *coordination with authorized users, make analyses*  
7           *and research available to the public on an ongoing*  
8           *basis to promote the objectives of this section.*

9           “(h) *GRANTS TO STATES.—*

10           “(1) *IN GENERAL.—The Secretary, in consulta-*  
11           *tion with the Secretary of Labor, may award grants*  
12           *to States for the purpose of establishing and main-*  
13           *taining State all-payer claims databases that improve*  
14           *transparency of data in order to meet the goals of*  
15           *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 appro-*  
22           *priated \$100,000,000 for the period of fiscal years*  
23           *2020 through 2029 for the purpose of awarding*  
24           *grants to States under this subsection.*

25           “(i) *EXEMPTION FROM PUBLIC DISCLOSURE.—*

1           “(1) *IN GENERAL.*—*Claims data provided to the*  
2           *database, and the database itself shall not be consid-*  
3           *ered public records and shall be exempt from public*  
4           *disclosure requirements.*

5           “(2) *RESTRICTIONS ON USES FOR CERTAIN PRO-*  
6           *CEEDINGS.*—*Data disclosed to authorized users shall*  
7           *not be subject to discovery or admission as public in-*  
8           *formation, or evidence in judicial or administrative*  
9           *proceedings without consent of the affected parties.*

10          “(j) *DEFINITIONS.*—

11           “(1) *INDIVIDUALLY IDENTIFIABLE HEALTH IN-*  
12           *FORMATION.*—*The term ‘individually identifiable*  
13           *health information’ has the meaning given such term*  
14           *in section 1171(6) of the Social Security Act.*

15           “(2) *PROPRIETARY FINANCIAL INFORMATION.*—  
16           *The term ‘proprietary financial information’ means*  
17           *data that would disclose the terms of a specific con-*  
18           *tract between an individual health care provider or*  
19           *facility and a specific group health plan, Medicaid*  
20           *managed care organization or other managed care en-*  
21           *tity, or health insurance issuer offering group or indi-*  
22           *vidual coverage.*

23           “(k) *RULE OF CONSTRUCTION.*—*Nothing in this sec-*  
24           *tion shall be construed to affect or modify enforcement of*  
25           *the privacy, security, or breach notification rules promul-*

1 *gated under section 264(c) of the Health Insurance Port-*  
2 *ability and Accountability Act of 1996 (or successor regula-*  
3 *tions).”.*

4 *(b) GAO REPORT.—*

5 *(1) IN GENERAL.—The Comptroller General of*  
6 *the United States shall conduct a study on—*

7 *(A) the performance of the entity awarded*  
8 *a contract under section 2795(a) of the Public*  
9 *Health Service Act, as added by subsection (a),*  
10 *under such contract;*

11 *(B) the privacy and security of the informa-*  
12 *tion reported to the entity; and*

13 *(C) the costs incurred by such entity in per-*  
14 *forming such duties.*

15 *(2) REPORTS.—Not later than 2 years after the*  
16 *effective date of the first contract entered into under*  
17 *section 2795(a) of the Public Health Service Act, as*  
18 *added by subsection (a), and again not later than 4*  
19 *years after such effective date, the Comptroller Gen-*  
20 *eral of the United States shall submit to Congress a*  
21 *report containing the results of the study conducted*  
22 *under paragraph (1), together with recommendations*  
23 *for such legislation and administrative action as the*  
24 *Comptroller General determines appropriate.*

1 **SEC. 304. PROTECTING PATIENTS AND IMPROVING THE AC-**  
 2 **CURACY OF PROVIDER DIRECTORY INFORMA-**  
 3 **TION.**

4 (a) *IN GENERAL.*—*Subpart II of part A of title XXVII*  
 5 *of the Public Health Service Act (42 U.S.C. 300gg–11 et*  
 6 *seq.), as amended by sections 301 and 302, is further*  
 7 *amended by adding at the end the following:*

8 **“SEC. 2729C. PROTECTING PATIENTS AND IMPROVING THE**  
 9 **ACCURACY OF PROVIDER DIRECTORY INFOR-**  
 10 **MATION.**

11 *“(a) NETWORK STATUS OF PROVIDERS.—*

12 *“(1) IN GENERAL.—Beginning on the date that*  
 13 *is one year after the date of enactment of this section,*  
 14 *a group health plan or a health insurance issuer of-*  
 15 *fering group or individual health insurance coverage*  
 16 *shall—*

17 *“(A) establish business processes to ensure*  
 18 *that all enrollees in such plan or coverage receive*  
 19 *proof of a health care provider’s network status,*  
 20 *based on what a plan or issuer knows or could*  
 21 *reasonably know—*

22 *“(i) through a written electronic com-*  
 23 *munication from the plan or issuer to the*  
 24 *enrollee, as soon as practicable and not*  
 25 *later than 1 business day after a telephone*

1            *inquiry is made by such enrollee for such*  
2            *information;*

3            *“(ii) through an oral confirmation,*  
4            *documented by such issuer or coverage, and*  
5            *kept in the enrollee’s file for a minimum of*  
6            *2 years; and*

7            *“(iii) in real-time through an online*  
8            *health care provider directory search tool*  
9            *maintained by the plan or issuer; and*

10           *“(B) include in any print directory a dis-*  
11           *closure that the information included in the di-*  
12           *rectory is accurate as of the date of the last data*  
13           *update and that enrollees or prospective enrollees*  
14           *should consult the group health plan or issuer’s*  
15           *electronic provider directory on its website or*  
16           *call a specified customer service telephone num-*  
17           *ber to obtain the most current provider directory*  
18           *information.*

19           *“(2) GROUP HEALTH PLAN AND HEALTH INSUR-*  
20           *ANCE ISSUER BUSINESS PROCESSES.—Beginning on*  
21           *the date that is one year after the date of enactment*  
22           *of the Lower Health Care Costs Act, a group health*  
23           *plan or a health insurance issuer offering group or*  
24           *individual health insurance coverage shall establish*  
25           *business processes to—*

1           “(A) verify and update, at least once every  
2           90 days, the provider directory information for  
3           all providers included in the online health care  
4           provider directory search tool described in para-  
5           graph (1)(A)(iii); and

6           “(B) remove any provider from such online  
7           directory search tool if such provider has not  
8           verified the directory information within the pre-  
9           vious 6 months or the plan or issuer has been  
10          unable to verify the provider’s network partici-  
11          pation.

12          “(b) *COST-SHARING LIMITATIONS.*—

13                 “(1) *IN GENERAL.*—A group health plan or a  
14                 health insurance issuer offering group or individual  
15                 health insurance coverage shall not apply, and shall  
16                 ensure that no provider applies cost-sharing to an en-  
17                 rollee for treatment or services provided by a health  
18                 care provider in excess of the normal cost-sharing ap-  
19                 plied for in-network care (including any balance bill  
20                 issued by the health care provider involved), if such  
21                 enrollee, or health care provider referring such en-  
22                 rollee, demonstrates (based on the electronic, written  
23                 information described in subsection (a)(1)(A)(i), the  
24                 oral confirmation described in subsection  
25                 (a)(1)(A)(ii), or a copy of the online provider direc-

1        *tory described in subsection (a)(1)(A)(iii) on the date*  
2        *the enrollee attempted to obtain the provider's net-*  
3        *work status) that the enrollee relied on the informa-*  
4        *tion described in subsection (a)(1), if the provider's*  
5        *network status or directory information on such di-*  
6        *rectory was incorrect at the time the treatment or*  
7        *services involved was provided.*

8                *“(2) REFUNDS TO ENROLLEES.—If a health care*  
9        *provider submits a bill to an enrollee in violation of*  
10        *paragraph (1), and the enrollee pays such bill, the*  
11        *provider shall reimburse the enrollee for the full*  
12        *amount paid by the enrollee in excess of the in-net-*  
13        *work cost-sharing amount for the treatment or serv-*  
14        *ices involved, plus interest, at an interest rate deter-*  
15        *mined by the Secretary.*

16                *“(c) PROVIDER BUSINESS PROCESSES.—A health care*  
17        *provider shall have in place business processes to ensure the*  
18        *timely provision of provider directory information to a*  
19        *group health plan or a health insurance issuer offering*  
20        *group or individual health insurance coverage to support*  
21        *compliance by such plans or issuers with subsection (a)(1).*  
22        *Such providers shall submit provider directory information*  
23        *to a plan or issuers, at a minimum—*

1           “(1) when the provider begins a network agree-  
2           ment with a plan or with an issuer with respect to  
3           certain coverage;

4           “(2) when the provider terminates a network  
5           agreement with a plan or with an issuer with respect  
6           to certain coverage;

7           “(3) when there are material changes to the con-  
8           tent of provider directory information described in  
9           subsection (a)(1); and

10          “(4) every 90 days throughout the duration of  
11          the network agreement with a plan or issuer.

12          “(d) ENFORCEMENT.—

13                 “(1) IN GENERAL.—Subject to paragraph (2), a  
14                 health care provider that violates a requirement under  
15                 subsection (c) or takes actions that prevent a group  
16                 health plan or health insurance issuer from com-  
17                 plying with subsection (a)(1) or (b) shall be subject to  
18                 a civil monetary penalty of not more than \$10,000  
19                 for each act constituting such violation.

20                 “(2) SAFE HARBOR.—The Secretary may waive  
21                 the penalty described under paragraph (1) with re-  
22                 spect to a health care provider that unknowingly vio-  
23                 lates subsection (b)(1) with respect to an enrollee if  
24                 such provider rescinds the bill involved and, if appli-  
25                 cable, reimburses the enrollee within 30 days of the

1       *date on which the provider billed the enrollee in viola-*  
2       *tion of such subsection.*

3           “(3) *PROCEDURE.*—*The provisions of section*  
4       *1128A of the Social Security Act, other than sub-*  
5       *sections (a) and (b) and the first sentence of sub-*  
6       *section (c)(1) of such section, shall apply to civil*  
7       *money penalties under this subsection in the same*  
8       *manner as such provisions apply to a penalty or pro-*  
9       *ceeding under section 1128A of the Social Security*  
10       *Act.*

11          “(e) *SAVINGS CLAUSE.*—*Nothing in this section shall*  
12       *prohibit a provider from requiring in the terms of a con-*  
13       *tract, or contract termination, with a group health plan*  
14       *or health insurance issuer—*

15           “(1) *that the plan or issuer remove, at the time*  
16       *of termination of such contract, the provider from a*  
17       *directory of the plan or issuer described in subsection*  
18       *(a)(1); or*

19           “(2) *that the plan or issuer bear financial re-*  
20       *ponsibility, including under subsection (b), for pro-*  
21       *viding inaccurate network status information to an*  
22       *enrollee.*

23          “(f) *DEFINITION.*—*For purposes of this section, the*  
24       *term ‘provider directory information’ includes the names,*  
25       *addresses, specialty, and telephone numbers of individual*

1 *health care providers, and the names, addresses, and tele-*  
 2 *phone numbers of each medical group, clinic, or facility*  
 3 *contracted to participate in any of the networks of the*  
 4 *group health plan or health insurance coverage involved.*

5       “(g) *RULE OF CONSTRUCTION.*—*Nothing in this sec-*  
 6 *tion shall be construed to preempt any provision of State*  
 7 *law relating to health care provider directories or network*  
 8 *adequacy.”.*

9       (b) *EFFECTIVE DATE.*—*Section 2729C of the Public*  
 10 *Health Service Act, as added by subsection (a), shall take*  
 11 *effect with respect to plan years beginning on or after the*  
 12 *date that is 18 months after the date of enactment of this*  
 13 *Act.*

14 **SEC. 305. TIMELY BILLS FOR PATIENTS.**

15       (a) *IN GENERAL.*—

16               (1) *AMENDMENT.*—*Part P of title III of the Pub-*  
 17 *lic Health Service Act (42 U.S.C. 280g et seq.) is*  
 18 *amended by adding at the end the following:*

19 **“SEC. 399V-7. TIMELY BILLS FOR PATIENTS.**

20       “(a) *IN GENERAL.*—*The Secretary shall require—*

21               “(1) *health care facilities, or in the case of prac-*  
 22 *titioners providing services outside of such a facility,*  
 23 *practitioners, to provide to patients a list of services*  
 24 *rendered during the visit to such facility or practi-*  
 25 *tioner, and, in the case of a facility, the name of the*

1        *provider for each such service, upon discharge or end*  
2        *of the visit or by postal or electronic communication*  
3        *as soon as practicable and not later than 5 calendar*  
4        *days after discharge or date of visit; and*

5            *“(2) health care facilities and practitioners to*  
6        *furnish all adjudicated bills to the patient as soon as*  
7        *practicable, but not later than 45 calendar days after*  
8        *discharge or date of visit.*

9            *“(b) PAYMENT AFTER BILLING.—No patient may be*  
10        *required to pay a bill for health care services any earlier*  
11        *than 35 days after the postmark date of a bill for such serv-*  
12        *ices.*

13            *“(c) EFFECT OF VIOLATION.—*

14            *“(1) NOTIFICATION AND REFUND REQUIRE-*  
15        *MENTS.—*

16            *“(A) PROVIDER LISTS.—If a facility or*  
17        *practitioner fails to provide a patient a list as*  
18        *required under subsection (a)(1), such facility or*  
19        *practitioner shall report such failure to the Sec-*  
20        *retary.*

21            *“(B) BILLING.—If a facility or practitioner*  
22        *bills a patient after the 45-calendar-day period*  
23        *described in subsection (a)(2), such facility or*  
24        *practitioner shall—*

1           “(i) report such bill to the Secretary;  
2           and

3           “(ii) refund the patient for the full  
4           amount paid in response to such bill with  
5           interest, at a rate determined by the Sec-  
6           retary.

7           “(2) CIVIL MONETARY PENALTIES.—

8           “(A) IN GENERAL.—The Secretary may im-  
9           pose civil monetary penalties of up to \$10,000 a  
10          day on any facility or practitioner that—

11          “(i) fails to provide a list required  
12          under subsection (a)(1) more than 10 times,  
13          beginning on the date of such tenth failure;

14          “(ii) submits more than 10 bills out-  
15          side of the period described in subsection  
16          (a)(2), beginning on the date on which such  
17          facility or practitioner sends the tenth such  
18          bill;

19          “(iii) fails to report to the Secretary  
20          any failure to provide lists as required  
21          under paragraph (1)(A), beginning on the  
22          date that is 45 calendar days after dis-  
23          charge or visit; or

24          “(iv) fails to send any bill as required  
25          under subsection (a)(2), beginning on the

1           *date that is 45 calendar days after the date*  
2           *of discharge or visit, as applicable.*

3           “(B) *PROCEDURE.*—*The provisions of sec-*  
4           *tion 1128A of the Social Security Act, other than*  
5           *subsections (a) and (b) and the first sentence of*  
6           *subsection (c)(1) of such section, shall apply to*  
7           *civil money penalties under this subsection in*  
8           *the same manner as such provisions apply to a*  
9           *penalty or proceeding under section 1128A of the*  
10          *Social Security Act.*

11          “(3) *SAFE HARBOR.*—*The Secretary may exempt*  
12          *a practitioner or facility from the penalties under*  
13          *paragraph (2)(A) or extend the period of time speci-*  
14          *fied under subsection (a)(2) for compliance with such*  
15          *subsection if a practitioner or facility—*

16                 “(A) *makes a good-faith attempt to send a*  
17                 *bill within 30 days but is unable to do so be-*  
18                 *cause of an incorrect address; or*

19                 “(B) *experiences extenuating circumstances*  
20                 *(as defined by the Secretary), such as a hurri-*  
21                 *cane or cyberattack, that may reasonably delay*  
22                 *delivery of a timely bill.”.*

23          “(2) *RULEMAKING.*—*Not later than 1 year after*  
24          *the date of enactment of this Act, the Secretary shall*  
25          *promulgate final regulations to define the term “ex-*

1        *tenuating circumstance” for purposes of section*  
 2        *399V–7(c)(3)(B) of the Public Health Service Act, as*  
 3        *added by paragraph (1).*

4        *(b) GROUP HEALTH PLAN AND HEALTH INSURANCE*  
 5        *ISSUER REQUIREMENTS.—Subpart II of part A of title*  
 6        *XXVII of the Public Health Service Act (42 U.S.C. 300gg–*  
 7        *11), as amended by section 304, is further amended by add-*  
 8        *ing at the end the following:*

9        **“SEC. 2729D. TIMELY BILLS FOR PATIENTS.**

10        *“(a) IN GENERAL.—A group health plan or health in-*  
 11        *surance issuer offering group or individual health insur-*  
 12        *ance coverage shall have in place business practices with*  
 13        *respect to in-network facilities and practitioners to ensure*  
 14        *that claims are adjudicated in order to facilitate facility*  
 15        *and practitioner compliance with the requirements under*  
 16        *section 399V–7(a).*

17        *“(b) CLARIFICATION.—Nothing in subsection (a) pro-*  
 18        *hibits a provider and a group health plan or health insur-*  
 19        *ance issuer from establishing in a contract the timeline for*  
 20        *submission by either party to the other party of billing in-*  
 21        *formation, adjudication, sending of remittance information,*  
 22        *or any other coordination required between the provider*  
 23        *and the plan or issuer necessary for meeting the deadline*  
 24        *described in section 399V–7(a)(2).”.*

1           (c) *EFFECTIVE DATE.*—*The amendments made by sub-*  
 2 *sections (a) and (b) shall take effect 6 months after the date*  
 3 *of enactment of this Act.*

4 **SEC. 306. HEALTH PLAN OVERSIGHT OF PHARMACY BEN-**  
 5 **EFIT MANAGER SERVICES.**

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 amend-*  
 8 *ed by section 305(b), is further amended by adding at the*  
 9 *end the following:*

10 **“SEC. 2729E. HEALTH PLAN OVERSIGHT OF PHARMACY BEN-**  
 11 **EFIT MANAGER SERVICES.**

12           “(a) *IN GENERAL.*—*A group health plan or health in-*  
 13 *surance issuer offering group health insurance coverage or*  
 14 *an entity or subsidiary providing pharmacy benefits man-*  
 15 *agement services shall not enter into a contract with a drug*  
 16 *manufacturer, distributor, wholesaler, subcontractor, rebate*  
 17 *aggregator, or any associated third party that limits the*  
 18 *disclosure of information to plan sponsors in such a manner*  
 19 *that prevents the plan or coverage, or an entity or sub-*  
 20 *sidary providing pharmacy benefits management services*  
 21 *on behalf of a plan or coverage from making the reports*  
 22 *described in subsection (b).*

23           “(b) *REPORTS TO GROUP PLAN SPONSORS.*—

24                   “(1) *IN GENERAL.*—*Beginning with the first*  
 25 *plan year that begins after the date of enactment of*

1       *the Lower Health Care Costs Act, not less frequently*  
2       *than once every 6 months, a health insurance issuer*  
3       *offering group health insurance coverage or an entity*  
4       *providing pharmacy benefits management services on*  
5       *behalf of a group health plan shall submit to the plan*  
6       *sponsor (as defined in section 3(16)(B) of the Em-*  
7       *ployee Retirement Income Security Act of 1974) of*  
8       *such group health plan or health insurance coverage*  
9       *a report in accordance with this subsection and make*  
10       *such report available to the plan sponsor in a ma-*  
11       *chine-readable format. Each such report shall include,*  
12       *with respect to the applicable group health plan or*  
13       *health insurance coverage—*

14                “(A) *information collected from drug manu-*  
15                *facturers by such issuer or entity on the total*  
16                *amount of copayment assistance dollars paid, or*  
17                *copayment cards applied, that were funded by*  
18                *the drug manufacturer with respect to the enroll-*  
19                *ees in such plan or coverage;*

20                “(B) *a list of each covered drug dispensed*  
21                *during the reporting period, including, with re-*  
22                *spect to each such drug during the reporting pe-*  
23                *riod—*

24                        “(i) *the brand name, chemical entity,*  
25                        *and National Drug Code;*

1           “(ii) the number of enrollees for whom  
2           the drug was filled during the plan year,  
3           the total number of prescription fills for the  
4           drug (including original prescriptions and  
5           refills), and the total number of dosage  
6           units of the drug dispensed across the plan  
7           year, including whether the dispensing  
8           channel was by retail, mail order, or spe-  
9           cialty pharmacy;

10           “(iii) the wholesale acquisition cost,  
11           listed as cost per days supply and cost per  
12           pill, or in the case of a drug in another  
13           form, per dose;

14           “(iv) the total out-of-pocket spending  
15           by enrollees on such drug, including enrollee  
16           spending through copayments, coinsurance,  
17           and deductibles;

18           “(v) for any drug for which gross  
19           spending of the group health plan or health  
20           insurance coverage exceeded \$10,000 during  
21           the reporting period—

22           “(I) a list of all other available  
23           drugs in the same therapeutic category  
24           or class, including brand name drugs  
25           and biological products and generic

1                    *drugs or biosimilar biological products*  
2                    *that are in the same therapeutic cat-*  
3                    *egory or class; and*

4                    *“(II) the rationale for preferred*  
5                    *formulary placement of a particular*  
6                    *drug or drugs in that therapeutic cat-*  
7                    *egory or class;*

8                    *“(C) a list of each therapeutic category or*  
9                    *class of drugs that were dispensed under the*  
10                   *health plan or health insurance coverage during*  
11                   *the reporting period, and, with respect to each*  
12                   *such therapeutic category or class of drugs, dur-*  
13                   *ing the reporting period—*

14                   *“(i) total gross spending by the plan,*  
15                   *before manufacturer rebates, fees, or other*  
16                   *manufacturer remuneration;*

17                   *“(ii) the number of enrollees who filled*  
18                   *a prescription for a drug in that category*  
19                   *or class;*

20                   *“(iii) if applicable to that category or*  
21                   *class, a description of the formulary tiers*  
22                   *and utilization mechanisms (such as prior*  
23                   *authorization or step therapy) employed for*  
24                   *drugs in that category or class;*

1           “(iv) the total out-of-pocket spending  
2 by enrollees, including enrollee spending  
3 through copayments, coinsurance, and  
4 deductibles; and

5           “(v) for each therapeutic category or  
6 class under which 3 or more drugs are in-  
7 cluded on the formulary of such plan or cov-  
8 erage—

9           “(I) the amount received, or ex-  
10 pected to be received, from drug manu-  
11 facturers in rebates, fees, alternative  
12 discounts, or other remuneration—

13           “(aa) to be paid by drug  
14 manufacturers for claims incurred  
15 during the reporting period; or

16           “(bb) that is related to utili-  
17 zation of drugs, in such thera-  
18 peutic category or class;

19           “(II) the total net spending, after  
20 deducting rebates, price concessions, al-  
21 ternative discounts or other remunera-  
22 tion from drug manufacturers, by the  
23 health plan or health insurance cov-  
24 erage on that category or class of  
25 drugs; and

1                   “(III) the net price per course of  
2                   treatment or 30-day supply incurred  
3                   by the health plan or health insurance  
4                   coverage and its enrollees, after manu-  
5                   facturer rebates, fees, and other remu-  
6                   neration for drugs dispensed within  
7                   such therapeutic category or class dur-  
8                   ing the reporting period;

9                   “(D) total gross spending on prescription  
10                  drugs by the plan or coverage during the report-  
11                  ing period, before rebates and other manufac-  
12                  turer fees or remuneration;

13                  “(E) total amount received, or expected to  
14                  be received, by the health plan or health insur-  
15                  ance coverage in drug manufacturer rebates, fees,  
16                  alternative discounts, and all other remuneration  
17                  received from the manufacturer or any third  
18                  party, other than the plan sponsor, related to  
19                  utilization of drug or drug spending under that  
20                  health plan or health insurance coverage during  
21                  the reporting period;

22                  “(F) the total net spending on prescription  
23                  drugs by the health plan or health insurance cov-  
24                  erage during the reporting period; and

1           “(G) amounts paid directly or indirectly in  
2           rebates, fees, or any other type of remuneration  
3           to brokers, consultants, advisors, or any other in-  
4           dividual or firm who referred the group health  
5           plan’s or health insurance issuer’s business to the  
6           pharmacy benefit manager.

7           “(2) *PRIVACY REQUIREMENTS.*—Health insur-  
8           ance issuers offering group health insurance coverage  
9           and entities providing pharmacy benefits manage-  
10          ment services on behalf of a group health plan shall  
11          provide information under paragraph (1) in a man-  
12          ner consistent with the privacy, security, and breach  
13          notification regulations promulgated under section  
14          264(c) of the Health Insurance Portability and Ac-  
15          countability Act of 1996 (or successor regulations),  
16          and shall restrict the use and disclosure of such infor-  
17          mation according to such privacy regulations.

18          “(3) *DISCLOSURE AND REDISCLOSURE.*—

19                 “(A) *LIMITATION TO BUSINESS ASSOCI-*  
20                 *ATES.*—A group health plan receiving a report  
21                 under paragraph (1) may disclose such informa-  
22                 tion only to business associates of such plan as  
23                 defined in section 160.103 of title 45, Code of  
24                 Federal Regulations (or successor regulations).

1           “(B) *CLARIFICATION REGARDING PUBLIC*  
2           *DISCLOSURE OF INFORMATION.*—*Nothing in this*  
3           *section prevents a health insurance issuer offer-*  
4           *ing group health insurance coverage or an entity*  
5           *providing pharmacy benefits management serv-*  
6           *ices on behalf of a group health plan from plac-*  
7           *ing reasonable restrictions on the public disclo-*  
8           *sure of the information contained in a report de-*  
9           *scribed in paragraph (1), except that such issuer*  
10           *or entity may not restrict disclosure of such re-*  
11           *port to governmental agencies pursuant to an in-*  
12           *vestigation or enforcement action.*

13           “(C) *LIMITED FORM OF REPORT.*—*The Sec-*  
14           *retary shall define through rulemaking a limited*  
15           *form of the report under paragraph (1) required*  
16           *of plan sponsors who are drug manufacturers,*  
17           *drug wholesalers, or other direct participants in*  
18           *the drug supply chain, in order to prevent anti-*  
19           *competitive behavior.*

20           “(c) *LIMITATIONS ON SPREAD PRICING.*—

21           “(1) *PRESCRIPTION DRUG TRANSACTIONS WITH*  
22           *PHARMACIES INDEPENDENT OF THE ISSUER OR*  
23           *PHARMACY BENEFITS MANAGER.*—*If the pharmacy*  
24           *that dispenses a prescription drug to an enrollee in*  
25           *a group health plan or group or individual health in-*

1        *surance coverage is not wholly or partially-owned by*  
2        *such plan, such issuer, or an entity providing phar-*  
3        *macy benefit management services under such plan or*  
4        *coverage, such plan, issuer, or entity shall not charge*  
5        *the plan, issuer, or enrollee a price for such prescrip-*  
6        *tion drug that exceeds the price paid to the phar-*  
7        *macy, excluding penalties paid by pharmacies to such*  
8        *plan, issuer, or entity.*

9                *“(2) INTRA-COMPANY PRESCRIPTION DRUG*  
10                *TRANSACTIONS.—If the mail order, specialty, or retail*  
11                *pharmacy that dispenses a prescription drug to an*  
12                *enrollee in a group health plan or health insurance*  
13                *coverage is wholly or partially owned by, and submits*  
14                *claims to, such health insurance issuer or an entity*  
15                *providing pharmacy benefit management services*  
16                *under a group health plan or group or individual*  
17                *health insurance coverage, the price charged for such*  
18                *drug by such pharmacy to such group health plan or*  
19                *health insurance issuer offering group or individual*  
20                *health insurance coverage may not exceed the lesser*  
21                *of—*

22                        *“(A) the amount paid to the pharmacy for*  
23                        *acquisition of the drug; or*

24                        *“(B) the median price charged to the group*  
25                        *health plan or health insurance issuer when the*

1        *same drug is dispensed to enrollees in the plan*  
2        *or coverage by other similarly-situated phar-*  
3        *macies not wholly or partially owned by the*  
4        *health insurance issuer or entity providing phar-*  
5        *macy benefits management services, as described*  
6        *in paragraph (1).*

7        *“(3) SUPPLEMENTARY REPORTING FOR INTRA-*  
8        *COMPANY PRESCRIPTION DRUG TRANSACTIONS.—A*  
9        *health insurance issuer of group health insurance cov-*  
10       *erage or an entity providing pharmacy benefits man-*  
11       *agement services under a group health plan or group*  
12       *health insurance coverage that conducts transactions*  
13       *with a wholly or partially-owned pharmacy, as de-*  
14       *scribed in paragraph (2), shall submit, together with*  
15       *the report under subsection (b), a supplementary re-*  
16       *port every 6 months to the plan sponsor that in-*  
17       *cludes—*

18            *“(A) an explanation of any benefit design*  
19            *parameters that encourage enrollees in the plan*  
20            *or coverage to fill prescriptions at mail order,*  
21            *specialty, or retail pharmacies that are wholly or*  
22            *partially-owned by that issuer or entity;*

23            *“(B) the percentage of total prescriptions*  
24            *charged to the plan, coverage, or enrollees in the*  
25            *plan or coverage, that were dispensed by mail*

1           *order, specialty, or retail pharmacies that are*  
2           *wholly or partially-owned by the issuer or entity*  
3           *providing pharmacy benefits management serv-*  
4           *ices; and*

5           “(C) *a list of all drugs dispensed by such*  
6           *wholly or partially-owned pharmacy and*  
7           *charged to the plan or coverage, or enrollees of*  
8           *the plan or coverage, during the applicable quar-*  
9           *ter, and, with respect to each drug—*

10           “(i) *the amount charged per course of*  
11           *treatment or 30-day supply with respect to*  
12           *enrollees in the plan or coverage, including*  
13           *amounts charged to the plan or coverage*  
14           *and amounts charged to the enrollee;*

15           “(ii) *the median amount charged to the*  
16           *plan or coverage, per course of treatment or*  
17           *30-day supply, including amounts paid by*  
18           *the enrollee, when the same drug is dis-*  
19           *persed by other pharmacies that are not*  
20           *wholly or partially-owned by the issuer or*  
21           *entity and that are included in the phar-*  
22           *macy network of that plan or coverage;*

23           “(iii) *the interquartile range of the*  
24           *costs, per course of treatment or 30-day sup-*  
25           *ply, including amounts paid by the enrollee,*

1           *when the same drug is dispensed by other*  
2           *pharmacies that are not wholly or par-*  
3           *tially-owned by the issuer or entity and*  
4           *that are included in the pharmacy network*  
5           *of that plan or coverage;*

6           “(iv) *the lowest cost per course of treat-*  
7           *ment or 30-day supply, for such drug, in-*  
8           *cluding amounts charged to the plan or*  
9           *issuer and enrollee, that is available from*  
10          *any pharmacy included in the network of*  
11          *the plan or coverage.*

12          “(d) *FULL REBATE PASS-THROUGH TO PLAN.—*

13                 “(1) *IN GENERAL.—A pharmacy benefits man-*  
14                 *ager, a third-party administrator of a group health*  
15                 *plan, a health insurance issuer offering group health*  
16                 *insurance coverage, or an entity providing pharmacy*  
17                 *benefits management services under such health plan*  
18                 *or health insurance coverage shall remit 100 percent*  
19                 *of rebates, fees, alternative discounts, and all other re-*  
20                 *muneration received from a pharmaceutical manufac-*  
21                 *turer, distributor or any other third party, that are*  
22                 *related to utilization of drugs under such health plan*  
23                 *or health insurance coverage, to the group health*  
24                 *plan.*

1           “(2) *FORM AND MANNER OF REMITTANCE.*—*Such*  
2           *rebates, fees, alternative discounts, and other remun-*  
3           *eration shall be—*

4                   “(A) *remitted to the group health plan in a*  
5                   *timely fashion after the period for which such re-*  
6                   *bates, fees, or other remuneration is calculated,*  
7                   *and in no case later than 90 days after the end*  
8                   *of such period;*

9                   “(B) *fully disclosed and enumerated to the*  
10                   *group health plan sponsor, as described in (b)(1);*

11                   “(C) *available for audit by the plan spon-*  
12                   *sor, or a third-party designated by a plan spon-*  
13                   *sor no less than once per plan year; and*

14                   “(D) *returned to the issuer or entity pro-*  
15                   *viding pharmaceutical benefit management serv-*  
16                   *ices by the group health plan if audits by such*  
17                   *issuer or entity indicate that the amounts re-*  
18                   *ceived are incorrect after such amounts have been*  
19                   *paid to the group health plan.*

20           “(3) *AUDIT OF REBATE CONTRACTS.*—*A phar-*  
21           *macy benefits manager, a third-party administrator*  
22           *of a group health plan, a health insurance issuer of-*  
23           *fering group health insurance coverage, or an entity*  
24           *providing pharmacy benefits management services*  
25           *under such health plan or health insurance coverage*

1     *shall make rebate contracts with drug manufacturers*  
2     *available for audit by such plan sponsor or des-*  
3     *ignated third-party, subject to confidentiality agree-*  
4     *ments to prevent re-disclosure of such contracts.*

5     “(e) *ENFORCEMENT.*—

6             “(1) *IN GENERAL.*—*The Secretary, in consulta-*  
7     *tion with the Secretary of Labor and the Secretary of*  
8     *the Treasury, shall enforce this section.*

9             “(2) *FAILURE TO PROVIDE TIMELY INFORMA-*  
10     *TION.*—*A health insurance issuer or an entity pro-*  
11     *viding pharmacy benefit management services that*  
12     *violates subsection (a), fails to provide information*  
13     *required under subsection (b), engages in spread pric-*  
14     *ing as defined in subsection (c), or fails to comply*  
15     *with the requirements of subsection (d), or a drug*  
16     *manufacturer that fails to provide information under*  
17     *subsection (b)(1)(A), in a timely manner shall be sub-*  
18     *ject to a civil monetary penalty in the amount of*  
19     *\$10,000 for each day during which such violation*  
20     *continues or such information is not disclosed or re-*  
21     *ported.*

22             “(3) *FALSE INFORMATION.*—*A health insurance*  
23     *issuer, entity providing pharmacy benefit manage-*  
24     *ment services, or drug manufacturer that knowingly*  
25     *provides false information under this section shall be*

1       *subject to a civil money penalty in an amount not to*  
2       *exceed \$100,000 for each item of false information.*  
3       *Such civil money penalty shall be in addition to other*  
4       *penalties as may be prescribed by law.*

5               “(4) *PROCEDURE.*—*The provisions of section*  
6       *1128A of the Social Security Act, other than sub-*  
7       *section (a) and (b) and the first sentence of subsection*  
8       *(c)(1) of such section shall apply to civil monetary*  
9       *penalties under this subsection in the same manner as*  
10       *such provisions apply to a penalty or proceeding*  
11       *under section 1128A of the Social Security Act.*

12               “(5) *SAFE HARBOR.*—*The Secretary may waive*  
13       *penalties under paragraph (2), or extend the period*  
14       *of time for compliance with a requirement of this sec-*  
15       *tion, for an entity in violation of this section that has*  
16       *made a good-faith effort to comply with this section.*

17               “(f) *RULE OF CONSTRUCTION.*—*Nothing in this sec-*  
18       *tion shall be construed to prohibit payments to entities of-*  
19       *fering pharmacy benefits management services for bona fide*  
20       *services using a fee structure not contemplated by this sec-*  
21       *tion, provided that such fees are transparent to group health*  
22       *plans and health insurance issuers.*

23               “(g) *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 dis-*  
 3        *persed), 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 the*  
 7        *meaning given such term in section b1847A(c)(6)(B)*  
 8        *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 United*  
 14        *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;

5                   (iv) hospitals or group purchasing or-  
6                   ganizations; or

7                   (v) rehabilitation or physical therapy  
8                   facilities or services; and

9                   (B) include revenue- or profit-sharing  
10                  whether through a joint venture, management or  
11                  professional services agreement, or other form of  
12                  gain-sharing contract;

13               (2) describe Federal oversight of such relation-  
14               ships, including authorities of the Department of  
15               Health and Human Services and the Federal Trade  
16               Commission to review such relationships and their  
17               potential to increase costs for patients, and identify  
18               limitations in such oversight; and

19               (3) as appropriate, make recommendations to  
20               improve Federal oversight of such relationships.

21               (b) *REPORT.*—Not later than 1 year after the date of  
22               enactment of this Act, the Comptroller General of the United  
23               States shall prepare and submit a report on the study con-  
24               ducted under subsection (a) to the Committee on Health,  
25               Education, Labor, and Pensions of the Senate and the Com-

1 *mittee on Education and Labor and Committee on Energy*  
2 *and Commerce of the House of Representatives.*

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 the*  
9 *Employee Retirement Income Security Act of 1974 (29*  
10 *U.S.C. 1108(b)(2)) is amended—*

11 *(1) by striking “(2) Contracting or making” and*  
12 *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 clause*  
19 *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 the*  
2           *Secretary may establish in regulations to ac-*  
3           *count for inflation since the date of enactment of*  
4           *the Lower Health Care Costs Act, as appro-*  
5           *priate) or more in compensation, direct or indi-*  
6           *rect, to be received in connection with providing*  
7           *one or more of the following services, pursuant to*  
8           *the contract or arrangement, regardless of wheth-*  
9           *er such services will be performed, or such com-*  
10          *penetration received, by the covered service pro-*  
11          *vider, an affiliate, or a subcontractor:*

12                    “(AA) *Brokerage services, for which the*  
13                    *covered service provider, an affiliate, or a*  
14                    *subcontractor reasonably expects to receive*  
15                    *indirect compensation or direct compensa-*  
16                    *tion described in item (dd), provided to a*  
17                    *covered plan with respect to selection of in-*  
18                    *surance products (including vision and den-*  
19                    *tal), recordkeeping services, medical man-*  
20                    *agement vendor, benefits administration*  
21                    *(including vision and dental), stop-loss in-*  
22                    *surance, pharmacy benefit management*  
23                    *services, wellness services, transparency*  
24                    *tools and vendors, group purchasing organi-*  
25                    *zation preferred vendor panels, disease*

1            *management vendors and products, compli-*  
2            *ance services, employee assistance programs,*  
3            *or third party administration services.*

4            *“(BB) Consulting, for which the cov-*  
5            *ered service provider, an affiliate, or a sub-*  
6            *contractor reasonably expects to receive in-*  
7            *direct compensation or direct compensation*  
8            *described in item (dd), related to the devel-*  
9            *opment or implementation of plan design,*  
10           *insurance or insurance product selection*  
11           *(including vision and dental), record-*  
12           *keeping, medical management, benefits ad-*  
13           *ministration selection (including vision and*  
14           *dental), stop-loss insurance, pharmacy ben-*  
15           *efit management services, wellness design*  
16           *and management services, transparency*  
17           *tools, group purchasing organization agree-*  
18           *ments and services, participation in and*  
19           *services from preferred vendor panels, dis-*  
20           *ease management, compliance services, em-*  
21           *ployee assistance programs, or third party*  
22           *administration services.*

23           *“(cc) The term ‘affiliate’, with respect to a*  
24           *covered service provider, means an entity that*  
25           *directly or indirectly (through one or more inter-*

1            *mediaries) controls, is controlled by, or is under*  
2            *common control with, such provider, or is an of-*  
3            *ficer, director, or employee of, or partner in,*  
4            *such provider.*

5            *“(dd)(AA) The term ‘compensation’ means*  
6            *anything of monetary value, but does not include*  
7            *non-monetary compensation valued at \$250 (or*  
8            *such amount as the Secretary may establish in*  
9            *regulations to account for inflation since the date*  
10           *of enactment of the Lower Health Care Costs Act,*  
11           *as appropriate) or less, in the aggregate, during*  
12           *the term of the contract or arrangement.*

13           *“(BB) The term ‘direct compensation’*  
14           *means compensation received directly from a*  
15           *covered plan.*

16           *“(CC) The term ‘indirect compensation’*  
17           *means compensation received from any source*  
18           *other than the covered plan, the plan sponsor, the*  
19           *covered service provider, or an affiliate. Com-*  
20           *penetration received from a subcontractor is indi-*  
21           *rect compensation, unless it is received in con-*  
22           *nection with services performed under a contract*  
23           *or arrangement with a subcontractor.*

24           *“(ee) The term ‘responsible plan fiduciary’*  
25           *means a fiduciary with authority to cause the*

1           *covered plan to enter into, or extend or renew,*  
2           *the contract or arrangement.*

3           “(ff) *The term ‘subcontractor’ means any*  
4           *person or entity (or an affiliate of such person*  
5           *or entity) that is not an affiliate of the covered*  
6           *service provider and that, pursuant to a contract*  
7           *or arrangement with the covered service provider*  
8           *or an affiliate, reasonably expects to receive*  
9           *\$1,000 (or such amount as the Secretary may es-*  
10          *tablish in regulations to account for inflation*  
11          *since the date of enactment of the Lower Health*  
12          *Care Costs Act, as appropriate) or more in com-*  
13          *penensation for performing one or more services*  
14          *described in item (bb) under a contract or ar-*  
15          *rangement with the covered plan.*

16          “(II) *For purposes of this subparagraph, a de-*  
17          *scription of compensation or cost may be expressed as*  
18          *a monetary amount, formula, or a per capita charge*  
19          *for each enrollee or, if the compensation or cost can-*  
20          *not reasonably be expressed in such terms, by any*  
21          *other reasonable method, including a disclosure that*  
22          *additional compensation may be earned but may not*  
23          *be calculated at the time of contract if such a disclo-*  
24          *sure includes a description of the circumstances under*  
25          *which the additional compensation may be earned*

1        *and a reasonable and good faith estimate if the cov-*  
2        *ered service provider cannot otherwise readily describe*  
3        *compensation or cost and explains the methodology*  
4        *and assumptions used to prepare such estimate. Any*  
5        *such description shall contain sufficient information*  
6        *to permit evaluation of the reasonableness of the com-*  
7        *penetration or cost.*

8                *“(III) No person or entity is a ‘covered service*  
9        *provider’ within the meaning of subclause (I)(bb) sole-*  
10        *ly on the basis of providing services as an affiliate or*  
11        *a subcontractor that is performing one or more of the*  
12        *services described in subitem (AA) or (BB) of such*  
13        *subclause under the contract or arrangement with the*  
14        *covered plan.*

15                *“(iii) A covered service provider shall disclose to*  
16        *a responsible plan fiduciary, in writing, the fol-*  
17        *lowing:*

18                        *“(I) A description of the services to be pro-*  
19        *vided to the covered plan pursuant to the con-*  
20        *tract or arrangement.*

21                        *“(II) If applicable, a statement that the cov-*  
22        *ered service provider, an affiliate, or a subcon-*  
23        *tractor will provide, or reasonably expects to*  
24        *provide, services pursuant to the contract or ar-*

1           *rangement directly to the covered plan as a fidu-*  
2           *ciary (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          *ensation that the covered service provider, an*  
11          *affiliate, or a subcontractor reasonably expects to*  
12          *receive in connection with the services described*  
13          *in subclause (I)—*

14                 “(AA) *including compensation from a*  
15                 *vendor to a brokerage firm based on a struc-*  
16                 *ture of incentives not solely related to the*  
17                 *contract with the covered plan; and*

18                 “(BB) *not including compensation re-*  
19                 *ceived by an employee from an employer on*  
20                 *account of work performed by the employee.*

21                 “(bb) *A description of the arrangement be-*  
22                 *tween the payer and the covered service provider,*  
23                 *an affiliate, or a subcontractor, as applicable,*  
24                 *pursuant to which such indirect compensation is*  
25                 *paid.*

1           “(cc) *Identification of the services for which*  
2           *the indirect compensation will be received, if ap-*  
3           *plicable.*

4           “(dd) *Identification of the payer of the indi-*  
5           *rect compensation.*

6           “(V) *A description of any compensation*  
7           *that will be paid among the covered service pro-*  
8           *vider, an affiliate, or a subcontractor, in connec-*  
9           *tion with the services described in subclause (I)*  
10          *if such compensation is set on a transaction*  
11          *basis (such as commissions, finder’s fees, or other*  
12          *similar incentive compensation based on business*  
13          *placed or retained), including identification of*  
14          *the services for which such compensation will be*  
15          *paid and identification of the payers and recipi-*  
16          *ents of such compensation (including the status*  
17          *of a payer or recipient as an affiliate or a sub-*  
18          *contractor), regardless of whether such compensa-*  
19          *tion also is disclosed pursuant to subclause (III)*  
20          *or (IV).*

21          “(VI) *A description of any compensation*  
22          *that the covered service provider, an affiliate, or*  
23          *a subcontractor reasonably expects to receive in*  
24          *connection with termination of the contract or*  
25          *arrangement, and how any prepaid amounts*

1           *will be calculated and refunded upon such termi-*  
2           *nation.*

3           “(iv) *A covered service provider shall disclose to*  
4           *a responsible plan fiduciary, in writing a description*  
5           *of the manner in which the compensation described in*  
6           *clause (iii), as applicable, will be received.*

7           “(v)(I) *A covered service provider shall disclose*  
8           *the information required under clauses (iii) and (iv)*  
9           *to the responsible plan fiduciary not later than the*  
10          *date that is reasonably in advance of the date on*  
11          *which the contract or arrangement is entered into,*  
12          *and extended or renewed.*

13          “(II) *A covered service provider shall disclose*  
14          *any change to the information required under clause*  
15          *(iii) and (iv) as soon as practicable, but not later*  
16          *than 60 days from the date on which the covered serv-*  
17          *ice provider is informed of such change, unless such*  
18          *disclosure is precluded due to extraordinary cir-*  
19          *cumstances beyond the covered service provider’s con-*  
20          *trol, in which case the information shall be disclosed*  
21          *as soon as practicable.*

22          “(vi)(I) *Upon the written request of the respon-*  
23          *sible plan fiduciary or covered plan administrator, a*  
24          *covered service provider shall furnish any other infor-*  
25          *mation relating to the compensation received in con-*

1        *nection with the contract or arrangement that is re-*  
2        *quired for the covered plan to comply with the report-*  
3        *ing and disclosure requirements under this Act.*

4            *“(II) The covered service provider shall disclose*  
5        *the information required under clause (iii)(I) reason-*  
6        *ably in advance of the date upon which such respon-*  
7        *sible plan fiduciary or covered plan administrator*  
8        *states that it is required to comply with the applica-*  
9        *ble reporting or disclosure requirement, unless such*  
10       *disclosure is precluded due to extraordinary cir-*  
11       *cumstances beyond the covered service provider’s con-*  
12       *trol, in which case the information shall be disclosed*  
13       *as soon as practicable.*

14           *“(vii) No contract or arrangement will fail to be*  
15        *reasonable under this subparagraph solely because the*  
16        *covered service provider, acting in good faith and*  
17        *with reasonable diligence, makes an error or omission*  
18        *in disclosing the information required pursuant to*  
19        *clause (iii) (or a change to such information disclosed*  
20        *pursuant to clause (v)(II)) or clause (vi), provided*  
21        *that the covered service provider discloses the correct*  
22        *information to the responsible plan fiduciary as soon*  
23        *as practicable, but not later than 30 days from the*  
24        *date on which the covered service provider knows of*  
25        *such error or omission.*

1           “(viii)(I) Pursuant to subsection (a), subpara-  
2           graphs (C) and (D) of section 406(a)(1) shall not  
3           apply to a responsible plan fiduciary, notwith-  
4           standing any failure by a covered service provider to  
5           disclose information required under clause (iii), if the  
6           following conditions are met:

7           “(aa) The responsible plan fiduciary did  
8           not know that the covered service provider failed  
9           or would fail to make required disclosures and  
10          reasonably believed that the covered service pro-  
11          vider disclosed the information required to be  
12          disclosed.

13          “(bb) The responsible plan fiduciary, upon  
14          discovering that the covered service provider  
15          failed to disclose the required information, re-  
16          quests in writing that the covered service pro-  
17          vider furnish such information.

18          “(cc) If the covered service provider fails to  
19          comply with a written request described in sub-  
20          clause (II) within 90 days of the request, the re-  
21          sponsible plan fiduciary notifies the Secretary of  
22          the covered service provider’s failure, in accord-  
23          ance with subclauses (II) and (III).

24          “(II) A notice described in subclause (I)(cc) shall  
25          contain—

1           “(aa) the name of the covered plan;

2           “(bb) the plan number used for the annual  
3 report on the covered plan;

4           “(cc) the plan sponsor’s name, address, and  
5 employer identification number;

6           “(dd) the name, address, and telephone  
7 number of the responsible plan fiduciary;

8           “(ee) the name, address, phone number,  
9 and, if known, employer identification number of  
10 the covered service provider;

11           “(ff) a description of the services provided  
12 to the covered plan;

13           “(gg) a description of the information that  
14 the covered service provider failed to disclose;

15           “(hh) the date on which such information  
16 was requested in writing from the covered service  
17 provider; and

18           “(ii) a statement as to whether the covered  
19 service provider continues to provide services to  
20 the plan.

21           “(III) A notice described in subclause (I)(cc)  
22 shall be filed with the Department not later than 30  
23 days following the earlier of—

1           “(aa) *The covered service provider’s refusal*  
2           *to furnish the information requested by the writ-*  
3           *ten request described in subclause (I)(bb); or*

4           “(bb) *90 days after the written request re-*  
5           *ferred to in subclause (I)(cc) is made.*

6           “(IV) *If the covered service provider fails to com-*  
7           *ply with the written request under subclause (I)(bb)*  
8           *within 90 days of such request, the responsible plan*  
9           *fiduciary shall determine whether to terminate or*  
10          *continue the contract or arrangement under section*  
11          *404. If the requested information relates to future*  
12          *services and is not disclosed promptly after the end*  
13          *of the 90-day period, the responsible plan fiduciary*  
14          *shall terminate the contract or arrangement as expe-*  
15          *ditiously as possible, consistent with such duty of*  
16          *prudence.*

17          “(ix) *Nothing in this subparagraph shall be con-*  
18          *strued to supersede any provision of State law that*  
19          *governs disclosures by parties that provide the services*  
20          *described in this section, except to the extent that such*  
21          *law prevents the application of a requirement of this*  
22          *section.”.*

23          (b) *APPLICABILITY OF EXISTING REGULATIONS.—*  
24          *Nothing in the amendments made by subsection (a) shall*  
25          *be construed to affect the applicability of section 2550.408b—*

1 *2 of title 29, Code of Federal Regulations (or any successor*  
 2 *regulations), with respect to any applicable entity other*  
 3 *than a covered plan or a covered service provider (as de-*  
 4 *fin ed in section 408(b)(2)(B)(ii) of the Employee Retire-*  
 5 *ment Income Security Act of 1974, as amended by sub-*  
 6 *section (a)).*

7 *(c) INDIVIDUAL MARKET COVERAGE.—Subpart 1 of*  
 8 *part B of title XXVII of the Public Health Service Act (42*  
 9 *U.S.C. 300gg–41 et seq.) is amended by adding at the end*  
 10 *the following:*

11 **“SEC. 2746. DISCLOSURE TO ENROLLEES OF INDIVIDUAL**  
 12 **MARKET COVERAGE.**

13 *“(a) IN GENERAL.—A health insurance issuer offering*  
 14 *individual health insurance coverage shall make disclosures*  
 15 *to enrollees in such coverage, as described in subsection (b),*  
 16 *and reports to the Secretary, as described in subsection (c),*  
 17 *regarding direct or indirect compensation provided to an*  
 18 *agent or broker associated with enrolling individuals in*  
 19 *such coverage.*

20 *“(b) DISCLOSURE.—A health insurance issuer de-*  
 21 *scribed in subsection (a) shall disclose to an enrollee the*  
 22 *amount of direct or indirect compensation provided to an*  
 23 *agent or broker for services provided by such agent or broker*  
 24 *associated with plan selection and enrollment. Such disclo-*  
 25 *sure shall be—*

1           “(1) made prior to the individual finalizing  
2           plan selection; and

3           “(2) included on any documentation confirming  
4           the individual’s enrollment.

5           “(c) *REPORTING*.—A health insurance issuer described  
6 in subsection (a) shall annually report to the Secretary,  
7 prior to the beginning of open enrollment, any direct or  
8 indirect compensation provided to an agent or broker asso-  
9 ciated with enrolling individuals in such coverage.

10          “(d) *RULEMAKING*.—Not later than 1 year after the  
11 date of enactment of the Lower Health Care Costs Act, the  
12 Secretary shall finalize, through notice-and-comment rule-  
13 making, the form and manner in which issuers described  
14 in subsection (a) are required to make the disclosures de-  
15 scribed in subsection (b) and the reports described in sub-  
16 section (c).”.

17          “(d) *TRANSITION RULE*.—No contract executed prior to  
18 the effective date described in subsection (e) by a group  
19 health plan subject to the requirements of section  
20 408(b)(2)(B) of the Employee Retirement Income Security  
21 Act of 1974 (as amended by subsection (a)) or by a health  
22 insurance issuer subject to the requirements of section 2746  
23 of the Public Health Service Act (as added by subsection  
24 (c)) shall be subject to the requirements of such section 408(  
25 b)(2)(B) or such section 2746, as applicable.

1       (e) *EFFECTIVE DATE.*—*The amendments made by sub-*  
 2 *sections (a) and (c) shall take effect 2 years after the date*  
 3 *of enactment of this Act.*

4 **SEC. 309. ENSURING ENROLLEE ACCESS TO COST-SHARING**  
 5 **INFORMATION.**

6       (a) *IN GENERAL.*—*Subpart II of part A of title XXVII*  
 7 *of the Public Health Service Act (42 U.S.C. 300gg–11 et*  
 8 *seq.), as amended by section 306, is further amended by*  
 9 *adding at the end the following:*

10 **“SEC. 2729F. PROVISION OF COST-SHARING INFORMATION.**

11       “(a) *PROVIDER DISCLOSURES.*—*A provider that is in-*  
 12 *network with respect to a group health plan or a health*  
 13 *insurance issuer offering group or individual health insur-*  
 14 *ance coverage shall provide to an enrollee in the plan or*  
 15 *coverage who submits a request for the information de-*  
 16 *scribed in paragraph (1) or (2), together with accurate and*  
 17 *complete information about the enrollee’s coverage under the*  
 18 *applicable plan or coverage—*

19               “(1) *as soon as practicable and not later than 2*  
 20 *business days after the enrollee requests such informa-*  
 21 *tion, a good faith estimate of the expected enrollee*  
 22 *cost-sharing for the provision of a particular health*  
 23 *care service (including any service that is reasonably*  
 24 *expected to be provided in conjunction with such spe-*  
 25 *cific service); and*

1           “(2) as soon as practicable and not later than 2  
2           business days after an enrollee requests such informa-  
3           tion, the contact information for any ancillary pro-  
4           viders for a scheduled health care service.

5           “(b) *INSURER DISCLOSURES*.—A group health plan or  
6 a health insurance issuer offering group or individual  
7 health insurance coverage shall provide an enrollee in the  
8 plan or coverage with a good faith estimate of the enrollee’s  
9 cost-sharing (including deductibles, copayments, and coin-  
10 surance) for which the enrollee would be responsible for pay-  
11 ing with respect to a specific health care service (including  
12 any service that is reasonably expected to be provided in  
13 conjunction with such specific service), as soon as prac-  
14 ticable and not later than 2 business days after a request  
15 for such information by an enrollee.

16           “(c) *ENFORCEMENT*.—

17           “(1) *IN GENERAL*.—Subject to paragraph (2), a  
18 health care provider that violates a requirement under  
19 subsection (a) shall be subject to a civil monetary  
20 penalty of not more than \$10,000 for each act consti-  
21 tuting such violation.

22           “(2) *PROCEDURE*.—The provisions of section  
23 1128A of the Social Security Act, other than sub-  
24 sections (a) and (b) and the first sentence of sub-  
25 section (c)(1) of such section, shall apply to civil

1       *money penalties under this subsection in the same*  
 2       *manner as such provisions apply to a penalty or pro-*  
 3       *ceeding under section 1128A of the Social Security*  
 4       *Act.”.*

5       ***(b) EFFECTIVE DATE.***—*Section 2729G of the Public*  
 6       *Health Service Act, as added by subsection (a), shall apply*  
 7       *with respect to plan years beginning on or after the date*  
 8       *that is 18 months after the date of enactment of this Act.*

9       **SEC. 310. STRENGTHENING PARITY IN MENTAL HEALTH**  
 10       **AND SUBSTANCE USE DISORDER BENEFITS.**

11       *Section 2726 of the Public Health Service Act (42*  
 12       *U.S.C. 300gg–26) is amended—*

13               *(1) in subsection (a), by adding at the end the*  
 14       *following:*

15               **“(8) COMPLIANCE REQUIREMENTS.—**

16                       **“(A) NONQUANTITATIVE TREATMENT LIM-**  
 17                       **TATION (NQTL) REQUIREMENTS.—***In the case of a*  
 18                       *group health plan or a health insurance issuer*  
 19                       *offering group or individual health insurance*  
 20                       *coverage that provides both medical and surgical*  
 21                       *benefits and mental health or substance use dis-*  
 22                       *order benefits and that imposes nonquantitative*  
 23                       *treatment limitations (referred to in this section*  
 24                       *as ‘NQTL’) on mental health or substance use*  
 25                       *disorder benefits, the plan or issuer offering*

1           *health insurance coverage in connection with*  
2           *such a plan, shall perform comparative analyses*  
3           *of the design and application of NQTLs in ac-*  
4           *cordance with the following process, and make*  
5           *available to the applicable State authority (or,*  
6           *as applicable, to the Secretary of Labor with re-*  
7           *spect to group health plans or the Secretary of*  
8           *Health and Human Services with respect to*  
9           *health insurance coverage), upon request within*  
10          *60 days beginning 6 months after the date of en-*  
11          *actment of the Lower Health Care Costs Act, the*  
12          *following information:*

13                   “(i) *The specific plan or coverage*  
14                   *terms regarding the NQTL, that applies to*  
15                   *such plan or coverage, and a description of*  
16                   *all mental health or substance use disorder*  
17                   *and medical or surgical benefits to which it*  
18                   *applies in each respective benefits classifica-*  
19                   *tion.*

20                   “(ii) *The factors used to determine that*  
21                   *the NQTL will apply to mental health or*  
22                   *substance use disorder benefits and medical*  
23                   *or surgical benefits.*

24                   “(iii) *The evidentiary standards used*  
25                   *for the factors identified in clause (ii), when*

1 applicable, provided that every factor shall  
2 be defined and any other source or evidence  
3 relied upon to design and apply the NQTL  
4 to mental health or substance use disorder  
5 benefits and medical or surgical benefits.

6 “(iv) The comparative analyses dem-  
7 onstrating that the processes, strategies, evi-  
8 dentiary standards, and other factors used  
9 to design the NQTL, as written, and the op-  
10 eration processes and strategies as written  
11 and in operation that are used to apply the  
12 NQTL for mental health or substance use  
13 disorder benefits are comparable to, and are  
14 applied no more stringently than, the proc-  
15 esses, strategies, evidentiary standards, and  
16 other factors used to design the NQTL, as  
17 written, and the operation processes and  
18 strategies as written and in operation that  
19 are used to apply the NQTL to medical or  
20 surgical benefits.

21 “(v) A disclosure of the specific find-  
22 ings and conclusions reached by the plan or  
23 coverage that the results of the analyses de-  
24 scribed in this subparagraph indicate that

1           *the plan or coverage is in compliance with*  
2           *this section.*

3           “(B) *SECRETARY REQUEST PROCESS.*—

4                 “(i) *SUBMISSION UPON REQUEST.*—

5           *With respect to group health plans or health*  
6           *insurance coverage for which the Secretary*  
7           *is enforcing this section in accordance with*  
8           *section 2723, the Secretary, in consultation*  
9           *with the Secretary of Labor and the Sec-*  
10          *retary of Treasury, shall request that a*  
11          *group health plan or a health insurance*  
12          *issuer offering group or individual health*  
13          *insurance coverage submit the comparative*  
14          *analyses described in subparagraph (A) for*  
15          *plans that involve potential violations of*  
16          *this section concerning NQTLs and any*  
17          *other instances in which the Secretary de-*  
18          *termines appropriate. The Secretary shall*  
19          *request not fewer than 20 such analyses per*  
20          *year.*

21                 “(ii) *ADDITIONAL INFORMATION.*—*In*  
22          *instances in which the Secretary has con-*  
23          *cluded that the plan or coverage has not*  
24          *submitted sufficient information for the Sec-*  
25          *retary to review the comparative analyses*

1           *described in subparagraph (A), as requested*  
2           *under clause (i), the Secretary shall specify*  
3           *to the plan or coverage the information the*  
4           *plan or coverage must submit to be respon-*  
5           *sive to the request under clause (i) for the*  
6           *Secretary to review the comparative anal-*  
7           *yses described in subparagraph(A) for com-*  
8           *pliance with this section. Nothing in this*  
9           *paragraph shall require the Secretary to*  
10          *conclude that a plan is in compliance with*  
11          *this section solely based upon the inspection*  
12          *of the comparative analyses described in*  
13          *subparagraph (A), as requested under clause*  
14          *(i).*

15                 “(iii) *REQUIRED ACTION.—In in-*  
16                 *stances in which the Secretary has reviewed*  
17                 *the comparative analyses described in sub-*  
18                 *paragraph (A), as requested under clause*  
19                 *(i), and determined that the plan or cov-*  
20                 *erage is not in compliance with this section,*  
21                 *the plan or coverage shall specify to the Sec-*  
22                 *retary the actions the plan or coverage will*  
23                 *take to be in compliance with this section.*  
24                 *Documents or communications produced in*  
25                 *connection with the Secretary’s rec-*

1            *ommendations to the plan or coverage shall*  
2            *not be subject to disclosure pursuant to sec-*  
3            *tion 552 of title 5, United States Code.*

4            *“(iv) REPORT.—Not later than 1 year*  
5            *after the date of enactment of this para-*  
6            *graph, and annually thereafter, the Sec-*  
7            *retary shall submit to the Committee on*  
8            *Education and Labor of the House of Rep-*  
9            *resentatives and the Committee on Health,*  
10           *Education, Labor, and Pensions of the Sen-*  
11           *ate a report that contains—*

12                    *“(I) a summary of the compara-*  
13                    *tive analyses requested under clause*  
14                    *(i), except that the identity of each*  
15                    *plan or coverage and any contracted*  
16                    *entity of a plan or coverage shall be re-*  
17                    *dacted;*

18                    *“(II) the Secretary’s conclusions*  
19                    *as to whether each plan or coverage*  
20                    *submitted sufficient information for the*  
21                    *Secretary to review the comparative*  
22                    *analyses requested under clause (i) for*  
23                    *compliance with this section;*

24                    *“(III) for each plan or coverage*  
25                    *that did submit sufficient information*

1 *for the Secretary to review the com-*  
2 *parative analyses requested under*  
3 *clause (i), the Secretary's conclusions*  
4 *as to whether and why the plan or cov-*  
5 *erage is in compliance with the disclo-*  
6 *sure requirements under this section;*

7 *“(IV) the Secretary's specifica-*  
8 *tions described in clause (ii) for each*  
9 *plan or coverage that the Secretary de-*  
10 *termined did not submit sufficient in-*  
11 *formation for the Secretary to review*  
12 *the comparative analyses requested*  
13 *under clause (i) for compliance with*  
14 *this section; and*

15 *“(V) the Secretary's specifications*  
16 *described in clause (iii) of the actions*  
17 *each plan or coverage that the Sec-*  
18 *retary determined is not in compliance*  
19 *with this section must take to be in*  
20 *compliance with this section, including*  
21 *the reason why the Secretary deter-*  
22 *mined the plan or coverage is not in*  
23 *compliance.*

24 *“(C) COMPLIANCE PROGRAM GUIDANCE*

25 *DOCUMENT UPDATE PROCESS.—*

1           “(i) *IN GENERAL.*—*The Secretary shall*  
2           *include select instances of noncompliance*  
3           *that the Secretary discovers upon reviewing*  
4           *the comparative analyses requested under*  
5           *subparagraph (B)(i) in the compliance pro-*  
6           *gram guidance document described in sec-*  
7           *tion 2726(a)(6), as it is updated every 2*  
8           *years, except that all instances shall be*  
9           *deidentified and such instances shall not*  
10           *disclose any protected health information or*  
11           *individually identifiable information.*

12           “(ii) *GUIDANCE AND REGULATIONS.*—  
13           *Not later than 18 months after the date of*  
14           *enactment of this paragraph, the Secretary*  
15           *shall finalize any draft or interim guidance*  
16           *and regulations relating to mental health*  
17           *parity under this section.*

18           “(iii) *STATE.*—*The Secretary shall*  
19           *share information on findings of compliance*  
20           *and noncompliance discovered upon review-*  
21           *ing the comparative analyses requested*  
22           *under subparagraph (B)(i) shall be shared*  
23           *with the State where the group health plan*  
24           *is located or the State where the health in-*  
25           *surance issuer is licensed to do business for*

1                   *coverage offered by a health insurance issuer*  
2                   *in the group market, in accordance with*  
3                   *section 2726(a)(6)(B)(iii)(II).”.*

4 **SEC. 311. TECHNICAL AMENDMENTS.**

5           (a) *ERISA.*—*Section 715 of the Employee Retirement*  
6 *Income Security Act of 1974 (29 U.S.C. 1185d) is amend-*  
7 *ed—*

8                   (1) *in subsection (a)(1), by striking “(as amend-*  
9 *ed by the Patient Protection and Affordable Care*  
10 *Act)” and inserting “(including any subsequent*  
11 *amendments to such part)”;* and

12                   (2) *in subsection (b)—*

13                           (A) *by striking “(as amended by the Patient*  
14 *Protection and Affordable Care Act)” and insert-*  
15 *ing “(including any subsequent amendments to*  
16 *such part)”;* and

17                           (B) *by striking “(as so amended)”.*

18           (b) *IRC.*—*Section 9815 of the Internal Revenue Code*  
19 *of 1986 is amended—*

20                   (1) *in subsection (a)(1), by striking “(as amend-*  
21 *ed by the Patient Protection and Affordable Care*  
22 *Act)” and inserting “(including any subsequent*  
23 *amendments to such part)”;* and

24                   (2) *in subsection (b)—*

1           (A) by striking “(as amended by the Patient  
2           Protection and Affordable Care Act)” and insert-  
3           ing “(including any subsequent amendments to  
4           such part)”; and

5           (B) by striking “(as so amended)”.

6           (c) *APPLICABILITY.*—The amendments made by sub-  
7           sections (a) and (b) shall take effect as though included in  
8           the enactment of the Patient Protection and Affordable Care  
9           Act (Public Law 111–148).

10 **SEC. 312. THIRD-PARTY ADMINISTRATORS.**

11           Any obligation on a third-party administrator under  
12           this Act (including the amendments made by this Act) shall  
13           not affect any other direct or indirect requirement under  
14           any other provision Federal law that applies to third-party  
15           administrators offering services to group health plans.

16 **SEC. 313. GROUP HEALTH PLAN REPORTING REQUIRE-**  
17 **MENTS.**

18           Part C of title XXVII of the Public Health Service Act  
19           (42 U.S.C. 300gg–91 et seq.), as amended by section 303,  
20           is further amended by adding at the end the following:

21 **“SEC. 2797. GROUP HEALTH PLAN REPORTING.**

22           “(a) *IN GENERAL.*—A group health plan or health in-  
23           surance issuer offering group or individual health insur-  
24           ance coverage shall submit to the Secretary, not later than

1 *March 1 of each year, the following information with re-*  
2 *spect to the health plan in the previous plan year:*

3           “(1) *The beginning and end dates of the plan*  
4 *year.*

5           “(2) *The number of enrollees.*

6           “(3) *Each State in which the plan is offered.*

7           “(4) *The 50 brand prescription drugs most fre-*  
8 *quently dispensed by pharmacies for claims paid by*  
9 *the issuer, and the total number of paid claims for*  
10 *each such drug.*

11           “(5) *The 50 most costly prescription drugs with*  
12 *respect to the plan by total annual spending, and the*  
13 *annual amount spent by the plan for each such drug.*

14           “(6) *The 50 prescription drugs with the greatest*  
15 *increase in plan expenditures over the plan year pre-*  
16 *ceding the plan year that is the subject of the report,*  
17 *and, for each such drug, the change in amounts ex-*  
18 *pended by the plan in each such plan year.*

19           “(7) *Total spending on health care services by*  
20 *such group health plan, broken down by—*

21                   “(A) *the type of costs, including—*

22                           “(i) *hospital costs;*

23                           “(ii) *health care provider and clinical*  
24 *service costs;*

25                           “(iii) *costs for prescription drugs; and*

1                   “(iv) other medical costs; and

2                   “(B) spending on prescription drugs by—

3                   “(i) the health plan; and

4                   “(ii) the enrollees.

5                   “(8) The average monthly premium—

6                   “(A) paid by employers on behalf of enroll-  
7                   ees; and

8                   “(B) paid by enrollees.

9                   “(9) Any impact on premiums by rebates, fees,  
10                  and any other remuneration paid by drug manufac-  
11                  turers to the plan or its administrators or service pro-  
12                  viders, with respect to prescription drugs prescribed  
13                  to enrollees in the plan, including—

14                  “(A) the amounts so paid for each thera-  
15                  peutic class of drugs; and

16                  “(B) the amounts so paid for each of the 25  
17                  drugs that yielded the highest amount of rebates  
18                  and other remuneration under the plan from  
19                  drug manufacturers during the plan year.

20                  “(10) Any reduction in premiums and out-of-  
21                  pocket costs associated with rebates, fees, or other re-  
22                  muneration described in paragraph (9).

23                  “(b) REPORT.—Not later than 18 months after the date  
24                  on which the first report is required under subsection (a)  
25                  and biannually thereafter, the Secretary, acting through the

1 *Assistant Secretary of Planning and Evaluation and in co-*  
2 *ordination with the Inspector General of the Department*  
3 *of Health and Human Services, shall make available on the*  
4 *internet website of the Department of Health and Human*  
5 *Services a report on prescription drug reimbursements*  
6 *under group health plans, prescription drug pricing trends,*  
7 *and the role of prescription drug costs in contributing to*  
8 *premium increases or decreases under such plans, aggre-*  
9 *gated in such a way as no drug or plan specific information*  
10 *will be made public.*

11       “(c) *PRIVACY PROTECTIONS.*—*No confidential or trade*  
12 *secret information submitted to the Secretary under sub-*  
13 *section (a) shall be included in the report under subsection*  
14 *(b).”.*

15 **SEC. 314. STUDY BY COMPTROLLER GENERAL OF UNITED**  
16 **STATES.**

17       (a) *IN GENERAL.*—*The Comptroller General of the*  
18 *United States (referred to in this section as the “Comp-*  
19 *troller General”)* shall, in consultation with appropriate  
20 *stakeholders, conduct a study on the role of pharmacy ben-*  
21 *efit managers.*

22       (b) *PERMISSIBLE EXAMINATION.*—*In conducting the*  
23 *study required under subsection (a), the Comptroller Gen-*  
24 *eral may examine various qualitative and quantitative as-*

1 *pects of the role of pharmacy benefit managers, such as the*  
2 *following:*

3           (1) *The role that pharmacy benefit managers*  
4 *play in the pharmaceutical supply chain.*

5           (2) *The state of competition among pharmacy*  
6 *benefit managers, including the market share for the*  
7 *Nation's largest pharmacy benefit managers.*

8           (3) *The use of rebates and fees by pharmacy ben-*  
9 *efit managers, including—*

10                   (A) *the extent to which rebates are passed*  
11 *on to health plans and whether such rebates are*  
12 *passed on to individuals enrolled in such plans;*

13                   (B) *the extent to which rebates are kept by*  
14 *such pharmacy benefit managers; and*

15                   (C) *the role of any fees charged by such*  
16 *pharmacy benefit managers.*

17           (4) *Whether pharmacy benefit managers struc-*  
18 *ture their formularies in favor of high-rebate prescrip-*  
19 *tion drugs over lower-cost, lower-rebate alternatives.*

20           (5) *The average prior authorization approval*  
21 *time for pharmacy benefit managers.*

22           (6) *Factors affecting the use of step therapy by*  
23 *pharmacy benefit managers.*

24           (c) *REPORT.—Not later than 3 years after the date of*  
25 *enactment of this Act, the Comptroller General shall submit*

1 *to the Secretary of Health and Human Services, the Com-*  
 2 *mittee on Health, Education, Labor, and Pensions of the*  
 3 *Senate, and the Committee on Energy and Commerce of*  
 4 *the House of Representatives a report containing the results*  
 5 *of the study conducted under subsection (a), including pol-*  
 6 *icy recommendations.*

7 **TITLE IV—IMPROVING PUBLIC**  
 8 **HEALTH**

9 **SEC. 401. IMPROVING AWARENESS OF DISEASE PREVEN-**  
 10 **TION.**

11 *The Public Health Service Act is amended by striking*  
 12 *section 313 of such Act (42 U.S.C. 245) and inserting the*  
 13 *following:*

14 **“SEC. 313. PUBLIC AWARENESS CAMPAIGN ON THE IMPOR-**  
 15 **TANCE OF VACCINATIONS.**

16 *“(a) IN GENERAL.—The Secretary, acting through the*  
 17 *Director of the Centers for Disease Control and Prevention*  
 18 *and in coordination with other offices and agencies, as ap-*  
 19 *propriate, shall award competitive grants to one or more*  
 20 *public or private entities to carry out a national, evidence-*  
 21 *based campaign to increase awareness and knowledge of the*  
 22 *safety and effectiveness of vaccines for the prevention and*  
 23 *control of diseases, combat misinformation about vaccines,*  
 24 *and disseminate scientific and evidence-based vaccine-re-*  
 25 *lated information, with the goal of increasing rates of vac-*

1 *ination across all ages, as applicable, particularly in com-*  
2 *munities with low rates of vaccination, to reduce and elimi-*  
3 *nate vaccine-preventable diseases.*

4       “(b) *CONSULTATION.*—*In carrying out the campaign*  
5 *under this section, the Secretary shall consult with appro-*  
6 *priate public health and medical experts, including the Na-*  
7 *tional Academy of Medicine and medical and public health*  
8 *associations and nonprofit organizations, in the develop-*  
9 *ment, implementation, and evaluation of the evidence-based*  
10 *public awareness campaign.*

11       “(c) *REQUIREMENTS.*—*The campaign under this sec-*  
12 *tion shall—*

13               “(1) *be a national, evidence-based initiative;*

14               “(2) *include the development of resources for*  
15 *communities with low rates of vaccination, including*  
16 *culturally- and linguistically-appropriate resources,*  
17 *as applicable;*

18               “(3) *include the dissemination of vaccine infor-*  
19 *mation and communication resources to public health*  
20 *departments, health care providers, and health care*  
21 *facilities, including such providers and facilities that*  
22 *provide prenatal and pediatric care;*

23               “(4) *be complementary to, and coordinated with,*  
24 *any other Federal, State, local, or Tribal efforts, as*  
25 *appropriate; and*

1           “(5) assess the effectiveness of communication  
2 strategies to increase rates of vaccination.

3           “(d) *ADDITIONAL ACTIVITIES.*—The campaign under  
4 this section may—

5           “(1) include the use of television, radio, the  
6 internet, and other media and telecommunications  
7 technologies;

8           “(2) be focused to address specific needs of com-  
9 munities and populations with low rates of vaccina-  
10 tion; and

11           “(3) include the dissemination of scientific and  
12 evidence-based vaccine-related information, such as—

13           “(A) advancements in evidence-based re-  
14 search related to diseases that may be prevented  
15 by vaccines and vaccine development;

16           “(B) information on vaccinations for indi-  
17 viduals and communities, including individuals  
18 for whom vaccines are not recommended by the  
19 Advisory Committee for Immunization Practices,  
20 and the effects of low vaccination rates within a  
21 community on such individuals;

22           “(C) information on diseases that may be  
23 prevented by vaccines; and

24           “(D) information on vaccine safety and the  
25 systems in place to monitor vaccine safety.

1 “(e) *EVALUATION.*—*The Secretary shall—*

2 “(1) *establish benchmarks and metrics to quan-*  
3 *titatively measure and evaluate the awareness cam-*  
4 *campaign under this section;*

5 “(2) *conduct qualitative assessments regarding*  
6 *the awareness campaign under this section; and*

7 “(3) *prepare and submit to the Committee on*  
8 *Health, Education, Labor, and Pensions of the Senate*  
9 *and Committee on Energy and Commerce of the*  
10 *House of Representatives an evaluation of the aware-*  
11 *ness campaign under this section.*

12 “(f) *SUPPLEMENT NOT SUPPLANT.*—*Funds appro-*  
13 *priated under this section shall be used to supplement and*  
14 *not supplant other Federal, State, and local public funds*  
15 *provided for activities described in this section.*

16 “(g) *AUTHORIZATION OF APPROPRIATIONS.*—*There*  
17 *are authorized to be appropriated to carry out this section*  
18 *and section 317(k) such sums as may be necessary for fiscal*  
19 *years 2020 through 2024.”*

20 **SEC. 402. GRANTS TO ADDRESS VACCINE-PREVENTABLE**  
21 **DISEASES.**

22 (a) *IN GENERAL.*—*Section 317(k)(1) of the Public*  
23 *Health Service Act (42 U.S.C. 247b(k)(1)) is amended—*

24 (1) *in subparagraph (C), by striking “; and”*  
25 *and inserting a semicolon;*

1           (2) *in subparagraph (D), by striking the period*  
2           *and inserting a semicolon; and*

3           (3) *by adding at the end the following:*

4           “(E) *planning, implementation, and evaluation*  
5           *of activities to address vaccine-preventable diseases,*  
6           *including activities to—*

7                 “(i) *identify communities at high risk of*  
8                 *outbreaks related to vaccine-preventable diseases,*  
9                 *including through improved data collection and*  
10                *analysis;*

11               “(ii) *pilot innovative approaches to improve*  
12                *vaccination rates in communities and among*  
13                *populations with low rates of vaccination;*

14               “(iii) *reduce barriers to accessing vaccines*  
15                *and evidence-based information about the health*  
16                *effects of vaccines;*

17               “(iv) *partner with community organiza-*  
18                *tions and health care providers to develop and*  
19                *deliver evidence-based interventions, including*  
20                *culturally- and linguistically-appropriate inter-*  
21                *ventions, to increase vaccination rates;*

22               “(v) *improve delivery of evidence-based vac-*  
23                *cine-related information to parents and others;*  
24                *and*

1           “(vi) improve the ability of State, local,  
2           tribal, and territorial public health departments  
3           to engage communities at high risk for outbreaks  
4           related to vaccine-preventable diseases; and

5           “(F) research related to strategies for improving  
6           awareness of scientific and evidence-based vaccine-re-  
7           lated information, including for communities with  
8           low rates of vaccination, in order to understand bar-  
9           riers to vaccination, improve vaccination rates, and  
10          assess the public health outcomes of such strategies.”.

11          (b) *SUPPLEMENTAL GRANT FUNDS.*—Section  
12 *330(d)(1) of the Public Health Service Act (42 U.S.C. 254b)*  
13 *is amended—*

14           (1) *in subparagraph (F), by striking “and” at*  
15 *the end;*

16           (2) *in subparagraph (G), by striking the period*  
17 *and and inserting “; and”; and*

18           (3) *by adding at the end the following:*

19                   “(H) improving access to recommended im-  
20                   munizations.”.

21 **SEC. 403. GUIDE ON EVIDENCE-BASED STRATEGIES FOR**  
22 **PUBLIC HEALTH DEPARTMENT OBESITY PRE-**  
23 **VENTION PROGRAMS.**

24          (a) *DEVELOPMENT AND DISSEMINATION OF AN EVI-*  
25 *DENCE-BASED STRATEGIES GUIDE.*—*The Secretary of*

1 *Health and Human Services (referred to in this section as*  
2 *the “Secretary”), acting through the Director of the Centers*  
3 *for Disease Control and Prevention, not later than 2 years*  
4 *after the date of enactment of this Act, shall—*

5           *(1) develop a guide on evidence-based strategies*  
6 *for State, territorial, and local health departments to*  
7 *use to build and maintain effective obesity prevention*  
8 *and reduction programs, and, in consultation with*  
9 *Indian Tribes and Tribal organizations, a guide on*  
10 *such evidence-based strategies with respect to Indian*  
11 *Tribes and Tribal organizations for such Indian*  
12 *Tribes and Tribal organizations to use for such pur-*  
13 *pose, both of which guides shall—*

14           *(A) describe an integrated program struc-*  
15 *ture for implementing interventions proven to be*  
16 *effective in preventing and reducing the inci-*  
17 *dence of obesity; and*

18           *(B) recommend—*

19           *(i) optimal resources, including staff-*  
20 *ing and infrastructure, for promoting nutri-*  
21 *tion and obesity prevention and reduction;*  
22 *and*

23           *(ii) strategies for effective obesity pre-*  
24 *vention programs for State, territorial, and*  
25 *local health departments, Indian Tribes,*

1                    *and Tribal organizations, including strate-*  
2                    *gies related to—*

3                    *(I) the application of evidence-*  
4                    *based and evidence-informed practices*  
5                    *to prevent and reduce obesity rates;*

6                    *(II) the development, implementa-*  
7                    *tion, and evaluation of obesity preven-*  
8                    *tion and reduction strategies for spe-*  
9                    *cific communities and populations;*

10                   *(III) demonstrated knowledge of*  
11                   *obesity prevention practices that reduce*  
12                   *associated preventable diseases, health*  
13                   *conditions, death, and health care*  
14                   *costs;*

15                   *(IV) best practices for the coordi-*  
16                   *nation of efforts to prevent and reduce*  
17                   *obesity and related chronic diseases;*

18                   *(V) addressing the underlying risk*  
19                   *factors and social determinants of*  
20                   *health that impact obesity rates; and*

21                   *(VI) interdisciplinary coordina-*  
22                   *tion between relevant public health of-*  
23                   *ficials specializing in fields such as*  
24                   *nutrition, physical activity, epidemi-*  
25                   *ology, communications, and policy im-*

1                    *plementation, and collaboration be-*  
 2                    *tween public health officials, commu-*  
 3                    *nity-based organizations, and others,*  
 4                    *as appropriate; and*

5                    *(2) disseminate the guides and current research,*  
 6                    *evidence-based practices, tools, and educational mate-*  
 7                    *rials related to obesity prevention, consistent with the*  
 8                    *guide, to State, territorial, and local health depart-*  
 9                    *ments, Indian Tribes, and Tribal organizations.*

10                  *(b) TECHNICAL ASSISTANCE.—The Secretary, acting*  
 11                  *through the Director of the Centers for Disease Control and*  
 12                  *Prevention, shall provide technical assistance to State, ter-*  
 13                  *ritorial, and local health departments, Indian Tribes, and*  
 14                  *Tribal organizations to support such health departments in*  
 15                  *implementing the guide developed under subsection (a)(1).*

16                  *(c) INDIAN TRIBES; TRIBAL ORGANIZATIONS.—The*  
 17                  *terms “Indian Tribe” and “Tribal organization” have the*  
 18                  *meanings given the terms “Indian tribe” and “tribal orga-*  
 19                  *nization”, respectively, in section 4 of the Indian Self-De-*  
 20                  *termination and Education Assistance Act (25 U.S.C.*  
 21                  *5304).*

22                  **SEC. 404. EXPANDING CAPACITY FOR HEALTH OUTCOMES.**

23                  *Title III of the Public Health Service Act is amended*  
 24                  *by inserting after section 330M (42 U.S.C. 254c–19) the*  
 25                  *following:*

1 **“SEC. 330N. EXPANDING CAPACITY FOR HEALTH OUT-**  
2 **COMES.**

3 “(a) *DEFINITIONS.—In this section:*

4 “(1) *ELIGIBLE ENTITY.—The term ‘eligible enti-*  
5 *ty’ means an entity providing health care services in*  
6 *rural areas, frontier areas, health professional short-*  
7 *age areas, or medically underserved areas, or to medi-*  
8 *cally underserved populations or Native Americans,*  
9 *including Indian tribes or tribal organizations.*

10 “(2) *HEALTH PROFESSIONAL SHORTAGE*  
11 *AREA.—The term ‘health professional shortage area’*  
12 *means a health professional shortage area designated*  
13 *under section 332.*

14 “(3) *INDIAN TRIBE.—The terms ‘Indian tribe’*  
15 *and ‘tribal organization’ have the meanings given*  
16 *such terms in section 4 of the Indian Self-Determina-*  
17 *tion and Education Assistance Act.*

18 “(4) *MEDICALLY UNDERSERVED POPULATION.—*  
19 *The term ‘medically underserved population’ has the*  
20 *meaning given the term in section 330(b)(3).*

21 “(5) *NATIVE AMERICANS.—The term ‘Native*  
22 *Americans’ has the meaning given such term in sec-*  
23 *tion 736 and includes Indian tribes and tribal orga-*  
24 *nizations.*

25 “(6) *TECHNOLOGY-ENABLED COLLABORATIVE*  
26 *LEARNING AND CAPACITY BUILDING MODEL.—The*

1        *term ‘technology-enabled collaborative learning and*  
2        *capacity building model’ means a distance health*  
3        *education model that connects health care profes-*  
4        *sionals, and particularly specialists, with multiple*  
5        *other health care professionals through simultaneous*  
6        *interactive videoconferencing for the purpose of facili-*  
7        *tating case-based learning, disseminating best prac-*  
8        *tices, and evaluating outcomes.*

9        *“(b) PROGRAM ESTABLISHED.—The Secretary shall,*  
10       *as appropriate, award grants to evaluate, develop, and, as*  
11       *appropriate, expand the use of technology-enabled collabo-*  
12       *rative learning and capacity building models, to increase*  
13       *access to health care services, such as those to address chron-*  
14       *ic diseases and conditions, mental health, substance use dis-*  
15       *orders, prenatal and maternal health, pediatric care, pain*  
16       *management, palliative care, and other specialty care in*  
17       *rural areas, frontier areas, health professional shortage*  
18       *areas, or medically underserved areas and for medically un-*  
19       *derserved populations or Native Americans, including In-*  
20       *dian Tribes and Tribal organizations.*

21       *“(c) USE OF FUNDS.—*

22                *“(1) IN GENERAL.—Grants awarded under sub-*  
23        *section (b) shall be used for—*

24                        *“(A) the development and acquisition of in-*  
25        *structional programming, and the training of*

1           *health care providers and other professionals that*  
2           *provide or assist in the provision of services*  
3           *through such models;*

4           “(B) *information collection and evaluation*  
5           *activities to study the impact of such models on*  
6           *patient outcomes and health care providers, and*  
7           *to identify best practices for the expansion and*  
8           *use of such models; or*

9           “(C) *other activities consistent with achiev-*  
10          *ing the objectives of the grants awarded under*  
11          *this section, as determined by the Secretary.*

12          “(2) *OTHER USES.—In addition to any of the*  
13          *uses under paragraph (1), grants awarded under sub-*  
14          *section (b) may be used for—*

15                 “(A) *equipment to support the use and ex-*  
16                 *pansion of technology-enabled collaborative*  
17                 *learning and capacity building models, includ-*  
18                 *ing for hardware and software that enables dis-*  
19                 *tance learning, health care provider support, and*  
20                 *the secure exchange of electronic health informa-*  
21                 *tion; or*

22                 “(B) *support for health care providers and*  
23                 *other professionals that provide or assist in the*  
24                 *provision of services through such models.*

1       “(d) *LENGTH OF GRANTS.*—Grants awarded under  
2 subsection (b) shall be for a period of up to 5 years.

3       “(e) *APPLICATION.*—An eligible entity that seeks to re-  
4 ceive a grant under subsection (b) shall submit to the Sec-  
5 retary an application, at such time, in such manner, and  
6 containing such information as the Secretary may require.  
7 Such application criteria shall include an assessment of the  
8 effect of technology-enabled collaborative learning and ca-  
9 pacity building models on patient outcomes and health care  
10 providers.

11       “(f) *ACCESS TO BROADBAND.*—In administering  
12 grants under this section, the Secretary may coordinate  
13 with other agencies to ensure that funding opportunities are  
14 available to support access to reliable, high-speed internet  
15 for grantees.

16       “(g) *TECHNICAL ASSISTANCE.*—The Secretary shall  
17 provide (either directly through the Department of Health  
18 and Human Services or by contract) technical assistance  
19 to eligible entities, including recipients of grants under sub-  
20 section (b), on the development, use, and evaluation of tech-  
21 nology-enabled collaborative learning and capacity building  
22 models in order to expand access to health care services pro-  
23 vided by such entities, including for medically underserved  
24 areas and to medically underserved populations or Native

1 *Americans, including Indian tribes and Tribal organiza-*  
2 *tions.*

3       “(h) *RESEARCH AND EVALUATION.*—*The Secretary, in*  
4 *consultation with stakeholders with appropriate expertise*  
5 *in such models, shall develop a strategic plan to research*  
6 *and evaluate the evidence for such models. The Secretary*  
7 *shall use such plan to inform the activities carried out*  
8 *under this section.*

9       “(i) *REPORT BY SECRETARY.*—*Not later than 4 years*  
10 *after the date of enactment of this section, the Secretary*  
11 *shall prepare and submit to the Committee on Health, Edu-*  
12 *cation, Labor, and Pensions of the Senate and the Com-*  
13 *mittee on Energy and Commerce of the House of Represent-*  
14 *atives, and post on the Internet website of the Department*  
15 *of Health and Human Services, a report including, at min-*  
16 *imum—*

17               “(1) *a description of any new and continuing*  
18 *grants awarded to entities under subsection (b) and*  
19 *the specific purpose and amounts of such grants;*

20               “(2) *an overview of—*

21                       “(A) *the evaluations conducted under sub-*  
22 *sections (b) or (f); and*

23                       “(B) *technical assistance provided under*  
24 *subsection (g); and*



1           “(A) assessing current data infrastructure  
2 capabilities and gaps to improve and increase  
3 consistency in data collection, storage, analysis,  
4 and, as appropriate, to improve dissemination of  
5 public health-related information;

6           “(B) improving secure public health data  
7 collection, transmission, exchange, maintenance,  
8 and analysis;

9           “(C) simplifying and supporting reporting  
10 by health care providers, as applicable, pursuant  
11 to State law, including through the use of health  
12 information technology, to State, local, Tribal,  
13 and territorial public health departments, in-  
14 cluding public health officials in multiple juris-  
15 dictions within such State, as appropriate;

16           “(D) enhancing interoperability of public  
17 health data systems (including systems created  
18 or accessed by public health departments) with  
19 health information technology, including health  
20 information technology certified under section  
21 3001(c)(5);

22           “(E) supporting earlier disease and health  
23 condition detection, such as through near real-  
24 time data monitoring, to support rapid public  
25 health responses; and

1           “(F) supporting activities within the appli-  
2           cable jurisdiction related to the expansion and  
3           modernization of electronic case reporting;

4           “(2) as appropriate, conduct activities related to  
5           the interoperability and improvement of applicable  
6           public health data systems used by the Centers for  
7           Disease Control and Prevention, and, in coordination  
8           with the Office of the National Coordinator for Health  
9           Information Technology, the designation of data and  
10          technology standards for health information systems  
11          of the public health infrastructure with deference  
12          given to standards published by standards develop-  
13          ment organizations and voluntary consensus-based  
14          standards bodies; and

15          “(3) develop and utilize public-private partner-  
16          ships for technical assistance and related implementa-  
17          tion support for State, local, Tribal, and territorial  
18          public health departments, and the Centers for Dis-  
19          ease Control and Prevention, on the expansion and  
20          modernization of electronic case reporting and public  
21          health data systems, as applicable.

22          “(b) REQUIREMENTS.—

23          “(1) IN GENERAL.—The Secretary may not  
24          award a grant under subsection (a)(1) unless the ap-  
25          plicant uses or agrees to use standards recognized by

1       *the National Coordinator for Health Information*  
2       *Technology pursuant to section 3001(c)(1) or adopted*  
3       *by the Secretary under section 3004.*

4               “(2) *WAIVER.—The Secretary may waive the re-*  
5       *quirement under paragraph (1) with respect to an*  
6       *applicant if the Secretary determines that the activi-*  
7       *ties under subsection (a) cannot otherwise be carried*  
8       *out within the applicable jurisdiction.*

9               “(3) *APPLICATION.—A State, local, Tribal, or*  
10       *territorial health department applying for a grant*  
11       *under this section shall submit an application to the*  
12       *Secretary at such time and in such manner as the*  
13       *Secretary may require. Such application shall include*  
14       *information describing—*

15                       “(A) *the activities that will be supported by*  
16                       *the grant; and*

17                       “(B) *how the modernization of such public*  
18                       *health data systems will support or impact the*  
19                       *public health infrastructure of the health depart-*  
20                       *ment, including a description of remaining gaps,*  
21                       *if any, and the actions needed to address such*  
22                       *gaps.*

23               “(c) *USE OF FUNDS.—An entity receiving a grant*  
24       *under this section may use amounts received under such*  
25       *grant for one or both of the following:*

1           “(1) Carrying out activities described in sub-  
2           section (a)(1) to support public health data systems  
3           (including electronic case reporting), which may in-  
4           clude support for, and training of, professionals with  
5           expertise in contributing to and using such systems  
6           (including public health data scientists).

7           “(2) Developing and disseminating information  
8           related to the use and importance of public health  
9           data.

10          “(d) *STRATEGY AND IMPLEMENTATION PLAN.*—Not  
11          later than 180 days after the date of enactment of the Lower  
12          Health Care Costs Act, the Secretary, acting through the  
13          Director of the Centers for Disease Control and Prevention,  
14          shall submit to the Committee on Health, Education, Labor,  
15          and Pensions of the Senate and the Committee on Energy  
16          and Commerce of the House of Representatives, a coordi-  
17          nated strategy and an accompanying implementation plan  
18          that identifies and demonstrates the steps the Secretary will  
19          carry out to—

20                 “(1) update and improve applicable public  
21                 health data systems used by the Centers for Disease  
22                 Control and Prevention; and

23                 “(2) carry out the activities described in this sec-  
24                 tion to support the improvement of State, local, Trib-  
25                 al, and territorial public health data systems.

1           “(e) *CONSULTATION.*—*The Secretary, acting through*  
2 *the Director of the Centers for Disease Control and Preven-*  
3 *tion, shall consult with State, local, Tribal, and territorial*  
4 *health departments, professional medical and public health*  
5 *associations, associations representing hospitals or other*  
6 *health care entities, health information technology experts,*  
7 *and other appropriate entities regarding the plan and*  
8 *grant program to modernize public health data systems*  
9 *pursuant to this section. Such activities may include the*  
10 *provision of technical assistance related to the exchange of*  
11 *information by such public health data systems used by rel-*  
12 *evant health care and public health entities at the local,*  
13 *State, Federal, Tribal, and territorial levels.*

14           “(f) *REPORT TO CONGRESS.*—*Not later than 1 year*  
15 *after the date of enactment of this section, the Secretary*  
16 *shall submit a report to the Committee on Health, Edu-*  
17 *cation, Labor, and Pensions of the Senate and the Com-*  
18 *mittee on Energy and Commerce of the House of Represent-*  
19 *atives that includes—*

20                   “(1) *a description of any barriers to—*

21                           “(A) *public health authorities implementing*  
22                           *interoperable public health data systems and*  
23                           *electronic case reporting;*

24                           “(B) *the exchange of information pursuant*  
25                           *to electronic case reporting; or*

1           “(C) reporting by health care providers  
2           using such public health data systems, as appro-  
3           priate, and pursuant to State law;

4           “(2) an assessment of the potential public health  
5           impact of implementing electronic case reporting and  
6           interoperable public health data systems; and

7           “(3) a description of the activities carried out  
8           pursuant to this section.

9           “(g) **ELECTRONIC CASE REPORTING.**—In this section,  
10          the term ‘electronic case reporting’ means the automated  
11          identification, generation, and bilateral exchange of reports  
12          of health events among electronic health record or health  
13          information technology systems and public health authori-  
14          ties.

15          “(h) **AUTHORIZATION OF APPROPRIATIONS.**—For the  
16          purpose of carrying out this section, there are authorized  
17          to be appropriated such sums as may be necessary for fiscal  
18          years 2020 through 2024.”.

19          **SEC. 406. INNOVATION FOR MATERNAL HEALTH.**

20          Title III of the Public Health Service Act is amended  
21          by inserting after section 330N of such Act, as added by  
22          section 404, the following:

23          **“SEC. 3300. INNOVATION FOR MATERNAL HEALTH.**

24          “(a) **IN GENERAL.**—The Secretary, in consultation  
25          with experts representing a variety of clinical specialties,

1 *State, tribal, or local public health officials, researchers,*  
2 *epidemiologists, statisticians, and community organiza-*  
3 *tions, shall establish or continue a program to award com-*  
4 *petitive grants to eligible entities for the purpose of—*

5           “(1) *identifying, developing, or disseminating*  
6 *best practices to improve maternal health care quality*  
7 *and outcomes, eliminate preventable maternal mor-*  
8 *tality and severe maternal morbidity, and improve*  
9 *infant health outcomes, which may include—*

10           “(A) *information on evidence-based prac-*  
11 *tices to improve the quality and safety of mater-*  
12 *nal health care in hospitals and other health care*  
13 *settings of a State or health care system, includ-*  
14 *ing by addressing topics commonly associated*  
15 *with health complications or risks related to pre-*  
16 *natal care, labor care, birthing, and postpartum*  
17 *care;*

18           “(B) *best practices for improving maternal*  
19 *health care based on data findings and reviews*  
20 *conducted 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; and*

1           “(C) *information on addressing deter-*  
2           *minants of health that impact maternal health*  
3           *outcomes for women before, during, and after*  
4           *pregnancy;*

5           “(2) *collaborating with State maternal mortality*  
6           *review committees to identify issues for the develop-*  
7           *ment and implementation of evidence-based practices*  
8           *to improve maternal health outcomes and reduce pre-*  
9           *ventable maternal mortality and severe maternal*  
10          *morbidity;*

11          “(3) *providing technical assistance and sup-*  
12          *porting the implementation of best practices identi-*  
13          *fied in paragraph (1) to entities providing health*  
14          *care services to pregnant and postpartum women; and*

15          “(4) *identifying, developing, and evaluating new*  
16          *models of care that improve maternal and infant*  
17          *health outcomes, which may include the integration of*  
18          *community-based services and clinical care.*

19          “(b) *ELIGIBLE ENTITIES.—To be eligible for a grant*  
20          *under subsection (a), an entity shall—*

21                 “(1) *submit to the Secretary an application at*  
22                 *such time, in such manner, and containing such in-*  
23                 *formation as the Secretary may require; and*

24                 “(2) *demonstrate in such application that the*  
25                 *entity is capable of carrying out data-driven mater-*

1        *nal safety and quality improvement initiatives in the*  
2        *areas of obstetrics and gynecology or maternal health.*

3        “(c) *AUTHORIZATION OF APPROPRIATIONS.—To carry*  
4        *out this section, there is authorized to be appropriated such*  
5        *sums as may be necessary for each of fiscal years 2020*  
6        *through 2024.”.*

7        **SEC. 407. TRAINING FOR HEALTH CARE PROVIDERS.**

8        *Title VII of the Public Health Service Act is amended*  
9        *by striking section 763 (42 U.S.C. 294p) and inserting the*  
10       *following:*

11       **“SEC. 763. TRAINING FOR HEALTH CARE PROVIDERS.**

12       *“(a) GRANT PROGRAM.—The Secretary shall establish*  
13       *a program to award grants to accredited schools of*  
14       *allopathic medicine, osteopathic medicine, and nursing,*  
15       *and other health professional training programs for the*  
16       *training of health care professionals to reduce and prevent*  
17       *discrimination (including training related to implicit bi-*  
18       *ases) in the provision of health care services related to pre-*  
19       *natal care, labor care, birthing, and postpartum care.*

20       *“(b) ELIGIBILITY.—To be eligible for a grant under*  
21       *subsection (a), an entity described in such subsection shall*  
22       *submit to the Secretary an application at such time, in*  
23       *such manner, and containing such information as the Sec-*  
24       *retary may require.*

1       “(c) *REPORTING REQUIREMENT.*—*Each entity award-*  
2 *ed a grant under this section shall periodically submit to*  
3 *the Secretary a report on the status of activities conducted*  
4 *using the grant, including a description of the impact of*  
5 *such training on patient outcomes, as applicable.*

6       “(d) *BEST PRACTICES.*—*The Secretary may identify*  
7 *and disseminate best practices for the training of health*  
8 *care professionals to reduce and prevent discrimination (in-*  
9 *cluding training related to implicit biases) in the provision*  
10 *of health care services related to prenatal care, labor care,*  
11 *birthing, and postpartum care.*

12       “(e) *AUTHORIZATION OF APPROPRIATIONS.*—*To carry*  
13 *out this section, there is authorized to be appropriated such*  
14 *sums as may be necessary for each of fiscal years 2020*  
15 *through 2024.”.*

16 **SEC. 408. STUDY ON TRAINING TO REDUCE AND PREVENT**  
17 **DISCRIMINATION.**

18       *Not later than 2 years after date of enactment of this*  
19 *Act, the Secretary of Health and Human Services (referred*  
20 *to in this section as the “Secretary”) shall, through a con-*  
21 *tract with an independent research organization, conduct*  
22 *a study and make recommendations for accredited schools*  
23 *of allopathic medicine, osteopathic medicine, and nursing,*  
24 *and other health professional training programs on best*  
25 *practices related to training to reduce and prevent dis-*

1 *crimination, including training related to implicit biases,*  
2 *in the provision of health care services related to prenatal*  
3 *care, labor care, birthing, and postpartum care.*

4 **SEC. 409. PERINATAL QUALITY COLLABORATIVES.**

5 *Section 317K(a)(2) of the Public Health Service Act*  
6 *(42 U.S.C. 247b–12(a)(2)) is amended by adding at the end*  
7 *the following:*

8 *“(E)(i) The Secretary, acting through the*  
9 *Director of the Centers for Disease Control and*  
10 *Prevention and in coordination with other offices*  
11 *and agencies, as appropriate, shall establish or*  
12 *continue a competitive grant program for the es-*  
13 *tablishment or support of perinatal quality*  
14 *collaboratives to improve perinatal care and*  
15 *perinatal health outcomes for pregnant and*  
16 *postpartum women and their infants. A State,*  
17 *Indian Tribe, or Tribal organization may use*  
18 *funds received through such grant to—*

19 *“(I) support the use of evidence-based*  
20 *or evidence-informed practices to improve*  
21 *outcomes for maternal and infant health;*

22 *“(II) work with clinical teams; experts;*  
23 *State, local, and, as appropriate, tribal*  
24 *public health officials; and stakeholders, in-*  
25 *cluding patients and families, to identify,*

1           develop, or disseminate best practices to im-  
2           prove perinatal care and outcomes; and

3           “(III) employ strategies that provide  
4           opportunities for health care professionals  
5           and clinical teams to collaborate across  
6           health care settings and disciplines, includ-  
7           ing primary care and mental health, as ap-  
8           propriate, to improve maternal and infant  
9           health outcomes, which may include the use  
10          of data to provide timely feedback across  
11          hospital and clinical teams to inform re-  
12          sponses, and to provide support and train-  
13          ing to hospital and clinical teams for qual-  
14          ity improvement, as appropriate.

15          “(ii) To be eligible for a grant under clause  
16          (i), an entity shall submit to the Secretary an  
17          application in such form and manner and con-  
18          taining such information as the Secretary may  
19          require.”.

20 **SEC. 410. INTEGRATED SERVICES FOR PREGNANT AND**  
21 **POSTPARTUM WOMEN.**

22          (a) *GRANTS.*—Title III of the Public Health Service  
23 Act is amended by inserting after section 330O of such Act,  
24 as added by section 406, the following:

1 **“SEC. 330P. INTEGRATED SERVICES FOR PREGNANT AND**  
 2 **POSTPARTUM WOMEN.**

3       “(a) *IN GENERAL.*—*The Secretary may award grants*  
 4 *for the purpose of establishing or operating evidence-based*  
 5 *or innovative, evidence-informed programs to deliver inte-*  
 6 *grated health care services to pregnant and postpartum*  
 7 *women to optimize the health of women and their infants,*  
 8 *including to reduce adverse maternal health outcomes, preg-*  
 9 *nancy-related deaths, and related health disparities (includ-*  
 10 *ing such disparities associated with racial and ethnic mi-*  
 11 *nority populations), and, as appropriate, by addressing*  
 12 *issues researched under subsection (b)(2) of section 317K.*

13       “(b) *INTEGRATED SERVICES FOR PREGNANT AND*  
 14 *POSTPARTUM WOMEN.*—

15               “(1) *ELIGIBILITY.*—*To be eligible to receive a*  
 16 *grant under subsection (a), a State, Indian Tribe, or*  
 17 *Tribal organization (as such terms are defined in sec-*  
 18 *tion 4 of the Indian Self-Determination and Edu-*  
 19 *cation Assistance Act) shall work with relevant stake-*  
 20 *holders that coordinate care (including coordinating*  
 21 *resources and referrals for health care and social serv-*  
 22 *ices) to develop and carry out the program, includ-*  
 23 *ing—*

24                       “(A) *State, Tribal, and local agencies re-*  
 25 *sponsible for Medicaid, public health, social serv-*

1            *ices, mental health, and substance use disorder*  
2            *treatment and services;*

3            *“(B) health care providers who serve preg-*  
4            *nant and postpartum women; and*

5            *“(C) community-based health organizations*  
6            *and health workers, including providers of home*  
7            *visiting services and individuals representing*  
8            *communities with disproportionately high rates*  
9            *of maternal mortality and severe maternal mor-*  
10           *bidity, and including those representing racial*  
11           *and ethnicity minority populations.*

12           *“(2) TERMS.—*

13           *“(A) PERIOD.—A grant awarded under*  
14           *subsection (a) shall be made for a period of 5*  
15           *years. Any supplemental award made to a*  
16           *grantee under subsection (a) may be made for a*  
17           *period of less than 5 years.*

18           *“(B) PREFERENCE.—In awarding grants*  
19           *under subsection (a), the Secretary shall—*

20           *“(i) give preference to States, Indian*  
21           *Tribes, and Tribal organizations that have*  
22           *the highest rates of maternal mortality and*  
23           *severe maternal morbidity relative to other*  
24           *such States, Indian Tribes, or Tribal orga-*  
25           *nizations, respectively; and*

1           “(i) shall consider health disparities  
2           related to maternal mortality and severe  
3           maternal morbidity, including such dispari-  
4           ties associated with racial and ethnic mi-  
5           nority populations.

6           “(C) PRIORITY.—In awarding grants under  
7           subsection (a), the Secretary shall give priority  
8           to applications from up to 15 entities described  
9           in subparagraph (B)(i).

10           “(D) EVALUATION.—The Secretary shall re-  
11           quire grantees to evaluate the outcomes of the  
12           programs supported under the grant.

13           “(c) AUTHORIZATION OF APPROPRIATIONS.—There are  
14           authorized to be appropriated to carry out this section such  
15           sums as may be necessary for each of fiscal years 2020  
16           through 2024.”.

17           (b) REPORT ON GRANT OUTCOMES AND DISSEMINA-  
18           TION OF BEST PRACTICES.—

19           (1) REPORT.—Not later than February 1, 2026,  
20           the Secretary of Health and Human Services shall  
21           submit to the Committee on Health, Education,  
22           Labor, and Pensions of the Senate and the Committee  
23           on Energy and Commerce of the House of Representa-  
24           tives a report that describes—

1           (A) *the outcomes of the activities supported*  
2           *by the grants awarded under the amendments*  
3           *made by this section on maternal and child*  
4           *health;*

5           (B) *best practices and models of care used*  
6           *by recipients of grants under such amendments;*  
7           *and*

8           (C) *obstacles identified by recipients of*  
9           *grants under such amendments, and strategies*  
10          *used by such recipients to deliver care, improve*  
11          *maternal and child health, and reduce health*  
12          *disparities.*

13          (2) *DISSEMINATION OF BEST PRACTICES.—Not*  
14          *later than August 1, 2026, the Secretary of Health*  
15          *and Human Services shall disseminate information*  
16          *on best practices and models of care used by recipi-*  
17          *ents of grants under the amendments made by this*  
18          *section (including best practices and models of care*  
19          *relating to the reduction of health disparities, includ-*  
20          *ing such disparities associated with racial and ethnic*  
21          *minority populations, in rates of maternal mortality*  
22          *and severe maternal morbidity) to relevant stake-*  
23          *holders, which may include health providers, medical*  
24          *schools, nursing schools, relevant State, tribal, and*  
25          *local agencies, and the general public.*

1 **SEC. 411. EXTENSION FOR COMMUNITY HEALTH CENTERS,**  
2 **THE NATIONAL HEALTH SERVICE CORPS, AND**  
3 **TEACHING HEALTH CENTERS THAT OPERATE**  
4 **GME PROGRAMS.**

5 (a) *COMMUNITY HEALTH CENTERS.*—Section  
6 10503(b)(1)(F) of the Patient Protection and Affordable  
7 Care Act (42 U.S.C. 254b–2(b)(1)(F)) is amended by strik-  
8 ing “fiscal year 2019” and inserting “each of fiscal years  
9 2019 through 2024”.

10 (b) *NATIONAL HEALTH SERVICE CORPS.*—Section  
11 10503(b)(2)(F) of the Patient Protection and Affordable  
12 Care Act (42 U.S.C. 254b–2(b)(2)(F)) is amended by strik-  
13 ing “and 2019” and inserting “through 2024”.

14 (c) *TEACHING HEALTH CENTERS THAT OPERATE*  
15 *GRADUATE MEDICAL EDUCATION PROGRAMS.*—Section  
16 340H(g)(1) of the Public Health Service Act (42 U.S.C.  
17 256h(g)(1)) is amended by striking “and 2019” and insert-  
18 ing “through 2024”.

19 (d) *APPLICATION OF PROVISIONS.*—Amounts appro-  
20 priated pursuant to this section for each of fiscal years 2019  
21 through 2024 shall be subject to the requirements contained  
22 in Public Law 115–245 for funds for programs authorized  
23 under sections 330 through 340 of the Public Health Service  
24 Act.

25 (e) *CONFORMING AMENDMENTS.*—Paragraph (4) of  
26 section 3014(h) of title 18, United States Code, as amended

1 *by section 50901 of Public Law 115–123, is amended by*  
2 *striking “and section 50901(e) of the Advancing Chronic*  
3 *Care, Extenders, and Social Services Act” and inserting “,*  
4 *section 50901(e) of the Advancing Chronic Care, Extenders,*  
5 *and Social Services Act, and section 411(d) of the Lower*  
6 *Health Care Costs Act”.*

7 **SEC. 412. OTHER PROGRAMS.**

8       (a) *TYPE I.*—*Section 330B(b)(2)(D) of the Public*  
9 *Health Service Act (42 U.S.C. 254c–2(b)(2)(D)) is amended*  
10 *by striking “and 2019” and inserting “through 2024”.*

11       (b) *INDIANS.*—*Subparagraph (D) of section 330C(c)(2)*  
12 *of the Public Health Service Act (42 U.S.C. 254c–*  
13 *3(c)(2)(D)) is amended by striking “and 2019” and insert-*  
14 *ing “through 2024”.*

15 **SEC. 413. NATIVE AMERICAN SUICIDE PREVENTION.**

16       *Section 520E(b) of the Public Health Service Act (42*  
17 *U.S.C. 290bb–36(b) is amended by inserting after para-*  
18 *graph (3) the following:*

19               “(4) *CONSULTATION.*—*A State applying for a*  
20 *grant or cooperative agreement under this section*  
21 *shall, in the development and implementation of a*  
22 *statewide early intervention strategy, consult or con-*  
23 *fer with entities described in paragraph (1)(C) in*  
24 *such State.”.*

1 **SEC. 414. MINIMUM AGE OF SALE OF TOBACCO PRODUCTS.**

2 (a) *IN GENERAL.*—Section 906(d) of the Federal Food,  
3 Drug, and Cosmetic Act (21 U.S.C. 387f(d)) is amended—

4 (1) in paragraph (3)(A)(ii), by striking “18  
5 years” and inserting “21 years”; and

6 (2) by adding at the end the following:

7 “(5) *MINIMUM AGE OF SALE.*—It shall be unlaw-  
8 ful for any retailer to sell a tobacco product to any  
9 person younger than 21 years of age.”

10 (b) *REGULATIONS.*—Not later than 180 days after the  
11 date of enactment of this Act, the Secretary of Health and  
12 Human Services (referred to in this section as the “Sec-  
13 retary”) shall publish in the Federal Register a final rule  
14 to update the regulations issued under chapter IX of the  
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387 et  
16 seq.) as appropriate, only to carry out the amendments  
17 made by subsection (a), including updating the relevant age  
18 verification requirements under part 1140 of title 21, Code  
19 of Federal Regulations to require age verification for indi-  
20 viduals under the age of 30. Such final rule shall—

21 (1) take full effect not later than 90 days after  
22 the date on which such final rule is published; and

23 (2) be deemed to be in compliance with all appli-  
24 cable provisions of chapter 5 of title 5, United States  
25 Code and all other provisions of law relating to rule-  
26 making procedures.

1           (c) *NOTIFICATION.*—Not later than 90 days after the  
2 date of enactment of this Act, the Secretary shall provide  
3 written notification to the Committee on Health, Edu-  
4 cation, Labor, and Pensions of the Senate and the Com-  
5 mittee on Energy and Commerce of the House of Represent-  
6 atives regarding the progress of the Department of Health  
7 and Human Services towards promulgating the final rule  
8 under subsection (b). If, 180 days after the date of enact-  
9 ment of this Act, such rule has not been promulgated in  
10 accordance with subsection (b), the Secretary shall provide  
11 a written notification and a justification for the delay in  
12 rulemaking to such committees.

13           (d) *PENALTIES FOR VIOLATIONS.*—

14           (1) *IN GENERAL.*—Section 103(q)(2) of the Fam-  
15 ily Smoking Prevention and Tobacco Control Act  
16 (Public Law 111–31) is amended—

17                   (A) in subparagraph (A), in the matter pre-  
18 ceding clause (i), by inserting “section 906(d)(5)  
19 or of” after “violations of”; and

20                   (B) in subparagraph (C), by inserting “sec-  
21 tion 906(d)(5) or of” after “a retailer of”.

22           (2) *REPEATED VIOLATIONS.*—Section 303(f)(8)  
23 of the Federal Food, Drug, and Cosmetic Act (21  
24 U.S.C. 333(f)(8)) is amended by inserting “section  
25 906(d)(5) or of” after “repeated violations of”.

1           (3)        *MISBRANDED        PRODUCTS.*—Section  
 2        903(a)(7)(B) of the *Federal Food, Drug, and Cosmetic*  
 3        Act (21 U.S.C. 387c) is amended by inserting “sec-  
 4        tion 906(d)(5) or of” after “violation of”.

5   **SEC. 415. SALE OF TOBACCO PRODUCTS TO INDIVIDUALS**  
 6                           **UNDER THE AGE OF 21.**

7        (a) *IN GENERAL.*—Section 1926 of the *Public Health*  
 8        Service Act (42 U.S.C. 300x–26) is amended—

9           (1) *in the heading*—

10                   (A) *by striking “STATE LAW REGARD-*  
 11                   *ING”;* and

12                   (B) *by striking “18” and inserting “21”;*

13           (2) *by striking subsections (a) and (d);*

14           (3) *by redesignating subsections (b) and (c) as*  
 15        *subsections (a) and (b), respectively;*

16           (4) *by amending subsection (a), as so redesign-*  
 17        *ated, to read as follows:*

18        “(a) *IN GENERAL.*—A funding agreement for a grant  
 19        under section 1921 is that the State involved will—

20                   “(1) *annually conduct random, unannounced in-*  
 21                   *spections to ensure that retailers do not sell tobacco*  
 22                   *products to individuals under the age of 21; and*

23                   “(2) *annually submit to the Secretary a report*  
 24                   *describing—*

1           “(A) the activities carried out by the State  
2 to ensure that retailers do not sell tobacco prod-  
3 ucts to individuals under the age of 21;

4           “(B) the extent of success the State has  
5 achieved in ensuring that retailers do not sell to-  
6 bacco products to individuals under the age of  
7 21; and

8           “(C) the strategies to be utilized by the  
9 State to ensure that retailers do not sell tobacco  
10 products to individuals under the age of 21 dur-  
11 ing the fiscal year for which the grant is  
12 sought.”;

13 (5) in subsection (b), as so redesignated—

14           (A) by striking paragraphs (1), (2), (3),  
15 and (4);

16           (B) by striking “Before making” and in-  
17 serting the following:

18           “(1) IN GENERAL.—Before making”;

19           (C) by striking “for the first applicable fis-  
20 cal year or any subsequent fiscal year”;

21           (D) by striking “subsections (a) and (b)”  
22 and inserting “subsection (a)”;

23           (E) by striking “equal to—” and inserting  
24 “up to 10 percent of the amount determined

1           *under section 1933 for the State for the applica-*  
2           *ble fiscal year.”; and*

3           *(F) by adding at the end the following:*

4           “(2) *LIMITATION.—*

5           “(A) *IN GENERAL.—A State shall not have*  
6           *funds withheld pursuant to paragraph (1) if*  
7           *such State for which the Secretary has made a*  
8           *determination of noncompliance under such*  
9           *paragraph—*

10           *“(i) certifies to the Secretary by May*  
11           *1 of the fiscal year for which the funds are*  
12           *appropriated, consistent with subparagraph*  
13           *(B), that the State will commit additional*  
14           *State funds, in accordance with paragraph*  
15           *(1), to ensure that retailers do not sell to-*  
16           *bacco products to individuals under 21*  
17           *years of age;*

18           *“(ii) agrees to comply with a nego-*  
19           *tiated agreement for a corrective action*  
20           *plan that is approved by the Secretary and*  
21           *carried out in accordance with guidelines*  
22           *issued by the Secretary; or*

23           *“(iii) is a territory that receives less*  
24           *than \$1,000,000 for a fiscal year under sec-*  
25           *tion 1921.*

1                   “(B) CERTIFICATION.—

2                   “*(i) IN GENERAL.—The amount of*  
3                   *funds to be committed by a State pursuant*  
4                   *to subparagraph (A)(i) shall be equal to 1*  
5                   *percent of such State’s substance abuse allo-*  
6                   *cation determined under section 1933 for*  
7                   *each percentage point by which the State*  
8                   *misses the retailer compliance rate goal es-*  
9                   *tablished by the Secretary.*

10                   “*(ii) STATE EXPENDITURES.—For a*  
11                   *fiscal year in which a State commits funds*  
12                   *as described in clause (i), such State shall*  
13                   *maintain State expenditures for tobacco*  
14                   *prevention programs and for compliance ac-*  
15                   *tivities at a level that is not less than the*  
16                   *level of such expenditures maintained by the*  
17                   *State for the preceding fiscal year, plus the*  
18                   *additional funds for tobacco compliance ac-*  
19                   *tivities required under clause (i). The State*  
20                   *shall submit a report to the Secretary on all*  
21                   *State obligations of funds for such fiscal*  
22                   *year and all State expenditures for the pre-*  
23                   *ceding fiscal year for tobacco prevention*  
24                   *and compliance activities by program activ-*  
25                   *ity by July 31 of such fiscal year.*

1                   “(iii) *DISCRETION.*—*The Secretary*  
 2                   *shall exercise discretion in enforcing the*  
 3                   *timing of the State obligation of the addi-*  
 4                   *tional funds required by the certification*  
 5                   *described in subparagraph (A)(i) as late as*  
 6                   *July 31 of such fiscal year.*

7                   “(C) *FAILURE TO CERTIFY.*—*If a State de-*  
 8                   *scribed in subparagraph (A) fails to certify to*  
 9                   *the Secretary pursuant to subparagraph (A)(i)*  
 10                   *or enter into, or comply with, a negotiated agree-*  
 11                   *ment under subparagraph (A)(ii), the Secretary*  
 12                   *may take action pursuant to paragraph (1).”;*  
 13                   *and*

14                   (6) *by adding at the end the following:*

15                   “(c) *IMPLEMENTATION OF REPORTING REQUIRE-*  
 16                   *MENTS.*—

17                   “(1) *TRANSITION PERIOD.*—*The Secretary*  
 18                   *shall—*

19                   “(A) *not withhold amounts under subsection*  
 20                   *(b) for the 3-year period immediately following*  
 21                   *the date of enactment of the Lower Health Care*  
 22                   *Costs Act; and*

23                   “(B) *use discretion in exercising its author-*  
 24                   *ity under subsection (b) during the 2-year period*  
 25                   *immediately following the 3-year period de-*

1           *scribed in subparagraph (A), to allow for a tran-*  
2           *sition period for implementation of the reporting*  
3           *requirements under subsection (a)(2).*

4           “(2) *REGULATIONS OR GUIDANCE.*—*Not later*  
5           *than 180 days after the date of enactment of the*  
6           *Lower Health Care Costs Act the Secretary shall up-*  
7           *date regulations under part 96 of title 45, Code of*  
8           *Federal Regulations or guidance on the retailer com-*  
9           *pliance rate goal under subsection (b), the use of*  
10          *funds provided under section 1921 for purposes of*  
11          *meeting the requirements of this section, and report-*  
12          *ing requirements under subsection (a)(2).*

13          “(3) *COORDINATION.*—*The Secretary shall ensure*  
14          *the Assistant Secretary for Mental Health and Sub-*  
15          *stance Use coordinates, as appropriate, with the Com-*  
16          *missioner of Food and Drugs in providing technical*  
17          *assistance under this section to States, related to en-*  
18          *sureing retailers do not sell tobacco products to indi-*  
19          *viduals under the age of 21, that is consistent with*  
20          *applicable regulations issued by the Food and Drug*  
21          *Administration.*

22          “(d) *TRANSITIONAL GRANTS.*—

23                 “(1) *IN GENERAL.*—*The Secretary shall award*  
24                 *grants under this subsection to each State that re-*

1 *ceives funding under section 1921 to ensure compli-*  
2 *ance of each such State with this section.*

3 *“(2) USE OF FUNDS.—A State receiving a grant*  
4 *under this subsection—*

5 *“(A) shall use amounts received under such*  
6 *grant for activities to plan for or ensure compli-*  
7 *ance in the State with subsection (a); and*

8 *“(B) in the case of a State for which the*  
9 *Secretary has made a determination under sub-*  
10 *section (b) that the State is prepared to meet, or*  
11 *has met, the requirements of subsection (a), may*  
12 *use such funds for tobacco cessation activities,*  
13 *strategies to prevent the use of tobacco products*  
14 *by individuals under the age of 21, or allowable*  
15 *uses under section 1921.*

16 *“(3) SUPPLEMENT NOT SUPPLANT.—Grants*  
17 *under this subsection shall be used to supplement and*  
18 *not supplant other Federal, State, and local public*  
19 *funds provided for activities under paragraph (2).*

20 *“(4) AUTHORIZATION OF APPROPRIATIONS.—To*  
21 *carry out this subsection, there are authorized to be*  
22 *appropriated \$18,580,790 for each of fiscal years*  
23 *2020 through 2024.*

24 *“(5) SUNSET.—This subsection shall have no*  
25 *force or effect after September 30, 2024.*

1       “(e) *TECHNICAL ASSISTANCE.*—*The Secretary shall*  
 2 *provide technical assistance to States related to the activi-*  
 3 *ties required under this section.*”.

4       (b) *REPORT TO CONGRESS.*—*Not later than 3 years*  
 5 *after the date of enactment of this Act, the Secretary shall*  
 6 *submit to the Committee on Health, Education, Labor, and*  
 7 *Pensions of the Senate and the Committee on Energy and*  
 8 *Commerce of the House of Representatives a report on the*  
 9 *status of implementing the requirements of section 1926 of*  
 10 *the Public Health Service Act (42 U.S.C. 300x–26), as*  
 11 *amended by subsection (a), and a description of any tech-*  
 12 *nical assistance provided under subsection (e) of such sec-*  
 13 *tion, including the number of meetings requested and held*  
 14 *related to technical assistance.*

15       (c) *CONFORMING AMENDMENT.*—*Section 212 of divi-*  
 16 *sion D of the Consolidated Appropriations Act, 2010 (Pub-*  
 17 *lic Law 111–117) is repealed.*

18       **TITLE V—IMPROVING THE EX-**  
 19       **CHANGE OF HEALTH INFOR-**  
 20       **MATION**

21       **SEC. 501. REQUIREMENT TO PROVIDE HEALTH CLAIMS,**  
 22       **NETWORK, AND COST INFORMATION.**

23       (a) *IN GENERAL.*—*Part A of title XXVII of the Public*  
 24 *Health Service Act (42 U.S.C. 300gg et seq.) is amended*  
 25 *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, and  
6 use without special effort, through application program-  
7 ming interfaces (or successor technology or standards), the  
8 information described in subsection (b), in the manner de-  
9 scribed in subsection (b) and otherwise consistent with this  
10 section.

11       “(b) *INFORMATION.*—The following information is re-  
12 quired to be made available, as the Secretary may specify:

13               “(1) *Historical claims, provider encounter, and*  
14 *payment data for each enrollee, which shall—*

15                       “(A) *include adjudicated medical and pre-*  
16 *scription drug claims and equivalent encounters,*  
17 *including all data elements contained in such*  
18 *transactions—*

19                               “(i) *that were adjudicated by the group*  
20 *health plan or health insurance issuer dur-*  
21 *ing the previous 5 years or the enrollee’s en-*  
22 *tire period of enrollment in the applicable*  
23 *plan or coverage if such period is less than*  
24 *the previous 5 years;*

25                               “(ii) *that involve benefits managed by*  
26 *any third party, such as a pharmacy bene-*

1           *fits manager or radiology benefits manager*  
2           *that manages benefits or adjudicates claims*  
3           *on behalf of the plan or coverage; and*

4           “(iii) *from any other health plan or*  
5           *health insurance coverage offered by the*  
6           *same insurance issuer, in which the same*  
7           *enrollee was enrolled during the previous 5*  
8           *years; and*

9           “(B) *be available to an enrollee or former*  
10          *enrollee, the enrollee’s providers, and any third-*  
11          *party applications or services authorized by the*  
12          *enrollee—*

13           “(i) *through the application program-*  
14           *ming interfaces (or successor technology or*  
15           *standards) as required by this paragraph,*  
16           *in a single, longitudinal format that is easy*  
17           *to understand, secure, and that may update*  
18           *automatically;*

19           “(ii) *as soon as practicable, and in no*  
20           *case later than the period of time deter-*  
21           *mined by the Secretary, after the claim is*  
22           *adjudicated or the data is received by the*  
23           *health plan or health insurance issuer; and*

24           “(iii) *to the enrollee, former enrollee,*  
25           *and any providers or third-party applica-*

1            *tions or services authorized by the enrollee,*  
2            *for 5 years after the end date of the enroll-*  
3            *ee’s enrollment in the plan or in any cov-*  
4            *erage offered by the health insurance issuer.*

5            *“(2) Identifying directory information for all in-*  
6            *network providers, including facilities and practi-*  
7            *tioners, that participate in the plan or coverage,*  
8            *which shall—*

9            *“(A) include—*

10            *“(i) the national provider identifier for*  
11            *in-network facilities and practitioners; and*

12            *“(ii) the name, address, phone number,*  
13            *and specialty for each such facility and*  
14            *practitioner, based on the most recent inter-*  
15            *action between the plan or coverage and*  
16            *that facility or practitioner;*

17            *“(B) be capable of returning the informa-*  
18            *tion necessary to establish a list of participating*  
19            *in-network facilities and practitioners, in a*  
20            *given specialty or at a particular facility type,*  
21            *within a specified geographic radius; and*

22            *“(C) be capable of returning the network*  
23            *status, when presented with identifiers for a*  
24            *given enrollee and facility or practitioner.*

1           “(3) *Estimated enrollee out-of-pocket costs, in-*  
2 *cluding costs expected to be incurred through a de-*  
3 *ductible, co-payment, coinsurance, or other form of*  
4 *cost-sharing, for—*

5           “(A) *a designated set of common services or*  
6 *episodes of care, to be established by the Sec-*  
7 *retary through rulemaking, including, at a min-*  
8 *imum—*

9           “(i) *in the case of services provided by*  
10 *a hospital, the 100 most common diagnosis-*  
11 *related groups, as used in the Medicare In-*  
12 *patient Prospective Patient System (or suc-*  
13 *cessor episode-based reimbursement method-*  
14 *ology) at that hospital, based on claims*  
15 *data adjudicated by the group health plan*  
16 *or health insurance issuer;*

17           “(ii) *in the case of services provided in*  
18 *an out-patient setting, including radiology,*  
19 *lab tests, and out-patient surgical proce-*  
20 *dures, any service rendered by the facility*  
21 *or practitioner, and reimbursed by the*  
22 *health plan or health insurance issuer; and*

23           “(iii) *in the case of post-acute care, in-*  
24 *cluding home health providers, skilled nurs-*  
25 *ing facilities, inpatient rehabilitation facili-*

1            *ties, and long-term care hospitals, the pa-*  
2            *tient out-of-pocket costs for an episode of*  
3            *care, as the Secretary may determine, which*  
4            *permits users to reasonably compare costs*  
5            *across different facility and service types;*  
6            *and*

7            *“(B) all prescription drugs currently in-*  
8            *cluded on any tier of the formulary of the plan*  
9            *or coverage.*

10           *“(4) A list of the categories of providers of ancil-*  
11           *lary services, as defined in section 2719(A)(i)(3), for*  
12           *which the plan or coverage has no in-network pro-*  
13           *viders.*

14           *“(c) AVAILABILITY AND ACCESS.—Subject to all appli-*  
15           *cable Federal and State privacy, security, and breach noti-*  
16           *fication laws, the application programming interfaces, in-*  
17           *cluding all data required to be made available through such*  
18           *interfaces, shall—*

19           *“(1) be made available by the applicable group*  
20           *health plan or health insurance issuer, at no charge,*  
21           *to—*

22           *“(A) enrollees and prospective enrollees in*  
23           *the group health plan or health insurance cov-*  
24           *erage;*

1           “(B) third parties authorized by the en-  
2           rollee;

3           “(C) facilities and practitioners who are  
4           under contract with the plan or coverage; and

5           “(D) business associates of such facilities  
6           and practitioners, as defined in section 160.103  
7           of title 45, Code of Federal Regulations (or any  
8           successor regulations);

9           “(2) be available to enrollees in the group health  
10          plan or health insurance coverage, and to third-party  
11          applications or services facilitating such access by en-  
12          rollees, during the enrollment process and for a min-  
13          imum of 5 years after the end date of the enrollee’s  
14          enrollment in the plan or in any coverage offered by  
15          the health insurance issuer;

16          “(3) permit persistent access by third party ap-  
17          plications or services authorized by the enrollee, for a  
18          reasonable period of time, consistent with the require-  
19          ments of the HIPAA Security rule (part 160 of title  
20          45 Code of Federal Regulations and subparts A and  
21          C of part 164 of such title);

22          “(4) employ the applicable content, vocabulary,  
23          and technical standards, as determined by the Sec-  
24          retary pursuant to title XXX; and

1           “(5) *employ security and authentication stand-*  
2           *ards, as the Secretary determines appropriate.*”

3           “(d) *RULE OF CONSTRUCTION REGARDING PRIVACY.—*  
4           *Nothing in this section shall be construed to alter existing*  
5           *obligations of a covered entity or business associate under*  
6           *the privacy, security, and breach notification rules promul-*  
7           *gated under section 264(c) of the Health Insurance Port-*  
8           *ability and Accountability Act or section 13402 of the*  
9           *HITECH Act, or to alter the Secretary’s existing authority*  
10          *to modify such rules, under part 2 of title 42, Code of Fed-*  
11          *eral Regulations (or successor regulations), under section*  
12          *444 of the General Education Provisions Act (20 U.S.C.*  
13          *1232g) (commonly referred to as the ‘Family Educational*  
14          *Rights and Privacy Act of 1974’), under the amendments*  
15          *made by the Genetic Information Nondiscrimination Act,*  
16          *or under State privacy law.”.*

17          “(b) *EFFECTIVE DATE.—Section 2715B of the Public*  
18          *Health Service Act, as added by subsection (a), shall take*  
19          *effect 18 months after the date of enactment of this Act.*”

20          **SEC. 502. RECOGNITION OF SECURITY PRACTICES.**

21          *Part 1 of subtitle D of the Health Information Tech-*  
22          *nology for Economic and Clinical Health Act (42 U.S.C.*  
23          *17931 et seq.) is amended by adding at the end the fol-*  
24          *lowing:*

1 **“SEC. 13412. RECOGNITION OF SECURITY PRACTICES.**

2       “(a) *IN GENERAL.*—Consistent with the authority of  
3 the Secretary under sections 1176 and 1177 of the Social  
4 Security Act, when making determinations relating to fines  
5 under section 13410, decreasing the length and extent of an  
6 audit under section 13411, or remedies otherwise agreed to  
7 by the Secretary, the Secretary shall consider whether the  
8 covered entity or business associate has adequately dem-  
9 onstrated that it had, for not less than the previous 12  
10 months, recognized security practices in place that may—

11               “(1) mitigate fines under section 13410;

12               “(2) result in the early, favorable termination of  
13 an audit under section 13411; and

14               “(3) mitigate the remedies that would otherwise  
15 be agreed to in any agreement with respect to resolv-  
16 ing potential violations of the HIPAA Security rule  
17 (part 160 of title 45 Code of Federal Regulations and  
18 subparts A and C of part 164 of such title) between  
19 the covered entity or business associate and the De-  
20 partment of Health and Human Services.

21       “(b) *DEFINITION AND MISCELLANEOUS PROVISIONS.*—

22               “(1) *RECOGNIZED SECURITY PRACTICES.*—The  
23 term ‘recognized security practices’ means the stand-  
24 ards, guidelines, best practices, methodologies, proce-  
25 dures, and processes developed under section 2(c)(15)  
26 of the National Institute of Standards and Technology

1 *Act, the approaches promulgated under section 405(d)*  
2 *of the Cybersecurity Act of 2015, and other programs*  
3 *and processes that address cybersecurity and that are*  
4 *developed, recognized, or promulgated through regula-*  
5 *tions under other statutory authorities. Such practices*  
6 *shall be determined by the covered entity or business*  
7 *associate.*

8 *“(2) LIMITATION.—Nothing in this section shall*  
9 *be construed as providing the Secretary authority to*  
10 *increase fines under section 13410, or the length, ex-*  
11 *tent or quantity of audits under section 13411, due*  
12 *to a lack of compliance with the recognized security*  
13 *practices.*

14 *“(3) NO LIABILITY FOR NONPARTICIPATION.—*  
15 *Subject to paragraph (4), nothing in this section shall*  
16 *be construed to subject a covered entity or business as-*  
17 *sociate to liability for electing not to engage in the*  
18 *recognized security practices defined by this section.*

19 *“(4) RULE OF CONSTRUCTION.—Nothing in this*  
20 *section shall be construed to limit the Secretary’s au-*  
21 *thority to enforce the HIPAA Security rule (part 160*  
22 *of title 45 Code of Federal Regulations and subparts*  
23 *A and C of part 164 of such title), or to supersede*  
24 *or conflict with an entity or business associate’s obli-*  
25 *gations under the HIPAA 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 date  
8 of enactment of this Act, the Comptroller General of the  
9 United States shall conduct a study to—

10 (1) *describe the roles of Federal agencies and the*  
11 *private sector with respect to protecting the privacy*  
12 *and security of individually identifiable health infor-*  
13 *mation transmitted electronically to and from entities*  
14 *not covered by the regulations promulgated under sec-*  
15 *tion 264(c) of the Health Insurance Portability and*  
16 *Accountability Act of 1996 (42 U.S.C. 1320d–2 note);*

17 (2) *identify recent developments regarding the*  
18 *use of application programming interfaces to access*  
19 *individually identifiable health information, and im-*  
20 *plications for the privacy and security of such infor-*  
21 *mation;*

22 (3) *identify practices in the private sector, such*  
23 *as terms and conditions for use, relating to the pri-*  
24 *vacv, disclosure, and secondary uses of individually*  
25 *identifiable health information transmitted electroni-*  
26 *cally to or from entities, selected by an individual,*

1       that are not subject to the regulations promulgated  
2       under section 264(c) of the Health Insurance Port-  
3       ability and Accountability Act of 1996; and

4               (4) identify steps the public and private sectors  
5       can take to improve the private and secure access to  
6       and availability of individually identifiable health  
7       information.

8       (b) *REPORT.*—Not later than 1 year after the date of  
9       enactment of this Act, the Comptroller General of the United  
10      States shall submit to Congress a report concerning the  
11      findings of the study conducted under subsection (a).

12      **SEC. 504. TECHNICAL CORRECTIONS.**

13      (a) *IN GENERAL.*—Section 3022(b) of the Public  
14      Health Service Act (42 U.S.C. 300jj–52(b)) is amended by  
15      adding at the end the following new paragraph:

16               “(4) *APPLICATION OF AUTHORITIES UNDER IN-*  
17      *SPECTOR GENERAL ACT OF 1978.*—In carrying out  
18      this subsection, the Inspector General shall have the  
19      same authorities as provided under section 6 of the  
20      Inspector General Act of 1978 (5 U.S.C. App.).”.

21      (b) *EFFECTIVE DATE.*—The amendment made by sub-  
22      section (a) shall take effect as if included in the enactment  
23      of the 21st Century Cures Act (Public Law 114–255).

1 **SEC. 505. PUBLIC MEETING.**

2       (a) *IN GENERAL.*—Not later than 180 days after the  
3 date of enactment of this Act, the Secretary of Health and  
4 Human Services shall convene a public meeting for pur-  
5 poses of discussing and providing input on patient-match-  
6 ing metrics for the purpose of enabling interoperability and  
7 the exchange of health information across health care orga-  
8 nizations.

9       (b) *EXPERTS.*—The public meeting under this section  
10 may include—

11           (1) *representatives of relevant Federal agencies*  
12 *(including representatives from the Office of the Na-*  
13 *tional Coordinator for Health Information Tech-*  
14 *nology);*

15           (2) *State, local, Tribal, and territorial public*  
16 *health officials;*

17           (3) *stakeholders with expertise in health informa-*  
18 *tion exchange;*

19           (4) *stakeholders with expertise in capabilities*  
20 *relevant to patient matching, such as experts in*  
21 *informatics and data analytics;*

22           (5) *stakeholders affected by record-matching (in-*  
23 *cluding patients, hospitals, health systems, payers,*  
24 *health information exchanges, and prescription drug*  
25 *monitoring programs); and*

1           (6) *other representatives, as the Secretary deter-*  
2           *mines appropriate.*

3           (c) *TOPICS.—Such public meeting shall include a dis-*  
4           *ussion of—*

5           (1) *standards and processes for assessing the ac-*  
6           *curacy of patient-matching algorithms;*

7           (2) *performance metrics for health care providers*  
8           *purchasing patient-matching technology and algo-*  
9           *rithm developers;*

10          (3) *the development of benchmarks for the accu-*  
11          *racy of patient-matching algorithms;*

12          (4) *considerations for State, local, Tribal, and*  
13          *territorial capabilities and infrastructure related to*  
14          *data exchange, interoperability, and matching patient*  
15          *records;*

16          (5) *opportunities for the incorporation of inno-*  
17          *vative technologies to improve patient matching; and*

18          (6) *privacy and security protections.*



Calendar No. 133

116<sup>TH</sup> CONGRESS  
1<sup>ST</sup> Session

**S. 1895**

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**A BILL**

To lower health care costs.

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July 8, 2019

Reported with an amendment